UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, *et al.*,

Defendants.

Civil Action No. 1:25-cv-3452

DECLARATION OF PATRICK COSTELLO

I, Patrick Costello, declare as follows:

1. I am over the age of eighteen, and I am competent to provide this declaration.

2. I have worked for Amgen since 2007, holding roles of increasing responsibility in Amgen's finance, marketing, and value and access organizations. Since 2007, I have held the following roles: Accounting Manager (2007 to 2008); Finance Manager (2008 to 2011); Finance Sr. Manager (2011 to 2016); Finance Director (2016 to 2019); Marketing Director (2019 to 2020); Contracts and Pricing Director (2021); Executive Director, United States Value and Access (2021 to June 2024). Since June 2024 I have been in my current role, Associate Vice President,

Case 1:25-cv-3452-DDD-STV
Exhibit 12

United States Value and Access.

3. My professional experiences and leadership roles at Amgen have given me significant knowledge about how the pharmaceutical supply chain works, including standard industry practice for the pricing and distribution of prescription drugs. I am also well acquainted with Amgen's pricing and distribution practices for Enbrel, including with respect to wholesalers, pharmacies, and health care providers.

STANDARD INDUSTRY PRACTICE

4. As a general matter, pharmaceutical manufacturers sell drugs to wholesalers and other distributors ("direct customers"), which in turn sell the drugs to other downstream purchasers, such as pharmacies and hospitals ("indirect purchasers"). The price at which manufacturers sell their drugs to wholesalers is typically referred to as the "Wholesale Acquisition Cost" or "WAC." The WAC is a national list price that does not reflect any reductions, including the (often substantial) rebates demanded of manufacturers by pharmacy benefit managers (PBMs), or discounts applicable to pharmacies, hospitals, and other entities that purchase drugs from wholesalers.

5. Wholesalers typically sell drugs to indirect purchasers at WAC or at a price lower than WAC. Wholesalers' profit margins generally come from discounts they obtain from the manufacturer for prompt payment and/or from administrative or service fees they charge to the manufacturer for managing distribution of its drugs.

6. Wholesalers are at times required to provide discounts or other price

reductions at the point of purchase (e.g., when a drug is sold by the wholesaler to an indirect purchaser, it may include a discount indicated by the manufacturer). The wholesalers then seek reimbursement from the manufacturer for such discounts. This standard practice is known in the industry as a "chargeback."

7. As a general matter, Amgen is contractually obligated to reimburse wholesalers for certain discounts, deductions, rebates, and/or allowances the wholesalers provide to indirect customers (e.g., discounts to 340B covered entities or other government purchasers, or Amgen's contracted discounts to commercial indirect customers, such as hospitals and pharmacies). Accordingly, Amgen utilizes chargebacks to credit wholesalers for the amount of such discounts for drugs the wholesalers sell to indirect customers. Without that reimbursement, wholesalers would lose money. Buying high and selling low is unprofitable in any industry, but it is especially so with respect to pharmaceutical wholesalers, which operate on extremely thin margins and generally do not have the capacity to absorb uncompensated discounts.

THE COLORADO LEGISLATION AND THE ENBREL UPPER PAYMENT LIMIT

8. I am aware of the legislation Colorado enacted in 2021 creating a new Prescription Drug Affordability Review Board with the power to impose price controls, termed "upper payment limits," on sales of prescription drugs dispensed or distributed in Colorado.

9. I am also aware that the Board has adopted a final rule imposing an

upper payment limit of $600.00 per 50 milligram/milliliter unit on Amgen's drug Enbrel, with an effective date of January 1, 2027. This amount is more than 70 percent below Enbrel's current WAC of $2,039.40 per 50 milligram/milliliter unit.

10. I understand that the statute defines an upper payment limit as "the maximum amount that may be paid or billed for a prescription drug that is dispensed or distributed in Colorado in any financial transaction concerning the purchase of or reimbursement for the prescription drug," Colo. Rev. Stat. § 10-16-1401(23).

11. Amgen's sales of Enbrel are financial transactions concerning the purchase of or reimbursement for a prescription drug. I understand, however, that Colorado has claimed in prior litigation that an upper payment limit would apply to sales made by Amgen's wholesalers and distributors but not to sales made by Amgen itself.

THE EFFECTS OF THE UPPER PAYMENT LIMIT ON AMGEN

12. Even assuming that the upper payment limit applies only to "downstream" transactions (such as wholesalers' sales to pharmacies, specialty pharmacies, and hospitals), it will predictably operate as an effective cap on the net price Amgen can charge wholesalers. (Specialty pharmacies provide specialized or more complex pharmacy services, including shipments of certain medications for chronic and other serious conditions directly to patients. They often provide additional services that help ensure patients can access their medication.)

13. First, based on my experience in the industry, and as a matter of basic

economics and common sense, if the upper payment limit is imposed on wholesalers' sales of Enbrel, there is no realistic chance that wholesalers will absorb the discount required to comply with the upper payment limit without passing the cost on to Amgen. Indeed, Amgen is contractually required to reimburse wholesalers for such legally required discounts.

14. Second, as described above, Amgen cannot reasonably expect wholesalers to purchase products at WAC, without any discount or reimbursement from Amgen, if Colorado dictates that wholesalers must sell the products for less than WAC (as it will if the upper payment limit takes effect as scheduled). Like any other rational economic actor, wholesalers will not agree to purchase a product for more than what they can lawfully recover from reselling that product. Otherwise, the wholesalers would lose money on each sale. The upper payment limit will thus function as a cap on Amgen's net price for affected units of Enbrel.

15. Third, if for some reason Amgen and a wholesaler are unable to come to an agreement regarding how to compensate the wholesaler for the cost of complying with the upper payment limit for Enbrel, Amgen will still be negatively impacted. Amgen will lose revenue due to the loss of sales, as the wholesaler will choose to purchase alternative products not subject to an upper payment limit. And whether or not an agreement is ultimately reached, Amgen will incur administrative costs negotiating with its wholesalers over these issues.

16. Fourth, besides forcing Amgen to lower its net price for affected units of

Enbrel, Colorado's upper payment limit may also disrupt the broader market for Enbrel and damage Amgen's business relationships, reputation, and goodwill. For example, indirect purchasers outside of Colorado (to whom the upper payment limit does not apply) may object to being charged higher prices than indirect purchasers in Colorado. Amgen will incur additional costs negotiating with such customers and dealing with these and other broader market effects of the upper payment limit.

17. I am therefore certain that Amgen will incur costs as a result of the imposition of the upper payment limit on "downstream" sales of Enbrel. There is no scenario in which the upper payment limit for Enbrel will not negatively affect Amgen. Irrespective of where in the supply chain the upper payment limit on Enbrel is applied, it will disrupt the market for Enbrel and reduce the amount of revenue Amgen can obtain from sales of Enbrel.

18. While the Board set the upper payment limit to take effect January 1, 2027, Amgen will begin incurring costs well in advance of that date. For example, Amgen will need to incur costs to modify its payment systems to ensure that transactions affected by the upper payment limit are identified and that the upper payment limit is accounted for. Planning and implementing these changes will likely take at least twelve months. Amgen will also need to incur costs to address this issue with its wholesalers and specialty pharmacies. And Amgen will need to address objections raised by indirect purchasers in other states.

19. What is more, none of this is likely to benefit patients. To the contrary, because the upper payment limit would force market participants to operate under economically irrational conditions, the ultimate effect is more likely to restrict patient access than enhance it.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 18th day of November 2025.

By: _____
Patrick Costello

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 001-37702

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**95-3540776**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Amgen Center Drive	
Thousand Oaks	
California	**91320-1799**
(Address of principal executive offices)	(Zip Code)

(805) 447-1000

(Registrant's telephone number, including area code)

Case 1:25-cv-3452-DDD-STV

Exhibit 14

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol (s)	Name of each exchange on which registered
Common stock, $0.0001 par value	**AMGN**	**The Nasdaq Global Select Market**
2.00% Senior Notes due 2026	**AMGN26**	**The Nasdaq Global Select Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company	Emerging growth company
☒	☐	☐	☐	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☒

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $150.1 billion as of the last business day of the registrant's most recently completed second fiscal quarter.(A)

(A) Excludes 879,180 shares of common stock held by directors and executive officers, and any stockholders whose ownership exceeds ten percent of the shares outstanding, as of the last business day of the registrant's most recently completed second fiscal quarter. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

539,067,675

(Number of shares of common stock outstanding as of February 10, 2026)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2026 Annual Meeting of Stockholders to be held on May 19, 2026, are incorporated by reference into Part III of this annual report.

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Defined Terms and Products

Defined terms

We use several terms in this Annual Report on Form 10-K, including but not limited to those that are finance, regulation and disease-state related as well as names of other companies, which are provided below.

Term	Description
2017 Tax Act	Tax Cuts and Jobs Act of 2017
340B Program	Federal 340B Drug Pricing Program
AI	artificial intelligence
Amended 2009 Plan	Amended and Restated 2009 Equity Incentive Plan
AOCI	accumulated other comprehensive income (loss)
AstraZeneca	AstraZeneca plc
ASU	Accounting Standards Update
ATMOS	Amgen Technology and Medical Organizations
B-ALL	B-cell acute lymphoblastic leukemia
BeOne	BeOne Medicines Ltd. (formerly BeiGene, Ltd.)
BiTE®	bispecific T-cell engager
BLA	Biologics License Application
BPCIA	Biologics Price Competition and Innovation Act of 2009
CCPA	California Consumer Privacy Act of 2018
CDT	Cybersecurity & Digital Trust
CGRP	calcitonin gene-related peptide
ChemoCentryx	ChemoCentryx, Inc.
chemotherapy	anticancer medicines
CHMP	Committee for Medicinal Products for Human Use
CIO	Chief Information Officer
CISO	Chief Information Security Officer
CMS	Centers for Medicare & Medicaid Services
COSO	Committee of Sponsoring Organizations of the Treadway Commission
CRCC	Corporate Responsibility and Compliance Committee
DLL3	delta-like ligand 3
DOJ	U.S. Department of Justice
EC	European Commission
EMA	European Medicines Agency
EO	Executive Order
EPO	European Patent Office
EPS	earnings per share
EU	European Union
FASB	Financial Accounting Standards Board
FCPA	U.S. Foreign Corrupt Practices Act
FDA	U.S. Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
Fitch	Fitch Ratings, Inc.
GAAP	U.S. generally accepted accounting principles
GDPR	General Data Protection Regulation
GIPR	glucose-dependent insulinotropic polypeptide receptor
GLP-1	glucagon like peptide 1
HHS	U.S. Department of Health and Human Services

Term	Description
Horizon	Horizon Therapeutics plc
IGF-1R	insulin-like growth factor-1 receptor
IgG4-RD	Immunoglobulin G4-related disease
IND	Investigational New Drug Application
IPR&D	in-process research and development
IRA	Inflation Reduction Act of 2022
IRS	Internal Revenue Service
July MFN Letter	Letter dated July 31, 2025, by the Administration to a number of pharmaceutical manufacturers, including Amgen
KRAS	Kirsten rat sarcoma viral oncogene homologue
Kyowa Kirin	Kyowa Kirin Co., Ltd.
LDL-C	low-density lipoprotein cholesterol
MAA	Marketing Authorisation Application
MD&A	management's discussion and analysis
MFN	Most-Favored-Nations
MFN EO	Most-Favored-Nations Prescription Drug Pricing Executive Order, dated May 12, 2025
Moody's	Moody's Investors Service, Inc.
MRD	minimal residual disease
Neumora	Neumora Therapeutics, Inc.
NIH	National Institutes of Health
NOL	net operating loss
NSCLC	non-small cell lung cancer
OB3	P.L. 119-21, also The One Big Beautiful Bill Act signed into law on July 4, 2025
OECD	Organisation for Economic Co-operation and Development
PBM	pharmacy benefit manager
PCSK9	proprotein convertase subtilisin/kexin type 9
PDAB	Prescription Drug Affordability Board
R&D	research and development
RANKL	receptor activator of nuclear factor kappa-B ligand
RAR	Revenue Agent Report
RAS	Rat sarcoma viral oncogene
REMS	Risk Evaluation and Mitigation Strategy
ROU	right-of-use
ROW	rest of world
RSUs	restricted stock units
S&P	Standard & Poor's Financial Services LLC
SEC	U.S. Securities and Exchange Commission
SG&A	selling, general and administrative
SOFR	Secured Overnight Financing Rate
TED	thyroid eye disease
Teneobio	Teneobio, Inc.
U.S. Treasury	U.S. Department of the Treasury
USPTO	U.S. Patent and Trademark Office
UTB	unrecognized tax benefit

Products

The brand names of our products, our delivery devices and certain of our product candidates and their associated generic names are provided below.

Term	Description
ACTIMMUNE	ACTIMMUNE® (interferon gamma-1b)
Aimovig	Aimovig® (erenumab-aooe)
AMJEVITA/AMGEVITA	AMJEVITA® (adalimumab-atto)/AMGEVITA™ (adalimumab)
Aranesp	Aranesp® (darbepoetin alfa)
AutoTouch	AutoTouch®
AVSOLA	AVSOLA® (infliximab-axxq)
BKEMV/BEKEMV	BKEMV® (eculizumab-aeeb)/BEKEMV™ (eculizumab)
BLINCYTO	BLINCYTO® (blinatumomab)
BUPHENYL	BUPHENYL® (sodium phenylbutyrate)
ConfiPen	ConfiPen™
Corlanor	Corlanor® (ivabradine)
ENBREL	Enbrel® (etanercept)
ENBREL Mini	ENBREL Mini®
EPOGEN	EPOGEN® (epoetin alfa)
EVENITY	EVENITY® (romosozumab-aqqg)
IMDELLTRA/IMDYLLTRA	IMDELLTRA® (tarlatamab-dlle)/IMDYLLTRA™ (tarlatamab)
IMLYGIC	IMLYGIC® (talimogene laherparepvec)
KANJINTI	KANJINTI® (trastuzumab-anns)
KRYSTEXXA	KRYSTEXXA® (pegloticase)
KYPROLIS	KYPROLIS® (carfilzomib)
LUMAKRAS/LUMYKRAS	LUMAKRAS®/LUMYKRAS™ (sotorasib)
MariTide	Maridebart cafraglutide (MariTide™)
MVASI	MVASI® (bevacizumab-awwb)
Neulasta	Neulasta® (pegfilgrastim)
NEUPOGEN	NEUPOGEN® (filgrastim)
Nplate	Nplate® (romiplostim)
Onpro	Onpro®
Otezla	Otezla® (apremilast)
Parsabiv	Parsabiv® (etelcalcetide)
PAVBLU	PAVBLU® (aflibercept-ayyh)
PENNSAID	PENNSAID® (diclofenac sodium topical solution) 2%
PROCYSBI	PROCYSBI® (cysteamine bitartrate)
Prolia	Prolia® (denosumab)
QUINSAIR	QUINSAIR® (levofloxacin)
RAVICTI	RAVICTI® (glycerol phenylbutyrate)
RAYOS	RAYOS® (prednisone)
Repatha	Repatha® (evolocumab)
RIABNI	RIABNI® (rituximab-arrx)
Sensipar/Mimpara	Sensipar®/Mimpara™ (cinacalcet)
SureClick	SureClick®
TAVNEOS	TAVNEOS® (avacopan)
TEPEZZA	TEPEZZA® (teprotumumab-trbw)

Term	Description
TEZSPIRE	TEZSPIRE® (tezepelumab-ekko)
UPLIZNA	UPLIZNA® (inebilizumab-cdon)
Vectibix	Vectibix® (panitumumab)
WEZLANA/WEZENLA	WEZLANA® (ustekinumab-auub)/WEZENLA™ (ustekinumab)
XGEVA	XGEVA® (denosumab)

Products referenced in this report that are not included in the above list are the properties of their respective owners.

PART I

Item 1. BUSINESS

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") discovers, develops, manufactures and delivers innovative medicines to fight some of the world's toughest diseases. We focus on areas of high unmet medical need and leverage our expertise to strive for solutions that dramatically improve people's lives, while also reducing the social and economic burden of disease. We helped launch the biotechnology industry more than 45 years ago and have grown to be one of the world's leading independent biotechnology companies. Our robust pipeline includes potential first-in-class medicines at all stages of development. We have a presence in approximately 100 countries worldwide.

Amgen was incorporated in California in 1980 and became a Delaware corporation in 1987. Amgen operates in one operating segment: human therapeutics.

Significant Developments

Following is a summary of significant developments affecting our business that have occurred and that we have reported since the filing of our Annual Report on Form 10-K for the year ended December 31, 2024.

Products/Pipeline

Repatha

In August 2025, we announced that the FDA broadened the approved use of Repatha to include adults at increased risk for major adverse cardiovascular events (MACE) due to uncontrolled low-density lipoprotein cholesterol (LDL-C), removing the previous requirement that a patient have been diagnosed with cardiovascular (CV) disease.

In November 2025, we announced detailed results from the Phase 3 VESALIUS-CV clinical trial, which showed that Repatha achieved statistically significant and clinically meaningful reductions in MACEs in high-risk adults without a prior heart attack or stroke, when added to statins or other LDL-C–lowering treatments. Repatha demonstrated a 25% relative reduction in the risk of a composite of coronary heart disease (CHD) death, heart attack or ischemic stroke (3-P MACE), and a 19% reduction in a broader composite that also included any ischemia-driven arterial revascularization (4-P MACE). Repatha also reduced the risk of heart attack by 36%. In a cohort of patients included in a lipid sub-study, the median achieved LDL-C was 45 mg/dL compared to 109 mg/dL in the placebo arm. No new safety signals were identified, and tolerability was consistent with the current prescribing information in the United States.

UPLIZNA

In April 2025, we announced the FDA approved UPLIZNA for the treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients. UPLIZNA is the first and only FDA approved treatment for adults living with IgG4-RD.

In December 2025, we announced the FDA approved UPLIZNA for the treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) and anti-muscle specific tyrosine kinase (MuSK) antibody positive.

IMDELLTRA/IMDYLLTRA

In June 2025, we announced interim results from the global Phase 3 DeLLphi-304 trial evaluating IMDELLTRA/IMDYLLTRA in patients with small cell lung cancer (SCLC) who had progressed on or after one line of platinum-based chemotherapy. The study demonstrated that IMDELLTRA/IMDYLLTRA significantly reduced the risk of death by 40% compared to standard-of-care chemotherapy, with a median overall survival of 13.6 months compared to 8.3 months. Additionally, IMDELLTRA/IMDYLLTRA showed a statistically significant improvement in median progression-free survival of 4.2 months compared to 3.7 months and enhanced patient-reported outcomes related to cancer-associated symptoms, including dyspnea and cough. The safety profile of IMDELLTRA/IMDYLLTRA was consistent with prior studies.

In November 2025, we announced that the FDA granted full approval for IMDELLTRA for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy, converting its prior accelerated approval to full approval based on results from the global Phase 3 DeLLphi-304 study.

TEZSPIRE

In October 2025, we announced that the FDA approved TEZSPIRE as an add-on maintenance treatment of inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP) in adult and pediatric patients aged 12 years and older.

TEPEZZA

In June 2025, the European Commission granted marketing authorization approval of TEPEZZA for treatment of adults with moderate-to-severe thyroid eye disease (TED).

Maridebart cafraglutide (MariTide™)

In March 2025, we announced the initiation of two global Phase 3 studies to evaluate MariTide, a differentiated antibody-peptide conjugate that activates the glucagon like peptide 1 (GLP-1) receptor and antagonizes the glucose-dependent insulinotropic polypeptide receptor (GIPR), in chronic weight management: one study in adults living with obesity or overweight without Type 2 diabetes and another study in adults living with obesity or overweight with Type 2 diabetes.

In June 2025, the underlying details from Part 1 of the Phase 2 study of MariTide and complete results from the primary analysis of the Phase 1 pharmacokinetics low dose initiation (PK-LDI) study evaluating lower starting doses of MariTide were presented at the American Diabetes Association 85th Scientific Sessions and simultaneously published in *The New England Journal of Medicine*.

In November 2025, we announced that, in addition to the two global Phase 3 studies announced in March 2025, four global Phase 3 studies were underway, with studies in adults living with established atherosclerotic cardiovascular disease and obesity or overweight; in adults living with heart failure with preserved or mildly reduced ejection fraction and obesity; in adults living with obstructive sleep apnea on positive airway pressure therapy and living with obesity or overweight; and in adults living with obstructive sleep apnea not on positive airway pressure therapy and living with obesity or overweight.

In January 2026, we announced that Part 2 of the Phase 2 chronic weight management study, an exploratory evaluation of MariTide treatment for an additional 52 weeks in people who lost at least 15% of their body weight in the 52-week Part 1 of the Phase 2 chronic weight management study, is complete. Key findings included the following: the large majority of participants maintained the weight loss achieved in Part 1 for an additional 52 weeks on a lower monthly dose or quarterly dose of MariTide; the second year of MariTide treatment was very well tolerated, including at quarterly doses, with a very low incidence of nausea and vomiting and no new safety signals observed; and improvements in cardiometabolic parameters were sustained with MariTide at effective maintenance doses for a full second year.

In January 2026 we also announced that a Phase 2 study of MariTide for the treatment of Type 2 diabetes in adults living with and without obesity has completed the 24-week timepoint. Key findings included the following: robust and clinically meaningful reduction in both hemoglobin A1c (HbA1c) and weight with monthly MariTide at 24 weeks, which is in line with results seen in the Type 2 diabetes population in Part 1 of the Phase 2 chronic weight management study, at 24 weeks; safety and tolerability profile consistent with the GLP-1 class, where the most common side effects were gastrointestinal-related, predominantly mild-to-moderate in nature, and occurred primarily during dose escalation; and favorable improvement in cardiometabolic parameters.

TAVNEOS

TAVNEOS was approved by the FDA in October 2021 for the adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (AAV) in combination with standard therapy including glucocorticoids. TAVNEOS was developed by ChemoCentryx. Amgen acquired ChemoCentryx in October 2022, after TAVNEOS had been on the market for a year. On January 16, 2026, the FDA requested that ChemoCentryx voluntarily withdraw TAVNEOS from the U.S. market. The FDA raised concerns about the process followed by ChemoCentryx to re-adjudicate primary endpoint results for 9 of the 331 patients in its pivotal clinical trial. Hepatotoxicity, which is a known infrequent risk of TAVNEOS treatment for AAV, was also raised in the context of the benefit-risk profile of the medicine. Amgen is not aware of any issue with the underlying patient data from the ChemoCentryx clinical trial, and after review of the relevant clinical data and years of real-world evidence, Amgen is confident that TAVNEOS demonstrates effectiveness and a favorable benefit–risk profile. On January 28, 2026, following FDA regulatory process, Amgen informed the FDA that it did not intend to withdraw TAVNEOS from the market. Amgen is evaluating next steps with the FDA to determine a path forward, while keeping patient safety, needs and support at the forefront.

Bemarituzumab

In February 2026, we announced that, based upon data from the FORTITUDE-101 and FORTITUDE-102 Phase 3 studies, the Company does not intend to pursue regulatory approval of bemarituzumab in first-line gastric cancer.

Rocatinlimab

In January 2026, we and Kyowa Kirin agreed to terminate the rocatinlimab collaboration agreement and to transition control of the global development and commercialization program to Kyowa Kirin, subject to receipt of clearance under the

Hart-Scott-Rodino Antitrust Improvements Act of 1976. In February 2026, we received such regulatory clearance. In the first quarter of 2026, Kyowa Kirin will assume full responsibility for rocatinlimab worldwide, except that Amgen will continue to manufacture rocatinlimab and perform other transition activities for an agreed upon period of time.

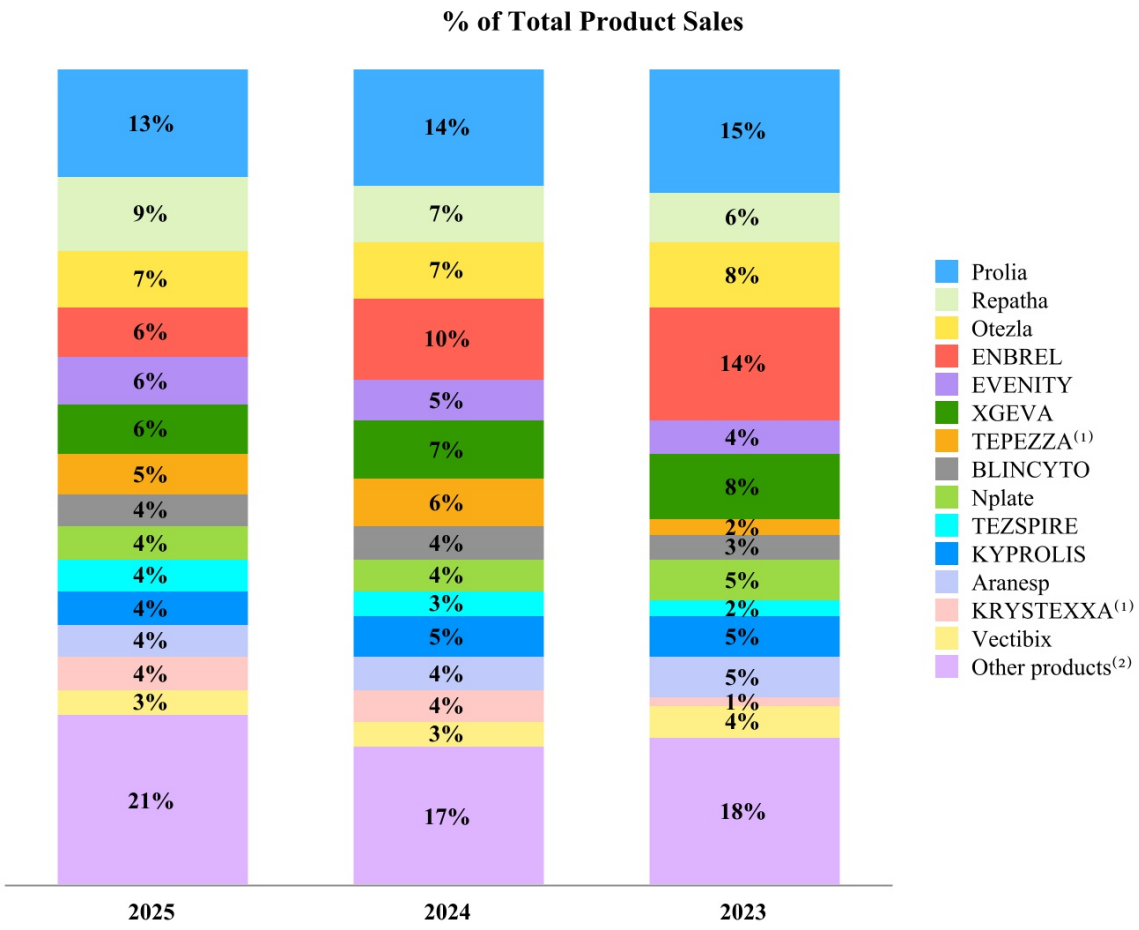
Marketing, Distribution and Selected Marketed Products

The largest concentration of our sales and marketing forces is based in the United States and Europe. We also commercialize and market our products into other geographic territories, including Japan, China and other parts of Asia, Latin America and the Middle East by using our own affiliates, by acquiring existing third-party businesses or product rights or by collaborating with third parties. In the Asia Pacific region, we also sell our products in partnership with other companies, including Astellas Pharma Inc., BeOne, Mitsubishi Tanabe Pharma Corporation, Takeda Pharmaceutical Co., Ltd. and Kyowa Kirin. This international footprint allows us to deliver our medicines to more patients globally. See Business Relationships for our significant alliances. Whether we use our own sales and marketing forces or a third party's services varies across these markets. Such use typically depends on several factors, including the nature of entry into the new market, the size of an opportunity and operational capabilities. Together with our collaborators, we market our products to healthcare providers, including physicians or their clinics, dialysis centers, hospitals and pharmacies.

In the United States, substantially all of our sales are to pharmaceutical wholesale distributors, which is the principal means of distributing our products to healthcare providers. We market certain products through direct-to-patient channels, including print, television and online media. For further discussion, see Government Regulation—*Regulation in the United States—Regulation of Product Marketing and Promotion*. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country.

Our product sales to three large wholesalers, McKesson Corporation, Cencora, Inc. and Cardinal Health, Inc., each individually accounted for more than 10% of total revenues for each of the years 2025, 2024 and 2023. On a combined basis, these wholesalers accounted for 77%, 77% and 79% of worldwide gross revenues for 2025, 2024 and 2023, respectively. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

Our products are marketed around the world, with the United States as our largest market. The following chart shows our product sales by principal product, and the table below (dollar amounts in millions) shows product sales by geography for the years 2025, 2024 and 2023.



	2025		2024		2023	
Product Sales by Geography:						
U.S.	$ 25,656	73 %	$ 23,301	73 %	$ 19,272	72 %
ROW	9,492	27 %	8,725	27 %	7,638	28 %
Total	$ 35,148	100 %	$ 32,026	100 %	$ 26,910	100 %

(1) TEPEZZA and KRYSTEXXA were acquired from our Horizon acquisition on October 6, 2023, and include product sales in the periods after the acquisition date.

(2) Consists of product sales of our non-principal products.

Prolia

We market Prolia in many countries around the world. Prolia and XGEVA contain the same active ingredient but are approved for different indications, patient populations, dose and frequency of administration. Prolia was launched in the United States and Europe in 2010. In the United States, it is used primarily in the indication for the treatment of postmenopausal women with osteoporosis at high risk of fracture and for treatment to increase bone mass in men with osteoporosis at high risk of fracture. In Europe, Prolia is used primarily for the treatment of osteoporosis in men and postmenopausal women at increased risk of fracture. Our patents for RANKL antibodies, including sequences, for Prolia expired in February 2025 in the United States and in November 2025 in select countries in Europe.

Repatha

We market Repatha, a PCSK9 inhibitor, in many countries around the world. Repatha was launched in 2015 and is indicated to reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults at increased risk for these events. Repatha is also indicated to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). See Significant Developments for additional information regarding regulatory developments.

Otezla

We market Otezla, a small molecule that inhibits phosphodiesterase 4 (PDE4), in many countries around the world. Otezla was acquired from Bristol Myers Squibb Company in November 2019 after its acquisition of Celgene Corporation. Otezla is an oral therapy approved for the treatment of adults with plaque psoriasis across all severities (in the United States, Japan and Australia) and moderate-to-severe plaque psoriasis (in other global markets, including Europe); for adults with active psoriatic arthritis; for adults with oral ulcers associated with Behçet's disease; and for pediatric patients six years of age and older and weighing at least 20 kilograms with moderate-to-severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Otezla is also approved in Japan for the treatment of palmoplantar pustulosis (PPP).

ENBREL

We market ENBREL, a tumor necrosis factor blocker, in the United States and Canada. ENBREL was launched in 1998 and is used primarily in indications for the treatment of adult patients with moderately-to-severely active rheumatoid arthritis, patients with chronic moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and patients with active psoriatic arthritis.

EVENITY

Together with our collaboration partners, we market EVENITY in many countries around the world. EVENITY was launched in the United States and Japan in 2019. In the United States, it is used in the indication for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In Japan, EVENITY is used primarily in the indication for the treatment of osteoporosis in men and postmenopausal women at high risk of fracture.

XGEVA

We market XGEVA in many countries around the world. Prolia and XGEVA contain the same active ingredient but are approved for different indications, patient populations, dose and frequency of administration. XGEVA was launched in 2010 and is used primarily in the indication for prevention of skeletal-related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with bone metastases from solid tumors and multiple myeloma. Our patents for RANKL antibodies, including sequences, for XGEVA expired in February 2025 in the United States and in November 2025 in select countries in Europe.

TEPEZZA

We market TEPEZZA for the treatment of TED in multiple countries globally, including the United States, Japan, Brazil, among others. TEPEZZA was acquired through our Horizon acquisition in October 2023. TEPEZZA is a fully human monoclonal antibody and a targeted inhibitor of the insulin-like growth factor-1 receptor (IGF-1R) that is the first and only approved medicine for the treatment of TED. See Significant Developments for additional information regarding regulatory developments.

BLINCYTO

We market BLINCYTO in many countries around the world. BLINCYTO was launched in 2014 and has proven efficacy in a wide range of patients with CD19-positive B-cell acute lymphoblastic leukemia (B-ALL), including those who are MRD(–) or MRD(+) in frontline consolidation, and those with relapsed or refractory (R/R) disease. Acute lymphoblastic leukemia (ALL) is a cancer of the blood in which a particular kind of white blood cell is growing out of control.

Nplate

We market Nplate in many countries around the world. Nplate was launched in 2008 and is indicated to treat thrombocytopenia in patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.

TEZSPIRE

Together with our collaboration partner, we market TEZSPIRE in many countries around the world. TEZSPIRE is currently approved for the treatment of severe uncontrolled asthma (SUA) in the United States, Europe, Japan and more than 70 countries across the globe. In addition, TEZSPIRE is approved for chronic rhinosinusitis with nasal polyps (CRSwNP) in the United States, Europe and several additional countries. TEZSPIRE is a first-in-class human monoclonal antibody that works on the primary source of inflammation: the airway epithelium, which is the first point of contact for viruses, allergens, pollutants and other environmental insults. See Significant Developments for additional information regarding regulatory developments.

KYPROLIS

We market KYPROLIS primarily in the United States and Europe. KYPROLIS was launched in 2012 and is indicated in combination with (i) dexamethasone, (ii) lenalidomide plus dexamethasone, (iii) daratumumab plus dexamethasone, (iv) daratumumab plus hyaluronidase-fihj plus dexamethasone, and (v) isatuximab plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. It is also approved as a single agent for patients with relapsed or refractory multiple myeloma who have received one or more previous therapies.

Aranesp

We market Aranesp primarily in the United States and Europe. Aranesp was launched in 2001 and is indicated to treat a lower-than-normal number of red blood cells (anemia) caused by chronic kidney disease (CKD) in both patients on dialysis and patients not on dialysis. Aranesp is also indicated for anemia in certain patients with non-myeloid malignancies who are receiving concomitant myelosuppressive chemotherapy.

KRYSTEXXA

We market KRYSTEXXA in the United States. KRYSTEXXA was acquired through our Horizon acquisition in October 2023. KRYSTEXXA is the first and only FDA-approved medicine for the treatment of chronic refractory gout.

Vectibix

We market Vectibix in many countries around the world. Vectibix was launched in 2006 and is indicated for the treatment of patients with wild-type RAS metastatic colorectal cancer (mCRC, which is a cancer that has spread outside the colon and rectum) and in the United States, in combination with LUMAKRAS, for the treatment of adult patients with KRAS G12C-mutated mCRC, who have received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy. RAS status is determined by an FDA-approved test.

Other Marketed Products

We also market a number of other products in various markets worldwide, including but not limited to MVASI, PAVBLU, UPLIZNA, IMDELLTRA/IMDYLLTRA, AMJEVITA/AMGEVITA, TAVNEOS, Neulasta, LUMAKRAS/LUMYKRAS, RAVICTI, Parsabiv, Aimovig, WEZLANA/WEZENLA and PROCYSBI.

Patents

The following table lists our outstanding material patents for the indicated product by territory, general subject matter and latest expiry date. Certain of the European patents are subjects of supplemental protection certificates that provide additional protection for the products in certain European countries beyond the dates listed in the table. See footnotes to the patent table below.

One or more patents with the same or earlier expiry dates may fall under the same general subject matter and are not listed separately.

Product	Territory	General subject matter	Expiration
Repatha® (evolocumab)	U.S.	Antibodies	8/27/2029
	U.S.	Methods of treatment	5/10/2032
	Europe	Compositions[1]	8/22/2028
	Europe	Methods of treatment	5/10/2032
	Europe	Formulation	5/3/2033
Otezla®/Otezla XR™ (apremilast)	U.S.	Compositions and compounds[2]	2/16/2028
	U.S.	Oral dosage forms for extended release and methods of treatment	5/27/2042
Enbrel® (etanercept)	U.S.	Fusion protein and pharmaceutical compositions	11/22/2028
	U.S.	DNA encoding fusion protein and methods of making fusion protein	4/24/2029
	U.S.	Formulations and methods of preparing formulations	10/19/2037
	U.S.	Methods of treatment using formulations	2/22/2038
EVENITY® (romosozumab-aqqg)	U.S.	Antibodies	4/25/2026
	U.S.	Formulation and methods of using formulation	5/11/2031
	U.S.	Methods of treatment	4/9/2033
	Europe	Antibodies[1]	4/28/2026
	Europe	Formulation and methods of using formulation	5/11/2031
	Europe	Methods of treatment	4/18/2032
TEPEZZA® (teprotumumab-trbw)[3]	U.S.	IGF-1R antibodies	3/3/2029
	U.S.	Methods of treatment	12/11/2039
BLINCYTO® (blinatumomab)	U.S.	Pharmaceutical compositions and bifunctional polypeptides	4/6/2030
	U.S.	Method of treatment	8/26/2031
	Europe	Bifunctional polypeptides[1]	11/26/2024
	Europe	Method of treatment	11/6/2029
Nplate® (romiplostim)	U.S.	Formulation	2/12/2028
	Europe	Formulation	4/20/2027
TEZSPIRE® (tezepelumab-ekko)	U.S.	Polypeptides	2/3/2034
	U.S.	Methods of treatment	8/23/2038
	Europe	Polypeptides[1]	9/9/2028
KYPROLIS® (carfilzomib)	U.S.	Compositions and compounds[4]	12/7/2027
	U.S.	Methods of making	5/8/2033
	Europe	Compositions, compounds and methods of treatment[1]	12/7/2025
	Europe	Pharmaceutical compositions and methods of making	5/8/2033
KRYSTEXXA® (pegloticase)	U.S.	Polypeptides and pharmaceutical compositions	4/11/2026
	U.S.	Methods of treatment, including combination therapy	10/5/2040
UPLIZNA® (inebilizumab-cdon)	U.S.	CD19 antibodies and pharmaceutical compositions	6/11/2034
	Europe	CD19 antibodies, pharmaceutical compositions and methods of treatment[1]	9/7/2027
IMDELLTRA®(tarlatamab-dlle)/IMDYLLTRA™ (tarlatamab)	U.S.	Bifunctional polypeptides[5]	8/12/2036
	Europe	Bifunctional polypeptides	8/1/2036
TAVNEOS® (avacopan)	U.S.	Compounds and pharmaceutical compositions	1/6/2034
	U.S.	Formulations	11/27/2039
	U.S.	Amorphous forms and pharmaceutical compositions and uses thereof	11/27/2039
	Europe	Compounds, pharmaceutical compositions, and methods of treatment[1]	12/21/2029
	Europe	Formulations	11/27/2039
LUMAKRAS®/LUMYKRAS™ (sotorasib)	U.S.	Compounds and pharmaceutical compositions	5/21/2038
	U.S.	Crystalline form, pharmaceutical compositions and methods of treatment	5/20/2040
	U.S.	Methods of treatment	9/15/2040
	Europe	Compounds, pharmaceutical compositions and methods of treatment	5/21/2038

Product	Territory	General subject matter	Expiration
Parsabiv® (etelcalcetide)	U.S.	Compound and pharmaceutical composition	2/7/2031
	U.S.	Formulation	6/27/2034
	U.S.	Methods of making	8/9/2035
	Europe	Compound and pharmaceutical composition[1]	7/29/2030
	Europe	Formulation	6/27/2034
	Europe	Methods of making	4/3/2035
Aimovig® (erenumab-aooe)	U.S.	Polynucleotides encoding CGRP receptor antibodies and methods of making antibodies	12/11/2031
	U.S.	CGRP receptor antibodies	5/17/2032
	U.S.	Methods of treatment	4/22/2036
	U.S.	Compositions and pharmaceutical formulations	4/1/2039
	Europe	CGRP receptor antibodies[1]	12/18/2029
	Europe	Methods of treatment	8/10/2035

(1) A European patent with this subject matter may also be entitled to supplemental protection in one or more countries in Europe, and the length of any such extension will vary by country. For example, supplementary protection certificates have been issued related to the indicated products for patents in at least the following countries:

- evolocumab — France, Italy, Spain and the United Kingdom, expiring in 2031
- romosozumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2031
- blinatumomab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2029
- tezepelumab — France, Italy and Spain, expiring in 2033
- carfilzomib — France, Germany, Italy, Spain and the United Kingdom, expiring in 2030
- inebilizumab — France, Germany, Italy and Spain, expiring in 2032
- avacopan — France, Italy, Spain and the United Kingdom, expiring in 2034
- etelcalcetide — France, Germany, Italy, Spain and the United Kingdom, expiring in 2031
- erenumab — France, Germany, Italy, Spain and the United Kingdom, expiring in 2033

(2) Pediatric exclusivity granted to August 16, 2028 for a patent with this subject matter.

(3) We have biologic exclusivity in the United States and regulatory exclusivity in Europe covering teprotumumab-trbw that will expire in 2032 and 2035, respectively.

(4) Pediatric exclusivity granted to June 7, 2028 for a patent with this subject matter.

(5) A patent with this subject matter may be entitled to patent term extension in the United States.

Competition

We operate in a highly competitive environment. A number of our marketed products are indicated for disease areas in which other products or treatments are currently available or are being pursued by our competitors through R&D activities. Additionally, some competitor-marketed products target the same genetic pathways as our recently launched marketed products or product candidates. This competition could impact the pricing and market share of our products. We continue to pursue ways of increasing the value of our medicines through innovations, which can include expanding the disease areas for which our products are indicated and finding new methods to make the delivery or manufacture of our medicines easier and less costly. Such activities can offer important opportunities for differentiation. We plan to continue pursuing innovation efforts to strengthen our competitive position. Such position may be based on, among other things, safety, efficacy, reliability, availability, patient convenience, delivery devices, price, reimbursement, access to and timing of market entry and patent position and expiration.

Certain of the existing patents on our principal products have expired, and we face new and increasing competition, including from biosimilars and generics. A biosimilar is another version of a biological product for which marketing approval is sought or has been obtained based on a demonstration that it is "highly similar" to the original reference product. We have experienced adverse effects from biosimilar competition on our originator product sales. Companies have launched versions of EPOGEN, NEUPOGEN, Neulasta and ENBREL (Canada only) with U.S. ENBREL biosimilars approved but not launched. Once multiple biosimilar versions of one of our originator products have launched, competition intensifies rapidly, resulting in accelerated net price declines for both the reference and the biosimilar products. For example, our patents for RANKL antibodies, including sequences, for Prolia and XGEVA expired in February 2025 in the United States and in November 2025 in select countries in Europe, and we expect accelerated sales erosion driven by increased competition, as multiple biosimilars have launched in the United States and ROW. See also Government Regulation—*Regulation in the United States—Approval of Biosimilars*.

We also have our own biosimilar products both in the United States and ROW that are competing against branded and biosimilar versions of our competitors' products. Since 2018, we have launched eight biosimilars, including the 2025 U.S. launches of WEZLANA, a biosimilar to STELARA®, and BKEMV, a biosimilar to SOLIRIS®. We expect additional biosimilar competition against both our branded and biosimilar products in the future across markets. Although biosimilars compete on price, we believe many patients, providers and payers will continue to place high value on the reputation, supply reliability and safety of our products. As additional biosimilar competitors come to market, we will continue to leverage our global experience to distinguish against both branded and biosimilar competitors.

Although most of our products are biologics, some are small molecule products, including Otezla, KYPROLIS and LUMAKRAS/LUMYKRAS. Because the FDA approval process permits generic manufacturers to rely on the safety and efficacy data of the innovator product rather than having to conduct their own costly and time-consuming clinical trials, generic manufacturers can often develop and market their competing versions of our small molecule products at much lower prices. For example, following loss of exclusivity of patents directed to cinacalcet, the active ingredient in our small molecule calcimimetic Sensipar, we lost a significant share of the market and corresponding revenues in a very short period of time.

The introduction of new products, the development of new processes or technologies by competitors or the emergence of new information about existing products may result in (i) increased competition for our marketed products, even for those protected by patents and/or (ii) reductions in the prices we receive from selling our products. In addition, the development of new treatment options or standards of care may reduce the use of our products or may limit the utility and application of ongoing clinical trials of our product candidates. (As used in this document, the term *clinical trials* may include prospective clinical trials, observational studies, registries and other studies.) See Item 1A. Risk Factors—*Our products face substantial competition and our product candidates are also likely to face substantial competition* and Item 1A. Risk Factors—*We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future*.

The following table reflects our significant competitors for our principal products and is not exhaustive.

Product	Territory	Competitor-marketed product	Competitors
Prolia	U.S., Europe & Asia Pacific	Bisphosphonates, including generics	Various
	U.S., Europe & Asia Pacific	Denosumab biosimilars	Various
Repatha	U.S., Europe & Asia Pacific	LEQVIO®	Novartis AG
	U.S., Europe & Asia Pacific	PRALUENT®	Regeneron Pharmaceuticals, Inc. Sanofi
Otezla	U.S. & Europe	Skyrizi®	AbbVie Inc.
	U.S. & Europe	Taltz®	Eli Lilly and Company
	U.S. & Europe	Tremfya®	Johnson & Johnson Innovative Medicine(1)
	U.S. & Europe	HUMIRA® (2)	AbbVie Inc.
	U.S. & Europe	Cosentyx®	Novartis AG
	U.S. & Europe	SOTYKTU®	Bristol Myers Squibb Company
	U.S. & Europe	Topical products	Various
ENBREL	U.S.	HUMIRA® (2)	AbbVie Inc.
	U.S.	RINVOQ®	AbbVie Inc.
	U.S.	ORENCIA®	Bristol Myers Squibb Company
	U.S.	Xeljanz®	Pfizer Inc.
	U.S.	Cosentyx®	Novartis AG
	Canada	Etanercept biosimilars	Various
EVENITY	U.S.	Bisphosphonates, including generics	Various
	Japan	Teribone™	Asahi Kasei Pharma
XGEVA	U.S. & Europe	Zoledronate generics	Various
	U.S., Europe & Asia Pacific	Denosumab biosimilars	Various
BLINCYTO	U.S. & Europe	BESPONSA®	Pfizer Inc.
	U.S. & Europe	Chemotherapy regimen	Various
Nplate	U.S. & Europe	PROMACTA®/REVOLADE™	Novartis AG
TEZSPIRE	U.S.	DUPIXENT®	Regeneron Pharmaceuticals, Inc. Sanofi
	U.S.	FASENRA®	AstraZeneca
	U.S.	NUCALA®	GSK plc.
	U.S.	XOLAIR®	Genentech, Inc. Novartis AG
KYPROLIS	U.S. & Europe	DARZALEX®	Johnson & Johnson Innovative Medicine(1)
	U.S. & Europe	POMALYST®/IMNOVID®	Celgene Corporation(3)
	U.S. & Europe	REVLIMID® (4)	Various
	U.S.	VELCADE®	Takeda Oncology(5)
	U.S.	CARVYKTI®	Johnson & Johnson Innovative Medicine(1) Legend Biotech
Aranesp	U.S.	PROCRIT® (6)	Johnson & Johnson Innovative Medicine(1)
	U.S. & Europe	Epoetin alfa biosimilars	Various

Vectibix	U.S. & Europe	Avastin®	F. Hoffmann-La Roche Ltd. (Roche)
	U.S. & Europe	ERBITUX®	Eli Lilly and Company Merck KGaA
	U.S.	KEYTRUDA®	Merck & Co., Inc.
	U.S. & Europe	Chemotherapy regimen	Various

(1) A subsidiary of Johnson & Johnson.

(2) Approved biosimilars for HUMIRA® available.

(3) A subsidiary of Bristol-Myers Squibb Company.

(4) REVLIMID® also includes generics.

(5) A subsidiary of Takeda Pharmaceutical Co., Ltd.

(6) PROCRIT® competes with Aranesp in supportive cancer care and predialysis settings.

TEPEZZA and KRYSTEXXA currently do not face any direct competitors in the United States, Europe or Japan. TEPEZZA faces competition from other therapies, such as corticosteroids, which have been used on an off-label basis to alleviate some of the symptoms of TED. TEPEZZA and KRYSTEXXA may face competition from competitor medicines currently in clinical trials. See TEPEZZA and KRYSTEXXA sections above and Government Regulation—*Regulation of Orphan Medicines.*

Reimbursement

Sales of our products are dependent on the availability and extent of coverage and reimbursement from third-party payers. In many markets around the world, these payers, including government health systems, private health insurers and other organizations, remain focused on reducing the cost of healthcare; and their efforts have intensified, in part, as a result of uncertain macroeconomic conditions, rising healthcare costs and pressures on healthcare budgets. Drugs remain heavily scrutinized for cost containment. As a result, payers have been and continue to be more restrictive regarding the use of biopharmaceutical products and are scrutinizing the prices of these products while requiring a higher level of clinical evidence to support the benefits such products bring to patients and the broader healthcare system. For example, as discussed below, payers are increasingly using stricter utilization management criteria, such as prior authorization and step therapy, to contain or reduce costs. These pressures become intensified when our products become subject to competition, including from biosimilars.

In the United States, healthcare providers and other entities such as pharmacies and PBMs are reimbursed for covered services and products they deliver through both private-payer and government healthcare programs such as Medicare and Medicaid. We provide negotiated rebates or discounts to healthcare providers, private payers, government payers and PBMs. In addition, we are required to (i) provide rebates or discounts on our products that are reimbursed through certain government programs, including Medicare and Medicaid, and (ii) provide discounts to qualifying healthcare providers under the 340B Program. There has been an increase in the number of entities participating in the 340B Program and in the volume of our medicines dispensed through 340B channels. As a result, this expanded utilization of the 340B Program has had a negative impact on the Company's financial performance.

Both private and some government payers use formularies to manage access to and utilization of drugs. A drug's inclusion and favorable positioning on a formulary are essential to ensure patients have full access to a particular drug. Even when access is available, some patients abandon their prescriptions for economic reasons. Payers continue to institute cost reduction and containment measures that lower drug utilization and/or spending altogether and/or shift a greater portion of the costs to patients. Such measures include, but are not limited to, more-limited benefit plan designs, higher patient co-pays or coinsurance obligations, limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs), stricter utilization management criteria (such as prior authorization and step therapy) before a patient may get access to a drug, higher-tier formulary placement that increases the level of patient out-of-pocket costs and formulary exclusion, which effectively encourages patients and providers to seek alternative treatments or pay 100% of the cost of a drug. The use of such measures by PBMs and insurers has continued to intensify and has thereby limited Amgen product usage and sales. Furthermore, in the United States, the top six integrated health plans and PBMs controlled about 89% of all pharmacy prescriptions. As a result, PBMs and insurers have greater market power and negotiating leverage to mandate stricter utilization criteria and/or exclude drugs from their formularies in favor of competitor drugs or alternative treatments. In highly competitive treatment markets such as the markets for ENBREL, Otezla, Repatha and

Aimovig, PBMs are also able to exert negotiating leverage by requiring incremental rebates from manufacturers in order for them to gain and/or maintain their formulary position.

In addition to market actions taken by private and government payers in the United States, policy makers in both of the major U.S. political parties have supported policies to lower drug costs. See Item 1A. Risk Factors—*Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability*. For example, in 2022, the IRA was enacted and includes provisions requiring that beginning in 2026, mandatory price setting be introduced in Medicare for certain drugs paid for under Parts B and D, whereby manufacturers must accept a price established by the government or face penalties on all U.S. sales (starting with 10 drugs effective January 1, 2026, adding 15 in 2027 and 2028, and adding 20 in 2029 and subsequent years such that by 2031 approximately 100 drugs would be subject to such set prices). CMS has set Medicare Part D prices for ENBREL, effective January 1, 2026, and Otezla, effective January 1, 2027, in each case at significantly lower prices that are expected to negatively impact their profitability in Medicare. See Part IV—Note 13, Goodwill and other intangible assets, to the Consolidated Financial Statements for additional information related to the Otezla intangible asset impairment charges. Also under the IRA, starting on January 1, 2024, Medicare Part D was redesigned to cap beneficiary out-of-pocket costs and reduce Federal reinsurance in the catastrophic phase, increasing cost-sharing obligations for Part D plans and manufacturers, including by requiring manufacturer discounts. Further, the IRA created a mechanism for CMS to collect rebates from manufacturers if Medicare price increases outpace inflation. We began to accrue for rebate obligations on October 1, 2022 for Medicare Part D and on January 1, 2023 for Medicare Part B.

In addition to the IRA, other proposed U.S. policy actions focus on drug pricing, including the Most-Favored-Nations Prescription Drug Pricing Executive Order (MFN EO) that is aimed at using price benchmarks from other developed countries to set U.S. pricing targets, and the July MFN Letter that was delivered to a number of pharmaceutical companies, including Amgen. The July MFN Letter called for drug manufacturers to: 1) extend MFN pricing to Medicaid; 2) guarantee MFN pricing to Medicaid, Medicare and commercial payers on all newly launched drugs; 3) use future increased revenues from outside the U.S. to lower U.S. drug prices; and 4) participate in direct-to-patient models to provide MFN pricing for certain drugs. In December 2025, we announced that we are taking actions that satisfy the components outlined in the July MFN Letter, including the Administration's MFN pricing requests. We also announced the expansion of our direct-to-patient program, AmgenNow™, to include Aimovig and AMJEVITA, supplementing our existing offering of Repatha, all of which are available through AmgenNow™ and are expected to be available through TrumpRx following the platform's launch. See Item 1A. Risk Factors—*Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability*.

Other potential policies cover a wide range of areas, including allowing the importation of drugs from other countries; increasing transparency in drug pricing; using third-party value assessments to determine drug prices; referencing foreign prices; and changes to government rebate programs. For example, on January 5, 2024, the FDA authorized Florida to move forward with its importation program proposal, which excludes biologics. Further, at the state level, eight states (Colorado, Maine, Maryland, Minnesota, New Hampshire, New Jersey, Oregon and Washington) have enacted laws that establish PDABs to identify drugs that pose affordability challenges, and in four states (Colorado, Maryland, Minnesota and Washington) include authority for the state PDAB to set upper payment limits on certain drugs for in-state patients, payers and providers.

In many countries outside the United States, government-sponsored healthcare systems are the main payers for drugs and biologics. Governments and payers are using a range of tools to drive prices down, including mandatory price controls, international reference pricing, therapeutic-reference pricing, higher rebates, incentives for generics and biosimilars, and mandated price cuts. Pricing and reimbursement reforms under consideration in the United States—including proposals to expand government negotiation and increase payer leverage—may further amplify global pricing pressures, as many countries reference or react to U.S. pricing dynamics. Health technology assessment bodies increasingly evaluate the added benefit of new therapies, and these judgments shape reimbursement levels and coverage terms. Many countries also narrow coverage relative to product labels or impose volume caps to limit use. We expect governments to continue taking aggressive steps to reduce spending on drugs and biologics, and fiscal constraints may limit willingness to approve or provide access to innovative therapies and new technologies. Potential EU pharmaceutical legislation may also influence pricing and reimbursement frameworks, which could affect patient access.

The dynamics and developments discussed above create pressures on the pricing and potential usage of our products and on the industry. Given the diverse interests in play between payers, biopharmaceutical manufacturers, policy makers, healthcare providers and independent organizations, if and whether the parties involved can achieve alignment on the matters discussed above remain unclear, and the outcome of any such alignment is difficult to predict. We remain focused on pricing our products responsibly and delivering breakthrough treatments for unmet medical needs. Amgen is committed to working with the entire healthcare community to ensure continued innovation and to facilitate patient access to needed medicines. We do this by:

- investing billions of dollars annually in R&D;

- pricing our medicines to reflect the value they provide;
- developing more affordable therapeutic choices in the form of high-quality and reliably supplied biosimilars;
- partnering with payers to share risk and accountability for health outcomes;
- providing patient support and education programs;
- expanding patient access to our medicines, including through direct-to-patient channels;
- continuing to deliver a reliable supply of medicines through our additional investments in U.S. manufacturing;
- helping patients in financial need access our medicines; and
- working with policy makers, patients and other stakeholders to establish a sustainable healthcare system with access to affordable care and in which patients and their healthcare professionals are the primary decision makers.

See Item 1A. Risk Factors—*Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability* and Item 1A. Risk Factors—*Guidelines and recommendations published by various organizations can reduce the use of our products.*

Manufacturing, Distribution and Raw Materials

Manufacturing

We believe we are a leader in the manufacture of biologics and that our manufacturing capabilities represent a competitive advantage. The products we manufacture consist of both biologics and small molecule drugs. The majority of our products are biologics that are produced in living cells and that are inherently complex due to naturally occurring molecular variations. Highly specialized knowledge and extensive process and product characterization are required to transform laboratory-scale processes into reproducible commercial manufacturing processes. Further, our expertise in the manufacture of biologics has positioned us well for leadership in the global biosimilars market. For additional information regarding manufacturing facilities, see Item 2. Properties.

We are expanding our manufacturing capacity and incorporating state-of-the-art technologies to allow us to optimize our manufacturing network and mitigate risks while working to continue to ensure adequate supply of our products to patients worldwide. See *Manufacturing Initiatives* below for additional discussion of our manufacturing expansion efforts. Our new state-of-the-art biomanufacturing facilities, including our facility in North Carolina and FDA-approved facility in Ohio, have been constructed at a lower cost and with greater speed as compared to traditional facilities. For example, our facility in North Carolina has equipment that is portable and smaller, which provides greater flexibility and speed in the manufacture of different medicines simultaneously, allowing us to respond to changing demands for our medicines with increased scale and agility. Furthermore, such state-of-the-art facilities incorporate multiple innovative technologies, automation solutions and environmental sustainability, thus requiring smaller manufacturing footprints and offering greater environmental benefits, including reduced consumption of water and energy and lower levels of carbon emissions. For example, our facility in North Carolina and our FDA-approved facility in Ohio contain many examples of environmental commitments, including on-site photovoltaic renewable energy generation at both sites. We expect our North Carolina facility's carbon footprint, water usage and waste disposed to be substantially lower than that of a traditional drug substance manufacturing facility. Similarly, we expect lower carbon footprint, water usage and waste disposed per unit at our Ohio facility as compared to traditional packaging and assembly facilities.

Our internal manufacturing network has commercial production capabilities for bulk manufacturing, formulation, fill, finish, tableting and final device assembly. These activities are performed within the United States, including in the U.S. territory of Puerto Rico, Rhode Island, Ohio and California facilities, as well as internationally in our Ireland, Netherlands and Singapore facilities. In addition, we use third-party contract manufacturers to supplement the capacity or capability of our commercial manufacturing network.

To support our clinical trials, we manufacture product candidates primarily at our California facilities. We also use third-party contract manufacturers, including contract manufacturers that were added to our clinical manufacturing network from the Horizon acquisition, to supplement the capacity or capability of our overall clinical manufacturing network.

See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing expansion operations and the global supply of our products.

Distribution

We operate distribution centers in the U.S. territory of Puerto Rico, Kentucky, California and the Netherlands for worldwide distribution of the majority of our commercial and clinical products. We also use third-party distributors to supplement distribution of our products worldwide.

Other

In addition to the manufacturing and distribution activities noted above, each of our manufacturing locations includes key manufacturing support functions such as quality control, process development, engineering, procurement, production scheduling and warehousing. Certain of those manufacturing and distribution activities are highly regulated by the FDA as well as international regulatory agencies. See Government Regulation—*Regulation in the United States—Regulation of Manufacturing Standards*.

Manufacturing Initiatives

As discussed above, we are expanding our capacity and advancing new innovations to support anticipated patient demand for our current and future products.

In January 2025, we opened our Holly Springs, North Carolina site, a cutting-edge drug substance facility. Upon FDA approval, this facility will increase our biologics manufacturing capacity. Also in January 2025, we broke ground on a second drug substance manufacturing facility at this location. This second facility will incorporate state-of-the-art technologies and sustainable practices. The result is a more flexible and efficient facility, with a smaller physical footprint, reduced consumption of water and energy, and lower levels of carbon emissions than a traditional facility.

Additionally, in 2025 we announced expansions of our manufacturing network in New Albany, Ohio and the U.S. territory of Puerto Rico, further strengthening our U.S.-based manufacturing capabilities. Our Ohio expansion builds on our existing biomanufacturing facility, which received FDA licensure for commercial production in January 2024 and supports final product assembly and packaging using state-of-the-art technologies and automation.

These expansion initiatives further enhance our manufacturing network to support reliable and efficient supply of our medicines to patients worldwide. We continue evaluating our manufacturing network to ensure we maintain appropriate levels of operational flexibility and risk management needed to support our global operations.

Numerous tariffs and trade protection measures have been proposed and, in some cases, implemented by the United States and other countries. We continue to evaluate our global supply chains, sourcing strategies and manufacturing network and to implement measures to minimize the impact of existing and potential future tariffs. See Item 1A. Risk factors—*Our sales and operations are subject to the risks of doing business internationally, including in new or emerging markets*, and Part II—Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview.

See Item 1A. Risk Factors—*Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales*.

Raw Materials and Medical Devices

Certain raw materials, medical devices (including companion diagnostics) and components necessary for the commercial and/or clinical manufacturing of our products are provided by and are the proprietary products of unaffiliated third-party suppliers, certain of which may be our only source for such materials. We work to manage the risk associated with such sole suppliers by means of inventory management, relationship management and evaluation of alternative sources when feasible. We also monitor the financial condition and manufacturing quality and compliance of key suppliers and their ability to supply our needs. See Item 1A. Risk Factors—*We rely on third-party suppliers for certain of our raw materials, medical devices and components.*

We perform various procedures to help authenticate the sources of raw materials, including intermediary materials used in the manufacture of our products; the procedures are incorporated into the manufacturing processes we and our third-party contract manufacturers perform and include verification of country of origin.

To better ensure supply, Amgen has a risk mitigation strategy that uses a combination of methods, including multiple sources or backup inventory of critical raw materials. As part of our ongoing business continuity efforts, we continue to closely monitor our inventory levels and have taken additional measures to mitigate against raw material supply interruption. We also continue to assess the potential impacts of existing and proposed tariffs on our raw material and medical device supply chains and implement sourcing and inventory strategies intended to minimize the impacts from existing and potential future tariffs. See

Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

Government Regulation

Regulation by government authorities in the United States and other countries is a significant factor in the production and marketing of our products and our ongoing R&D activities. To clinically test, manufacture and market products for therapeutic use, we must satisfy mandatory procedures and safety and effectiveness standards established by various regulatory bodies. Compliance with these standards is complex, and failure to comply with any of these standards can result in significant implications. See Item 1A. Risk Factors for a discussion of factors, including global regulatory implications, that can adversely impact our development and marketing of commercial products.

Regulation in the United States

In the United States, the Public Health Service Act; the FDCA; and the regulations promulgated thereunder as well as other federal and state statutes and regulations govern, among other things, the production, research, development, testing, manufacture, quality control, labeling, storage, record keeping, approval, advertising, promotion and distribution of our products in addition to the reporting of certain payments and other transfers of value to healthcare professionals and teaching hospitals.

Clinical Development and Product Approval. Drug development in our industry is complex, challenging and risky, and failure rates are high. Product development cycles are typically very long—approximately 10 to 15 years from discovery to market. A potential new medicine must undergo many years of preclinical and clinical testing to establish its safety and efficacy for use in humans at appropriate dosing levels and with an acceptable risk–benefit profile. We continue to work toward reducing cycle times by applying our expertise in human genetics and innovation in technology, clinical trials and real-world evidence. See Research and Development and Selected Product Candidates section below.

After laboratory analysis and preclinical testing in animals, we file an IND with the FDA to begin human testing. Typically, we undertake an FDA-designated three-phase human clinical testing program.

- In Phase 1, we conduct small clinical trials to investigate the safety and proper dose ranges of our product candidates in a small number of human subjects.
- In Phase 2, we conduct clinical trials to investigate side-effect profiles and the efficacy of our product candidates in a patient population larger than Phase 1 but still relatively small, who have the disease or condition under study.
- In Phase 3, we conduct clinical trials to investigate the short- and long-term safety and efficacy of our product candidates, compared to commonly used treatments, in a large number of patients who have the disease or condition under study.

The FDA monitors the progress of each trial conducted under an IND and may, at its discretion, reevaluate, alter, suspend or terminate the testing based on data accumulated to that point and the FDA's risk–benefit assessment with regard to the patients enrolled in the trial. The results of preclinical and clinical trials are submitted to the FDA in the form of either a BLA for biologic products or a New Drug Application for small molecule products. We are not permitted to market or promote a new product until the FDA has approved our marketing application.

Approval of Biosimilars. The Affordable Care Act authorized the FDA to approve biosimilars via a separate, abbreviated pathway. The pathway allows sponsors of a biosimilar to seek and obtain regulatory approval based in part on the nonclinical-trial and clinical-trial data of an originator product to which the biosimilar has been demonstrated to be "highly similar" and to have no clinically meaningful differences with regard to safety, purity and potency. The relevance of demonstrating "similarity" is that in many cases, biosimilars can be brought to market without conducting the full suite of clinical trials typically required of originators, because risk–benefit has previously been established. To preserve incentives for future innovation, the law establishes a period of exclusivity for originators' products, which in general prohibits biosimilars from gaining FDA approval based in part on reliance on or reference to the originator's data in their application to the FDA for 12 years after initial FDA approval of the originator product. The law does not change the duration of patents granted on biologic products. As part of the implementation of the abbreviated approval pathway for biosimilars, the FDA released a number of guidance documents, some of which remain in draft form. See Item 1A. Risk Factors—*We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future*.

Regulation of Product Marketing and Promotion. The FDA regulates the marketing and promotion of drug products. Our product promotions for approved product indications must comply with the statutory standards of the FDCA and the FDA's implemented regulations and guidance. The FDA's review of marketing and promotional activities encompasses but is not limited to direct-to-patient advertising, healthcare-provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA may also review industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. The FDA may take enforcement action against a company for violations of the FDA's advertising and labeling laws and regulations. Enforcement action may include product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Failure to comply with the FDA's regulations also can result in adverse publicity or increased scrutiny of company activities by the U.S. Congress or other legislators. Additionally, as described below, such failure may lead to additional liability under U.S. healthcare fraud and abuse laws.

Regulation of Manufacturing Standards. The FDA regulates and inspects the equipment, facilities, laboratories and processes used in the manufacturing and testing of products prior to granting approval to market products. If, after receiving approval from the FDA, we make a material change in manufacturing equipment, location or process, additional regulatory review may be required. We also must adhere to current Good Manufacturing Practice regulations and product-specific regulations enforced by the FDA through its facilities inspection program. The FDA conducts regular, periodic visits to reinspect our equipment, facilities, laboratories and processes following an initial approval.

Regulation of Combination Products. Combination products are defined by the FDA as products composed of two or more regulated components (e.g., a biologic and/or drug and a device). Biologics/drugs and devices each have their own regulatory requirements, and combination products may have additional requirements. A number of our marketed products meet this definition and are regulated under this framework, and we expect that a number of our pipeline product candidates will be evaluated for regulatory approval under this framework as well.

Regulation of Orphan Medicines. Orphan drugs are defined by the FDA as products intended to treat a rare disease or condition that affects less than 200,000 persons in the United States. A company must request orphan drug designation prior to filing, and if the product is ultimately approved for the designated rare disease or condition, it may qualify for seven years of orphan drug exclusivity during which the FDA will not approve another sponsor's marketing application for the same drug for the same indication. Orphan drug exclusivity will not bar approval of another medicine for the same indication if it is shown to be clinically superior. In the United States, a number of our products, including products such as BLINCYTO and UPLIZNA, have orphan drug exclusivity under this framework for specific indications.

Regulation Outside the United States

In EU countries as well as in the United Kingdom, Switzerland, Canada, Australia and Japan, regulatory requirements and approval processes are similar in principle to those in the United States.

In the EU, there are currently two potential tracks for seeking marketing approval for a product not authorized in any EU member state: a decentralized procedure and a centralized procedure. In the *decentralized procedure*, identical applications for marketing authorization are submitted simultaneously to the national regulatory agencies. Regulatory review is led by one member state (the reference-member state), and its assessment—based on safety, quality and efficacy—is reviewed and approved (assuming there are no concerns that the product poses a serious risk to public health) by the other member states from which the applicant is seeking approval (the concerned-member states). The decentralized procedure leads to a series of single national approvals in all relevant countries. In the *centralized procedure*, which is required of all products derived from biotechnology, a company submits a single MAA to the EMA, which conducts an evaluation of the dossier, drawing upon its scientific resources across Europe. If the drug product is proven to fulfill requirements for quality, safety and efficacy, the EMA's CHMP adopts a positive opinion, which is transmitted to the EC for final decision on granting of the marketing authorization. Even though the EC generally follows the CHMP's opinion, it is not bound to do so. Subsequent commercialization is enabled by country-by-country reimbursement approval.

In the EU, biosimilars are approved under a specialized pathway of the centralized procedure. As with the U.S. pathway, an applicant seeks and obtains regulatory approval for a biosimilar once the data exclusivity period for the original reference product has expired, relying, in part, on the data submitted for the originator product together with data evidencing that the biosimilar is "highly similar" with regard to quality, safety and efficacy to the original reference product authorized in the European Economic Area. See Item 1A. Risk Factors—*We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future*.

In the EU, Regulation (EC) No 141/2000, as implemented by Regulation (EC) No. 847/2000, provides that a medicine can be designated as an orphan medicinal product by the EC if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition. An application for the designation of a medicinal product as an orphan medicinal product may be submitted at any stage of development of the medicinal product but before the filing of an MAA. A marketing authorization for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought. Approved orphan drugs in the EU receive 10 years of market exclusivity for the approved indication in all EU member states. We currently have orphan medicinal product designation for BLINCYTO in the EU and may seek medicinal product designation for a number of our products in the future.

Other countries such as those in Latin America and the Middle East have review processes and data requirements similar to those of the EU and in some cases can rely on prior marketing approval from U.S. or EU regulatory authorities. The regulatory process in these countries may include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements.

In Asia Pacific, a number of countries such as China, Japan, South Korea and Taiwan may require local clinical-trial data for bridging purposes as part of the drug registration process in addition to global clinical trials, which can add to overall drug development and registration timelines. In many Asian markets, registration timelines may be influenced by prior marketing approvals in reference jurisdictions (e.g. the United States or the EU). In some markets in Asia, such as China, Indonesia and Thailand, regulatory timelines can be more variable. The regulatory process may also include manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements. Countries such as Australia and Japan have more mature regulatory systems which may allow for submissions under comparatively more predictable time frames. With regard to biosimilars, several of these countries have pathways to register biosimilars (e.g., Australia, India, Singapore, South Korea and Taiwan), and biosimilar products in market (e.g., Australia, Japan, South Korea and Taiwan).

In some countries, such as Japan and those in the EU, medical devices may be subject to regulatory regimes whereby manufacturers must establish that their medical devices conform to essential requirements set out in the law for the particular device category. For example, in the EU, with limited exceptions, medical devices placed on the market must bear the Conformité Européenne marking to indicate their conformity with legal requirements.

Post-approval Phase

After approval, we continue to monitor adverse events and product complaints reported following the use of our products through routine postmarketing surveillance and studies when applicable. We report such events to the appropriate regulatory agencies as required by local regulations for individual cases and aggregate reports. We proactively monitor (according to good pharmacovigilance practices) and ensure the implementation of signal detection, assessment and the communication of adverse events that may be associated with the use of our products. We also proactively monitor product complaints through our quality systems, which includes assessing our drug delivery devices for device complaints, adverse events and malfunctions. We may also be required by regulatory agencies to conduct further clinical trials on our marketed products as a condition of their approval or to provide additional information on safety and efficacy. Health regulators, including the FDA, have authority to mandate labeling changes to products at any point based on new safety information or as part of an evolving label change to a particular class of products.

Health regulators, including the FDA, also have authority both before and after approval to require that a company implement a risk management program for a product to ensure that the benefits of the drug outweigh the risks. Each risk management program is unique and varies depending on the specific factors required. In the United States, such a risk management program is known as a REMS, and we currently have REMSs for Prolia, Nplate and BLINCYTO.

Other Regulation

We are also subject to various laws pertaining to healthcare fraud and abuse, including antikickback laws and false-claims laws. Antikickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for or to induce the referral of business, including the purchase or prescribing of a particular drug that is reimbursed by a state or federal program. False-claims laws prohibit knowingly and willingly presenting, or causing to be presented, for payment to third-party payers (including Medicare and Medicaid) any claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as by the possibility

of exclusion from federal healthcare programs (including Medicare and Medicaid). Liability under false-claims laws may also arise when violation of certain laws or regulations related to the underlying product (e.g., a violation regarding improper promotional activity or unlawful payments) contributes to the submission of a false claim. See Item 1A. Risk Factors—*Our business may be affected by litigation and government investigations*.

The FCPA prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA arguably includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anticorruption laws and/or regulations. Failure by our employees, agents, contractors, vendors, licensees, partners or collaborators to comply with the FCPA and other anticorruption laws and/or regulations could result in significant civil or criminal penalties.

We are subject to various laws and regulations globally with regard to privacy and data protection. These laws and regulations involve the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environments regarding privacy and data protection are continually evolving and developing because these issues are subjects of increasing amounts of attention in countries globally. For example, we are subject to the EU's GDPR, which became effective on May 25, 2018; the CCPA, which became effective on January 1, 2020; the California Privacy Rights Act of 2020, which amended the CCPA and became effective on January 1, 2023; and China's Personal Information Protection Law, which became effective on November 1, 2021. Other jurisdictions where we operate have enacted or proposed similar legislation and/or regulations, such as consumer privacy laws that went into effect in Virginia, Colorado, Utah, Connecticut and Florida in 2023 and Oregon, Texas and Montana in 2024. Consumer privacy laws were also passed in other states, including Iowa, Delaware, New Hampshire, Nebraska, New Jersey, Tennessee, Minnesota, Maryland, Indiana, Kentucky and Rhode Island, and became effective or are scheduled to become effective in 2025 through 2026. In April 2023, a new type of state privacy law focused on protection of consumer health data emerged in Washington with the enactment of the My Health My Data Act, with similar legislation passed subsequently in Nevada. Both these new consumer health privacy laws became effective on March 31, 2024. Further, in 2024, the EU Artificial Intelligence (AI) Act, formally known as Regulation (EU) 2024/1689, was passed into law. Certain provisions of this regulation, such as transparency obligations and governance structures, became effective in February and August 2025, and the regulation will become fully effective on August 2, 2026. The regulation establishes a risk-based framework governing the development, deployment and use of AI systems across the EU. High-risk AI systems are subject to stringent requirements such as mandatory risk assessments, technical documentation, bias mitigation and explainability standards. Non-compliance with these current and future laws could result in significant penalties.

Our business has been and will continue to be subject to various other U.S. and foreign laws, rules and regulations, including provisions of the IRA and OB3. See Reimbursement section above.

Research and Development and Selected Product Candidates

We focus our R&D on novel human therapeutics for the treatment of serious illness. We capitalize on our strengths in human genetics, novel biology and protein engineering. We leverage our biologic expertise and seek to choose the optimal modality for a drug target and disease, and we use cutting-edge science and technology to study subtle biological mechanisms in search of therapies that will improve the lives of those who suffer from diseases. See Government Regulation—*Clinical Development and Product Approval* section above.

Our discovery research programs may therefore yield targets that lead to the development of human therapeutics delivered as large molecules, small molecules, other combination modalities or new modalities. We have increasingly focused our efforts on human genetics when possible to enhance the likelihood of success. We have major R&D centers in the United States in Thousand Oaks and San Francisco, California; Iceland; and the United Kingdom, as well as smaller research centers and development facilities globally. Additionally, in 2025, we broke ground on a new state-of-the-art R&D facility in Thousand Oaks, California, to further enhance collaboration and innovation across R&D and process development activities. See Item 2. Properties.

Our clinical trial activities are conducted by both our internal staff and third-party contract clinical trial service providers. To increase the number and diversity of patients available for enrollment in our clinical trials and to meet evolving regulatory expectations, we have opened clinical sites and will continue opening clinical sites and enrolling patients in a number of geographic locations. With regard to our clinical trial activities, we are continuously monitoring the possible impacts from health-related events, geopolitical conflicts and natural disasters. We are working to mitigate effects on future study enrollment in our clinical trials; and we are evaluating the impact in all relevant countries. We remain focused on supporting our active clinical sites in their providing care for patients and in our providing investigational drug supply. See Government Regulation—*Regulation in the United States—Clinical Development and Product Approval* for a discussion of government regulation over clinical development. Also see Item 1A. Risk Factors—*We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.*

For the years ended December 31, 2025, 2024 and 2023, our R&D expenses were $7.3 billion, $6.0 billion and $4.8 billion, respectively. We expect to continue allocating significant resources to our R&D activities.

Some of our competitors are actively engaged in R&D in areas in which we have products or in which we are developing product candidates or new indications for existing products. For example, we compete with other clinical trials for eligible patients, which may limit the number of available patients who meet the criteria for certain clinical trials. The competitive marketplace for our product candidates is greatly dependent on the timing of entry into the market. Early entry may have important advantages in gaining product acceptance, thereby contributing to a product's eventual success and profitability. Accordingly, we expect that in some cases, the relative speed with which we can develop products, complete clinical testing, receive regulatory approval and supply commercial quantities of a product to the market will be important to our competitive position.

In addition to product candidates and marketed products generated from our internal R&D efforts, we acquire companies, acquire and license certain product and R&D technology rights and establish R&D arrangements with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed product base. In pursuing these R&D arrangements and licensing or acquisition activities, we face competition from other pharmaceutical and biotechnology companies that also seek to license or acquire technologies, product candidates or marketed products from those entities performing the R&D.

The following table shows a selection of certain of our product candidates by phase of development in our therapeutic areas of focus as of February 3, 2026, unless otherwise indicated. The information in this section does not include, among other things, other, nonregistrational clinical trials that we may conduct for purposes other than for submission to regulatory agencies for their approval of a new product indication.

We may conduct nonregistrational clinical trials for various reasons, including to evaluate real-world outcomes or to collect additional safety information with regard to the use of products.

	Investigational indications (programs)
Phase 3	
BLINCYTO	Ph-negative B-ALL
Dazodalibep	Sjögren's disease
IMDELLTRA/IMDYLLTRA	Small cell lung cancer
LUMAKRAS/LUMYKRAS	Metastatic colorectal cancer
	Non-small cell lung cancer
MariTide	Chronic weight management
	Cardiovascular disease
	Heart failure
	Obstructive sleep apnea
Nplate	Chemotherapy-induced thrombocytopenia
Olpasiran	Cardiovascular disease
Pegloticase	Subcutaneous administration for uncontrolled gout
Repatha	Cardiovascular disease
Rocatinlimab[(1)]	Moderate-to-severe atopic dermatitis
	Prurigo nodularis
TEPEZZA	Subcutaneous administration for TED
	Chronic/low clinical activity score TED in Japan
TEZSPIRE	Chronic obstructive pulmonary disease
	Eosinophilic esophagitis
Xaluritamig	Metastatic castrate resistant prostate cancer
ABP 206	Investigational biosimilar to OPDIVO® (nivolumab)
ABP 234	Investigational biosimilar to KEYTRUDA® (pembrolizumab)
ABP 692	Investigational biosimilar to OCREVUS® (ocrelizumab)

	Investigational indications (programs)
Phase 2	
Blinatumomab	Refractory rheumatoid arthritis
	Systemic lupus erythematosus with and without nephritis
Daxdilimab	Dermatomyositis and anti-synthetase inflammatory myositis
	Discoid lupus erythematosus
Inebilizumab	Systemic lupus erythematosus with nephritis
MariTide	Type 2 diabetes
Rocatinlimab[(1)]	Moderate-to-severe asthma
AMG 104	Asthma
AMG 193	Non-small cell lung cancer
AMG 329	Sjögren's disease
AMG 732	TED
Phase 1	
Xaluritamig	Ewing Sarcoma
AMG 193	Other tumors
AMG 305	Solid tumors
AMG 355	Solid tumors
AMG 410	Solid tumors
AMG 513	Obesity
AMG 691	Asthma

(1) See Significant Developments for additional information regarding the termination of our collaboration agreement with Kyowa Kirin.

Phase 3 Clinical trials investigate the short- and long-term safety and efficacy of our product candidates, compared to commonly used treatments, in a large number of patients who have the disease or condition under study.

Phase 2 Clinical trials investigate side-effect profiles and efficacy of product candidates in a larger patient population than Phase 1, but still relatively small, who have the disease or condition under study.

Phase 1 Clinical trials investigate the safety and proper dose ranges of product candidates usually in a small number of human subjects.

Phase 3 Product Candidate Program Changes

As of February 4, 2025, we had 25 Phase 3 programs studied in investigational indications. As of February 3, 2026, we had 23 Phase 3 programs being studied in investigational indications, as six programs initiated Phase 3 studies, five programs received regulatory approval, one program was stopped, one program was no longer being pursued and one program concluded. These changes are set forth in the following table.

Molecule	Investigational indications (programs)	Program changes
AMJEVITA	Interchangeability study	Approved by the FDA
Bemarituzumab	Gastric and gastroesophageal junction cancer	Stopped
EVENITY	Male osteoporosis	No longer pursued
MariTide	Chronic weight management	Initiated two global Phase 3 studies
	Cardiovascular disease	Initiated global Phase 3 study
	Heart failure	Initiated global Phase 3 study
	Obstructive sleep apnea	Initiated two global Phase 3 studies
Otezla	Palmoplantar pustulosis	Approved in Japan
Pegloticase	Subcutaneous administration for uncontrolled gout	Initiated Phase 3 study
TEZSPIRE	Chronic obstructive pulmonary disease	Initiated Phase 3 study
	Chronic rhinosinusitis with nasal polyps	Approved by the FDA and the EC
	Severe asthma	Concluded
UPLIZNA	IgG4-RD	Approved by the FDA and the EC
	Generalized myasthenia gravis	Approved by the FDA

Phase 3 Product Candidate Patent Information

The following table describes our composition-of-matter patents that have been issued thus far for our product candidates in Phase 3 development that have yet to be approved for any indication in the United States or the EU. Patents for products already approved for one or more indications in the United States or the EU but that are currently undergoing Phase 3 clinical trials for additional indications have been previously described. See Marketing, Distribution and Selected Marketed Products—*Patents*.

Molecule	Territory	General subject matter	Estimated expiration[1]
Dazodalibep	U.S.	Polypeptides	2034
	Europe	Polypeptides	2032
MariTide	U.S.	Antibody-peptide conjugates	2038
	Europe	Antibody-peptide conjugates	2038
Olpasiran	U.S.	Compounds	2036
	Europe	Compounds	2036
Rocatinlimab[2]	U.S.	Polypeptides	2028
	Europe	Polypeptides	2026
Xaluritamig	U.S.	Polypeptides	2039

(1) Patent expiration estimates are based on issued patents, which may be challenged, invalidated or circumvented by competitors. The estimates do not include any term adjustments, extensions or supplemental protection certificates that may be obtained in the future and thereby extend these dates. Corresponding patent applications are pending in other jurisdictions. Additional patents may be filed or issued and may provide additional exclusivity for the product candidate or its use. In addition to patent exclusivity, the product candidates may be protected by regulatory exclusivities upon approval in some countries. For example, new chemical entities would receive a five year exclusivity period and new molecular entities would receive a 12 year exclusivity period in the United States, whereas new chemical and molecular entities would receive a 10 year exclusivity period in Europe.

(2) See Significant Developments for additional information regarding the termination of our collaboration agreement with Kyowa Kirin.

Phases 2 and 3 Program Descriptions

The following provides additional information about selected products and product candidates that have advanced into human clinical trials.

Blinatumomab

Blinatumomab is an anti-CD19 x anti-CD3 BiTE® molecule. It is being investigated for the treatment of both refractory rheumatoid arthritis and systemic lupus erythematosus with and without nephritis.

BLINCYTO

BLINCYTO is an anti-CD19 x anti-CD3 BiTE® molecule. It is being investigated for the treatment of newly diagnosed adults with B-ALL.

Daxdilimab

Daxdilimab is a fully human monoclonal antibody against ILT7 that depletes certain dendritic cells. It is being investigated for the treatment of both dermatomyositis and anti-synthetase inflammatory myositis and discoid lupus erythematosus.

Dazodalibep

Dazodalibep is a fusion protein binding CD40L on T cells, blocking their interaction with CD40-expressing B cells. It is being investigated for the treatment of Sjögren's disease.

IMDELLTRA/IMDYLLTRA

IMDELLTRA/IMDYLLTRA is an anti-DLL3 x anti-CD3 BiTE® molecule. It is being investigated for the treatment of small cell lung cancer. See Significant Developments for additional information regarding clinical trial updates.

Inebilizumab

Inebilizumab is a humanized, affinity-optimized, afucosylated IgG1 kappa (IgG1κ) monoclonal antibody that binds to the B cell-specific surface antigen CD19. It is being investigated as a treatment for patients with systemic lupus erythematosus with nephritis.

LUMAKRAS/LUMYKRAS

LUMAKRAS/LUMYKRAS is a $KRAS^{G12C}$ small molecule inhibitor. It is being investigated in colorectal cancer, NSCLC and other solid tumor cancers.

Maridebart cafraglutide

MariTide is a differentiated antibody-peptide conjugate that activates the GLP-1 receptor and antagonizes the GIPR. It is being investigated for the treatment of chronic weight management, cardiovascular disease, heart failure, obstructive sleep apnea and Type 2 diabetes. See Significant Developments for additional information regarding clinical trial updates.

Nplate

Nplate is a thrombopoietin receptor agonist (TPO-RA). It is being investigated for the treatment of chemotherapy-induced thrombocytopenia (CIT).

Olpasiran

Olpasiran is a small interfering RNA (siRNA) that lowers lipoprotein(a) (Lp(a)). It is being investigated for the treatment of atherosclerotic cardiovascular disease (ASCVD).

Pegloticase

Pegloticase is a PEGylated uricase approved for the treatment of uncontrolled gout by intravenous administration. It is being investigated for subcutaneous administration when co-administered with methotrexate.

Repatha

Repatha is a human monoclonal antibody that inhibits PCSK9. See Significant Developments for additional information regarding clinical trial updates.

Rocatinlimab

Rocatinlimab is a monoclonal antibody that inhibits OX-40. It is being investigated in Phase 3 studies for the treatment of moderate-to-severe atopic dermatitis and prurigo nodularis. It is also being investigated in a Phase 2 study for the treatment of moderate-to-severe asthma. See Significant Developments for additional information regarding the termination of our collaboration agreement with Kyowa Kirin.

TEPEZZA

TEPEZZA is a monoclonal antibody against IGF-1R. It is being investigated for subcutaneous administration for the treatment of TED and chronic/low clinical activity score TED in Japan.

TEZSPIRE

TEZSPIRE is a human monoclonal antibody that inhibits the action of thymic stromal lymphopoietin. It is being investigated for the treatment of chronic obstructive pulmonary disease and eosinophilic esophagitis. TEZSPIRE is being developed in collaboration with AstraZeneca.

Xaluritamig

Xaluritamig is an anti-six transmembrane epithelial antigen of the prostate 1 (STEAP1) x anti-CD3 XmAb® BiTE® molecule. It is being investigated for the treatment of prostate cancer.

ABP 206

ABP 206, a biosimilar candidate to OPDIVO®, is a monoclonal antibody that binds to the receptor protein called programmed death protein 1 (PD-1).

ABP 234

ABP 234, a biosimilar candidate to KEYTRUDA®, is a monoclonal antibody that binds to the receptor protein PD-1. It is being investigated in a Phase 3 study for biosimilarity to KEYTRUDA®. The reference-product primary condition is NSCLC.

ABP 692

ABP 692, a biosimilar candidate to OCREVUS®, is a monoclonal antibody that binds to CD20, which is a protein found on the surface of B-cells.

AMG 104

AMG 104 is a human anti-TSLP Fab. It is being investigated for the treatment of asthma and is being developed in collaboration with AstraZeneca.

AMG 193

AMG 193 is a small molecule methylthioadenosine (MTA) cooperative protein arginine methyltransferase 5 (PRMT5) inhibitor. It is being investigated for the treatment of NSCLC.

AMG 329

AMG 329 is a fully human monoclonal antibody that binds and neutralizes the function of the FLT3-ligand, thereby reducing both conventional and plasmacytoid dendritic cells. It is being investigated for the treatment of Sjögren's disease.

AMG 732

AMG 732 is a monoclonal antibody against IGF-1R. It is being investigated for the treatment of TED.

Business Relationships

From time to time, we enter into business relationships, including joint ventures and collaborative arrangements, for the R&D, manufacture and/or commercialization of products and/or product candidates. In addition, we acquire product and R&D technology rights and establish R&D collaborations with third parties to enhance our strategic position within our industry by strengthening and diversifying our R&D capabilities, product pipeline and marketed-product base. These arrangements generally provide for nonrefundable upfront license fees, development and commercial-performance milestone payments, cost sharing, royalties and/or profit sharing. The activities under these collaboration agreements are performed with no guarantee of either technological or commercial success, and each is unique in nature.

Trade secret protection for our unpatented confidential and proprietary information is important to us. To protect our trade secrets, we generally require counterparties to execute confidentiality agreements upon commencement of a business relationship with us. However, others could either develop independently the same or similar information or unlawfully obtain access to our information.

AstraZeneca plc

We are in a collaboration with AstraZeneca for the development and commercialization of TEZSPIRE.[1] Under our collaboration, both companies share global costs, profits and losses equally after payment by AstraZeneca of a mid-single-digit royalty to Amgen. AstraZeneca leads global development. In North America, Amgen, as the principal, recognizes product sales of TEZSPIRE in the United States, and AstraZeneca, as the principal, recognizes product sales of TEZSPIRE in Canada. AstraZeneca leads commercialization for TEZSPIRE outside North America. Amgen manufactures and supplies TEZSPIRE worldwide.

UCB

We are in a collaboration with UCB for the development and commercialization of EVENITY. Under our collaboration, UCB has rights to lead commercialization for EVENITY in most countries in Europe. Amgen, as the principal, leads commercialization for EVENITY and recognizes product sales in all other territories, including the United States. Global development costs and commercialization profits and losses related to the collaboration are shared equally. Amgen manufactures and supplies EVENITY worldwide.

BeOne Medicines Ltd.

In January 2020, we acquired an equity stake in BeOne for approximately $2.8 billion in cash as part of a collaboration agreement to expand our oncology presence in China. For additional information regarding our equity investment in BeOne, see Part IV—Note 10, Investments, to the Consolidated Financial Statements. Under the collaboration, BeOne began selling XGEVA in 2020, BLINCYTO in 2021 and KYPROLIS in 2022 in China, and Amgen shares profits and losses equally during the product-specific commercialization periods. Following entry into an amendment to this collaboration by Amgen and BeOne on November 11, 2025, BeOne will retain the right to commercialize XGEVA, BLINCYTO and KYPROLIS in China for so long as such products are sold in China. Amgen manufactures and supplies the collaboration products to BeOne.

In addition, we jointly develop a portion of our oncology portfolio with BeOne, which shares in global R&D costs by providing cash and development services of up to $1.25 billion. Upon regulatory approval, BeOne will assume commercialization rights in China for a specified period, and Amgen and BeOne will share profits and losses equally until certain of these product rights revert to Amgen. Upon return of the product rights, Amgen will pay royalties to BeOne on sales in China for a specified period. For product sales outside China, Amgen also pays royalties to BeOne.

For financial information about our significant collaborative arrangements, see Part IV—Note 9, Collaborations, to the Consolidated Financial Statements.

[1] We are also in a collaboration with AstraZeneca for the development of AMG 104. See Research and Development and Selected Product Candidates section above.

Human Capital Resources

Overview

Amgen's approach to human capital resource management starts with our mission to serve patients. We strive to serve patients by transforming the promise of science and biotechnology into therapies that have the power to restore health or save lives. The complexities of our industry along with the challenges of running an enterprise focused on the discovery, development, manufacture and commercialization of innovative medicines, require a highly engaged and committed workforce.

As of December 31, 2025, Amgen had approximately 31,500 staff members in over 50 countries, including approximately 13,000 staff members outside the United States, and we continue to experience overall low turnover rates. We also supplement our workforce with independent contractors, contingent workers and temporary workers, as needed. Outside of the United States, some of our employees are represented by unions or works councils. We consider our staff relations to be good, supported by regular assessments of staff engagement surveys on a wide range of topics (including flexible work environments, career development, and maintaining a culture of compliance). Our engagement scores were above general market benchmarks in 2025. We discuss the results of these surveys with our workforce and our Board of Directors. Reflecting our staff members' desire to retain a flexible approach to work, we offer a flexible workspace initiative that enables many employees to work together with their manager to determine the location that best enables their work at hand, supporting virtual work as well as working in person.

Compensation, Benefits and Development

Our approach to employee compensation and benefits is designed to deliver cash, equity and benefit programs that are competitive with those offered by leading companies in the biotechnology and pharmaceutical industries, and to attract, motivate and retain talent with a focus on encouraging performance, promoting accountability and adherence to our values and alignment with the interests of the Company's stockholders.

Our base pay program aims to compensate staff members relative to the value of the contributions of their role, which takes into account the skills, knowledge and abilities required to perform each position, as well as the experience brought to the job. We also provide annual incentive programs to reward our staff in alignment with achievement of Company-wide goals that are established annually and designed to drive aspects of our strategic priorities that support and advance our strategy across our Company and are intended to positively position us for both near- and long-term success. The majority of our staff members are also eligible for equity award grants under our long-term incentive program that are designed to align the interests of our staff members with those of our stockholders. For senior level staff, a significant proportion of equity award value is dependent on Company performance.

All staff participate in a regular performance measurement process through which staff receive performance and development feedback, and pay is aligned to performance. Our values and leadership attributes are an integral part of the performance assessments of our staff members, and these evaluations serve as an important information tool and basis for promotion and compensation decisions.

Our staff receive, and are guided by, regular trainings that help them understand what is expected of them. Further, to support the development of our staff, we provide a variety of programs, including leadership development programs, classroom-based and virtual instructor-led courses, and self-paced learning options as well as mentoring, networking and coaching opportunities. In 2025, we invested in general upskilling of our staff on skills for the future, including topics such as AI. We also maintain a global talent marketplace that enables staff to contribute to work beyond their core responsibilities, providing opportunities to broaden professional networks, support organizational priorities and develop additional skills.

Our benefit programs are generally broad-based, promote health and overall well-being and emphasize saving for retirement. All regular U.S. staff members are eligible to participate in the same core health and welfare and retirement savings plans. Other U.S. employee benefits include adoption assistance, paid parental leave programs, access to childcare, employee assistance programs, employee stock purchase plan, flexible spending accounts, life insurance, long-term care and business travel accident insurance, short and long-term disability benefits, wellness benefits and work-life resources and referrals. Comparable programs and benefits are available globally, with the same health and well-being intent, and consistent with local statutory requirements.

Our Compensation and Management Development Committee provides oversight of our compensation plans, policies and programs.

Total Workforce Health

Creating a safe and healthy workplace for our staff is an important priority at Amgen. Our goal is to have a world class safety record through safety leadership, engaged staff, risk management practices and integrating safety throughout our

business processes. We provide job-specific safety training tailored to each role, and to foster our safety culture, we implement a comprehensive safety program and reinforce desired safety behaviors, driving to understand and mitigate the root cause of safety incidents and manage and control variability. We track injuries and near-miss incidents through our incident tracking system, and we use leading indicators to assess the effectiveness of our safety programs and make course corrections as needed. Additionally, we perform formal executive management review of functional safety performance for Operations, Global Commercial Operations and R&D on a quarterly basis with a focus on identifying early signals and taking action to drive continuous improvement.

Our CRCC provides general oversight of our safety programs and initiatives.

Culture

We believe that our culture helps attract and retain a strong and engaged workforce informed by the varied experiences represented, which fosters innovation, collaboration and productivity as we execute on our mission to serve patients. A cross-functional, executive-level council, which includes our CEO, regularly discusses matters related to workplace culture and, as appropriate, takes actions to support and evolve Amgen's culture.

In our effort to attract and retain the best talent, we seek out and support talent across the globe. As part of our multidimensional hiring and talent development strategy, our Apprenticeship Program launched in 2023 in our Manufacturing and ATMOS functions and expanded to include another cohort of apprentices at our North Carolina site in January 2025. Our Apprenticeship Program is a skills-based approach and is designed to invest in our future workforce through attracting, hiring and upskilling non-four-year degreed talent in the United States. Through the Apprenticeship Program, we provide individuals with classroom-based and on-the-job training as well as mentorship opportunities needed to develop proficiency in targeted business areas and roles. Multiple cohorts are underway across various sites, including a new 18 month manufacturing apprenticeship at Amgen North Carolina, which serves as a key talent pipeline. We believe that our Apprenticeship Program and other skills-based approaches to hiring provide us with access to a larger pool of highly motivated and productive talent while also providing greater access to jobs in innovative sectors of the economy.

Our Compensation and Management Development Committee oversees our labor and employment policies, programs and initiatives, including those relating to our talent strategy and culture.

Information about Our Executive Officers

The executive officers of the Company as of February 13, 2026, are set forth below.

Mr. Robert A. Bradway, age 63, has served as a director of the Company since 2011 and Chairman of the Board of Directors since 2013. Mr. Bradway has been the Company's President since 2010 and Chief Executive Officer since 2012. From 2010 to 2012, Mr. Bradway served as the Company's President and Chief Operating Officer. Mr. Bradway joined the Company in 2006 as Vice President, Operations Strategy, and served as Executive Vice President and Chief Financial Officer from 2007 to 2010. Prior to joining the Company, Mr. Bradway was a Managing Director at Morgan Stanley in London, where, beginning in 2001, he had responsibility for the firm's banking department and corporate finance activities in Europe. Mr. Bradway has been a director of The Boeing Company, an aerospace company and manufacturer of commercial airplanes, defense, space and securities systems, since 2016. He has served on the board of trustees of the University of Southern California since 2014.

Dr. James E. Bradner, age 53, became Executive Vice President, Research and Development, in 2023 and also served as the Company's Chief Scientific Officer from 2023 to 2024. Prior to joining the Company, in 2023, Dr. Bradner was a clinician at the Dana-Farber Cancer Institute, a comprehensive cancer treatment and research institution, and a principal teaching affiliate at Harvard Medical School. From 2016 to 2022, Dr. Bradner served as President of the Novartis Institutes for BioMedical Research, the research and early development organizational unit of Novartis AG, where he was a member of the Executive Committee. Dr. Bradner previously served on the faculty at Harvard Medical School.

Mr. Murdo Gordon, age 59, became Executive Vice President, Global Commercial Operations, in 2018. Prior to joining the Company, Mr. Gordon was Chief Commercial Officer at Bristol-Myers Squibb Company (BMS), a pharmaceutical company, from 2016 to 2018. Mr. Gordon served as Head of Worldwide Markets at BMS from 2015 to 2016. Prior to this, Mr. Gordon served in a variety of leadership roles at BMS for more than 25 years.

Mr. Jonathan P. Graham, age 65, became Executive Vice President and General Counsel and Secretary in 2019. Mr. Graham joined the Company in 2015 to serve as Senior Vice President, General Counsel and Secretary. Prior to joining Amgen, from 2006 to 2015, Mr. Graham was Senior Vice President and General Counsel at Danaher Corporation. From 2004 to 2006, Mr. Graham was Vice President, Litigation and Legal Policy, at General Electric Company (GE). Prior to GE, Mr. Graham was a partner at Williams & Connolly LLP.

Mr. Peter H. Griffith, age 67, became Executive Vice President and Chief Financial Officer in 2020. Mr. Griffith joined the Company in 2019 as Executive Vice President, Finance. Prior to joining Amgen, Mr. Griffith was President of Sherwood Canyon Group, LLC, a private equity firm. From 1997 to 2019, Mr. Griffith was a partner at EY, an accounting and professional services firm, and served in a variety of senior leadership roles, with his last position being Global Vice Chair, Corporate Development. Prior to EY, Mr. Griffith was a Managing Director and head of the investment banking division of Wedbush Securities Inc.

Ms. Nancy A. Grygiel, age 58, became Senior Vice President and Chief Compliance Officer in 2020. Ms. Grygiel joined the Company in 2015 and has held leadership roles within the worldwide compliance and business ethics organization, including as Vice President, Compliance, from 2016 to 2020. Prior to joining Amgen, from 2011 to 2015, Ms. Grygiel served as Vice President, Compliance, Corporate & International, at Allergan, Inc. (Allergan). Prior to Allergan, Ms. Grygiel held several management positions at Mylan Pharmaceuticals, Inc.

Ms. Rachna Khosla, age 53, became Senior Vice President, Business Development, in 2021. Ms. Khosla joined the Company in 2013 and has held leadership roles in corporate development, licensing, and mergers and acquisitions, including as Vice President Business Development, from 2018 to 2021. Prior to joining the Company, Ms. Khosla was a Director at Lazard Ltd. (Lazard) responsible for healthcare mergers and acquisitions. Prior to Lazard, Ms. Khosla held various roles in investment banking (mergers and acquisitions) and corporate venture capital at Credit Suisse Group AG, Sanofi Aventis, Aventis Capital, J.P. Morgan Chase & Co., and Salomon Brothers, Inc.

Mr. Derek Miller, age 53, became Senior Vice President, Human Resources, in 2022. Mr. Miller joined the Company in 2003 and has held human resources leadership roles of increasing responsibility during his tenure. Mr. Miller's experience spans each of the Company's major business functions, including Vice President, Global Total Rewards, from 2020 to 2022 and Vice President, Human Resources, from 2018 to 2020.

Dr. David M. Reese, age 63, became the Company's inaugural Executive Vice President and Chief Technology Officer in 2023, responsible for accelerating the use of technology and artificial intelligence across the organization. From 2018 to 2023, Dr. Reese served as Executive Vice President, Research and Development. Dr. Reese joined the Company in 2005 and has held leadership roles in development, translational, and medical sciences, and discovery research, including as Senior Vice President, Translational Sciences and Oncology, from 2017 to 2018. Prior to joining Amgen, Dr. Reese was a cofounder, president, and chief medical officer of Translational Oncology Research International, a not-for-profit academic clinical research organization, and director of Clinical Research at the Breast Cancer International Research Group. Dr. Reese previously served on the faculty at the University of California, Los Angeles and the University of California, San Francisco.

Mr. Esteban Santos, age 58, became Executive Vice President, Operations, in 2016. Mr. Santos joined the Company in 2007 and has held a number of leadership roles at the Company in engineering, manufacturing, site operations and drug product, including Senior Vice President, Manufacturing, from 2013 to 2016. Prior to joining the Company, Mr. Santos served as Site General Manager of Johnson & Johnson's (J&J) Cordis operation in Puerto Rico. Prior to J&J, Mr. Santos held several management positions in GE's industrial and transportation businesses.

Geographic Area Financial Information

For financial information concerning the geographic areas in which we operate, see Part IV—Note 3, Revenues, and Note 12, Property, plant and equipment, to the Consolidated Financial Statements.

Investor Information

Financial and other information about us is available on our website at www.amgen.com. We make available on our website, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with or furnish it to the U.S. Securities and Exchange Commission (SEC). In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected without charge at the SEC's website at www.sec.gov. (These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing.)

Item 1A. RISK FACTORS

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. You should carefully consider the risks and uncertainties our business faces. The risks described below are not the only ones we face. Our business is also subject to the risks that affect many other companies, such as employment relations, general economic conditions, geopolitical events and international operations. Further, additional risks not currently known to us or that we currently believe are immaterial may in the future materially and adversely affect our business, operations, liquidity and stock price.

SUMMARY

Risks Related to Government Regulations and Third-Party Policies

- Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.
- Guidelines and recommendations published by various organizations can reduce the use of our products.
- We could be subject to additional tax liabilities, including from an adverse outcome in our ongoing tax dispute with the IRS and other tax examinations, enactment of the OECD minimum corporate tax rate agreement and the adoption and interpretation of new tax legislation, including OB3. Such tax liabilities could adversely affect our profitability and results of operations.
- Our business may be affected by litigation and government investigations.

Risks Related to Economic Conditions and Operating a Global Business

- Our efforts to collaborate with or acquire other companies, products, or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions.
- A breakdown of our information technology systems, cyberattack or information security breach could significantly compromise the confidentiality, integrity and availability of our information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.
- Our sales and operations are subject to the risks of doing business internationally, including in new or emerging markets.
- We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

Risks Related to Competition

- Our products face substantial competition and our product candidates are also likely to face substantial competition.
- Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.
- We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future.
- Concentration of sales at certain of our wholesaler distributors, and consolidation of private payers, such as insurers, and PBMs has negatively affected, and may continue to negatively affect, our business.

Risks Related to Research and Development

- We may not be able to develop commercial products despite significant investments in R&D.
- We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.
- Our current products and products in development cannot be sold without regulatory approval.

- Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.
- Some of our pharmaceutical pipeline and our commercial product sales rely on collaborations with third parties, which may adversely affect the development and sales of our products.

Risks Related to Operations

- We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.
- We rely on third-party suppliers for certain of our raw materials, medical devices and components.
- Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.
- Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our sustainability objectives.
- The effects of global climate change and related natural disasters could negatively affect our business and operations.

General Risk Factors

- Global economic conditions may negatively affect us and may magnify certain risks that affect our business.
- Our stock price is volatile.

RISKS RELATED TO GOVERNMENT REGULATIONS AND THIRD-PARTY POLICIES

Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.

Sales of our products depend on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers continue to pursue initiatives to manage drug utilization and contain costs. Payers are increasingly focused on costs, which has resulted, and is expected to continue to result, in lower reimbursement rates for our products and/or narrower patient populations for which payers will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payer dynamics, have limited, and are likely to continue to limit, our ability to set or adjust the price of our products based on their value, which can have a material adverse effect on our business. In the United States, a number of legislative and regulatory proposals have been introduced and/or signed into law to lower drug prices. These include the IRA that enables the U.S. government to set prices for certain drugs in Medicare, redesigns Medicare Part D benefits to shift a greater proportion of the costs to manufacturers and health plans, and enables the U.S. government to impose penalties if drug prices are increased at a rate faster than inflation (IRA Inflation Penalties). On July 4, 2025, OB3 was enacted and included several changes to Medicare, Medicaid and Affordable Care Act policies, including provisions affecting eligibility, that, when implemented, are expected to adversely affect coverage and reimbursement for our products. On May 12, 2025, the Administration issued the Most-Favored-Nations (MFN) Prescription Drug Pricing Executive Order (MFN EO) aimed at using price benchmarks from other developed countries to set U.S. pricing targets. Subsequently, on July 31, 2025 the Administration sent letters to many pharmaceutical manufacturers, including Amgen (the July MFN Letter) as further described below, outlining steps that such manufacturers could take to advance actions consistent with elements of the MFN EO. In December 2025, we announced that we are taking actions that satisfy the components outlined in the July MFN Letter, including the Administration's MFN pricing requests. Further, the Administration has called on Congress to enact legislation that would codify the terms that the Administration arrived at with recipients of the July MFN Letter (the MFN Terms). The details of such legislative framework are unknown and, if enacted, such legislation could apply to a broader range of products, payers or pricing arrangements for a longer period than those resulting from the MFN Terms. Additional proposals focused on drug pricing continue to be debated, and additional executive orders or regulatory initiatives focused on drug pricing and competition may be adopted and implemented in some form. It remains unclear what further policies, legislation and/or actions the Administration, Congress, or state governments will advance with respect to other drug pricing proposals or other healthcare regulations affecting pharmaceuticals, including the MFN EO, IRA and OB3 implementation, trade policies, or state laws affecting the 340B Program or Medicaid reimbursement that could ultimately be adopted more broadly. To the extent such actions reduce or modify coverage or reimbursement for our products, increase rebates or other costs, constrain pricing decisions, or otherwise limit product use, they would have an adverse effect on our business and results of operations.

—Changing U.S. federal coverage and reimbursement policies and practices have affected, and are likely to continue to affect, access to, pricing of, and sales of our products

A substantial proportion of our U.S. business relies on reimbursement from federal government healthcare programs and commercial insurance plans regulated by federal and state governments. See Item 1. Business—Reimbursement. Our business has been, and will continue to be, affected by legislative actions changing U.S. federal reimbursement policy. For example, the IRA includes provisions requiring mandatory pricing in Medicare for certain drugs under Parts B and D (starting with 10 drugs effective January 1, 2026, adding 15 in 2027 and 2028, and adding 20 in 2029 and subsequent years such that, by 2031, approximately 100 drugs would be subject to such set prices). CMS has set Medicare Part D prices for ENBREL, effective January 1, 2026, and Otezla, effective January 2027, in each case at significantly lower prices that are expected to negatively impact their profitability in Medicare. See Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of operations—*Product sales*. Further, CMS has issued guidance that allows for the re-setting of prices for drugs for which it previously set a price. Depending on the growth and success of our medicines, other of our medicines may also be subject to selection by CMS in the next, or in a future, cycle of mandatory Medicare price setting, we may be required to accept a price set by the government for Medicare using the process that was applied to ENBREL and Otezla. On April 15, 2025, the Administration issued an executive order (the April 2025 EO) that, among other directives, directs HHS to work with Congress to align the treatment of small molecule drugs and biologics in the Medicare price setting program under the IRA. It is currently unclear how such modifications would affect the timeframe in which Medicare price setting becomes applicable for selected drugs or biologics. Also under the IRA, Medicare Part D was redesigned to cap beneficiary out-of-pocket costs and reduce Federal reinsurance in the catastrophic phase; increasing cost-sharing obligations for Part D plans and manufacturers, including by requiring manufacturer discounts. Further, the IRA inflation penalties allow CMS to collect rebates from manufacturers if Medicare price increases outpace inflation, and several of our products have been subject to such IRA inflation rebates. The IRA's Medicare price setting and Medicare redesign have had, and are likely to have, an adverse effect on our sales, our business and our results of operations, and such impact is expected to increase through the end of the decade and will depend on factors including the extent of our portfolio's exposure to Medicare reimbursement, the rate of inflation over time, the number of our products selected for Medicare price setting and the timing of market entry of generic or biosimilar competition. Further, following the enactment of the IRA, the environment remains dynamic, and U.S. policymakers continue to demonstrate interest in health care and drug pricing changes as well as potential changes affecting intellectual property. For example, in April 2024, CMS finalized policy changes that will give Part D plans more flexibility to substitute biosimilars for innovator products on formularies in 2025. Implementation of OB3 also may impact access to and reimbursement of our products. For example, the Congressional Budget Office has projected that the OB3 will result in significant reductions in federal Medicaid spending over the next decade and an increase in the number of people without health insurance. These developments would place greater stress on state budgets and hospital finances, and could result in reduced access to medicines, additional pressure to further discount medicines and further growth of 340B Program utilization. The MFN EO directs HHS to pursue pricing policies that align U.S. drug prices with the prices available in certain comparably developed countries and directs a range of actions to advance that objective, including through regulatory, trade and other policy measures. In July 2025, the Administration delivered the July MFN Letter to us and a number of other manufacturers that called for drug manufacturers to: 1) extend MFN pricing to Medicaid; 2) guarantee MFN pricing to Medicaid, Medicare and commercial payers on all newly launched drugs; 3) use future increased revenues from outside the U.S. to lower U.S. drug prices; and 4) participate in direct-to-patient models to provide MFN pricing for certain drugs. Since the issuance of the July MFN Letter, most recipients have announced that they have reached agreement with the Administration to address the matters described in the letter. In December 2025, we announced that we are taking actions that satisfy the components outlined in the July MFN Letter, including the Administration's MFN pricing requests. We also announced the expansion of our direct-to-patient program. While this development reflects ongoing engagement on pricing policy, the ultimate effects on our pricing, reimbursement, net sales and profitability remain uncertain in light of evolving regulatory and policy expectations.

We also face risks related to the reporting of pricing data that affects reimbursement of and discounts provided for our products. U.S. government price reporting regulations are complex and may require biopharmaceutical manufacturers to update certain previously submitted data. If our submitted pricing data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse effect on our business and results of operations. In addition, as a result of restating previously reported price data, we may be required to pay additional rebates and provide additional discounts.

—Changing reimbursement and pricing actions in various states have negatively affected, and may continue to negatively affect, access to, and have affected, and may continue to affect, sales of our products

At the state level, legislation, government actions and ballot initiatives can also affect how our products are covered and reimbursed and/or create additional pressure on our pricing decisions. Existing and proposed state pricing laws, which may move forward more rapidly than similar efforts at the federal level, have added complexity to the pricing of drugs. A number of states have adopted, and many other states are considering, PDABs, drug importation programs, reference pricing schemes and

other drug pricing actions, including proposals designed to require biopharmaceutical manufacturers to report to the state proprietary pricing information or provide advance notice of certain price increases.

States continue to pursue laws related to price controls, referencing the IRA and seeking to regulate and prohibit restrictions on the 340B Program. For example, following the passage of the IRA, bills have been proposed in multiple states that would apply the drug price caps set by HHS for Medicare to drug prices in an individual state, and such references to IRA price caps have also been included in PDAB legislation. For Medicaid patients, states have established a Medicaid drug spending cap (New York) and implemented a new review and supplemental rebate negotiation process (Massachusetts). Eight states (Colorado, Maine, New Hampshire, New Jersey, Maryland, Minnesota, Oregon and Washington) have enacted laws that establish PDABs to identify drugs that pose affordability challenges, and four such states include authority for the state PDABs to set upper payment limits on certain drugs for in-state patients, payers and providers. In 2025, Maryland expanded the scope of its PDAB law to include the commercial market. The eight states with enacted PDAB laws are in various phases of implementation, with Colorado's PDAB being the furthest along. The Colorado PDAB deemed three of five drugs "unaffordable," including ENBREL, and in October 2025 the Colorado PDAB established an Upper Payment Limit (UPL) substantially lower than the wholesale acquisition cost of ENBREL that would be generally applicable to all formulations of ENBREL, effective no earlier than January 1, 2027, and will be reviewed annually. On July 16, 2025, Washington state's PDAB selected ENBREL for one of its first affordability reviews. Following the timeline and process established by the state for such affordability review, the manufacturer and the PDAB will undertake a number of required interactions. However, the Washington state PDAB may not establish a UPL for any prescription drug before January 1, 2027. Further, inappropriate expanded utilization of the 340B Program from broadened application of the 340B discounts has had, and is expected to continue to have, a negative impact on the Company's product sales, business and results of operations. Twenty states (Louisiana, Arkansas, West Virginia, Minnesota, Mississippi, Missouri, Maryland, North Dakota, South Dakota, Utah, Nebraska, New Mexico, Colorado, Tennessee, Oregon, Vermont, Hawaii, Oklahoma, Rhode Island and Maine) have enacted laws with mandates on manufacturers participating in the 340B Program, and, in 2025, no fewer than 30 states have introduced similar legislation. These bills vary, but typically include provisions restricting a manufacturer's ability to direct drugs in 340B channels, recognizing 340B contract pharmacies and a prohibition on requiring the inclusion of 340B claims modifiers. With OB3's reductions to federal Medicaid funding to states, increased pressure is anticipated for providers to find and preserve existing revenue sources at the state level, which may result in increased use of 340B contract pharmacy mandates. In *Genesis Health Care, Inc. v. Becerra*, the U.S. District Court for the District of South Carolina issued an order in November 2023 enjoining the Health Resources and Services Administration from enforcing a more restrictive interpretation against Genesis Health Care as to who qualifies as a patient under the 340B Program, which could, if adopted more broadly, affect the scope of eligibility for 340B discounts. Since this decision, various courts have reached differing conclusions on challenges to state laws regulating aspects of the 340B Program, with some courts declining to enjoin such laws and others granting relief to challengers. Certain appellate courts have issued decisions both upholding certain state 340B statues and affirming the denial of preliminary injunctive relief to manufacturers, while litigation and appeals concerning the validity, interpretation, and enforcement of these laws remain ongoing.

Additionally, in 2024, the FDA authorized Florida to move forward with its importation program proposal, though the state has not yet completed any significant steps towards importation within the two-year authorization window. Colorado, Maine, New Hampshire, New Mexico, Texas and Vermont have also enacted state importation laws, and some have submitted plans for approval to the FDA. Other states could adopt similar approaches or could pursue different policy changes in a continuing effort to reduce their costs. Further, the April 2025 EO also directs HHS to, within 90 days, streamline and improve the drug importation program to ease the process for states to obtain drug importation approvals. On May 21, 2025, the FDA issued a press release indicating it was taking steps to enhance state importation programs and would offer individual states and tribes the opportunity to submit draft proposals for pre-review and to meet with the agency to obtain initial feedback prior to formally submitting importation proposals. While under federal law biologics remain exempt from such state importation activities, our small molecule products could be impacted by these initiatives.

Ultimately, existing or future state government actions or ballot initiatives may also have a material adverse effect on our product sales, business and results of operations.

—U.S. commercial payer actions have affected, and may continue to affect, access to and sales of our products

Payers, including healthcare insurers, PBMs, integrated healthcare delivery systems (vertically-integrated organizations built from consolidations of healthcare insurers and PBMs) and group purchasing organizations, are continuing to seek ways to further reduce their costs. With increasing frequency, payers are adopting benefit plan changes that shift a greater proportion of drug costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient co-pay or coinsurance obligations and more significant limitations on patients' use of manufacturer commercial co-pay assistance programs. Further, government regulation of payers may affect these trends. Payers, including PBMs, have sought, and continue to seek, price discounts or rebates in connection with the placement of our products on their formularies or those they

manage, and to also impose restrictions on access to, or usage of, our products (such as Step Therapy), require that patients receive the payer's prior authorization before covering the product, and/or to exclude certain indications for which our products are approved.

Further, significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs, which places greater pressure on pricing and usage negotiations with biopharmaceutical manufacturers, significantly increasing discount and rebate requirements and limiting patient access and usage. See *—Concentration of sales at certain of our wholesaler distributors, and consolidation of private payers, such as insurers, and PBMs has negatively affected, and may continue to negatively affect, our business.* This high degree of consolidation among insurers, PBMs and other payers, including integrated healthcare delivery systems and/or with specialty or mail-order pharmacies and pharmacy retailers, has increased the negotiating leverage such entities have over us and other biopharmaceutical manufacturers and has resulted in greater price discounts, rebates and service fees realized by those payers from our business. Our business is also affected by policies implemented by private healthcare entities that process Medicare claims, including Medicare Administrative Contractors. Each of CVS, Express Scripts and United Health Group (among the top six integrated health plans and PBMs) have Rebate Management Organizations that further increase their leverage to negotiate deeper discounts on their behalf and for the benefit of their other customers. Ultimately, additional discounts, rebates, fees, coverage changes, plan changes, restrictions or exclusions imposed by these commercial payers could have a material adverse effect on our product sales, business and results of operations. See *—Concentration of sales at certain of our wholesaler distributors, and consolidation of private payers, such as insurers, and PBMs has negatively affected, and may continue to negatively affect, our business.*

—Government and commercial payer actions outside the United States have affected and will continue to affect access to and sales of our products

Outside the United States, we expect countries will also continue to take actions to reduce their drug expenditures and to reduce intellectual property protections. See Item 1. Business—Reimbursement. Pressures to decrease drug expenditures may intensify as governments take actions to address budgets strained by high inflation and weak economic conditions, including in Europe, where sustained fiscal pressures continue to challenge public healthcare systems. In addition, policies under consideration or adopted in the United States that reference or tie drug prices to those paid in foreign jurisdictions, including through most-favored-nation or similar pricing approaches, could increase the significance of pricing decisions in such foreign jurisdictions. Further, the EU is currently undergoing a review and revision of its general pharmaceutical legislation that, while full implementation is not expected before 2027, has led to proposals that would reduce intellectual property protection for new products (including potentially shortening the duration of regulatory data exclusivity and orphan drug exclusivity protections), as well as change the reimbursement and regulatory landscape. International reference pricing has been widely used by many countries outside the United States to control costs. International reference pricing policies can change quickly and frequently and may not reflect differences in the burden of disease, indications, market structures or affordability across countries or regions. Other expenditure control practices, including the use of revenue clawbacks, rebates and caps on product sales, are also used in various foreign jurisdictions. In addition, countries may refuse to reimburse, or may restrict the reimbursed population for a product, when their national health technology assessments do not consider a medicine to demonstrate sufficient clinical benefit beyond existing therapies or to meet certain cost effectiveness thresholds. For example, despite the EMA's approval of Repatha for the treatment of patients with established atherosclerotic disease, prior to 2020, the reimbursement of Repatha in France was limited to a narrower patient population (such as those with homozygous familial hypercholesterolemia (HoFH)) following a national health technology assessment. Many countries decide on reimbursement between potentially competing products through national or regional tenders that often result in one product receiving most, or all of, the sales in that country or region. Failure to obtain coverage and reimbursement for our products, a deterioration in their existing coverage and reimbursement, or a decline in the timeliness or certainty of payment by payers to hospitals and other providers, has negatively affected, and may further negatively affect, the ability or willingness of healthcare providers to prescribe our products for their patients and otherwise negatively affect the use of our products or the prices we realize for them. Such failures and changes have had, and could in the future have, a material adverse effect on our product sales, business and results of operations.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. Professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, as well as patient communities. Recommendations by government agencies or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies. In addition, a growing number of organizations are providing assessments of the value and pricing of biopharmaceutical products, and even organizations whose guidelines have historically been focused on clinical matters have begun to incorporate analyses of the cost effectiveness of various treatments into their treatment guidelines and recommendations. Value assessments may come from private organizations that publish their findings and offer recommendations relating to the products' reimbursement by government and

private payers. Some companies and payers have announced pricing and payment decisions based in part on the assessments of private organizations. In addition, government health technology assessment organizations in many countries make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service effects of new, emerging and existing medicines and treatments. Such health technology assessment organizations have *recommended*, and may in the future recommend, reimbursement for certain of our products for a narrower indication than was approved by applicable regulatory agencies or may recommend against reimbursement entirely. See *Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability*. The EU has adopted and begun implementing Regulation 2021/2282 on Health Technology Assessment, which establishes a permanent framework for cooperation among EU member states on joint clinical assessments and scientific consultations of health technologies, with key provisions that became applicable in January 2025, and further phased implementation continuing through 2030. These and other such recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could have a material adverse effect on our product sales, business and results of operations. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price of our common stock.

We could be subject to additional tax liabilities, including from an adverse outcome in our ongoing tax dispute with the IRS and other tax examinations, enactment of the OECD minimum corporate tax rate agreement and the adoption and interpretation of new tax legislation, including OB3. Such tax liabilities could adversely affect our profitability and results of operations.

We are subject to income and other taxes in the United States and other jurisdictions in which we do business. As a result, our provision for income taxes is derived from a combination of applicable tax rates in the various places we operate. Significant judgment is required for determining our provision for income tax.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes can and have arisen with tax authorities involving issues regarding the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and relevant facts, and such tax authorities (including the IRS) are becoming more aggressive in its audits and are particularly focused on such matters.

In 2017, we received an RAR and a modified RAR from the IRS for the years 2010–2012, proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagreed with the proposed adjustments and calculations, and in 2021, we filed a petition in the U.S. Tax Court to contest two duplicate Statutory Notices of Deficiency (Notices) for the years 2010–2012. The Notices seek to increase our U.S. taxable income for the years 2010–2012.

In 2020, we received an RAR and a modified RAR from the IRS for the years 2013–2015, also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010–2012. We disagreed with the proposed adjustments and calculations, and in 2022, we filed a petition in the U.S. Tax Court to contest a Notice for the years 2013–2015. The Notice seeks to increase our U.S. taxable income for the years 2013–2015 and asserts penalties.

We firmly believe that the IRS positions set forth in the 2010–2012 and 2013–2015 Notices are without merit. We continue to contest the 2010–2012 and 2013–2015 Notices through the judicial process. The two cases were consolidated in 2022. The trial began on November 4, 2024 and concluded on January 17, 2025. The parties filed opening post-trial briefs on June 13, 2025, and the Court held oral argument on July 16, 2025. The parties filed post-trial reply briefs on October 10, 2025. The Company expects a decision from the U.S. Tax Court no earlier than the second half of 2026.

We are currently also under examination by the IRS for the years 2016–2018 with respect to issues similar to those for the 2010 through 2015 period. As a result of the audit, the IRS could propose adjustments or penalties that, in all or part, relate to issues in the 2010-2015 dispute. We expect that the IRS will begin its audit of 2019–2022 in the first half of 2026, and we believe that it may seek to continue to audit similar issues related to the allocation of income between the United States and our foreign jurisdictions. In addition, we are under examination by a number of state and foreign tax jurisdictions.

Final resolution of these complex tax matters is not likely within the next 12 months. We continue to believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse effect on the results of our operations. See Part II, Item 7.

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Our provision for income taxes and results of operations in the future could be adversely affected by changes to our operating structure, changes in the mix of income and expenses in countries with differing tax rates, changes in the valuation of deferred tax assets and liabilities and changes in applicable tax laws, regulations or administrative interpretations thereof. The 2017 Tax Act is complex and a large volume of regulations and guidance has been issued and could be subject to different interpretations. We could face audit challenges to our application of the 2017 Tax Act.

As previously reported, the OECD reached an agreement to align countries on a minimum corporate tax rate and an expansion of the taxing rights of market countries. Select individual countries, including the United Kingdom, EU member countries, and Singapore, have enacted the global minimum tax agreement that took effect starting in 2024. On January 5, 2026, the OECD issued additional administrative guidance related to the global minimum tax agreement that exempts U.S. companies from extra territorial minimum taxes effective January 1, 2026. We are monitoring the potential 2026 impact of such administrative guidance as jurisdictions enact the new rules. Delays, modifications or repeal, in whole or in part, of the administrative guidance or the OECD agreement itself, either by all OECD participants or unilaterally by individual countries, could result in negative impacts on our overall tax rate.

OB3 includes significant provisions related to taxation, such as the permanent extension of certain expiring provisions of the 2017 Tax Act, and modifications to the international tax framework. This legislation has multiple effective dates, with certain provisions effective in 2026 and beyond. While we have incorporated the impact of OB3 in our 2025 financial statements, the legislation is complex and guidance could be issued that could impact our 2025 or future U.S. taxes.

Changes to existing tax law in the United States, the U.S. territory of Puerto Rico or other jurisdictions, including the changes and potential changes discussed above, could result in tax increases where we do business and could have a material adverse effect on the results of our operations.

Our business may be affected by litigation and government investigations.

We and certain of our subsidiaries are involved in legal proceedings. See Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements. Civil and criminal litigation is inherently unpredictable, and the outcome can result in costly verdicts, fines and penalties, exclusion from federal healthcare programs and/or injunctive relief that affect how we operate our business. Defense of litigation claims can be expensive, time consuming and distracting, and it is possible that we could incur judgments or enter into settlements of claims for monetary damages or change the way we operate our business, which could have a material adverse effect on our product sales, business and results of operations. In addition, product liability is a major risk in testing and marketing biotechnology and pharmaceutical products. We may face substantial product liability exposure in human clinical trials and for products we sell after regulatory approval. Product liability claims, regardless of their merits, could be costly and divert management's attention and could adversely affect our reputation and the demand for our products. We and certain of our subsidiaries have previously been, and currently are, named as defendants in product liability actions for certain of our products.

We are also involved in government investigations that arise in the ordinary course of our business. In recent years, there has been a trend of increasing government investigations and litigations against companies operating in our industry, both in the United States and around the world. See *Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.* Our business activities outside of the United States are subject to the FCPA and similar antibribery or anticorruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. We cannot ensure that all our employees, agents, contractors, vendors, licensees, partners or collaborators will comply with all applicable laws and regulations. We entered into a corporate integrity agreement with the DOJ and the Office of Inspector General of the HHS to settle certain allegations relating to our support of independent charitable organizations that provide patients with financial assistance to access their medicines that required us to maintain a corporate compliance program and to undertake a set of defined corporate integrity obligations that we completed in 2024. While we fully complied with all of our obligations under the corporate integrity agreement, we may be subject to future corporate integrity agreements and failure to comply could result in substantial penalties and potential exclusion from government healthcare programs. We may also see new government investigations of or actions against us citing novel theories of recovery. For example, prosecutors are placing greater scrutiny on patient support programs, including commercial copay assistance programs, and further enforcement actions and investigations regarding such programs could limit our ability to provide co-pay assistance to commercial patients. Greater scrutiny has also been placed on sponsorships, speaker programs and other arrangements where healthcare professionals receive remuneration, travel or other value to participate in certain events, and further enforcement actions could adversely affect our ability to participate in such arrangements. Any of these results could have a material adverse effect on our business and results of operations.

RISKS RELATED TO ECONOMIC CONDITIONS AND OPERATING A GLOBAL BUSINESS

Our efforts to collaborate with or acquire other companies, products, or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions.

We seek innovation through significant investment in both internal R&D and external transactions, including collaborations, partnerships, alliances, licenses, joint ventures, mergers and acquisitions (collectively, acquisition activity). Acquisition activities may be subject to regulatory approvals or other requirements that are not within our control. Antitrust scrutiny by regulatory agencies and changes to regulatory approval process in the U.S. and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. There can be no assurance that such regulatory or other approvals will be obtained or that all closing conditions required in connection with our acquisition activities will be satisfied or waived, which could result in us being unable to complete the planned acquisition activities.

Acquisition activities are complex, time consuming and expensive and may result in unanticipated costs, delays, or other operational or financial problems related to integrating the acquired company and business with our company, which may divert our management's attention from other business issues and opportunities may prevent us from realizing the anticipated benefits of such transactions within the expected timeframe or at all.

We may pay substantial amounts of cash, incur debt or issue equity securities to pay for acquisition activities, which could adversely affect our liquidity or result in dilution to our stockholders, and could adversely affect our credit ratings and cost of capital. For example, the primary sources of funds for our acquisition of Horizon were those received from our $24 billion of senior notes issued on March 2, 2023, together with the $4 billion drawn down from our term loan facility, of which we repaid $2.2 billion, and while the Company currently has investment grade credit ratings and substantially returned to its pre-acquisition capital structure, when the Company incurred this substantial additional indebtedness the credit rating agencies downgraded our credit ratings. Further, failures or difficulties in integrating or retaining key personnel, or in integrating the operations of the businesses, products or assets we acquire (including related technology, research, development and commercial operations, compliance programs, manufacturing, distribution and general business operations and procedures and sustainability activities) may adversely affect our ability to realize the benefits of the transaction or grow our business, and may result in asset impairment or restructuring charges. These and other challenges may arise in connection with our acquisitions, including our acquisitions of ChemoCentryx, Horizon and Dark Blue Therapeutics and/or our collaborations with BeOne and Kyowa Kirin, or with other acquisition activities, which could have a material adverse effect on our business, results of operations and stock price.

We may not realize the anticipated strategic benefits of our acquisitions. Our assumptions and estimates about the future revenue growth of acquired products may prove to be incorrect. Business integrations generally are complex, time consuming and expensive, and we may experience unanticipated costs, delays or other operational or financial challenges. These integration efforts may also divert our management's attention and resources away from other business operations, which may disrupt to some degree our ongoing business. Failure to successfully fully integrate acquired businesses into ours and/or achieve anticipated strategic benefits may result in our incurring significant asset impairment or restructuring charges, and could have a material adverse effect on our business, results of operations and stock price.

A breakdown of our information technology systems, cyberattack or information security breach could significantly compromise the confidentiality, integrity and availability of our information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.

To achieve our business objectives, we rely on sophisticated information technology systems, including hardware, software, technology infrastructure, online sites and networks for both internal and external operations, mobile applications, cloud services, artificial intelligence (AI)-enabled tools and systems, and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. Internal or external events that compromise the confidentiality, integrity and availability of our systems and data may significantly interrupt the operation of our business, result in significant costs and/or adversely affect our reputation.

Our information technology systems, including AI-enabled tools and systems are highly integrated into our business, including our R&D efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. Further, as the majority of our employees work remotely for some portion of their jobs in our hybrid work environment, our reliance on our and third-party information technology systems has increased substantially and is expected to continue to increase. Remote and hybrid working arrangements, including those of many third-party providers, can increase cybersecurity risks due to the challenges associated with managing remote computing assets and security vulnerabilities that are

present in many non-corporate and home networks. The complexity and interconnected nature of software, hardware and our systems make them vulnerable to breakdown or other service interruptions, and to software errors or defects, misconfiguration and other security vulnerabilities. For example, in July 2024, businesses worldwide were affected by an information technology outage due to a faulty software update issued by a cybersecurity firm. Although our systems and operations were temporarily affected by the outage, the impact of this firm's faulty update on the Company was immaterial to our business operations. However, there can be no assurance that a future similar incident would not result in a material adverse effect on our business or results of operations. Upgrades or changes to our systems or the software that we use have resulted and we expect, in the future, will result in the introduction of new cybersecurity vulnerabilities and risks. In the past, we have identified security vulnerabilities introduced into our information systems arising from flaws in third-party software that we had purchased and installed, which required us to apply emergency patches to certain systems. While we did not experience any significant adverse effects as a result of these vulnerabilities, there can be no assurance that we will timely identify and address future vulnerabilities. Our systems are also subject to frequent perimeter network reconnaissance and scanning, phishing and other cyberattacks. For example, as a result of our cybersecurity monitoring of the Horizon legacy information systems, we detected phishing activity in the accounts of two Horizon executives. These accounts were de-activated, the incidents were investigated and the determination was made separately by both our internal cybersecurity team and our external digital forensics and incident response supplier that no confidential information had been exfiltrated, and the incidents are now closed. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication, and intensity, and are becoming increasingly difficult to detect and increasingly sophisticated in using techniques and tools, including AI, that circumvent security controls, evade detection and remove forensic evidence. Such attacks include the use of harmful and virulent malware, including ransomware or other denials of service, which can be deployed through various means, including the software supply chain, e-mail, malicious websites and/or the use of social engineering/phishing, and/or AI to orchestrate and automate sophisticated cyberattacks, including the documented instance in which an AI agent was used to conduct a large-scale intrusion campaign, potentially lowering the barriers to high-speed, high-volume attacks.

We have also experienced denial of service attacks against our network, and, although such attacks did not succeed, there can be no assurance that our efforts to guard against the wide and growing variety of potential attack techniques will be successful in the future. Attacks such as those experienced by government entities (including those that approve and/or regulate our products, such as the EMA) and other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access or protect important data, and could have a material adverse effect on our ability to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and/or distributing our products. For example, in 2017, a pharmaceutical company experienced a cyberattack involving virulent malware that significantly disrupted its operations, including its research and sales operations and the production of some of its medicines and vaccines. As a result of the cyberattack, its orders and sales for certain products were negatively affected. In late 2020, SolarWinds Corporation, a leading provider of software for monitoring and managing information technology infrastructure, disclosed that it had suffered a cybersecurity incident whereby attackers had inserted malicious code into legitimate software updates for its products that were installed by myriad private and government customers, enabling the attackers to access a backdoor to such systems. We also rely on third-party providers for certain identity, authentication and access management services. In the past, a security incident affecting such a third-party provider exposed several hundred corporate customers to potential unauthorized access to systems and data. Although that breach did not have a significant effect on our business, there can be no assurance that a similar future breach would not result in a material adverse effect on our business or results of operations.

Our systems also contain and use a high volume of sensitive data, including intellectual property, trade secrets and other proprietary business information, financial information, regulatory information, strategic plans, sales trends and forecasts, litigation materials and/or personal identifiable information belonging to us, our staff, our patients, customers and/or other parties. In some cases, we use third-party service providers to collect, process, store, manage or transmit such data, which has increased our risk. Intentional or inadvertent data privacy or security breaches (including cyberattacks) resulting from attacks or lapses by employees, service providers (including providers of information technology-specific services), business partners, nation states (including groups associated with or supported by foreign intelligence agencies), organized crime organizations, "hacktivists" or others, create risks that our sensitive data may be exposed to unauthorized persons, our competitors or the public. Malicious actors, including those working under state-sponsored campaigns, have sought employment, often in remote information technology roles, as a means to gain inside access at targeted companies. In two separate incidents, the most recent of which occurred in 2025, individuals used fraudulent identification in connection with their hiring by the Company. While these individuals were detected and terminated before any data was extracted or malware installed, there can be no assurance that future attempts by similar actors will be unsuccessful.

System vulnerabilities and/or cybersecurity breaches experienced by our third-party service providers have constituted a substantial share of the information security risks that have affected us. For example, in the past we have experienced cybersecurity incidents involving third-party service providers, including incidents in which unauthorized third parties accessed or exfiltrated certain information, including non-significant Amgen data and personally identifiable patient information, and we

have made required regulatory notifications in connection with certain such incidents. In November 2025, a third-party service provider had a cybersecurity incident in which Amgen-related information was accessed and disclosed by a threat actor that, upon review, did not involve information material to the Company. Although these supplier data breaches have not resulted in material adverse effects on our business, there can be no assurance that a similar future cybersecurity incident would not result in a material adverse effect on our business or results of operations. Further, the timeliness of our awareness of a cybersecurity incident affects our ability to respond to and work to mitigate the severity of such events. For example, we have previously experienced incidents in which third-party vendors initially reported that cyberattacks did not involve our data but later determined that attackers had accessed limited, non-significant Amgen information. Although such incidents have not resulted in significant adverse effects on our business, future incidents in which we do not receive timely or complete information regarding the nature or scope of a cybersecurity event could impair our response and could have a material adverse effect on our business.

Cyberattackers are also increasingly exploiting vulnerabilities in commercially available software from shared or open-source code. We rely on third party commercial software that have had and may have such vulnerabilities, but as use of open-source code is frequently not disclosed, our ability to fully assess this risk to our systems is limited. Although these vulnerabilities did not result in any significant adverse effects on us, there can be no assurances that a similar future vulnerability in the software and services that we use would not result in a material adverse effect on our business or results of operations.

Domestic and global government regulators, our business partners, suppliers with whom we do business, companies that provide us or our partners with business services and companies we have acquired or may acquire face similar risks. Security breaches of their systems or service outages have adversely affected systems and could, in the future, affect our systems and security, leave us without access to important systems, products, raw materials, components, services or information, or expose our confidential data or sensitive personal information. For example, we have experienced cybersecurity incidents at third-party vendors that provide testing, analytical, information technology and clinical data services, which required us to temporarily disconnect our systems from those vendors. Although these incidents did not result in breaches of our systems or significantly affect product availability, a prolonged or more widespread service outage affecting these or other vendors, particularly where a vendor is a single source for critical services, could have a material adverse effect on our business or results of operations. In 2024, Change Healthcare, a large U.S. insurance claim and co-pay card processing clearinghouse, experienced a ransomware attack that has caused significant disruptions to healthcare provider and pharmacy operations. While Change Healthcare does not directly provide us with services, disruptions to co-pay card support, insurance billing and Medicaid rebate processing led to lost sales and required us to take action to help patients access their medications and to provide extended payment terms to certain customers. Although services have been rerouted and restored, and the impact on our business was immaterial, similar disruptions may occur in the future stemming from the interconnectedness of the U.S. healthcare ecosystem and industry reliance on centralized claims processing systems and networks, and such future disruptions may have a material adverse effect on our business or results of operations. In addition, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers and patients. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls, or procedures, will be fully implemented, complied with or effective in protecting our information technology systems and sensitive data.

Although we have experienced system breakdowns, attacks and information security breaches, we do not believe such breakdowns, attacks and breaches have had a material adverse effect on our business or results of operations. We will continue to experience varying degrees of cyberattacks and other incidents in the future. Even though we continue to invest in the monitoring, protection and resilience of our critical and/or sensitive data and systems, there can be no assurance that our efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks and/or breaches of our systems that could adversely affect our business and operations and/or result in the loss or exposure of critical, proprietary, private, confidential or otherwise sensitive data, which could result in material financial, legal business or reputational harm to us or negatively affect our stock price. While we maintain cyber-liability insurance, our insurance is not sufficient to cover us against all losses that could potentially result from a service interruption, breach of our systems or loss of our critical or sensitive data.

We are also subject to various laws and regulations globally regarding cybersecurity, privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environment regarding privacy and data protection continues to evolve and receive significant attention globally. For example, we are subject to the EU's GDPR and the California Consumer Privacy Act, as amended (CCPA), both of which impose comprehensive data protection obligations and provide for substantial penalties for noncompliance. Similar consumer privacy and data protection laws have been enacted or proposed in more than half of U.S. states, many of which impose obligations and restrictions that are comparable to, or in some cases more stringent than, those under the CCPA. Outside the United States, other jurisdictions where we operate have passed, or continue to propose, data

privacy or cybersecurity legislation and/or regulations. For example, in China, the Personal Information Protection Law and the Data Security Law, which regulate data processing activities associated with personal and nonpersonal data, builds upon the existing Cybersecurity Law. Failure to comply with these current and future laws could result in significant penalties and reputational harm and could have a material adverse effect on our business and results of operations.

We are adopting and exploring the use of AI in our business, and as an emerging and rapidly evolving technology, our use of AI introduces potential opportunities but also presents risks that could adversely affect our operations, information security and reputation. AI systems may produce inaccurate or flawed outputs due to flawed algorithms, or insufficient and/or erroneous training data. Reliance on flawed outputs could prevent us from effectively utilizing AI in our business or result in lower quality decision-making. We may also become vulnerable to operational disruptions if the AI technologies we use experience downtimes or are compromised by cyberattacks. If we do not effectively implement guardrails and train our staff on the safe and proper use of AI, or if our staff fail to effectively adhere to our established guardrails and training on the use of AI, we may experience adverse effects on our business, including data breaches, the loss of confidential information (including our intellectual property), unintentional disclosure of personal data, or other misuse of our proprietary information. Further, several governments and regulatory authorities have proposed or passed laws and regulations governing the use of AI. For example, the European Parliament has adopted the Artificial Intelligence Act establishing EU-wide rules on data quality, transparency, human oversight and accountability with respect to the use of AI, and U.S. federal and state governments, including California, have enacted or are considering laws regulating the development and use of AI. In 2024, the EU also revised its Cybersecurity Directive NIS2 rules that create new cybersecurity risk management and reporting obligations. Failure to comply with these current and future laws could result in significant penalties and reputational harm and could have a material adverse effect on our business and results of operations.

Our sales and operations are subject to the risks of doing business internationally, including in new or emerging markets.

As we continue our expansion efforts in emerging markets around the world, through acquisitions and licensing transactions as well as through the development and introduction, both independently and through collaborations such as our collaboration with BeOne, of our products in new markets, we face numerous risks to our business. There is no guarantee that our efforts and strategies to expand sales in new or emerging markets will succeed. Our international business, including in China and emerging market countries, may be especially vulnerable to periods of global, national, and local political, legal, regulatory and financial instability, including issues of geopolitical relations, the imposition of international sanctions in response to certain state actions and/or sovereign debt issues, and management of health and healthcare policies. For example, the BIOSECURE Act, signed into law in December 2025 and subject to phased implementation over the next several years through agency guidance and rulemaking, prohibits federal contracting with companies that have commercial connections with enumerated "biotechnology companies of concern" located in certain geographies, including China, could restrict our ability to contract or collaborate with such biotechnology companies in the future. If relations between the United States and other governments deteriorate, our business and investments in such markets may also be adversely affected. We may also be required to increase our reliance on third-party agents and unfamiliar operations and arrangements, including those previously utilized by companies we partner with or acquire in emerging markets. See *We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications*. Our expansion efforts in China and new and emerging markets around the world are dependent upon the existence or establishment of an environment that is predictable, navigable and supportive of biopharmaceutical innovation, sustained access for our products and predictable pricing controls. China has implemented and enforced regulations governing human genetic resources, including strict requirements with respect to the collection, use and transmission of Chinese human genetic materials and data, and has expanded regulations on the conduct of biotechnology R&D activities in China. For example, between 2020 and 2022, we experienced delays in our applications to the Human Genetic Resources Administration of China that sought approval to conduct clinical trials in China. Further, recent increases in tariffs imposed on certain goods imported into the United States, including inputs relevant to biopharmaceutical manufacturing, have raised our production costs to a limited degree in 2025, and, going forward, such tariffs, together with the imposition of tariffs from agreements the Administration has made with other countries and other potential future tariffs, could further increase our production costs and/or potentially disrupt the operation of our supply chain. See *Global economic conditions may negatively affect us and may magnify certain risks that affect our business.* Our international operations and business may also be subject to less protective intellectual property or other applicable laws, diverse data privacy and protection requirements, changing tax laws and tariffs, trade restrictions or other barriers designed to protect industry in the home country against foreign competition, far-reaching antibribery and anticorruption laws and regulations and/or evolving legal and regulatory environments. For example, cross-border data transfer compliance requirements in China, as well as the DOJ final rule on preventing access to Americans' bulk sensitive personal data by "countries of concern," may also impose additional costs of doing business, including costs associated with localizing operations.

In response to the ongoing armed conflict in Ukraine, the U.S. government, numerous state governments, the EU and other countries in which we conduct business have imposed a wide range of economic sanctions that restrict commerce and

business dealings with Russia, certain regions of Ukraine and certain entities and individuals. Additionally, the recent armed conflict in the Middle East has caused regional disruptions to economic activity. For a description of the conflict's impact on our third-party contract manufacturing of KRYSTEXXA, see *Our efforts to collaborate with or acquire other companies, products, or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions*. These conflicts, in addition to other geopolitical tensions, may also precipitate or amplify the other risks described herein, including risks relating to global economic conditions, cybersecurity, clinical trials and supply chains, which could adversely affect our business, operations and financial condition and results.

We are subject to fluctuations in foreign currency exchange rates relative to the U.S. dollar in the non-U.S. jurisdictions where we do business. While we have a program in place that is designed to reduce our exposure to foreign currency exchange rate fluctuations through foreign currency hedging arrangements, our hedging efforts do not completely offset the effect of these fluctuations on our revenues and earnings. Overall, the legal and operational challenges of our international business operations, along with government controls, the challenges of attracting and retaining qualified personnel and obtaining and/or maintaining necessary regulatory or pricing approvals of our products, may result in material adverse effects on our international product sales, business and results of operations. In addition, pricing pressures and price controls in non-U.S. jurisdictions could adversely affect our sales and revenues, and further, to the extent that those prices are included in MFN calculations, such inclusion may affect our strategy with respect to such jurisdictions.

We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The capital and credit markets may experience extreme volatility and disruption, which may lead to uncertainty and liquidity issues for both borrowers and investors. For example, in early 2020, there were significant disruptions in the commercial paper market and several borrowers were unable to obtain funding at normal rates or maturities, which resulted in a significant increase in draws of corporate credit lines with banks. Similarly, the bond markets experienced extreme volatility in terms of interest rates and credit spreads, with several days without new issuances of corporate bonds.

We expect to access the capital markets, from time to time, to supplement our existing funds and cash generated from operations to satisfy our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other strategic business initiatives we plan to pursue, including acquisitions and licensing activities. In the event of adverse capital and credit market conditions, we may be unable to obtain capital market financing on favorable terms, or at all, which could have a material adverse effect on our business and results of operations or our ability to complete business acquisitions. Changes in credit ratings issued by nationally recognized credit-rating agencies could also adversely affect our ability to obtain capital and credit market financing and the cost of such financing and have an adverse effect on the market price of our securities.

RISKS RELATED TO COMPETITION

Our products face substantial competition and our product candidates are also likely to face substantial competition.

We operate in a highly competitive environment. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—*Competition*. We expect that our products and product candidates will compete with existing drugs, new drugs currently in development, drugs currently approved for other indications that may later be approved for the same indications as those of our products and drugs approved for other indications that are used off-label. Large pharmaceutical companies and generics manufacturers of pharmaceutical products have expanded into, and are expected to continue expanding into, the biotechnology field, and some pharmaceutical companies and generics manufacturers have formed partnerships to pursue biosimilars. With the proliferation of companies pursuing biopharmaceuticals, several of our biosimilar products have entered, and a number of our product candidates are expected to enter, markets with one or more competitors or with competitors soon to arrive. In addition, some of our competitors may have technical, competitive or other advantages over us for the development of technologies and processes or greater experience in particular therapeutic areas, and consolidation among pharmaceutical and biotechnology companies can enhance such advantages. These advantages may make it difficult for us to compete with them successfully to discover, develop and market new products and for our current products to compete with new products or new product indications they may bring to market. As a result, our products have been competing and may continue to compete, and our product candidates may compete, against products or product candidates that offer higher rebates or discounts, lower prices, equivalent or superior efficacy, better safety profiles, easier administration, earlier market availability, established market position or other competitive features. If we are unable to compete effectively, this could reduce our sales, which could have a material adverse effect on our business and results of operations.

Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.

Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. Driven by cost pressures, efforts to limit or weaken patent protection for our industry are increasing. For example, the COVID-19 pandemic resulted in increased interest in compulsory licenses, march-in rights or other governmental interventions, both in the United States and internationally, related to the procurement of drugs, and governments and international bodies have since adopted or considered regulations that could facilitate the use of such measures during public health or other emergencies. At the end of 2023, the prior Administration released a proposed framework that would consider price as a factor when determining whether to exercise march-in rights pursuant to the Bayh-Dole Act with respect to drugs or other taxpayer-funded inventions, and the status and potential implementation of such framework remains uncertain. Further, in early 2025, the Administration took actions affecting federal workforce staffing and operations. Significant reductions of, or disruptions to, staffing and resources available at the USPTO could lead to delays in the examination or approval of patent applications, or other challenges to securing and/or enforcing our intellectual property rights.

Third parties have challenged and may continue to challenge, invalidate or circumvent our patents (including any patent applications, term extensions, term adjustments and supplemental protection certificates) relating to our products, product candidates and technologies. See Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements. Challenges to patents have come from potential competitors or from parties other than those who sought to market a potentially-infringing product. In addition, in certain cases our patent positions have not protected us, and may not protect us, against competitors with similar products or technologies because competing products or technologies may not infringe our patents. For certain of our products and/or product candidates, third parties may obtain patents that claim the product, one or more of its uses, the drug delivery device used to administer the product, or our manufacturing process used to make the product, and they may seek to prevent us from commercializing the product and/or seek payment of a royalty on the product's sales in one or more territories. Further, disputes may arise with third parties from whom we have licensed rights to intellectual property necessary for the development and commercialization of some of our products. In addition, our intellectual property licensing and related business practices have been, and may in the future be, subject to antitrust and competition law scrutiny, which could result in litigation, enforcement actions and/or restrictions on our business. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products. We have been in the past, are currently and expect to be in the future, involved in patent litigation. These matters have included, and may in the future include, litigation with manufacturers of products that purport to be biosimilars of certain of our products for patent infringement, invalidity, unenforceability and failure to comply with certain provisions of the BPCIA, and litigation with manufacturers of innovator products that allege patent infringement. A determination made by a court, agency or tribunal concerning infringement, validity, enforceability, injunctive or economic remedy, or the right to patent protection, for example, are typically subject to appellate or administrative review. Upon review, such initial determinations may be afforded little or no deference by the reviewing tribunal and may be affirmed, reversed or made the subject of reconsideration through further proceedings. A patent dispute or litigation has not discouraged, and may not in the future discourage, a potential violator from bringing the allegedly infringing product to market prior to a final resolution of the dispute or litigation. The period from inception until resolution of a patent dispute or litigation is subject to the availability and schedule of the court, agency or tribunal before which the dispute or litigation is pending. We have been, and may in the future be, subject to competition during this period and may not be able to recover fully from the losses, damages and harms we incur from infringement by the competitor product even if we prevail. Moreover, if we lose or settle current or future litigations at certain stages or entirely, we could be subject to competition and/or significant liabilities, be required to enter into third-party licenses for the infringed product or technology or be required to cease using the technology or product in dispute. In addition, we cannot guarantee that such licenses will be available on terms acceptable to us, or at all.

Further, under the Hatch–Waxman Act, our products approved by the FDA under the FDCA have been, and may in the future be, the subject of patent litigation with generics competitors before expiry of the five-year period of data exclusivity provided for under the Hatch-Waxman Act and prior to the expiration of the patents listed for the product. Likewise, our innovative biologic products have been, and may in the future be, the subject of patent litigation prior to the expiration of our patents and, with respect to competitors seeking approval as a biosimilar or interchangeable version of our products, prior to the 12-year exclusivity period provided under the BPCIA. In addition, we have faced, and may in the future face, patent litigation involving claims that our biosimilar product candidates infringe the patents of other companies, including those that manufacture, market or sell the applicable reference products or who are developing or have developed other biosimilar versions of such products. Patents held by other entities have contributed, and may in the future contribute, to a decision by us to not pursue all of the labeled indications of the applicable reference product. However, a decision not to pursue all of the labeled indications of the applicable reference product might not avoid, or end, potential litigation. While we have attempted, and expect to continue to attempt, to challenge the patents held by other companies, our efforts may be unsuccessful. For

examples of and information related to our patent litigation, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

Certain of the existing patents on our products have expired or will soon expire. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—*Patents*. As our patents expire, competitors are able to legally produce and market similar products or technologies, including biosimilars, which has had, and may continue to have, a material adverse effect on our product sales, business and results of operations. In addition, competitors have been, and may continue to be, able to invalidate, design around or otherwise circumvent our patents and sell competing products.

We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future.

We currently face competition from biosimilars and generics in most of the territories in which we operate, including the United States and Europe, and we expect to face increasing biosimilar and/or generics competition this year and beyond. Expiration or successful challenge of applicable patent rights or expiration of an applicable exclusivity period has accelerated such competition, and we expect to face more litigation regarding the validity and/or scope of our patents. Our products have also experienced greater competition from lower cost biosimilars or generics that come to market when branded products that compete with our products lose their own patent protection. To the extent that governments adopt more permissive regulatory approval standards and competitors are able to obtain broader or expedited marketing approval for biosimilars and generics, the rate of increased competition for our products would likely accelerate. For example, both the EMA and FDA have increasingly supported streamlined biosimilar approval pathways in which comparative clinical efficacy testing may not be routinely required, and in recent years have, on a case by case basis, accepted applications without such testing.

In the EU, biosimilars are evaluated for marketing authorization pursuant to a set of general and product class-specific guidelines. In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some EU countries and some Canadian provinces have adopted biosimilar uptake measures such as physician prescribing quotas or automatic pharmacy substitution of biosimilars for the corresponding reference products. Some EU countries impose automatic price reductions upon market entry of one or more biosimilar competitors. Regulatory authorities in the EU, including the EMA and the EU Heads of Medicines' Agencies (HMA) have articulated a position that biosimilar medicines approved in the EU are "interchangeable" with their reference products and other biosimilars of the same reference product for purposes of prescribing. Increased regulatory clarity regarding interchangeability, together with national pricing, tendering and reimbursement policies, has coincided with continued growth in biosimilar utilization and increased competitive pressure on innovative biologic products in Europe. While the degree of competitive effects of biosimilar competition differs between EU countries and between products, biosimilar competition has had, and is expected to continue to have, an effect on the sales of innovative biologic products in Europe.

In the United States, the BPCIA authorizes the FDA to approve biosimilars via a separate, abbreviated pathway. See Item 1. Business—Government Regulation—*Regulation in the United States—Approval of Biosimilars*. In the United States, the FDA has approved numerous biosimilars, including biosimilar versions of Neulasta, EPOGEN, ENBREL, Prolia and XGEVA, and a growing number of companies have announced that they are also developing biosimilar versions of our products. For example, a number of biosimilar versions of Prolia and/or XGEVA have been approved in the United States and EU, and impact to our Prolia and XGEVA sales are expected to accelerate as the number of additional competitors continues to increase. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—*Competition*. Manufacturers of biosimilars have attempted, and may in the future attempt, to compete with our products by offering greater discounts or rebates, contracts that offer longer-term pricing or a broader portfolio of other products, or lower list prices. Companies pursuing development of biosimilar versions of our products have challenged and may continue to challenge our patents well in advance of the expiration of our material patents. For examples of and information related to our biosimilars and generics patent litigation, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements. See also *Our intellectual property positions may be challenged, invalidated or circumvented, or we may fail to prevail in current and future intellectual property litigation.*

Under the U.S. biosimilar regulatory framework, certain biosimilars have been approved as interchangeable with their reference products, which can allow pharmacists, subject to state law, to substitute those biosimilars for our products without prior prescriber approval and could increase competitive pressure on our products. In addition, critics of the 12-year exclusivity period for biologics may continue to seek to shorten that period or encourage narrower interpretations of the statutory provisions governing eligibility for exclusivity, and the FDA could adopt interpretations of the biologics exclusivity framework that limit the scope or duration of exclusivity for certain products or product changes. Legislative and regulatory initiatives may seek to further promote competition by facilitating generic and biosimilar approval and commercialization, including by reducing regulatory requirements, limiting the scope of patent protections or disputes, or adopting reimbursement, substitution or disclosure policies that favor biosimilars. Any such developments could accelerate biosimilar competition and adversely affect the sales of our products.

Upon the expiration or loss of patent protection and/or applicable exclusivity for one of our products, we can lose the majority of revenues for that product in a very short period of time. See Item 1. Business—Marketing, Distribution and Selected Marketed Products—*Competition*. Additionally, if one of our products is the subject of an FDA Written Request for pediatric studies and we are unable to adequately complete these studies, we may not obtain the pediatric exclusivity award that extends unexpired regulatory exclusivity for the product (and existing patents for a small molecule product) by an additional six months. Further, the FDA released draft guidance contemplating that pediatric exclusivity may not be granted for studies conducted solely to fulfill Pediatric Research Equity Act (PREA) requirements.

While we are unable to predict the precise effects and timing of biosimilars and generics on our products, we are currently facing and expect to face greater competition in the United States, Europe and elsewhere as a result of biosimilar and generic competition and, in turn, downward pressure on our product prices and sales. This competition has had, and could increasingly have, a material adverse effect on our product sales, business and results of operations. State laws may also have an impact on our business. For example, certain states have enacted, or proposed, laws that restrict, or prohibit, "pay for delay" settlements of patent infringement claims filed by manufacturers of generics or biosimilars by creating the presumption that such agreements are anticompetitive. In addition, federal legislative proposals targeting such settlements continue to be introduced and advanced in Congress. These developments could result in prolonged litigation or fewer settlements of patent infringement disputes.

Concentration of sales at certain of our wholesaler distributors, and consolidation of private payers, such as insurers, and PBMs has negatively affected, and may continue to negatively affect, our business.

Certain of our distributors, customers and payers have substantial purchasing leverage, due to the volume of our products they purchase or the number of patient lives for which they provide coverage. The substantial majority of our U.S. product sales is made to three pharmaceutical product wholesaler distributors: McKesson Corporation, Cencora, Inc. (formerly AmerisourceBergen Corporation) and Cardinal Health, Inc. These distributors, in turn, sell our products to their customers, which include physicians or their clinics, dialysis centers, hospitals and pharmacies. Similarly, as discussed above, there has been significant consolidation in the health insurance industry, including that a small number of PBMs now oversee a substantial percentage of total covered lives in the United States. See *Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability.* For example, the six largest PBMs in the United States are now part of major health insurance providers, and the Federal Trade Commission's interim report released in 2024 showed that they nationally account for 94% of prescription drug claims. The growing concentration of purchasing and negotiating power by these entities has, and may continue to, put pressure on our pricing due to their ability to extract price discounts on our products, fees for other services or rebates, negatively affecting our bargaining position, sales and/or profit margins. In addition, decisions by these entities to purchase or cover less or none of our products in favor of competing products could have a material adverse effect on our product sales, business and results of operations due to their purchasing volume. Further, if one of our significant wholesale distributors encounters financial or other difficulties and becomes unable or unwilling to pay us all amounts that such distributor owes us on a timely basis, or at all, it could negatively affect our business and results of operations. In addition, if one of our significant wholesale distributors becomes insolvent or otherwise unable to continue its commercial relationship with us in its present form, it could significantly disrupt our business and adversely affect our product sales, our business and results of operations unless suitable alternatives are timely found or lost sales are absorbed by another distributor.

RISKS RELATED TO RESEARCH AND DEVELOPMENT

We may not be able to develop commercial products despite significant investments in R&D.

Amgen invests heavily in R&D. Successful product development in the biotechnology industry is highly uncertain, and very few R&D projects yield approved and commercially viable products. Product candidates, including biosimilar product candidates, or new indications for existing products (collectively, product candidates) that appear promising in the early phases of development have failed to reach the market for a number of reasons, such as:

- the product candidate did not demonstrate acceptable clinical trial results even though it achieved its primary endpoints and/or demonstrated positive preclinical or early clinical trial results, for reasons that could include changes in the standard of care of medicine or expectations of health authorities;
- the product candidate was not effective or not more effective than currently available or potentially competitive therapies in treating a specified condition or illness;
- the product candidate was not cost effective in light of existing or potentially competitive therapeutics;
- the product candidate had harmful side effects in animals or humans;
- the necessary regulatory bodies, such as the FDA or EMA, did not approve the product candidate for an intended use;

- reimbursement for the product candidate is limited despite regulatory approval;
- the product candidate was not economical for us to manufacture and/or commercialize;
- the patient population size is smaller than anticipated;
- other parties had or may have had proprietary rights relating to our product candidate, such as patent rights, and did not let us sell it on reasonable terms, or at all;
- we and certain of our licensees, partners, contracted organizations or independent investigators failed to effectively conduct clinical development or clinical manufacturing activities;
- the pathway to regulatory approval or reimbursement for product candidates was uncertain or not well-defined;
- the biosimilar product candidate failed to demonstrate the requisite biosimilarity to the applicable reference product, or was otherwise determined by a regulatory authority to not meet applicable standards for approval; and
- a companion diagnostic device that is required with the use of a product candidate is not approved by the necessary regulatory authority.

We believe that genetics, together with the benefit of artificial intelligence and computational evidence, could meaningfully aid our search for new medicines and help guide our R&D decisions and investments, and have focused our R&D strategy on drug targets validated by genetic or other compelling human evidence. We have invested considerable time, energy and resources into developing our expertise in human genetics and acquiring access to libraries of genetic information, and are applying artificial intelligence to our R&D activities, including applying such technologies to advance our human data efforts and our generative biology platform that seek to discover and design new drugs. However, product candidates based on genetically validated targets or developed with the assistance of such technologies remain subject to the uncertainties of the drug development process and may not reach the market for a number of reasons, including the factors listed above.

We must conduct clinical trials in humans before we commercialize and sell any of our product candidates or existing products for new indications.

Before a product may be sold, we must conduct clinical trials to demonstrate that our product candidates are safe and effective for use in humans. The results of those clinical trials are used as the basis to obtain approval from regulatory authorities such as the FDA and EMA. See *Our current products and products in development cannot be sold without regulatory approval*. We are required to conduct clinical trials using an appropriate number of trial sites and patients to support the product label claims. The length of time, number of trial sites and number of patients required for clinical trials vary substantially, and we may spend several years and incur substantial expense in completing certain clinical trials. In addition, we may have difficulty finding a sufficient number of clinical trial sites and/or patients to participate in our clinical trials, particularly if competitors are conducting clinical trials in similar patient populations and/or in rare disease therapy clinical trials due to the inherently small patient population potentially served by such therapies. Patients may withdraw from clinical trials at any time (including trials in which patients believe that they may not be receiving a clinical benefit), and evolving legal obligations including, but not limited to, privacy laws and/or other restrictions in certain countries may restrict the ability of clinical trial investigators to conduct further follow-up on such patients, which may adversely affect the interpretation of study results. Regulatory authorities may also pause or halt conduct of clinical trials based on their appraisal of the potential or actual risks of continuing the study. Delays and complications in planned clinical trials can result in increased development costs, associated delays in regulatory approvals and in product candidates reaching the market and revisions to existing product labels.

Further, to increase the number of patients available for enrollment in our clinical trials, we have opened, and will continue to open, clinical sites and enroll patients in a number of locations where our experience conducting clinical trials is more limited, including India, China, South Korea, the Philippines, Singapore, Saudi Arabia and some Central and South American countries, either through utilization of third-party contract clinical trial providers entirely or in combination with local staff. Conducting clinical trials in locations where we have limited experience requires substantial time and resources to understand the unique regulatory environments of individual countries. For other examples of the risks of conducting clinical trials in China, see also *Our sales and operations are subject to the risks of doing business internationally, including in emerging markets*. Further, we must ensure the timely production, distribution and delivery of the clinical supply of our product candidates to numerous and varied clinical trial sites. Additionally, regional disruptions, including natural and man-made disasters, health emergencies (such as novel viruses or pandemics), or geopolitical conflicts (such as the ongoing armed conflicts in Ukraine and the Middle East) have significantly disrupted the timing of clinical trials, and in the future could disrupt the timing, execution and outcome of clinical trials. If we fail to adequately manage the design, execution and diverse regulatory aspects of our clinical trials or to manage the production or distribution of our clinical supply, or such sites experience disruptions as a result of a natural/man-made disaster, health emergency or geopolitical conflict, corresponding

regulatory approvals may be delayed or we may fail to gain approval for our product candidates or could lose our ability to market existing products in certain therapeutic areas or altogether. If we are unable to market and sell our products or product candidates or to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations could be materially and adversely affected.

We rely on independent third-party clinical investigators to recruit patients and conduct clinical trials on our behalf in accordance with applicable study protocols, laws and regulations. We also rely on unaffiliated third-party vendors to perform certain aspects of our clinical trial operations, including that such vendors have appropriate experienced staff to execute on such activities. Further, the disease states that we are studying, such as cancers, require complex treatment protocols that may be difficult to consistently apply across global trial sites, which can impact the quality, interpretability, timing and/or registrability of the data generated. In some circumstances, we enter into co-development arrangements with other pharmaceutical and medical devices companies that provide for the other company to conduct certain clinical trials for the product we are co-developing or to develop a diagnostic test used in screening or monitoring patients in our clinical trials. See *Some of our pharmaceutical pipeline and our commercial product sales rely on collaborations with third parties, which may adversely affect the development and sales of our products.* We also may acquire companies that have past or ongoing clinical trials or rights to products or product candidates for which clinical trials have been or are being conducted. These trials may not have been conducted to the same standards as ours; however, once an acquisition has been completed we assume responsibility for the conduct of these trials, including any potential risks and liabilities associated with the past and prospective conduct of those trials. If regulatory authorities determine that we or others, including our licensees or co-development partners, or the independent investigators or vendors selected by us, our co-development partners or by a company we have acquired or from which we have acquired rights to a product or product candidate, have not complied with regulations applicable to the clinical trials, those authorities may refuse or reject some or all of the clinical trial data or take other actions that could delay or otherwise negatively affect our ability to obtain or maintain marketing approval of the product or indication. In addition, delays or failures to develop diagnostic tests or delivery devices for our clinical trials can affect the timely enrollment of such trials and lead to delays or inability to obtain marketing approval. If we were unable to market and sell our products or product candidates, our business and results of operations could be materially and adversely affected.

In addition, some of our clinical trials utilize drugs and combination products manufactured and marketed by other pharmaceutical companies or vendors. These drugs, devices and/or products may be administered or used in clinical trials in combination with one of our products or product candidates or in a head-to-head study comparing the products' or product candidates' relative efficacy and safety. In the event that any of these vendors or pharmaceutical companies have unforeseen issues that negatively affect the quality of their work product or create a shortage of supply, or if we are otherwise unable to obtain an adequate supply of these other drugs, our ability to complete our applicable clinical trials and/or evaluate clinical results may also be negatively affected. As a result, such quality or supply problems could adversely affect our ability to timely file for, gain or maintain regulatory approvals worldwide.

Clinical trials must generally be designed based on the current standard of medical care. However, in certain diseases, such as cancer, the standard of care is evolving rapidly. In some cases, we may design a clinical trial based on the standard of care we anticipate will exist at the time our study is completed. The duration of time needed to complete certain clinical trials may result in the design of such clinical trials being based on standards of medical care that are no longer or that have not become the current standards by the time such trials are completed, limiting the utility and application of such trials. Additionally, the views of regulatory agencies relating to the requirements for accelerated approval have evolved over time, and trial designs that were sufficient to support accelerated approvals for some oncology products may not be considered sufficient for later candidates. In addition, access to expedited regulatory programs, including priority review vouchers and other programs tied to agency-designated national or public health priorities, is subject to evolving agency eligibility criteria and guidance, and may not be available for our product candidates or may not result in expedited review or approval. We may not obtain favorable clinical trial results and therefore may not be able to obtain regulatory approval for new product candidates or new indications for existing products and/or maintain our current product labels. Participants in clinical trials of our products and product candidates may also suffer adverse medical events or side effects that could, among other factors, delay or terminate clinical trial programs and/or require additional or longer trials to gain approval.

Even after a product is on the market, safety concerns may require additional or more extensive clinical trials as part of a risk management plan for our product or for approval of a new indication. Additional clinical trials we initiate, including those required by the FDA, could result in substantial additional expense, and the outcomes could result in further label restrictions or the loss of regulatory approval for an approved indication, each of which could have a material adverse effect on our product sales, business and results of operations. Additionally, any negative results from such trials could materially affect the extent of approvals, the use, reimbursement and sales of our products, our business and results of operations.

Our current products and products in development cannot be sold without regulatory approval.

Our business is subject to extensive regulation by numerous state and federal government authorities in the United States, including the FDA, and by foreign regulatory authorities, including the EMA. We are required in the United States and in the other regions and countries in which we, or our partners and affiliates, sell to obtain approval from regulatory authorities before we manufacture, market and sell our products. Once our products are approved, the FDA and other U.S. and ex-U.S. regulatory agencies have substantial authority to require additional testing and reporting, perform inspections, change product labeling or mandate withdrawals of our products. Failure to comply with applicable regulatory requirements may subject us to administrative and/or judicially imposed sanctions or monetary penalties as well as reputational and other harms. The sanctions could include the FDA's or ex-U.S. regulatory authorities' refusals to approve pending applications, delays in obtaining or withdrawals of approvals, delays or suspensions of clinical trials, warning letters, product recalls or seizures, total or partial suspensions of our operations, injunctions, fines, civil penalties and/or criminal prosecutions.

Obtaining and maintaining regulatory approvals have been, and will continue to be, increasingly difficult, time-consuming and costly. Legislative bodies or regulatory agencies could enact new laws or regulations, change existing laws or regulations or change their interpretations of laws or regulations at any time, which could affect our ability to obtain or maintain approval of our products or product candidates. The rate and degree of change in existing laws and regulations and regulatory expectations have accelerated in established markets, and regulatory expectations continue to evolve in emerging markets. We are unable to predict whether and when any further changes to laws or regulatory policies affecting our business could occur, such as changes to laws or regulations governing manufacturer communications concerning drug products and drug product candidates and whether such changes could have a material adverse effect on our product sales, business and results of operations. Further, we are reliant on regulators having the resources necessary to evaluate and approve our products. In the United States, federal government shutdowns have occurred and such shutdowns have disrupted certain regulatory activities. Any future government shutdowns or workforce constraints may delay or disrupt regulatory activities, including those with respect to our ongoing clinical programs, the manufacture of our products and product candidates and product approvals.

Recent initiatives to reduce the size and budgets of government agencies, including the HHS, FDA and NIH, may adversely impact our operations. In particular, reductions in staffing and resources at the FDA could result in delays in regulatory review timelines and marketing application and supplement approvals. Changes in leadership at the FDA may also result in shifts in perspectives on the drug approval process and regulatory priorities. Further, implementation of new policy initiatives without guidance or rulemaking has reduced transparency and increased uncertainty with respect to agency actions. Additionally, funding reductions and caps on research overhead costs imposed on the NIH and its programs may result in grant funding cutbacks for scientific and disease-related research at academic institutions and research centers, and such reductions, over the longer term, may slow the overall discovery and development of new therapies and/or slow or interrupt the flow of innovation into the pharmaceutical development pipeline. These developments and others associated with the reduction of personnel and budgets at the regulatory agencies that oversee our industry and operations may adversely affect our business activities, including our ongoing and future clinical research and drug development programs, research collaborations, manufacturing activities and regulatory submissions.

Regulatory authorities have questioned, and may in the future question, the sufficiency for approval of the endpoints we select for our clinical trials. A number of our products and product candidates have been evaluated in clinical trials using surrogate endpoints that measure an effect that is known to correlate with an ultimate clinical benefit. For example, a therapeutic oncology product candidate may be evaluated for its ability to reduce or eliminate minimal residual disease (MRD), or to extend the length of time during and after the treatment that a patient lives without the disease worsening, measured by progression-free survival (PFS). Demonstrating that the product candidate induces MRD-negative responses or produces a statistically significant improvement in PFS does not necessarily mean that the product candidate will show a statistically significant improvement in overall survival or the time that the patients remain alive. In the cardiovascular setting, a heart disease therapeutic candidate may be evaluated for its ability to reduce LDL-C levels, as an elevated LDL-C level has been a surrogate endpoint for cardiovascular events such as death, heart attack and stroke. The use of surrogate endpoints such as PFS and LDL-C reduction, in the absence of other measures of clinical benefit, may not be sufficient for broad usage or approval even when such results are statistically significant. Regulatory authorities could also add new requirements, such as the completion of enrollment in a confirmatory study or the completion of an outcomes study or a meaningful portion of an outcomes study, as conditions for obtaining approval or obtaining an indication. For example, despite demonstrating that Repatha reduced LDL-C levels in a broad patient population, only after our large phase 3 outcomes study evaluating the ability of Repatha to prevent cardiovascular events met certain of its primary composite endpoint and key secondary composite endpoint did the FDA grant a broader approval of Repatha to reduce the risk of certain cardiovascular events. There may also be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to other existing treatment options can be shown. The imposition of additional requirements or our inability to meet them in a timely fashion, or at all, has delayed, and may in the future delay, our clinical development and

regulatory filing efforts, delay or prevent us from obtaining regulatory approval for new product candidates or new indications for existing products, or prevent us from maintaining our current product labels.

Some of our products have been approved by U.S. and ex-U.S. regulatory authorities on an accelerated or conditional basis with full approval conditioned upon fulfilling the requirements of regulators. For example, the FDA has approved LUMAKRAS under accelerated approval for the treatment of adult patients with KRAS G12C-mutated local advanced or metastatic NSCLC. Following our submission of the LUMAKRAS/LUMYKRAS CodeBreaK 200 Phase 3 confirmatory data in March 2023 to the FDA and EMA, we received a Complete Response Letter from the FDA and a new post-marketing requirement for an additional confirmatory study to support full approval. Regulatory authorities are placing greater focus on whether the sponsors of products originally approved on an accelerated or conditional basis have met the conditions of the accelerated or conditional approvals. If we are unable to fulfill the regulators' requirements that were conditions of a product's accelerated or conditional approval and/or if regulators reevaluate the data or risk-benefit profile of our product, the conditional approval may not result in full approval or may be revoked or not renewed. Alternatively, we may be required to change the product's labeled indications, conduct an additional confirmatory clinical trial, or even withdraw the product from the market.

Regulatory authorities can also impose post-marketing pediatric study requirements. Failure to fulfill such requirements may result in regulatory or enforcement action, including financial penalties or the invalidation of a product's marketing authorization.

Safety problems or signals can arise as our products and product candidates are evaluated in clinical trials, including investigator sponsored studies, or as our marketed products are used in clinical practice. We are required continuously to collect and assess adverse events reported to us and to communicate to regulatory agencies these adverse events and safety signals regarding our products. Regulatory agencies periodically perform inspections of our pharmacovigilance processes, including our adverse event reporting. In the United States, for our products with approved Risk Evaluation and Mitigation Strategies (REMS, see Item 1. Business—Government Regulation—*Post-approval Phase*), we are required to submit periodic assessment reports to the FDA to demonstrate that the goals of the REMS are being met. REMS and other risk management programs are designed to help ensure that a drug's benefits outweigh the risks and vary in the elements they contain. If the FDA is not satisfied with the results of the periodic assessment reports we submit for any of our REMS, the FDA may also modify our REMS or take other regulatory actions, such as implementing revised or restrictive labeling. The drug delivery devices approved for use in combination with our products are also subject to regulatory oversight and review for safety and malfunctions. See *Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks*. If regulatory agencies determine that we or other parties (including our clinical trial investigators, those operating our patient support programs or licensees of our products) have not complied with the applicable reporting, other pharmacovigilance or other safety or quality assessment requirements, we may become subject to additional inspections, warning letters or other enforcement actions, including fines, marketing authorization withdrawal and other penalties. Our product candidates and marketed products can also be affected by safety problems or signals occurring with respect to products that are similar to ours or that implicate an entire class of products. Further, as a result of clinical trials, including sub-analyses or meta-analyses of earlier clinical trials (a meta-analysis involves the use of various statistical methods to combine results from previous separate but related studies) performed by us or others, concerns may arise about the sufficiency of the data or studies underlying a product's approved label. Such actual or perceived safety problems or concerns can lead to:

- revised or restrictive labeling for our products, or the potential for restrictive labeling that has resulted, and may in the future result, in our decision not to commercialize a product candidate;
- requirement of risk management or minimization activities or other regulatory agency compliance actions related to the promotion and sale of our products;
- post-marketing commitments, mandated post-marketing requirements or pharmacovigilance programs for our approved products;
- product recalls of our approved products;
- required changes to the processes used in the manufacture of our products, which could increase our manufacturing costs and affect the availability of contract manufacturers we may utilize to assist in such manufacturing;
- revocation of approval for our products from the market completely, or within particular therapeutic areas or patient types;
- increased timelines or delays in being approved by the FDA or other regulatory bodies; and/or
- treatments or product candidates not being approved by regulatory bodies.

For example, after an imbalance in positively adjudicated cardiovascular serious adverse events was observed in one of the phase 3 clinical trials for EVENITY but not in another, larger phase 3 study, in April 2019 the FDA approved EVENITY for the treatment of osteoporosis in postmenopausal women at high risk for fracture, along with a post-marketing requirement. The requirement includes a five-year observational feasibility study that could be followed by a comparative safety study or trial.

Regulatory authorities also require that our products are tested and controlled for impurities. Impurities exceeding established limits may lead to delayed product approvals or disrupt the manufacture and distribution of our products. For example, certain jurisdictions and regulatory agencies, including the FDA and EMA, require risk assessments, and if applicable, testing, for the presence of nitrosamine impurities in certain small molecule drugs, and we are following the established process of evaluating potentially impacted small molecule products.

In addition to our innovative products, we are working to develop and commercialize biosimilar versions of a number of products currently manufactured, marketed and sold by other pharmaceutical companies. In some markets outside the United States and EU, there is not yet a legislative or regulatory pathway for the approval of biosimilars. In the United States, the BPCIA provides for such a pathway. Discussions within the FDA and other regulatory authorities, and between regulatory authorities and sponsors, continue as to the evidence needed to demonstrate biosimilarity or interchangeability for specific products. See *We currently face competition from biosimilars and generics and expect to face increasing competition from biosimilars and generics in the future.* Delays or uncertainties in the development or implementation of such pathways, or changes in existing regulatory pathways, including degradation of regulatory standards, could result in delays or difficulties in getting our biosimilar products approved by regulatory authorities, subject us to unanticipated development costs or otherwise reduce the value of the investments we have made in the biosimilars area. Further, we cannot predict the extent to which any potential legislative or policy initiatives would affect the biosimilar pathway or have a material adverse effect on our development of biosimilars, on our marketed biosimilars or on our pursuit of interchangeability designations for any biosimilar. In addition, if we are unable to bring our biosimilar products to market on a timely basis and secure "first-to-market" or other advantageous positions, our future biosimilar sales, business and results of operations could be materially and adversely affected.

Some of our products are used with drug delivery or companion diagnostic devices that have their own regulatory, manufacturing and other risks.

Many of our products and product candidates may be used in combination with a drug delivery device, such as an injector or other delivery system. For example, Neulasta is available as part of the Neulasta Onpro kit, our AutoTouch reusable autoinjector is used with ENBREL Mini single-dose prefilled cartridges, Repatha can be administered with the Repatha SureClick autoinjector, and WEZLANA uses our ConfiPen drug delivery device. In addition, some of our products or product candidates, including many of our oncology product candidates and products, including LUMAKRAS/LUMYKRAS, may also require the use of a companion or other diagnostic device such as a device that determines whether the patient is eligible to use our drug or that helps ensure its safe and effective use. In some regions, including the United States, regulatory authorities may require contemporaneous approval of the companion diagnostic device and the therapeutic product; in others the regulatory authorities may require a separate study of the companion diagnostic device. Our product candidates or expanded indications of our products used with such devices may not be approved or may be substantially delayed in receiving regulatory approval if development or approval of such devices is delayed, such devices do not also gain or maintain regulatory approval or clearance, or if such devices do not remain commercially available. When approval of the product and device is sought under a single marketing drug application, the increased complexity of the review process may delay receipt of regulatory approval. In addition, some of these devices may be provided by single-source unaffiliated third-party companies. We are dependent on the sustained cooperation and effort of those third-party companies to supply and/or market the devices and, in some cases, to conduct the studies required for approval or clearance by the applicable regulatory agencies. We are also dependent on those third-party companies continuing to meet applicable regulatory or other requirements. See *We rely on third-party suppliers for certain of our raw materials, medical devices and components*. Failure to successfully develop, modify, or supply the devices, delays in or failures of the Amgen or third-party studies, or failure by us or the third-party companies to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs; delays in, or failure to obtain or maintain, regulatory approval; and/or associated delays in a product candidate reaching the market or in the addition of new indications for existing products. We are also required to collect and assess user complaints, adverse events and malfunctions regarding our devices, and actual or perceived safety problems or concerns with a device used with our product can lead to regulatory actions and adverse effects on our products. See *Our current products and products in development cannot be sold without regulatory approval*. Additionally, regulatory agencies conduct routine monitoring and inspections to identify and evaluate potential issues with our devices. For example, in 2017, the FDA reported on its adverse event reporting system that it was evaluating our Neulasta Onpro kit. Subsequently, we implemented device and labeling enhancements to address product complaints received on this device. We continuously monitor complaints and adverse events and implement additional enhancements as needed. Loss of regulatory approval or clearance of a device that is used with our product may also result in

the removal of our product from the market. Further, failure to successfully develop, supply, or gain or maintain approval for these devices could adversely affect sales of the related approved products. See also *We rely on third-party suppliers for certain of our raw materials, medical devices and components.*

Some of our pharmaceutical pipeline and our commercial product sales rely on collaborations with third parties, which may adversely affect the development and sales of our products.

We depend on alliances with other companies, including pharmaceutical and biotechnology companies, vendors and service providers, for the development of a portion of the products in our pharmaceutical pipeline and for the commercialization and sales of certain of our commercial products. For example, we have collaborations with third parties under which we share development rights, obligations and costs and/or commercial rights and obligations. See Item 1. Business—Business Relationships.

Failures by these parties to meet their contractual, regulatory, or other obligations to us or any disruption in the relationships between us and these third parties, could have a material adverse effect on our pharmaceutical pipeline and business. In addition, our collaborative relationships for R&D and/or commercialization and sales often extend for many years and have given, and may in the future give, rise to disputes regarding the relative rights, obligations and revenues of us and our collaboration partners, including the ownership or prosecution of intellectual property and associated rights and obligations. This could result in the loss of intellectual property rights or protection, delay the development and sale of potential pharmaceutical products, affect the sale and delivery of our commercialized products and lead to lengthy and expensive litigation, administrative proceedings or arbitration.

RISKS RELATED TO OPERATIONS

We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials.

The global supply of our products and product candidates for commercial sales and for use in our clinical trials is significantly dependent on the uninterrupted and efficient operation of our manufacturing facilities, in particular those in the U.S. territory of Puerto Rico and Thousand Oaks, California. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

We currently perform a substantial majority of our clinical manufacturing that supports our product candidates at our facility in Thousand Oaks, California. A substantial disruption in our ability to operate our Thousand Oaks manufacturing facility could materially and adversely affect our ability to supply our product candidates for use in our clinical trials, leading to delays in development of our product candidates.

In addition, we currently perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico. Puerto Rico has experienced, and continues to be vulnerable to, natural disasters, including hurricanes and earthquakes, that have disrupted the functioning of critical infrastructure such as electric power, water supply, communications networks and transportation systems. The ongoing instability of the island's electric grid has required, at times, sustained reliance on backup generation, and disruptions affecting the island have also impacted certain third-party suppliers and logistics providers. In addition, public health emergencies, labor disruptions, economic challenges and other events affecting Puerto Rico could further disrupt our manufacturing operations, the availability of labor and utilities, and/or the transportation of supplies and finished products. Although our ability to manufacture and supply our products has not, to date, been significantly affected by such events, these challenges, or a combination of these challenges, or other issues that create a substantial disruption to our ability to operate our Puerto Rico manufacturing facility or get supplies and manufactured products transported to and from that location, could make it more expensive or difficult for us to operate in Puerto Rico, and could materially and adversely affect our ability to supply our products and affect our product sales. See *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales*.

We rely on third-party suppliers for certain of our raw materials, medical devices and components.

We rely on unaffiliated third-party suppliers for certain raw materials, medical devices and components necessary for the manufacturing of our commercial and clinical products. Certain of those raw materials, medical devices and components are proprietary products of those unaffiliated third-party suppliers and are specifically cited in our drug applications with regulatory agencies so that they must be obtained from that specific sole source or sources and could not be obtained from another supplier unless and until the regulatory agency approved such supplier. For example, we rely on a single source for the SureClick autoinjectors used in the drug delivery of a number of our products, including Repatha and ENBREL. Also, certain of the raw

materials required in the commercial and clinical manufacturing of our products are sourced from other countries and/or derived from biological sources, including mammalian tissues, bovine serum and human serum albumin.

Among the reasons we may be unable to obtain these raw materials, medical devices and components include:

- regulatory requirements or action by regulatory agencies or others;
- adverse financial or other strategic developments at, or affecting, the supplier, including bankruptcy;
- unexpected demand for, or shortage of, raw materials, medical devices or components;
- failure to comply with our quality standards which results in quality and product failures, complaints, product contamination and/or recall;
- a material shortage, contamination, recall and/or restrictions on the use of certain biologically derived substances or other raw materials;
- discovery of previously unknown or undetected imperfections in raw materials, medical devices or components;
- cyberattacks on supplier systems;
- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes (such as strikes) or shortages, including from the effects of health emergencies (such as novel viruses or pandemics) or natural disasters;
- tariffs or other trade barriers that increase costs, limit availability, or disrupt the flow of goods; and
- geopolitical conflicts (such as the ongoing conflicts in Ukraine and the Middle East).

For example, in prior years we have experienced shortages in certain components necessary for the formulation, fill and finish of certain of our products in our Puerto Rico facility, and we have also experienced shortages related to single use systems and packaging which has caused disruptions to our manufacturing plans. Further quality issues that result in unexpected additional demand for certain components have resulted in shortages and, in the future, may lead to shortages of required raw materials or components. We may experience similar or other shortages in the future resulting in delayed shipments, supply constraints, clinical trial delays, contract disputes and/or stock-outs of our products. These, or other similar events, could negatively affect our ability to satisfy demand for our products or conduct clinical trials, which could have a material adverse effect on our product sales, business and results of operations.

Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.

Manufacturing biologic and small molecule human therapeutic products is difficult, complex and highly regulated. We manufacture many of our commercial products and product candidates internally. In addition, we use third-party contract manufacturers to produce, or assist in the production of, a number of our products, and we currently use contract manufacturers to produce, or assist in the production of, a number of our late-stage product candidates and drug delivery devices. The number of third-party contract manufacturers that we use has increased with our acquisition of Horizon, as Horizon required contract manufacturers for all of its products. See Item 1. Business—Manufacturing, Distribution and Raw Materials—*Manufacturing*; and *Our efforts to collaborate with or acquire other companies, products, or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions*. Our ability to adequately and timely manufacture and supply our products (and product candidates to support our clinical trials) is dependent on the uninterrupted and efficient operation of our facilities and those of our third-party contract manufacturers. For example, our acquisition of Horizon resulted in the addition of more than 30 contract manufacturing organizations (CMOs) to our operations, many of which are single-source suppliers, including the CMO that produces TEPEZZA drug substance and the CMO that produces all of our KRYSTEXXA drug substance in Israel, which is affected by the current conflict in the Middle East. Our manufacturing and supply operations may be affected by:

- capacity of manufacturing facilities;
- contamination by microorganisms or viruses, or foreign particles from the manufacturing process;
- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes or shortages, including the effects of health emergencies (such as novel viruses or pandemics) or natural disasters;

- compliance with regulatory requirements;
- changes in forecasts of future demand;
- timing and actual number of production runs and production success rates and yields;
- updates of manufacturing specifications;
- contractual disputes with our suppliers and contract manufacturers;
- timing and outcome of product quality testing;
- power failures and/or other utility failures;
- cyberattacks on supplier systems;
- breakdown, failure, substandard performance or improper installation or operation of equipment (including our information technology systems and network-connected control systems or those of our contract manufacturers or third-party service providers);
- delays in the ability of the FDA or foreign regulatory agencies to provide us necessary reviews, inspections and approvals, including as a result of a subsequent extended U.S. federal or other government shutdowns;
- tariffs or other trade barriers that increase costs, limit availability, or disrupt the flow of goods; and/or
- geopolitical conflicts (such as the ongoing conflicts in Ukraine and the Middle East).

If any of these or other problems affect production in one or more of our facilities or those of our third-party contract manufacturers, or if we do not accurately forecast demand for our products or the amount of our product candidates required in clinical trials, we may be unable to start or increase production in our unaffected facilities to meet demand, particularly where such facilities are operating at or near capacity. If the efficient manufacture and supply of our products or product candidates is interrupted, we may experience delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends, contract disputes and/or recalls of our products. From time to time, we have initiated recalls of certain lots of our products. For example, in July 2014 we initiated a voluntary recall of an Aranesp lot distributed in the EU after particles were detected in a quality control sample following distribution of that lot, and in April 2018 we initiated a precautionary recall of two batches of Vectibix distributed in Switzerland after potential crimping defects were discovered in the metal seals on some product vials. If we are at any time unable to provide an uninterrupted supply of our products to patients, we may lose patients and physicians may elect to prescribe competing therapeutics instead of our products, which could have a material adverse effect on our product sales, business and results of operations.

We are expanding our manufacturing capabilities to support current and anticipated demand for our products and product candidates. These expansion efforts are complex, capital-intensive and subject to significant risks, including construction, validation and quality assurance challenges; delays or unfavorable outcomes from regulatory inspections or approvals; labor availability and workforce readiness issues; supply chain disruptions; and contractual disputes with suppliers or contractors. We may be unable to realize anticipated efficiencies or returns on our investments if there are delays or failures of our product development programs or our receipt of regulatory approvals, if our new or expanded facilities require extended periods to achieve planned production capacity or expected yields, or if demand for our products or product candidates changes or fails to materialize. These efforts often rely on a single or limited number of vendors and suppliers, and identifying or qualifying alternatives may not be feasible or may require significant time and expense due to the specialized nature of our manufacturing requirements. In addition, tariffs on imported equipment, construction materials or key inputs have increased our costs to a limited extent in 2025, and, going forward, such tariffs, or other tariffs imposed in the future, could further increase costs, potentially disrupt supply chains, and put at risk the timely and cost-effective execution of these projects.

Our manufacturing processes, those of our third-party contract manufacturers and those of certain of our third-party service providers must undergo regulatory approval processes and are subject to continued review by the FDA and other regulatory authorities. It can take longer than five years to build, validate and license another manufacturing plant, and it can take longer than three years to qualify and license a new contract manufacturer or service provider. If we elect or are required to make changes to our manufacturing processes because of new regulatory requirements, new interpretations of existing requirements or other reasons, this could increase our manufacturing costs and result in delayed shipments, delays in our clinical trials, supply constraints, stock-outs, adverse event trends or contract negotiations or disputes. Such manufacturing challenges may also occur if our existing contract manufacturers are unable or unwilling to timely implement such changes, or at all.

In addition, regulatory agencies conduct routine monitoring and inspections of our manufacturing facilities and processes as well as those of our third-party contract manufacturers and service providers. If regulatory authorities determine that we or our third-party contract manufacturers or certain of our third-party service providers have violated regulations, they may mandate corrective actions and/or issue warning letters, or even restrict, suspend or revoke our prior approvals, prohibiting us from manufacturing our products or conducting clinical trials or selling our marketed products, either until we or the affected third-party contract manufacturers or third-party service providers comply, or indefinitely. See *Our current products and products in development cannot be sold without regulatory approval.* Such issues may also delay the approval of product candidates we have submitted for regulatory review, even if such product candidates are not directly related to the products, devices or processes at issue with regulators. Regulatory authorities may also interpret issues identified with respect to a single manufacturing line as reflecting broader quality or procedural concerns that apply to other lines or facilities, which could delay approvals or adversely affect operations at other facilities. Because our third-party contract manufacturers and certain of our third-party service providers are subject to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and third-party service providers may not be available on a timely basis, or at all. If we or our third-party contract manufacturers or third-party service providers cease or interrupt production or if our third-party contract manufacturers and third-party service providers fail to supply materials, products or services to us, we may experience delayed shipments, delays in our clinical trials, supply constraints, contract disputes, stock-outs and/or recalls of our products. Additionally, we distribute a substantial volume of our commercial products through our primary distribution centers in Louisville, Kentucky for the United States and in Breda, Netherlands for Europe and much of the rest of the world. We also conduct most of the labeling and packaging of our products distributed in Europe and much of the rest of the world in Breda. Our ability to timely supply products is dependent on the uninterrupted and efficient operations of our distribution and logistics centers, our third-party logistics providers and our labeling and packaging facility in Breda. Further, we rely on commercial transportation, including air and sea freight, for the distribution of our products to our customers, which has been negatively affected by pandemics, labor unrest, natural disasters and geopolitical security threats.

Changes in laws or regulations with respect to the use and/or presence of certain chemicals in our products or the components used in the research, development, manufacture and/or packaging of our products could also disrupt or restrict our ability to develop, produce or sell our products. For example, the EU, Canada, the U.S. Congress, the U.S. Environmental Protection Agency, and several U.S. states are considering legislation and/or policies to address the reporting, presence, and/or use, of certain chemicals in certain of the components used in the manufacture or packaging of commercial products, including chemicals known as per- and polyfluorinated substances (PFAS). In 2024, Canada (through Environment and Climate Change Canada) issued a notice requiring reporting on PFAS manufacture, import, and use in Canada. In addition, proposed legislation in several jurisdictions are under consideration to prohibit or otherwise regulate the importation, manufacture, or distribution of goods containing PFAS, and some such proposals do not provide exemptions for drug products, medical devices, their packaging, or the materials used in the research, development, or manufacture of such products or devices. For example, the EU is considering a ban on PFAS in the manufacturing and packaging of pharmaceutical products that could affect pharmaceutical research and development activities and commercial distribution. Some proposals, if enacted without exemptions for pharmaceutical products, and materials used in their research, development, and manufacture, or without adequate time to research and develop or otherwise identify alternative materials or suppliers, may cause significant disruptions to our ability to manufacture and supply products to the affected jurisdictions, potentially resulting in a material adverse effect on our business.

There have also been legislative and administrative proposals seeking to incentivize greater drug manufacturing in the United States with the stated goal of improving supply reliability in the United States. For example, one legislative proposal would have prohibited the U.S. Department of Veterans Affairs from purchasing certain drugs that have active pharmaceutical ingredients manufactured outside the United States. While we perform a substantial majority of our commercial manufacturing activities in the United States, including in the U.S. territory of Puerto Rico, and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California, the passage of such legislation could result in foreign governments enacting retaliatory legislation or regulatory actions, which may have an adverse effect on our product sales, business and results of operations.

Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our sustainability objectives.

We continue to work towards operating our business in a sustainable manner. Stakeholders, including our investors and our employees, have increasingly focused on, and are expected to continue to focus on, our sustainability practices. Policymakers, regulators and investors globally have increased their focus on sustainability matters, resulting in rapidly evolving and diverging expectations and standards. For example, California recently enacted the Climate Corporate Data Accountability Act that requires, among other things, disclosure of greenhouse gas emissions. In contrast, a number of states have adopted or proposed laws or policies that restrict the consideration of sustainability or other non-financial factors in connection with certain investment or business decisions, which may conflict with the expectations of some of our stakeholders. If our sustainability practices fail to meet stakeholders' expectations and applicable standards, or if we fail to comply with

sustainability-related regulations across our global business, there could be a material adverse effect on our reputation, business and, ultimately, our stock price.

Our sustainability report is made available on our website and describes our current sustainability goals and the progress we have made on the sustainability issues that we believe our external and internal stakeholders consider to be important, based on surveys, interviews and certain frameworks for corporate responsibility. Achieving our sustainability goals requires long-term investments and broad, coordinated activity, and we may be required to incur additional costs or allocate additional resources towards monitoring, reporting and implementing our sustainability programs. Further, we may fail to accurately assess our stakeholders' sustainability priorities and concerns, as such priorities and concerns have been rapidly changing. While we have achieved most of our goals set in prior years, whether we can achieve our current and future sustainability goals continues to be uncertain and remains subject to numerous risks, including evolving regulatory requirements and social expectations affecting sustainability practices, our ability to recruit, develop and retain a diverse workforce, the availability of suppliers and collaboration partners that can meet our environmental goals, the effects of the organic growth of our business and potential acquisitions of other businesses on our sustainability performance, and the availability and cost of technologies or resources, such as carbon credits, that support our goals. Any failure or perceived failure to meet our sustainability program priorities could result in a material adverse effect on our reputation, business and stock price.

The effects of global climate change and related natural disasters could negatively affect our business and operations.

Many of our operations and facilities, including those essential to our manufacturing, R&D and distribution activities, are in locations that are subject to natural disasters, including droughts, fires, extreme temperatures, hurricanes, tropical storms and/or floods. For example, in 2017 Hurricane Maria caused catastrophic damage, compounded in 2022 by Hurricane Fiona, to the U.S. territory of Puerto Rico, where we perform a substantial majority of our commercial manufacturing activities. Although our site was well-protected and suffered minimal damage, there can be no assurances that we would have similar results in the face of future natural disasters. The severity and frequency of weather-related natural disasters has been amplified, and is expected to continue to be amplified by, global climate change. For example, in January 2025, Los Angeles county experienced unprecedented wildfires, and while the natural disaster did not impact our facilities or their operations, a number of our staff members lost their homes or were subject to evacuation orders and/or multiple-day power outages. Such natural disasters have caused, and in the future may cause, damage to and/or disrupt our operations, which may result in a material adverse effect on our product sales, business and results of operations. Our suppliers, vendors and business partners also face similar risks, and any disruption to their operations could have an adverse effect on our supply and manufacturing chain. Further, many of our key facilities are located on islands, including Puerto Rico, Singapore and Ireland, which rely on essential port facilities that may be vulnerable to climate change-related or other natural disasters. Although we have detailed business continuity plans in place and periodic assessments of our natural disaster risk, any natural disaster may also result in prolonged interruption to our critical operational and business activities, and we may be required to incur significant costs to remedy the effects of such natural disasters and fully resume operations, which may result in a material adverse effect on our product sales, business and results of operations. See *We perform a substantial majority of our commercial manufacturing activities at our facility in the U.S. territory of Puerto Rico and a substantial majority of our clinical manufacturing activities at our facility in Thousand Oaks, California; significant disruptions or production failures at these facilities could significantly impair our ability to supply our products or continue our clinical trials* and *Manufacturing difficulties, disruptions or delays could limit supply of our products and limit our product sales.*

GENERAL RISK FACTORS

Global economic conditions may negatively affect us and may magnify certain risks that affect our business.

Our operations and performance have been affected, and may continue to be affected, by uncertain global economic conditions, including those arising from geopolitical and trade policy tensions and market volatility. In addition, fiscal and budgetary pressures in the United States and other jurisdictions, including uncertainty around, or reprioritization of, government funding and constrained government resources, may disrupt government operations and regulatory activities and increase pressure on healthcare budgets and reimbursement policies. See *Our sales depend on coverage and reimbursement from government and commercial third-party payers, and pricing and reimbursement pressures have affected, and are likely to continue to affect, our profitability*. As a result of global economic conditions, some third-party payers may delay or be unable to satisfy their reimbursement obligations. Job losses or other economic hardships (including inflation) may also affect patients' ability to afford healthcare as a result of increased co-pay or deductible obligations, greater cost sensitivity to existing co-pay or deductible obligations, lost healthcare insurance coverage or for other reasons. We believe such conditions have led and could continue to lead to reduced demand for our products, which could have a material adverse effect on our product sales, business and results of operations. Our operational costs, including the cost of energy, materials, labor, distribution and our other operational and facilities costs are subject to market conditions and have been adversely affected by tariffs to a limited extent. Although we monitor our distributors', customers' and suppliers' financial condition and their liquidity to mitigate our business risks, some of our distributors, customers and suppliers may become insolvent, which could have a material adverse effect on

our product sales, business and results of operations. A significant worsening of global economic conditions could precipitate or materially amplify the other risks described herein. On April 2, 2025, the Administration issued an executive order (the April 2025 Tariff EO) imposing a universal 10% tariff on all imported goods, with certain exceptions including pharmaceuticals. The April 2025 Tariff EO imposed additional higher tariffs on approximately 60 countries with which the United States has trade deficits. Recent and ongoing changes in U.S. trade and tariff policies, including the imposition, modification, suspension and threatened expansion of tariffs on imported goods, as well as retaliatory measures by foreign governments, have increased uncertainty in the overall business and operating environment. Although certain pharmaceutical products are exempt from some tariffs, these measures have increased, and may continue to increase, our costs, including for materials, components and supplies used in research and development and manufacturing activities, have adversely affected, and may continue to adversely affect, our operations in various markets, and could disrupt global supply chains. On October 24, 2025, the Administration initiated, under the Trade Act of 1974, a Section 301 investigation of China's implementation of the Economic and Trade Agreement between the U.S. and Chinese governments. This investigation, and any other 301 investigations initiated, may result in additional tariffs on imported goods from China and any other foreign markets subsequently investigated, respectively, potentially including pharmaceutical products and other goods that Amgen requires for the manufacture of our products. If subject to Section 301 tariffs, China, and other affected foreign governments, may retaliate against such tariffs by imposing tariffs of their own on U.S.-made goods. Given the many uncertainties and variables, it is currently unclear the extent, and degree, to which existing and future tariffs will disrupt and adversely affect our business activities (including product sales, and conduct of clinical trial and research and development activities), and the global economic environment, and/or amplify the other risks described herein.

We maintain a significant portfolio of investments on our consolidated balance sheets. Global capital markets have experienced, and may continue to experience, periods of volatility and disruption, including as a result of interest rate fluctuations, inflation, liquidity conditions, credit market stress and geopolitical events. Certain of our assets, including equity investments, are exposed to market fluctuations that, in a sustained or recurrent series of market disruptions, could result in impairments or losses on sale. The value of our investments may also be adversely affected by interest rate fluctuations, inflation, downgrades in credit ratings, illiquidity in the capital markets, geopolitical events and other factors that may result in other-than-temporary declines in the value of our investments. Any of those events could cause us to record impairment charges with respect to our investment portfolio or to realize losses on sales of investments. We also maintain a majority of our cash and cash equivalents in accounts with major multi-national financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can adversely affect the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Inability to access, or a delay in accessing these funds, could adversely affect our business and financial position.

Our stock price is volatile.

Our stock price, like that of our peers in the biotechnology and pharmaceutical industries, is volatile. Our revenues and operating results may fluctuate from period to period for a number of reasons. Events such as a delay in product development, changes to our expectations or strategy or even a relatively small revenue shortfall may cause financial results for a period to be below our expectations or projections. As a result, our revenues and operating results and, in turn, our stock price may be subject to significant fluctuations. Announcements or discussions, including via social media channels, of possible restrictive actions by government or private payers that would negatively affect our business or industry if ultimately enacted or adopted may also cause our stock price to fluctuate, whether or not such restrictive actions ever actually occur. Similarly, actual or perceived safety issues with our products or similar products or unexpected clinical trial results can have an immediate and rapid effect on our stock price, whether or not our operating results are materially affected.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 1C. CYBERSECURITY

Risk Management and Strategy

Amgen has a multi-layered and iterative approach towards assessing, identifying, managing and mitigating risks from cybersecurity threats. The Amgen Technology & Medical Organizations (ATMOS) function is designed to support our productivity, innovation and outreach globally through the quality delivery of information systems, solutions and services for our business and operations. The ATMOS function has a Cybersecurity & Digital Trust (CDT) team that assesses and reduces cybersecurity exposure, including by providing employees with training and resources to identify potential cybersecurity threats and implementing information technology security practices. The CDT team also monitors for cybersecurity threat activity and seeks to mitigate the impact from cybersecurity incidents by deploying information security engineers, system architects, analysts and cybersecurity specialists to provide monitoring, reporting and management of cybersecurity incidents.

To evaluate the progress of its activities, our ATMOS function uses various industry and regulatory frameworks as guides to assess the state of the Company's cybersecurity program maturity and controls, including our organizational, people, physical and technological controls. The CDT team also conducts reviews and evaluations of our cybersecurity resilience program with Amgen's Cybersecurity & Digital Trust Governance Council (which includes leaders from CDT, Worldwide Compliance and Business Ethics, Regulatory Affairs, Operations, R&D, Global Commercial Operations, Corporate Audit, Finance, Law and Business Development functions).

Our cybersecurity risk management program is considered by and integrated into our Company-wide Enterprise Risk Management program and shares common methodologies, reporting channels and governance processes that apply across the Enterprise Risk Management program to that of other enterprise level risks (such as product development, safety and surveillance, financial and intellectual property risks). Regular evaluations are conducted of the greatest risks to our business and their underlying risk drivers as well as the associated mitigation activities, maturity and controls. This program is overseen by our Executive Vice President and Chief Financial Officer and guided by the Enterprise Risk Council, a cross-functional group of the Company's business leaders representing key business functions that is co-chaired by our Chief Audit Executive. The results of the enterprise risk evaluations and the status and operation of the Enterprise Risk Management program are presented to our Board of Directors, which oversees the Company's enterprise-level risks.

Further, our corporate audit function is responsible for assessing risk and testing whether, and the extent to which, our information security policies and practices are being implemented effectively within our business and by third party providers. Findings from such reports and related corrective action plans are shared with our CDT team, Company leadership, and the Audit Committee and Corporate Responsibility and Compliance Committee (CRCC) of our Board of Directors.

In addition to leveraging the Company's own information technology resources, our Incident Response and Cyber Threat Intelligence teams engage, as needed, third-party cybersecurity risk assessors and consultants to assist in recognizing threats, identifying security vulnerabilities and evaluating the impact of cybersecurity attacks and incidents when they occur. On a biennial basis, our ATMOS also engages external third-party experts to assess the Company's cybersecurity control maturity across the organization and develops plans to address such experts' recommendations.

Our CDT function has processes to oversee and identify the risks of cybersecurity threats associated with third-party service providers and monitors and works to mitigate the impact of cybersecurity incidents encountered by our third-party service providers. Upon becoming aware of cybersecurity incidents encountered by our third-party service providers, the CDT function's Incident Response and Cyber Threat Intelligence teams are deployed to evaluate and mitigate the impact of such incidents on our business.

In connection with our adoption of artificial intelligence (AI) tools in our business, including AI tools customized for our business and a variety of Amgen-built tools for use across applications, the Company established an AI Governance Council composed of cross-functional leadership that oversees the safe adoption of third-party AI services, including by establishing guardrails to reduce risks and allocating resources to provide staff training on the proper use of AI and responsible AI practices. The AI Governance Council is co-sponsored by our Chief Compliance Officer and Senior Vice President, Artificial Intelligence & Data.

Despite our layered controls and cybersecurity efforts, the Company and its third-party vendors have experienced cyberattacks and information security vulnerabilities, and while such incidents have not had a material adverse effect on the Company, there can be no assurance that future cybersecurity attacks or incidents would not result in a material adverse effect

on our business strategy, results of operations or financial condition. For examples of such matters and a discussion of the risks that we face, see Item 1A. Risk Factors—*A breakdown of our information technology systems, cyberattack or information security breach could significantly compromise the confidentiality, integrity and availability of our information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.* However, we have not identified risk from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations or financial condition.

Governance

Our Board of Directors oversees an enterprise-wide approach to risk management, including risks related to information systems and cybersecurity, and each Board committee has primary risk oversight responsibilities aligned with its areas of focus. At each regular meeting of the Board, the Board receives and considers reports from each of its committees, and such reports provide additional detail on significant risk management issues as appropriate, including cybersecurity. The CRCC is the committee that has primary oversight responsibility for the Company's information systems and management of cybersecurity and receives reports from our Senior Vice President and Chief Information Officer (CIO) and Chief Information Security Officer (CISO) that includes reviews of our information systems strategy, technology investments, cybersecurity risks and incidents, and third-party risk management, as well as an annual evaluation of the Company's cybersecurity status. The Board's Audit Committee has oversight responsibility of our internal controls, assurances and financial risks. The Audit Committee is provided with copies of materials presented to our CRCC by our CIO and CISO and receives reports from our CIO regarding topics including integration or implementation of new financial systems and key controls and governance designed to address cybersecurity risks associated with the use of such new financial systems.

Our management team, including our CIO and CISO, supervises efforts to prevent, detect, mitigate and remediate cybersecurity risks and incidents through various means, which may include briefings from internal information security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the information systems environment.

Our CISO, who heads our CDT team and is accountable for the Company's cybersecurity risk management program, joined the Company's information systems organization in 2016, is a Certified Information Systems Security Professional and is certified in risk and information systems control. Previously, our CISO served in both leadership and operational positions as a cybersecurity professional in the U.S. government and was a cybersecurity consultant, providing a wide range of cybersecurity services to various U.S. government agencies and departments. Our CISO is overseen by our CIO, who has 28 years of experience in information systems (including over 15 years at the Company and more than 6 years as a senior technology executive outside of Amgen), and holds a Computer Information Systems B.S. and an Information Technology Management MBA. Our Executive Vice President and Chief Technology Officer (CTO) leads our ATMOS function and oversees our CIO.

As leaders of the Technology and CDT functions within ATMOS, respectively, the Company's CIO and CISO are informed about and monitor significant cybersecurity threats and incidents through the Company's internal cybersecurity reporting structure. Our CDT team is responsible for monitoring and detecting cybersecurity threats and incidents. Our CDT team, overseen by our CISO, is also responsible for the mitigation and remediation of cybersecurity incidents. When members of the CDT team detect a cybersecurity threat or incident or are made aware of a cybersecurity incident encountered by a third-party service provider, the discovery is communicated to the Incident Response team, which includes our CISO and other senior members of the CDT function. The Incident Response team evaluates the severity of the cybersecurity threat or incident and shares its findings with our CISO.

Our CISO and/or his senior team leaders, in addition to our CIO and CTO, also provide regular reports to executives leading our Finance, Compliance, Law and Human Resources functions on potentially significant cybersecurity incidents and the progress made towards mitigation and remediation of those incidents. These leaders oversee reporting to our CRCC and Audit Committee, and reporting of such cybersecurity incidents is included in the course of regular meetings of such committees. Additionally, in appropriate circumstances, reporting of potentially significant cybersecurity incidents is made directly to the leaders of our CRCC and Audit Committee or directly to the Board of Directors outside of their regular meeting schedule. Further, in support of our internal controls, our CISO also reviews cybersecurity matters and trends with our Accounting and Law functions at least on a quarterly basis.

In 2025, we substantially transitioned or decommissioned the technology systems from the legacy Horizon environment to the Amgen environment. The remaining systems are being monitored by the Amgen cybersecurity team in accordance with the governance processes detailed above.

Item 2. PROPERTIES

As of December 31, 2025, we owned or leased approximately 160 properties. The locations and primary functions of significant properties are summarized in the following tables:

U.S. Location:	Manufacturing	Administrative	R&D	Sales and marketing	Warehouse	Distribution center
Thousand Oaks, CA[1]	x	x	x	x	x	x
Juncos, Puerto Rico	x	x			x	x
West Greenwich, RI	x	x			x	
Deerfield, IL		x	x	x		
Cambridge, MA			x			
New Albany, OH	x	x			x	
San Francisco, CA			x			
Tampa, FL		x		x		
Louisville, KY					x	x
Other U.S. cities[2]		x	x	x		

ROW Location:	Manufacturing	Administrative	R&D	Sales and marketing	Warehouse	Distribution center
Canada		x	x	x		
China		x		x		
Denmark		x	x	x		
Germany		x	x	x		
Iceland		x	x			
India		x				
Ireland	x	x		x	x	x
Netherlands	x	x		x	x	x
Singapore	x	x		x	x	
Other countries[2]		x	x	x	x	

[1] Corporate headquarters.

[2] Includes smaller properties in other U.S. and ROW locations, primarily for administrative and sales and marketing.

Excluded from the information above are (i) undeveloped land and leased properties that have been abandoned and (ii) certain buildings we still own but that are no longer used in our business. Additionally, in 2025 we broke ground on our second drug substance manufacturing facility in Holly Springs, North Carolina; announced expansions of our manufacturing network in Ohio and the U.S. territory of Puerto Rico; and broke ground on a new, state-of-the-art science and innovation center at our corporate headquarters in Thousand Oaks, California. There are no material encumbrances on our owned properties.

We believe our facilities are suitable for their intended uses and, in conjunction with our third-party contract manufacturing agreements, provide adequate capacity and are sufficient to meet our expected needs. See Item 1A. Risk Factors for a discussion of the factors that could adversely impact our manufacturing operations and the global supply of our products.

See Item 1. Business—Manufacturing, Distribution and Raw Materials.

Item 3. LEGAL PROCEEDINGS

Certain of the legal proceedings in which we are involved are discussed in Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements and are hereby incorporated by reference.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

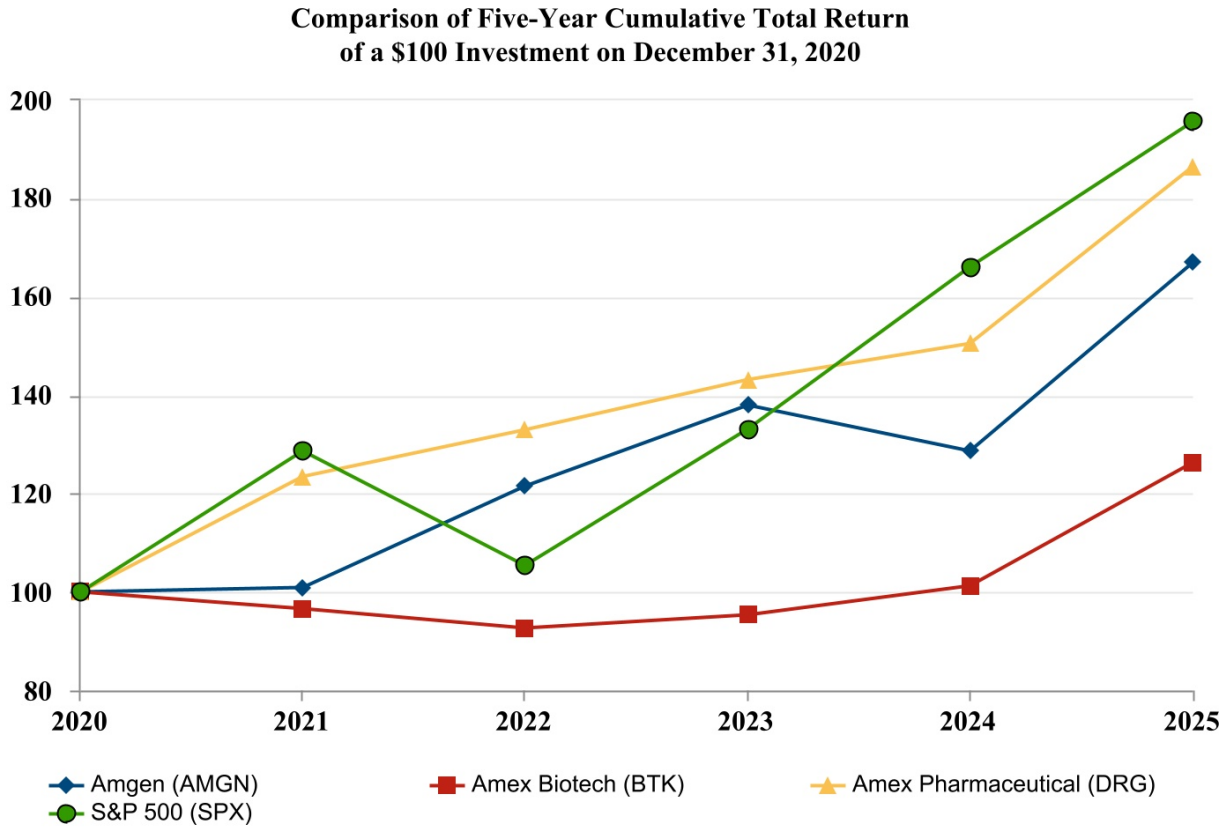
Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Common stock

Our common stock trades on the Nasdaq Global Select Market under the symbol AMGN. As of February 10, 2026, there were approximately 3,824 holders of record of our common stock.

Performance graph

The following graph shows the value of an investment of $100 on December 31, 2020, in each of Amgen common stock, the Amex Biotech Index, the Amex Pharmaceutical Index and Standard & Poor's 500 Index. All values assume reinvestment of the pretax value of dividends and are calculated as of December 31 of each year. The historical stock price performance of the Company's common stock shown in the performance graph is not necessarily indicative of future stock price performance.



	12/31/2020	12/31/2021	12/31/2022	12/31/2023	12/31/2024	12/31/2025
Amgen (AMGN)	$100.00	$100.87	$121.54	$137.97	$128.71	$166.88
Amex Biotech (BTK)	$100.00	$96.48	$92.61	$95.27	$101.21	$126.28
Amex Pharmaceutical (DRG)	$100.00	$123.37	$132.94	$143.21	$150.48	$186.40
Standard & Poor's 500 (SPX)	$100.00	$128.68	$105.29	$133.03	$165.98	$195.62

The material in the above performance graph is not soliciting material, is not deemed filed with the SEC and is not incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made on, before or after the date of this filing and irrespective of any general incorporation language in such filing.

Stock repurchase program

During the year ended December 31, 2025, we had one outstanding stock repurchase program, under which repurchase activity was as follows:

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced program	Maximum dollar value that may yet be purchased under the program
October 1–October 31	—	$ —	—	$ 6,779,253,902
November 1–November 30	—	$ —	—	$ 6,779,253,902
December 1–December 31	—	$ —	—	$ 6,779,253,902
	—		—	
January 1–December 31[1]	—	$ —	—	

[1] During the year ended December 31, 2025, the Company purchased 1,700 shares at an average price paid of $284.67 per share from staff members to satisfy federal law compliance obligations. These shares were not repurchased under our stock repurchase program.

Dividends

For the years ended December 31, 2025 and 2024, we paid quarterly dividends. We expect to continue to pay quarterly dividends, although the amount and timing of any future dividends are subject to approval by our Board of Directors. Additional information required by this item is incorporated herein by reference to Part IV—Note 17, Stockholders' equity, to the Consolidated Financial Statements.

Securities Authorized for Issuance Under Existing Equity Compensation Plans

Information about securities authorized for issuance under existing equity compensation plans is incorporated by reference from Part III, Item 12—Securities Authorized for Issuance Under Existing Equity Compensation Plans.

Item 6. RESERVED

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following MD&A is intended to assist the reader in understanding Amgen's business. MD&A is provided as a supplement to, and should be read in conjunction with, our consolidated financial statements and accompanying notes. Our results of operations discussed in MD&A are presented in conformity with GAAP. Amgen operates in one operating segment: human therapeutics. Therefore, our results of operations are discussed on a consolidated basis.

Forward-looking statements

This report and other documents we file with the SEC contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about us, our future performance, our business, our beliefs and our management's assumptions. In addition, we, or others on our behalf, may make forward-looking statements in press releases, written statements or our communications and discussions with investors and analysts in the normal course of business through meetings, webcasts, phone calls and conference calls. Such words as "expect," "anticipate," "outlook," "could," "target," "project," "intend," "plan," "believe," "seek," "estimate," "should," "may," "assume" and "continue" as well as variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and they involve certain risks, uncertainties and assumptions that are difficult to predict. We describe our respective risks, uncertainties and assumptions that could affect the outcome or results of operations in Part I, Item 1A. Risk Factors. We have based our forward-looking statements on our management's beliefs and assumptions based on information available to our management at the time the statements are made. We caution you that actual outcomes and results may differ materially from what is expressed, implied or forecasted by our forward-looking statements. Reference is made in particular to forward-looking statements regarding product sales, regulatory activities, clinical trial results, reimbursement, expenses, EPS, liquidity and capital resources, trends, planned dividends, stock repurchases and collaborations. Except as required under the federal securities laws and the rules and regulations of the SEC, we do not have any intention or obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

Overview

Amgen Inc. (including its subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") discovers, develops, manufactures and delivers innovative medicines to fight some of the world's toughest diseases. We focus on areas of high unmet medical need and leverage our expertise to strive for solutions that dramatically improve people's lives, while also reducing the social and economic burden of disease. We helped launch the biotechnology industry more than 45 years ago and have grown to be one of the world's leading independent biotechnology companies. Our robust pipeline includes potential first-in-class medicines at all stages of development.

Our principal products are Prolia, Repatha, Otezla, ENBREL, EVENITY, XGEVA, TEPEZZA, BLINCYTO, Nplate, TEZSPIRE, KYPROLIS, Aranesp, KRYSTEXXA and Vectibix. We also market a number of other products, including but not limited to MVASI, PAVBLU, UPLIZNA, IMDELLTRA/IMDYLLTRA, AMJEVITA/AMGEVITA, TAVNEOS, Neulasta, LUMAKRAS/LUMYKRAS, RAVICTI, Parsabiv, Aimovig, WEZLANA/WEZENLA and PROCYSBI. For additional information about our products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products.

Our strategy is the integrated set of actions we take to improve our competitive position in the industry. In 2025, we generated strong sales growth across our product portfolio and regions; advanced our innovative pipeline; and continued to expand and enhance our world-class manufacturing network. We accomplished these objectives while maintaining a strategic and disciplined approach to capital allocation, including retiring $6.0 billion of debt.

In 2025, we achieved several significant regulatory, clinical and operational milestones. We obtained multiple regulatory approvals, including new indications for UPLIZNA and TEZSPIRE; a broadened FDA approval for Repatha; and full FDA approval for IMDELLTRA for the treatment of ES-SCLC. We also advanced our innovative pipeline, including the initiation of six global Phase 3 clinical studies for MariTide and the reporting of Phase 3 data across several programs. In addition, we continued to invest in expanding and enhancing our manufacturing capacity, including facilities in Ohio, North Carolina and the U.S. territory of Puerto Rico. Furthermore, in 2025 we also broke ground on a new state-of-the-art R&D facility in Thousand Oaks, California, to further enhance collaboration and innovation across R&D and process development activities. For additional information on our pipeline and clinical development updates, see Part I, Item 1. Business—Research and Development and Selected Product Candidates, and Part I, Item 1. Business—Significant Developments. For additional information on our manufacturing operations, see Part I, Item 1. Business—Manufacturing, Distribution and Raw Materials.

Total product sales increased 10% in 2025, driven by volume growth of 13%, partially offset by declines in net selling price of 3%.

Cash flows from operating activities in 2025 totaled $10.0 billion, which supported investment in our business, including capital expenditures of $1.9 billion to enhance and expand our manufacturing network, and allowed us to both reduce our debt and return capital to shareholders through the payment of cash dividends. For 2025, we retired $6.0 billion of debt and increased our quarterly cash dividend by 6% to $2.38 per share of common stock. In December 2025, the Board of Directors declared a cash dividend of $2.52 per share of common stock for the first quarter of 2026, an increase of 6% over the same period in the prior year, to be paid in March 2026.

Amgen's approach to human capital management focuses on attracting, developing and retaining a highly skilled global workforce to support the discovery, development and commercialization of innovative medicines. Our compensation, benefits and development programs are designed to promote performance, accountability, adherence to Company values and alignment with shareholder interests. We believe our culture supports innovation, collaboration and productivity as we execute on our mission to serve patients. For additional information, see Part I, Item 1. Business—Human Capital Resources.

We have a long-standing ambition to be environmentally responsible, and we regularly set targets to challenge ourselves to deliver further improvements. As part of our environmental sustainability efforts, we have established long-term targets to meet by 2027, including achieving carbon neutrality, reducing water consumption by 40% and reducing waste disposed by 75%.[2,3]

Our long-term success depends, to a great extent, on our ability to continue to discover, develop and commercialize innovative products and acquire or collaborate on therapies currently in development by other companies. We must grow sales from existing and new products to achieve revenue growth and to offset revenue losses caused by products' loss of their exclusivity or launches of competing products. For example, our patents for RANKL antibodies, including sequences, for Prolia and XGEVA expired in February 2025 in the United States and in November 2025 in select countries in Europe. Certain of our products face increasing pressure from competition, including biosimilars and generics. For additional information, including information on the expirations of patents for various products, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—*Patents*, and Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—*Competition*. We devote considerable resources to R&D activities, but successful product development in the biotechnology industry is highly uncertain. We also face increasing regulatory scrutiny of safety and efficacy both before and after products launch.

Tariffs and trade protection measures

Recent and ongoing changes in U.S. trade and tariff policies, including the imposition, modification, suspension and threatened expansion of tariffs on imported goods, as well as retaliatory measures by foreign governments, have increased uncertainty in the overall business and operating environment. Numerous tariffs and trade protection measures have been proposed, and in a number of cases, implemented by the United States and other countries, including the April 2025 Tariff EO, which imposed a universal 10% tariff on goods imported into the United States, with certain exceptions including pharmaceuticals. Further, there were previous proposals for sector-specific tariffs on our industry, and in December 2025, in recognition of our capital investments in U.S. manufacturing, we received relief from Section 232 tariffs, pending final determination under such section of the Trade Expansion Act of 1962, for approximately the next three years. Tariffs and trade protection measures may adversely affect our business and results of operations. For additional discussion of these and other risks, see Part I, Item 1A. Risk Factors, of this Annual Report on Form 10-K.

Macroeconomic and other challenges

Uncertain macroeconomic conditions, including the risk of inflation, fluctuating interest rates and instability in the financial system, as well as rising healthcare costs, continue to pose challenges to our business. Uncertainty around tariffs and trade protection measures in the United States and other countries, including the imposition, modification, suspension and threatened expansion of tariffs on imported goods, along with ongoing geopolitical conflicts and rising geopolitical tensions, continue to create additional uncertainty in global macroeconomic conditions. Additionally, with public and private healthcare-provider focus, the industry continues to be subject to cost containment measures and significant pricing pressures, resulting in net price declines.

Moreover, provisions of the IRA, as well as the expanded utilization of the 340B Program, have negatively affected, and are likely to continue to negatively affect, our business. For example, CMS has selected ENBREL and Otezla for Medicare price setting beginning in 2026 and 2027, respectively. In addition to the IRA, other recent and proposed U.S. policy actions focus on drug pricing, including the Most-Favored-Nations Prescription Drug Pricing Executive Order (MFN EO) and the July MFN Letter that was delivered to a number of pharmaceutical companies, including Amgen. In December 2025, we announced

[2] Represents reductions against established baselines, taking into account only verified reduction projects and does not take into account changes associated with contraction or expansion of the Company.
[3] Carbon neutrality goal refers to Scopes 1 and 2.

that we are taking actions that satisfy the components outlined in the July MFN Letter, including the Administration's MFN pricing requests. We also announced the expansion of our direct-to-patient program. While this development reflects ongoing engagement on pricing policy, the ultimate effects on our pricing, reimbursement, net sales and profitability remain uncertain in light of such evolving regulatory and policy expectations. For additional discussion of these and other risks, see Part I, Item 1A. Risk Factors, of this Annual Report on Form 10-K.

Finally, wholesale and end-user buying patterns can affect our product sales. These buying patterns can cause fluctuations in quarterly product sales, but have generally not been significant to date when comparing full-year product performance to the prior year. See Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products, and Part I, Item 1A. Risk Factors, of this Annual Report on Form 10-K for further discussion of certain factors that could impact our future product sales.

Selected financial information

The following is an overview of our results of operations (in millions, except percentages and per-share data):

	Year ended December 31, 2025	Change	Year ended December 31, 2024
Product sales:			
U.S.	$ 25,656	10 %	$ 23,301
ROW	9,492	9 %	8,725
Total product sales	35,148	10 %	32,026
Other revenues	1,603	15 %	1,398
Total revenues	$ 36,751	10 %	$ 33,424
Operating expenses	$ 27,671	6 %	$ 26,166
Operating income	$ 9,080	25 %	$ 7,258
Net income	$ 7,711	89 %	$ 4,090
Diluted EPS	$ 14.23	88 %	$ 7.56
Diluted shares	542	0 %	541

In the following discussion of changes in product sales, any reference to volume growth or decline refers to changes in the purchases of our products by healthcare providers (such as physicians or their clinics), dialysis centers, hospitals and pharmacies. In addition, any reference to increases or decreases in inventory refers to changes in inventory held by wholesaler customers and end users (such as pharmacies).

Total product sales increased 10% in 2025, driven by volume growth of 13%, partially offset by declines in net selling price of 3%. U.S. volume grew 13% and ROW volume grew 14%, driven by volume growth in certain brands, including Repatha, PAVBLU, EVENITY, IMDELLTRA/IMDYLLTRA and TEZSPIRE.

For 2026, we expect volume growth from certain brands to be partially offset by net selling price declines. Further, the first quarter of a year historically represents the lowest product sales quarter for the year, in part due to plan changes, insurance reverifications and higher co-pay expenses as U.S. patients work through deductibles, including for ENBREL and Otezla, and to a lesser extent for KRYSTEXXA, TEZSPIRE and Repatha, particularly for products acquired through pharmacy benefit programs.

Other revenues increased 15% for 2025, primarily driven by higher royalty income.

Operating expenses increased 6% for 2025, primarily driven by investments in Later-Stage Clinical Programs and Otezla intangible asset impairment charges in 2025, partially offset by lower amortization expense from acquisition-related assets, including the fair value step-up of inventory acquired from Horizon. See Part IV—Note 13, Goodwill and other intangible assets, to the Consolidated Financial Statements, for additional information related to the Otezla intangible asset impairment charges.

Uncertain macroeconomic conditions, including uncertainty around tariffs and trade protection measures, ongoing geopolitical conflicts and rising geopolitical tensions, changes in the healthcare ecosystem, and potential government policy actions, including MFN pricing or similar drug pricing reforms, have the potential to introduce variability into product sales. Furthermore, product sales continue to be impacted by actions from governments and other entities to address macroeconomic challenges, provisions of the IRA, expanded utilization of the 340B Program and growth in numbers of Medicaid enrollees and uninsured individuals. See Part I, Item 1. Business—Reimbursement, and Part I, Item 1A. Risk Factors, of this Annual Report on Form 10-K.

Results of operations

Product sales

Worldwide product sales were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
Prolia	$ 4,414	1 %	$ 4,374	8 %	$ 4,048
Repatha	3,016	36 %	2,222	36 %	1,635
Otezla	2,265	7 %	2,126	(3)%	2,188
ENBREL	2,226	(33)%	3,316	(10)%	3,697
EVENITY	2,100	34 %	1,563	35 %	1,160
XGEVA	2,084	(6)%	2,225	5 %	2,112
TEPEZZA[1]	1,903	3 %	1,851	*	448
BLINCYTO	1,559	28 %	1,216	41 %	861
Nplate	1,524	5 %	1,456	(1)%	1,477
TEZSPIRE [2]	1,478	52 %	972	71 %	567
KYPROLIS	1,412	(6)%	1,503	7 %	1,403
Aranesp	1,389	4 %	1,342	(1)%	1,362
KRYSTEXXA[1]	1,340	13 %	1,185	*	272
Vectibix	1,175	12 %	1,045	6 %	984
Other products[3]	7,263	29 %	5,630	20 %	4,696
Total product sales	$ 35,148	10 %	$ 32,026	19 %	$ 26,910
Total U.S.	$ 25,656	10 %	$ 23,301	21 %	$ 19,272
Total ROW	9,492	9 %	8,725	14 %	7,638
Total product sales	$ 35,148	10 %	$ 32,026	19 %	$ 26,910

* Change in excess of 100%

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[1] TEPEZZA and KRYSTEXXA were acquired from our Horizon acquisition on October 6, 2023, and include product sales in the periods after the acquisition date.

[2] TEZSPIRE is marketed by our collaborator AstraZeneca outside the United States.

[3] Consists of product sales of our non-principal products.

Future sales of our products will depend in part on the factors discussed in the Overview, Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—*Competition*, Part I, Item 1. Business—Reimbursement, Part I, Item 1A. Risk Factors, and any additional factors discussed in the individual product sections below. In addition, for a list of our products' significant competitors, see Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products—*Competition*.

Prolia

Total Prolia sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
Prolia — U.S.	$ 2,978	3 %	$ 2,885	6 %	$ 2,733
Prolia — ROW	1,436	(4)%	1,489	13 %	1,315
Total Prolia	$ 4,414	1 %	$ 4,374	8 %	$ 4,048

The increase in global Prolia sales for 2025 was primarily driven by volume growth of 2% and favorable changes to estimated sales deductions of 2%, partially offset by lower net selling price.

The increase in global Prolia sales for 2024 was driven by volume growth.

As disclosed in Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products, our patents for RANKL antibodies, including sequences, for Prolia expired in February 2025 in the United States and in November 2025 in select countries in Europe. For 2026, we expect accelerated sales erosion driven by increased competition, as multiple biosimilars have launched in the United States and ROW.

For a discussion of ongoing litigation related to Prolia, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

Repatha

Total Repatha sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
Repatha — U.S.	$ 1,663	46 %	$ 1,139	44 %	$ 793
Repatha — ROW	1,353	25 %	1,083	29 %	842
Total Repatha	$ 3,016	36 %	$ 2,222	36 %	$ 1,635

The increase in global Repatha sales for 2025 was driven by volume growth. For 2026, we expect product sales for Repatha to follow the historical pattern of lower sales in the first quarter relative to subsequent quarters, as discussed above. Additionally, for 2026, we expect net selling price to decline by approximately mid-single digits.

The increase in global Repatha sales for 2024 was primarily driven by volume growth of 43%, partially offset by lower net selling price of 10%.

For a discussion of ongoing litigation related to Repatha, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

Otezla

Total Otezla sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
Otezla — U.S.	$ 1,839	8 %	$ 1,699	(4)%	$ 1,777
Otezla — ROW	426	0 %	427	4 %	411
Total Otezla	$ 2,265	7 %	$ 2,126	(3)%	$ 2,188

The increase in global Otezla sales for 2025 was primarily driven by volume growth of 3% and favorable changes to estimated sales deductions of 2%. For 2026, we expect product sales for Otezla to follow the historical pattern of lower sales in the first quarter relative to subsequent quarters, as discussed above.

In January 2025, Otezla was selected by CMS for Medicare price setting that will be applicable beginning in 2027. As a result, we expect further declines in net selling price driven by Medicare price setting beginning in 2027. See Part IV—Note 13, Goodwill and other intangible assets, to the Consolidated Financial Statements for additional information related to the Otezla intangible asset impairment charges.

The decrease in global Otezla sales for 2024 was primarily driven by lower net selling price of 8%, partially offset by volume growth of 3%.

ENBREL

Total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
ENBREL — U.S.	$ 2,199	(33)%	$ 3,288	(10)%	$ 3,650
ENBREL — Canada	27	(4)%	28	(40)%	47
Total ENBREL	$ 2,226	(33)%	$ 3,316	(10)%	$ 3,697

The decrease in ENBREL sales for 2025 was primarily driven by lower net selling price of 36% resulting from the impact of increased 340B Program mix, U.S. Medicare Part D redesign and higher commercial discounts, partially offset by volume growth of 4%. For 2026, we expect product sales for ENBREL to follow the historical pattern of lower sales in the first quarter relative to subsequent quarters, as discussed above.

The decrease in ENBREL sales for 2024 was driven by lower net selling price.

EVENITY

Total EVENITY sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
EVENITY — U.S.	$ 1,600	41 %	$ 1,131	40 %	$ 809
EVENITY — ROW	500	16 %	432	23 %	351
Total EVENITY	$ 2,100	34 %	$ 1,563	35 %	$ 1,160

The increases in global EVENITY sales for 2025 and 2024 were driven by volume growth.

XGEVA

Total XGEVA sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
XGEVA — U.S.	$ 1,355	(10)%	$ 1,507	(1)%	$ 1,527
XGEVA — ROW	729	2 %	718	23 %	585
Total XGEVA	$ 2,084	(6)%	$ 2,225	5 %	$ 2,112

The decrease in global XGEVA sales for 2025 was driven by lower volume.

The increase in global XGEVA sales for 2024 was driven by higher net selling price.

As disclosed in Part I, Item 1. Business—Marketing, Distribution and Selected Marketed Products, our patents for RANKL antibodies, including sequences, for XGEVA expired in February 2025 in the United States and in November 2025 in select countries in Europe. For 2026, we expect accelerated sales erosion driven by increased competition, as multiple biosimilars have launched in the United States and ROW.

For a discussion of ongoing litigation related to XGEVA, see Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements.

TEPEZZA

Total TEPEZZA sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
TEPEZZA — U.S.	$ 1,758	(4)%	$ 1,835	*	$ 441
TEPEZZA — ROW	145	*	16	*	7
Total TEPEZZA	$ 1,903	3 %	$ 1,851	*	$ 448

* Change in excess of 100%

The increase in global TEPEZZA sales for 2025 was primarily driven by higher net selling price.

TEPEZZA was acquired on October 6, 2023 from our Horizon acquisition and generated $1.9 billion and $448 million in product sales for 2024 and 2023, respectively. As TEPEZZA was acquired on October 6, 2023, there were no recorded product sales in the period prior to the acquisition date.

BLINCYTO

Total BLINCYTO sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
BLINCYTO — U.S.	$ 1,049	31 %	$ 800	41 %	$ 566
BLINCYTO — ROW	510	23 %	416	41 %	295
Total BLINCYTO	$ 1,559	28 %	$ 1,216	41 %	$ 861

The increases in global BLINCYTO sales for 2025 and 2024 were driven by volume growth.

Nplate

Total Nplate sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
Nplate — U.S.	$ 1,027	6 %	$ 970	(3)%	$ 996
Nplate — ROW	497	2 %	486	1 %	481
Total Nplate	$ 1,524	5 %	$ 1,456	(1)%	$ 1,477

Global Nplate sales for 2025 increased 5% and included U.S. government orders of $90 million and $128 million for 2025 and 2024, respectively. Excluding the U.S. government orders from this comparison, global Nplate sales increased 8% for 2025, driven by volume growth.

Global Nplate sales for 2024 decreased 1% and included U.S. government orders of $128 million and $286 million for 2024 and 2023, respectively. Excluding the U.S. government orders from this comparison, global Nplate sales increased 12% for 2024, driven by volume growth of 8% and higher net selling price of 6%.

TEZSPIRE

Total TEZSPIRE sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
TEZSPIRE — U.S.	$ 1,478	52 %	$ 972	71 %	$ 567

The increases in TEZSPIRE sales for 2025 and 2024 were driven by volume growth. For 2026, we expect product sales for TEZSPIRE to follow the historical pattern of lower sales in the first quarter relative to subsequent quarters, as discussed above.

KYPROLIS

Total KYPROLIS sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
KYPROLIS — U.S.	$ 913	(4)%	$ 948	3 %	$ 921
KYPROLIS — ROW	499	(10)%	555	15 %	482
Total KYPROLIS	$ 1,412	(6)%	$ 1,503	7 %	$ 1,403

The decrease in global KYPROLIS sales for 2025 was primarily driven by lower volume due to increased competition.

The increase in global KYPROLIS sales for 2024 was driven by volume growth outside the United States.

Aranesp

Total Aranesp sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
Aranesp — U.S.	$ 416	8 %	$ 386	(15)%	$ 452
Aranesp — ROW	973	2 %	956	5 %	910
Total Aranesp	$ 1,389	4 %	$ 1,342	(1)%	$ 1,362

The increase in global Aranesp sales for 2025 was driven by volume growth.

Global Aranesp sales for 2024 remained relatively unchanged as unfavorable changes to both estimated sales deductions and foreign currency exchange rates were offset by volume growth outside the United States.

KRYSTEXXA

Total KRYSTEXXA sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
KRYSTEXXA — U.S.	$ 1,340	13 %	$ 1,185	*	$ 272

* Change in excess of 100%

The increase in KRYSTEXXA sales for 2025 was driven by volume growth and higher net selling price. For 2026, we expect product sales for KRYSTEXXA to follow the historical pattern of lower sales in the first quarter relative to subsequent quarters, as discussed above.

KRYSTEXXA was acquired on October 6, 2023 from our Horizon acquisition and generated $1.2 billion and $272 million in product sales for 2024 and 2023, respectively. As KRYSTEXXA was acquired on October 6, 2023, there were no recorded product sales in the period prior to the acquisition date.

Vectibix

Total Vectibix sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
Vectibix — U.S.	$ 604	16 %	$ 519	13 %	$ 461
Vectibix — ROW	571	9 %	526	1 %	523
Total Vectibix	$ 1,175	12 %	$ 1,045	6 %	$ 984

The increase in global Vectibix sales for 2025 was primarily driven by volume growth.

The increase in global Vectibix sales for 2024 was driven by higher net selling price of 8% and volume growth of 4%, partially offset by unfavorable changes to foreign currency exchange rates.

Other products

Other product sales by geographic region were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
MVASI — U.S.	$ 573	28 %	$ 449	(12)%	$ 511
MVASI — ROW	198	(29)%	278	(4)%	289
PAVBLU — U.S.	691	*	31	N/A	—
PAVBLU — ROW	9	N/A	—	N/A	—
UPLIZNA — U.S.[1]	528	68 %	314	*	60
UPLIZNA — ROW[1]	127	95 %	65	*	5
IMDELLTRA — U.S.	513	*	115	N/A	—
IMDYLLTRA — ROW	114	N/A	—	N/A	—
AMJEVITA — U.S.	48	(76)%	202	60 %	126
AMGEVITA — ROW	549	(2)%	559	12 %	500
TAVNEOS — U.S.	423	65 %	256	*	126
TAVNEOS — ROW	36	33 %	27	*	8
Neulasta — U.S.	359	13 %	318	(55)%	710
Neulasta — ROW	76	(33)%	113	(18)%	138
LUMAKRAS — U.S.	211	(1)%	214	9 %	197
LUMYKRAS — ROW	152	12 %	136	64 %	83
RAVICTI — U.S.[1]	337	(15)%	396	*	86
RAVICTI — ROW[1]	21	31 %	16	*	1
Parsabiv — U.S.	192	(5)%	203	(11)%	228
Parsabiv— ROW	161	5 %	153	14 %	134
Aimovig — U.S.	311	1 %	308	2 %	303
Aimovig — ROW	23	10 %	21	5 %	20
WEZLANA — U.S.	123	N/A	—	N/A	—
WEZENLA — ROW	150	*	27	N/A	—
PROCYSBI — U.S.[1]	233	5 %	221	*	49
PROCYSBI — ROW[1]	7	(13)%	8	*	1
Other — U.S.[2]	895	(11)%	1,010	11 %	911
Other — ROW[2]	203	7 %	190	(10)%	210
Total other product sales	$ 7,263	29 %	$ 5,630	20 %	$ 4,696
Total U.S. — other products	$ 5,437	35 %	$ 4,037	22 %	$ 3,307
Total ROW — other products	1,826	15 %	1,593	15 %	1,389
Total other product sales	$ 7,263	29 %	$ 5,630	20 %	$ 4,696

* Change in excess of 100%

N/A = not applicable

[1] UPLIZNA, RAVICTI and PROCYSBI were acquired from our Horizon acquisition on October 6, 2023, and include product sales in the periods after the acquisition date.

[2] Consists of product sales from (i) AVSOLA, KANJINTI, EPOGEN, RIABNI, BKEMV/BEKEMV, IMLYGIC, NEUPOGEN, Corlanor and Sensipar/Mimpara; and (ii) ACTIMMUNE, BUPHENYL, RAYOS, QUINSAIR, DUEXIS, VIMOVO and PENNSAID in the periods after our Horizon acquisition on October 6, 2023.

Operating expenses

Operating expenses were as follows (dollar amounts in millions):

	Year ended December 31, 2025	Change	Year ended December 31, 2024	Change	Year ended December 31, 2023
Cost of sales	$ 12,037	(6)%	$ 12,858	52 %	$ 8,451
% of product sales	34.2 %		40.1 %		31.4 %
% of total revenues	32.8 %		38.5 %		30.0 %
Research and development	$ 7,272	22 %	$ 5,964	25 %	$ 4,784
% of product sales	20.7 %		18.6 %		17.8 %
% of total revenues	19.8 %		17.8 %		17.0 %
Selling, general and administrative	$ 7,050	(1)%	$ 7,096	15 %	$ 6,179
% of product sales	20.1 %		22.2 %		23.0 %
% of total revenues	19.2 %		21.2 %		21.9 %
Other	$ 1,312	*	$ 248	(72)%	$ 879
Total operating expenses	$ 27,671	6 %	$ 26,166	29 %	$ 20,293

* Change in excess of 100%

Cost of sales

Cost of sales decreased to 32.8% of total revenues for 2025, driven by lower amortization expense from acquisition-related assets, including the fair value step-up of inventory acquired from Horizon, and lower manufacturing costs, partially offset by higher profit share expense and changes in our sales mix. See Part IV—Note 4, Acquisition, to the Consolidated Financial Statements.

Cost of sales increased to 38.5% of total revenues for 2024, driven by higher amortization expense from Horizon acquisition-related assets and, to a lesser extent, higher profit share and royalty expense, partially offset by the prior year impact of the 2022 Puerto Rico tax law change that replaced an excise tax with an income tax beginning in 2023. For 2024, the unfavorable impact from product sales mix of certain Amgen products was offset by the favorable impact on product sales mix of the addition of acquired Horizon products.

Research and development

The Company groups all of its R&D activities and related expenditures into three categories: (i) Research and Early Pipeline, (ii) Later-Stage Clinical Programs and (iii) Marketed Product Support. These categories are described below:

Category	Description
Research and Early Pipeline	R&D expenses incurred in activities substantially in support of early research through the completion of Phase 1 clinical trials, including drug discovery, toxicology, pharmacokinetics and drug metabolism and process development
Later-Stage Clinical Programs	R&D expenses incurred in or related to Phase 2 and Phase 3 clinical programs intended to result in registration of a new product or a new indication for an existing product primarily in the United States or the EU
Marketed Product Support	R&D expenses incurred in support of the Company's marketed products that are authorized to be sold primarily in the United States or the EU. Includes clinical trials designed to gather information on product safety (certain of which may be required by regulatory authorities) and their product characteristics after regulatory approval has been obtained, as well as the costs of obtaining regulatory approval of a product in a new market after approval in either the United States or the EU has been obtained

R&D expense by category was as follows (in millions):

	Years ended December 31,		
	2025	2024	2023
Research and Early Pipeline	$ 1,732	$ 1,534	$ 1,584
Later-Stage Clinical Programs	4,281	2,830	1,898
Marketed Product Support	1,259	1,600	1,302
Total R&D expense	$ 7,272	$ 5,964	$ 4,784

The increase in R&D expense for 2025 was driven by investments in Later-Stage Clinical Programs, including those related to MariTide, and in Research and Early Pipeline, partially offset by lower spend in Marketed Product Support. This increase includes the impact of business development activities in 2025.

The increase in R&D expense for 2024 was driven by investments in Later-Stage Clinical Programs and Marketed Product Support, including Horizon-acquired programs.

We expect to continue to grow our spend on Later-Stage Clinical Programs as we advance our pipeline.

Selling, general and administrative

The decrease in SG&A expense for 2025 was driven by lower Horizon acquisition-related expenses and lower amortization expense from acquisition-related assets, partially offset by higher general and administrative expenses.

The increase in SG&A expense for 2024 was primarily driven by expenses from the acquired Horizon business and other commercial expenses, partially offset by lower acquisition-related expenses related to the Horizon acquisition incurred in 2024.

Other

Other operating expenses for 2025 included Otezla intangible asset impairment charges of $1.2 billion. See Part IV—Note 13, Goodwill and other intangible assets, to the Consolidated Financial Statements.

Other operating expenses for 2024 included impairment charges associated with IPR&D intangible assets related to our Teneobio acquisition in 2021 and expenses related to cost-savings initiatives incurred in 2024.

Other operating expenses for 2023 included a net IPR&D intangible asset impairment charge for AMG 340 and expenses related to our restructuring plan that were both initiated and substantially completed in 2023.

Nonoperating expenses/income and income taxes

Nonoperating expenses/income and income taxes were as follows (dollar amounts in millions):

	Years ended December 31,		
	2025	2024	2023
Interest expense, net	$ (2,755)	$ (3,155)	$ (2,875)
Other income, net	$ 2,651	$ 506	$ 2,833
Provision for income taxes	$ 1,265	$ 519	$ 1,138
Effective tax rate	14.1 %	11.3 %	14.5 %

Interest expense, net

The decrease in Interest expense, net, for 2025 was primarily due to lower average debt outstanding driven by deleveraging and, to a lesser extent, lower weighted-average fixed and floating interest rates on the debt. See Part IV—Note 16, Financing arrangements, to the Consolidated Financial Statements.

The increase in Interest expense, net, for 2024 was primarily due to higher average debt outstanding and higher weighted-average fixed and floating interest rates on the debt.

Other income, net

The increase in Other income, net, for 2025 was primarily due to current year net unrealized gains on equity investments, primarily BeOne, compared to net unrealized losses on equity investments in the prior year. See Part IV—Note 10, Investments, to the Consolidated Financial Statements.

The decrease in Other income, net, for 2024 was primarily due to net unrealized losses on equity investments in 2024 compared to net unrealized gains on equity investments in 2023, as well as reduced interest income as a result of lower average cash balances. The 2023 net unrealized gains on equity investments were principally composed of amounts recognized on our BeOne investment in the first quarter of 2023 as a result of a change from the equity method of accounting to recording this investment at fair value with changes in fair value recognized in earnings.

Income taxes

The increase in our effective tax rate for 2025 compared with 2024 was primarily due to a change in earnings mix, including the net unrealized gains on equity investments compared to net unrealized losses on equity investments in the prior year, partially offset by the prior-year deferred tax adjustments associated with U.S. tax on the earnings of our foreign subsidiaries and the current year Otezla intangible asset impairment charges and related tax impacts. See Part IV—Note 10, Investments, and Note 13, Goodwill and other intangible assets, to the Consolidated Financial Statements for additional information on our equity investments and Otezla impairment charges, respectively.

In 2021, the OECD reached an initial agreement to align countries on a minimum corporate tax rate and an expansion of the taxing rights of market countries. Select individual countries, including the United Kingdom, EU member countries and Singapore, have enacted the global minimum tax agreement that took effect starting in 2024. Singapore's enactment of the agreement, effective 2025, applies irrespective of the Company's incentive grant. On January 5, 2026, the OECD issued additional administrative guidance related to the global minimum tax agreement that exempts U.S. companies from extra territorial minimum taxes effective January 1, 2026. The new guidance did not impact our 2025 results. We are monitoring the potential 2026 impact of the guidance as jurisdictions may enact the new rules. See Part I, Item 1A. Risk Factors—*We could be subject to additional tax liabilities, including from an adverse outcome in our ongoing tax dispute with the IRS and other tax examinations, enactment of the OECD minimum corporate tax rate agreement and the adoption and interpretation of new tax legislation, including OB3. Such tax liabilities could adversely affect our profitability and results of operations.*

On July 4, 2025, OB3 was enacted in the United States. OB3 has various provisions, including the permanent extension of certain expiring provisions of the 2017 Tax Act, and modifications to the international tax framework. The legislation has multiple effective dates, with certain provisions effective in 2026 and beyond.

In 2017, we received an RAR and a modified RAR from the IRS for the years 2010–2012, proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagreed with the proposed adjustments and calculations, and in 2021, we filed a petition in the U.S. Tax Court to contest two duplicate Statutory Notices of Deficiency (Notices) for the years 2010–2012. The Notices seek to increase our U.S. taxable income for the years 2010–2012 by an amount that would result in additional federal tax of approximately $3.6 billion plus interest. Any additional tax that could be imposed for the years 2010–2012 would be reduced by up to approximately $900 million of repatriation tax previously accrued and paid on our foreign earnings.

In 2020, we received an RAR and a modified RAR from the IRS for the years 2013–2015, also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010–2012. We disagreed with the proposed adjustments and calculations, and in 2022, filed a petition in the U.S. Tax Court to contest a Notice for the years 2013–2015. The Notice seeks to increase our U.S. taxable income for the years 2013–2015 by an amount that would result in additional federal tax of approximately $5.1 billion, plus interest, and asserts penalties of approximately $2.0 billion. Any additional tax that could be imposed for the years 2013–2015 would be reduced by up to approximately $2.2 billion of repatriation tax previously accrued and paid on our foreign earnings.

We firmly believe that the IRS positions set forth in the 2010–2012 and 2013–2015 Notices are without merit. We continue to contest the 2010–2012 and 2013–2015 Notices through the judicial process. The two cases were consolidated in the U.S. Tax Court in 2022. The trial began on November 4, 2024 and concluded on January 17, 2025. The parties filed opening post-trial briefs on June 13, 2025, and the Court held oral argument on July 16, 2025. The parties filed post-trial reply briefs on October 10, 2025. The Company expects a decision from the U.S. Tax Court no earlier than the second half of 2026.

We are currently under examination by the IRS for the years 2016–2018 with respect to issues similar to those for the 2010 through 2015 period. We expect that the IRS will begin its audit of 2019–2022 in the first half of 2026, and we believe

that it may seek to continue to audit similar issues related to the allocation of income between the United States and our foreign jurisdictions. In addition, we are under examination by a number of state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We continue to believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our consolidated financial statements.

See Part I, Item 1A. Risk Factors—*We could be subject to additional tax liabilities, including from an adverse outcome in our ongoing tax dispute with the IRS and other tax examinations, enactment of the OECD minimum corporate tax rate agreement and the adoption and interpretation of new tax legislation, including OB3. Such tax liabilities could adversely affect our profitability and results of operations;* Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates—*Income taxes*; and Part IV—Note 7, Income taxes, to the Consolidated Financial Statements for further discussion.

Financial condition, liquidity and capital resources

Selected financial data was as follows (in millions):

	December 31,	
	2025	2024
Cash and cash equivalents	$ 9,129	$ 11,973
Total assets	$ 90,586	$ 91,839
Current portion of long-term debt	$ 4,599	$ 3,550
Long-term debt	$ 50,005	$ 56,549
Stockholders' equity	$ 8,658	$ 5,877

Cash and cash equivalents

Our balance of cash and cash equivalents was $9.1 billion as of December 31, 2025. The primary objective of our investment portfolio is to maintain safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with primarily investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

Capital allocation

Consistent with the objective to optimize our capital structure, we deploy our accumulated cash balances in a strategic manner and consider a number of alternatives, including investments in innovation both internally and externally (including investments that expand our portfolio of products in areas of therapeutic interest), capital expenditures, repayment of debt, payment of dividends and stock repurchases.

We intend to continue investing in our business while returning capital to stockholders through the payment of cash dividends and stock repurchases. This reflects our desire to optimize our cost of capital and our confidence in the future cash flows of our business. The timing and amount of future dividends and stock repurchases will vary based on a number of factors, including future capital requirements for strategic transactions, debt levels and debt service requirements, our credit rating, availability of financing on acceptable terms, changes to applicable tax laws or corporate laws, changes to our business model and periodic determination by our Board of Directors that cash dividends and/or stock repurchases are in the best interests of stockholders and are in compliance with applicable laws and the Company's agreements. In addition, the timing and amount of stock repurchases may also be affected by our overall level of cash, stock price and blackout periods, during which we are restricted from repurchasing stock. The manner of stock repurchases may include block purchases, tender offers, accelerated share repurchases and market transactions.

The Board of Directors declared quarterly cash dividends of $2.38, $2.25 and $2.13 per share of common stock paid in 2025, 2024 and 2023, respectively, reflecting year-over-year increases of 6% for both 2025 and 2024. In December 2025, the Board of Directors declared a cash dividend of $2.52 per share of common stock for the first quarter of 2026, an increase of 6% over the same period in the prior year, which will be paid in March 2026.

We also return capital to stockholders through our stock repurchase program. During 2025 and 2023, we did not repurchase shares under the stock repurchase program. During 2024, we repurchased $200 million of common stock under the stock repurchase program. As of December 31, 2025, $6.8 billion of authorization remained available under the stock repurchase program.

As a result of stock repurchases and quarterly dividend payments, we had an accumulated deficit as of December 31, 2025 and 2024. Our accumulated deficit is not anticipated to affect our future ability to operate, repurchase stock, pay dividends or repay our debt given our expected continued profitability and strong financial position.

We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital, capital expenditure and debt service requirements, pay dividends and repurchase stock, and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities. We anticipate that our liquidity needs can be met through a variety of sources, including cash provided by operating activities, borrowings through commercial paper and/or syndicated credit facilities, and access to other domestic and foreign debt markets and equity markets. See Part I, Item 1A. Risk Factors—*Global economic conditions may negatively affect us and may magnify certain risks that affect our business*.

Financing arrangements

To help meet our liquidity requirements, we have entered into various financing arrangements. The noncurrent portions of our long-term borrowings as of December 31, 2025 and 2024, were $50.0 billion and $56.5 billion, respectively. The carrying values of our long-term borrowings are net of fair value adjustments for interest rate swaps and unamortized discounts, premiums and offering costs. As of December 31, 2025, S&P, Moody's and Fitch assigned credit ratings to our outstanding senior notes of BBB+, Baa1 and BBB+, respectively, which are considered investment grade. Unfavorable changes to these ratings may have an adverse impact on future financings.

During 2023, in connection with our acquisition of Horizon, we issued $24.0 billion of debt composed of eight series of notes and borrowed $4.0 billion under a term loan credit agreement, of which $1.8 billion of borrowings was outstanding as of December 31, 2025.

During 2025, we retired $6.0 billion of debt, consisting of $5.0 billion of debt repayments and $1.0 billion of debt repurchases. The debt repurchases were completed for an aggregate cost of $683 million and resulted in a $264 million gain on extinguishment of debt. We periodically consider the repurchase of our debt when conditions are favorable. Gains on extinguishment of debt are recorded in Other income, net in the Consolidated Statements of Income.

During 2024, we retired $4.5 billion of debt, consisting of $3.6 billion of debt repayments, of which $2.2 billion related to repayments on our term loans, and $875 million of debt repurchases. The debt repurchases were completed for an aggregate cost of $659 million and resulted in a $215 million gain on extinguishment of debt.

During 2023, we retired $2.3 billion of debt, consisting of $1.5 billion of debt repayments and $881 million of debt repurchases. The debt repurchases were completed for an aggregate cost of $647 million and resulted in a $225 million gain on extinguishment of debt.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that effectively converted a fixed-rate interest coupon for certain of our debt issuances to a floating, SOFR-based coupon over the terms of the respective notes. These interest rate swap contracts qualify and are designated as fair value hedges. As of both December 31, 2025 and 2024, we had interest rate swap contracts with an aggregate notional amount of $6.7 billion.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts, which effectively converted the interest payments and principal repayment of the respective notes from euros and pounds sterling to U.S. dollars. These cross-currency swap contracts qualify and are designated as cash flow hedges. As of both December 31, 2025 and 2024, we had cross-currency swap contracts with an aggregate notional amount of $2.7 billion.

In 2025, we increased the capacity of our commercial paper program from $2.5 billion to $4.0 billion, which allows us to issue up to $4.0 billion of unsecured commercial paper to fund working capital needs. We did not issue any commercial paper during 2025, 2024 or 2023, and no commercial paper was outstanding as of December 31, 2025 and 2024.

In 2023, we amended and restated our syndicated, unsecured, revolving credit agreement, under which we may borrow up to $4.0 billion for general corporate purposes, including as a liquidity backstop for our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $1.25 billion with the agreement of the banks. Each bank that is a party to the agreement has an initial commitment term of five years. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the

unused portion of the facility based on our current credit rating. Generally, we would be charged interest for any amounts borrowed under this facility, based on our current credit rating, at (i) SOFR plus 1.01% or (ii) the highest of (A) the administrative agent bank base commercial lending rate, (B) the overnight federal funds rate plus 0.50% or (C) one-month SOFR plus 1.1%. As of December 31, 2025 and 2024, no amounts were outstanding under this facility.

Also in 2023, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time, with terms to be determined at the time of issuance. This shelf registration statement expired in February 2026, and our Board has approved a new shelf registration statement to replace it.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement and term loan credit agreement include a financial covenant that requires us to maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (consolidated earnings before interest, taxes, depreciation and amortization) to (ii) Consolidated Interest Expense, each as defined and described in the respective agreements. We were in compliance with all applicable covenants under these arrangements as of December 31, 2025.

These financing arrangements are more fully discussed in Part IV—Note 16, Financing arrangements, and Note 19, Derivative instruments, to the Consolidated Financial Statements.

Cash flows

Our summarized cash flow activity was as follows (in millions):

	Years ended December 31,		
	2025	2024	2023
Net cash provided by operating activities	$ 9,958	$ 11,490	$ 8,471
Net cash used in investing activities	$ (1,943)	$ (1,046)	$ (26,204)
Net cash (used in) provided by financing activities	$ (10,859)	$ (9,415)	$ 21,048

Operating

Cash provided by operating activities has been and is expected to continue to be our primary recurring source of funds. Cash provided by operating activities decreased in 2025 as compared to 2024 due to the timing of working capital items primarily driven by higher collections in the fourth quarter of 2024, partially offset by higher net income after adjustments for noncash items and lower interest payments.

Cash provided by operating activities increased in 2024 as compared to 2023 due to higher net income after adjustments for noncash items and the timing of working capital items primarily driven by higher collections in the fourth quarter of 2024.

Investing

Cash used in investing activities during 2025 and 2024 was primarily due to $1.9 billion and $1.1 billion, respectively, of capital expenditures, including construction costs for new plants and expansion of manufacturing capacity.

Cash used in investing activities during 2023 was primarily due to $27.0 billion of net cash used for the purchase of Horizon and $1.1 billion of capital expenditures, partially offset by net cash inflows related to marketable securities of $1.7 billion.

We currently estimate 2026 investments in capital projects to be approximately $2.6 billion. A majority of the increase in expenditures relates to construction costs for new plants and expansion of manufacturing capacity to enable supply of products and product candidates.

Financing

Cash used in financing activities during 2025 was primarily due to the repayment and extinguishment of debt of $5.0 billion and $683 million, respectively, and the payment of dividends of $5.1 billion.

Cash used in financing activities during 2024 was primarily due to the payment of dividends of $4.8 billion, the repayment and extinguishment of debt of $3.6 billion and $659 million, respectively, and payments to repurchase common stock of $200 million.

Cash provided by financing activities during 2023 was primarily due to net proceeds from long-term debt issuances of $27.8 billion primarily in connection with the acquisition of Horizon, partially offset by the payment of dividends of $4.6 billion and the repayment and extinguishment of debt of $1.5 billion and $647 million, respectively.

See Part IV—Note 10, Investments; Note 16, Financing arrangements; and Note 17, Stockholders' equity, to the Consolidated Financial Statements.

Capital requirements

We have material cash requirements to pay third parties under various contractual obligations discussed below.

We are obligated to pay interest and repay principal under our various financing arrangements, including amounts under interest rate swap and cross-currency swap contracts related to certain of our long-term debt obligations. For information on scheduled debt maturities and payments under derivative contracts associated with our long-term debt obligations, see Part IV—Note 16, Financing arrangements, and Note 19, Derivative instruments, to the Consolidated Financial Statements.

We are obligated to make payments for operating leases, including rental commitments on unoccupied leases and leases that have not yet commenced. For information on these obligations, see Part IV—Note 14, Leases, to the Consolidated Financial Statements.

As of December 31, 2025, we have purchase obligations of approximately $6.9 billion primarily related to (i) R&D commitments (including those related to clinical trials) for new and existing products, (ii) capital expenditures and (iii) open purchase orders for the acquisition of goods and services in the ordinary course of business. Most of these obligations are expected to be paid within one year, and payment of certain of these amounts may be reduced based on certain future events.

In addition to the purchase obligations noted above and upon the achievement of various development, regulatory and commercial milestones for agreements we have entered into with third parties, we are contractually obligated to pay additional amounts that, in the aggregate, are significant. These payments are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring, and any resulting cash requirements are managed through our operational budgeting processes. Except with respect to the fair value of the contingent consideration of approximately $161 million as of December 31, 2025, these obligations are not recorded on our Consolidated Balance Sheets. As of December 31, 2025, the maximum amount that may be payable in the future for agreements we have entered into with third parties is approximately $7.2 billion.

We have recorded liabilities for UTBs that, because of their nature, have a high degree of uncertainty regarding the timing of future cash payment and other events that extinguish these liabilities. See Part IV—Note 7, Income taxes, to the Consolidated Financial Statements.

Critical accounting policies and estimates

The preparation of our consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. Our significant accounting policies are included in Part IV—Note 1, Summary of significant accounting policies, to the Consolidated Financial Statements. The following are considered critical to our consolidated financial statements because they require the most difficult, subjective or complex judgments, often because of the need to make estimates about matters that are inherently uncertain.

Product sales and sales deductions

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate. Accruals are also adjusted to reflect actual results. Amounts recorded in Accrued liabilities in the Consolidated Balance Sheets for sales deductions were as follows (in millions):

	Rebates	Chargebacks	Other deductions	Total
Balance as of December 31, 2022	$ 4,879	$ 849	$ 258	$ 5,986
Additions [1]	263	24	39	326
Amounts charged against product sales	14,328	13,349	2,533	30,210
Payments	(13,634)	(13,125)	(2,492)	(29,251)
Balance as of December 31, 2023	5,836	1,097	338	7,271
Amounts charged against product sales	17,404	14,882	3,060	35,346
Payments	(16,423)	(14,817)	(2,972)	(34,212)
Balance as of December 31, 2024	6,817	1,162	426	8,405
Amounts charged against product sales	21,697	16,988	3,298	41,983
Payments	(19,675)	(16,852)	(3,255)	(39,782)
Balance as of December 31, 2025	$ 8,839	$ 1,298	$ 469	$ 10,606

[1] Represents sales deductions assumed from the Horizon acquisition.

For the years ended December 31, 2025, 2024 and 2023, total sales deductions were 54%, 52% and 53% of gross product sales, respectively. The increase in the total sales deductions balance as of December 31, 2025, compared with December 31, 2024, was primarily driven by an increase in gross sales and timing of payments. Included in the amounts are immaterial net adjustments related to prior-year sales due to changes in estimates.

In the United States, we use wholesalers as the principal means of distributing our products to healthcare providers such as physicians or their clinics, dialysis centers, hospitals and pharmacies. Products we sell in Europe are distributed principally to hospitals and/or wholesalers depending on the distribution practice in each country where the products are sold. We monitor the inventory levels of our products at our wholesalers by using data from our wholesalers and other third parties, and we believe wholesaler inventories have been maintained at appropriate levels (generally two to three weeks) given end-user demand. Accordingly, historical fluctuations in wholesaler inventory levels have not significantly affected our method of estimating sales deductions.

Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given year, can be affected by the mix of products sold.

Rebates include primarily amounts paid to payers and providers in the United States, including those paid to state Medicaid programs and those related to the IRA, and are based on contractual arrangements or statutory requirements that vary by product, by payer and by individual payer plans. As we sell products, we estimate the amount of rebate we will pay based on

the product sold, contractual terms, estimated patient population, historical experience and wholesaler inventory levels; and we accrue these rebates in the period the related sales are recorded. We then adjust the rebate accruals as more information becomes available and to reflect actual claims experience. Estimating such rebates is complicated, in part because of the time delay between the date of sale and the actual settlement of the liability. We believe the methodology we use to accrue for rebates is reasonable and appropriate given current facts and circumstances, but actual results may differ.

Wholesaler chargebacks relate to our contractual agreements to sell products to healthcare providers in the United States at fixed prices that are lower than the prices we charge wholesalers. When healthcare providers purchase our products through wholesalers at these reduced prices, wholesalers charge us for the difference between their purchase prices and the contractual prices between Amgen and the healthcare providers. The provision for chargebacks is based on expected sales by our wholesaler customers to healthcare providers. Accruals for wholesaler chargebacks are less difficult to estimate than rebates are, and they closely approximate actual results because chargeback amounts are fixed at the date of purchase by the healthcare providers and because we generally settle the liability for these deductions within a few weeks.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates in the various jurisdictions in which we operate.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by tax authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of UTBs is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by tax authorities, new information obtained during a tax examination or resolution of an examination. We believe our estimates for uncertain tax positions are appropriate and sufficient for any assessments that may result from examinations of our tax returns. We recognize both accrued interest and penalties, when appropriate, related to UTBs in income tax expense. See Part IV—Note 7, Income taxes, to the Consolidated Financial Statements.

Certain items are included in our tax return at different times than they are reflected in the financial statements, and they cause temporary differences between the tax bases of assets and liabilities and their reported amounts. Such temporary differences create deferred tax assets and liabilities. Deferred tax assets are generally items that can be used as tax deductions or credits in tax returns in future years but for which we have already recorded the tax benefit in the consolidated financial statements. We establish valuation allowances against our deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities are either (i) tax expenses recognized in the consolidated financial statements for which payment has been deferred, (ii) expenses for which we have already taken a deduction on the tax return but have not yet recognized in the consolidated financial statements or (iii) liabilities for the difference between the book basis and the tax basis of the intangible assets acquired in many business combinations, because future expenses associated with these assets most often will not be tax deductible.

Amgen is subject to current U.S. tax on the earnings of our foreign subsidiaries. We previously established deferred taxes related to this U.S. tax, which requires us to recognize deferred taxes for temporary basis differences expected to reverse and be subject to this tax in future years. These are ongoing adjustments that are likely to occur in future periods.

We are a vertically integrated enterprise with operations in the United States and various foreign jurisdictions. In the jurisdictions where we conduct operations, we are subject to income tax based on the tax laws and principles of such jurisdictions and on the functions, risks and activities performed therein. Our pretax income is therefore attributed to domestic or foreign sources based on the operations performed and the risks assumed in each location, as well as on the tax laws and principles of the respective taxing jurisdictions. For example, we conduct significant operations in Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes, pertaining to manufacturing, distribution and other related functions to meet our worldwide product demand. Income from our operations in Puerto Rico is subject to tax incentive grants through 2050.

In 2017, we received an RAR and a modified RAR from the IRS for the years 2010–2012, proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagreed with the proposed adjustments and calculations, and in 2021, filed a petition in the U.S. Tax Court to contest two duplicate Statutory Notices of Deficiency (Notices) for the years 2010–2012. The Notices seek to increase our U.S. taxable income for the years 2010–2012 by an amount that would result in additional federal tax of approximately $3.6 billion plus interest. Any additional tax that could be imposed for the years 2010–2012 would be reduced by up to approximately $900 million of repatriation tax previously accrued and paid on our foreign earnings.

In 2020, we received an RAR and a modified RAR from the IRS for the years 2013–2015, also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010–2012. We disagreed with the proposed adjustments and calculations, and in 2022, filed a petition in the U.S. Tax Court to contest a Notice for the years 2013–2015. The Notice seeks to increase our U.S. taxable income for the years 2013–2015 by an amount that would result in additional federal tax of approximately $5.1 billion, plus interest, and asserts penalties of approximately $2.0 billion. Any additional tax that could be imposed for the years 2013–2015 would be reduced by up to approximately $2.2 billion of repatriation tax previously accrued and paid on our foreign earnings.

We firmly believe that the IRS positions set forth in the 2010–2012 and 2013–2015 Notices are without merit. We continue to contest the 2010–2012 and 2013–2015 Notices through the judicial process. The two cases were consolidated in the U.S. Tax Court in 2022. The trial began on November 4, 2024, and concluded on January 17, 2025. The parties filed opening post-trial briefs on June 13, 2025, and the Court held oral argument on July 16, 2025. The parties filed post-trial reply briefs on October 10, 2025. The Company expects a decision from the U.S. Tax Court no earlier than the second half of 2026.

We are currently under examination by the IRS for the years 2016–2018 with respect to issues similar to those for the 2010 through 2015 period. We expect that the IRS will begin its audit of 2019–2022 in the first half of 2026, and we believe that it may seek to continue to audit similar issues related to the allocation of income between the United States and our foreign jurisdictions. In addition, we are under examination by a number of state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We continue to believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our consolidated financial statements.

See Part I, Item 1A. Risk Factors—*We could be subject to additional tax liabilities, including from an adverse outcome in our ongoing tax dispute with the IRS and other tax examinations, enactment of the OECD minimum corporate tax rate agreement and the adoption and interpretation of new tax legislation, including OB3. Such tax liabilities could adversely affect our profitability and results of operations;* Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Income taxes; and Part IV—Note 7, Income taxes, to the Consolidated Financial Statements for further discussion.

Our operations are subject to the tax laws, regulations and administrative practices of the United States, the U.S. territory of Puerto Rico, U.S. state jurisdictions and other countries in which we do business. Significant changes in these rules could have a material adverse effect on our results of operations. See Part I, Item 1A. Risk Factors—*We could be subject to additional tax liabilities, including from an adverse outcome in our ongoing tax dispute with the IRS and other tax examinations, enactment of the OECD minimum corporate tax rate agreement and the adoption and interpretation of new tax legislation, including OB3. Such tax liabilities could adversely affect our profitability and results of operations.*

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters such as intellectual property disputes, contractual disputes and class action suits that are complex in nature and have outcomes that are difficult to predict. We describe our legal proceedings and other matters that are significant or that we believe could become significant in Part IV—Note 20, Contingencies and commitments, to the Consolidated Financial Statements. We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

While it is not possible to accurately predict or determine the eventual outcomes of these items, an adverse determination in one or more of these items currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Valuation of assets and liabilities in connection with acquisitions

We have acquired and continue to acquire intangible assets in connection with business combinations and asset acquisitions. These intangible assets consist primarily of technology associated with currently marketed human therapeutic products and IPR&D product candidates. Discounted cash flow models are typically used to determine the fair values of these intangible assets for purposes of allocating consideration paid to the net assets acquired in an acquisition. See Part IV—Note 4, Acquisition, to the Consolidated Financial Statements. These models require the use of significant estimates and assumptions, including but not limited to:

- determining the timing and expected costs to complete in-process projects, taking into account the stage of completion at the acquisition date;
- projecting the probability and timing of obtaining marketing approval from the FDA and other regulatory agencies for product candidates;
- estimating the timing of and future net cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates to calculate the present values of the cash flows.

Significant estimates and assumptions are also required to determine the business combination date fair values of any contingent consideration obligations incurred in connection with business combinations. In addition, we must revalue these obligations each subsequent reporting period until the related contingencies are resolved and record changes in their fair values in earnings. The acquisition date fair values of contingent consideration obligations incurred or assumed in the acquisitions were determined using a combination of valuation techniques. Significant estimates and assumptions required for these valuations included but were not limited to the timing and probability of achieving regulatory milestones, product sales projections under various scenarios and discount rates used to calculate the present value of the required payments. These estimates and assumptions are required to be updated in order to revalue these contingent consideration obligations each reporting period. Accordingly, subsequent changes in underlying facts and circumstances could result in changes in these estimates and assumptions, which could have a material impact on the estimated future fair values of these obligations.

We believe the fair values used to record intangible assets acquired and contingent consideration obligations incurred in connection with business combinations and asset acquisitions are based on reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Impairment of long-lived assets

We review the carrying value of our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such circumstances exist, an estimate of undiscounted future cash flows to be generated by the long-lived asset is compared with the carrying value to determine whether an impairment exists. If an asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value.

Indefinite-lived intangible assets, composed of IPR&D projects acquired in a business combination that have not reached technological feasibility or that lack regulatory approval at the time of acquisition, are reviewed for impairment annually, whenever events or changes in circumstances indicate that the carrying amount may not be recoverable and upon establishment of technological feasibility or regulatory approval. We test for impairment by comparing the fair value of the asset to its carrying value. If the asset's carrying value exceeds its fair value, an impairment charge is recorded for the difference, and its carrying value is reduced accordingly.

Estimating future cash flows of an IPR&D product candidate for purposes of an impairment analysis requires us to make significant estimates and assumptions regarding the amount and timing of costs to complete the project and the amount, timing and probability of achieving revenues from the completed product similar to how the acquisition date fair value of the project was determined, as described above. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market these products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods which could have a material adverse effect on our results of operations.

We believe our estimations of future cash flows used for assessing impairment of long-lived assets are based on reasonable assumptions given the facts and circumstances as of the related dates of the assessments.

Recently issued accounting standards

See Part IV—Note 1, Summary of significant accounting policies, to the Consolidated Financial Statements for a discussion of recently issued accounting pronouncements.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks that may result from changes in interest rates, foreign currency exchange rates and prices of equity instruments as well as changes in general economic conditions in the countries where we conduct business. To reduce certain of these risks, we enter into various types of foreign currency and interest rate derivative hedging transactions as part of our risk management program. We do not use derivatives for speculative trading purposes.

In the discussion that follows, we assumed a hypothetical change in interest rates of 100 basis points from those as of December 31, 2025 and 2024. Except as noted below, we also assumed a hypothetical 20% change in foreign currency exchange rates against the U.S. dollar based on its position relative to other currencies as of December 31, 2025 and 2024.

Interest-rate-sensitive financial instruments

Our portfolio of available-for-sale investments as of December 31, 2025 and 2024, was composed almost entirely of U.S. Treasury securities and money market mutual funds. The fair values of our available-for-sale investments were $8.5 billion and $11.5 billion as of December 31, 2025 and 2024, respectively. Duration is a sensitivity measure that can be used to approximate the change in the value of a security that will result from a 100 basis point change in interest rates. Applying a duration model, a hypothetical 100 basis point increase in interest rates as of December 31, 2025 and 2024, would not have resulted in a material reduction in the fair values of these securities. In addition, a hypothetical 100 basis point decrease in interest rates as of December 31, 2025 and 2024, would not result in a material effect on income in the respective ensuing year.

As of December 31, 2025, we had outstanding notes with an aggregate carrying value of $52.8 billion and an aggregate fair value of $51.0 billion. As of December 31, 2024, we had outstanding notes with an aggregate carrying value of $58.3 billion and an aggregate fair value of $54.9 billion. Our outstanding notes were composed of debt with fixed interest rates. Changes in interest rates do not affect interest expense on fixed-rate debt. Changes in interest rates would, however, affect the fair values of fixed-rate debt. A hypothetical 100 basis point decrease in interest rates relative to interest rates as of December 31, 2025 and 2024, would have resulted in increases of $4.4 billion and $4.7 billion, respectively, in the aggregate fair values of our outstanding debt on these dates. The sensitivity analysis of the notes does not consider the impact that hypothetical changes in interest rates would have on related interest rate swap contracts and cross-currency swap contracts, discussed below. In addition, the analysis above does not include our term loans, which had a carrying value of $1.8 billion at both December 31, 2025 and 2024. The fair value of our term loan is approximated at its carrying value as this debt instrument bears interest at a floating rate.

To achieve a desired mix of fixed-rate and floating-rate debt, we entered into interest rate swap contracts that qualified and were designated for accounting purposes as fair value hedges for certain of our fixed-rate debt. These interest rate swap contracts effectively converted a fixed-rate interest coupon to a floating-rate SOFR-based coupon over the terms of the respective notes. Interest rate swap contracts with an aggregate notional amount of $6.7 billion were outstanding as of both December 31, 2025 and 2024. A hypothetical 100 basis point increase in interest rates relative to interest rates as of December 31, 2025 and 2024, would have resulted in reductions in fair values of approximately $240 million and $220 million, respectively, on our interest rate swap contracts on these dates. Analysis of the interest rate swap contracts does not consider the impact that hypothetical changes in interest rates would have on the related fair values of debt that these interest-rate-sensitive instruments were designed to offset.

As of both December 31, 2025 and 2024, we had outstanding cross-currency swap contracts with an aggregate notional amount of $2.7 billion that hedge our foreign-currency-denominated debt and related interest payments. These contracts effectively convert interest payments and principal repayment of this debt to U.S. dollars from euros and pounds sterling and are designated for accounting purposes as cash flow hedges. A hypothetical 100 basis point adverse movement in interest rates relative to interest rates as of December 31, 2025 and 2024, would not have a material effect on the fair values of our cross-currency swap contracts.

Foreign-currency-sensitive financial instruments

Our international operations are affected by fluctuations in the value of the U.S. dollar compared with foreign currencies, predominantly the euro. Increases and decreases in our international product sales from movements in foreign currency exchange rates are partially offset by corresponding increases or decreases in our international operating expenses. Increases and decreases in our foreign-currency-denominated assets from movements in foreign currency exchange rates are partially offset by corresponding increases or decreases in our foreign-currency-denominated liabilities. To further reduce our net exposure to foreign currency exchange rate fluctuations on our results of operations, we enter into foreign currency forward and cross-currency swap contracts.

As of December 31, 2025, we had outstanding euro- and pound-sterling-denominated debt with both a principal carrying value and a fair value of $2.5 billion. As of December 31, 2024, we had outstanding euro- and pound-sterling-denominated debt with both a principal carrying value and a fair value of $2.2 billion. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2025, would have resulted in an increase in fair value of this debt of approximately $490 million on this date and a reduction in income in the ensuing year of approximately $490 million. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2024, would have resulted in an increase in fair value of this debt of $440 million on this date and a reduction in income in the ensuing year of $450 million. The impact on income from these hypothetical changes in foreign currency exchange rates would be substantially offset by the impact such changes would have on related cross-currency swap contracts, which are in place for the related foreign-currency-denominated debt.

We have cross-currency swap contracts that are designated as cash flow hedges of our debt denominated in euros and pounds sterling with an aggregate notional amount of $2.7 billion as of both December 31, 2025 and 2024. A hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would have resulted in reductions in the fair values of these contracts of approximately $500 million and $450 million on these dates, respectively. The impact of this hypothetical adverse movement in foreign currency exchange rates on ensuing years' income from these contracts would be fully offset by corresponding hypothetical changes in the carrying amounts of the related hedged debt.

We enter into foreign currency forward contracts that are designated for accounting purposes as cash flow hedges of certain anticipated foreign currency transactions. As of December 31, 2025, the fair values of these contracts were a $195 million asset and a $213 million liability. As of December 31, 2024, the fair values of these contracts were a $420 million asset and an $8 million liability. As of December 31, 2025, we had primarily euro-based open foreign currency forward contracts with an aggregate notional amount of $7.8 billion. As of December 31, 2024, we had primarily euro-based open foreign currency forward contracts with an aggregate notional amount of $7.2 billion. With regard to foreign currency forward contracts that were open as of December 31, 2025, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2025, would have resulted in a reduction in fair value of these contracts of approximately $1.5 billion on this date and in the ensuing year, a reduction in income of approximately $800 million. With regard to contracts that were open as of December 31, 2024, a hypothetical 20% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2024, would have resulted in a reduction in fair value of these contracts of approximately $1.3 billion on this date and in the ensuing year, a reduction in income of $700 million. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign-currency-sensitive instruments were designed to offset.

As of December 31, 2025 and 2024, we had open, short-duration, foreign currency forward contracts that mature in one month or less, that had aggregate notional amounts of $240 million and $148 million, respectively, and that hedged fluctuations of certain assets and liabilities denominated in foreign currencies but were not designated as hedges for accounting purposes. These contracts had no material net unrealized gains or losses as of December 31, 2025 and 2024. With regard to these foreign currency forward contracts that were open as of December 31, 2025 and 2024, a hypothetical 5% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates on these dates would not have a material effect on the fair values of these contracts or related income in the respective ensuing years. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on assets and liabilities that these foreign-currency-sensitive instruments were designed to offset.

Market-price-sensitive financial instruments

As of December 31, 2025 and 2024, we were exposed to price risk on equity securities included in our portfolio of investments, which were acquired primarily for the promotion of business and strategic objectives. These investments include our investment in BeOne, as well as other publicly and privately held small-capitalization stocks and limited partnerships that invest in early-stage biotechnology companies. A 20% decrease in the aggregate value of our equity investment portfolio as of December 31, 2025 and 2024, would result in losses in fair value of approximately $1.4 billion and $950 million, respectively.

Counterparty credit risks

Our financial instruments, including derivatives, are subject to counterparty credit risk, which we consider as part of the overall fair value measurement. Our financial risk management policy limits derivative transactions by requiring that transactions be made only with institutions with minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch; and it places exposure limits on the amount with any individual counterparty. In addition, we have an investment policy that limits

investments to certain types of debt and money market instruments issued by institutions with investment-grade credit ratings and places restriction on maturities and concentrations by asset class and issuer.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item is incorporated herein by reference to the financial statements and schedule listed in Item 15(a)1 and (a)2 of Part IV and included in this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

We maintain "disclosure controls and procedures," as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, that are designed to ensure that information required to be disclosed in Amgen's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. These controls and procedures are also designed to ensure that such information is accumulated and communicated to Amgen's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, Amgen's management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, Amgen's management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation under the supervision and with the participation of our management, including Amgen's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Amgen's disclosure controls and procedures. Based upon their evaluation and subject to the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2025.

Management determined that as of December 31, 2025, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP in the United States. However, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and reporting.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria set forth by the COSO in Internal Control—Integrated Framework (2013 framework). Based on our assessment, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2025, based on the COSO criteria.

The effectiveness of the Company's internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report appearing below, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2025.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Amgen Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Amgen Inc.'s internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Amgen Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2025 and 2024, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 and our report dated February 13, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Los Angeles, California
February 13, 2026

Item 9B. OTHER INFORMATION

Rule 10b5-1 trading arrangements

During the three months ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information about our Directors is incorporated by reference from the section entitled ITEM 1—ELECTION OF DIRECTORS in our Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2025 (the Proxy Statement). Information about the procedures by which stockholders may recommend nominees for the Board of Directors is incorporated by reference from APPENDIX A—AMGEN INC. BOARD OF DIRECTORS GUIDELINES FOR DIRECTOR QUALIFICATIONS AND EVALUATIONS and OTHER MATTERS—Stockholder Proposals for the 2027 Annual Meeting in our Proxy Statement. Information about our Audit Committee, members of the committee and our Audit Committee financial experts is incorporated by reference from the section entitled CORPORATE GOVERNANCE—Audit Committee in our Proxy Statement. Information about our insider trading policies and procedures is incorporated by reference from the section entitled COMPENSATION DISCUSSION AND ANALYSIS—COMPENSATION POLICIES AND PRACTICES—Insider Trading Policies and Procedures in our Proxy Statement. A copy of our Insider Trading Policy and our securities transactions pre-clearance practices and procedures are incorporated by reference to this Annual Report on Form 10-K as Exhibits 19.1 and 19.2, respectively. Information about our executive officers is contained in the discussion entitled Part I, Item 1. Business—Information about our Executive Officers.

Code of Ethics

We maintain a Code of Ethics for the Chief Executive Officer and Senior Financial Officers applicable to our principal executive officer, principal financial officer, principal accounting officer or controller and other persons performing similar functions. To view this code of ethics free of charge, please visit our website at www.amgen.com. (The website address is not intended to function as a hyperlink, and the information contained in our website is not intended to be a part of this filing.) We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to or a waiver from a provision of this code of ethics, if any, by posting such information on our website as set forth above.

Item 11. EXECUTIVE COMPENSATION

Information about director and executive compensation is incorporated by reference from the sections entitled COMPENSATION DISCUSSION AND ANALYSIS, EXECUTIVE COMPENSATION TABLES, DIRECTOR COMPENSATION and OTHER COMPENSATION MATTERS in our Proxy Statement. Information about compensation committee matters is incorporated by reference from the sections entitled CORPORATE GOVERNANCE—Compensation and Management Development Committee and COMPENSATION COMMITTEE REPORT in our Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Existing Equity Compensation Plans

The following table sets forth certain information as of December 31, 2025, concerning the shares of our common stock that may be issued under any form of award granted under our equity compensation plans in effect as of December 31, 2025, including upon the exercise of options, upon the vesting of awards of RSUs or when performance units are earned and related dividend equivalents have been granted.

	(a)	(b)	(c)
Plan category	**Number of securities to be issued upon exercise of outstanding options and rights**	**Weighted-average exercise price of outstanding options and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**
Equity compensation plans approved by Amgen security holders:			
Amended and Restated 2009 Equity Incentive Plan[(1)]	11,098,368	$ 234.45	35,004,385
Amended and Restated 1991 Equity Incentive Plan[(2)]	100		
Amended and Restated Employee Stock Purchase Plan			3,813,679
Total approved plans	11,098,468	$ 234.45	38,818,064
Equity compensation plan not approved by Amgen security holders:			
Amgen Profit Sharing Plan for Employees in Ireland[(3)]			150,740
Horizon stock plans[(4)]	132,521		
Total unapproved plans	132,521	—	150,740
Total all plans	11,230,989	$ 234.45	38,968,804

(1) The Amended 2009 Plan employs a fungible share-counting formula for determining the number of shares available for issuance under the plan. In accordance with this formula, each option or stock appreciation right counts as one share, while each RSU, performance unit or dividend equivalent counts as 1.9 shares. The number under column (a) represents the actual number of shares issuable under our outstanding awards without giving effect to the fungible share-counting formula. The number under column (c) represents the number of shares available for issuance under this plan based on each such available share counting as one share. Commencing with the grants made in April 2012, RSUs and performance units accrue dividend equivalents that are payable in shares only to the extent and when the underlying RSUs vest or underlying performance units have been earned and the related shares are issued to the grantee. The performance units granted under this plan are earned based on the accomplishment of specified performance goals at the end of their respective three-year performance periods; the number of performance units granted represent target performance, and the maximum number of units that could be earned based on our performance is 200% of the performance units granted in 2023, 2024 and 2025.

As of December 31, 2025, the number of outstanding awards under column (a) includes (i) 6,064,625 shares issuable upon the exercise of outstanding options with a weighted-average exercise price of $234.45; (ii) 3,797,669 shares issuable upon the vesting of outstanding RSUs, including 221,796 related dividend equivalents; and (iii) 1,236,074 shares subject to outstanding 2023, 2024 and 2025 performance units, including 74,616 related dividend equivalents. The weighted-average exercise price shown in column (b) is for the outstanding options only. The number of available shares under column (c) represents the number of shares that remain available for future issuance under this plan as of December 31, 2025, employing the fungible share formula and presumes the issuance of target shares under the performance units granted in 2023, 2024 and 2025 and related dividend equivalents. The numbers under columns (a) and (c) do not give effect to the additional shares that could be issuable in the event that above target performance on the performance goals under these outstanding performance units is achieved. Maximum performance under these goals could result in 200% of target shares being awarded for performance units granted in 2023, 2024 and 2025.

(2) This plan has terminated as to future grants. The number under column (a) with respect to this plan includes 100 shares issuable upon the settlement of deferred RSUs.

(3) The Profit Sharing Plan was approved by the Board of Directors on July 28, 2011. The Profit Sharing Plan permits eligible employees of the Company's subsidiaries located in Ireland who participate in the Profit Sharing Plan to apply a

portion of their qualifying bonus and salary to the purchase of the Company's common stock on the open market at the market price by a third-party trustee as described in the Profit Sharing Plan.

(4) The Horizon Therapeutics Public Limited Company Amended and Restated 2014 Equity Incentive Plan, the Horizon Therapeutics Public Limited Company Amended and Restated 2020 Equity Incentive Plan and 2020 Restricted Stock Unit Award Sub-Plan and the Horizon Therapeutics Public Limited Company Amended and Restated 2018 Equity Incentive Plan and 2018 Restricted Stock Unit Award Sub-Plan (collectively, the "Horizon stock plans") were acquired on October 6, 2023, pursuant to our acquisition of Horizon. In connection with the closing of the Horizon acquisition and pursuant to its terms, outstanding RSUs issued under the Horizon stock plans were converted into Amgen RSUs, and these plans terminated as to future grants on October 6, 2023.

Security Ownership of Directors and Executive Officers and Certain Beneficial Owners

Information about security ownership of certain beneficial owners and management is incorporated by reference from the sections entitled SECURITY OWNERSHIP OF DIRECTORS AND EXECUTIVE OFFICERS and SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS in our Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Information about certain relationships and related transactions and director independence is incorporated by reference from the sections entitled CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS and CORPORATE GOVERNANCE—Director Independence in our Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information about the fees for professional services rendered by our independent registered public accountants is incorporated by reference from the section entitled AUDIT MATTERS—Independent Registered Public Accountants in our Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)1. Index to Financial Statements

The following Consolidated Financial Statements are included herein:

	Page number
Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	F-1
Consolidated Statements of Income for each of the three years in the period ended December 31, 2025	F-4
Consolidated Statements of Comprehensive Income for each of the three years in the period ended December 31, 2025	F-5
Consolidated Balance Sheets as of December 31, 2025 and 2024	F-6
Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2025	F-7
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2025	F-8
Notes to Consolidated Financial Statements	F-9

(a)2. Index to Financial Statement Schedules

The following Schedule is filed as part of this Annual Report on Form 10-K:

	Page number
Schedule II. Valuation and Qualifying Accounts	F-61

All other schedules are omitted because they are not applicable, not required or because the required information is included in the consolidated financial statements or notes thereto.

(a)3. Exhibits

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of Amgen Inc. (As Restated March 6, 2013.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2013 on May 3, 2013 and incorporated herein by reference.)
3.2	Amended and Restated Bylaws of Amgen Inc. (As Amended and Restated February 15, 2016.) (Filed as an exhibit to Form 8-K on February 17, 2016 and incorporated herein by reference.)
4.1	Form of stock certificate for the common stock, par value $.0001 of the Company. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1997 on May 14, 1997 and incorporated herein by reference.)
4.2	Form of Indenture, dated January 1, 1992. (Filed as an exhibit to Form S-3 Registration Statement filed on December 19, 1991 and incorporated herein by reference.)
4.3	Agreement of Resignation, Appointment and Acceptance dated February 15, 2008. (Filed as an exhibit to Form 10-K for the year ended December 31, 2007 on February 28, 2008 and incorporated herein by reference.)
4.4	First Supplemental Indenture, dated February 26, 1997. (Filed as an exhibit to Form 8-K on March 14, 1997 and incorporated herein by reference.)
4.5	8-1/8% Debentures due April 1, 2097. (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)
4.6	Officer's Certificate of Amgen Inc., dated April 8, 1997, establishing a series of securities entitled "8 1/8% Debentures due April 1, 2097." (Filed as an exhibit to Form 8-K on April 8, 1997 and incorporated herein by reference.)

Exhibit No.	Description
4.7	Indenture, dated August 4, 2003. (Filed as an exhibit to Form S-3 Registration Statement on August 4, 2003 and incorporated herein by reference.)
4.8	Corporate Commercial Paper - Master Note between and among Amgen Inc., as Issuer, Cede & Co., as Nominee of The Depository Trust Company, and Citibank, N.A., as Paying Agent. (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 1998 on May 13, 1998 and incorporated herein by reference.)
4.9	Officers' Certificate of Amgen Inc., dated May 30, 2007, including form of the Company's 6.375% Senior Notes due 2037. (Filed as an exhibit to Form 8-K on May 30, 2007 and incorporated herein by reference.)
4.10	Officers' Certificate of Amgen Inc., dated May 23, 2008, including form of the Company's 6.90% Senior Notes due 2038. (Filed as exhibit to Form 8-K on May 23, 2008 and incorporated herein by reference.)
4.11	Officers' Certificate of Amgen Inc., dated January 16, 2009, including form of the Company's 6.40% Senior Notes due 2039. (Filed as exhibit to Form 8-K on January 16, 2009 and incorporated herein by reference.)
4.12	Officers' Certificate of Amgen Inc., dated March 12, 2010, including form of the Company's 5.75% Senior Notes due 2040. (Filed as exhibit to Form 8-K on March 12, 2010 and incorporated herein by reference.)
4.13	Officers' Certificate of Amgen Inc., dated September 16, 2010, including form of the Company's 4.95% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on September 17, 2010 and incorporated herein by reference.)
4.14	Officers' Certificate of Amgen Inc., dated June 30, 2011, including form of the Company's 5.65% Senior Notes due 2042. (Filed as an exhibit to Form 8-K on June 30, 2011 and incorporated herein by reference.)
4.15	Officers' Certificate of Amgen Inc., dated November 10, 2011, including form of the Company's 5.15% Senior Notes due 2041. (Filed as an exhibit to Form 8-K on November 10, 2011 and incorporated herein by reference.)
4.16	Officers' Certificate of Amgen Inc., dated December 5, 2011, including form of the Company's 5.50% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on December 5, 2011 and incorporated herein by reference.)
4.17	Officers' Certificate of Amgen Inc., dated May 15, 2012, including form of the Company's 5.375% Senior Notes due 2043. (Filed as an exhibit to Form 8-K on May 15, 2012 and incorporated herein by reference.)
4.18	Officers' Certificate of Amgen Inc., dated September 13, 2012, including form of the Company's 4.000% Senior Notes due 2029. (Filed as an exhibit to Form 8-K on September 13, 2012 and incorporated herein by reference.)
4.19	Indenture, dated May 22, 2014, between Amgen Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee. (Filed as an exhibit to Form 8-K on May 22, 2014 and incorporated herein by reference.)
4.20	Officer's Certificate of Amgen Inc., dated May 1, 2015, including forms of the Company's 3.125% Senior Notes due 2025 and 4.400% Senior Notes due 2045. (Filed as an exhibit on Form 8-K on May 1, 2015 and incorporated herein by reference.)
4.21	Officer's Certificate of Amgen Inc., dated as of February 25, 2016, including form of the Company's 2.000% Senior Notes due 2026. (Filed as an exhibit on Form 8-K on February 26, 2016 and incorporated herein by reference.)
4.22	Officer's Certificate of Amgen Inc., dated as of June 14, 2016, including forms of the Company's 4.563% Senior Notes due 2048 and 4.663% Senior Notes due 2051. (Filed as an exhibit to Form 8-K on June 14, 2016 and incorporated herein by reference.)
4.23	Officer's Certificate of Amgen Inc., dated as of August 19, 2016, including forms of the Company's 2.600% Senior Notes due 2026. (Filed as an exhibit to Form 8-K on August 19, 2016 and incorporated herein by reference.)
4.24	Officer's Certificate of Amgen Inc., dated as of November 2, 2017, including in the form of the Company's 3.200% Senior Notes due 2027. (Filed as an exhibit to Form 8-K on November 2, 2017 and incorporated herein by reference.)
4.25	Officer's Certificate of Amgen Inc., dated as of February 21, 2020, including forms of the Company's 1.900% Senior Notes due 2025, 2.200% Senior Notes due 2027, 2.450% Senior Notes due 2030, 3.150% Senior Notes due 2040 and 3.375% Senior Notes due 2050. (Filed as an exhibit to Form 8-K on February 21, 2020 and incorporated herein by reference.)

Exhibit No.	Description
4.26	Officer's Certificate of Amgen Inc., dated as of May 6, 2020, including form of the Company's 2.300% Senior Notes due 2031. (Filed as an exhibit to Form 8-K on May 6, 2020 and incorporated herein by reference.)
4.27	Officer's Certificate of Amgen Inc., dated as of August 17, 2020, including forms of the Company's 2.770% Senior Notes due 2053. (Filed as an exhibit to Form 8-K on August 18, 2020 and incorporated herein by reference.)
4.28	Officer's Certificate of Amgen Inc., dated as of August 9, 2021, including forms of the Company's 1.650% Senior Notes due 2028, 2.000% Senior Notes due 2032, 2.800% Senior Notes due 2041 and 3.000% Senior Notes due 2052. (Filed as an exhibit to Form 8-K on August 9, 2021 and incorporated herein by reference.)
4.29	Officer's Certificate of Amgen Inc., dated as of February 22, 2022, including forms of the Company's 3.000% Senior Notes due 2029, 3.350% Senior Notes due 2032, 4.200% Senior Notes due 2052 and 4.400% Senior Notes due 2062. (Filed as an exhibit to Form 8-K on February 22, 2022 and incorporated herein by reference.)
4.30	Officer's Certificate of Amgen Inc., dated as of August 18, 2022, including forms of the Company's 4.050% Senior Notes due 2029, 4.200% Senior Notes due 2033 and 4.875% Senior Notes due 2053. (Filed as an exhibit to Form 8-K on August 18, 2022 and incorporated herein by reference.)
4.31	Officer's Certificate of the Company, dated as of March 2, 2023, including forms of the Company's 5.250% Senior Notes due 2025, 5.507% Senior Notes due 2026, 5.150% Senior Notes due 2028, 5.250% Senior Notes due 2030, 5.250% Senior Notes due 2033, 5.600% Senior Notes due 2043, 5.650% Senior Notes due 2053 and 5.750% Senior Notes due 2063. (Filed as an exhibit to Form 8-K on March 2, 2023 and incorporated herein by reference.)
4.32*	Description of Amgen Inc.'s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
10.1+	Amgen Inc. Second Amended and Restated 2009 Equity Incentive Plan. (Filed as Appendix C to the Definitive Proxy Statement on Schedule 14A on April 17, 2024 and incorporated herein by reference.)
10.2*+	Form of Grant of Stock Option Agreement for the Amgen Inc. Second Amended and Restated 2009 Equity Incentive Plan. (As Amended and Restated on December 8, 2025.)
10.3*+	Form of Restricted Stock Unit Agreement for the Amgen Inc. Second Amended and Restated 2009 Equity Incentive Plan. (As Amended and Restated on December 8, 2025.)
10.4+	Amgen Inc. 2009 Performance Award Program. (As Amended and Restated on May 31, 2024.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2024 on August 7, 2024 and incorporated herein by reference.)
10.5*+	Form of Performance Unit Agreement for the Amgen Inc. 2009 Performance Award Program. (As Amended and Restated on December 8, 2025.)
10.6+	Amgen Inc. 2009 Director Equity Incentive Program. (As Amended and Restated on May 31, 2024.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2024 on August 7, 2024 and incorporated herein by reference.)
10.7+	Form of Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended and Restated on May 31, 2024.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2024 on August 7, 2024 and incorporated herein by reference.)
10.8+	Form of Cash-Settled Restricted Stock Unit Agreement for the Amgen Inc. 2009 Director Equity Incentive Program. (As Amended and Restated on May 31, 2024.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2024 on August 7, 2024 and incorporated herein by reference.)
10.9+	Amgen Inc. Supplemental Retirement Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.9.1+	First Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)

Exhibit No.	Description
10.9.2+	Second Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 23, 2019. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.9.3+	Third Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 20, 2021. (Filed as an exhibit to Form 10-K for the year ended December 31, 2021 on February 16, 2022 and incorporated herein by reference.)
10.9.4+	Fourth Amendment to the Amgen Inc. Supplemental Retirement Plan, effective October 20, 2022. (Filed as an exhibit to Form 10-K for the year ended December 31, 2022 on February 9, 2023 and incorporated herein by reference.)
10.9.5+	Fifth Amendment to the Amgen Inc. Supplemental Retirement Plan, effective January 1, 2024. (Filed as an exhibit to Form 10-K for the year ended December 31, 2023 on February 14, 2024 and incorporated herein by reference.)
10.10+	Amended and Restated Amgen Change of Control Severance Plan. (As Amended and Restated effective December 9, 2010 and subsequently amended effective March 2, 2011.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2011 on May 10, 2011 and incorporated herein by reference.)
10.11+	Amgen Inc. Executive Incentive Plan. (As Amended and Restated effective January 1, 2022.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2022 on April 28, 2022 and incorporated herein by reference.)
10.12+	Amgen Nonqualified Deferred Compensation Plan. (As Amended and Restated effective October 16, 2013.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2013 on February 24, 2014 and incorporated herein by reference.)
10.12.1+	First Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective October 14, 2016. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2016 on October 28, 2016 and incorporated herein by reference.)
10.12.2+	Second Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective January 1, 2020. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.12.3+	Third Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective January 1, 2022. (Filed as an exhibit to Form 10-K for the year ended December 31, 2021 on February 16, 2022 and incorporated herein by reference.)
10.12.4+	Fourth Amendment to the Amgen Nonqualified Deferred Compensation Plan, effective January 1, 2024. (Filed as an exhibit to Form 10-K for the year ended December 31, 2023 on February 14, 2024 and incorporated herein by reference.)
10.13+	Aircraft Time Sharing Agreement, dated December 3, 2021, by and between Amgen Inc. and Robert A. Bradway. (Filed as an exhibit to Form 10-K for the year ended December 31, 2021 on February 16, 2022 and incorporated herein by reference.)
10.14+	Agreement between Amgen Inc. and James Bradner, dated December 13, 2023. (Filed as an exhibit to Form 10-K for the year ended December 31, 2023 on February 14, 2024 and incorporated herein by reference.)
10.15	Term Loan Credit Agreement, dated as of December 22, 2022, by and among Amgen Inc., Citibank, N.A., as administrative agent, Bank of America, N.A., as syndication agent, Citibank, N.A., Bank of America, N.A., Goldman Sachs Bank USA and Mizuho Bank, Ltd., as lead arrangers and book runners, Goldman Sachs Bank USA and Mizuho Bank, Ltd. as documentation agents, and the other banks party thereto. (Filed as an exhibit to Form 8-K on December 22, 2022 and incorporated herein by reference.)
10.16	Third Amended and Restated Credit Agreement, dated as of March 9, 2023, among Amgen Inc., the Banks therein named, Citibank, N.A., as Administrative Agent, and JPMorgan Chase Bank, N.A., as Syndication Agent. (Filed as an exhibit to Form 8-K on March 9, 2023 and incorporated herein by reference.)

Exhibit No.	Description
10.17	Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited dated May 10, 2002 (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) and Amendment No. 1, effective June 9, 2003, to Collaboration and License Agreement between Amgen Inc. and Celltech R&D Limited (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2023 on February 14, 2024 and incorporated herein by reference.)
10.17.1	Amendment No. 2 to Collaboration and License Agreement, effective November 14, 2016, between Amgen Inc. and Celltech R&D Limited. (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2023 on February 14, 2024 and incorporated herein by reference.)
10.18	Letter Agreement, dated June 25, 2019, by and between Amgen Inc. and UCB Celltech (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2019 on July 31, 2019 and incorporated herein by reference.)
10.19	Collaboration Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene Switzerland GmbH, a wholly-owned subsidiary of BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.19.1	First Amendment to Collaboration Agreement, dated April 20, 2022, by and between Amgen Inc. and BeiGene Switzerland GmbH, and BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2022 on August 5, 2022 and incorporated herein by reference.)
10.19.2	Second Amendment to Collaboration Agreement, entered into as of February 26, 2023, by and between Amgen Inc. and BeiGene Switzerland GmbH, and BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-Q for the quarter ended March 31, 2023 on April 28, 2023 and incorporated herein by reference.)
10.19.3	Letter Agreement, dated May 9, 2025, by and between Amgen Inc. and BeiGene Switzerland GmbH, a wholly owned subsidiary of BeiGene, Ltd.[1] (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2025 on August 5, 2025 and incorporated herein by reference.)
10.19.4	Letter Agreement, dated August 11, 2025, by and between Amgen Inc. and BeOne Medicines I GmbH and BeOne Medicines Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2025 on November 5, 2025 and incorporated herein by reference.)
10.19.5*	Letter Agreement, dated October 1, 2025, by and between Amgen Inc. and BeOne Medicines I GmbH and BeOne Medicines Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.)
10.19.6*	Third Amendment to Collaboration Agreement, dated October 31, 2025, by and among Amgen Inc., BeOne Medicines I GmbH, and BeOne Medicines Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.)
10.19.7*	Fourth Amendment to Collaboration Agreement, dated November 11, 2025, by and among Amgen Inc., BeOne Medicines I GmbH, and BeOne Medicines Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.)
10.20	Guarantee, dated as of October 31, 2019, made by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-K for the year ended December 31, 2019 on February 12, 2020 and incorporated herein by reference.)
10.21	Share Purchase Agreement, dated October 31, 2019, by and between Amgen Inc. and BeiGene, Ltd. (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed). (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)

Exhibit No.	Description
10.21.1	Amendment No. 1 to Share Purchase Agreement, dated December 6, 2019, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Schedule 13D on January 8, 2020 and incorporated herein by reference.)
10.21.2	Restated Amendment No. 2 to Share Purchase Agreement, dated September 24, 2020, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 10-Q for the quarter ended September 30, 2020 on October 29, 2020 and incorporated herein by reference.)
10.21.3	Amendment No. 3 to Share Purchase Agreement, dated January 30, 2023, by and among BeiGene, Ltd. and Amgen Inc. (Filed as an exhibit to Form 8-K on January 31, 2023 and incorporated herein by reference.)
10.22	Collaboration Agreement dated March 30, 2012 by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, a wholly owned subsidiary of AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2022 on August 5, 2022 and incorporated herein by reference.)
10.22.1	Amendment No. 1 to the Collaboration Agreement, dated October 1, 2014, by and among Amgen Inc., AstraZeneca Collaboration Ventures, LLC and AstraZeneca Pharmaceuticals LP (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2022 on August 5, 2022 and incorporated herein by reference.)
10.22.2	Amendment Nos. 2 through 6 to the March 30, 2012 Collaboration Agreement between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC, dated May 2 and 27 and October 2, 2016, January 31, 2018, and May 15, 2020, respectively (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2020 on July 29, 2020 and incorporated herein by reference.)
10.22.3	Amendment No. 7 to the Collaboration Agreement, dated December 17, 2020, by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC (portions of the exhibit have been omitted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2020 on February 9, 2021 and incorporated herein by reference.)
10.22.4	Amendment No. 8 to the Collaboration Agreement, dated November 19, 2021, by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2021 on February 16, 2022 and incorporated herein by reference.)
10.22.5	Letter Agreement Regarding the Collaboration Agreement, dated as of December 1, 2023, by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-K for the year ended December 31, 2023 on February 14, 2024 and incorporated herein by reference.)
10.22.6	Amendment No. 9 to the Collaboration Agreement, dated May 20, 2025, by and between Amgen Inc. and AstraZeneca Collaboration Ventures, LLC (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential.) (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2025 on August 5, 2025 and incorporated herein by reference.)
10.23	License and Collaboration Agreement, dated June 1, 2021, by and between Amgen Inc. and Kyowa Kirin Co., Ltd.[2] (portions of the exhibit have been omitted because they are both (i) not material and (ii) is the type of information that the Company treats as private or confidential). (Filed as an exhibit to Form 10-Q for the quarter ended June 30, 2021 on August 4, 2021 and incorporated herein by reference.)
19.1	Amgen Inc. Insider Trading Policy. (Filed as an exhibit to Form 10-K for the year ended December 31, 2024 on February 14, 2025 and incorporated herein by reference.)
19.2	Amgen Inc. Securities Transactions Blackout and Pre-Clearance Practices and Procedures. (Filed as an exhibit to Form 10-K for the year ended December 31, 2024 on February 14, 2025 and incorporated herein by reference.)
21*	Subsidiaries of the Company.

Exhibit No.	Description
23	Consent of the Independent Registered Public Accounting Firm. The consent is set forth on page 96 of this Annual Report on Form 10-K.
24	Power of Attorney. The Power of Attorney is set forth on page 97 of this Annual Report on Form 10-K.
31*	Rule 13a-14(a) Certifications.
32**	Section 1350 Certifications.
97	Policy Relating to Recovery of Erroneously Awarded Compensation. (Filed as an exhibit to Form 10-K for the year ended December 31, 2024 on February 14, 2025 and incorporated herein by reference.)
101.INS	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* = filed herewith
** = furnished herewith and not “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended
+ = management contract or compensatory plan or arrangement
[1] In May 2025, BeiGene, Ltd. changed its name to BeOne Medicines Ltd., and BeiGene Switzerland GmbH changed its name to BeOne Medicines I GmbH.
[2] See Significant Developments for additional information regarding the termination of our collaboration agreement with Kyowa Kirin.

Item 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMGEN INC.
(Registrant)

Date: February 13, 2026 By: /s/ PETER H. GRIFFITH

Peter H. Griffith
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-3 No. 333-269670) of Amgen Inc.,
- Registration Statements (Form S-8 Nos. 333-159377 and 333-280155) pertaining to the Amgen Inc. Second Amended and Restated 2009 Equity Incentive Plan,
- Registration Statement (Form S-8 No. 33-39183) pertaining to the Amgen Inc. Amended and Restated Employee Stock Purchase Plan,
- Registration Statements (Form S-8 Nos. 33-39104, 333-144581 and 333-216719) pertaining to the Amgen Retirement and Savings Plan,
- Registration Statements (Form S-8 Nos. 33-47605, 333-144580 and 333-216715) pertaining to The Retirement and Savings Plan for Amgen Manufacturing Limited LLC (formerly known as The Retirement and Savings Plan for Amgen Manufacturing, Limited),
- Registration Statements (Form S-8 Nos. 333-81284, 333-177868, 333-216723 and 333-260723) pertaining to the Amgen Nonqualified Deferred Compensation Plan,
- Registration Statements (Form S-8 Nos. 333-176240 and 333-260724) pertaining to the Amgen Profit Sharing Plan for Employees in Ireland, and
- Registration Statement (Form S-8 No. 333-274900) pertaining to the Horizon Therapeutics Public Limited Company Amended and Restated 2014 Equity Incentive Plan, Horizon Therapeutics Public Limited Company Amended and Restated 2018 Equity Incentive Plan and 2018 Restricted Stock Unit Award Sub-Plan, and Horizon Therapeutics Public Limited Company Amended and Restated 2020 Equity Incentive Plan and 2020 Restricted Stock Unit Award Sub-Plan;

of our reports dated February 13, 2026, with respect to the consolidated financial statements of Amgen Inc. and the effectiveness of internal control over financial reporting of Amgen Inc. included in this Annual Report (Form 10-K) of Amgen Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

Los Angeles, California
February 13, 2026

EXHIBIT 24

POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Robert A. Bradway, Peter H. Griffith and Jonathan P. Graham, or any of them, his or her attorney-in-fact, each with the power of substitution and re-substitution, for him or her in any and all capacities, to sign any amendments to this Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/S/ ROBERT A. BRADWAY **Robert A. Bradway**	Chairman of the Board, Chief Executive Officer and President, and Director (Principal Executive Officer)	2/13/2026
/S/ PETER H. GRIFFITH **Peter H. Griffith**	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	2/13/2026
/S/ MATTHEW C. BUSCH **Matthew C. Busch**	Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)	2/13/2026
/S/ WANDA M. AUSTIN **Wanda M. Austin**	Director	2/13/2026
/S/ MICHAEL V. DRAKE **Michael V. Drake**	Director	2/13/2026
/S/ BRIAN J. DRUKER **Brian J. Druker**	Director	2/13/2026
/S/ ROBERT A. ECKERT **Robert A. Eckert**	Director	2/13/2026
/S/ GREG C. GARLAND **Greg C. Garland**	Director	2/13/2026
/S/ CHARLES M. HOLLEY, JR. **Charles M. Holley, Jr.**	Director	2/13/2026
/S/ S. OMAR ISHRAK **S. Omar Ishrak**	Director	2/13/2026
/S/ TYLER JACKS **Tyler Jacks**	Director	2/13/2026
/S/ MARY E. KLOTMAN **Mary E. Klotman**	Director	2/13/2026
/S/ ELLEN J. KULLMAN **Ellen J. Kullman**	Director	2/13/2026
/S/ AMY E. MILES **Amy E. Miles**	Director	2/13/2026

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Amgen Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Amgen Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes and financial statement schedule listed in the Index at Item 15(a)2 (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 13, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Sales deductions

Description of the Matter

As of December 31, 2025, the Company recorded accrued sales deductions of $10.6 billion. As described in Note 1 to the financial statements under the caption “Product sales and sales deductions,” revenues from product sales are recognized net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively sales deductions), which are established at the time of sale.

Auditing the estimation of sales deductions, specifically estimated chargebacks, commercial rebates, and Medicaid rebates related to U.S. product sales, which are netted against product sales, is complex, requires significant judgment, and the amounts involved are material to the financial statements taken as a whole. Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, and is based on an amount that reflects the consideration to which the Company expects to be entitled, which represents an amount that is net of accruals for estimated sales deductions. The estimated sales deductions are based on current contractual and statutory requirements, market events and trends, internal and external historical data, and forecasted customer buying patterns.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the sales deduction processes. This included testing controls over management’s review of significant assumptions and inputs used in the estimate of sales deductions, including actual sales, contractual terms, historical experience, wholesaler inventory levels, demand data and estimated patient population. We also tested management’s controls over the accuracy of forecasting demand activity as well as the completeness and accuracy of the significant components included in the final sales deduction estimates.

To test management’s estimated sales deductions, we obtained management’s calculations for the respective estimates and performed the following procedures, among others. We tested management’s estimation process over the determination of sales discount accruals by developing an independent expectation of the estimated accrual balances, including comparing accrual balances recorded by management to those implied by historical payment trends, evaluating trends in actual sales and discount accrual balances, testing a sample of credits issued and payments made throughout the year, and agreeing rates to underlying contract terms.

Unrecognized tax benefits

Description of the Matter

As discussed in Notes 1 and 7 to the consolidated financial statements, the Company operates in various jurisdictions in which differing interpretations of complex tax laws and regulations create uncertainty and necessitate the use of significant judgment in the determination of the Company's unrecognized tax benefits, particularly in the U.S. federal tax jurisdiction where the Company has significant assets and operations. In this regard, the Company uses significant judgment in (1) determining whether a tax position's technical merits are more-likely-than-not to be sustained and (2) measuring the amount of tax benefit that qualifies for recognition. As of December 31, 2025, the Company accrued $4.4 billion of gross unrecognized tax benefits. Auditing the assessment of the technical merits and measurement of the Company's unrecognized tax benefits is challenging due to the high degree of estimation and management judgment, given the ultimate resolution is dependent on uncontrollable factors such as the resolution of audit disputes with the IRS and results of the U.S. Tax Court case.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the Company's process to assess the technical merits of its tax positions, as well as management's process to measure the unrecognized tax benefits of those tax positions, particularly in regard to matters in dispute with the IRS. This included testing controls over management's review of the inputs, calculations, assumptions and methods selected to measure the amount of tax benefits that qualify for recognition.

We involved tax controversy and transfer pricing subject matter professionals to assist in assessing the technical merits and measurement of certain of the Company's unrecognized tax benefits. Depending on the nature of the specific tax position and, as applicable, developments with the relevant tax authorities, our procedures included obtaining and reviewing the Company's correspondence with such tax authorities and evaluating certain third-party advice to support the Company's evaluations and recorded positions. We evaluated the status of the ongoing U.S. Tax Court case and developments in the applicable regulatory environments to assess potential effects on the Company's recorded positions. We assessed management's consideration of current tax controversy, litigation and tax litigation trends. We analyzed the assumptions and data used by the Company when it determined the amount of tax benefits to recognize, including applicable interest and penalties, and we tested the accuracy of those underlying calculations. We have also evaluated the Company's income tax disclosures included in Note 7 in relation to these matters.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1980.
Los Angeles, California
February 13, 2026

AMGEN INC.

CONSOLIDATED STATEMENTS OF INCOME

Years ended December 31, 2025, 2024 and 2023

(In millions, except per-share data)

	2025	2024	2023
Revenues:			
Product sales	$ 35,148	$ 32,026	$ 26,910
Other revenues	1,603	1,398	1,280
Total revenues	36,751	33,424	28,190
Operating expenses:			
Cost of sales	12,037	12,858	8,451
Research and development	7,272	5,964	4,784
Selling, general and administrative	7,050	7,096	6,179
Other	1,312	248	879
Total operating expenses	27,671	26,166	20,293
Operating income	9,080	7,258	7,897
Other income (expense):			
Interest expense, net	(2,755)	(3,155)	(2,875)
Other income, net	2,651	506	2,833
Income before income taxes	8,976	4,609	7,855
Provision for income taxes	1,265	519	1,138
Net income	$ 7,711	$ 4,090	$ 6,717
Earnings per share:			
Basic	$ 14.33	$ 7.62	$ 12.56
Diluted	$ 14.23	$ 7.56	$ 12.49
Weighted-average shares used in the calculation of earnings per share:			
Basic	538	537	535
Diluted	542	541	538

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

Years ended December 31, 2025, 2024 and 2023

(In millions)

	2025	2024	2023
Net income	$ 7,711	$ 4,090	$ 6,717
Other comprehensive (loss) income, net of reclassification adjustments and taxes:			
Gains (losses) on foreign currency translation adjustments	172	(76)	50
(Losses) gains on cash flow hedges	(377)	309	(150)
Other	13	(10)	42
Other comprehensive (loss) income, net of reclassification adjustments and taxes	(192)	223	(58)
Comprehensive income	$ 7,519	$ 4,313	$ 6,659

See accompanying notes.

AMGEN INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2025 and 2024

(In millions, except per-share data)

	2025	2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,129	$ 11,973
Trade receivables, net	9,570	6,782
Inventories	6,225	6,998
Other current assets	4,133	3,277
Total current assets	29,057	29,030
Property, plant and equipment, net	7,913	6,543
Intangible assets, net	22,276	27,699
Goodwill	18,680	18,637
Other noncurrent assets	12,660	9,930
Total assets	$ 90,586	$ 91,839
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,367	$ 1,908
Accrued liabilities	18,523	17,641
Current portion of long-term debt	4,599	3,550
Total current liabilities	25,489	23,099
Long-term debt	50,005	56,549
Long-term deferred tax liabilities	1,366	1,616
Long-term tax liabilities	2,690	2,349
Other noncurrent liabilities	2,378	2,349
Contingencies and commitments (see Note 20)		
Stockholders' equity:		
Common stock and additional paid-in capital; $0.0001 par value per share; 2,750.0 shares authorized; outstanding—538.8 shares in 2025 and 536.9 shares in 2024	34,023	33,533
Accumulated deficit	(25,107)	(27,590)
Accumulated other comprehensive loss	(258)	(66)
Total stockholders' equity	8,658	5,877
Total liabilities and stockholders' equity	$ 90,586	$ 91,839

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Years ended December 31, 2025, 2024 and 2023

(In millions, except per-share data)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
Balance as of December 31, 2022	534.0	$ 32,514	$ (28,622)	$ (231)	$ 3,661
Net income	—	—	6,717	—	6,717
Other comprehensive loss, net of taxes	—	—	—	(58)	(58)
Dividends declared on common stock ($8.64 per share)	—	—	(4,644)	—	(4,644)
Issuance of common stock in connection with equity award programs	1.4	95	—	—	95
Stock-based compensation expense	—	454	—	—	454
Equity awards issued for Horizon acquisition, net	—	141	—	—	141
Tax impact related to employee stock-based compensation expense	—	(134)	—	—	(134)
Balance as of December 31, 2023	535.4	33,070	(26,549)	(289)	6,232
Net income	—	—	4,090	—	4,090
Other comprehensive income, net of taxes	—	—	—	223	223
Dividends declared on common stock ($9.13 per share)	—	—	(4,931)	—	(4,931)
Issuance of common stock in connection with equity award programs	2.2	189	—	—	189
Stock-based compensation expense	—	530	—	—	530
Tax impact related to employee stock-based compensation expense	—	(256)	—	—	(256)
Repurchases of common stock	(0.7)	—	(200)	—	(200)
Balance as of December 31, 2024	536.9	33,533	(27,590)	(66)	5,877
Net income	—	—	7,711	—	7,711
Other comprehensive loss, net of taxes	—	—	—	(192)	(192)
Dividends declared on common stock ($9.66 per share)	—	—	(5,228)	—	(5,228)
Issuance of common stock in connection with equity award programs	1.9	191	—	—	191
Stock-based compensation expense	—	494	—	—	494
Tax impact related to employee stock-based compensation expense	—	(195)	—	—	(195)
Balance as of December 31, 2025	538.8	$ 34,023	$ (25,107)	$ (258)	$ 8,658

See accompanying notes.

AMGEN INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2025, 2024 and 2023

(In millions)

	2025	2024	2023
Cash flows from operating activities:			
Net income	$ 7,711	$ 4,090	$ 6,717
Noncash adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation, amortization and other	5,167	5,592	4,071
Impairment of intangible assets	1,200	159	851
Stock-based compensation expense	494	530	431
Deferred income taxes	(721)	(1,228)	(1,273)
(Gains) losses on equity securities	(2,064)	159	(1,565)
Other items, net	149	(177)	(277)
Changes in operating assets and liabilities, net of acquisitions:			
Trade receivables, net	(2,676)	441	(1,015)
Inventories	886	2,532	491
Other assets	(1,267)	(652)	(564)
Accounts payable	428	312	(402)
Accrued income taxes, net	(2,068)	(1,011)	(1,031)
Long-term tax liabilities	311	(492)	371
Accrued liabilities	499	92	953
Accrued sales incentives and allowance	2,065	1,194	935
Other liabilities	(156)	(51)	(222)
Net cash provided by operating activities	9,958	11,490	8,471
Cash flows from investing activities:			
Cash paid for acquisitions, net of cash acquired	(53)	—	(26,989)
Proceeds from sales of marketable securities	—	—	1,123
Proceeds from maturities of marketable securities	—	—	550
Purchases of property, plant and equipment	(1,858)	(1,096)	(1,112)
Other	(32)	50	224
Net cash used in investing activities	(1,943)	(1,046)	(26,204)
Cash flows from financing activities:			
Net proceeds from issuance of debt	—	—	27,777
Extinguishment of debt	(683)	(659)	(647)
Repayment of debt	(5,000)	(3,600)	(1,454)
Repurchases of common stock	—	(200)	—
Dividends paid	(5,124)	(4,832)	(4,556)
Other	(52)	(124)	(72)
Net cash (used in) provided by financing activities	(10,859)	(9,415)	21,048
(Decrease) increase in cash and cash equivalents	(2,844)	1,029	3,315
Cash and cash equivalents at beginning of year	11,973	10,944	7,629
Cash and cash equivalents at end of year	$ 9,129	$ 11,973	$ 10,944

See accompanying notes.

AMGEN INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2025

1. Summary of significant accounting policies

Business

Amgen Inc. (including its consolidated subsidiaries, referred to as "Amgen," "the Company," "we," "our" or "us") is a global biotechnology pioneer that discovers, develops, manufactures and delivers innovative human therapeutics. We operate our business in one operating segment: human therapeutics. See Note 2, Segment and other information.

Principles of consolidation

The consolidated financial statements include the accounts of Amgen and its majority-owned subsidiaries. In determining whether we are the primary beneficiary of a variable interest entity, we consider whether we have both the power to direct activities of the entity that most significantly impact the entity's economic performance and the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity. We do not have any significant interests in any variable interest entities of which we are the primary beneficiary. All material intercompany transactions and balances have been eliminated in consolidation. Certain reclassifications have been made to prior periods in the consolidated financial statements and accompanying notes to conform with the current presentation.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Revenues

Product sales and sales deductions

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expect to be entitled, net of accruals for estimated rebates, wholesaler chargebacks, discounts and other deductions (collectively, sales deductions) and returns established at the time of sale.

We analyze the adequacy of our accruals for sales deductions quarterly. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that an adjustment is appropriate. Accruals are also adjusted to reflect actual results. Accruals for sales deductions are based primarily on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual and statutory requirements, specific known market events and trends, internal and external historical data and forecasted customer buying patterns. Sales deductions are substantially product specific and therefore, for any given period, can be affected by the mix of products sold. Included in sales deductions are immaterial net adjustments related to prior-period sales due to changes in estimates.

Returns are estimated through comparison of historical return data with their related sales on a production lot basis. Historical rates of return are determined for each product and are adjusted for known or expected changes in the marketplace specific to each product, when appropriate. Historically, sales return provisions have amounted to less than 1% of gross product sales. Changes in estimates for prior-period sales return provisions have historically been immaterial.

Our payment terms vary by types and locations of customers and by products or services offered. Payment terms differ by jurisdiction and customer, but payment is generally required in a term ranging from 30 to 120 days from date of shipment or satisfaction of the performance obligation. For certain products or services and certain customer types, we may require payment before products are delivered or services are rendered to customers.

Indirect taxes collected from customers and remitted to government authorities that are related to sales of the Company's products, primarily in Europe, are excluded from revenues.

As a practical expedient, sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in SG&A expense in the Consolidated Statements of Income.

Other revenues

Other revenues consist primarily of royalty income and corporate partner revenues. Royalties from licensees are based on third-party sales of licensed products and are recorded when the related third-party product sale occurs. Royalty income is estimated based on historical and forecasted sales trends. Corporate partner revenues are composed mainly of license fees and milestones earned and our share of commercial profits generated from collaborations. See Arrangements with multiple-performance obligations, discussed below.

Arrangements with multiple-performance obligations

From time to time, we enter into arrangements for the R&D, manufacture and/or commercialization of products and product candidates. Such arrangements may require us to deliver various rights, services and/or goods, including intellectual property rights/licenses, R&D services, manufacturing services and/or commercialization services. The underlying terms of these arrangements generally provide for consideration to Amgen in the form of nonrefundable, upfront license fees; development and commercial-performance milestone payments; royalty payments; and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or by using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods or services is transferred. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. We utilize the sales- and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

Research and development costs

R&D costs are expensed as incurred and primarily include salaries, benefits and other staff-related costs; facilities and overhead costs; clinical trial and related clinical manufacturing costs; contract services and other outside costs; information systems' costs; and amortization of acquired technology used in R&D with alternative future uses. R&D expenses also include costs and cost recoveries associated with third-party R&D arrangements, including upfront fees and milestones paid to third parties in connection with technologies that had not reached technological feasibility and did not have an alternative future use. Net payment or reimbursement of R&D costs is recognized when the obligations are incurred or as we become entitled to the cost recovery. See Note 9, Collaborations.

Selling, general and administrative costs

SG&A costs are primarily composed of salaries, benefits and other staff-related costs associated with sales and marketing, finance, legal and other administrative personnel; facilities and overhead costs; outside marketing, advertising and legal expenses; the U.S. healthcare reform federal excise fee on Branded Prescription Pharmaceutical Manufacturers and Importers; and other general and administrative costs. Advertising costs are expensed as incurred and were $963 million, $987 million and $647 million during the years ended December 31, 2025, 2024 and 2023, respectively. SG&A expenses also include costs and cost recoveries associated with marketing and promotion efforts under certain collaborative arrangements. Net payment or reimbursement of SG&A costs is recognized when the obligations are incurred or we become entitled to the cost recovery. See Note 9, Collaborations.

Leases

At inception of a contract, we determine whether an arrangement is or contains a lease. For all leases, we determine the classification as either operating or financing. Operating leases are included in Other noncurrent assets, Accrued liabilities and Other noncurrent liabilities in our Consolidated Balance Sheets.

ROU assets represent our right to use an underlying asset for the lease term, and lease liabilities represent our obligation to make lease payments under the lease. Lease recognition occurs at the commencement date, and lease liability amounts are based on the present value of lease payments made during the lease term. Our lease terms may include options to extend or terminate a lease when it is reasonably certain that we will exercise that option. Because most of our leases do not provide information to determine an implicit interest rate, we use our incremental borrowing rate in determining the present value of

lease payments. ROU assets also include any lease payments made prior to the commencement date less lease incentives received. Operating lease expense is recognized on a straight-line basis over the lease term.

We have lease agreements with both lease and nonlease components, which are generally accounted for together as a single lease component. In addition, for certain vehicle and equipment leases, we apply a portfolio approach to determine the lease term and discount rate.

Stock-based compensation

We have stock-based compensation plans under which various types of equity-based awards are granted, including RSUs, performance units and stock options. The fair values of RSUs and stock option awards, which are subject only to service conditions with graded vesting, are recognized as compensation expense, generally on a straight-line basis over the service period, net of estimated forfeitures. The fair values of performance unit awards are recognized as compensation expense, generally on a straight-line basis from the grant date to the end of the performance period. See Note 5, Stock-based compensation.

Income taxes

We provide for income taxes based on pretax income and applicable tax rates in the various jurisdictions in which we operate. Significant judgment is required in determining our provision for income taxes and income tax assets and liabilities, including evaluating uncertainties in the application of accounting principles and complex tax laws. Deferred income taxes are recorded for the expected tax consequences of temporary differences between the bases of assets and liabilities, as well as for loss and tax credit carryforwards for financial reporting purposes and amounts recognized for income tax purposes. We record a valuation allowance to reduce our deferred tax assets to the amount of future tax benefit that is more likely than not to be realized.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by tax authorities based on the technical merits of the position. The tax benefit recognized in the consolidated financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of UTBs is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by tax authorities, new information obtained during a tax examination or resolution of an examination. We recognize both accrued interest and penalties, when appropriate, related to UTBs in income tax expense. See Note 7, Income taxes.

Amgen is subject to current U.S. tax on the earnings of our foreign subsidiaries. We previously established deferred taxes related to this U.S. tax, which requires us to recognize deferred taxes for temporary basis differences expected to reverse and be subject to this tax in future years. These are ongoing adjustments that are likely to occur in future periods.

Acquisitions

We first determine whether a set of assets acquired constitutes a business and should be accounted for as a business combination. If the assets acquired do not constitute a business, we account for the transaction as an asset acquisition. Business combinations are accounted for by means of the acquisition method of accounting. Under the acquisition method, assets acquired, including IPR&D projects, and liabilities assumed are recorded in our consolidated financial statements at their respective fair values as of the acquisition date. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with a business combination, including the assumption of an acquiree's liability arising from an acquisition it consummated prior to our acquisition, are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies have been resolved. The resulting changes in fair values are recorded in earnings. In contrast, asset acquisitions are accounted for by using a cost accumulation and allocation model. Under this model, the cost of the acquisition is allocated to the assets acquired and liabilities assumed. IPR&D projects with no alternative future use are recorded in R&D expense upon acquisition, and contingent consideration obligations incurred in connection with an asset acquisition are recorded when it is probable that they will occur and they can be reasonably estimated. See Note 4, Acquisition, and Note 18, Fair value measurement.

Cash equivalents

We consider cash equivalents to be only those investments that are highly liquid, that are readily convertible to cash and that mature within three months from the date of purchase.

Interest-bearing securities

We consider our interest-bearing securities investment portfolio as available-for-sale, and accordingly, these investments are recorded at fair value, with unrealized gains and losses recorded in AOCI. Investments with maturities beyond one year may be classified as short-term marketable securities in the Consolidated Balance Sheets due to their highly liquid nature and because they represent the Company's investments that are available for current operations. See Note 10, Investments, and Note 18, Fair value measurement.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner that approximates the first-in, first-out method. Net realizable value is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. See Note 11, Inventories.

Derivatives

We recognize all of our derivative instruments as either assets or liabilities at fair value in the Consolidated Balance Sheets. The accounting for changes in the fair value of a derivative instrument depends on whether the derivative has been formally designated and qualifies as part of a hedging relationship under the applicable accounting standards and, further, on the type of hedging relationship. For derivatives formally designated as hedges, we assess both at inception and quarterly thereafter whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item. Our derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings. See Note 18, Fair value measurement, and Note 19, Derivative instruments.

Property, plant and equipment, net

Property, plant and equipment is recorded at historical cost, net of accumulated depreciation, amortization and, if applicable, impairment charges. We review our property, plant and equipment assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Depreciation is recorded over the assets' useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or lease terms. See Note 12, Property, plant and equipment.

Cloud computing arrangements

We capitalize qualifying implementation costs under cloud computing arrangements (CCA). Capitalized CCA implementation costs are allocated between Other current assets and Other noncurrent assets in the Consolidated Balance Sheets. As of December 31, 2025 and 2024, capitalized CCA implementation costs totaled $272 million and $227 million, respectively. For critical software-as-a-service (SaaS) platforms, amortization is recorded over an established four-year period, and for all other arrangements, amortization is recorded over the expected term of the related contract.

Goodwill and other intangible assets

Finite-lived intangible assets are recorded at cost, net of accumulated amortization and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recorded over the assets' estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See Note 13, Goodwill and other intangible assets.

The fair values of IPR&D projects acquired in a business combination that are not complete are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related R&D efforts. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written off immediately. Major risks and uncertainties are often associated with IPR&D projects because we are required to obtain regulatory approvals before marketing the resulting products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods.

Capitalized IPR&D projects are reviewed for impairment annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. We consider various factors for potential impairment, including the current legal and regulatory environment and the competitive landscape. Adverse clinical trial results, significant delays in obtaining marketing approval, the inability to bring a product to market and the introduction or advancement of competitors' products could result in partial or full impairment of the related intangible assets.

We perform an impairment test of goodwill annually and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. To date, an impairment of goodwill has not been recorded. See Note 13, Goodwill and other intangible assets.

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. Certain of these proceedings are discussed in Note 20, Contingencies and commitments. We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Foreign currency translation

The net assets of international subsidiaries whose functional currencies are not in U.S. dollars are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translation of the net assets of these subsidiaries at changing rates are recognized in AOCI. The subsidiaries' earnings are translated into U.S. dollars by using average exchange rates.

Equity investments

Marketable and nonmarketable equity securities

Investments in publicly traded equity securities with readily determinable fair values are recorded at quoted market prices for identical securities, with changes in fair value recorded in Other income, net, in the Consolidated Statements of Income. Investments in equity securities without readily determinable fair values are recorded at cost less impairment, if any, adjusted for changes resulting from observable price changes in orderly transactions for identical or similar securities. Such adjustments are recorded in Other income, net, in the Consolidated Statements of Income.

Equity method investments

Equity investments that give us the ability to exert significant influence, but not control, over an investee are accounted for under the equity method of accounting, unless we have elected the fair value option. For equity method investments for which the fair value option has been elected, changes in fair value are recorded in Other income, net, in the Consolidated Statements of Income.

Additionally, we hold investments in limited partnerships, which primarily invest in early-stage biotechnology companies. As a practical expedient, such limited partnership investments are measured by using our proportionate share of the net asset values of the underlying investments held by the limited partnerships, with such changes included in Other income, net, in the Consolidated Statements of Income.

Recently adopted accounting pronouncements

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, to improve income tax disclosure requirements by requiring more detailed information in several income tax disclosures, such as enhancing disclosure of income taxes paid and requiring disaggregation of the effective income tax rate reconciliation. The standard is effective for public business entities such as Amgen for annual periods beginning after December 15, 2024. Early adoption is permitted, and entities may apply the standard prospectively or retrospectively. We prospectively adopted this standard in fiscal year 2025, which resulted in incremental income taxes disclosures. See Note 7, Income taxes.

Recent accounting pronouncements not yet adopted

In November 2024, the FASB issued ASU No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, to improve disclosures about a public business entity's expenses by requiring disaggregated disclosures of certain types of expenses, including purchases of inventory, employee compensation, depreciation, intangible amortization and depletion, as applicable, for each income statement caption that includes those expenses. In addition, the standard will require entities to define and disclose total selling expenses. The standard is effective for public business entities such as Amgen for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027. Early adoption is permitted, and entities may apply the standard prospectively or retrospectively. We are currently evaluating the impact of adopting this standard on our consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU No. 2025-06, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software, to modernize the accounting for software costs, including updating guidance on the recognition and measurement of costs incurred in connection with development and implementation activities related to internal-use software. The standard is effective for all entities for annual periods beginning after December 15, 2027, and interim periods within those annual periods. Early adoption is permitted, and entities may apply the standard prospectively or retrospectively. We evaluated the impact of adopting this new standard on our consolidated financial statements and related disclosures and do not expect the adoption to have a material impact.

2. Segment and other information

We operate our business in one operating segment, which also represents one reportable segment: human therapeutics. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting.

The human therapeutics segment is engaged in the discovery, development, manufacturing and delivery of innovative medicines to fight some of the world's toughest diseases. The Company's Chief Executive Officer has been identified as the chief operating decision maker (CODM). The CODM manages and allocates resources on a consolidated basis. The determination of a single segment is consistent with the financial information regularly reviewed by the CODM for purposes of evaluating performance and allocating resources, which is reviewed on a consolidated basis.

As the Company's CODM evaluates the financial performance of the Company's human therapeutics segment on a consolidated basis, the measure of segment performance is net income, as reflected in the Consolidated Statements of Income. The CODM uses net income to allocate resources on a consolidated basis, which enables the CODM to assess both the overall level of resources available and optimize distribution of resources across functions, therapeutic areas, regions and R&D programs in line with our long-term corporate-wide strategic goals. In addition, the CODM may also evaluate financial performance based on net income adjusted for certain items that are unusual and non-recurring. As the Company manages its assets on a consolidated basis, the measure of segment assets is total assets, as reflected in the Consolidated Balance Sheets. See Note 10, Investments, for further information regarding equity method investments, and Net cash used in investing activities in the Consolidated Statements of Cash Flows for further information regarding capital expenditures.

The following table provides segment revenues, significant segment expenses, other segment items and reported segment net income for the Company's one reportable segment, as well as a reconciliation of segment net income to the Company's total consolidated net income for the years ended December 31, 2025, 2024 and 2023 (in millions):

	Years ended December 31,		
	2025	2024	2023
Revenues:			
Product sales	$ 35,148	$ 32,026	$ 26,910
Other revenues	1,603	1,398	1,280
Total revenues	36,751	33,424	28,190
Less:			
Manufacturing cost of sales[1][2]	9,845	11,118	7,347
Profit share and royalties in cost of sales[1]	2,192	1,740	1,104
Research and development[1]	7,272	5,964	4,784
Sales and marketing[1]	4,590	4,713	3,784
General and administrative[1]	2,460	2,383	2,395
Other segment items[3]	(931)	252	(729)
Interest income	(408)	(510)	(1,225)
Interest expense, net	2,755	3,155	2,875
Provision for income taxes	1,265	519	1,138
Segment net income	7,711	4,090	6,717
Reconciliation of profit or loss:			
Adjustments and reconciling items	—	—	—
Consolidated net income	$ 7,711	$ 4,090	$ 6,717

[1] During the years ended December 31, 2025, 2024 and 2023, we recognized amortization expense on our intangible assets of $4.3 billion, $4.8 billion and $3.2 billion, respectively. Amortization of intangible assets is primarily included in Cost of sales in the Consolidated Statements of Income. In addition, during the years ended December 31, 2025, 2024 and 2023, we recognized depreciation and ROU asset amortization expense of $887 million, $805 million and $824 million, respectively.

[2] During the years ended December 31, 2025, 2024 and 2023, manufacturing cost of sales included amortization of step-up to fair value of inventory acquired in business combinations of $1.3 billion, $2.4 billion and $656 million, respectively.

[3] Other segment items included in Segment net income primarily consists of: (i) fair value adjustments on equity securities (see Note 10, Investments); (ii) net impairment charges on intangible assets (see Note 13, Goodwill and other intangible assets); and (iii) expenses related to restructuring and cost-savings initiatives.

3. Revenues

We operate our business in one operating segment, which also represents one reportable segment: human therapeutics. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Revenues by product and by geographic area, based on customers' locations, are presented below. A substantial portion of ROW product sales relates to products sold in Europe.

Revenues were as follows (in millions):

	Year ended December 31, 2025			Year ended December 31, 2024			Year ended December 31, 2023		
	U.S.	ROW	Total	U.S.	ROW	Total	U.S.	ROW	Total
Prolia	$ 2,978	$ 1,436	$ 4,414	$ 2,885	$ 1,489	$ 4,374	$ 2,733	$ 1,315	$ 4,048
Repatha	1,663	1,353	3,016	1,139	1,083	2,222	793	842	1,635
Otezla	1,839	426	2,265	1,699	427	2,126	1,777	411	2,188
ENBREL	2,199	27	2,226	3,288	28	3,316	3,650	47	3,697
EVENITY	1,600	500	2,100	1,131	432	1,563	809	351	1,160
XGEVA	1,355	729	2,084	1,507	718	2,225	1,527	585	2,112
TEPEZZA[1]	1,758	145	1,903	1,835	16	1,851	441	7	448
BLINCYTO	1,049	510	1,559	800	416	1,216	566	295	861
Nplate	1,027	497	1,524	970	486	1,456	996	481	1,477
TEZSPIRE [2]	1,478	—	1,478	972	—	972	567	—	567
KYPROLIS	913	499	1,412	948	555	1,503	921	482	1,403
Aranesp	416	973	1,389	386	956	1,342	452	910	1,362
KRYSTEXXA[1]	1,340	—	1,340	1,185	—	1,185	272	—	272
Vectibix	604	571	1,175	519	526	1,045	461	523	984
Other products[3]	5,437	1,826	7,263	4,037	1,593	5,630	3,307	1,389	4,696
Total product sales[4]	25,656	9,492	35,148	23,301	8,725	32,026	19,272	7,638	26,910
Other revenues	763	840	1,603	562	836	1,398	534	746	1,280
Total revenues	$ 26,419	$ 10,332	$ 36,751	$ 23,863	$ 9,561	$ 33,424	$ 19,806	$ 8,384	$ 28,190

(1) TEPEZZA and KRYSTEXXA were acquired from the acquisition of Horizon on October 6, 2023, and include product sales in the periods after the acquisition date.

(2) TEZSPIRE is marketed by our collaborator AstraZeneca outside the United States.

(3) Consists of product sales of our non-principal products.

(4) Hedging gains and losses, which are included in product sales, were not material for the years ended December 31, 2025, 2024 and 2023.

In the United States, we sell primarily to pharmaceutical wholesale distributors that we use as the principal means of distributing our products to healthcare providers. Outside the United States, we sell principally to healthcare providers and/or pharmaceutical wholesale distributors depending on the distribution practice in each country. We monitor the financial condition of our larger customers and limit our credit exposure by setting credit limits and, in certain circumstances, by requiring letters of credit or obtaining credit insurance.

For each of the years ended December 31, 2025, 2024 and 2023, we had product sales to three customers that individually accounted for more than 10% of total revenues. For the year ended December 31, 2025, on a combined basis, these customers accounted for 77% of total gross revenues as shown in the following table. Certain information with respect to these customers was as follows (dollar amounts in millions):

	Years ended December 31,		
	2025	2024	2023
McKesson Corporation:			
Gross product sales	$ 26,253	$ 22,173	$ 19,035
% of total gross revenues	34 %	33 %	33 %
Cencora, Inc.:			
Gross product sales	$ 20,986	$ 18,387	$ 16,625
% of total gross revenues	27 %	27 %	29 %
Cardinal Health, Inc.:			
Gross product sales	$ 12,562	$ 11,278	$ 9,775
% of total gross revenues	16 %	17 %	17 %

As of December 31, 2025 and 2024, amounts due from these three customers each exceeded 10% of gross trade receivables and accounted for 75% and 70%, respectively, of net trade receivables on a combined basis. As of December 31, 2025 and 2024, 21% and 26%, respectively, of net trade receivables were due from customers located outside the United States, the majority of which were from Europe. Our total allowance for doubtful accounts as of December 31, 2025 and 2024, was not material.

4. Acquisition

Acquisition of Horizon Therapeutics plc

On October 6, 2023, Amgen completed its acquisition of Horizon by acquiring all of the outstanding shares of Horizon for $116.50 per share in cash, representing a total consideration of approximately $27.8 billion. Horizon is a global biotechnology company focused on the discovery, development and commercialization of medicines that address critical needs of patients impacted by rare, autoimmune and severe inflammatory diseases. The acquisition, which was accounted for as a business combination, aligns with Amgen's core strategy of delivering innovative medicines that make a significant difference for patients suffering from serious diseases and strengthens Amgen's leading rare disease portfolio by adding first-in-class, early-in-lifecycle medicines, including TEPEZZA for TED, KRYSTEXXA for chronic refractory gout and UPLIZNA for neuromyelitis optica spectrum disorder. Upon its acquisition, Horizon became a wholly owned subsidiary of Amgen, and its operations have been included in our consolidated financial statements commencing on the acquisition date.

During the year ended December 31, 2024, the purchase price allocation of the acquisition was completed and measurement period adjustments were finalized, which included changes to the purchase price allocation that resulted in a net increase of approximately $25 million to goodwill. The measurement period adjustments resulted primarily from adjustments to acquired assets and liabilities, including deferred tax attributes, based on facts and circumstances that existed as of the acquisition date and did not result from events subsequent to the acquisition date. The adjustments did not have a significant impact on Amgen's results of operations during the year ended December 31, 2024, and would not have had a significant impact on prior-period results if the adjustments had been made as of the acquisition date.

The following table summarizes the final total consideration and allocated acquisition date fair values of assets acquired and liabilities assumed, inclusive of measurement-period adjustments (in millions):

Cash and cash equivalents	$	681
Inventories		5,014
Property, plant and equipment, net		318
Finite-lived intangible assets—developed-product-technology rights		19,590
IPR&D		1,060
Goodwill		3,136
Deferred tax asset		795
Deferred tax liability		(2,488)
Other assets and liabilities, net		(273)
Total assets acquired, net of liabilities assumed	$	27,833

The $27.8 billion total consideration for this transaction consisted of (i) cash consideration transferred to common shareholders of $26.7 billion; (ii) cash consideration transferred to vested and outstanding options, outstanding RSU awards and outstanding performance share unit awards of $523 million; (iii) fair value of Amgen replacement awards (based on conversion of outstanding employee RSU awards) of $180 million representing noncash consideration; and (iv) a portion of Horizon's debt, settled by Amgen on the acquisition closing date, of $382 million. Amgen issued 1.7 million replacement equity awards with the original vesting conditions, the fair value of which was determined based on the acquisition date fair value based on the conversion calculation. See Note 5, Stock-based compensation.

The estimated fair values of $20.7 billion for the developed-product-technology rights and IPR&D intangible assets were determined using a multi-period excess earnings income approach that discounts expected future cash flows to present value by applying a discount rate that represents the estimated rate that market participants would use to value the intangible assets. The projected cash flows were based on certain assumptions attributable to the respective intangible asset, including estimates of future revenues and expenses, the time and resources needed to complete development and the probabilities of obtaining marketing approval from the FDA and other regulatory agencies. The developed-product-technology rights are being amortized on a straight-line basis over a weighted-average period of approximately 10 years from the acquisition date using the straight-line methodology.

The estimated fair value of the acquired inventory of $5.0 billion was determined using the comparative sales method, which uses actual or expected selling prices of inventory as the base amount to which adjustments for selling effort and a profit on the buyer's effort are applied. The inventory fair value adjustment is being amortized using a weighted-average inventory turnover, which we estimate to approximate 27 months from the acquisition date.

A deferred tax liability of $2.5 billion was recognized on the temporary differences related to the book bases and tax bases of the acquired identifiable assets and assumed liabilities, primarily driven by the intangible assets acquired, as well as associated deferred tax asset for anticipatory foreign tax credits of $795 million.

The excess of the acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $3.1 billion was recorded as goodwill, which is not deductible for tax purposes. The goodwill value represents expected synergies from the marketed products acquired and other benefits.

During the three months ended December 31, 2023, the Company incurred approximately $487 million of acquisition costs related to the closing of our Horizon acquisition, consisting of $167 million for share-based payments to settle non-vested equity awards attributable to post-combination services, severance and other employee-related expenses and $320 million for transaction costs. These costs were included primarily in SG&A expense in the Consolidated Statements of Income.

Supplemental Pro Forma Financial Information

The following table presents the unaudited supplemental pro forma results of a hypothetical combined Amgen and Horizon entity for the years ended December 31, 2023 and 2022, as if the acquisition of Horizon had occurred on January 1, 2022 (in millions):

	Years ended December 31,	
	2023	2022
Total revenues	$ 30,969	$ 29,964
Net income	$ 5,383	$ 2,381

The unaudited supplemental pro forma combined financial information was prepared using the acquisition method of accounting and was based on the historical financial information of Amgen and Horizon. In order to reflect the occurrence of the acquisition on January 1, 2022, the unaudited supplemental pro forma financial information includes adjustments to reflect: (i) incremental amortization expense based on the fair values of the identifiable intangible assets and inventory step-up; (ii) the additional interest expense associated with the issuance of debt to finance the acquisition; (iii) the reclassification of transaction and other acquisition-related costs incurred during the three months ended December 31, 2023, to the year ended December 31, 2022; and (iv) the income tax impact using an estimated effective tax rate applied to the combined entity. The unaudited supplemental pro forma financial information is not necessarily indicative of what the consolidated results of operations would have been had the acquisition been completed on January 1, 2022. In addition, the unaudited pro forma financial information is not a projection of future results of operations of the combined company, nor does it reflect the expected realization of any synergies or cost savings associated with the acquisition.

5. Stock-based compensation

Our Amended 2009 Plan authorizes for issuance to employees of Amgen and nonemployee members of our Board of Directors shares of our common stock pursuant to grants of equity-based awards, including RSUs, stock options and performance units. The pool of shares available under the Amended 2009 Plan is reduced by one share for each stock option granted and by 1.9 shares for other types of awards granted, including full-value awards. In general, if any shares subject to an award granted under the Amended 2009 Plan expire or become forfeited, terminated or canceled without the issuance of shares, the shares subject to such awards are added back into the authorized pool on the same basis that they were removed. In addition, under the Amended 2009 Plan, shares withheld to pay for minimum statutory tax obligations with respect to full-value awards are added back into the authorized pool on the basis of 1.9 shares. As of December 31, 2025, the Amended 2009 Plan provides for future grants and/or issuances of up to approximately 35 million shares of our common stock. Stock-based awards under our employee compensation plans are made with newly issued shares reserved for this purpose.

The following table reflects the components of stock-based compensation expense recognized in our Consolidated Statements of Income (in millions):

	Years ended December 31,		
	2025	2024	2023
RSUs	$ 333	$ 351	$ 309
Performance units	112	133	121
Stock options	49	46	43
Total stock-based compensation expense, pretax	494	530	473
Tax benefit from stock-based compensation expense	(106)	(114)	(102)
Total stock-based compensation expense, net of tax	$ 388	$ 416	$ 371

Restricted stock units and stock options

Eligible employees generally receive an annual grant of RSUs and, for certain executive-level employees, stock options, with the size and type of award generally determined by the employee's salary grade and performance level. Certain management and professional-level employees typically receive RSU grants upon commencement of employment. Nonemployee members of our Board of Directors also receive an annual grant of RSUs.

Our RSU and stock option grants provide for accelerated or continued vesting in certain circumstances as defined in the plans and related grant agreements, including upon death, disability, termination in connection with a change in control and the retirement of employees who meet certain service and/or age requirements. For awards granted prior to April 1, 2025, RSUs and stock options generally vest in equal amounts on the second, third and fourth anniversaries of the grant date. Effective for awards granted on or after April 1, 2025, RSUs and stock options generally vest in equal amounts on the first, second, third and fourth anniversaries of the grant date. RSUs accrue dividend equivalents, which are typically payable in shares only when and to the extent the underlying RSUs vest and are issued to the recipient.

Restricted stock units

The grant date fair value of an RSU equals the closing price of our common stock on the grant date, as RSUs accrue dividend equivalents during their vesting period, except with respect to certain holders of Horizon unvested RSUs who were granted replacement Amgen RSUs in 2023 under the original terms of the awards in connection with the Horizon acquisition based on the terms of the transaction. See Note 4, Acquisition. Subsequent to the Horizon acquisition, $42 million of the RSUs were accelerated and cash settled in 2023. The weighted-average grant date fair values per unit of RSUs granted (excluding replacement awards granted to Horizon RSU holders) during the years ended December 31, 2025, 2024 and 2023, were $273.10, $301.36 and $237.70, respectively.

The following table summarizes information regarding our RSUs:

	Year ended December 31, 2025	
	Units (in millions)	Weighted-average grant date fair value
Balance nonvested as of December 31, 2024	3.5	$ 265.07
Granted	1.6	$ 273.10
Vested	(1.2)	$ 243.73
Forfeited	(0.2)	$ 277.14
Balance nonvested as of December 31, 2025	3.7	$ 274.23

The total grant date fair values of RSUs that vested during the years ended December 31, 2025, 2024 and 2023, were $283 million, $401 million and $309 million, respectively.

Stock options

The exercise price of stock options is set as the closing price of our common stock on the grant date, and the related number of shares granted is fixed at that point in time. Awards expire 10 years from the date of grant. We use the Black–Scholes option valuation model to estimate the grant date fair value of stock options.

The weighted-average assumptions used in the option valuation model and the resulting weighted-average grant date fair values of stock options granted were as follows:

	Years ended December 31,		
	2025	2024	2023
Closing price of our common stock on grant date	$ 270.44	$ 300.30	$ 235.97
Expected volatility (average of implied and historical volatility)	27.8 %	26.9 %	23.3 %
Expected life (in years)	5.7	5.7	5.7
Risk-free interest rate	4.0 %	4.4 %	3.4 %
Expected dividend yield	3.2 %	3.2 %	3.5 %
Fair value of stock options granted	$ 62.76	$ 69.34	$ 41.86

The following table summarizes information regarding our stock options:

	Year ended December 31, 2025			
	Options (in millions)	Weighted-average exercise price	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in millions)
Balance unexercised as of December 31, 2024	5.9	$ 225.84		
Granted	0.9	$ 270.44		
Exercised	(0.6)	$ 202.34		
Expired/forfeited	(0.1)	$ 258.80		
Balance unexercised as of December 31, 2025	6.1	$ 234.45	6.0	$ 563
Vested or expected to vest as of December 31, 2025	5.9	$ 233.42	5.9	$ 555
Exercisable as of December 31, 2025	3.5	$ 211.48	4.4	$ 401

The total intrinsic values of options exercised during the years ended December 31, 2025, 2024 and 2023, were $70 million, $70 million and $33 million, respectively. The actual tax benefits realized from tax deductions from option exercises during the years ended December 31, 2025, 2024 and 2023, were $15 million, $15 million and $7 million, respectively.

As of December 31, 2025, $537 million of unrecognized compensation cost was related to nonvested RSUs and unvested stock options, which is expected to be recognized over a weighted-average period of 1.7 years.

Performance units

Certain management-level employees also receive annual grants of performance units, which give the recipient the right to receive common stock that is contingent upon achievement of specified preestablished goals over the performance period, which is generally three years. The performance goals for the units granted during the years ended December 31, 2025, 2024 and 2023, which are accounted for as equity awards, are based on (i) Amgen's total stockholder return compared with a comparator group of companies, which are considered market conditions and are therefore reflected in the grant date fair values of the units, and (ii) Amgen's stand-alone financial performance measures, which are considered performance conditions. The expense recognized for awards is based on the grant date fair value of a unit multiplied by the number of units expected to be earned with respect to the related performance conditions, net of estimated forfeitures. Depending on the outcome of these performance goals, a recipient may ultimately earn a number of units greater or less than the number of units granted. Shares of our common stock are issued on a one-for-one basis for each performance unit earned. In general, performance unit awards vest at the end of the performance period. The performance award program provides for accelerated or continued vesting in certain circumstances as defined in the plan, including upon death, disability, a change in control and retirement of employees who meet certain service and/or age requirements. Performance units accrue dividend equivalents that are typically payable in shares only when and to the extent the underlying performance units vest and are issued to the recipient, including with respect to market and performance conditions that affect the number of performance units earned.

We use a payout simulation model to estimate the grant date fair value of performance units. The weighted-average assumptions used in the payout simulation model and the resulting weighted-average grant date fair values of performance units granted were as follows:

	Years ended December 31,		
	2025	2024	2023
Closing price of our common stock on grant date	$ 270.44	$ 300.30	$ 235.97
Volatility	24.2 %	22.1 %	21.6 %
Risk-free interest rate	3.7 %	4.6 %	3.7 %
Fair value of units granted	$ 290.24	$ 321.61	$ 252.49

The payout simulation model assumes correlations of returns of the stock prices of our common stock and the common stocks of the comparator groups of companies and stock price volatilities of the comparator groups of companies to simulate stockholder returns over the performance periods and their resulting impact on the payout percentages based on the contractual terms of the performance units.

As of December 31, 2025 and 2024, 1.2 million and 1.4 million performance units were outstanding, respectively, with weighted-average grant date fair values per unit of $278.62 and $263.86 per unit, respectively. During the year ended December 31, 2025, 0.3 million performance units with a weighted-average grant date fair value per unit of $290.24 were granted, and 0.1 million performance units with a weighted-average grant date fair value per unit of $278.87 were forfeited.

The total fair values of performance units paid during the years ended December 31, 2025, 2024 and 2023, were $163 million, $182 million and $109 million, respectively, based on the number of performance units earned multiplied by the closing stock price of our common stock on the last day of the performance period.

As of December 31, 2025, $64 million of unrecognized compensation cost was related to nonvested performance units, which is expected to be recognized over a weighted-average period of one year.

6. Defined contribution plan

The Company has defined contribution plans to which certain employees of the Company and participating subsidiaries may defer compensation for income tax purposes. Participants are eligible to receive matching contributions based on their contributions, in addition to other Company contributions. Defined contribution plan expenses were $407 million, $375 million and $311 million for the years ended December 31, 2025, 2024 and 2023, respectively.

7. Income taxes

Income before income taxes included the following (in millions):

	Years ended December 31,		
	2025	2024	2023
Domestic	$ 8,220	$ 4,040	$ 4,047
Foreign	756	569	3,808
Total income before income taxes	$ 8,976	$ 4,609	$ 7,855

The provision for income taxes included the following (in millions):

	Years ended December 31,		
	2025	2024	2023
Current provision:			
Federal	$ 959	$ 965	$ 1,524
State	35	33	43
Foreign	971	759	786
Total current provision	1,965	1,757	2,353
Deferred benefit:			
Federal	(465)	(860)	(1,124)
State	7	(18)	(25)
Foreign	(242)	(360)	(66)
Total deferred benefit	(700)	(1,238)	(1,215)
Total provision for income taxes	$ 1,265	$ 519	$ 1,138

Deferred income taxes reflect the tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, tax credit carryforwards and the tax effects of NOL carryforwards. As of December 31, 2022, we elected to establish deferred taxes with respect to the U.S. tax on the earnings of our foreign subsidiaries for the reversal of temporary items in future years. Significant components of our deferred tax assets and liabilities were as follows (in millions):

	December 31,	
	2025	2024
Deferred income tax assets:		
NOL and credit carryforwards	$ 1,368	$ 1,352
Accrued expenses	890	693
Capitalized research and development expenses	1,655	1,762
Investments	—	1
Expenses capitalized for tax	218	200
Earnings of foreign subsidiaries	2,305	1,496
Stock-based compensation	138	130
Other	349	361
Total deferred income tax assets	6,923	5,995
Valuation allowance	(1,299)	(1,019)
Net deferred income tax assets	5,624	4,976
Deferred income tax liabilities:		
Acquired intangible assets	(2,065)	(2,573)
Debt	(260)	(264)
Fixed assets	(192)	(143)
Fair value of acquired inventory	(28)	(114)
Investments	(422)	—
Other	(271)	(244)
Total deferred income tax liabilities	(3,238)	(3,338)
Total deferred income taxes, net	$ 2,386	$ 1,638

The Company has determined that unremitted foreign earnings are not considered indefinitely reinvested to the extent foreign earnings can be distributed without a significant tax cost.

Valuation allowances are provided to reduce the amounts of our deferred tax assets to an amount that is more likely than not to be realized based on an assessment of positive and negative evidence, including estimates of future taxable income necessary to realize future deductible amounts.

The valuation allowance increased in 2025, primarily driven by the Company’s expectation that certain foreign amortization deductions are expected to expire unutilized.

As of December 31, 2025, we had $109 million of federal tax credit carryforwards available to reduce future federal income taxes and have provided a $31 million valuation allowance on those federal tax credit carryforwards. The federal tax credit carryforwards expire between 2032 and 2041. We had $1.3 billion of state tax credit carryforwards available to reduce future state income taxes and have provided a valuation allowance for $1.2 billion of those state tax credit carryforwards. We had $148 million of tax credit carryforwards related to our foreign jurisdictions available to offset future foreign income taxes for which we have provided a $123 million valuation allowance.

As of December 31, 2025, we had $34 million of federal NOL carryforwards available to reduce future federal income taxes and have provided no valuation allowance on those federal NOL carryforwards. Additionally, $12 million of those federal NOL carryforwards have no expiration; the remainder begin to expire between 2027 and 2033. We had $971 million of state NOL carryforwards available to reduce future state income taxes and have provided a valuation allowance for $836 million of those state NOL carryforwards. We had $1.4 billion of foreign NOL carryforwards available to reduce future foreign income

taxes and have provided a valuation allowance for $239 million of those foreign NOL carryforwards. For the foreign NOLs with no valuation allowance provided, $120 million have no expiration; and the remainder will expire between 2026 and 2034.

The reconciliations of the total gross amounts of UTBs were as follows (in millions):

	Years ended December 31,		
	2025	2024	2023
Beginning balance	$ 4,184	$ 4,012	$ 3,770
Additions based on tax positions related to the current year	190	188	196
Additions based on tax positions related to prior years	14	9	56
Reductions for tax positions of prior years	(13)	(12)	—
Reductions for expiration of statute of limitations	—	(9)	(4)
Settlements	(4)	(4)	(6)
Ending balance	$ 4,371	$ 4,184	$ 4,012

Substantially all of the UTBs as of December 31, 2025, if recognized, would affect our effective tax rate. As a result, we remeasured our UTBs accordingly.

Interest and penalties related to UTBs are included in our provision for income taxes. During the years ended December 31, 2025, 2024 and 2023, we recognized $264 million, $282 million and $287 million, respectively, of interest and penalties through the income tax provision in the Consolidated Statements of Income. The decrease in interest expense for the year ended December 31, 2025, was primarily due to lower interest rates in 2025 compared to those in 2024. As of December 31, 2025 and 2024, accrued interest and penalties associated with UTBs were $1.9 billion and $1.6 billion, respectively.

The reconciliations between the federal statutory tax rate applied to income before income taxes and our effective tax rate for 2025 were as follows (in millions, except percentages):

	Year ended December 31, 2025	
	Tax Effect	Effective Tax Rate
Federal statutory tax rate	$ 1,885	21.0 %
Foreign tax effects:		
Ireland:		
Tax rate differential	316	3.5 %
Valuation allowance	119	1.3 %
Other	22	0.2 %
Puerto Rico:		
Tax rate differential	469	5.2 %
Act 52 - withholding tax	456	5.1 %
Act 52 - income tax	(968)	(10.8)%
Singapore:		
Tax incentive grant	(122)	(1.4)%
Pillar Two minimum tax	147	1.6 %
Other	(29)	(0.3)%
Other foreign jurisdictions	199	2.2 %
Effect of cross-border tax laws:		
U.S. tax on foreign subsidiaries (net of credits and deferred taxes)	(545)	(6.0)%
Foreign-derived intangible income	(222)	(2.5)%
Other	(18)	(0.2)%
Tax credits:		
Credit on foreign taxes imposed on U.S. income	(456)	(5.0)%
Research and development tax credits	(272)	(3.0)%
Other adjustments	86	1.0 %
Changes in unrecognized tax benefits (primarily interest)	198	2.2 %
Effective tax rate	$ 1,265	14.1 %

The reconciliations between the federal statutory tax rate applied to income before income taxes and our effective tax rate for 2024 and 2023 were as follows:

	Years ended December 31,	
	2024	2023
Federal statutory tax rate	21.0 %	21.0 %
Foreign earnings	(5.8)%	(5.1)%
Foreign-derived intangible income	(3.0)%	(1.3)%
Credits, Puerto Rico excise tax	— %	0.3 %
Interest on uncertain tax positions	4.2 %	2.6 %
Credits, primarily federal R&D	(5.4)%	(3.5)%
Other, net	0.3 %	0.5 %
Effective tax rate	11.3 %	14.5 %

The effective tax rates for the years ended December 31, 2025, 2024 and 2023, differ from the federal statutory rate primarily due to impacts of the jurisdictional mix of income and expenses. Substantially all of the benefit to our effective tax rate from foreign earnings results from locations in which the Company has significant manufacturing operations, including Singapore, Ireland and Puerto Rico, a territory of the United States that is treated as a foreign jurisdiction for U.S. tax purposes. Our operations in Puerto Rico are subject to tax incentive grants through 2050 and the Company's operations in Singapore are

subject to a tax incentive grant through 2036. Effective January 1, 2024, selected individual countries, including the United Kingdom and EU member countries, have enacted the global minimum tax agreement. Additional countries, including Singapore, enacted the minimum tax agreement effective January 1, 2025. Singapore's enactment of the agreement applies irrespective of the Company's incentive grant. Due to the currently enacted scope of the agreement, the Company and its subsidiaries are now subject to a 15% minimum tax rate on adjusted financial statement income. Our foreign earnings are also subject to U.S. tax at a reduced rate of 10.5%.

Income taxes paid (net of refunds received) included the following (in millions):

	Year ended December 31, 2025
U.S. payments (federal and state)	$ 3,390
Puerto Rico payments	610
Other foreign payments	300
Total income taxes paid (net of refunds received)	$ 4,300

Income taxes paid (net of refunds received) during the years ended December 31, 2024 and 2023, were $2.9 billion and $3.4 billion, respectively.

On July 4, 2025, OB3 was enacted in the United States. OB3 has various provisions, including the permanent extension of certain expiring provisions of the 2017 Tax Act, and modifications to the international tax framework. The legislation has multiple effective dates, with certain provisions effective in 2026 and beyond. The impact of these changes was recorded in 2025.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and certain foreign jurisdictions. Our income tax returns are routinely examined by tax authorities in those jurisdictions. Significant disputes can arise and have arisen with tax authorities involving issues regarding the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and relevant facts. Tax authorities, including the IRS, are becoming more aggressive and are particularly focused on such matters.

In 2017, we received an RAR and a modified RAR from the IRS for the years 2010–2012, proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico. We disagreed with the proposed adjustments and calculations, and in 2021, filed a petition in the U.S. Tax Court to contest two duplicate Statutory Notices of Deficiency (Notices) for the years 2010–2012. The Notices seek to increase our U.S. taxable income for the years 2010–2012 by an amount that would result in additional federal tax of approximately $3.6 billion plus interest. Any additional tax that could be imposed for the years 2010–2012 would be reduced by up to approximately $900 million of repatriation tax previously accrued and paid on our foreign earnings.

In 2020, we received an RAR and a modified RAR from the IRS for the years 2013–2015, also proposing significant adjustments that primarily relate to the allocation of profits between certain of our entities in the United States and the U.S. territory of Puerto Rico similar to those proposed for the years 2010–2012. We disagreed with the proposed adjustments and calculations, and in 2022, filed a petition in the U.S. Tax Court to contest a Notice for the years 2013–2015. The Notice seeks to increase our U.S. taxable income for the years 2013–2015 by an amount that would result in additional federal tax of approximately $5.1 billion, plus interest, and asserts penalties of approximately $2.0 billion. Any additional tax that could be imposed for the years 2013–2015 would be reduced by up to approximately $2.2 billion of repatriation tax previously accrued and paid on our foreign earnings.

We firmly believe that the IRS positions set forth in the 2010–2012 and 2013–2015 Notices are without merit. We continue to contest the 2010–2012 and 2013–2015 Notices through the judicial process. The two cases were consolidated in the U.S. Tax Court in 2022. The trial began on November 4, 2024 and concluded on January 17, 2025. The parties filed opening post-trial briefs on June 13, 2025, and the Court held oral argument on July 16, 2025. The parties filed post-trial reply briefs on October 10, 2025. The Company expects a decision from the U.S. Tax Court no earlier than the second half of 2026.

We are currently under examination by the IRS for the years 2016–2018 with respect to issues similar to those for the 2010 through 2015 period. We expect that the IRS will begin its audit of 2019-2022 in the first half of 2026, and we believe that it may seek to continue to audit similar issues related to the allocation of income between the United States and our foreign jurisdictions. In addition, we are under examination by a number of state and foreign tax jurisdictions.

Final resolution of these complex matters is not likely within the next 12 months. We continue to believe our accrual for income tax liabilities is appropriate based on past experience, interpretations of tax law, application of the tax law to our facts

and judgments about potential actions by tax authorities; however, due to the complexity of the provision for income taxes and uncertain resolution of these matters, the ultimate outcome of any tax matters may result in payments substantially greater than amounts accrued and could have a material adverse impact on our consolidated financial statements.

We are no longer subject to U.S. federal income tax examinations for years ended on or before December 31, 2009.

8. Earnings per share

The computation of basic EPS is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which primarily include shares that may be issued under our stock option, restricted stock and performance unit award programs (collectively, dilutive securities), as determined by using the treasury stock method.

The computations for basic and diluted earnings per share were as follows (in millions, except per-share data):

	Years ended December 31,		
	2025	2024	2023
Income (Numerator):			
Net income for basic and diluted earnings per share	$ 7,711	$ 4,090	$ 6,717
Shares (Denominator):			
Weighted-average shares for basic earnings per share	538	537	535
Effect of dilutive securities	4	4	3
Weighted-average shares for diluted earnings per share	542	541	538
Basic earnings per share	$ 14.33	$ 7.62	$ 12.56
Diluted earnings per share	$ 14.23	$ 7.56	$ 12.49

For each of the three years ended December 31, 2025, the number of antidilutive employee stock-based awards excluded from the computation of diluted EPS was not significant.

9. Collaborations

A collaborative arrangement is a contractual arrangement that involves a joint operating activity. Such arrangements involve two or more parties that are both (i) active participants in the activity and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

From time to time, we enter into collaborative arrangements for the R&D, manufacture and/or commercialization of products and/or product candidates. These collaborations generally provide for nonrefundable upfront license fees, development and commercial-performance milestone payments, cost sharing, royalties and/or profit sharing. Our collaboration arrangements are performed with no guarantee of either technological or commercial success, and each arrangement is unique in nature. See Note 1, Summary of significant accounting policies, for additional discussion of revenues recognized under these types of arrangements. Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line items in the Consolidated Statements of Income, net of any payments due to or reimbursements due from our collaboration partners, with such reimbursements being recognized at the time the party becomes obligated to pay. Our significant arrangements are discussed below.

AstraZeneca plc

We are in a collaboration with AstraZeneca for the development and commercialization of TEZSPIRE. Under our collaboration, both companies share global costs, profits and losses equally after payment by AstraZeneca of a mid-single-digit royalty to Amgen. AstraZeneca leads global development. In North America, Amgen, as the principal, recognizes product sales of TEZSPIRE in the United States, and AstraZeneca, as the principal, recognizes product sales of TEZSPIRE in Canada. AstraZeneca leads commercialization for TEZSPIRE outside North America. Amgen manufactures and supplies TEZSPIRE worldwide.

During the years ended December 31, 2025, 2024 and 2023, global profit and loss share expenses were $587 million, $412 million and $310 million, respectively, and were recorded primarily in Cost of sales in the Consolidated Statements of

Income. Net costs due to AstraZeneca for global development and commercialization were not material during the years ended December 31, 2025, 2024 and 2023.

UCB

We are in a collaboration with UCB for the development and commercialization of EVENITY. Under our collaboration, UCB has rights to lead commercialization for EVENITY in most countries in Europe. Amgen, as the principal, leads commercialization for EVENITY and recognizes product sales in all other territories, including the United States. Global development costs and commercialization profits and losses related to the collaboration are shared equally. Amgen manufactures and supplies EVENITY worldwide.

During the years ended December 31, 2025, 2024 and 2023, global profit and loss share expenses were $721 million, $547 million and $396 million, respectively, and were recorded primarily in Cost of sales in the Consolidated Statements of Income. Net costs recovered from and due to UCB during the years ended December 31, 2025, 2024 and 2023, were not material.

BeOne Medicines Ltd.

In January 2020, we acquired an equity stake in BeOne for approximately $2.8 billion in cash as part of a collaboration agreement to expand our oncology presence in China. For additional information regarding our equity investment in BeOne, see Note 10, Investments. Under the collaboration, BeOne began selling XGEVA in 2020, BLINCYTO in 2021 and KYPROLIS in 2022 in China, and Amgen shares profits and losses equally during the product-specific commercialization periods. Following entry into an amendment by Amgen and BeOne on November 11, 2025, BeOne will retain the right to commercialize XGEVA, BLINCYTO and KYPROLIS in China for so long as such products are sold in China. Amgen manufactures and supplies the collaboration products to BeOne.

In addition, we jointly develop a portion of our oncology portfolio with BeOne, which shares in global R&D costs by providing cash and development services of up to $1.25 billion. Upon regulatory approval, BeOne will assume commercialization rights in China for a specified period, and Amgen and BeOne will share profits and losses equally until certain of these product rights revert to Amgen. Upon return of the product rights, Amgen will pay royalties to BeOne on sales in China for a specified period. For product sales outside China, Amgen also pays royalties to BeOne.

During the years ended December 31, 2025, 2024 and 2023, net costs recovered from BeOne for oncology product candidates were $181 million, $122 million and $109 million, respectively, and were recorded as an offset to R&D expense in the Consolidated Statements of Income. During the years ended December 31, 2025, 2024 and 2023, product sales from Amgen to BeOne under the collaboration were $266 million, $259 million and $125 million, respectively, and were recorded in Product sales in the Consolidated Statements of Income. Profit and loss share expenses related to the product-specific commercialization period were not material during the years ended December 31, 2025, 2024 and 2023. Royalties on product sales of oncology portfolio products outside of China were not material for the years ended December 31, 2025, 2024 and 2023.

Kyowa Kirin Co., Ltd.

Since 2021, we have been in a collaboration agreement with Kyowa Kirin to jointly develop and commercialize rocatinlimab, an anti-OX40 fully human monoclonal antibody, worldwide, except in Japan. Rocatinlimab is for the treatment of atopic dermatitis, with potential for treatment of other autoimmune diseases.

Amgen and Kyowa Kirin share equally the global development costs, except in Japan, and the U.S. commercialization costs. Outside the United States and Japan, any commercialization costs incurred by Kyowa Kirin will be reimbursed by Amgen. We may also be required to make milestone payments of up to $850 million contingent upon the achievement of certain regulatory events and commercial thresholds. We will also pay Kyowa Kirin significant double-digit royalties on global sales, except in Japan.

In January 2026, we and Kyowa Kirin agreed to terminate the rocatinlimab collaboration agreement and to transition control of the global development and commercialization program to Kyowa Kirin, subject to receipt of clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. In February 2026, we received such regulatory clearance. In the first quarter of 2026, Kyowa Kirin will assume full responsibility for rocatinlimab worldwide, except that Amgen will continue to manufacture rocatinlimab and perform other transition activities for an agreed upon period of time.

During the years ended December 31, 2025, 2024 and 2023, net costs recovered from Kyowa Kirin were $117 million, $166 million and $93 million, respectively, and were recorded as an offset to R&D expense in the Consolidated Statements of Income.

Other

In addition to the collaborations discussed above, we have various other collaborations that are not individually significant to our business at this time. Pursuant to the terms of those agreements, we may be required to pay additional amounts, or we may receive additional amounts upon the achievement of various development and commercial milestones that in the aggregate could be significant. We may also incur or have reimbursed to us significant R&D costs if a related product candidate were to advance to late-stage clinical trials. In addition, if any products related to these collaborations are approved for sale, we may be required to pay significant royalties, or we may receive significant royalties on future sales. The payments of these amounts, however, are contingent upon the occurrence of various future events that have high degrees of uncertainty of occurrence.

10. Investments

Available-for-sale investments

The amortized cost, gross unrealized gains, gross unrealized losses and fair values of interest-bearing securities, which are classified as available for sale, by type of security were as follows (in millions):

Types of securities as of December 31, 2025	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury bills	$ 998	$ —	$ —	$ 998
Money market mutual funds	7,395	—	—	7,395
Other short-term interest-bearing securities	132	—	—	132
Total available-for-sale investments	$ 8,525	$ —	$ —	$ 8,525

Types of securities as of December 31, 2024	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair values
U.S. Treasury bills	$ 997	$ —	$ —	$ 997
Money market mutual funds	10,354	—	—	10,354
Other short-term interest-bearing securities	135	—	—	135
Total available-for-sale investments	$ 11,486	$ —	$ —	$ 11,486

The fair values of available-for-sale investments by location in the Consolidated Balance Sheets were as follows (in millions):

	December 31,	
Consolidated Balance Sheets locations	2025	2024
Cash and cash equivalents	$ 8,525	$ 11,486
Total available-for-sale investments	$ 8,525	$ 11,486

Cash and cash equivalents in the above table excludes bank account cash of $604 million and $487 million as of December 31, 2025 and 2024, respectively.

All interest-bearing securities as of December 31, 2025 and 2024, mature in one year or less. For the years ended December 31, 2025, 2024 and 2023, interest income on these investments was $408 million, $510 million and $1.2 billion, respectively.

For the years ended December 31, 2025, 2024 and 2023, realized gains and losses on interest-bearing securities were not material and were recorded in Other income, net, in the Consolidated Statements of Income. The cost of securities sold is based on the specific-identification method.

The primary objective of our investment portfolio is to maintain safety of principal, prudent levels of liquidity and acceptable levels of risk. Our investment policy limits interest-bearing security investments to certain types of debt and money market instruments issued by institutions with investment-grade credit ratings, and it places restrictions on maturities and concentration by asset class and issuer.

Equity securities

BeOne Medicines Ltd.

As of December 31, 2025 and 2024, our ownership interest in BeOne was approximately 17.1% and 17.8%, respectively, and the fair values of our investment were $5.8 billion and $3.5 billion, respectively, which were included in Other noncurrent assets in the Consolidated Balance Sheets. We account for our ownership interest as an equity security with a readily determinable fair value, which is carried at fair value with changes in fair value recorded in Other income, net, in the Consolidated Statements of Income. See Note 18, Fair value measurement. During the years ended December 31, 2025, 2024 and 2023, we recognized unrealized gains of $2.3 billion, $82 million, and $1.2 billion respectively, in Other income, net, in the Consolidated Statements of Income. For information on a collaboration agreement we entered into with BeOne in connection with this investment, see Note 9, Collaborations.

Subject to certain exceptions or otherwise agreed to by BeOne, while Amgen holds at least 5.0% of BeOne's outstanding common stock, (A) we may only sell our BeOne equity investment via: (i) a registered public offering, (ii) a sale under Rule 144 of the Securities Act of 1933 (the "Securities Act") or (iii) a private sale exempt from registration requirements under the Securities Act, and (B) we may not sell more than 5.0% of BeOne's outstanding common stock in any rolling 12-month period.

Other equity securities

Excluding our equity investments in BeOne (discussed above) and Neumora (discussed below), we held investments in other equity securities with readily determinable fair values (publicly traded securities) of $326 million and $314 million as of December 31, 2025 and 2024, respectively, which were included in Other noncurrent assets in the Consolidated Balance Sheets. For the years ended December 31, 2025, 2024 and 2023, net unrealized gains and losses on publicly traded securities resulted in a net gain of $109 million, a net loss of $21 million and a net gain of $98 million, respectively. Realized gains and losses on publicly traded securities for the years ended December 31, 2025, 2024 and 2023, were not material.

We held investments of $362 million and $319 million in equity securities without readily determinable fair values as of December 31, 2025 and 2024, respectively, which were included in Other noncurrent assets in the Consolidated Balance Sheets. For the years ended December 31, 2025, 2024 and 2023, gains due to upward adjustments and gains realized upon dispositions of these securities were not material. For the years ended December 31, 2025, 2024 and 2023 downward adjustments were not material. Adjustments were based on observable price transactions.

Equity Method Investments

Neumora Therapeutics, Inc.

As of December 31, 2025 and 2024, our ownership interest in Neumora was approximately 21.2% and 21.9%, respectively, and the fair values of our investment were $63 million and $375 million, respectively, which were included in Other noncurrent assets in the Consolidated Balance Sheets. Although our equity investment qualifies us for the equity method of accounting, we have elected the fair value option to account for our investment. See Note 18, Fair value measurement. Under the fair value option, changes in the fair value of the investment are recognized through earnings in Other income, net, in the Consolidated Statements of Income each reporting period. We believe the fair value option best reflects the economics of the underlying transaction. During the years ended December 31, 2025, 2024 and 2023, we recognized unrealized losses of $312 million and $228 million and an unrealized gain of $238 million, respectively, for the change in fair values in Other income, net, in the Consolidated Statements of Income.

We are contractually restricted from selling more than 5.0% of Neumora's outstanding common stock in any rolling 12-month period for as long as we hold at least 10.0% of their outstanding common stock, subject to certain exceptions or otherwise agreed to by Neumora.

Limited partnerships

We held limited partnership investments of $253 million and $262 million as of December 31, 2025 and 2024, respectively, which were included in Other noncurrent assets in the Consolidated Balance Sheets. These investments, which are primarily investment funds of early-stage biotechnology companies, are accounted for by using the equity method of accounting and are measured by using our proportionate share of the net asset values of the underlying investments held by the limited partnerships as a practical expedient. These investments are typically redeemable only through distributions upon liquidation of the underlying assets. As of December 31, 2025, we had $134 million of unfunded additional commitments to be made for these investments during the next several years. For the years ended December 31, 2025, 2024 and 2023, net gains and losses recognized from our limited partnership investments were not material.

11. Inventories

Inventories consisted of the following (in millions):

	December 31,	
	2025	2024
Raw materials	$ 915	$ 818
Work in process	3,425	4,120
Finished goods	1,885	2,060
Total inventories	$ 6,225	$ 6,998

12. Property, plant and equipment

Property, plant and equipment consisted of the following (dollar amounts in millions):

		December 31,	
	Useful life (in years)	2025	2024
Land	—	$ 348	$ 346
Buildings and improvements	10-40	4,932	4,803
Manufacturing equipment	8-12	3,589	3,291
Laboratory equipment	8-12	1,438	1,345
Fixed equipment	12	2,668	2,592
Capitalized software	3-5	1,554	1,442
Other	5-10	1,114	1,059
Construction in progress	—	3,390	2,053
Property, plant and equipment, gross		19,033	16,931
Less accumulated depreciation and amortization		(11,120)	(10,388)
Property, plant and equipment, net		$ 7,913	$ 6,543

During the years ended December 31, 2025, 2024 and 2023, we recognized depreciation and amortization expense associated with our property, plant and equipment of $763 million, $694 million and $685 million, respectively.

Geographic information

Certain geographic information with respect to property, plant and equipment, net, was as follows (in millions):

	December 31,	
	2025	2024
U.S.	$ 5,188	$ 4,156
Puerto Rico	1,273	1,174
ROW	1,452	1,213
Total property, plant and equipment, net	$ 7,913	$ 6,543

13. Goodwill and other intangible assets

Goodwill

The changes in the carrying amounts of goodwill were as follows (in millions):

	December 31,	
	2025	2024
Beginning balance	$ 18,637	$ 18,629
Changes to goodwill resulting from acquisitions, net[1]	—	25
Foreign currency translation adjustments	43	(17)
Ending balance	$ 18,680	$ 18,637

[1] For 2024, changes to Goodwill consisted of measurement-period adjustments related to our Horizon acquisition.

Other intangible assets

Other intangible assets consisted of the following (in millions):

	December 31,					
	2025			2024		
	Gross carrying amounts	Accumulated amortization	Other intangible assets, net	Gross carrying amounts	Accumulated amortization	Other intangible assets, net
Finite-lived intangible assets:						
Developed-product-technology rights	$ 47,805	$ (26,754)	$ 21,051	$ 48,611	$ (22,594)	$ 26,017
Licensing rights	3,917	(3,522)	395	3,875	(3,392)	483
R&D technology rights	1,425	(1,305)	120	1,374	(1,235)	139
Marketing-related rights	1,203	(1,203)	—	1,202	(1,202)	—
Total finite-lived intangible assets	54,350	(32,784)	21,566	55,062	(28,423)	26,639
Indefinite-lived intangible assets:						
In-process research and development	710	—	710	1,060	—	1,060
Total other intangible assets	$ 55,060	$ (32,784)	$ 22,276	$ 56,122	$ (28,423)	$ 27,699

Developed-product-technology rights consists of rights related to marketed products acquired in business combinations. Licensing rights primarily consists of contractual rights to receive future milestone, royalty and profit-sharing payments; capitalized payments to third parties for milestones related to regulatory approvals to commercialize products; and upfront payments associated with royalty obligations for marketed products. R&D technology rights pertains to technologies used in R&D that have alternative future uses. Marketing-related rights primarily consists of rights related to the sale and distribution of marketed products.

The Company monitors intangible assets for impairment on a quarterly basis. In January 2025, as part of the IRA, the Company's product Otezla was selected by CMS for Medicare price setting that will be applicable beginning on January 1, 2027. The earlier than anticipated selection resulted in a decrease in the estimated future cash flows for the product in the United States. This selection represented a triggering event that required the Company to evaluate the underlying developed-product-technology rights for impairment. In the first quarter of 2025, the Company utilized a discounted cash flow analysis based on Level 3 inputs, including estimated product sales, operating expenses and a discount rate, that resulted in an intangible asset fair value of $4.0 billion, which was lower than the carrying value of $4.8 billion, and a partial impairment of $800 million. In the third quarter of 2025, new facts and circumstances, primarily from the CMS price setting process, indicated a further triggering event that required the Company to evaluate the underlying developed-product-technology rights for impairment. A subsequent discounted cash flow analysis, prepared using the same Level 3 input framework and updated assumptions, resulted in a revised intangible asset fair value of $3.0 billion, which was lower than the carrying value of $3.4 billion, and an additional impairment of $400 million. The aggregate impairment charges of $1.2 billion during the year ended December 31, 2025 were recognized in Other operating expenses in the Consolidated Statements of Income. See Note 18, Fair value measurement.

The developed-product-technology rights intangible assets related to TAVNEOS have a carrying value of $2.5 billion as of December 31, 2025 with $2.4 billion related to the U.S. market. On January 16, 2026, the FDA requested that ChemoCentryx voluntarily withdraw TAVNEOS from the U.S. market. Amgen is confident that TAVNEOS demonstrates effectiveness and a favorable benefit–risk profile. On January 28, 2026, following FDA regulatory process, Amgen informed the FDA that it did not intend to withdraw TAVNEOS from the market. Amgen is evaluating next steps with the FDA to determine a path forward. Future changes to estimated TAVNEOS cash flows could unfavorably impact the Company's ability to recover the carrying value of the related intangible asset.

IPR&D consists of R&D projects acquired in a business combination that are not complete at the time of acquisition due to remaining technological risks and/or lack of receipt of required regulatory approvals. All IPR&D projects have major risks and uncertainties associated with the timely and successful completion of the development and commercialization of product candidates, including our ability to confirm safety and efficacy based on data from clinical trials, our ability to obtain necessary regulatory approvals and our ability to successfully complete these tasks within budgeted costs. We are not permitted to market a human therapeutic without obtaining regulatory approvals, and such approvals require the completion of clinical trials that demonstrate that a product candidate is safe and effective. In addition, the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans as well as competitive product launches, affect the revenues a product can generate. Consequently, the eventual realized values, if any, of acquired IPR&D projects may vary from their estimated fair values. We review IPR&D projects for impairment annually, whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable and upon the establishment of technological feasibility or regulatory approval. During the year ended December 31, 2023, the development of AMG 340 acquired in connection with our Teneobio acquisition was terminated, resulting in an impairment charge of $783 million, which was recognized in Other operating expenses in the Consolidated Statements of Income.

During the second quarter of 2025, the FDA approved UPLIZNA for the IgG4-RD indication, and commercialization commenced in the United States. As a result, the Company reclassified the related intangible asset with a gross carrying value of $350 million from IPR&D to developed-product-technology rights and began amortizing it on a straight-line basis over its estimated useful life of approximately 11 years from the date placed in service.

During the years ended December 31, 2025, 2024 and 2023, we recognized amortization of our finite-lived intangible assets of $4.3 billion, $4.8 billion and $3.2 billion, respectively. Amortization of intangible assets is primarily included in Cost of sales in the Consolidated Statements of Income. As of December 31, 2025, the total estimated future amortization of our finite-lived intangible assets for the years ending December 31, 2026, 2027, 2028, 2029 and 2030, was $3.6 billion, $3.5 billion, $2.8 billion, $2.3 billion and $2.2 billion, respectively.

14. Leases

We lease certain facilities and equipment related primarily to R&D, administrative and commercial activities. Leases with terms of 12 months or less are expensed as incurred and are not recorded in the Consolidated Balance Sheets.

Most leases include one or more options to renew, with renewal terms that may extend the lease term up to ten years. The exercise of lease renewal options is at our sole discretion. In addition, some of our lease agreements include rental payments adjusted periodically for inflation. Our lease agreements neither contain residual value guarantees nor impose significant restrictions or covenants. We sublease certain real estate to third parties. Our sublease portfolio consists of operating leases from former R&D and administrative spaces.

The following table summarizes information related to our leases, all of which are classified as operating, included in our Consolidated Balance Sheets (in millions):

	December 31,	
Consolidated Balance Sheets locations	**2025**	**2024**
Assets:		
Other noncurrent assets	$ 602	$ 557
Liabilities:		
Accrued liabilities	$ 135	$ 107
Other noncurrent liabilities	696	673
Total lease liabilities	$ 831	$ 780

The components of net lease costs were as follows (in millions):

	Years ended December 31,		
Lease costs	**2025**	**2024**	**2023**
Operating[1]	$ 265	$ 219	$ 208
Sublease income	(9)	(17)	(28)
Total net lease costs	$ 256	$ 202	$ 180

[1] Includes short-term leases and variable lease costs, which were not material for the years ended December 31, 2025, 2024 and 2023.

Maturities of lease liabilities as of December 31, 2025, were as follows (in millions):

Maturity dates	**Amounts**
2026	$ 148
2027	153
2028	128
2029	99
2030	77
Thereafter	362
Total lease payments[1]	967
Less imputed interest	(136)
Present value of lease liabilities	$ 831

[1] Includes future rental commitments for properties that have been subleased in the amount of $99 million. We expect to receive total future rental income of $54 million related to noncancellable subleases.

The weighted-average remaining lease terms and weighted-average discount rates were as follows:

	December 31,	
	2025	**2024**
Weighted-average remaining lease term (in years)	8.7	9.3
Weighted-average discount rate	4.0 %	3.7 %

Cash and noncash information related to our leases was as follows (in millions):

	Years ended December 31,		
	2025	**2024**	**2023**
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows for operating leases	$ 157	$ 156	$ 182
ROU assets obtained in exchange for lease obligations:			
Operating leases	$ 217	$ 126	$ 245

As of December 31, 2025, there were no future lease payments for leases that have not yet commenced.

15. Other current assets and accrued liabilities

Other current assets consisted of the following (in millions):

	December 31,	
	2025	2024
Prepaid expenses	$ 2,945	$ 2,139
Other	1,188	1,138
Total other current assets	$ 4,133	$ 3,277

Accrued liabilities consisted of the following (in millions):

	December 31,	
	2025	2024
Sales deductions	$ 10,606	$ 8,405
Employee compensation and benefits	1,437	1,329
Dividends payable	1,358	1,278
Income taxes payable	379	2,583
Other	4,743	4,046
Total accrued liabilities	$ 18,523	$ 17,641

16. Financing arrangements

Our borrowings consisted of the following (in millions):

	December 31,	
	2025	2024
1.90% notes due 2025 (1.90% 2025 Notes)	$ —	$ 500
5.25% notes due 2025 (5.25% 2025 Notes)	—	2,000
3.125% notes due 2025 (3.125% 2025 Notes)	—	1,000
2.00% €750 million notes due 2026 (2.00% 2026 euro Notes)	881	777
5.507% notes due 2026 (5.507% 2026 Notes)	—	1,500
2.60% notes due 2026 (2.60% 2026 Notes)	1,250	1,250
Term loan due October 2026	1,800	1,800
5.50% £475 million notes due 2026 (5.50% 2026 pound sterling Notes)	640	595
2.20% notes due 2027 (2.20% 2027 Notes)	1,724	1,724
3.20% notes due 2027 (3.20% 2027 Notes)	1,000	1,000
5.15% notes due 2028 (5.15% 2028 Notes)	3,750	3,750
1.65% notes due in 2028 (1.65% 2028 Notes)	1,234	1,234
3.00% notes due 2029 (3.00% 2029 Notes)	750	750
4.05% notes due 2029 (4.05% 2029 Notes)	1,250	1,250
4.00% £700 million notes due 2029 (4.00% 2029 pound sterling Notes)	944	876
2.45% notes due 2030 (2.45% 2030 Notes)	1,250	1,250
5.25% notes due 2030 (5.25% 2030 Notes)	2,750	2,750
2.30% notes due 2031 (2.30% 2031 Notes)	1,250	1,250
2.00% notes due 2032 (2.00% 2032 Notes)	987	1,001
3.35% notes due 2032 (3.35% 2032 Notes)	1,000	1,000
4.20% notes due 2033 (4.20% 2033 Notes)	750	750
5.25% notes due 2033 (5.25% 2033 Notes)	4,250	4,250
6.375% notes due 2037 (6.375% 2037 Notes)	478	478
6.90% notes due 2038 (6.90% 2038 Notes)	254	254
6.40% notes due 2039 (6.40% 2039 Notes)	333	333
3.15% notes due 2040 (3.15% 2040 Notes)	1,478	1,668
5.75% notes due 2040 (5.75% 2040 Notes)	373	373
2.80% notes due 2041 (2.80% 2041 Notes)	568	776
4.95% notes due 2041 (4.95% 2041 Notes)	600	600
5.15% notes due 2041 (5.15% 2041 Notes)	729	729
5.65% notes due 2042 (5.65% 2042 Notes)	415	415
5.60% notes due 2043 (5.60% 2043 Notes)	2,750	2,750
5.375% notes due 2043 (5.375% 2043 Notes)	185	185
4.40% notes due 2045 (4.40% 2045 Notes)	2,250	2,250
4.563% notes due 2048 (4.563% 2048 Notes)	1,415	1,415
3.375% notes due 2050 (3.375% 2050 Notes)	1,462	1,764
4.663% notes due 2051 (4.663% 2051 Notes)	3,541	3,541
3.00% notes due 2052 (3.00% 2052 Notes)	703	890
4.20% notes due 2052 (4.20% 2052 Notes)	882	895
4.875% notes due 2053 (4.875% 2053 Notes)	1,000	1,000
5.65% notes due 2053 (5.65% 2053 Notes)	4,250	4,250
2.77% notes due 2053 (2.77% 2053 Notes)	940	940
4.40% notes due 2062 (4.40% 2062 Notes)	1,128	1,165
5.75% notes due 2063 (5.75% 2063 Notes)	2,750	2,750

	December 31,	
	2025	2024
Other notes due 2097	100	100
Total principal amount of debt	56,044	61,778
Unamortized bond discounts, premiums and issuance costs, net	(1,306)	(1,360)
Fair value adjustments	(161)	(343)
Other	27	24
Total carrying value of debt	54,604	60,099
Less current portion	(4,599)	(3,550)
Total long-term debt	$ 50,005	$ 56,549

There are no material differences between the effective interest rates and coupon rates of our notes, except for the 4.563% 2048 Notes, the 4.663% 2051 Notes and the 2.77% 2053 Notes, which have effective interest rates of 6.3%, 5.6% and 5.2%, respectively.

Under the terms of all of our outstanding notes, except our Other notes due 2097, in the event of a change-in-control triggering event we may be required to purchase all or a portion of these debt securities at prices equal to 101% of the principal amounts of the notes plus accrued and unpaid interest. In addition, all of our outstanding notes—except our Other notes due 2097—may be redeemed at any time at our option—in whole or in part—at the principal amounts of the notes being redeemed plus accrued and unpaid interest and make-whole amounts, which are defined by the terms of the notes. Certain of the redeemable notes do not require the payment of make-whole amounts if redeemed during a specified period of time immediately prior to the maturity of the notes. Such time periods range from one month to six months prior to maturity.

Debt issuances and acquisition-related financing

We did not issue debt securities during the years ended December 31, 2025 and 2024.

In March 2023, in connection with the acquisition of Horizon (see Note 4, Acquisition), we issued the following series of notes (in millions):

	Principal Amount
5.25% 2025 Notes	$ 2,000
5.507% 2026 Notes	1,500
5.15% 2028 Notes	3,750
5.25% 2030 Notes	2,750
5.25% 2033 Notes	4,250
5.60% 2043 Notes	2,750
5.65% 2053 Notes	4,250
5.75% 2063 Notes	2,750
Total	$ 24,000

Also in connection with the acquisition of Horizon, we entered into a $4.0 billion term loan credit agreement in December 2022. In October 2023, in connection with the completion of the acquisition of Horizon, we borrowed $4.0 billion under the term loan credit agreement, of which $2.2 billion was repaid during 2024. As of December 31, 2025, we had $1.8 billion of borrowings outstanding under the term loan credit agreement, which has an interest rate of three-month SOFR plus 1.225% and is due in October 2026.

Debt extinguishment

In 2025, we repurchased an aggregate principal amount of our debt of $1.0 billion, including portions of the 2.00% 2032 Notes, 3.15% 2040 Notes, 2.80% 2041 Notes, 3.375% 2050 Notes, 3.00% 2052 Notes, 4.20% 2052 Notes and 4.40% 2062 Notes, for an aggregate cost of $683 million, which resulted in a $264 million gain on extinguishment of debt recorded in Other income, net, in the Consolidated Statements of Income.

In 2024, we repurchased an aggregate principal amount of our debt of $875 million, including portions of the 3.15% 2040 Notes, 2.80% 2041 Notes, 3.375% 2050 Notes, 3.00% 2052 Notes, 4.20% 2052 Notes and 4.40% 2062 Notes, for an aggregate

cost of $659 million, which resulted in a $215 million gain on extinguishment of debt recorded in Other income, net, in the Consolidated Statements of Income.

In 2023, we repurchased an aggregate principal amount of our debt of $881 million, including portions of the 2.00% 2032 Notes, 3.15% 2040 Notes, 2.80% 2041 Notes, 3.375% 2050 Notes, 3.00% 2052 Notes, 4.20% 2052 Notes and 4.40% 2062 Notes, for an aggregate cost of $647 million, which resulted in a $225 million gain on extinguishment of debt recorded in Other income, net, in the Consolidated Statements of Income.

Debt repayments

In 2025, debt repayments totaled $5.0 billion, including repayments in full of the $500 million aggregate principal amount of the 1.90% 2025 Notes, $2.0 billion aggregate principal amount of the 5.25% 2025 Notes, $1.0 billion aggregate principal amount of the 3.125% 2025 Notes and $1.5 billion aggregate principal amount of the 5.507% 2026 Notes.

In 2024, debt repayments totaled $3.6 billion, including the full $2.0 billion aggregate principal amount on the term loan due April 2025, $200 million of the aggregate principal amount on the term loan due October 2026 and the full $1.4 billion aggregate principal amount of the 3.625% 2024 Notes.

In 2023, debt repayments totaled $1.5 billion, including the full $750 million aggregate principal amount of the 2.25% 2023 Notes and the full CHF700 million aggregate principal amount ($704 million upon settlement of the related cross-currency swap) of the 0.41% 2023 Swiss franc Bonds.

Interest rate swaps

To achieve a desired mix of fixed-rate and floating-rate debt, we enter into interest rate swap contracts that effectively convert fixed-rate interest coupons for certain of our debt instruments to floating SOFR-based coupons over the terms of the respective debt instruments. These interest rate swap contracts qualify and are designated as fair value hedges. For information regarding the terms of these contracts, see Note 19, Derivative instruments.

Cross-currency swaps

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term notes denominated in foreign currencies, we entered into cross-currency swap contracts. The terms of these contracts outstanding as of December 31, 2025, effectively convert the interest payments and principal repayments on our 2.00% 2026 euro Notes, 5.50% 2026 pound sterling Notes and 4.00% 2029 pound sterling Notes from euros and pounds sterling to U.S. dollars. These cross-currency swap contracts have been designated as cash flow hedges. For information regarding the terms of these contracts, see Note 19, Derivative instruments. Cross-currency swap contracts associated with other foreign denominated debt previously outstanding were settled in connection with the repayment of such debt, as discussed above.

Shelf registration statement and other facilities

As of December 31, 2025, we have a commercial paper program that allows us to issue up to $4.0 billion of unsecured commercial paper to fund working capital needs. As of December 31, 2025 and 2024, we had no amounts outstanding under our commercial paper program.

In the first quarter of 2023, we amended and restated our syndicated, unsecured, revolving credit agreement, under which we may borrow up to $4.0 billion for general corporate purposes, including as a liquidity backstop for our commercial paper program. The commitments under the revolving credit agreement may be increased by up to $1.25 billion with the agreement of the banks. Each bank that is a party to the agreement has an initial commitment term of five years. This term may be extended for up to two additional one-year periods with the agreement of the banks. Annual commitment fees for this agreement are 0.09% of the unused portion of the facility based on our current credit rating. Generally, we would be charged interest for any amounts borrowed under this facility, based on our current credit rating, at (i) SOFR plus 1.01% or (ii) the highest of (A) the administrative agent bank base commercial lending rate, (B) the overnight federal funds rate plus 0.50% or (C) one-month SOFR plus 1.1%. As of December 31, 2025 and 2024, no amounts were outstanding under this facility.

In February 2023, we filed a shelf registration statement with the SEC that allows us to issue unspecified amounts of debt securities; common stock; preferred stock; warrants to purchase debt securities, common stock, preferred stock or depositary shares; rights to purchase common stock or preferred stock; securities purchase contracts; securities purchase units; and depositary shares. Under this shelf registration statement, all of the securities available for issuance may be offered from time to time, with terms to be determined at the time of issuance. This shelf registration statement expired in February 2026, and our Board has approved a new shelf registration statement to replace it.

Certain of our financing arrangements contain nonfinancial covenants. In addition, our revolving credit agreement and term loan agreement include a financial covenant, which requires us to maintain a specified minimum interest coverage ratio of (i) the sum of consolidated net income, interest expense, provision for income taxes, depreciation expense, amortization expense, unusual or nonrecurring charges and other noncash items (Consolidated EBITDA) to (ii) Consolidated Interest Expense, each as defined and described in the respective agreements. We were in compliance with all applicable covenants under these arrangements as of December 31, 2025.

Contractual maturities of debt obligations

The aggregate contractual maturities of our debt obligations as of December 31, 2025, were as follows (in millions):

Maturity dates	Amounts
2026	$ 4,571
2027	2,724
2028	4,984
2029	2,943
2030	4,000
Thereafter	36,822
Total	$ 56,044

Interest costs

Interest costs are expensed as incurred except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest costs capitalized for the years ended December 31, 2025, 2024 and 2023, were not material. Interest paid, net of amounts capitalized and including the ongoing impact of interest rate and cross-currency swap contracts, during the years ended December 31, 2025, 2024 and 2023 was $2.9 billion, $3.3 billion and $2.4 billion, respectively.

17. Stockholders' equity

Stock repurchase program

During the years ended December 31, 2025 and 2023, we did not repurchase shares under our stock repurchase program. During the year ended December 31, 2024, we repurchased 0.7 million shares of our common stock for a total cost of $200 million under our stock repurchase program. As of December 31, 2025, $6.8 billion of authorization remained available under the stock repurchase program.

Dividends

Our Board of Directors declared quarterly dividends per share of $2.38, $2.25 and $2.13, which were paid in each of the four quarters of 2025, 2024 and 2023, respectively.

Historically, we have declared dividends in December of each year, which were paid in the first quarter of the following fiscal year and in March, July and October, which were paid in the second, third and fourth quarters, respectively, of the same fiscal year. Additionally, in December 2025, the Board of Directors declared a quarterly cash dividend of $2.52 per share of common stock, which will be paid in March 2026, to all stockholders of record as of the close of business on February, 13 2026.

Accumulated other comprehensive loss

The components of AOCI were as follows (in millions):

	Foreign currency translation adjustments	Cash flow hedges	Other	AOCI
Balance as of December 31, 2022	$ (348)	$ 128	$ (11)	$ (231)
Foreign currency translation adjustments	50	—	—	50
Unrealized gains	—	28	—	28
Reclassification adjustments into earnings	—	(222)	—	(222)
Other	—	—	42	42
Income taxes	—	44	—	44
Balance as of December 31, 2023	(298)	(22)	31	(289)
Foreign currency translation adjustments	(76)	—	—	(76)
Unrealized gains	—	506	—	506
Reclassification adjustments into earnings	—	(117)	—	(117)
Other	—	—	(10)	(10)
Income taxes	—	(80)	—	(80)
Balance as of December 31, 2024	(374)	287	21	(66)
Foreign currency translation adjustments	172	—	—	172
Unrealized losses	—	(250)	—	(250)
Reclassification adjustments into earnings	—	(231)	—	(231)
Other	—	—	13	13
Income taxes	—	104	—	104
Balance as of December 31, 2025	$ (202)	$ (90)	$ 34	$ (258)

With respect to the table above, income tax expenses or benefits for unrealized gains and losses and the related reclassification adjustments to earnings for cash flow hedges were a $53 million benefit and a $51 million benefit in 2025, a $105 million expense and a $25 million benefit in 2024, and a $6 million expense and a $50 million benefit in 2023, respectively.

Reclassifications out of AOCI and into earnings were as follows (in millions):

	Years ended December 31,			
Components of AOCI	2025	2024	2023	Consolidated Statements of Income locations
Cash flow hedges:				
Foreign currency forward contract gains	$ 10	$ 192	$ 180	Product sales
Cross-currency swap contract gains (losses)	221	(75)	42	Other income, net
	231	117	222	Income before income taxes
	(51)	(25)	(50)	Provision for income taxes
	$ 180	$ 92	$ 172	Net income

Other

In addition to common stock, our authorized capital includes 5 million shares of preferred stock, $0.0001 par value. As of December 31, 2025 and 2024, no shares of preferred stock were issued or outstanding.

18. Fair value measurement

To estimate the fair values of our financial assets and liabilities, we use valuation approaches within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing an asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing an asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is divided into three levels based on the source of inputs as follows:

Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access
Level 2 — Valuations for which all significant inputs are observable either directly or indirectly—other than Level 1 inputs
Level 3 — Valuations based on inputs that are unobservable and significant to the overall fair value measurement

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used for measuring fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level of input used that is significant to the overall fair value measurement.

The fair values of each major class of the Company's financial assets and liabilities measured at fair value on a recurring basis were as follows (in millions):

Fair value measurement as of December 31, 2025, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury bills	$ —	$ 998	$ —	$ 998
Money market mutual funds	7,395	—	—	7,395
Other short-term interest-bearing securities	—	132	—	132
Equity securities	6,144	—	—	6,144
Derivatives:				
Foreign currency forward contracts	—	196	—	196
Cross-currency swap contracts	—	48	—	48
Total assets	$ 13,539	$ 1,374	$ —	$ 14,913
Liabilities:				
Derivatives:				
Foreign currency forward contracts	$ —	$ 214	$ —	$ 214
Cross-currency swap contracts	—	320	—	320
Interest rate swap contracts	—	293	—	293
Contingent consideration obligations	—	—	161	161
Total liabilities	$ —	$ 827	$ 161	$ 988

Fair value measurement as of December 31, 2024, using:	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Available-for-sale securities:				
U.S. Treasury bills	$ —	$ 997	$ —	$ 997
Money market mutual funds	10,354	—	—	10,354
Other short-term interest-bearing securities	—	135	—	135
Equity securities	4,188	—	—	4,188
Derivatives:				
Foreign currency forward contracts	—	420	—	420
Total assets	$ 14,542	$ 1,552	$ —	$ 16,094
Liabilities:				
Derivatives:				
Foreign currency forward contracts	$ —	$ 8	$ —	$ 8
Cross-currency swap contracts	—	483	—	483
Interest rate swap contracts	—	531	—	531
Contingent consideration obligations	—	—	106	106
Total liabilities	$ —	$ 1,022	$ 106	$ 1,128

Interest-bearing and equity securities

The fair values of our U.S. Treasury bills are determined by utilizing third-party pricing services, which obtain pricing data from active market makers and brokers. The fair values of our money market mutual funds and equity investments in publicly traded securities, including our equity investments in BeOne and Neumora, as of December 31, 2025 and 2024, are based on quoted market prices in active markets, with no valuation adjustment.

Derivatives

All of our foreign currency forward contracts, cross-currency swap contracts and interest rate swap contracts are with counterparties that have minimum credit ratings of A– or equivalent by S&P, Moody's or Fitch. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that uses an income-based industry-standard valuation model for which all significant inputs are observable either directly or indirectly. These inputs, as applicable, include foreign currency exchange rates, SOFR, swap rates, obligor credit default swap rates and cross-currency basis swap spreads. Certain inputs, when applicable, are at commonly quoted intervals. See Note 19, Derivative instruments.

Contingent consideration obligations

As a result of business development activity, we have incurred contingent consideration obligations as discussed below. The contingent consideration obligations are recorded at their fair values by using probability-adjusted discounted cash flows, and we revalue these obligations each reporting period until the related contingencies have been resolved. The fair value measurements of these obligations are based on significant unobservable inputs related to licensing rights and product candidates acquired through business development activity, and they are reviewed quarterly by management in our R&D and commercial sales organizations. The inputs include, as applicable, estimated probabilities and the timing of achieving specified development, regulatory and commercial milestones as well as estimated annual sales. Significant changes that increase or decrease the probabilities of achieving the related development, regulatory and commercial events or that shorten or lengthen the time required to achieve such events or that increase or decrease estimated annual sales would result in corresponding increases or decreases in the fair values of the obligations, as applicable. Changes in the fair values of contingent consideration obligations are recognized in Other operating expenses in the Consolidated Statements of Income.

Changes in the carrying amounts of contingent consideration obligations were as follows (in millions):

	Years ended December 31,	
	2025	2024
Beginning balance	$ 106	$ 96
Additions	68	—
Payments	(7)	(8)
Net changes in valuations	(6)	18
Ending balance	$ 161	$ 106

As of December 31, 2025 and 2024, our contingent consideration obligations were primarily the result of our acquisition of Teneobio in October 2021, which obligates us to make payments to the former shareholders upon achievement of separate development and regulatory milestones with regard to various R&D programs, and other business development activity in 2025.

Summary of the fair values of other financial instruments

Cash equivalents

The fair values of cash equivalents are approximated at their carrying values due to the short-term nature of such financial instruments.

Borrowings

We estimate the fair values of our fixed-rate debt by using Level 2 inputs. As of December 31, 2025 and 2024, the aggregate fair values of our fixed-rate debt were $51.0 billion and $54.9 billion, respectively, and the carrying values of our fixed-rate debt were $52.8 billion and $58.3 billion, respectively. The estimate of the fair value of our term loan is approximated at its carrying value as of December 31, 2025 and 2024, as this debt instrument bears interest at a floating rate.

During the years ended December 31, 2025 and 2024, there were no transfers of assets or liabilities between fair value measurement levels. Except with respect to the partial impairments of the Otezla intangible asset in 2025 and the IPR&D intangible impairment of AMG 340 in 2023 as disclosed in Note 13, Goodwill and other intangible assets, there were no material remeasurements of the fair values of assets and liabilities that are not measured at fair value on a recurring basis.

19. Derivative instruments

The Company is exposed to foreign currency exchange rate and interest rate risks related to its business operations. To reduce our risks related to such exposures, we use or have used certain derivative instruments, including foreign currency forward, foreign currency option, cross-currency swap, forward interest rate and interest rate swap contracts. We have designated certain of our derivatives as cash flow and fair value hedges; we also have derivatives not designated as hedges. We do not use derivatives for speculative trading purposes.

Cash flow hedges

We are exposed to possible changes in the values of certain anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates primarily associated with our euro-denominated international product sales. The foreign currency exchange rate fluctuation exposure associated with cash inflows from our international product sales is partially offset by corresponding cash outflows from our international operating expenses. To further reduce this exposure, we enter into foreign currency forward contracts to hedge a portion of our projected international product sales up to a maximum of three years into the future; and at any given point in time, a higher percentage of nearer-term projected product sales is being hedged than in successive periods.

As of December 31, 2025 and 2024, we had outstanding foreign currency forward contracts with aggregate notional amounts of $7.8 billion and $7.2 billion, respectively. We have designated these foreign currency forward contracts, which are primarily euro based, as cash flow hedges. Accordingly, we record unrealized gains and losses on these contracts in AOCI in the Consolidated Balance Sheets, and we reclassify them to Product sales in the Consolidated Statements of Income in the same periods during which the hedged transactions affect earnings.

To hedge our exposure to foreign currency exchange rate risk associated with certain of our long-term debt denominated in foreign currencies, we enter into cross-currency swap contracts. Under the terms of such contracts, we paid euros and pounds sterling and received U.S. dollars for the notional amounts at the inception of the contracts; and based on these notional amounts, we exchange interest payments at fixed rates over the terms of the contracts by paying U.S. dollars and receiving euros and pounds sterling. In addition, we will pay U.S. dollars to and receive euros and pounds sterling from the counterparties at the maturities of the contracts for these same notional amounts. The terms of these contracts correspond to the related hedged debt, thereby effectively converting the interest payments and principal repayment on the debt from euros and pounds sterling to U.S. dollars. We have designated these cross-currency swap contracts as cash flow hedges. Accordingly, the unrealized gains and losses on these contracts are recorded in AOCI in the Consolidated Balance Sheets and reclassified to Other income, net, in the Consolidated Statements of Income in the same periods during which the hedged debt affects earnings.

The notional amounts and interest rates of our cross-currency swaps as of December 31, 2025, were as follows (notional amounts in millions):

	Foreign currency			U.S. dollars	
Hedged notes	**Notional amounts**		**Interest rates**	**Notional amounts**	**Interest rates**
2.00% 2026 euro Notes	€	750	2.0 %	$ 833	3.9 %
5.50% 2026 pound sterling Notes	£	475	5.5 %	$ 747	6.0 %
4.00% 2029 pound sterling Notes	£	700	4.0 %	$ 1,111	4.7 %

In connection with the anticipated issuance of long-term fixed-rate debt, we occasionally enter into forward interest rate contracts in order to hedge the variability in cash flows due to changes in the applicable U.S. Treasury rate between the time we enter into these contracts and the time the related debt is issued. Gains and losses on forward interest rate contracts, which are designated as cash flow hedges, are recognized in AOCI in the Consolidated Balance Sheets and are amortized into Interest expense, net, in the Consolidated Statements of Income over the terms of the associated debt issuances. In 2025, we entered into forward interest rate contracts with an aggregate notional amount of $500 million. Amounts recognized in connection with forward interest rate contracts during the years ended December 31, 2025, 2024 and 2023, and amounts expected to be recognized during the next 12 months on forward interest rate contracts were not material.

Unrealized gains and losses recognized in AOCI for our derivative instruments designated as cash flow hedges were as follows (in millions):

	Years ended December 31,		
Derivatives in cash flow hedging relationships	**2025**	**2024**	**2023**
Foreign currency forward contracts	$ (464)	$ 585	$ (14)
Cross-currency swap contracts	214	(79)	73
Forward interest rate contracts	—	—	(31)
Total unrealized (losses) gains	$ (250)	$ 506	$ 28

Fair value hedges

To achieve a desired mix of fixed-rate and floating-rate debt, we enter into interest rate swap contracts that qualify for and are designated as fair value hedges. These interest rate swap contracts effectively convert fixed-rate coupons to floating-rate SOFR-based coupons over the terms of the related hedge contracts. As of both December 31, 2025 and 2024, we had interest rate swap contracts with an aggregate notional amount of $6.7 billion that hedge certain portions of our long-term debt. In 2025, interest rate swap contracts with an aggregate notional amount of $1.0 billion matured in connection with the repayment of the 3.125% 2025 Notes. Also in 2025, we entered into $1.0 billion of new interest rate swap contracts to hedge a portion of our 5.25% 2033 Notes.

As of December 31, 2025 and 2024, the interest rates on the portion of notes for which we have entered into interest rate swap contracts and the related notional amounts of these contracts were as follows (dollar amounts in millions):

	December 31,			
	2025		2024	
Notes	Notional amounts	Interest rates	Notional amounts	Interest rates
3.125% 2025 Notes	$ —	N/A	$ 1,000	SOFR + 2.1%
2.60% 2026 Notes	1,250	SOFR + 2.1%	1,250	SOFR + 2.1%
2.45% 2030 Notes	1,000	SOFR + 1.3%	1,000	SOFR + 1.3%
2.30% 2031 Notes	500	SOFR + 1.1%	500	SOFR + 1.1%
5.25% 2033 Notes	2,400	SOFR + 1.8%	1,400	SOFR + 1.8%
4.663% 2051 Notes	1,500	SOFR + 4.3%	1,500	SOFR + 4.3%
Total notional amounts	$ 6,650		$ 6,650	

N/A = not applicable

For interest rate swap contracts that qualify for and are designated as fair value hedges, we recognize in Interest expense, net, in the Consolidated Statements of Income the unrealized gain or loss on the derivative resulting from the change in fair value during the period, as well as the offsetting unrealized loss or gain of the hedged item resulting from the change in fair value during the period attributable to the hedged risk. If a hedging relationship involving an interest rate swap contract is terminated, the gain or loss realized on contract termination is recorded as an adjustment to the carrying value of the debt and amortized into Interest expense, net, over the remaining term of the previously hedged debt.

The hedged liabilities and related cumulative-basis adjustments for fair value hedges of those liabilities were recorded in the Consolidated Balance Sheets as follows (in millions):

	Carrying amounts of hedged liabilities[1]		Cumulative amounts of fair value hedging adjustments related to the carrying amounts of the hedged liabilities[2]	
	December 31,		December 31,	
Consolidated Balance Sheets locations	2025	2024	2025	2024
Current portion of long-term debt	$ 1,273	$ 1,045	$ 23	$ 45
Long-term debt	$ 5,112	$ 5,152	$ (184)	$ (388)

[1] Current portion of long-term debt includes $47 million and $56 million of carrying value with discontinued hedging relationships as of December 31, 2025 and 2024, respectively. Long-term debt includes $185 million and $232 million of carrying value with discontinued hedging relationships as of December 31, 2025 and 2024, respectively.

[2] Current portion of long-term debt includes $47 million and $56 million of hedging adjustments on discontinued hedging relationships as of December 31, 2025 and 2024, respectively. Long-term debt includes $85 million and $132 million of hedging adjustments on discontinued hedging relationships as of December 31, 2025 and 2024, respectively.

Impact of hedging transactions

The following tables summarize the amounts recorded in income and expense line items and the effects thereon from fair value and cash flow hedging, including discontinued hedging relationships (in millions):

	Year ended December 31, 2025		
	Product sales	Other income, net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 35,148	$ 2,651	$ (2,755)
The effects of cash flow and fair value hedging:			
Gains on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency forward contracts	$ 10	$ —	$ —
Cross-currency swap contracts	$ —	$ 221	$ —
(Losses) gains on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ (182)
Derivatives designated as hedging instruments	$ —	$ —	$ 238

	Year ended December 31, 2024		
	Product sales	Other income, net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 32,026	$ 506	$ (3,155)
The effects of cash flow and fair value hedging:			
Gains (losses) on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency forward contracts	$ 192	$ —	$ —
Cross-currency swap contracts	$ —	$ (75)	$ —
Gains on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ 29
Derivatives designated as hedging instruments	$ —	$ —	$ 40

	Year ended December 31, 2023		
	Product sales	Other income, net	Interest expense, net
Total amounts recorded in income and (expense) line items presented in the Consolidated Statements of Income	$ 26,910	$ 2,833	$ (2,875)
The effects of cash flow and fair value hedging:			
Gains on cash flow hedging relationships reclassified out of AOCI:			
Foreign currency forward contracts	$ 180	$ —	$ —
Cross-currency swap contracts	$ —	$ 42	$ —
(Losses) gains on fair value hedging relationships—interest rate swap agreements:			
Hedged items[1]	$ —	$ —	$ (118)
Derivatives designated as hedging instruments	$ —	$ —	$ 205

[1] Gains (losses) on hedged items do not exactly offset losses (gains) on the related designated hedging instruments due to amortization of the cumulative amounts of fair value hedging adjustments included in the carrying amount of the hedged debt for discontinued hedging relationships and the recognition of gains on terminated hedges when the corresponding hedged item was paid down in the period.

No portions of our cash flow hedge contracts were excluded from the assessment of hedge effectiveness. As of December 31, 2025, the amount of net losses on our foreign currency forward and cross-currency swap contracts expected to be reclassified out of AOCI and recognized into earnings during the next 12 months was $120 million.

Derivatives not designated as hedges

To reduce our exposure to foreign currency fluctuations in certain assets and liabilities denominated in foreign currencies, we enter into foreign currency forward contracts that are not designated as hedging transactions. Most of these exposures are hedged on a month-to-month basis. As of December 31, 2025 and 2024, the total notional amounts of these foreign currency forward contracts were $240 million and $148 million, respectively. Gains and losses recognized in earnings for our derivative instruments not designated as hedging instruments were not material for the years ended December 31, 2025, 2024 and 2023.

Fair values of derivatives

The fair values of derivatives included in the Consolidated Balance Sheets were as follows (in millions):

	Derivative assets		Derivative liabilities	
December 31, 2025	**Consolidated Balance Sheets locations**	**Fair values**	**Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency forward contracts	Other current assets/ Other noncurrent assets	$ 195	Accrued liabilities/ Other noncurrent liabilities	$ 213
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	48	Accrued liabilities/ Other noncurrent liabilities	320
Interest rate swap contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	293
Total derivatives designated as hedging instruments		243		826
Derivatives not designated as hedging instruments:				
Foreign currency forward contracts	Other current assets	1	Accrued liabilities	1
Total derivatives not designated as hedging instruments		1		1
Total derivatives		$ 244		$ 827

	Derivative assets		Derivative liabilities	
December 31, 2024	**Consolidated Balance Sheets locations**	**Fair values**	**Consolidated Balance Sheets locations**	**Fair values**
Derivatives designated as hedging instruments:				
Foreign currency forward contracts	Other current assets/ Other noncurrent assets	$ 420	Accrued liabilities/ Other noncurrent liabilities	$ 8
Cross-currency swap contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	483
Interest rate swap contracts	Other current assets/ Other noncurrent assets	—	Accrued liabilities/ Other noncurrent liabilities	531
Total derivatives designated as hedging instruments		420		1,022
Derivatives not designated as hedging instruments:				
Foreign currency forward contracts	Other current assets	—	Accrued liabilities	—
Total derivatives not designated as hedging instruments		—		—
Total derivatives		$ 420		$ 1,022

For additional information, see Note 18, Fair value measurement.

Our derivative contracts that were in liability positions as of December 31, 2025, contain certain credit-risk-related contingent provisions that would be triggered if (i) we were to undergo a change in control and (ii) our or the surviving entity's creditworthiness deteriorates, which is generally defined as having either a credit rating that is below investment grade or a materially weaker creditworthiness after the change in control. If these events were to occur, the counterparties would have the right, but not the obligation, to close the contracts under early-termination provisions. In such circumstances, the counterparties could request immediate settlement of these contracts for amounts that approximate the then current fair values of the contracts. In addition, our derivative contracts are not subject to any type of master netting arrangement, and amounts due either to or from a counterparty under the contracts may be offset against other amounts due either to or from the same counterparty only if an event of default or termination, as defined, were to occur.

The cash flow effects of our derivative contracts in the Consolidated Statements of Cash Flows are primarily included in Net cash provided by operating activities, except for the settlement of notional amounts of cross-currency swaps, which are included in Net cash (used in) provided by financing activities.

20. Contingencies and commitments

Contingencies

In the ordinary course of business, we are involved in various legal proceedings, government investigations and other matters that are complex in nature and have outcomes that are difficult to predict. See Part I, Item 1A. Risk Factors—*Our business may be affected by litigation and government investigations.* We describe our legal proceedings and other matters that are significant or that we believe could become significant in this footnote.

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of the liability that has been accrued previously.

Our legal proceedings involve various aspects of our business and a variety of claims, some of which present novel factual allegations and/or unique legal theories. The outcomes of these proceedings are inherently uncertain and depend on a variety of factors, including the development of the factual record, judicial or administrative rulings, and, in certain cases, the outcome of appellate review. Further, certain of the matters pending against us are at earlier stages of the legal process, which in complex proceedings of the sort we face often extend for several years, and have not progressed sufficiently through discovery and/or the development of important factual information and legal issues to enable us to estimate. Accordingly, except for amounts accrued, in each of the matters described in this filing in which we could incur a liability, our opponents seek an award of a not-yet-estimable amount of damages or an amount that is not material. While it is not possible to accurately predict or determine the eventual outcomes of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our consolidated results of operations, financial position or cash flows.

Certain recent developments concerning our legal proceedings and other matters are discussed below.

Repatha Patent Litigation

Patent Disputes in the International Region

We are involved in and expect future involvement in additional disputes regarding our PCSK9 patents in other jurisdictions and regions. This includes matters filed against us and that we have filed in Germany and Japan.

Germany

In February 2016, the EPO granted European Patent No. 2,215,124 (the EP'124 Patent) to Amgen. This patent describes and claims monoclonal antibodies to PCSK9 and methods of treatment and Sanofi filed an opposition to the patent in the EPO seeking to invalidate it. In November 2016, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A. and Sanofi Winthrop Industrie S.A. filed a joint opposition against Amgen's patent, and each of Eli Lilly and Company, Regeneron Pharmaceuticals, Inc. (Regeneron) and Strawman Ltd. also filed oppositions to Amgen's patent. In November 2018, the EPO confirmed the validity of Amgen's EP'124 Patent, which was appealed to the Technical Board of Appeal (TBA). On October 29, 2020, the TBA upheld the validity of certain claims, including claims that protect Repatha, but ruled that broader claims encompassing PRALUENT® were invalid. As a result of the TBA's decision, any national litigations regarding infringement of the EP`124 Patent by PRALUENT® were terminated.

In Germany, Sanofi-Aventis Deutschland GmbH and Regeneron filed actions in the Regional Court of Munich seeking damages arising from the provisional enforcement of an injunction against PRALUENT® that was lifted after the TBA's October 2020 ruling on the EP'124 Patent. On May 8, 2024, the Regional Court of Munich issued a preliminary decision. The case is still pending, but further proceedings were stayed on December 9, 2025.

Also in Germany, on July 21, 2022, Sanofi Biotechnology SAS filed an action against Amgen GmbH and Amgen (Europe) B.V. before the Regional Court of Dusseldorf alleging that the marketing and sale of Repatha infringes European Patent No. 2,756,004 (the EP'004 Patent), which Sanofi Biotechnology SAS licensed from Regeneron. Sanofi Biotechnology SAS is seeking infringement damages and injunctive relief. On May 13, 2024, the Regional Court of Dusseldorf stayed the hearing on Sanofi Biotechnology SAS' infringement action pending the outcome of Amgen's nullity action against the EP'004 Patent before the German Federal Patent Court. On December 29, 2025, the Regional Court of Dusseldorf lifted the stay and scheduled an oral hearing on May 12, 2026 to address whether Amgen infringes the EP'004 Patent in Germany.

On August 3, 2023, Amgen GmbH filed a nullity action before the German Federal Patent Court seeking invalidation of Regeneron's EP'004 Patent. On November 25, 2025, the German Federal Patent Court upheld the validity of Regeneron's EP'004 Patent.

Unified Patent Court of the European Union

Actions concerning Amgen's European Patent 3,666,797 (the EP'797 Patent)

On June 1, 2023, Amgen filed an action before the Munich Local Division of the Unified Patent Court (UPC) against Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Groupe S.A., Sanofi Winthrop Industrie S.A. (collectively, Sanofi-Aventis), and Regeneron alleging that the importation, marketing, sale and use of PRALUENT® infringes Amgen's EP'797 Patent seeking an injunction and damages for past infringement. Regeneron filed counterclaims for revocation, but on February 5, 2024, the court transferred the counterclaims to the Central Division of the UPC that is presiding over Sanofi's revocation action. The Munich Local Division of the UPC scheduled the hearing on Amgen's EP'797 Patent infringement action to begin on October 16, 2024.

On June 29, 2023, the Central Division of the UPC served Amgen with an action that was filed by Sanofi-Aventis that seeks revocation of the EP'797 Patent. The Central Division of the UPC scheduled a hearing on the revocation action and on July 16, 2024, the Central Division of the UPC rendered its decision, concluding that the patent claims are invalid and revoked the EP'797 Patent. Subsequently, on July 29, 2024, the Munich Local Division of the UPC stayed Amgen's action against Sanofi-Aventis alleging that the importation, marketing, sale and use of PRALUENT® infringes the EP'797 Patent. On September 13, 2024, Amgen filed a statement of appeal with the Court of Appeals of the UPC to set aside the Central Division of the UPC's decision to revoke the EP'797 Patent. On August 12, 2025, the Court of Appeals of the UPC heard oral argument on Amgen's appeal seeking to set aside the Central Division of the UPC's decision to revoke Amgen's EP'797 Patent and on November 25, 2025, the Court of Appeals of the UPC issued a decision upholding the validity of Amgen's EP'797 Patent. On January 26, 2026, Sanofi and Regeneron filed an application for rehearing and sought an order from the Court of Appeals of the UPC that the lodging of its application for rehearing suspends the UPC's decision upholding the validity of the EP'797 Patent. On January 29, 2026, the Court of Appeals of the UPC issued an order giving Amgen the opportunity to respond to the request for rehearing by February 26, 2026. On February 5, 2026, Amgen filed its reply to Sanofi's request for suspension.

On December 30, 2025, following on the Court of Appeals of the UPC's decision finding the EP'797 Patent valid, the Munich Local Division of the UPC lifted the stay on Amgen's case alleging that PRALUENT® infringes Amgen's EP'797 Patent. The Court scheduled an interim conference to take place on June 26, 2026, and an oral argument to take place on November 19, 2026.

Actions concerning Regeneron's European Patent 3,536,712 (the EP'712 Patent)

On January 10, 2024, Sanofi Biotechnologies SAS (Sanofi Biotechnologies) and Regeneron filed an action (the UPC Action Concerning the EP'712 Patent) against Amgen Inc., Amgen Europe B.V., Amgen N.V., Amgen GmbH, Amgen B.V., Amgen SAS, and Amgen S.R.L before the Dusseldorf Local Division of the UPC, alleging infringement of Regeneron's EP'712 Patent, which Sanofi Biotechnology SAS licensed from Regeneron. Sanofi and Regeneron are seeking an injunction against the sale, marketing, use, importation, or storage of Repatha for certain specified uses in Belgium, France, Germany, Italy and the Netherlands. Amgen filed counterclaims for invalidity and non-infringement. On February 25, 2025, a hearing on the validity and infringement of the EP'712 Patent was held before the Dusseldorf Local Division of the UPC.

On May 13, 2025, the Dusseldorf Local Division of the UPC issued a decision that the EP'712 Patent is valid but not infringed by Amgen. On July 11, Amgen filed its statement of appeal against the part of the Dusseldorf Local Division of the UPC's decision finding that the EP'712 Patent is valid. On July 14, 2025, Sanofi and Regeneron filed their statement of appeal against the decision of the Dusseldorf Local Division of the UPC finding the EP'712 Patent not infringed by Amgen. On September 15, 2025, Amgen and Sanofi and Regeneron filed their respective grounds of appeal. On December 15, 2025, the parties filed responses to the grounds of appeal.

Actions concerning Regeneron's European Patent 4,252,857 (the EP'857 Patent)

On September 25, 2024, Sanofi Biotechnologies and Regeneron filed a brief seeking to expand the ongoing action before the Dusseldorf Local Division of the UPC concerning the EP'712 Patent, alleging that Amgen's Repatha infringes a newly-issued patent, European Patent No. 4,252,857 (the EP'857 Patent) and seeking an injunction against the marketing, use, or importation of Repatha in 18 countries (Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Romania, Slovenia and Sweden) and damages for past infringement (the UPC Action Concerning the EP'857 Patent). On December 13, 2024, the Dusseldorf Local Division of the UPC denied Sanofi and Regeneron's request to extend the complaint. On February 4, 2025, the Dusseldorf Local Division of the UPC formally ordered separation of the EP'857 Patent from the ongoing EP'712 Patent litigation.

On June 9, 2025, Sanofi filed a motion seeking to stay the UPC Action Concerning the EP'857 Patent, which Amgen opposed. On August 6, 2025, the Dusseldorf Local Division of the UPC stayed the UPC Action Concerning the EP'857 Patent until the Court of Appeals of the UPC reaches a decision on the appeal from the UPC Action Concerning the EP'712 Patent.

European Patent Office

Proceedings concerning Amgen's EP'797 Patent

On November 16, 2023 and February 29, 2024, Sanofi-Aventis and Regeneron each filed a notice of opposition against Amgen's EP'797 Patent before the EPO's Opposition Division. A hearing was held beginning on March 31, 2025 and on April 3, 2025, the Opposition Division determined the claims of the EP'797 Patent are valid.

On April 16, 2025, Sanofi-Aventis and Regeneron filed notices of appeal and requested expedited appeal proceedings. The EPO TBA has scheduled a hearing on Sanofi's and Regeneron's appeals against the Opposition Division's decision upholding the validity of Amgen's EP'797 Patent to take place on April 13-15, 2026. On January 26, 2026, Amgen filed its reply to Sanofi-Aventis's and Regeneron's grounds of appeal.

Proceedings concerning Regeneron's EP'712 Patent

On February 29, 2024, Amgen filed a notice of opposition and grounds of opposition before the EPO against Regeneron's EP'712 Patent. On March 15, 2024, the EPO notified the parties that the opposition will be accelerated in view of the infringement action pending against Amgen on the EP'712 Patent in the Dusseldorf Local Division of the UPC. On March 12, 2025, following a hearing on Amgen's opposition to Regeneron's EP'712 Patent, the Opposition Division determined that the claims of the EP'712 Patent are valid, and issued its written decision on April 24, 2025.

On April 25, 2025, Amgen filed a notice of appeal and request for expedited appeal proceedings. On June 2, 2025, the EPO TBA accelerated Amgen's appeal from the EPO's decision that Regeneron's EP'712 Patent is valid and scheduled oral argument to take place on March 25, 2026.

Proceedings concerning Regeneron's EP'857 Patent

On June 23, 2025, Amgen filed a notice of opposition and grounds of opposition before the EPO against Regeneron's EP'857 Patent. On July 7, 2025, the EPO notified the parties that the opposition proceedings concerning the EP'857 Patent have been accelerated due to the pending parallel proceedings before the UPC, and Regeneron's response to Amgen's grounds of opposition must accordingly be filed by October 7, 2025. The EPO Opposition Division scheduled a hearing to take place on Amgen's opposition against Regeneron's EP'857 Patent on June 9-10, 2026.

Japan

On April 24, 2020, the Supreme Court of Japan declined to hear Sanofi K.K.'s appeals making final the Intellectual Property High Court's (IP High Court) decisions that PRALUENT® infringes Amgen's valid patent rights in Japan.

On June 24, 2020, Amgen filed written answers to the invalidity trials initiated by Regeneron on February 12, 2020 before the Japan Patent Office (JPO) seeking to invalidate Amgen's Japanese patents that were previously held infringed by PRALUENT® and valid over challenges filed by Sanofi K.K. On April 15, 2021, the JPO dismissed Regeneron's invalidity trials, and in August 2021 Regeneron appealed the decisions to the IP High Court. On January 26, 2023, the IP High Court found Amgen's patent claims invalid for lacking adequate support and Amgen appealed to the Supreme Court of Japan on March 13, 2023. On September 15, 2023, the Supreme Court of Japan declined to hear Amgen's appeal. The case was remanded to the JPO for further proceedings, however the case is currently stayed.

On March 31, 2021, Amgen initiated damages proceedings against Sanofi K.K. and Sanofi K.K. raised new validity challenges to Amgen patents. On September 27, 2023, the Tokyo District Court found Amgen's patent claims invalid and dismissed Amgen's lawsuit for damages. Amgen appealed the Tokyo District Court's decision to the IP High Court on December 28, 2023. The IP High Court rejected Amgen's appeal and remanded the case to the JPO. Amgen then sought amended patent claims before the JPO. The JPO rejected Amgen's amended claims, and Amgen appealed the JPO's decision to the IP High Court on September 16, 2024. On April 15, 2025, the IP High Court dismissed Amgen's appeal and, on May 27, 2025, Amgen filed petition for acceptance of an appeal before the Supreme Court of Japan.

Prolia/XGEVA Biologics Price Competition and Innovation Act (BPCIA) Litigation

Amgen Inc. et al. v. Shanghai Henlius Biotech Inc. et al.

On June 25, 2025, Amgen Inc. and Amgen Manufacturing Limited LLC filed a lawsuit in the U.S. District Court for the District of New Jersey (New Jersey District Court) against Shanghai Henlius Biotech Inc., Shanghai Henlius Biologics Co., Ltd,

Organon LLC and Organon & Co. (collectively, the Shanghai Henlius and Organon Defendants) based on the submission to the FDA of a BLA seeking approval to market and sell a biosimilar version of Amgen's Prolia and XGEVA products. The complaint asserts infringement of the following patents: U.S. Patent Nos. 7,364,736; 7,888,101; 7,928,205; 8,053,236; 8,217,153; 8,460,896; 8,680,248; 9,228,168; 9,359,435; 10,106,829; 10,227,627; 10,513,723; 10,583,397; 10,655,156; 10,894,972; 11,077,404; 11,098,079; 11,192,919; 11,254,963; 11,319,568; 11,434,514; 11,459,595; 11,492,372; 11,946,085; 11,952,605; and 12,084,686 (collectively, the Asserted Patents against the Shanghai Henlius and Organon Defendants). Amgen seeks a judgment from the New Jersey District Court that the Shanghai Henlius and Organon Defendants have infringed or will infringe one or more claims of each of the Asserted Patents against the Shanghai Henlius and Organon Defendants and based on that judgment, a permanent injunction prohibiting the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the accused proposed denosumab biosimilar by the Shanghai Henlius and Organon Defendants before expiration of each of the patents found to be infringed. Amgen also seeks monetary remedies for any past acts of infringement.

On June 25, 2025, this litigation became a member of In Re: Denosumab Patent Litigation multi-district litigation with other cases involving Prolia/XGEVA biosimilars pending in the district. On September 5, 2025, the Shanghai Henlius and Organon Defendants responded to the complaint, asserting counterclaims for invalidity and non-infringement and affirmative defenses. On October 10, 2025, Amgen responded to those counterclaims and asserted its affirmative defenses. A claim construction hearing will be scheduled after June 23, 2027, and the joint pretrial order is due April 28, 2028. A trial date has not yet been set.

Amgen Inc. et al. v. Hikma Pharmaceuticals USA Inc. et al.

On June 25, 2025, Amgen Inc. and Amgen Manufacturing Limited LLC filed a lawsuit in the New Jersey District Court against Hikma Pharmaceuticals USA Inc., Gedeon Richter Plc., and Gedeon Richter USA, Inc. (collectively, the Hikma and Gedeon Richter Defendants) based on the submission to the FDA of a BLA seeking approval to market and sell a biosimilar version of Amgen's Prolia and XGEVA products. The complaint asserts infringement of the following patents: U.S. Patent Nos. 7,364,736; 7,888,101; 7,928,205; 8,053,236; 8,058,418; 8,460,896; 8,680,248; 9,012,178; 9,228,168; 9,328,134; 9,359,435; 9,371,554; 10,106,829; 10,167,492; 10,227,627; 10,513,723; 10,583,397; 10,822,630; 10,894,972; 11,077,404; 11,098,079; 11,130,980; 11,192,919; 11,254,963; 11,299,760; 11,319,568; 11,434,514; 11,459,595; 11,492,372; 11,946,085; 11,952,605; and 12,084,686 (collectively, the Asserted Patents against the Hikma and Gedeon Richter Defendants). Amgen seeks a judgment from the New Jersey District Court that the Hikma and Gedeon Richter Defendants have infringed or will infringe one or more claims of each of the Asserted Patents against the Hikma and Gedeon Richter Defendants and based on that judgment, a permanent injunction prohibiting the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the accused proposed denosumab biosimilar before expiration of each of the patents found to be infringed. Amgen also seeks monetary remedies for any past acts of infringement. On June 25, 2025, this litigation became a member of In Re: Denosumab Patent Litigation multi-district litigation with other cases involving Prolia/XGEVA biosimilars pending in the district. A trial date has not yet been set.

On September 5, 2025, the Hikma and Gedeon Richter Defendants responded to the complaint, asserting counterclaims and affirmative defenses on September 5, 2025. On October 10, 2025, Amgen responded to those counterclaims and asserted its affirmative defenses. Pursuant to a consent order providing leave to amend, Amgen filed an Amended Complaint on November 14, 2025, adding Gedeon Richter (Schweiz) AG as a defendant to the litigation.

The parties entered into a settlement agreement that resolves the patent litigation related to the Hikma denosumab biosimilar products in the United States. Accordingly, the New Jersey District Court entered a Consent Judgment and Injunction on November 24, 2025, finding the claims of Amgen's U.S. patents asserted against the Hikma and Gedeon Richter Defendants valid, enforceable and infringed by Hikma's denosumab biosimilars in the United States and enjoining Defendants from importing, making, using, offering to sell or selling the Hikma denosumab biosimilar products in the United States before January 1, 2026, except as may be permitted by the agreement or by statue.

Amgen Inc. et al. v. Amneal Pharmaceuticals, Inc. et al.

On November 6, 2025, Amgen Inc. and Amgen Manufacturing Limited LLC filed a lawsuit in the New Jersey District Court against Amneal Pharmaceuticals, Inc., Amneal Pharmaceuticals LLC, GH Genhelix S.A., Universal Farma S.L., and Mabxience Research S.L., (collectively, the Amneal and Mabxience Defendants) based on the submission to the FDA of a BLA seeking approval to market and sell a biosimilar version of Amgen's Prolia and XGEVA products. The complaint asserts infringement of the following patents: U.S. Patent Nos. 7,364,736; 7,888,101; 7,928,205; 8,053,236; 8,058,418; 8,460,896; 8,680,248; 9,012,178; 9,228,168; 9,320,816; 9,328,134; 9,359,435; 10,106,829; 10,167,492; 10,227,627; 10,513,723; 10,583,397; 10,655,156; 10,822,630; 10,894,972; 11,077,404; 11,098,079; 11,130,980; 11,254,963; 11,299,760; 11,319,568; 11,434,514; 11,459,595; 11,946,085; 11,952,605; 12,084,686 (collectively, the Asserted Patents against the Amneal and Mabxience Defendants). Amgen seeks a judgment from the New Jersey District Court that the Amneal and Mabxience

Defendants have infringed or will infringe one or more claims of each of the Asserted Patents against the Amneal and Mabxience Defendants and based on that judgment, a permanent injunction prohibiting the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the accused denosumab biosimilar by the Amneal and Mabxience Defendants before expiration of each of the patents found to be infringed. Amgen also seeks monetary remedies for any past acts of infringement. On January 9, 2026 and January 23, 2026, respectively, the Amneal and Mabxience Defendants responded to the complaint asserting affirmative defenses.

This litigation is part of the In Re: Denosumab Patent Litigation multi-district litigation with other patent cases involving Prolia/XGEVA biosimilars pending in the district. A claim construction hearing will be scheduled after June 23, 2027, and the joint pretrial order is due April 28, 2028. A trial date has not yet been set.

Amgen Inc. et al. v. Dr. Reddy's Laboratories Ltd., et al.

On November 6, 2025, Amgen Inc. and Amgen Manufacturing Limited LLC filed a lawsuit in the New Jersey District Court against Dr. Reddy's Laboratories Ltd., Dr. Reddy's Laboratories SA, Dr. Reddy's Laboratories Inc., Alvotech Hf, and Alvotech Swiss AG (collectively, the Dr. Reddy's and Alvotech Defendants) based on the submission to the FDA of a BLA seeking approval to market and sell a biosimilar version of Amgen's Prolia and XGEVA products. The complaint asserts infringement of the following patents: U.S. Patent Nos. 7,364,736; 7,888,101; 7,928,205; 8,053,236; 8,058,418; 8,460,896; 8,680,248; 9,012,178; 9,228,168; 9,328,134; 9,359,435; 10,106,829; 10,167,492; 10,227,627; 10,513,723; 10,583,397; 10,822,630; 10,894,972; 11,077,404; 11,098,079; 11,130,980; 11,192,919; 11,254,963; 11,299,760; 11,319,568; 11,434,514; 11,459,595; 11,492,372; 11,946,085; 11,952,605; 12,084,686 (collectively, the Asserted Patents against the Dr. Reddy's and Alvotech Defendants). Amgen seeks a judgment from the New Jersey District Court that the Dr. Reddy's and Alvotech Defendants have infringed or will infringe one or more claims of each of the Asserted Patents against the Dr. Reddy's and Alvotech Defendants and based on that judgment, a permanent injunction prohibiting the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the accused proposed denosumab biosimilar by the Dr. Reddy's and Alvotech Defendants before expiration of each of the patents found to be infringed. Amgen also seeks monetary remedies for any past acts of infringement. On January 9, 2026, the Dr. Reddy's and Alvotech Defendants responded to the complaint asserting counterclaims for invalidity and non-infringement and affirmative defenses. On January 30, 2026, Amgen responded to those counterclaims and asserted its affirmative defenses.

This litigation is part of the In Re: Denosumab Patent Litigation multi-district litigation with other patent cases involving Prolia/XGEVA biosimilars pending in the district. A claim construction hearing will be scheduled after June 23, 2027, and the joint pretrial order is due April 28, 2028. A trial date has not yet been set.

Amgen Inc. et al. v Alkem Laboratories Ltd., et al.

On November 14, 2025, Amgen Inc. and Amgen Manufacturing Limited LLC filed a lawsuit in the New Jersey District Court against Alkem Laboratories Ltd., Ascend Laboratories, LLC, and Enzene Biosciences (collectively, the Alkem Defendants) based on the submission to the FDA of a BLA seeking approval to market and sell a biosimilar version of Amgen's Prolia and XGEVA products. The complaint asserts infringement of the following patents: U.S. Patent Nos. 7,364,736; 7,662,930; 7,888,101; 7,928,205; 8,053,236; 8,058,418; 8,247,210; 8,460,896; 8,680,248; 9,012,178; 9,228,168; 9,328,134; 9,359,435; 10,106,829; 10,167,492; 10,227,627; 10,513,723; 10,583,397; 10,655,156; 10,822,630; 10,894,972; 10,907,186; 11,077,404; 11,098,079; 11,130,980; 11,192,919; 11,254,963; 11,299,760; 11,319,568; 11,434,514; 11,459,595; 11,492,372; 11,946,085; 11,952,605; 12,084,686 (collectively, the Asserted Patents against the Alkem Defendants). Amgen seeks a judgment from the New Jersey District Court that the Alkem Defendants have infringed or will infringe one or more claims of each of the Asserted Patents against the Alkem Defendants and based on that judgment, a permanent injunction prohibiting the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the accused proposed denosumab biosimilar by the Alkem Defendants before expiration of each of the patents found to be infringed. Amgen also seeks monetary remedies for any past acts of infringement. On January 23, 2026, the Alkem Defendants responded to the complaint asserting affirmative defenses and counterclaims. On February 12, 2026, the Alkem Defendants filed an amended answer asserting affirmative defenses and counterclaims.

This litigation is part of the In Re: Denosumab Patent Litigation multi-district litigation with other patent cases involving Prolia/XGEVA biosimilars pending in the district. A claim construction hearing will be scheduled after June 23, 2027, and the joint pretrial order is due April 28, 2028. A trial date has not yet been set.

PAVBLU® (aflibercept-ayyh) Patent Litigation

On January 10, 2024, Regeneron filed a lawsuit in the U.S. District Court for the Central District of California (California Central District Court) against Amgen alleging infringement of 32 patents listed by Regeneron in the BPCIA exchange (the 2024 Complaint). The lawsuit stems from Amgen's submission of an application under the BPCIA for FDA licensure of

PAVBLU as biosimilar to Regeneron's EYLEA®. By its complaint, Regeneron seeks, among other remedies, an injunction prohibiting the commercial manufacture, use, offer for sale or sale in the United States or import into the United States of PAVBLU before the expiration of each of the patents found to be infringed. Amgen responded to Regeneron's complaint on February 2, 2024, denying infringement and asserting counterclaims seeking a declaratory judgment that the asserted patents are not infringed, invalid, and/or unenforceable.

On April 11, 2024, the Judicial Panel on Multidistrict Litigation granted a motion filed by Regeneron requesting transfer of Regeneron's patent infringement lawsuit pending against Amgen in the California Central District Court to the U.S. District Court for the Northern District of West Virginia (West Virginia District Court) for coordinated and consolidated pretrial proceedings with the five other cases involving EYLEA® biosimilars pending in that district.

On June 7, 2024, Regeneron filed a motion in the West Virginia District Court for a preliminary injunction to prohibit Amgen from engaging in the manufacture, use, offer for sell or sale within the United States, or importation into the United States, of PAVBLU until resolution of this lawsuit or the entry of a permanent injunction, whichever comes first. Regeneron's motion focused on U.S. Patent No. 11,084,865, a formulation patent. On September 23, 2024, the West Virginia District Court denied Regeneron's motion for a preliminary injunction, and Regeneron filed a notice of appeal, a motion to expedite the appeal, and an emergency motion for an injunction pending resolution of the appeal and for an administrative stay with the U.S. Court of Appeals for the Federal Circuit (Federal Circuit Court). On September 25, 2024, the Federal Circuit Court issued an order temporarily enjoining the launch of PAVBLU on an administrative basis while it considered Regeneron's motion for an injunction pending appeal. On October 22, 2024, the Federal Circuit Court denied Regeneron's motion for an injunction pending appeal and lifted the temporary injunction that was entered on September 25, 2024. Oral argument for the appeal was held on January 14, 2025. On March 14, 2025, the U.S. Court of Appeals for the Federal Circuit affirmed the denial by the West Virginia District Court of Regeneron's motion for a preliminary injunction.

On June 17, 2025, Regeneron filed a second lawsuit in the California Central District Court against Amgen alleging infringement of U.S. Patent No. 12,331,099 (the '099 Patent), also a formulation patent. By its complaint, Regeneron seeks, among other remedies, damages and an injunction prohibiting the commercial manufacture, use, offer for sale or sale in the United States or import into the United States of PAVBLU before the expiration of the '099 Patent. In July 2025, the Judicial Panel on Multidistrict Litigation issued an Order transferring the case from the California Central District Court to the West Virginia District Court for coordinated and consolidated pretrial proceedings with the other cases involving EYLEA® biosimilars pending in the district, and on July 31, 2025 the case was opened in the West Virginia District Court.

On September 12, 2025, Amgen responded to Regeneron's complaint asserting infringement of the '099 Patent, denying infringement and asserting counterclaims seeking a declaratory judgment that the '099 Patent is not infringed, invalid, and/or unenforceable, and counterclaims for Sherman Act (15 U.S.C. § 2) monopolization through Walker Process fraud, Sherman Act (15 U.S.C. § 2) attempted monopolization through Walker Process fraud, and unlawful and unfair practices under the California Unfair Competition Law. By its counterclaims, Amgen seeks, among other remedies, damages and an injunction against conduct by Regeneron. On September 29, 2025, the West Virginia District Court entered a scheduling order for the matters pending in the multidistrict litigation, including a claim construction hearing for November 23, 2026. On November 12, 2025, Regeneron filed a motion to strike certain of Amgen's affirmative defenses and to dismiss certain of Amgen's counterclaims, including the counterclaim seeking a declaratory judgment that the '099 Patent is unenforceable, the counterclaims for Sherman Act monopolization and attempted monopolization, and the counterclaim for unlawful and unfair practices under the California Competition Law.

On January 7, 2026, the West Virginia District Court entered a stipulation and order of dismissal that dismissed with prejudice Regeneron's claims with respect to 15 of the patents asserted in the 2024 Complaint and dismissed without prejudice Amgen's counterclaims and affirmative defenses with respect to those patents. Also on January 7, 2026, the West Virginia District Court granted Regeneron's motion for leave to amend the 2024 Complaint. The 2024 Complaint as amended alleges infringement of 19 patents and seeks, among other remedies, damages and an injunction prohibiting the commercial manufacture, use, offer for sale or sale in the United States or import into the United States of PAVBLU before the expiration of each of the patents found to be infringed.

KYPROLIS® (carfilzomib) Abbreviated New Drug Application (ANDA) Patent Litigation

Onyx Therapeutics, Inc. v. Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited.

On September 4, 2025, Onyx Therapeutics, Inc. (Onyx Therapeutics, a wholly-owned subsidiary of Amgen) filed a lawsuit in the U.S. District Court for the District of Delaware (Delaware District Court) against Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited (collectively, Amneal), asserting infringement of U.S. Patent No. 7,737,112 (the '112 Patent) based on Amneal's submission of an application pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act seeking FDA approval to market a generic version of KYPROLIS. Onyx Therapeutics seeks an order from the

Delaware District Court making any FDA approval of Amneal's application effective no earlier than the expiration of the '112 Patent.

On November 6, 2025, Amneal answered the complaint and counterclaimed, seeking a declaration of non-infringement, and filed a motion for judgment on the pleadings of non-infringement. On December 8, 2025, Onyx answered Amneal's counterclaim, and on December 11, 2025, Onyx opposed Amneal's motion for judgment on the pleadings. On February 3, 2026, the Delaware District Court denied Amneal's motion for judgment on the pleadings.

TAVNEOS® (avacopan) Abbreviated New Drug Application (ANDA) Patent Litigation

ChemoCentryx, Inc. v. Zydus Pharmaceuticals (USA) Inc., Zydus Lifesciences Global FZE, and Zydus Lifesciences Limited

On January 16, 2026, ChemoCentryx, Inc. (ChemoCentryx, a wholly-owned subsidiary of Amgen) filed a lawsuit in the New Jersey District Court against Zydus Pharmaceuticals (USA) Inc., Zydus Lifesciences Global FZE, and Zydus Lifesciences Limited (collectively, Zydus) asserting infringement of U.S. Patent Nos. 11,603,356 (the '356 Patent) and 11,951,214 (the '214 Patent) based on Zydus's submission of an ANDA seeking FDA approval to market a generic version of TAVNEOS. ChemoCentryx seeks, among other things, an order from the New Jersey District Court making any FDA approval of Zydus's ANDA effective no earlier than the expiration of the '356 and '214 Patents.

ChemoCentryx, Inc. v. Annora Pharma Private Limited, Hetero USA Inc., and Hetero Labs Limited

On February 9, 2026, ChemoCentryx filed a lawsuit in the New Jersey District Court against Annora Pharma Private Limited, Hetero USA Inc., and Hetero Labs Limited (collectively, Annora) asserting infringement of the '356 Patent and the '214 Patent based on Annora's submission of an ANDA seeking FDA approval to market a generic version of TAVNEOS. ChemoCentryx seeks, among other things, an order from the New Jersey District Court making any FDA approval of Annora's ANDA effective no earlier than the expiration of the '356 and '214 Patents.

Antitrust Class Action

Regeneron Pharmaceuticals, Inc. Antitrust Action

On May 27, 2022, Regeneron filed suit against Amgen in the Delaware District Court for federal and state antitrust and unfair competition violations and tortious interference with prospective business relations. Regeneron alleges that Amgen's sales contracting practices for Repatha, ENBREL and Otezla with key insurers, third-party payers and PBMs have harmed the sales of its product PRALUENT® and focuses on two primary arguments: that Amgen improperly bundled sales of Repatha with ENBREL, Otezla and potentially other products and sought exclusive or de facto exclusive formulary positioning for Repatha. Amgen's initial responsive pleading, a motion to dismiss, was filed on August 1, 2022. The Delaware District Court denied Amgen's motion to dismiss the complaint.

On August 28, 2023, Regeneron filed its amended complaint, and on September 20, 2023, Amgen filed a counterclaim, alleging Regeneron's own anticompetitive conduct with respect to formulary position for Regeneron's drug, PRALUENT®, at CVS. Amgen notified the Delaware District Court that it would not be pursuing its counterclaim on April 24, 2025.

A jury trial was held in the Delaware District Court from May 5, 2025 to May 14, 2025. On May 15, 2025, the jury returned a verdict finding for Regeneron on its federal and state antitrust law and tortious interference claims but finding for Amgen on its below-cost pricing claim under California's Unfair Practices Act. The jury awarded Regeneron $135.6 million in compensatory damages on its antitrust claims (which are subject to trebling under applicable law), or in the alternative, in compensatory damages plus $271.2 million in punitive damages on its tortious interference claim, with such damages under either alternative claim totaling $406.8 million. As Regeneron must elect between recovery under the antitrust or tortious interference claims, any potential damages award would be limited to one of these claims. Although we cannot predict with certainty the ultimate outcome of this litigation, Amgen believes that the jury's decision and amounts awarded are inconsistent with the law and evidence at trial.

Both parties have filed post-trial motions. On June 12, 2025, Amgen filed a renewed motion for judgment as a matter of law or, in the alternative, for a new trial. Also on June 12, 2025, Regeneron filed a motion for permanent injunctive relief, a constructive trust, and prejudgment interest. Both motions were fully briefed and a hearing on the post-trial motions was held on August 27, 2025.

In assessing whether we should accrue a liability for this litigation in our consolidated financial statements, we considered various factors, including the legal and factual circumstances of the case, the jury's award, the court's post-trial proceedings, applicable law, and the likelihood that the jury's award will be upheld after post-trial briefing and potentially on appeal. As a

result of this review, we have determined, in accordance with applicable accounting standards, that it is not probable that we will incur a loss as a result of this litigation, and we have therefore not recorded a liability for this matter.

The ultimate result of this litigation, however, is uncertain because it is reasonably possible that by settlement or final court judgment that none, some, or all of the jury's verdict and other relief sought might ultimately be awarded but the size of an award, if any, is not estimable at this time.

CareFirst of Maryland Antitrust Class Action

On August 6, 2024, CareFirst of Maryland, Inc., Group Hospitalization and Medical Services, Inc., and CareFirst BlueChoice, Inc. (collectively, CareFirst), filed a proposed class action lawsuit against Amgen Inc., Amgen Manufacturing, Limited (corrected to Amgen Manufacturing Limited LLC in CareFirst's amended complaint on filed October 11, 2024), and Immunex Corporation in the U.S. District Court for the Eastern District of Virginia (District Court for the Eastern District of Virginia), alleging federal and state antitrust claims and state consumer protection and unjust enrichment claims. CareFirst alleges that, in 2004, Amgen entered into an anticompetitive agreement with certain F. Hoffman-La Roche AG entities (Roche) and other parties that provided Amgen with rights to Roche's patents in a manner that enabled Amgen to allegedly unlawfully extend the life of patents applicable to ENBREL and, thereby, delay biosimilar entry. On November 4, 2024, Amgen filed a motion to dismiss, and CareFirst thereafter filed a second amended complaint on November 25, 2024. On January 8, 2025, Amgen filed a motion to dismiss the second amended complaint.

On September 30, 2025, the District Court for the Eastern District of Virginia issued an order granting in part and denying in part Amgen's motion to dismiss. The court dismissed CareFirst's antitrust claim under Puerto Rico law and its unjust enrichment claims under the laws of seven states and Puerto Rico, but otherwise permitted the claims to proceed. On October 20, 2025, Amgen filed a motion asking the district court to certify its order on the motion to dismiss for interlocutory appeal to the U.S. Court of Appeals for the Fourth Circuit. On November 3, 2025, CareFirst filed its opposition to Amgen's motion to certify for interlocutory appeal. On November 7, 2025, Amgen filed its answer to the second amended complaint, and on November 10, 2025, Amgen filed its reply in support of its motion to certify for interlocutory appeal.

Sandoz Inc. Antitrust Action

On April 11, 2025, Sandoz Inc. (Sandoz) filed a complaint in the U.S. District Court for the Eastern District of Virginia against Amgen Inc., Amgen Manufacturing Limited LLC, and Immunex Corporation claiming violations of the antitrust laws and tortious interference related to Amgen's patent rights to ENBREL, and seeking damages, injunctive relief and attorneys' fees. The factual allegations that form the basis for the claims of Sandoz's complaint are substantially similar to those asserted in the lawsuit filed against Amgen in the same court by CareFirst.

On June 20, 2025, Amgen filed a motion to dismiss the complaint. Sandoz filed its opposition to the motion to dismiss on July 21, 2025, and on August 21, 2025, Amgen filed its reply in support of the motion to dismiss.

Other Similar Antitrust Actions

In July and August 2025, seven lawsuits were filed in the California Superior Court in Ventura County, each alleging state law antitrust, consumer protection, and unjust enrichment claims, based on allegations substantially similar to those in the CareFirst class action. The cases were filed by: Centene Corporation, WellCare Health Plans, Inc., New York Quality Healthcare Corporation d/b/a Fidelis Care, and Health Net, LLC (collectively, Centene) on July 29, 2025; Humana Inc. (Humana) on July 29, 2025; Molina Healthcare, Inc. (Molina) on July 29, 2025; Blue Cross and Blue Shield of Florida, Inc. and Health Options, Inc. d/b/a Florida Blue HMO (collectively, BCBSFL) on July 29, 2025; Blue Cross and Blue Shield of Kansas City (BCBSKC) on July 29, 2025; Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc. (collectively, BCBSMA) on August 8, 2025; and Health Care Services Corp. (HCSC) on August 21, 2025. Amgen subsequently removed the cases filed by BCBSFL, BCBSKC, BCBSMA, and HCSC to the California Central District Court. On September 29, 2025, HCSC voluntarily dismissed its case without prejudice. On October 1, 2025, BCBSFL, BCBSKC, and BCBSMA voluntarily dismissed their cases without prejudice.

On January 8, 2026, Amgen filed demurrers to the complaints filed by Centene, Humana, and Molina, seeking the dismissal of the claims in those complaints, with prejudice. On February 2, 2026, the complaint in the Centene case was amended to join BCBSFL, BCBSKC, BCBSMA, and HCSC as additional plaintiffs. Humana and Molina filed their opposition to Amgen's demurrers on February 5, 2026, and Amgen's replies are due on February 26, 2026. On February 5, Amgen filed a demurrer to the amended Centene complaint; Centene's opposition to the demurrer was filed February 9, 2026 and Amgen's reply is due February 26, 2026.

U.S. Tax Litigation and Related Matters

Amgen Inc. & Subsidiaries v. Commissioner of Internal Revenue

See Note 7, Income taxes, for discussion of the IRS tax dispute and the Company's petitions in the U.S. Tax Court.

Securities Class Action Litigation (Roofers Local No. 149 Pension Fund)

On March 13, 2023, Roofers Local No. 149 Pension Fund filed a purported class action (Roofers Securities Class Action) against Amgen, Robert Bradway and Peter Griffith in the U.S. District Court for the Southern District of New York (Southern District Court of New York). The action was brought on behalf of an alleged class of Amgen shareholders who owned stock between July 29, 2020 and April 27, 2022 (the alleged class period). Plaintiffs allege that the defendants made a series of materially false and misleading statements and omissions during the alleged class period regarding the failure to timely disclose the potential tax liability claimed by the IRS. Plaintiffs further allege that they and other purported class members suffered losses and damages resulting from declines in the market value of Amgen's common stock after the potential tax liability claimed by the IRS was disclosed.

On August 31, 2023, plaintiff filed an amended complaint and Amgen filed a motion to dismiss on November 6, 2023, which the Southern District Court of New York denied on September 30, 2024. On November 20, 2024, Amgen filed an answer to the amended complaint.

Pursuant to the Southern District Court of New York's order on September 11, 2025, the class certification briefing is due by April 24, 2026. The last day to file summary judgment motions is December 21, 2026, but no briefing schedule has been set and no trial date has been set.

On December 9, 2025, plaintiffs filed their motion for class certification. Amgen's opposition is due on March 9, 2026 and plaintiffs' reply is due May 8, 2026.

Shareholder Derivative Actions (Martin, Clearwater and DM Cohen)

On August 2, 2023, Leon Martin filed a derivative action (the Martin Derivative Action) captioned *Leon Martin v. Robert A. Bradway, et al., No. 1:23-cv-06754* (S.D.N.Y. Aug. 2, 2023), purportedly on behalf of Amgen, against Amgen, Robert Bradway, Peter Griffith and Amgen's independent Board members. The action was filed in the Southern District Court of New York as related to the pending Roofers Securities Class Action. The complaint in this matter alleges claims for violations of the Securities Exchange Act of 1934, breach of fiduciary duty, aiding and abetting breach of fiduciary duty, unjust enrichment and waste of corporate assets.

On December 7, 2023, Plaintiff filed a Notice of Voluntary Dismissal as to Board member Michael Drake.

On December 1, 2023, a second derivative action (the Clearwater Derivative Action) was filed, captioned *Cheri Clearwater v. Robert A. Bradway, et al., No. 1:23-cv-10538* (S.D.N.Y. Dec. 1, 2023), in the same court as the earlier-filed Martin Derivative Action. The second action is largely duplicative of the Martin Derivative Action, asserting the same claims purportedly on behalf of the Company against the individual directors that sat on Amgen's Board during the relevant time period (July 29, 2020 through April 27, 2022). The complaint asserts claims for breach of fiduciary duty, unjust enrichment, waste of corporate assets, abuse of control, gross mismanagement, and violations of Section 10(b) of the Exchange Act arising out of Amgen's disclosures with respect to its transfer pricing dispute with the IRS. However, the Clearwater Derivative Action complaint adds (1) two additional claims for violations of Sections 14(a) and 20(a) of the Exchange Act; (2) allegations that Amgen repurchased its own stock at artificially inflated prices during the relevant period; and (3) more detailed allegations as to why first making a demand on the Board would have been futile.

On January 16, 2024, the Southern District Court of New York consolidated the Martin Derivative Action and Clearwater Derivative Action (the Consolidated Action). The Southern District Court of New York entered an Order staying the Consolidated Action until a final judgment is entered in the Roofers Securities Class Action.

On February 12, 2025, DM Cohen, Inc. filed a third derivative action (the DM Cohen Derivative Action) captioned *DM Cohen, Inc. v. Robert A. Bradway, et al, No. 1:25-mc-00062* (S.D.N.Y. Feb. 12, 2025), purportedly on behalf of Amgen, against Amgen, Robert Bradway, Peter Griffith and Amgen's independent Board members. The DM Cohen Derivative Action was filed in the same court as the earlier filed Roofers Securities Class Action and the Consolidated Action. The complaint asserts claims for violations of the Securities Exchange Act of 1934, breach of fiduciary duty, waste of corporate assets and unjust enrichment.

The factual allegations that form the basis for the claims in the Consolidated Action and the DM Cohen Derivative Action are essentially the same as the allegations asserted in the Roofers Securities Class Action regarding purportedly false and

misleading statements and omissions made from July 29, 2020 through April 27, 2022 relating to Amgen's tax liabilities, business and finances, and the adequacy and maintenance of its internal controls.

On April 21, 2025, the Southern District Court of New York consolidated the derivative action filed by DM Cohen, Inc. with the Consolidated Action.

The case is stayed pending entry of a final judgment in the Roofers Securities Class action.

Shareholder Derivative Actions (Hamilton, Blackburn, Bryla)

On October 16, 2024, David Hamilton filed a derivative action in the Delaware Court of Chancery purportedly on behalf of Amgen, against nominal defendant Amgen, Robert Bradway, Peter Griffith and Amgen's Board members during the relevant time period (the Hamilton Derivative Action). The complaint in this matter alleges claims for breach of fiduciary duty and unjust enrichment.

On November 7, 2024, Charles Blackburn filed a derivative action in the Delaware Court of Chancery purportedly on behalf of Amgen, against nominal defendant Amgen, Robert Bradway, Peter Griffith and Amgen's Board members during the relevant time period (the Blackburn Derivative Action). The complaint alleges a claim for breach of fiduciary duty.

On December 6, 2024, Robert Bryla filed a derivative action in the Delaware Court of Chancery purportedly on behalf of Amgen, against nominal defendant Amgen, Robert Bradway, Peter Griffith and Amgen's Board members during the relevant time period (the Bryla Derivative Action). The complaint alleges claims for breach of fiduciary duty and unjust enrichment.

The factual allegations that form the basis for the claims in the Hamilton Derivative Action, Blackburn Derivative Action and Bryla Derivative Action are fundamentally the same as those asserted by the Roofers Local No. 149 Pension Fund on March 13, 2023 (alleging false and misleading statements and omissions made from July 29, 2020 through April 27, 2022 relating to Amgen's tax liabilities, business and finances, and the adequacy and maintenance of its internal controls).

On April 9, 2025, the Delaware Court of Chancery consolidated the derivative actions filed by each of David Hamilton, Charles Blackburn and Robert Bryla purportedly on behalf of Amgen against nominal defendant Amgen, Robert Bradway, Peter Griffith and Amgen's independent Board members.

The case is stayed pending entry of a final judgment in the Roofers Securities Class Action.

Shareholder Derivative Actions (Sieveking, Tierney)

On April 2, 2025, Carolyn Sieveking and James P. Tierney filed a derivative action (the Sieveking Derivative Action) in the Delaware District Court purportedly on behalf of Amgen, against nominal defendant Amgen, Robert Bradway, Peter Griffith, Linda Louie and Amgen's Board members during the relevant time period (the Sieveking Derivative Action). The complaint alleges claims for violations of Section 10(b), Rule 10b5 and Section 20(a) of the Securities Exchange Act of 1934, and breach of fiduciary duty.

The factual allegations that form the basis for the claims in the Sieveking Derivative Action is fundamentally the same as those asserted by the Roofers Local No. 149 Pension Fund.

On June 9, 2025, the Delaware District Court stayed the case pending entry of a final judgment in the Roofers Securities Class Action.

ChemoCentryx, Inc. Securities Matters

On May 5 and June 8 of 2021, ChemoCentryx and its Chief Executive Officer were named as defendants in two putative shareholder class actions filed in the U.S. District Court for the Northern District of California (Northern District Court of California). These cases were consolidated into *Homyk v. ChemoCentryx, Inc.* in which the plaintiffs allege violations of Sections 10(b) and 20(a) of the Securities Exchange Act in connection with statements regarding the New Drug Application for TAVNEOS and the underlying Phase 3 clinical trial, seeking an award of damages, interest and attorneys' fees. On March 28, 2022, the plaintiffs filed their consolidated amended complaint, and on May 19, 2022, ChemoCentryx moved to dismiss these claims.

On February 23, 2023, the Northern District Court of California substantially denied ChemoCentryx's motion to dismiss the matter in its entirety, while granting the motion to dismiss with respect to certain allegations of the plaintiffs. On August 25, 2023, the lead plaintiff moved to certify a class composed of all purchasers of ChemoCentryx stock between November 25, 2019 and May 6, 2021.

On March 6, 2024, the Northern District Court of California certified a class of all persons who purchased or otherwise acquired the common stock of ChemoCentryx between November 26, 2019 and May 6, 2021. The deadline for class members to opt out of the class action was January 14, 2025.

On August 15, 2025, the Northern District Court of California granted defendants' motion for summary judgment in its entirety and denied lead plaintiff's motion for partial summary judgment. On September 12, 2025, the lead plaintiff filed a notice of appeal to the Ninth Circuit Court of Appeals, and filed its opening brief on January 5, 2026.

On January 27, 2026, the parties informed the Court of Appeals they had reached an agreement to settle the case on a class-wide basis, subject to approval by the district court.

Opt-Out Cases

Prior to the opt-out deadline, on May 2, 2024, RA Capital Healthcare Fund, LP filed two securities cases (which are similar to the class action), in the California Superior Court in Ventura County and in the Northern District Court of California, against ChemoCentryx and its former Chief Executive Officer, Dr. Thomas Schall. On July 2, 2024, the state court stayed the case pending an order on summary judgment in the federal class action. Defendants, including ChemoCentryx, moved to dismiss the complaint, and on June 13, 2025, the court issued an order staying the federal case pending resolution of the class action. The court did not reach the merits of defendants' motion to dismiss.

Commitments – U.S. repatriation tax

Under the 2017 Tax Act, we elected to pay in eight annual installments the repatriation tax related primarily to prior indefinitely invested earnings of our foreign operations. The final U.S. repatriation tax payment of $1.8 billion was made in 2025.

SCHEDULE II

AMGEN INC.

VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 2025, 2024 and 2023

(In millions)

Allowance for doubtful accounts	Balance at beginning of period	Additions charged to costs and expenses	Deductions	Other changes	Balance at end of period
2025	$ 38	$ 1	$ —	$ 4	$ 43
2024	$ 28	$ 13	$ —	$ (3)	$ 38
2023	$ 22	$ 6	$ —	$ —	$ 28

DESCRIPTION OF AMGEN INC.'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of February 10, 2026, Amgen Inc. has two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): (1) our common stock, par value $0.0001 per share (the "Common Stock"); and (2) our 2.000% Senior Notes due 2026 (the "Notes").

DESCRIPTION OF COMMON STOCK

The following description of our capital stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our restated certificate of incorporation, as amended ("certificate of incorporation") and our amended and restated bylaws, each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K ("Annual Report"). The terms "Amgen" "we," "our," and "us" refer solely to Amgen Inc. and not its subsidiaries.

Our authorized capital stock includes 2,750,000,000 shares of Common Stock. Each holder of our Common Stock is entitled to one vote per share on all matters to be voted upon by our stockholders. Upon any liquidation, dissolution or winding up of our business, the holders of our Common Stock are entitled to share equally in all assets available for distribution after payment of all liabilities, subject to the liquidation preference of shares of preferred stock, if any, then outstanding. Our Common Stock has no preemptive or conversion rights. All outstanding shares of common stock are fully paid and non-assessable. Our outstanding shares of common stock are quoted on the Nasdaq Global Select Market under the symbol "AMGN."

Dividends

Subject to preferences that may be applicable to any preferred stock (if any such stock be issued and outstanding), the holders of Common Stock are entitled ratably to receive dividends, if any, declared by our board of directors out of funds legally available for the payment of dividends.

Anti-Takeover Effects of Delaware Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. Under Section 203, we would generally be prohibited from engaging in any business combination with any interested stockholder for a period of three years following the time that this stockholder became an interested stockholder unless:

- prior to such time, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Under Section 203, a "business combination" includes:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- any transaction which results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or of such subsidiary to the interested stockholder, subject to limited exceptions;

- any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation which has the effect, directly or indirectly, of increasing the proportionate share of the stock of any class or series, or securities convertible into the stock of any class or series, of the corporation or of any such subsidiary which is owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation or any direct or indirect majority-owned subsidiary of the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

Transfer Agent

The transfer agent and registrar for our Common Stock is the American Stock Transfer & Trust Company.

DESCRIPTION OF THE NOTES

The following description of our Notes is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to the indenture, dated as of May 22, 2014 (the "Indenture"), between us and The Bank of New York Mellon Trust Company, N.A., as trustee (the "Trustee"), which are incorporated by reference as exhibits to the Annual Report of which this Exhibit 4.32 is a part. The Notes are traded on The Nasdaq Stock Market LLC under the trading symbol of "AMGN26." We encourage you to read the above referenced Indenture for additional information.

General

We issued €750,000,000 in aggregate principal amount of 2.000% Senior Notes, maturing February 25, 2026 and bearing interest at a rate of 2.000% per annum, payable annually on February 25 of each year. As of February 10, 2026, €750,000,000 aggregate principal amount of the Notes was outstanding.

We may, without notice to or the consent of the holders or beneficial owners of the Notes of any series, create and issue additional Notes and/or notes having the same ranking, interest rate, maturity and other terms as the Notes of that series. Any additional debt securities having such similar terms, together with that series of Notes, could be considered part of the same series of Notes under the Indenture; *provided* that, in the case of any notes represented by global notes, for so long as may be required by the United States Securities Act of 1933, as amended (the "Securities Act"), or the procedures of the common depositary, the Euroclear System ("Euroclear") or Clearstream Banking, S.A. ("Clearstream") (or a successor or clearing system), such additional Notes will be represented by one or more separate global notes in accordance with the terms of the Indenture and subject to applicable transfer or other restrictions.

The Notes are redeemable prior to maturity as described below under the headings "—Optional Redemption" and "—Redemption Upon Changes in Withholding Taxes." The Notes do not have the benefit of any sinking funds. The Notes of each series are issued only in registered form without coupons attached in minimum denominations of €100,000 and any integral multiple of €1,000 in excess thereof. Each series of Notes are represented by one or more global securities deposited with, or on behalf of, a common depositary for Euroclear and Clearstream (the "global notes").

Certain Definitions

As used herein, the following terms have the meanings set forth below.

"*Attributable Liens*" means in connection with a sale and lease-back transaction the lesser of:

(1) the fair market value of the assets subject to such transaction; and

(2) the present value (discounted at a rate per annum equal to the average interest borne by all outstanding debt securities issued under the Indenture (which may include debt securities in addition to the Notes) determined on a weighted average basis and compounded semi-annually) of the obligations of the lessee for rental payments during the term of the related lease.

"*Business Day*" means any day on which commercial banks and foreign exchange markets are open for business in New York and London and which is a day on which the Trans-European Automated Real-Time Gross Settlement Express Transfer System (TARGET2) is operating.

"*Calculation Agent*" means an independent financial institution appointed by Amgen, which may include the paying agent, any of the managers or their respective affiliates who agree to serve in such capacity.

"*Capital Lease*" means any Indebtedness represented by a lease obligation of a Person incurred with respect to real property or equipment acquired or leased by such Person and used in its business that is required to be recorded as a capital lease in accordance with GAAP.

"*Consolidated Net Worth*" means, as of any date of determination, the Stockholders' Equity of us and our Consolidated Subsidiaries on that date.

"*Consolidated Subsidiary*" means, as of any date of determination and with respect to any Person, any Subsidiary of that Person whose financial data is, in accordance with GAAP, reflected in that Person's consolidated financial statements.

"*Credit Facilities*" means, one or more debt facilities (including, without limitation, the revolving credit agreement and the term loan credit agreement, as applicable) or commercial paper facilities, in each case, with banks or other institutional lenders providing for revolving credit loans, term loans, receivables financing (including through the sale of receivables to such lenders or to special purpose entities formed to borrow from such lenders against such receivables) or letters of credit, in each case, as amended, restated, modified, renewed, refunded, replaced (whether upon or after termination or otherwise) or refinanced (including by means of sales of debt securities to institutional investors) in whole or in part from time to time.

"*Exempted Debt*" means the sum of the following as of the date of determination:

(1) our Indebtedness incurred after the first issue date of the Notes and secured by Liens not permitted by the first sentence under "—Limitation on Liens" below; and

(2) our and our Subsidiaries' Attributable Liens in respect of sale and lease-back transactions entered into after the first issue date of the Notes pursuant to the second paragraph of "—Limitation on Sale and Lease-Back Transactions" below.

"*GAAP*" means accounting principles generally accepted in the United States set forth in the Accounting Standards Codification of the Financial Accounting Standards Board or in such other documents by such other entity as have been approved by a significant segment of the accounting profession, which are in effect as of the date of determination.

"*Governmental Agency*" means:

(1) any foreign, federal, state, county or municipal government, or political subdivision thereof;

(2) any governmental or quasi-governmental agency, authority, board, bureau, commission, department, instrumentality or public body;

(3) any court or administrative tribunal; and

(4) with respect to any Person, any arbitration tribunal or other nongovernmental authority to whose jurisdiction that Person has consented.

"*Hedging Obligations*" means, with respect to any specified Person, the obligations of such Person under:

(1) interest rate swap agreements (whether from fixed to floating or from floating to fixed), interest rate cap agreements and interest rate collar agreements;

(2) other agreements or arrangements designed to manage interest rates or interest rate risk; and

(3) other agreements or arrangements designed to protect such Person against fluctuations in currency exchange rates or commodity prices.

"*Indebtedness*" of any Person means, without duplication, any indebtedness, whether or not contingent, in respect of borrowed money or evidenced by bonds, notes, debentures or similar instruments or letters of credit (or reimbursement agreements with respect thereto) or representing the balance deferred and unpaid of the purchase price of any Property (including pursuant to Capital Leases), except any such balance that constitutes an accrued expense or trade payable, if and to the extent any of the foregoing indebtedness would appear as a liability upon a balance sheet of such Person prepared on a consolidated basis in accordance with GAAP (but does not include

contingent liabilities which appear only in a footnote to a balance sheet), and shall also include, to the extent not otherwise included, the guaranty of items which would be included within this definition.

"*Laws*" means, collectively, all foreign, federal, state and local statutes, treaties, rules, regulations, ordinances, codes and administrative or controlling precedents of any Governmental Agency.

"*Lien*" means any lien, security interest, charge or encumbrance of any kind (including any conditional sale or other title retention agreement, any lease in the nature thereof, and any agreement to give any security interest).

"*Make-Whole Amount*" means the excess of (1) the net present value, on the redemption date, of the principal being redeemed or paid and the amount of interest (exclusive of interest accrued to the date of redemption) that would have been payable if such redemption had not been made, over (2) the aggregate principal amount of the Notes being redeemed or paid. Net present value shall be determined by discounting, on a semi-annual basis, such principal and interest at the Reinvestment Rate (as defined below and as determined on the third Business Day preceding the date such notice of redemption is given) from the respective dates on which such principal and interest would have been payable if such redemption had not been made.

"*Permitted Liens*" means:

(1) Liens securing Indebtedness under Credit Facilities;

(2) Liens on accounts receivable, merchandise inventory, equipment, and patents, trademarks, trade names and other intangibles, securing our Indebtedness;

(3) Liens on any of our assets, any of our Subsidiaries' assets, or the assets of any joint venture to which we or any of our Subsidiaries is a party, created solely to secure obligations incurred to finance the refurbishment, improvement or construction of such asset, which obligations are incurred no later than 24 months after completion of such refurbishment, improvement or construction, and all renewals, extensions, refinancings, replacements or refundings of such obligations;

(4) (a) Liens given to secure the payment of the purchase price incurred in connection with the acquisition (including acquisition through merger or consolidation) of Property (including shares of stock), including Capital Lease transactions in connection with any such acquisition, and (b) Liens existing on Property at the time of acquisition thereof or at the time of acquisition by us or one of our Subsidiaries of any Person then owning such Property whether or not such existing Liens were given to secure the payment of the purchase price of the Property to which they attach; provided that, with respect to clause (a), the Liens shall be given within 24 months after such acquisition and shall attach solely to the Property acquired or purchased and any improvements then or thereafter placed thereon;

(5) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of customs duties in connection with the importation of goods;

(6) Liens upon specific items of inventory or other goods and proceeds of any Person securing such Person's obligations in respect of bankers' acceptances issued or created for the account of such Person to facilitate the purchase, shipment or storage of such inventory or other goods;

(7) Liens securing reimbursement obligations with respect to letters of credit that encumber documents and other Property relating to such letters of credit and the products and proceeds thereof;

(8) Liens on key-man life insurance policies granted to secure our Indebtedness against the cash surrender value thereof;

(9) Liens encumbering customary initial deposits and margin deposits and other Liens in the ordinary course of business, in each case securing Hedging Obligations and forward contract, option, futures contracts, futures options or similar agreements or arrangements designed to protect us or any of our Subsidiaries from fluctuations in interest rates, currencies or the price of commodities;

(10) Liens arising out of conditional sale, title retention, consignment or similar arrangements for the sale of goods entered into by us or any of our Subsidiaries in the ordinary course of business;

(11) pre-existing Liens on assets acquired by us or any of our Subsidiaries after the first issue date of the Notes;

(12) Liens in our favor or the favor of any of our Subsidiaries;

(13) inchoate Liens incident to construction or maintenance of real property, or Liens incident to construction or maintenance of real property, now or hereafter filed of record for sums not yet delinquent or being contested in good faith, if reserves or other appropriate provisions, if any, as shall be required by GAAP shall have been made therefor;

(14) statutory Liens arising in the ordinary course of business with respect to obligations which are not delinquent or are being contested in good faith, if reserves or other appropriate provisions, if any, as shall be required by GAAP shall have been made therefor;

(15) Liens consisting of pledges or deposits to secure obligations under workers' compensation laws or similar legislation, including Liens of judgments thereunder which are not currently dischargeable;

(16) Liens consisting of pledges or deposits of Property to secure performance in connection with operating leases made in the ordinary course of business to which we or any of our Subsidiaries is a party as lessee, provided the aggregate value of all such pledges and deposits in connection with any such lease does not at any time exceed 16 2⁄3% of the annual fixed rentals payable under such lease;

(17) Liens consisting of deposits of Property to secure our statutory obligations or statutory obligations of any of our Subsidiaries in the ordinary course of its business;

(18) Liens consisting of deposits of Property to secure (or in lieu of) surety, appeal or customs bonds in proceedings to which we or any of our Subsidiaries is a party in the ordinary course of its business, but not in excess of $75,000,000;

(19) purchase money Liens or purchase money security interests upon or in any Property acquired or held by us or any of our Subsidiaries in the ordinary course of business to secure the purchase price of such Property or to secure indebtedness incurred solely for the purpose of financing the acquisition of such Property;

(20) Liens on an asset created in connection with the acquisition, construction or development of additions, extensions or improvements to such asset which shall be financed by obligations described in Sections 142, 144(a) or 144(c) of the Code, or by obligations entitled to substantially similar tax benefits under other legislation or regulations in effect from time to time; and

(21) Liens on Property subject to escrow or similar arrangements established in connection with litigation settlements.

"*Person*" means any individual, corporation, partnership, joint venture, association, limited liability company, joint-stock company, trust, unincorporated organization or government or any agency or political subdivision thereof.

"*Property*" means any property or asset, whether real, personal or mixed, or tangible or intangible.

"*Reference Bund*" means the Federal Government Bond of Bundesrepublik Deutschland due February 15, 2026, with ISIN 0001102390.

"*Reference Dealers*" means each of the four banks selected by a Calculation Agent which are primary European government security dealers, and their respective successors, or market makers in pricing corporate bond issues.

"*Reinvestment Rate*" means 0.300% plus the average of the four quotations given by the Reference Dealers of the mid-market annual yield to maturity of the Reference Bund at 11: 00 a.m. (Central European time ("CET")) on the fourth Business Day preceding such redemption date and if the Reference Bund is no longer outstanding, a Similar Security will be chosen by the Calculation Agent at 11: 00 a.m. (CET) on the third Business Day in London preceding such redemption date, quoted in writing by the Calculation Agent to us.

"*Similar Security*" means a reference bond or reference bonds issued by the German Federal Government having an actual or interpolated maturity comparable with the remaining term of the Notes that would be utilized, at the time of selection and in accordance with customary financial practice, in pricing new issues of corporate debt securities of comparable maturity to the remaining term of the Notes.

"*Stockholders' Equity*" means, as of any date of determination, stockholders' equity as of that date determined in accordance with GAAP; provided that there shall be excluded from Stockholders' Equity any amount attributable to capital stock that is, directly or indirectly, required to be redeemed or repurchased by the issuer thereof at a specified date or upon the occurrence of specified events or at the election of the holder thereof.

"*Subsidiary*" of any specified person means any corporation, association or other business entity of which more than 50% of the total voting power of shares of capital stock entitled (without regard to the occurrence of any contingency) to vote in the election of directors, managers or trustees thereof is at the time owned or controlled, directly or indirectly, by such person or one or more of the other Subsidiaries of that person or a combination thereof.

Paying Agent and Registrar

The Bank of New York Mellon, London Branch, is the principal paying agent for the Notes (the "principal paying agent"). The Bank of New York Mellon Trust Company, N.A., is the security registrar for the Notes. Upon notice to the Trustee, we may change any paying agent or security registrar, and we or any of our subsidiaries may act as paying agent or registrar.

Interest

The Notes accrue interest at a rate of 2.000% per annum. The Notes accrue interest on their stated principal amounts from the most recent interest payment date on which interest has been paid or duly provided for. Accrued and unpaid interest on the Notes are payable annually in arrears on February 25 of each year. In each case, interest is paid to the holder in whose name a note is registered at the close of business on the day that is one Business Day prior to the relevant interest payment date.

Interest on the Notes is computed on the basis of the actual number of days in the period for which interest is being calculated and the actual number of days from and including the last date on which interest was paid on the Notes, to but excluding the next scheduled interest payment date. This payment convention is referred to as Actual/

Actual (ICMA) as defined in the rulebook of the International Capital Market Association. If any date on which interest, principal or premium is payable on the Notes is not a Business Day, then payment of such amounts payable on such date will be made on the next succeeding day that is a Business Day (and, except as provided under "—Payment of Additional Amounts," without any interest or other payment in respect of any such delay) with the same force and effect as if made on such interest payment date or maturity date, as the case may be.

Any amounts payable on any Notes that are not punctually paid on any payment date will cease to be payable to the person in whose name such Notes are registered on the relevant record date, and such defaulted payment will instead be payable to the person in whose name such Notes are registered on the special record date or other specified date determined in accordance with the Indenture.

Ranking

The Notes are senior unsecured obligations of Amgen. The Notes rank:

- equal in right of payment to all of our other existing and future senior unsecured indebtedness;
- senior in right of payment to all of our existing and future subordinated indebtedness; and
- effectively subordinated in right of payment to all of our subsidiaries' obligations (including secured and unsecured obligations) and subordinated in right of payment to our secured obligations, to the extent of the assets securing such obligations.

The Notes and the Indenture do not limit our ability to incur additional indebtedness. We may incur substantial additional amounts of indebtedness in the future.

Optional Redemption

The Notes may be redeemed prior to maturity at our option, at any time in whole or from time to time in part. If the Notes are redeemed before November 25, 2025 (three months prior to the maturity date of the Notes), the redemption price will equal the sum of (1) 100% of the principal amount being redeemed, plus accrued and unpaid interest to, but not including, the redemption date, and (2) the Make-Whole Amount, if any. If the Notes are redeemed on or after November 25, 2025 (three months prior to the maturity date of the Notes), the redemption price will equal 100% of the principal amount being redeemed, plus accrued and unpaid interest to, but not including, the redemption date.

If we give notice as provided in the Indenture and funds for the redemption of any Notes called for redemption sufficient to pay the redemption price have been deposited with the principal paying agent on or before 10:00 a.m., London time, on the redemption date, such Notes will cease to bear interest on the date fixed for redemption. Thereafter, the only right of the holders of such Notes will be to receive payment of the redemption price.

Upon surrender of a note that is redeemed in part, we shall execute and the Trustee shall authenticate for the holder a new note of the same series and the same maturity equal in principal amount to the unredeemed portion of the note surrendered.

The Notes are redeemable prior to maturity as described below under the headings "—Optional Redemption" and "—Redemption Upon Changes in Withholding Taxes." The Notes do not have the benefit of any sinking funds. The Notes of each series are issued only in registered form without coupons attached in minimum denominations of €100,000 and any integral multiple of €1,000 in excess thereof. Each series of Notes are represented by one or more global securities deposited with, or on behalf of, a common depositary for Euroclear and Clearstream (the "global notes").

Payments on the global notes are made through the principal paying agent (as defined herein under the heading "—Paying Agent and Registrar"). Payments on the Notes are made at the specified office or agency of the principal paying agent; *provided* that all such payments with respect to Notes represented by one or more global notes registered in the name of or held by a nominee of Euroclear or Clearstream, as applicable, will be by wire transfer of immediately available funds to the account specified by the holder or holders thereof.

In addition, at our option, if certificated notes are issued, we may make payments by check mailed to the holder's registered address or by wire transfer to the account shown on the register for the certificated notes.

If certificated notes are issued, they will be issued only in minimum denominations of €100,000 principal amount and integral multiples of €1,000 in excess thereof upon receipt by the applicable registrar of instructions relating thereto and any certificates and other documentation required under the Indenture. It is expected that such instructions will be based upon directions received by Euroclear or Clearstream, as applicable, from the participant which owns the relevant book-entry interests. Certificated notes issued in exchange for book-entry interests will, except as provided in the Indenture, be subject to, and will have a legend with respect to the restrictions on transfer summarized below.

Subject to the restrictions on transfer referred to above, Notes issued as certificated notes may be transferred or exchanged, in whole or in part, in minimum denominations of €100,000 principal amount and integral multiples of €1,000 in excess thereof to persons who take delivery thereof in the form of certificated notes. In connection with any such transfer or exchange, the Indenture requires the transferring or exchanging holder to, among other things, furnish appropriate endorsements and transfer documents, to furnish information regarding the account of the transferee at Euroclear or Clearstream, where appropriate, to furnish certain certificates and opinions, and to pay any tax or other governmental charge in connection with such transfer or exchange. Any such transfer or exchange will otherwise be made without charge to the holder.

Notwithstanding the foregoing, we are not required to register the transfer or exchange of any Notes:

- for a period of 15 days prior to any date fixed for the redemption of the Notes;
- for a period of 15 days immediately prior to the date fixed for selection of Notes to be redeemed in part;
- for a period of 15 days prior to the record date with respect to any interest payment date; or
- which the holder has tendered (and not withdrawn) for repurchase in connection with a change of control offer.

Redemption Upon Changes in Withholding Taxes

If (a) as a result of any change in, or amendment to, the laws (or any regulations or rulings promulgated thereunder) of the United States (or any political subdivision or taxing authority thereof or therein having power to tax) (a "Relevant Taxing Jurisdiction"), or any change in, or amendment to, the official position regarding the application or interpretation of such laws, regulations or rulings (including by virtue of a holding, judgment or order by a court of competent jurisdiction or a change in published administrative practice), which change or amendment is announced on or after the date of the applicable prospectus supplement, we become or will become obligated to pay additional amounts as described herein under the heading "—Payment of Additional Amounts" or (b) any act is taken by a Relevant Taxing Jurisdiction on or after the date of the applicable prospectus supplement, whether or not such act is taken with respect to us or any affiliate, that results in a substantial probability that we will or may be required to pay such additional amounts, then we may, at our option, redeem the Notes of any affected series, as a whole but not in part, upon not less than 15 days' nor more than 60 days' published notice in accordance with the applicable notice requirement, at 100% of their principal amount, together with interest accrued thereon to the date fixed for redemption; *provided* that we determine, in our business judgment, that the obligation to pay such additional amounts cannot be avoided by the use of reasonable measures available to us (which does not include substitution of the obligor under the Notes). No redemption pursuant to (a) or (b) above may be made unless we have received an opinion of independent counsel to the effect that as a result of such change or amendment we will, or that an act taken by a Relevant Taxing Jurisdiction has resulted in a substantial probability that we will, or may, be required to pay the additional amounts described herein under the heading "—Payment of Additional Amounts," and we shall have delivered to the Trustee a certificate, signed by a duly authorized officer, stating that based on such opinion we are entitled to redeem the Notes pursuant to their terms.

Notice of Redemption

We will publish a notice of any redemption of any affected series of Notes described above in accordance with the applicable notice provisions. If fewer than all of the Notes are to be redeemed at any time, the principal paying agent will select the Notes to be redeemed in accordance with the rules of the principal securities exchange, if any, on which the Notes are listed at such time or, if the not Notes are not listed on a securities exchange, in accordance with the rules of Euroclear or Clearstream, or absent any such rules, *pro rata*, by lot; *provided, however*, that no such partial redemption shall reduce the portion of the principal amount of a note not redeemed to less than

€100,000. The principal paying agent shall not be liable for any selections made by it in accordance with this paragraph.

We will give notice of any optional redemption to the registered holders of Notes at least 15 but not more than 60 days before a redemption date. The notice shall identify the Notes to be redeemed and shall state:

- the redemption date;
- the redemption price;
- the name and address of the paying agent;
- if any Notes are being redeemed in part, the portion of the principal amount of such notes to be redeemed and that, after the redemption date and upon surrender of such Notes, a new note or notes in principal amount equal to the unredeemed portion of the original note shall be issued in the name of the holder of the Notes thereof upon cancellation of the original note;
- that the notes called for redemption must be surrendered to the paying agent to collect the redemption price;
- that interest on the Notes called for redemption ceases to accrue on and after the redemption date unless we default in the deposit of the redemption price; and
- the CUSIP and/or ISIN number of the Notes.

At our request, the Trustee shall give the notice of redemption in our name and at our expense.

Payment of Additional Amounts

All payments of principal and interest on the Notes will be made free and clear of and without withholding or deduction for or on account of any present or future tax, assessment or other governmental charge (collectively, "Taxes") imposed by any Relevant Taxing Jurisdiction, unless the withholding of such Taxes is required by law or the official interpretation or administration thereof. We will, subject to the exceptions and limitations set forth below, pay such additional amounts as are necessary in order that the net payment of the principal of and interest on the applicable series of Notes to a holder who is not a U.S. person for U.S. federal income tax purposes, after deduction for any present or future Taxes of any Relevant Taxing Jurisdiction, imposed by withholding with respect to the payment, will not be less than the amount provided in such Notes to be then due and payable*; provided*, *however*, that the foregoing obligation to pay additional amounts shall not apply:

(1) to any Taxes that are imposed or withheld solely by reason of the holder or beneficial owner, or a fiduciary, settlor, beneficiary, member or shareholder of the holder if the holder is an estate, trust, partnership or corporation, or a person holding a power over an estate or trust administered by a fiduciary holder, being considered as:

(a) being or having been present or engaged in a trade or business in the United States or having or having had a permanent establishment in the United States;

(b) having a current or former relationship with the United States, including a relationship as a citizen or resident thereof;

(c) being or having been a foreign or domestic personal holding company, a passive foreign investment company or a controlled foreign corporation with respect to the United States or a corporation that has accumulated earnings to avoid U.S. federal income tax;

(d) being or having been a "10-percent shareholder" of the obligor under the Notes within the meaning of section 871(h)(3) of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), or any successor provision; or

(e) being or having been a bank receiving interest described in section 881(c)(3)(A) of the Code or any successor provision;

(2) to any holder that is not the sole beneficial owner of the note, or a portion thereof, or that is a fiduciary or partnership, but only to the extent that a beneficiary or settlor with respect to the fiduciary, a beneficial owner or member of the partnership would not have been entitled to the payment of an additional amount had the beneficiary, settlor, beneficial owner or member received directly its beneficial or distributive share of the payment;

(3) to any Taxes that are imposed or withheld solely by reason of the failure to (a) comply with certification, identification or information reporting requirements concerning the nationality, residence, identity or connection with a Relevant Taxing Jurisdiction of the holder or beneficial owner of such note, if compliance is required by statute or by regulation of the Relevant Taxing Jurisdiction as a precondition to relief or exemption from such Taxes (including the submission of an applicable U.S. Internal Revenue Service ("IRS") Form W-8 (with any required attachments)) or (b) comply with any informational gathering and reporting requirements or to take any similar action (including entering into any agreement with the IRS), in each case, that are required to obtain the maximum available exemption from withholding by a Relevant Taxing Jurisdiction that is available to payments received by or on behalf of the holder;

(4) to any Taxes that are imposed otherwise than by withholding from the payment;

(5) to any Taxes that are imposed or withheld solely by reason of a change in law, regulation, or administrative or judicial interpretation that becomes effective more than 15 days after the payment becomes due or is duly provided for, whichever occurs later;

(6) to any estate, inheritance, gift, sales, excise, transfer, wealth or personal property tax or a similar tax, assessment or governmental charge;

(7) to any Taxes required to be withheld by any paying agent from any payment of principal of or interest on any note, if such payment can be made without such withholding by any other paying agent;

(8) to any Taxes that are imposed or levied by reason of the presentation (where presentation is required in order to receive payment) of such notes for payment on a date more than 30 days after the date on which such payment became due and payable, except to the extent that the holder or beneficial owner thereof would have been entitled to additional amounts had the notes been presented for payment on any date during such 30 day period;

(9) to any Taxes that are imposed or withheld pursuant to Sections 1471 through 1474 of the Code, as of the issue date (or any amended or successor version of such sections), any U.S. Treasury Regulations promulgated thereunder, any official interpretations thereof, any similar law or regulation adopted pursuant to an intergovernmental agreement between a non-U.S. jurisdiction and the United States with respect to the foregoing or any agreements entered into pursuant to Section 1471(b)(1) of the Code; or

(10) in the case of any combination of any items (1) through (9).

The notes are subject in all cases to any tax, fiscal or other law or regulation or administrative or judicial interpretation applicable thereto. Except as specifically provided under this heading "—Payment of Additional Amounts," we are not required to make any payment with respect to any tax, assessment or governmental charge imposed by any government or a political subdivision or taxing authority thereof or therein.

Change of Control Offer

If a change of control triggering event occurs, unless we have exercised our option to redeem the notes as described above, we will be required to make an offer (the "change of control offer") to each holder of the notes to repurchase all or any part (equal to €100,000 or integral multiples of €1,000 in excess thereof) of that holder's notes on the terms set forth in such notes. In the change of control offer, we will be required to offer payment in cash equal to 101 % of the aggregate principal amount of notes repurchased, plus accrued and unpaid interest, if any, on the notes repurchased to the date of repurchase (the "change of control payment"). Within 30 days following any change of control triggering event, a notice will be provided to holders of the notes describing the transaction that constitutes the change of control triggering event and offering to repurchase the notes on the date specified in the notice, which date will be no earlier than 30 days and no later than 60 days from the date such notice is provided (the "change of control payment date"); provided, however, that in no event will the change of control payment date occur prior to the date 90 days following the first issue date of the notes.

On the change of control payment date, we will, to the extent lawful:

- accept for payment all notes or portions of notes properly tendered pursuant to the change of control offer;

- by 10:00 a.m., London time, deposit with the principal paying agent an amount equal to the change of control payment in respect of all notes or portions of notes properly tendered; and

- deliver or cause to be delivered to the Trustee the notes properly accepted together with an officer's certificate stating the aggregate principal amount of notes or portions of notes being repurchased.

We will not repurchase any notes if there has occurred and is continuing on the change of control payment date an event of default under the Indenture, other than a default in the payment of the change of control payment upon a change of control triggering event.

We will comply with the requirements of Rule 14e-1 under the U.S. Securities Exchange Act of 1934, as amended (the "Exchange Act"), and any other securities laws and regulations thereunder to the extent those laws and regulations are applicable in connection with the repurchase of the notes as a result of a change of control triggering event. To the extent that the provisions of any such securities laws or regulations conflict with the change of control offer provisions of the notes, we will comply with those securities laws and regulations and will not be deemed to have breached our obligations under the change of control offer provisions of the notes by virtue of any such conflict.

For purposes of the change of control offer provisions of the notes, the following terms will be applicable:

"*Beneficial owner*" shall be determined in accordance with Rules 13d-3 and 13d-5 under the Exchange Act or any successor provisions, except that a person will be deemed to have beneficial ownership of all shares that person has the right to acquire irrespective of whether that right is exercisable immediately or only after the passage of time.

"*Change of control*" means the occurrence of any of the following: (1) the consummation of any transaction (including, without limitation, any merger or consolidation) the result of which is that any person or group (other than our company or one of our subsidiaries) becomes the beneficial owner, directly or indirectly, of more than 50% of our voting stock or other voting stock into which our voting stock is reclassified, consolidated, exchanged or changed, measured by voting power rather than number of shares; provided, however, that a person shall not be deemed beneficial owner of, or to own beneficially, (A) any securities tendered pursuant to a tender or exchange offer made by or on behalf of such person or any of such person's affiliates until such tendered securities are accepted for purchase or exchange thereunder, or (B) any securities if such beneficial ownership (i) arises solely as a result of a revocable proxy delivered in response to a proxy or consent solicitation made pursuant to the applicable rules and regulations under the Exchange Act, and (ii) is not also then reportable on Schedule 13D (or any successor schedule) under the Exchange Act; (2) the direct or indirect sale, transfer, conveyance or other disposition (other than by way of merger or consolidation), in one or more series of related transactions, of all or substantially all of our assets and the assets of our subsidiaries, taken as a whole, to one or more persons or groups (other than our company or one of our subsidiaries), provided that none of the circumstances in this clause (2) will be a change of control if the persons that beneficially own our voting stock immediately prior to the transaction own, directly or indirectly, shares with a majority of the total voting power of all outstanding voting securities of the surviving or transferee person that are entitled to vote generally in the election of that person's board of directors, managers or trustees immediately after the transaction; (3) we consolidate with, or merge with or into any person, or any person consolidates with, or merges with or into, us, in any such event pursuant to a transaction in which any of our outstanding voting stock or the voting stock of such other person is converted into or exchanged for cash, securities or other property, other than such transaction where the shares of our voting stock outstanding immediately prior to

such transaction constitute, or are converted into or exchanged for, a majority of the voting stock of the surviving person or any direct or indirect parent company of the surviving person immediately after giving effect to such transaction; or (4) the adoption of a plan relating to our liquidation or dissolution. Notwithstanding the foregoing, a transaction will not be deemed to involve a change of control under clause (1) above if (i) we become a direct or indirect wholly-owned subsidiary of a holding company and (ii) (A) the direct or indirect holders of the voting stock of such holding company immediately following that transaction are substantially the same as the holders of our voting stock immediately prior to that transaction or (B) immediately following that transaction no person (other than a holding company satisfying the requirements of this sentence) is the beneficial owner, directly or indirectly, of more than 50% of the voting stock of such holding company.

"*Change of control triggering event*" means the occurrence of both a change of control and a rating event.

"*Fitch*" means Fitch, Inc., and its successors.

"*Group*" has the meaning given by Section 13(d) and 14(d) of the Exchange Act or any successor provisions and includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the Exchange Act or any successor provision.

"*Investment grade rating*" means a rating equal to or higher than Baa3 (or the equivalent) by Moody's, BBB—(or the equivalent) by S&P and BBB—(or the equivalent) by Fitch, and the equivalent investment grade credit rating from any additional rating agency or rating agencies selected by us.

"*Moody's*" means Moody's Investors Service, Inc., and its successors.

"*Person*" has the meaning given by Section 13(d) and 14(d) of the Exchange Act or any successor provisions.

"*Rating agencies*" means (1) each of Fitch, Moody's and S&P; and (2) if any of Fitch, Moody's or S&P ceases to rate the notes or fails to make a rating of the notes publicly available for reasons outside of our control, a "nationally recognized statistical rating organization" within the meaning of Section 3(a)(62) of the Exchange Act selected by us (as certified by a resolution of our Board of Directors) as a replacement agency for Fitch, Moody's or S&P, or all of them, as the case may be.

"*Rating event*" means the rating on the applicable series of notes is lowered by at least two of the three rating agencies and the notes are rated below an investment grade rating by at least two of the three rating agencies on any day during the period commencing 60 days prior to the first public notice of the occurrence of a change of control or our intention to effect a change of control and ending 60 days following consummation of such change of control (which period will be extended so long as the rating of the applicable series of notes is under publicly announced consideration for a possible downgrade by any of the rating agencies).

"*S&P*" means Standard & Poor's Rating Services, a division of The McGraw-Hill Companies, Inc., and its successors.

"*Voting stock*" as applied to stock of any person, means shares, interests, participations or other equivalents in the equity interest (however designated) in such person having ordinary voting power for the election of a majority of the directors (or the equivalent) of such person, other than shares, interests, participations or other equivalents having such power only by reason of the occurrence of a contingency.

Certain Covenants

Limitation on Liens

We will not, nor will we permit any of our Subsidiaries to, create or incur any Lien on any of our or their respective Properties, whether now owned or hereafter acquired, or upon any income or profits therefrom, in order to secure any of our Indebtedness, without effectively providing that each series of notes shall be equally and ratably secured until such time as such Indebtedness is no longer secured by such Lien, except:

(1) Liens existing as of the first issue date of the notes;

(2) Liens granted after the first issue date of the notes on any of our or our Subsidiaries' Properties securing our Indebtedness created in favor of the holders of the notes;

(3) Liens securing our Indebtedness which are incurred to extend, renew or refinance Indebtedness which is secured by Liens permitted to be incurred under the Indenture; provided that those Liens do not extend to or cover any of our or our Subsidiaries' Property other than the Property securing the Indebtedness being refinanced and that the principal amount of such Indebtedness does not exceed the principal amount of the Indebtedness being refinanced;

(4) Liens created in substitution of or as replacements for any Liens permitted by the clauses directly above, provided that, based on a good faith determination of one of our officers, the Property encumbered under any such substitute or replacement Lien is substantially similar in nature to the Property encumbered by the otherwise permitted Lien which is being replaced; and

(5) Permitted Liens.

Notwithstanding the foregoing, we and any of our Subsidiaries may, without securing any series of notes, create or incur Liens which would otherwise be subject to the restrictions set forth in the preceding paragraph, if after giving effect thereto, Exempted Debt does not exceed the greater of (a) 35% of Consolidated Net Worth calculated as of the date of the creation or incurrence of the Lien or (b) 35% of Consolidated Net Worth calculated as of the first issue date of the notes.

Limitation on Sale and Lease-Back Transactions

We will not, nor will we permit any of our Subsidiaries to, enter into any sale and lease-back transaction for the sale and leasing back of any Property, whether now owned or hereafter acquired, of ours or any of our Subsidiaries, unless:

(1) such transaction was entered into prior to the first issue date of the notes;

(2) such transaction was for the sale and leasing back to us of any Property by one of our Subsidiaries;

(3) such transaction involves a lease for less than three years;

(4) we would be entitled to incur Indebtedness secured by a mortgage on the property to be leased in an amount equal to the Attributable Liens with respect to such sale and lease-back transaction without equally and ratably securing the notes pursuant to the first paragraph of "—Limitation on Liens" above; or

(5) we apply an amount equal to the fair value of the Property sold to the purchase of Property or to the retirement of our or any of our Subsidiaries' long-term Indebtedness within 120 days of the effective date of any such sale and lease-back transaction. In lieu of applying such amount to such retirement, we may, or may cause any of our Subsidiaries to, deliver debt securities to the Trustee therefor for cancellation, such debt securities to be credited at the cost thereof to us.

Notwithstanding the foregoing, we and any of our Subsidiaries may enter into any sale lease-back transaction which would otherwise be subject to the foregoing restrictions if after giving effect thereto and at the time of determination, Exempted Debt does not exceed the greater of (a) 35% of Consolidated Net Worth calculated as of the closing date of the sale-leaseback transaction or (b) 35% of Consolidated Net Worth calculated as of the first issue date of the notes.

Events of Default

Event of default means, with respect to each series of notes, any of the following:

- default in the payment of any interest on the notes of that series when it becomes due and payable, and continuance of such default for a period of 30 days (unless the entire amount of the payment is deposited by us with the Trustee or with the principal paying agent prior to the expiration of the 30-day period);

- default in the payment of principal of the notes of that series at their maturity;

- default in the performance or breach of any other covenant or warranty by us in the Indenture (other than defaults pursuant to the previous two bullet points above or pursuant to a covenant or warranty that has been included in the Indenture solely for the benefit of a series of debt securities other than that series of notes), which default continues uncured for a period of 90 days after we receive written notice from the Trustee or we and the Trustee receive written notice from the holders of not less than a majority in principal amount of the outstanding Notes of the affected series as provided in the Indenture; or

- certain voluntary or involuntary events of bankruptcy, insolvency or reorganization of our company.

No event of default with respect to the Notes (except as to certain events of bankruptcy, insolvency or reorganization) necessarily constitutes an event of default with respect to any other series of debt securities. The occurrence of an event of default may constitute an event of default under our bank credit agreements in existence from time to time. In addition, the occurrence of certain events of default or an acceleration under the Indenture may constitute an event of default under certain of our other indebtedness outstanding from time to time.

We will provide the Trustee written notice of any default or event of default within 30 days of becoming aware of the occurrence of such default or event of default, which notice will describe in reasonable detail the status of such default or event of default and what action we are taking or propose to take in respect thereof.

If an event of default with respect to a series of Notes occurs and is continuing (other than an event of default regarding certain events of bankruptcy, insolvency or reorganization of our company), then the Trustee or the holders of not less than a majority in principal amount of the outstanding Notes of that series may, by a notice in writing to us (and to the Trustee if given by the holders), declare to be due and payable immediately the principal of, and accrued and unpaid interest, if any, on all Notes of that series. In the case of an event of default resulting from certain events of bankruptcy, insolvency or reorganization, the principal of and accrued and unpaid interest, if any, on all outstanding debt securities issued under the Indenture will become and be immediately due and payable without any declaration or other act on the part of the Trustee or any holder of outstanding debt securities, including the Notes. At any time after a declaration of acceleration with respect to a series of Notes has been made, and before a judgment or decree for payment of the money due has been obtained by the Trustee, the holders of a majority in principal amount of the outstanding Notes of that series may, by written notice to us and the Trustee, rescind and annul such acceleration if all events of default, other than the non-payment of accelerated principal and interest, if any, with respect to the Notes of that series, have been cured or waived as provided in the Indenture.

The Indenture provides that the Trustee will be under no obligation to exercise any of its rights or powers under the Indenture at the request of any holder of notes, unless the Trustee receives indemnity satisfactory to it against any cost, liability or expense which might be incurred by it in exercising such right or power. Subject to certain rights of the Trustee, the holders of a majority in principal amount of the outstanding Notes of the affected series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the Trustee or exercising any trust or power conferred on the Trustee with respect to the Notes of that series.

No holder of any Note of any series will have any right to institute any proceeding, judicial or otherwise, with respect to the Indenture, or for the appointment of a receiver or Trustee, or for any remedy under the Indenture unless, among other things:

- that holder has previously given to the Trustee written notice of a continuing event of default with respect to the Notes of that series; and

- the holders of at least a majority in principal amount of the outstanding Notes of that series have made written request, and offered reasonable indemnity or security, to the Trustee to institute the proceeding as Trustee, and the Trustee has not received from the holders of a majority in principal amount of the outstanding Notes of that series a direction inconsistent with that request and has failed to institute the proceeding within 60 days.

Notwithstanding any other provision in the Indenture, the holder of any Note will have an absolute and unconditional right to receive payment of the principal of, premium and any interest on that Note on or after the due dates expressed in that Note and to institute suit for the enforcement of any such payment.

If any securities are outstanding under the Indenture, the Indenture requires us, within 120 days after the end of each fiscal year, to furnish to the Trustee a statement as to our compliance with the indenture. If a default or event of default occurs and is continuing with respect to notes of any series and if it is known to a responsible officer of the Trustee, the Trustee shall deliver to each holder of the Notes of that series notice of a default or event of default within 90 days after it occurs. The Indenture provides that the Trustee may withhold notice to the holders of the Notes of any default or event of default (except in the case of a default or event of default in payment of principal of or interest on any Note of that series) with respect to Notes of that series if it in good faith determines that withholding notice is in the interest of the holders of those Notes.

Modification and Waiver

We and the Trustee may modify and amend the Indenture or Notes of any series without the consent of any holder of Notes:

- to cure any ambiguity, defect or inconsistency;
- to comply with the covenant described below under the heading "—Consolidation, Merger and Sale of Assets;"
- to provide for uncertificated notes in addition to or in place of certificated notes;
- to add guarantees with respect to Notes of any series or secure notes of any series;
- to surrender any of our rights or powers under the Indenture;
- to add covenants or events of default for the benefit of the holders of Notes of any series;
- to comply with the applicable procedures of the applicable depositary;
- to make any change that would not adversely affect the rights of any holder of Notes in any material respect;
- to provide for the issuance of and establish the form and terms and conditions of additional Notes of any series as permitted by the Indenture;
- to effect the appointment of a successor trustee with respect to the Notes and to add to or change any of the provisions of the Indenture to provide for or facilitate administration by more than one trustee; or
- to comply with requirements of the U.S. Securities and Exchange Commission in order to effect or maintain the qualification of the Indenture under the U.S. Trust Indenture Act of 1939.

We may also modify and amend the Indenture with the consent of the holders of at least a majority in principal amount of the outstanding Notes of each series affected by the modifications or amendments. We may not

make any modification or amendment without the consent of the holders of each affected Note then outstanding if that amendment will:

- reduce the amount of Notes whose holders must consent to an amendment, supplement or waiver;
- reduce the rate of or extend the time for payment of interest (including any additional amounts) on the Notes;
- reduce the principal of or premium on or change the fixed maturity of the Notes;
- waive a default in the payment of the principal of, premium or interest on the notes (except a rescission of acceleration of the notes by the holders of at least a majority in aggregate principal amount of the then outstanding Notes of that series and a waiver of the payment default that resulted from such acceleration);
- make the principal of or interest on the Notes payable in currency other than that stated in the Notes;
- make any change to certain provisions of the Indenture relating to, among other things, the right of holders of the Notes to receive payment of the principal of, premium and interest on the Notes and to institute suit for the enforcement of any such payment and to waivers or amendments; or
- waive a redemption payment with respect to the Notes.

Except for certain specified provisions, the holders of at least a majority in principal amount of the outstanding Notes of the affected series may, on behalf of the holders of all the Notes of that series, waive our compliance with provisions of the Indenture. The holders of a majority in principal amount of the outstanding Notes of the affected series may, on behalf of the holders of all the Notes of such series, waive any past default under the Indenture with respect to that series and its consequences, except a default in the payment of the principal of, premium or any interest on any Note of that series; provided, however, that the holders of a majority in principal amount of the outstanding Notes of the affected series may rescind an acceleration and its consequences, including any related payment default that resulted from such acceleration.

No amendment to cure any ambiguity, defect or inconsistency in the Indenture made solely to conform the Indenture to the description of notes contained in the applicable prospectus supplement will be deemed to adversely affect the interests of the holders of the Notes.

Consolidation, Merger and Sale of Assets

We may not consolidate with or merge with or into, or convey, transfer or lease all or substantially all of our properties and assets to, any person, which we refer to as a "successor person," unless:

- we are the surviving corporation or the successor person (if other than Amgen) is organized and validly existing under the laws of any U.S. domestic jurisdiction and expressly assumes, pursuant to a supplemental Indenture, our obligations on the notes and under the Indenture; and
- immediately after giving effect to the transaction, no default or event of default shall have occurred and be continuing under the Indenture.

Notwithstanding the foregoing, any of our Subsidiaries may consolidate with, merge into or transfer all or part of its properties and assets to us.

Defeasance and Covenant Defeasance

Legal Defeasance

The Indenture provides that we may be discharged from any and all obligations in respect of the Notes (subject to certain exceptions). We will be so discharged upon the deposit with the Trustee, in trust, of money, U.S. government obligations and/or foreign government obligations that, through the payment of interest and principal in accordance with their terms, will provide money, U.S. government obligations or foreign government obligations in an amount sufficient in the opinion of a nationally recognized firm of independent public accountants or investment bank to pay and discharge each installment of principal of, premium and interest on the Notes on the stated maturity of those payments in accordance with the terms of the Indenture and the Notes.

This discharge may occur only if, among other things, we have delivered to the Trustee an opinion of counsel stating that we have received from, or there has been published by, the IRS a ruling or, since the date of execution of the Indenture, there has been a change in the applicable U.S. federal income tax law, in either case to the effect that, and based thereon such opinion shall confirm that, the holders of the Notes will not recognize income, gain or loss for U.S. federal income tax purposes as a result of the deposit, defeasance and discharge and will be subject to U.S. federal income tax on the same amounts and in the same manner and at the same times as would have been the case if such deposit, defeasance and discharge had not occurred.

Defeasance of Certain Covenants

The Indenture provides that upon compliance with certain conditions:

- we may omit to comply with the covenant described under the heading "—Consolidation, Merger and Sale of Assets" and certain other covenants set forth in the Indenture, as well as any additional covenants set forth in the applicable prospectus supplement; and

- any omission to comply with those covenants will not constitute a default or an event of default with respect to the Notes, which we refer to as a "covenant defeasance."

The conditions include:

- depositing with the Trustee money, U.S. government obligations and/or foreign government obligations that, through the payment of interest and principal in accordance with their terms, will provide money in an amount sufficient in the opinion of a nationally recognized firm of independent public accountants or investment bank to pay and discharge each installment of principal of, premium and interest on the notes on the stated maturity of those payments in accordance with the terms of the Indenture and the Notes; and

- delivering to the Trustee an opinion of counsel to the effect that the holders of the Notes will not recognize income, gain or loss for U.S. federal income tax purposes as a result of the deposit and related covenant defeasance and will be subject to U.S. federal income tax on the same amounts and in the same manner and at the same times as would have been the case if the deposit and related covenant defeasance had not occurred.

Covenant Defeasance and Events of Default

In the event we exercise our option to effect covenant defeasance with respect to any series of the Notes and the Notes of that series are declared due and payable because of the occurrence of any event of default, the amount of money, U.S. government obligations and/or foreign government obligations on deposit with the Trustee will be sufficient to pay amounts due on the Notes of that series at the time of their stated maturity but may not be sufficient to pay amounts due on the notes of that series at the time of the acceleration resulting from the event of default. In such a case, we would remain liable for those payments.

Concerning the Trustee

The Bank of New York Mellon Trust Company, N.A. is Trustee under the Indenture.

Governing Law

The Indenture and the Notes, including any claim or controversy arising out of or relating to the Indenture or the Notes, are governed by the laws of the State of New York.

Form of Award Notice

[*The information set forth in this Award Notice will be contained on the related pages on Merrill Lynch Benefits Website (or the website of any successor company to Merrill Lynch Bank & Trust Co., FSB). This Award Notice shall be replaced by the equivalent pages on such website. References to Award Notice in this Agreement shall then refer to the equivalent pages on such website.*]

This notice of Award (the "Award Notice") sets forth certain details relating to the grant by the Company to you of the Award identified below, pursuant to the Plan. The terms of this Award Notice are incorporated into the Stock Option Agreement (the "Agreement") that accompanies this Award Notice and made part of the Agreement. Capitalized terms used in this Award Notice that are not otherwise defined in this Award Notice have the meanings given to such terms in the Agreement.

Employee:
Employee ID:
Address:
Award Type:
Grant ID:
Plan: Amgen Inc. Second Amended and Restated 2009 Equity Incentive Plan, as amended and/or restated from time to time
Grant Date:
Grant Price: $_____
Number of Shares
Covered by Option:
Type: Non-qualified Stock Option
Expiration Date: The [_____ (__th)] anniversary of the Grant Date
Vesting Date: Means the vesting date indicated in the Vesting Schedule
Vesting Schedule: Means the schedule of vesting set forth under Vesting Details
Vesting Details: Means the presentation (tabular or otherwise) of the Vesting Date and the quantity of Shares vesting.

IMPORTANT NOTICE REGARDING ACCEPTANCE OF THE AWARD AND THE REQUIREMENT TO OPEN A BROKERAGE ACCOUNT[i]:

***RESIDENTS OF THE U.S. AND PUERTO RICO*:** Please read this Award Notice, the Plan and the Agreement (collectively, the "Grant Documents") carefully. If you, as a resident of the U.S. or Puerto Rico, do **not** wish to receive this Award and/or you do **not** consent and agree to the terms and conditions on which this Award is offered, as set forth in the Grant Documents, then you must reject the Award by contacting the Merrill Lynch call center at +1 (800) 97AMGEN (+1 (800) 972-6436) within the U.S., Puerto Rico and Canada or +1 (609) 818-8910

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[i] *This provision is only for use on the form of grant used for the U.S. and Puerto Rico.*

from all other countries (Merrill Lynch will accept the charges for your call) no later than the forty-fifth calendar day following the day on which this Award Notice is made available to you, in which case the Award will be cancelled. For the purpose of determining the forty-five calendar days, Day 1 will be the day **immediately** following the day on which this Award Notice is made available to you. Your failure to notify the Company of your rejection of the Award or your refusal of, or disagreement with, all terms and conditions of the Award, as set forth in the Grant Documents, within this specified period will constitute your acceptance of the Award and your agreement with all terms and conditions of the Award, as set forth in the Grant Documents. If you agree to the terms and conditions of your grant and you desire to accept it, then no further action is needed on your part to accept the grant. However, you must still open a brokerage account as directed by the Company, by 1:00 pm Pacific Time on or before the date that is 11 months after the Grant Date specified in this Award Notice. This step is necessary to process transactions related to your equity grant. **If you do not open a brokerage account by this deadline, your grant will be cancelled.**

GRANT OF STOCK OPTION AGREEMENT

THE SPECIFIC TERMS OF YOUR STOCK OPTION ARE FOUND IN THE PAGES RELATING TO THE GRANT OF STOCK OPTIONS FOUND ON MERRILL LYNCH BENEFITS WEBSITE (OR THE WEBSITE OF ANY SUCCESSOR COMPANY TO MERRILL LYNCH BANK & TRUST CO., FSB) (THE "AWARD NOTICE") WHICH ACCOMPANIES THIS DOCUMENT. THE TERMS OF THE AWARD NOTICE ARE INCORPORATED INTO THIS GRANT OF STOCK OPTIONS.

On the Grant Date, specified in the Award Notice, Amgen Inc., a Delaware corporation (the "Company"), has granted to you, the grantee named in the Award Notice, under the plan specified in the Award Notice (the "Plan"), an option (the "Option") to purchase the number of shares of the $0.0001 par value common stock of the Company (the "Shares") specified in the Award Notice, pursuant to the terms set forth in this Stock Option Agreement, any additional terms and conditions for your country set forth in the attached Appendix A and the Award Notice (collectively, the "Agreement") and the Plan. This Option is not intended to qualify and will not be treated as an "incentive stock option" within the meaning of Section 422 of the U.S. Internal Revenue Code of 1986, as amended (together with the regulations and other official guidance promulgated thereunder, the "Code"). Capitalized terms not defined herein shall have the meanings assigned to such terms in the Plan.

The terms and conditions of your Option are as follows:

I. Subject to the terms and conditions of the Plan and this Agreement, on each Vesting Date the Option shall vest with respect to the number of Shares indicated on the Vesting Schedule, provided that you have remained continuously and actively employed with the Company or an Affiliate through each applicable Vesting Date, unless [(i) your employment has terminated due to your Voluntary Termination (as defined in Section IV(A)(5)) or (ii)]*[ii] you experience a Qualified Termination (as defined in Section IV(B)(4)), or as otherwise determined by the Company in the exercise of its discretion as provided in Section IV(A)(7). This Option may only be exercised for whole shares of the Common Stock, and the Company shall be under no obligation to issue any fractional Shares to you. Subject to the limitations contained herein, this Option shall be exercisable with respect to each installment on or after the applicable Vesting Date. Notwithstanding anything herein to the contrary, the Vesting Schedule may be accelerated (by notice in writing) by the Company in its sole discretion at any time during the term of this Option. In addition, if not prohibited by local law, vesting may be suspended by the Company in its sole discretion during a leave of absence as provided from time to time according to Company policies and practices; provided, that, in no event shall any such suspension extend the term of this Option beyond the Expiration Date set forth on the Award Notice and in this Agreement.

[ii] *Section IV(A)(5) of this Agreement is not applicable to awards identified by the Administrator as new hire, retention or promotion grants and the provisions of such section shall be reserved and references thereto identified by an asterisk (*) shall be omitted from the agreements evidencing such grants.*

II. (1) The per Share exercise price of this Option is the Grant Price as defined in the Award Notice, being not less than the Fair Market Value of the Common Stock on the Grant Date of this Option.

(2) To the extent permitted by applicable statutes and regulations, payment of the exercise price per Share is due in full upon exercise of all or any part of each installment which has become exercisable by you by means of (i) cash or a check, (ii) any cashless exercise procedure through the use of a brokerage arrangement approved by the Company, or (iii) any other form of legal consideration that may be acceptable to the Board or the Committee in their discretion.

(3) Notwithstanding anything in Section II(2), to the extent permitted by applicable statutes and regulations, if, at the time of exercise, the Company's Common Stock is publicly traded and quoted regularly in the Wall Street Journal, payment of the exercise price may be made by delivery of already-owned Shares with a Fair Market Value equal to the exercise price of the Shares for which this Option is being exercised. The already-owned Shares must have been owned by you for the period required to avoid adverse accounting treatment and owned free and clear of any liens, claims, encumbrances or security interests. Payment may also be made by a combination of cash and already-owned Shares.

Notwithstanding the foregoing, the Company reserves the right to restrict the methods of payment of the exercise price if necessary or advisable to comply with applicable law or regulation, as determined by the Company in its sole discretion.

III. Notwithstanding anything to the contrary contain herein, the Company shall not take any actions that would violate the Securities Act, the Exchange Act, the Code, or any other securities or tax or other applicable law or regulation, or the rules of any Securities Exchange. The Company, in its sole discretion, may impose any timing or other restrictions with respect to the exercise of this Option arising from compliance with any securities or tax laws or other rules or regulations. Notwithstanding anything to the contrary contained herein, this Option may not be exercised and no Shares underlying the Option will be issued unless such Shares are then registered under the Securities Act, or, if such Shares are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act, and that the issuance satisfies all other applicable legal requirements. If the Option cannot be exercised and expires during this period, you will forfeit the Option and no Shares or value will be transferred to you.

IV. (A) The term of this Option commences on the Grant Date and, unless sooner terminated as set forth below or in the Plan, terminates on the [_____ (__th)] anniversary of the Grant Date (the "Expiration Date"). This Option shall terminate prior to the Expiration Date as follows: three (3) months after the termination of your employment with the Company or an Affiliate (as defined in the Plan) for any reason or for no reason, including if your employment is terminated by the Company or an Affiliate without Cause (as defined below), or in the event of

any other termination of your employment caused directly or indirectly by the Company or an Affiliate, unless:

(1) such termination of your employment is due to your Permanent and Total Disability (as defined below), in which case (i) the Option shall terminate on the Expiration Date and (ii) the vesting of the Option shall be accelerated in full and the Option shall be fully exercisable, subject to your execution and non-revocation of a general release and waiver in a form provided by the Company (for the purpose of resolving any potential or actual disputes arising from your employment and the termination of your employment with the Company) (a "Release") as of the day immediately preceding such termination of your employment with respect to the Option. Notwithstanding the foregoing, if the Option was granted in the calendar year in which such termination occurs, (i) the Option shall instead be accelerated to vest only with respect to a number of Shares equal to (A) the number of Shares subject to the Option multiplied by (B) a fraction, the numerator of which is the number of complete months you remained continuously and actively employed by the Company or an Affiliate during the calendar year in which your termination occurs, and the denominator of which is twelve (12), subject to your execution and non-revocation of a Release, and (ii) any portion of the Option (if any) that remains unvested following the acceleration provided for in clause (i) shall automatically expire and terminate on the date of the termination of your active employment due to your Permanent and Total Disability without consideration therefor;

(2) such termination of your employment is due to your death, in which case (i) the Option shall terminate on the Expiration Date and (ii) the vesting of the Option shall be accelerated to vest in full and the Option shall be fully exercisable as of the day immediately preceding your death with respect to the Option. Notwithstanding the foregoing, if the Option was granted in the calendar year in which your death occurs (i) the Option shall instead be accelerated to vest only with respect to a number of Shares equal to (A) the number of Shares subject to the Option multiplied by (B) a fraction, the numerator of which is the number of complete months you remained continuously and actively employed by the Company or an Affiliate during the calendar year in which your termination occurs, and the denominator of which is twelve (12), and (ii) any portion of the Option (if any) that remains unvested following the acceleration provided for in clause (i) shall automatically expire and terminate on the date of termination of your active employment due to your death without consideration therefor;

(3) during any part of such three (3) month period, this Option is not exercisable solely because of the condition set forth in Section III above, in which event this Option shall not terminate until the earlier of the Expiration Date or until it shall have been exercisable for an aggregate period of three (3) months after the termination of your employment;

(4) exercise of this Option within three (3) months after termination of your employment with the Company or with an Affiliate would result in liability under Section 16(b) of the Exchange Act, in which case this Option will terminate on the earliest of: (a) the tenth (10th) day after the last date upon which exercise would result in such liability; (b) six (6) months and ten (10) days after the termination of your employment with the Company or an Affiliate; or (c) the Expiration Date;

(5) [such termination of your employment is due to your voluntary termination (and such voluntary termination is not the result of Permanent and Total Disability (as defined below)) after you are at least sixty five (65) years of age, or after you are at least fifty-five (55) years of age and have been an employee of the Company and/or an Affiliate for at least ten (10) years in the aggregate as determined by the Company in its sole discretion according to Company policies and practices as in effect from time to time ("Voluntary Termination"), in which case (i) this Option shall terminate on the Expiration Date and (ii) the unvested portions of this Option will become exercisable pursuant to the Vesting Schedule without regard to your Voluntary Termination of your employment, subject to your execution and non-revocation of a Release. Notwithstanding the foregoing, if the Option was granted in the calendar year in which your Voluntary Termination occurs, (i) the Option will continue to vest and become exercisable pursuant to the Vesting Schedule only with respect to (A) a number of Shares equal to the number of Shares subject to the Option multiplied by (B) a fraction, the numerator of which is the number of complete months you remained continuously and actively employed by the Company or an Affiliate during the calendar year in which your termination occurs, and the denominator of which is twelve (12), and (ii) any portion of the Option (if any) that remains unvested following the acceleration provided for in clause (i) shall automatically expire and terminate on the date of the termination of your active employment due to your Voluntary Termination without consideration therefor. Notwithstanding the foregoing, in the event your Voluntary Termination occurs on or after the date of a Change of Control, then, to the extent permitted by applicable law, the vesting of the Option shall be accelerated to vest in full as of the day immediately prior to the date of your Voluntary Termination. Notwithstanding the definition of Voluntary Termination set forth above, if the Company receives an opinion of counsel that there has been a legal judgment and/or legal development in your jurisdiction that would likely result in the favorable treatment upon Voluntary Termination described above being deemed unlawful and/or discriminatory, then the Committee will not apply the favorable treatment described above;][Reserved]* [iii]

(6) such termination of your employment is due to a Qualified Termination, in which case, the Option shall terminate on the earlier of (a) the date that is three (3) months following the date of such Qualified Termination or (b) the Expiration Date, and, to the extent permitted by applicable law, the vesting of the Option shall be accelerated and the Option shall be fully exercisable as of the day immediately prior to the Qualified Termination; or

(7) the Company determines, in its sole discretion at any time during the term of this Option, in writing, to otherwise extend the period of time during which this Option will vest and may be exercised after termination of your employment; provided, that, in no event shall any such extension extend the term of this Option beyond the Expiration Date set forth on the Award Notice and in this Agreement.

[iii] *Section IV(A)(5) of this Agreement is not applicable to awards identified by the Administrator as new hire, retention or promotion grants and the provisions of such section shall be reserved and references thereto identified by an asterisk (*) shall be omitted from the agreements evidencing such grants.*

However, in any and all circumstances and except to the extent the Vesting Schedule has been accelerated by the Company in its sole discretion during the term of this Option or as a result of your Permanent and Total Disability or death as provided in Sections IV(A)(1) or IV(A)(2) above, respectively, [as a result of your Voluntary Termination as provided in Section IV(A)(5) above,]* as a result of a Qualified Termination as provided in Section IV(A)(6) above or as otherwise determined by the Company in the exercise of its discretion as provided in Section IV(A)(7) above, this Option may be exercised following termination of your employment only as to that number of Shares as to which it was exercisable on the date of termination of your employment under the provisions of Section I of this Agreement.

(B) For purposes of this Option:

(1) "termination of your employment" shall mean the last date you are either an active employee of the Company or an Affiliate or actively engaged as a Director to the Company or an Affiliate; in the event of termination of your employment (whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are employed or the terms of your employment agreement, if any), your right to receive options and vest under the Plan, if any, will terminate effective as of the date that you are no longer actively employed and will not be extended by any notice period (*e.g.*, active employment would not include any period of "garden leave" or similar period mandated under employment laws in the jurisdiction where you are employed or the terms of your employment agreement, if any). Your right, if any, to exercise the Option after termination of employment will be measured by the date of termination of your active employment and will not be extended by any notice period mandated under local law. The Administrator shall have the exclusive discretion to determine when you are no longer actively providing services for purposes of this Agreement (including whether you may still be considered to be providing services while on a leave of absence);

(2) "Cause" shall mean (i) your conviction of a felony (or similar crime under applicable law, as determined by the Company), or (ii) your engaging in conduct that constitutes willful gross neglect or willful gross misconduct in carrying out your duties, resulting, in either case, in material economic harm to the Company or any Affiliate, unless you believed in good faith that such conduct was in, or not contrary to, the best interests of the Company or any Affiliate. For purposes of clause (ii) above, no act, or failure to act, on your part shall be deemed "willful" unless done, or omitted to be done, by you not in good faith;

(3) "Permanent and Total Disability" shall have the meaning ascribed to such term under Section 22(e)(3) of the Code and with such permanent and total disability being certified prior to termination of your employment by (a) the U.S. Social Security Administration, (b) the comparable governmental authority applicable to an Affiliate, (c) such other body having the relevant decision-making power applicable to an Affiliate, or (d) an independent medical advisor appointed by the Company in its sole discretion, as applicable, in any such case;

(4) "Qualified Termination" shall mean

(a) if you are an employee who participates in the Change of Control Plan (as defined below), your termination of employment within two (2) years following a Change of Control (i) by the

Company or an Affiliate other than for Cause, Disability (as defined below) or as a result of your death, or (ii) by you for Good Reason (as defined in the Change of Control Plan); or

(b) if you are an employee who does not participate in the Change of Control Plan or the Change of Control Plan is no longer in effect, your termination of employment within two (2) years following a Change of Control by the Company or an Affiliate other than for Cause, Disability (as defined below) or as a result of your death;

(5) "Change of Control" shall mean the occurrence of any of the following:

(a) the acquisition (other than from the Company) by any person, entity or "group," within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act (excluding, for this purpose, the Company or any of its Affiliates, or any employee benefit plan of the Company or any of its Affiliates which acquires beneficial ownership of voting securities of the Company), of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of fifty percent (50%) or more of either the then outstanding Shares or the combined voting power of the Company's then outstanding voting securities entitled to vote generally in the election of directors; or

(b) the consummation by the Company of a reorganization, merger, consolidation, (in each case, with respect to which persons who were the stockholders of the Company immediately prior to such reorganization, merger or consolidation do not, immediately thereafter, own more than fifty percent (50%) of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities) or a liquidation or dissolution of the Company or of the sale of all or substantially all of the assets of the Company.

Notwithstanding anything herein or in any Award Agreement to the contrary, if a Change of Control constitutes a payment event with respect to any Award that is subject to United States income tax and which provides for a deferral of compensation that is subject to Section 409A of the Code, the transaction or event described in subsection (a) or (b), (c) above must also constitute a "change in control event," as defined in U.S. Treasury Regulation §1.409A-3(i)(5), in order to constitute a Change of Control for purposes of payment of such Award.

(6) "Change of Control Plan" shall mean the Company's change of control and severance plan, including the Amgen Inc. Change of Control Severance Plan, as amended and restated, effective as of December 9, 2010 (and any subsequent amendments thereto), or any equivalent plan governing the provision of benefits to eligible employees upon the occurrence of a Change of Control (including resulting from a termination of employment that occurs within a specified time period following a Change of Control), as in effect immediately prior to a Change of Control; and

(7) "Disability" shall mean your "disability" as determined in accordance with the Company's long-term disability plan as in effect immediately prior to a Change of Control.

V. (A) To the extent specified above, this Option may be exercised by delivering a notice of exercise in person, by mail, via electronic mail or facsimile or by other authorized method designated by the Company, together with the exercise price to the Company Stock Administrator, or to such other person as the Company Stock Administrator may designate,

during regular business hours, together with such additional documents as the Company may then require pursuant to Section 7.2(b) of the Plan.

(B) Regardless of any action the Company or your actual employer (the "Employer") takes with respect to any or all income tax (including federal, state and local taxes), social insurance, payroll tax, fringe benefit tax, payment on account or other tax-related items related to your participation in the Plan and legally applicable to you ("Tax Obligations"), you acknowledge that the ultimate liability for all Tax Obligations is and remains your responsibility and may exceed the amount, if any, actually withheld by the Company and/or your Employer. You further acknowledge that the Company and/or your Employer: (a) make no representations or undertakings regarding the treatment of any Tax Obligations in connection with any aspect of the Option grant or the underlying Shares, including, but not limited to, the grant, vesting or exercise of the Option, the subsequent sale of Shares acquired pursuant to such exercise and the receipt of any dividends; and (b) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Option to reduce or eliminate your liability for Tax Obligations or achieve any particular tax result. Furthermore, if you become subject to tax in more than one jurisdiction, you acknowledge that the Company and/or your Employer (or former employer, as applicable) may be required to withhold or account for Tax Obligations in more than one jurisdiction.

(C) Prior to any relevant taxable or tax withholding event, as applicable, you shall pay or make adequate arrangements satisfactory to the Company and/or your Employer to satisfy all Tax Obligations. In this regard, you authorize the Company and/or your Employer, or their respective agents, at their discretion, to satisfy all applicable Tax Obligations by one or a combination of the following:

(1) withholding from your wages or other cash compensation paid to you by the Company and/or your Employer;

(2) withholding from proceeds of the sale of Shares acquired upon exercise of the Option either through your voluntary sale or through a mandatory sale arranged by the Company (on your behalf pursuant to this authorization); or

(3) withholding in Shares issuable, or cash payable, upon exercise of the Option, provided that, if such Shares are withheld, the Company and your Employer shall only withhold an amount of Shares with a fair market value not to exceed the Tax Obligations as determined in the discretion of the Company or your Employer, as applicable.

Depending on the withholding method, the Company may withhold or account for Tax Obligations by considering applicable minimum statutory withholding rates or other applicable withholding rates, including maximum applicable rates. If the Tax Obligations are satisfied by withholding in Shares, for tax purposes you are deemed to have been issued the full number of Shares subject to the exercised Option, notwithstanding that a number of the Shares is

held back and not actually issued to you solely for the purpose of paying the Tax Obligations due as a result of any aspect of your participation in the Plan.

(D) Finally, you shall pay to the Company or your Employer any amount of Tax Obligations that the Company or your Employer may be required to withhold or account for as a result of your participation in the Plan that cannot be or were not satisfied by the means previously described. You agree to take any further actions and execute any additional documents as may be necessary to effectuate the provisions of this Section V. Notwithstanding anything to the contrary contained herein, the Company may refuse to issue or deliver the Shares or the proceeds of the sale of Shares if you fail to comply with your obligations in connection with the Tax Obligations.

VI. This Option is not transferable, except by will or the laws of descent and distribution, and is exercisable during your life only by you except if you have named a trust created for the benefit of you, your spouse, or members of your immediate family (a "Trust") as beneficiary of this Option, this Option may be exercised by the Trust after your death.

VII. Any notices provided for in this Option or the Plan shall be given in writing or electronically and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail or equivalent foreign postal service, postage prepaid, addressed to you at such address as is currently maintained in the Company's records or at such other address as you hereafter designate by written notice to the Company Stock Administrator. Such notices may be given using any automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, as approved by the Company.

VIII. This Option is subject to all the provisions of the Plan and its provisions are hereby made a part of this Option, including without limitation the provisions of Articles 6 and 7 of the Plan relating to Options, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of this Option and those of the Plan, the provisions of the Plan shall control.

IX. ***In order for the Company to facilitate your participation in the Plan, the Company and your Employer must collect and use personal data about you. In accordance with applicable laws, reasonable security measures will be implemented and maintained to protect the security of your personal data; however, you understand that absolute security cannot be guaranteed.***

You understand that the Company and your Employer may hold certain personal information about you, including your name, home address and telephone number, email address, date of birth, social insurance/security number (to the extent permitted under applicable local law), passport or other identification number, salary, nationality, job title/work history/service periods, residency status, citizenship, tax withholding and payroll data, any shares of stock or directorships held in the Company, details of all equity compensation or any other entitlement to Shares

awarded, cancelled, vested, unvested or outstanding in your favor, for the purposes of implementing, administering and managing the Plan ("personal data").

You authorize the transfer of your personal data to Merrill Lynch Bank & Trust Co., FSB, or any successor thereto, and any other third parties which may assist the Company (presently or in the future) with implementing, administering and managing your participation in the Plan to receive, possess, use, retain and transfer your personal data, in electronic or other form, for the purpose of implementing, administering and managing your participation in the Plan, including any requisite transfer of such personal data as may be required to any other broker, escrow agent or other third party with whom the Shares received upon exercise of this Option may be deposited. You understand that such authorized recipients of your personal data may be located in countries that do not provide the same level of data privacy laws and protections as the country in which your personal data originated. Transfers of personal data among Company and its group entities follow applicable laws and our Binding Corporate Rules (BCRs). For more information on Company's BCRs, please visit http://www.amgen.com/bcr/. You acknowledge that the collection, use and transfer of your personal data is necessary to facilitate your participation in the Plan, as well as to grant you Options or other equity awards and administer or maintain such awards.

You may correct or update your personal data previously provided to Company, by contacting your local human resources representative. Subject to applicable law, you may have additional rights, including the right to object and/or request destruction of your personal data. To exercise these rights, where applicable, please contact your local human resources representative.

X. The terms of this Option shall be governed by the laws of the State of Delaware without giving effect to principles of conflicts of laws. For purposes of litigating any dispute that arises hereunder, the parties hereby submit to and consent to the jurisdiction of the State of Delaware, and agree that such litigation shall be conducted in the courts of the State of Delaware, or the federal courts for the United States for the federal district located in the State of Delaware, and no other courts, where this Option is made and/or to be performed.

XI. Notwithstanding any provision of this Option to the contrary, if you are employed by the Company or an Affiliate in any of the countries identified in the attached Appendix A (which constitutes a part of this Agreement), are subject to the laws of any foreign jurisdiction, or relocate to one of the countries included in the attached Appendix A, the Option granted hereunder shall be subject to any additional terms and conditions for your country set forth in Appendix A and the following additional terms and conditions:

a. the terms and conditions of this Option, including Appendix A, are deemed modified to the extent necessary or advisable to comply with applicable foreign laws or facilitate the administration to the Plan;

b. if applicable, the effectiveness of this Option is conditioned upon its compliance with any applicable foreign laws, regulations, rules or

local governmental regulatory exemption and subject to receipt of any required foreign regulatory approvals; and

c. the Company may take any other action before or after the date of this Option that it deems advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals.

XII. (A) In accepting this Option, you acknowledge, understand and agree that:

(1) the Plan is established voluntarily by the Company, is discretionary in nature and may be modified, amended, suspended or terminated by the Company at any time, as provided in the Plan;

(2) the Plan is operated and the Options are granted solely by the Company, and only the Company is a party to this Agreement; accordingly, any rights you may have under this Agreement may be raised only against the Company but not any Affiliate (including, but not limited to, the Employer);

(3) no Affiliate (including, but not limited to, the Employer) has any obligation to make any payment of any kind to you under this Agreement;

(4) the grant of this Option is exceptional, voluntary and occasional and does not create any contractual or other right to receive future awards of options, or benefits in lieu of options even if options have been awarded in the past;

(5) all decisions with respect to future awards, if any, will be at the sole discretion of the Company;

(6) your participation in the Plan is voluntary;

(7) the grant of Options, the underlying Shares, and the income from and value of same, are not intended to replace any pension rights or compensation;

(8) neither the grant of options nor any provision of this Option, the Plan or the policies adopted pursuant to the Plan confer upon you any right with respect to employment or continuation of current employment and shall not interfere with the ability of your Employer to terminate your employment or service relationship (if any) at any time;

(9) in the event that you are not an employee of the Company or any Affiliate, the Option shall not be interpreted to form an employment contract or relationship with the Company or any Affiliate;

(10) the future value of the underlying Shares is unknown, indeterminable, and cannot be predicted with certainty;

(11) if the underlying Shares do not increase in value, this Option will have no value; if you exercise this Option and obtain Shares, the value of those Shares acquired upon exercise may increase or decrease in value, even below the Grant Price per Share;

(12) in consideration of the grant of this Option, no claim or entitlement to compensation or damages arises from forfeiture of options resulting from (i) the termination of your employment by the Company or an Affiliate (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are employed or the terms of your employment agreement, if any) and/or (ii) the application of the Clawback Policy as described in Section XVIII below, and you irrevocably release the Company and your Employer from any such claim that may arise; if, notwithstanding the foregoing, any such claim is found by a court of competent jurisdiction to have arisen, you shall be deemed irrevocably to have waived your entitlement to pursue such claim;

(13) unless otherwise agreed with the Company, the Options, the underlying Shares, and the income from and value of same, are not granted as consideration for, or in connection with, the service you may provide as a director of an Affiliate of the Company;

(14) except as otherwise provided in this Agreement or the Plan, the Options and the benefits evidenced by this Agreement do not create any entitlement to have the Options or any such benefits transferred to, or assumed by, another company nor to be exchanged, cashed out or substituted for, in connection with any corporate transaction affecting the shares of the Company; and

(15) the following provisions apply only if you are providing services outside the United States:

(i) for employment law purposes outside the United States, the Option, underlying Shares, and the income from and value of same, are not part of normal or expected compensation or salary for any purpose, including but not limited to for purposes of calculating any severance, resignation, termination, redundancy, dismissal, end of service payments, bonuses, holiday pay, long-service awards, pension or retirement benefits or similar mandatory payments; and

(ii) neither the Company, your Employer nor any Affiliate of the Company shall be liable for any foreign exchange rate fluctuation between your local currency and the United States Dollar that may affect the value of the Option or of any amounts due to you pursuant to the exercise of the Option or the subsequent sale of any Shares acquired upon exercise of the Option.

(B) The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan, or your acquisition or sale of the underlying Shares. You should consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

XIII. If one or more of the provisions of this Option shall be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and the invalid, illegal or unenforceable provisions shall be deemed null and void; however, to the extent permissible by law, any provisions which could be deemed null and void shall first be construed, interpreted or revised retroactively to permit this Option to be construed so as to foster the intent of this Option and the Plan.

XIV. By electing to accept this Agreement, you acknowledge that you are sufficiently proficient in English or have consulted with an advisor who is sufficiently proficient in English, so as to allow you to understand the terms and conditions of this Agreement. Furthermore, if you have received this Option or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control, unless otherwise required by applicable law.

XV. This Option is not intended to constitute "nonqualified deferred compensation" within the meaning of Code Section 409A but rather is intended to be exempt from the application of Code Section 409A. To the extent that this Option is nevertheless deemed to be subject to Code Section 409A for any reason, this Option shall be interpreted in accordance with Code Section 409A and U.S. Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Grant Date. Notwithstanding any provision herein to the contrary, in the event that following the Grant Date, the Committee (as defined in the Plan) determines that this Option may be or become subject to Code Section 409A, the Committee may adopt such amendments to the Plan and/or this Option or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Committee determines are necessary or appropriate to (a) exempt the Plan and/or this Option from the application of Code Section 409A and/or preserve the intended tax treatment of the benefits provided with respect to this Option, or (b) comply with the requirements of Code Section 409A; provided, however, that this paragraph shall not create an obligation on the part of the Committee to adopt any such amendment, policy or procedure or take any such other action.

XVI. By electing to accept this Option, you acknowledge receipt of this Option and hereby confirm your understanding that the terms set forth in this Option constitute, subject to the terms of the Plan, which terms shall control in the event of any conflict between the Plan and this Option, the entire agreement and understanding of the parties with respect to the matters contained herein and supersede any and all prior agreements, arrangements and understandings, both oral and written, between the parties concerning the subject matter of this Option. The Company may, in its sole discretion, decide to deliver any documents related to current or future participation in the Plan (including this Agreement) by electronic means. You hereby consent to receive such documents by electronic delivery and agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

XVII. The Company reserves the right to impose other requirements on your participation in the Plan, on this Option and on any Shares acquired under the Plan, to the extent the Company

determines it is necessary or advisable for legal or administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

XVIII. This Option, the Shares issuable under this Option, and all compensation payable with respect to it shall be subject to clawback, recoupment and/or recovery by the Company pursuant to any and all of the Company's policies with respect to the clawback, recoupment or recovery of compensation in effect as of the Grant Date or as may be adopted or maintained by the Company following the Grant Date, including, without limitation, the Company's Policy on Recovery of Erroneously Awarded Compensation (effective October 2, 2023) and Executive Officer Equity Recoupment Policy (effective December 31, 2020), as they shall be in effect and may be amended from time to time (collectively, the "Clawback Policy"), to the maximum extent permitted by applicable law.

XIX. You acknowledge that a waiver by the Company of breach of any provision of this Option shall not operate or be construed as a waiver of any other provision of this Option, or of any subsequent breach by you or any other grantee.

Very truly yours,

AMGEN INC.

By_____
Duly authorized on behalf
of the Board of Directors

APPENDIX A

ADDITIONAL TERMS AND CONDITIONS OF THE AMGEN INC. SECOND AMENDED AND RESTATED 2009 EQUITY INCENTIVE PLAN, AS AMENDED AND/OR RESTATED FROM TIME TO TIME

GRANT OF STOCK OPTION (BY COUNTRY)

Certain capitalized terms used but not defined in this Appendix A shall have the meanings set forth in the Plan and/or the Agreement to which this Appendix is attached.

TERMS AND CONDITIONS

This Appendix includes additional terms and conditions that govern any Options granted under the Plan if, under applicable law, you are a resident of, are deemed to be a resident of or are working in one of the countries listed below. Furthermore, the additional terms and conditions that govern any Options granted hereunder may apply to you if you transfer employment and/or residency to one of the countries listed below and the Company shall, in its discretion, determine to what extent the terms and conditions contained herein shall apply to you.

NOTIFICATIONS

This Appendix also includes notifications relating to exchange control and other issues of which you should be aware with respect to your participation in the Plan. The information is based on the exchange control, securities and other laws in effect in the countries to which this Appendix refers as of October 2025. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the notifications herein as the only source of information relating to the consequences of your participation in the Plan because the information may be outdated when you exercise the Options and acquire Shares under the Plan, or when you subsequently sell Shares acquired under the Plan.

In addition, the notifications are general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of any particular result. Accordingly, you should seek appropriate professional advice as to how the relevant laws in your country may apply to your situation. Finally, if you are a citizen or resident of a country other than the one in which you are currently residing and/or working or are considered a resident of another country for local law purposes, the information contained herein may not be applicable to you or you may be subject to the provisions of one or more jurisdictions.

ALL NON-U.S. JURISDICTIONS

TERMS AND CONDITIONS

Method of Exercise. The following provision replaces Section II(3):

To the extent permitted by applicable statutes and regulations, payment of the exercise price per Share is due in full in cash or check upon exercise of all or any part of this Option which has become exercisable by you. Due to legal restrictions outside the U.S., you are not permitted to pay the exercise price by delivery of already-owned Shares of a value equal to the exercise price of the Shares for which this Option is being exercised. Furthermore, payment may not be made by a combination of cash and already-owned Common Stock.

Tax Withholding. The following provision supplements Section V(C) of the Agreement:

In the event the Company withholds or accounts for Tax Obligations by considering maximum applicable rates in your jurisdiction(s), in the event of over-withholding, you may receive a refund of any over-withheld amount in cash and will not be entitled to the equivalent amount in Shares, or if not refunded, you may seek a refund from the local tax authorities. In the event of under-withholding, you may be required to pay any additional Tax Obligations directly to the applicable tax authority or to the Company and/or your Employer.

NOTIFICATIONS

Insider Trading Restrictions/Market Abuse Laws. You may be subject to insider trading restrictions and/or market abuse laws based on the exchange on which the Shares are listed and in applicable jurisdictions including the United States and your country or your broker's country, if different, which may affect your ability to accept, acquire, sell or otherwise dispose of Shares, rights to Shares (*e.g.*, Options) or rights linked to the value of Shares during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in applicable jurisdictions). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders you place before you possessed inside information. Furthermore, you could be prohibited from (i) disclosing the inside information to any third party, which may include fellow employees (other than on a "need to know" basis) and (ii) "tipping" third parties or causing them otherwise to buy or sell securities. Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. You are responsible for ensuring your compliance with any applicable restrictions and you should speak with your personal legal advisor on this matter.

Foreign Asset/Account, Tax Reporting Information. Your country of residence may have certain foreign asset and/or account reporting requirements which may affect your ability to acquire or hold Shares under the Plan or cash received from participating in the Plan (including from any dividends received, or sale proceeds arising from the sale of Shares) in a brokerage or bank account outside of your country. You may be required to report such accounts, assets or transactions to the tax or other authorities in your country. You also may be required to repatriate sale proceeds or other funds

received as a result of participating in the Plan to your country within a certain time after receipt. You are responsible for ensuring your compliance with such regulations, and you should speak with your personal legal advisor on this matter.

ALL EUROPEAN ECONOMIC AREA ("EEA") / EUROPEAN UNION ("EU") JURISDICTIONS, UNITED KINGDOM AND SWITZERLAND

TERMS AND CONDITIONS

Data Privacy Notice. This provision replaces Section IX of the Agreement:

Please refer to the Fair Processing Notice previously provided by your local human resources representative, which notice governs the collection, use and transfer of your personal data necessary for the Company to facilitate your participation in the Plan. If you have any questions or concerns regarding the Fair Processing Notice, including questions about your rights afforded thereunder, you should contact your local human resources representative or send an email to hrconnect@amgen.com.

For purposes of implementing, administering and managing the Plan, Company and your Employer may hold certain personal data about you, including your name, home address and telephone number, email address, date of birth, social insurance/security number (to the extent permitted under applicable local law), passport or other identification number, salary, nationality, job title/work history/service periods, residency status, citizenship, tax withholding and payroll data, any shares of stock or directorships held in the Company, details of all equity compensation or any other entitlement to Shares awarded, cancelled, vested, unvested or outstanding in your favor ("personal data").

You authorize the transfer of your personal data to Merrill Lynch Bank & Trust Co., FSB, or any successor thereto, and any other third parties which may assist the Company (presently or in the future) with implementing, administering and managing your participation in the Plan to receive, possess, use, retain and transfer your personal data, in electronic or other form, for the purpose of implementing, administering and managing your participation in the Plan, including any requisite transfer of such personal data as may be required to any other broker, escrow agent or other third party with whom the Shares received upon exercise of this Option may be deposited.

ARGENTINA

TERMS AND CONDITIONS

Method of Exercise. Due to legal restrictions in Argentina, you may be required to pay the exercise price for any Shares subject to the Option granted hereunder by a cashless sell-all exercise, such that all Shares will be sold immediately upon exercise and the cash proceeds of sale, less the exercise price, any Tax Obligations and broker's fees or commissions, will be remitted to you. The Company reserves the right to provide additional methods of exercise depending on local developments.

Labor Law Acknowledgement. The following provision supplements Section XII of the Agreement:

In accepting this Option, you acknowledge, understand and agree that the grant of the Option is made by the Company (not your Employer) in its sole discretion and that the value of the Option or any Shares acquired under the Plan shall not constitute salary or wages for any purpose under Argentine labor law including, but not limited to, the calculation of (i) any labor benefits including, without limitation, vacation pay, thirteenth salary, compensation in lieu of notice, annual bonus, disability, and leave of absence payments, etc., or (ii) any termination or severance indemnities or similar payments.

NOTIFICATIONS

Securities Law Information. The Option and the underlying Shares have not been and will not be publicly issued, placed, distributed, offered or listed in the Argentine capital markets, and, as a result, have not been and will not be registered with the Argentina Securities Commission (Comisión Nacional de Valores, "CNV"). Neither this nor any other offering material related to the Options nor the underlying Shares may be utilized in connection with any general offering to the public in Argentina. Any Argentine resident who acquires Shares under the Plan does so under their own responsibility under the terms of a private offering to the Argentine resident from outside Argentina. Any Argentine resident who acquires Shares shall not transfer such Shares to any other person within six (6) months of acquiring the Shares, unless the transaction is conducted outside Argentina.

Exchange Control Information. Provided you are not required to purchase foreign currency and remit funds out of Argentina to acquire Shares under the Plan, local exchange control restrictions would not apply. However, if so required, you personally are responsible for complying with any and all Argentine currency exchange regulations, approvals and reporting requirements. Exchange control requirements in Argentina are subject to change; you should consult with your personal advisor regarding any obligations you have under the Plan.

Foreign Asset/Account Reporting Information. If you are an Argentine resident, you are required to report certain information regarding any Shares you hold as of December 31 each year to the Argentine tax authorities on your annual tax return.

AUSTRALIA

NOTIFICATIONS

Securities Law Information. If you acquire Shares under the Plan and offer the Shares for sale to a person or entity resident in Australia, the offer may be subject to disclosure requirements under Australian law. You should consult with your own legal advisor before making any such offer in Australia.

Tax Information. Subdivision 83A-C of the Income Tax Assessment Act 1997 (Cth) applies to the Options granted under the Plan, such that the Options are intended to be subject to deferred taxation.

Exchange Control Information. If you are an Australian resident, exchange control reporting is required for cash transactions exceeding a certain threshold (currently AUD10,000) and for international fund transfers. If an Australian bank is assisting with the transaction, the bank will file the report on your behalf. If there is no Australian bank involved in the transfer, you will be required to file the report.

AUSTRIA

NOTIFICATIONS

Foreign Asset/Account Reporting Information. If you are an Austrian resident and you hold Shares acquired under the Plan outside of Austria, you may be subject to reporting obligations to the Austrian National Bank.

Exchange Control Information.
If the value of Shares meets or exceeds a certain threshold (currently, €5,000,000), you must report the securities held on a quarterly basis to the Austrian National Bank as of the last day of the quarter, on or before the 15th day of the month following the end of the calendar quarter. Further, if you hold cash in accounts outside Austria, monthly reporting requirements will apply, as explained in the next paragraph, if the aggregate transaction volume of such cash accounts meets or exceeds a certain threshold.

A separate reporting requirement applies when you sell Shares acquired under the Plan or receive a cash dividend paid on such Shares. In that case, there may be exchange control obligations if the cash proceeds are held outside of Austria. If the transaction volume of all cash accounts abroad meets or exceeds a certain threshold (currently €10,000,000), the movements and balances of all accounts must be reported monthly, as of the last day of the month, on or before the 15th day of the following month, on the prescribed forms.

BELGIUM

NOTIFICATIONS

Taxation of the Option. Your tax consequences will vary depending on when you accept the Option. If you accept the Option in writing within 60 days of the offer date, you will be subject to taxation on the 60th day after the offer date. If you accept the Option more than 60 days after the offer date, you will be subject to taxation at exercise. Please refer to the additional materials that will be delivered to you for a more detailed description of the tax consequences of accepting the Option. You should consult your personal tax advisor prior to accepting the Option.

Tax Reporting; Foreign Asset/Account Reporting Information. If you are a Belgian resident, you are required to report any securities (*e.g.*, Shares acquired under the Plan) held and bank

accounts (including brokerage accounts) opened and maintained outside of Belgium on your annual tax return. The first time you report the foreign security and/or bank account on your annual income tax return you will have to provide the National Bank of Belgium Central Contact Point with the account details of any such foreign accounts (including the account number, bank name and country in which such account was opened) in a separate form. This report, as well as information on how to complete it, can be found on the website of the National Bank of Belgium, www.nbb.be, under the *Kredietcentrales / Centrales des crédits* caption.

Stock Exchange Tax Information. A stock exchange tax applies to transactions executed by a Belgian resident through a non-Belgian financial intermediary, such as a U.S. broker. The stock exchange tax likely will apply when the Option is exercised and when Shares acquired under the Plan are sold. It is your responsibility to comply with this tax obligation, and you should consult your personal tax advisor for additional details on your obligations with respect to the stock exchange tax.

Annual Securities Accounts Tax Information. An annual securities accounts tax may be payable if the total value of securities held in a Belgian or foreign securities account (e.g., Shares acquired under the Plan) exceeds a certain threshold on four reference dates within the relevant reporting period (i.e., December 31, March 31, June 30 and September 30). In such case, the tax will be due on the value of the qualifying securities held in such account. It is your responsibility to comply with this obligation, and you should consult with your personal tax or financial advisor for additional details.

BRAZIL

TERMS AND CONDITIONS

Compliance with Law. By accepting the Option, you acknowledge that you agree to comply with applicable Brazilian laws and pay any and all applicable taxes associated with the exercise of the Option, the sale of Shares acquired under the Plan and the payment of dividends on such Shares.

Nature of Grant. This provision supplements Section XII of the Agreement:

In accepting this Option, you acknowledge (i) that you are making an investment decision, (ii) that the Options will be exercisable by you only if the vesting conditions are met and any necessary services are rendered by you during the vesting period set forth in the Vesting Schedule, and (iii) that the value of the underlying Shares is not fixed and may increase or decrease in value over the vesting period without compensation to you.

NOTIFICATIONS

Exchange Control Information. If you are resident or domiciled in Brazil, you will be required to submit annually a declaration of assets and rights held outside of Brazil to the Central Bank of Brazil if the aggregate value of such assets and rights on December 31 of each year exceeds US$1,000,000. If such amount exceeds US$100,000,000, the referenced declaration must be submitted quarterly, in the month following the end of each quarter. Assets and rights that must be reported include the following: (i) bank deposits; (ii) loans; (iii) financing transactions; (iv)

leases; (v) direct investments; (vi) portfolio investments, including Shares acquired under the Plan; (vii) financial derivatives investments; and (viii) other investments, such as real estate. Please note that foreign individuals holding Brazilian visas are considered Brazilian residents for purposes of this reporting requirement and must declare at least the assets held abroad that were acquired subsequent to the date of admittance as a resident of Brazil. Individuals holding assets and rights outside of Brazil valued at less than US$1,000,000 are not required to submit a declaration.

Tax on Financial Transactions. Payments to foreign countries, repatriation of funds into Brazil, and the conversion associated with such fund transfers into local currency, may be subject to the Tax on Financial Transactions. It is your responsibility to comply with any applicable Tax on Financial Transactions arising from participation in the Plan and you should consult your personal tax advisor for additional details.

BULGARIA

Exchange Control Information. You will be required to file statistical forms with the Bulgarian National Bank annually regarding your receivables in bank accounts abroad as well as securities held abroad (e.g., Shares acquired under the Plan) if the total sum of all such receivables and securities equals or exceeds a certain threshold as of the previous calendar year-end. The reports are due by March 31. You should contact your bank in Bulgaria for additional information regarding these requirements.

CANADA

TERMS AND CONDITIONS

Termination of Employment. Section IV(B)(1) of the Agreement is amended to read as follows:

(1) "termination of your employment" shall mean the last date you are either actually providing services to Company or an Affiliate or actually providing services as Director to the Company or an Affiliate; in the event of involuntary termination of your employment (regardless of the reason for such termination and whether or not later found to be invalid or unlawful, including for breaching applicable laws in the jurisdiction where you are employed or the terms of your employment agreement, if any) Except as explicitly and minimally required under applicable legislation, your right, if any, to earn, seek damages in lieu of, vest in, exercise, or otherwise benefit from or participate in any portion of the Option or the Plan will be measured by and immediately terminate, as of the termination of your employment (the "Termination Date").. Except as explicitly and minimally required under applicable legislation, the Termination Date will exclude and will not be extended by any period during which notice, pay in lieu of notice or related payments or damages are provided or required to be provided under applicable laws (including, but not limited to, statute, contract, common/civil law or otherwise).You will not earn or be entitled to any pro-rated vesting or extended exercisability or other benefits under or participation in the Plan for that portion of time before the Termination Date, nor will you be entitled to any compensation for lost vesting, exercisability, benefits, or other participation.

Subject to applicable legislation, if the date you are no longer actually providing services cannot be reasonably determined under the terms of this Agreement or the Plan, the Administrator shall have the exclusive discretion to determine when you are no longer actually providing services for purposes of this Agreement (including whether you may still be considered to be providing services while on a leave of absence).Notwithstanding the foregoing, if applicable employment standards legislation explicitly requires continued vesting or other participation during a statutory notice period, your right to vest in the Options or otherwise participate in or benefit from the Options under the Plan, if any, will terminate effective as of the last day of your minimum statutory notice period, but you will not earn or be entitled to pro-rated vesting or extended exercisability if the vesting date or exercisability period falls after the end of your statutory notice period, nor will you be entitled to any compensation for lost vesting, exercisability, benefits, or other participation;

Nature of Grant. Sections XII(3), XII(12) and XII(15)(i) of the Agreement are amended to read as follows:

(3) no Affiliate (including, but not limited to, the Employer) has any obligation to make any payment of any kind to you under this Agreement, except to the extent explicitly and minimally required under applicable legislation;

(12) in consideration of the grant of this Option, no claim or entitlement to compensation or damages arises from forfeiture of options resulting from (i) the termination of your employment by the Company or an Affiliate (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are employed or the terms of your employment agreement, if any) and/or (ii) the application of the Clawback Policy as described in Section XVIII below, except to the extent explicitly and minimally required under applicable legislation;

(15)(i) for employment law purposes outside the United States, the Option, underlying Shares, and the income from and value of same, are not part of normal or expected compensation or salary for any purpose, including but not limited to for purposes of calculating any severance, resignation, termination, redundancy, dismissal, end of service payments, bonuses, holiday pay, long-service awards, pension or retirement benefits or similar mandatory payments, except to the extent explicitly and minimally required under applicable legislation; and

The following provision will apply to you if you are a resident of Quebec:

French Language Documents. A French translation of this document and certain other documents related to this Award will be made available to you as soon as reasonably practicable. You understand that, from time to time, additional information related to the Award may be provided in English and such information may not be immediately available in French. However, upon request, the Company will provide a translation of such information into French as soon as reasonably practicable. Notwithstanding anything to the contrary in the Agreement, and unless you indicate otherwise, the French translation of this document and certain other documents related to the Award will govern your participation in the Plan.

Data Privacy Notice. This provision supplements Section IX of the Agreement:

You hereby authorize the Company and the Company's representative to discuss with and obtain all relevant information from all personnel (professional or not) involved in the administration of the Plan. You further authorize the Company, your Employer and Merrill Lynch Bank & Trust Co., FSB (or any other stock plan service provider) to disclose and discuss your participation in the Plan with their advisors. You also authorize the Company and your Employer to record such information and keep it in your file.

NOTIFICATIONS

Securities Law Information. You are permitted to sell Shares acquired through the Plan through the designated broker appointed under the Plan, if any, provided that the resale of such Shares takes place outside of Canada through the facilities of a stock exchange on which the Shares are listed (*e.g.*, the Nasdaq Global Select Market).

Foreign Asset/Account Reporting Information. Specified foreign property, including Shares, Options and other rights to receive Shares of a non-Canadian company held by a Canadian resident employee generally must be reported annually on a Form T1135 (Foreign Income Verification Statement) if the total cost of the employee's specified foreign property exceeds a certain threshold (currently C$100,000) at any time during the year. Thus, such Options must be reported – generally at nil cost – if the applicable cost threshold is exceeded because other specified foreign property is held by the employee. When Shares are acquired, their cost generally is the adjusted cost base ("ACB") of the Shares. The ACB ordinarily would equal the fair market value of the Shares at the time of acquisition, but if the employee owns other shares of the same company, this ACB may have to be averaged with the ACB of the other shares.

CHINA

TERMS AND CONDITIONS

The following terms apply only to nationals of the People's Republic of China (the "PRC") residing in the PRC:

Method of Exercise. Due to legal restrictions in the PRC, you will be required to pay the exercise price for any Shares subject to the Option granted hereunder by a cashless sell-all exercise, such that all Shares will be sold immediately upon exercise and the cash proceeds of sale, less the exercise price, any Tax Obligations and broker's fees or commissions, will be remitted to you. The Company reserves the right to provide additional methods of exercise depending on local developments.

Termination of Employment. To comply with requirements imposed by the State Administration of Foreign Exchange, to the extent that, under Section IV of the Agreement, you may exercise any Option after termination of your employment, you will be permitted to exercise such Option for the shorter of the period set forth in Section IV of the Agreement and six (6) months from the date of

termination of your employment; any unexercised Option shall immediately lapse six (6) months following the termination of your employment.

The Company reserves the right to impose such further restrictions or conditions as may be necessary to comply with changes in applicable local laws in the PRC.

Please note that the above provisions will apply to all Options granted to you under the Plan, as well as to any Options granted to you in the past under the Plan.

Exchange Control Requirements. You understand and agree that, pursuant to PRC exchange control requirements, you will be required to repatriate the cash proceeds from the sale of the Shares issued upon the exercise of the Option to China. You further understand that, under applicable laws, such repatriation of your cash proceeds will need to be effectuated through a special exchange control account established by the Company or any Affiliate, including your Employer, and you hereby consent and agree that any proceeds from the sale of the Shares may be transferred to such special account prior to being delivered to you. You also understand that the Company will deliver the proceeds to you as soon as possible, but that there may be delays in distributing the funds to you due to exchange control requirements in China. Proceeds may be paid to you in U.S. dollars or local currency at the Company's discretion. If the proceeds are paid to you in U.S. dollars, you will be required to set up a U.S. dollar bank account in China so that the proceeds may be deposited into this account. If the proceeds are paid to you in local currency, the Company is under no obligation to secure any particular currency conversion rate and the Company may face delays in converting the proceeds to local currency due to exchange control restrictions. You agree to bear any currency fluctuation risk between the date the Option is exercised and the time that (i) the Tax Obligations are converted to local currency and remitted to the tax authorities, and (ii) net proceeds are converted to local currency and distributed to you. You acknowledge that neither the Company nor any Affiliate will be held liable for any delay in delivering the proceeds to you. You agree to sign any agreements, forms and/or consents that may be requested by the Company or the Company's designated broker to effectuate any of the remittances, transfers, conversions or other processes affecting the proceeds. You further agree to comply with any other requirements that may be imposed by the Company in the future in order to facilitate compliance with exchange control requirements in China.

COLOMBIA

TERMS AND CONDITIONS

Labor Law Acknowledgement. The following provision supplements Section XII of the Agreement:

You acknowledge that pursuant to Article 15 of Law 50/1990 (Article 128 of the Colombian Labor Code), the Plan and related benefits do not constitute a component of "salary" for any purpose. Therefore, they are considered to be of an extraordinary nature and will not be included and/or considered for purposes of calculating any and all labor benefits, such as legal/fringe benefits, vacations, indemnities, payroll taxes, social insurance contributions and/or any other labor-related amounts, subject to the limitations provided in Law 1393/2010.

Mandate Letter. In accepting the Option, you agree that – if requested by the Company or the Employer – you will execute a Mandate Letter or such other document (whether electronically or by such other method as requested by the Company or the Employer) that the Company determines is necessary or advisable in order that (i) a sufficient number of Shares to be allocated to you upon vesting can be sold on your behalf to cover Tax Obligations required to be withheld by the Employer and (ii) the proceeds from such sale can be wired directly from the Company to the Employer in Colombia for remittance to the tax authorities.

NOTIFICATIONS

Securities Law Information. The Shares are not and will not be registered with the Colombian registry of publicly traded securities (*Registro Nacional de Valores y Emisores*) and therefore the Shares may not be offered to the public in Colombia. Nothing in this document should be construed as the making of a public offer of securities in Colombia.

Exchange Control Information. Investment in assets located abroad (such as Shares acquired under the Plan) does not require prior approval from the Central Bank (*Banco de la República*). Nonetheless, such investments are subject to registration before the Central Bank as foreign investments held abroad, regardless of value.

All payments for your investment originating in Colombia (and the liquidation of such investments) must be transferred through the Colombian foreign exchange market (*e.g.*, local banks), which includes the obligation to correctly complete and file the appropriate foreign exchange form (*declaración de cambio*).

Foreign Asset/Account Reporting Information. An annual information return may need to be filed with the Colombian Tax Office detailing any assets held abroad (including Shares acquired under the Plan). If the individual value of any of these assets exceeds a certain threshold, each asset must be described (*e.g.*, its nature and its value) and the jurisdiction in which it is located must be disclosed. It is your responsibility to comply with this tax reporting requirement.

CROATIA

NOTIFICATIONS

Exchange Control Information. Croatian residents may be required to report any foreign investments (including Shares acquired under the Plan) to the Croatian National Bank for statistical purposes. You should be aware that exchange control regulations in Croatia are subject to frequent change and you are solely responsible for ensuring your continued compliance with current Croatian exchange control laws.

CZECH REPUBLIC

NOTIFICATIONS

Exchange Control Information. If you are a resident of the Czech Republic, you may be required to notify the Czech National Bank ("CNB") of the acquisition of Shares under the Plan or maintenance of a foreign account if (i) you maintain foreign direct investments with a value of 2,500,000 Kč or more in the aggregate, (ii) you maintain a certain threshold of foreign financial assets, or (iii) you are specifically requested to do so by the CNB.

DENMARK

TERMS AND CONDITIONS

Danish Stock Option Act. In accepting this Option, you acknowledge that you have received an Employer Statement translated into Danish, which is being provided to comply with the Danish Stock Option Act (the "Act"). To the extent more favorable to you and required to comply with the Stock Option Act, as amended with effect from January 1, 2019. You also acknowledge any grant of the Option under the Plan made on or after January 1, 2019 is subject to the rules of the amended Act. Accordingly, you agree that the treatment of the Option upon the termination of your employment is governed solely by Section IV(B)(1) of the Agreement and any corresponding provisions in the Plan. The relevant termination provisions are also detailed in the Employer Statement

Please be aware that as set forth in Section 1 of the Act, the Act only applies to "employees" as that term is defined in Section 2 of the Act. If you are a member of the registered management of an Affiliate or Subsidiary in Denmark or otherwise do not satisfy the definition of employee, you will not be subject to the Act, and the Employer Statement will not apply to you.

NOTIFICATIONS

Foreign Asset/Account Reporting Information. The requirement to report certain information to the Danish Tax Administration via Form V or K was eliminated effective January 1, 2019. However, you still must report the foreign bank/brokerage accounts and their deposits, and Shares held in a foreign bank or brokerage account in your tax return under the section on foreign affairs and income.

EGYPT

NOTIFICATIONS

Exchange Control Information. If you transfer funds into or out of Egypt in connection with the exercise of the Option or the receipt of sale proceeds, you may be required to transfer the funds through a registered bank in Egypt.

FINLAND

NOTIFICATIONS

Foreign Asset/Account Reporting Information. There are no specific reporting requirements with respect to foreign assets/accounts. However, please note that you must check your pre-completed tax return to confirm that the ownership of Shares and other securities (foreign or domestic) are correctly reported. If you find any errors or omissions, you must make the necessary corrections electronically or by sending specific paper forms to the local tax authorities.

FRANCE

TERMS AND CONDITIONS

Language Consent. By accepting the grant, you confirm having read and understood the Plan and Agreement which were provided in the English language. You accept the terms of these documents accordingly.

Consentement Relatif à la Langue Utilisée. *En acceptant l'attribution, vous confirmez avoir lu et compris le Plan et le Contrat, qui ont été communiqués en langue anglaise. Vous acceptez les termes de ces documents en connaissance de cause.*

NOTIFICATIONS

Foreign Asset/Account Reporting Information. French residents and non-residents must declare to the Customs Authorities the cash and securities they import or export without the use of a financial institution when the value of such cash or securities exceeds a certain threshold (currently €10,000). French residents also must report all foreign bank and brokerage accounts on an annual basis (including accounts opened or closed during the tax year) on Form N° 3916, together with the income tax return. Failure to comply could trigger significant penalties.

GERMANY

NOTIFICATIONS

Foreign Asset/Account Reporting Information. If your acquisition of Shares under the Plan leads to a qualified participation at any point during the calendar year, you will need to report the acquisition when you file your tax return for the relevant year. A qualified participation is attained only in the unlikely event (i) you own at least 1% of the Company and the value of the Shares acquired exceeds a certain threshold (currently €150,000) or (ii) you hold Shares exceeding 10% of the Company's total Common Stock.

Exchange Control Information. Cross-border payments in excess of a certain threshold (currently €50,000) must be reported monthly to the German Federal Bank (*Bundesbank*). In case of payments in connection with securities (including proceeds realized upon the sale of Shares or the receipt of dividends), and/or if the Company withholds Shares with a value in excess of the applicable threshold for any Tax Obligations, the report must be made monthly following the month in which the payment was received and must be filed electronically. The form of report (*Allgemeines Meldeportal Statistik*) can be accessed via the *Bundesbank's* website (www.bundesbank.de) and is available in both German

and English. In addition, you may be required to report the acquisition or sale of Shares to the *Bundesbank* if the value of the Shares acquired or sold exceeds the applicable threshold. You are responsible for satisfying any applicable reporting obligation.

GREECE

NOTIFICATIONS

Foreign Asset/Account Reporting Information. The reporting of foreign assets (including Shares and other investments) is your own obligation and takes place through your annual tax return.

HONG KONG

TERMS AND CONDITIONS

Sale of Shares. Shares received at exercise are accepted as a personal investment. In the event that Shares are issued in respect of the Options within six (6) months of the Grant Date, you agree that you will not offer to the public or otherwise dispose of the Shares prior to the six (6)-month anniversary of the Grant Date.

NOTIFICATIONS

SECURITIES WARNING: *The contents of this document have not been reviewed by any regulatory authority in Hong Kong. You should exercise caution in relation to the offer. If you are in doubt about any of the contents of the Agreement, including this Appendix, or the Plan, you should obtain independent professional advice. The Option and any Shares issued in respect of the Option do not constitute a public offering of securities under Hong Kong law and are available only to members of the Board and Employees. The Agreement, including this Appendix, the Plan and other incidental communication materials have not been prepared in accordance with and are not intended to constitute a "prospectus" for a public offering of securities under the applicable securities legislation in Hong Kong. The Option and any documentation related thereto are intended solely for the personal use of each member of the Board and/or Employee and may not be distributed to any other person.*

HUNGARY

There are no country-specific provisions.

ICELAND

TERMS AND CONDITIONS

Method of Exercise. Due to legal restrictions in Iceland, you will be required to pay the exercise price for any Shares subject to the Option granted hereunder by a cashless sell-all exercise, such that all Shares will be sold immediately upon exercise and the cash proceeds of sale, less the exercise price,

any Tax Obligations and broker's fees or commissions, will be remitted to you. The Company reserves the right to provide additional methods of exercise depending on local developments.

NOTIFICATIONS

Exchange Control Information. Approval by the Central Bank of Iceland is no longer required to participate in the Plan, regardless of the value of the Shares acquired under the Plan. Despite the recent relaxation of the exchange control requirements, you should consult with your personal advisor to ensure compliance with applicable exchange control regulations in Iceland as such regulations are subject to frequent change. You are responsible for ensuring compliance with all exchange control laws in Iceland.

INDIA

TERMS AND CONDITIONS

Method of Exercise. Due to legal restrictions in India, you will not be permitted to pay the exercise price for Shares subject to the Option granted hereunder by a cashless "sell-to-cover" procedure, under which method a number of Shares with a value sufficient to cover the exercise price, brokerage fees and any applicable Tax Obligations would be sold upon exercise and you would receive only the remaining Shares subject to the exercised Option. The Company reserves the right to permit this procedure for payment of the exercise price in the future, depending on the development of local law.

NOTIFICATIONS

Exchange Control Information. If you remit funds from India to pay the exercise price, you may be subject to Tax Collection At Source ("TCS") if your annual remittances out of India exceed a certain amount (currently INR 1,000,000). You may be required to provide a declaration to the bank remitting the funds to determine if the TCS limit has been reached. If deemed necessary to comply with applicable laws, the Company may require you to pay for the shares purchased on exercise, and any Tax Obligations through a cashless "sell-all" exercise or net exercise method. The Company reserves the right to prescribe alternative methods of payment depending on the development of local laws.

You must repatriate any funds received in connection with the Option (e.g., proceeds from the Shares and the receipt of dividends) within such time as prescribed under applicable Indian exchange control laws, which may be amended from time to time, unless an exemption applies. You should obtain a foreign inward remittance certificate ("FIRC") from the bank in which you deposit the foreign currency and maintain the FIRC as evidence of the repatriation of funds in the event the Reserve Bank of India or the Employer requests proof of repatriation. It is your responsibility to comply with these requirements. Neither the Company nor the Employer will be liable for any fines or penalties resulting from your failure to comply with any applicable laws. You may be required to provide information regarding funds received from participation in the

Plan to the Company and/or the Employer to enable them to comply with their filing requirements under exchange control laws in India.

Foreign Asset/Account Reporting Information. You are required to declare foreign bank accounts and any foreign financial assets (including Shares held outside of India) in your annual tax return. It is your responsibility to comply with this reporting obligation, and you should consult your personal tax advisor in this regard.

IRELAND

TERMS AND CONDITIONS

Nature of Grant. This provision supplements Section XII of the Agreement:

In accepting this Option, you acknowledge that the benefits received under the Plan will not be taken into account for any redundancy or unfair dismissal claim.

ITALY

TERMS AND CONDITIONS

Method of Exercise. Due to legal restrictions in Italy, you will be required to pay the exercise price for any Shares subject to the Option granted hereunder by a cashless sell-all exercise, such that all Shares will be sold immediately upon exercise and the cash proceeds of sale, less the exercise price, any Tax Obligations and broker's fees or commissions, will be remitted to you. The Company reserves the right to provide additional methods of exercise depending on local developments.

Nature of Grant. In accepting this Option, you acknowledge that (1) you have received a copy of the Plan, the Agreement and this Appendix; (2) you have reviewed the applicable documents in their entirety and fully understand the contents thereof; and (3) you accept all provisions of the Plan, the Agreement and this Appendix.

For the Option granted, you further acknowledge that you have read and specifically and explicitly approve, without limitation, the following Sections of the Option Agreement: Section I, Section IV, Section V, Section X, Section XII, Section XIII, Section XIV, Section XVII and the Data Privacy Notice for All European Economic Area ("EEA") / European Union ("EU") Jurisdictions, United Kingdom and Switzerland in this Appendix.

NOTIFICATIONS

Foreign Asset/Account Reporting Information. Italian residents who, at any time during the fiscal year, hold foreign financial assets (including cash and Shares) which may generate income taxable in Italy are required to report these assets on their annual tax returns (UNICO Form, RW Schedule) for the year during which the assets are held, or on a special form if no tax return is due. These reporting

obligations will also apply to Italian residents who are the beneficial owners of foreign financial assets under Italian money laundering provisions.

Foreign Financial Assets Tax. The fair market value of any Shares held outside of Italy is subject to a foreign assets tax at a flat rate. The fair market value is considered to be the value of the Shares on the Nasdaq Global Select Market on December 31 of the applicable year in which you held the Shares (or when the Shares are acquired during the course of the year, the tax is levied in proportion to the actual days of holding over the calendar year). No tax payment duties arise if the amount of the foreign financial assets tax calculated on all financial assets held abroad does not exceed a certain threshold. You should consult with your personal tax advisor about the foreign financial assets tax.

JAPAN

NOTIFICATIONS

Exchange Control Information. If you acquire Shares valued at more than ¥100,000,000 in a single transaction, you must file a Securities Acquisition Report with the Ministry of Finance through the Bank of Japan within 20 days of the purchase of the Shares.

In addition, if you pay more than ¥30,000,000 in a single transaction for the purchase of Shares when you exercise the Option, you must file a Payment Report with the Ministry of Finance through the Bank of Japan by the 20th day of the month following the month in which the payment was made. The precise reporting requirements vary depending on whether or not the relevant payment is made through a bank in Japan.

A Payment Report is required independently from a Securities Acquisition Report. Therefore, if the total amount that you pay upon a one-time transaction for exercising the Option and purchasing Shares exceeds ¥100,000,000, then you must file both a Payment Report and a Securities Acquisition Report.

Foreign Asset/Account Reporting Information. You will be required to report to the Japanese tax authorities details of any assets held outside of Japan as of December 31st (including any Shares acquired under the Plan) to the extent such assets have a total net fair market value exceeding a certain threshold (currently ¥50,000,000). Such report will be due by June 30 each year. You should consult with your personal tax advisor as to whether the reporting obligation applies to you and whether you will be required to include in the report details of any outstanding Options, Shares or cash that you hold.

KOREA (SOUTH)

NOTIFICATIONS

Exchange Control Information. Korean residents who sell Shares acquired under the Plan and/or receive cash Dividends on the Shares must file a report with a Korean foreign exchange bank if the proceeds exceed a certain threshold (currently US$5,000 per transaction) and are deposited

into a non- Korean bank account. The report is not required if proceeds are deposited into a non-Korean brokerage account. It is your responsibility to ensure compliance with any applicable exchange control reporting obligations.

Foreign Asset/Account Reporting Information. To remit funds out of Korea to exercise the Option by means of a cash exercise method, you must obtain a confirmation of the remittance by a foreign exchange bank in Korea. This is an automatic procedure (*i.e.*, the bank does not need to approve the remittance and the process should not take more than a single day). You likely will need to present to the bank processing the transaction supporting documentation evidencing the nature of the remittance.

You are required to declare all foreign financial accounts (*e.g.* non-Korean bank accounts, brokerage accounts holding Shares, etc.) to the Korean tax authority and file a report regarding such accounts if the monthly balance of such accounts exceeds a certain threshold. It is your responsibility to comply with this reporting obligation, and you should consult your personal tax advisor to ensure compliance with this requirement.

LITHUANIA

NOTIFICATIONS

Foreign Asset/Account Reporting Information. If you (i) hold certain job positions established by the law or (ii) donate to political parties or political campaigners, you must file an Annual Asset Return of the Individual (Family) in Form No. FR0001 with respect to assets held outside of Lithuania (*e.g.*, Shares). If you open an account in a foreign financial institution and annual turnover in the account exceeds a certain threshold (currently €15,000), you must file a foreign account report.

MEXICO

TERMS AND CONDITIONS

Acknowledgement of the Agreement. In accepting the Option granted hereunder, you acknowledge that you have received a copy of the Plan, have reviewed the Plan and the Option Agreement, including this Appendix, in their entirety and fully understand and accept all provisions of the Plan and the Agreement, including this Appendix. You further acknowledge that you have read and specifically and expressly approve the terms and conditions of Section XII of the Agreement, in which the following is clearly described and established:

(1) Your participation in the Plan does not constitute an acquired right.

(2) The Plan and your participation in the Plan are offered by Amgen Inc. on a wholly discretionary basis.

(3) Your participation in the Plan is voluntary.

(4) Amgen Inc. and its Affiliates are not responsible for any decrease in the value of the Option granted and/or Shares issued under the Plan.

Labor Law Acknowledgement and Policy Statement. In accepting the Option granted hereunder, you expressly recognize that Amgen Inc., with registered offices at One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., is solely responsible for the administration of the Plan and that your participation in the Plan and acquisition of Shares do not constitute an employment relationship between you and Amgen Inc. since you are participating in the Plan on a wholly commercial basis and your sole employer is Amgen Mexico S.A. de C.V. ("Amgen-Mexico"). Based on the foregoing, you expressly recognize that the Plan and the benefits that you may derive from participation in the Plan do not establish any rights between you and your Employer, Amgen-Mexico, and do not form part of the employment conditions and/or benefits provided by Amgen-Mexico and any modification of the Plan or its termination shall not constitute a change or impairment of the terms and conditions of your employment.

You further understand that your participation in the Plan is as a result of a unilateral and discretionary decision of Amgen Inc.; therefore, Amgen Inc. reserves the absolute right to amend and/or discontinue your participation in the Plan at any time without any liability to you.

Finally, you hereby declare that you do not reserve to yourself any action or right to bring any claim against Amgen Inc. for any compensation or damages regarding any provision of the Plan or the benefits derived under the Plan, and you therefore grant a full and broad release to Amgen Inc., its Affiliates, stockholders, officers, agents or legal representatives with respect to any claim that may arise.

Spanish Translation

Reconocimiento del Otorgamiento. Al aceptar cualquier Opción bajo el presente documento, usted reconoce que ha recibido una copia del Plan, que ha revisado el mismo en su totalidad, así como también el Acuerdo de Opción, incluyendo este Apéndice, además que comprende y está de acuerdo con todas las disposiciones tanto del Plan y del Opción, incluyendo este Apéndice. Asimismo, usted reconoce que ha leído y manifiesta específicamente y expresamente la conformidad con los términos y condiciones establecidos en la Sección XII del Acuerdo de Opción, en los que se establece y describe claramente que:

(1) Su participación en el Plan de ninguna manera constituye un derecho adquirido.

(2) El Plan y su participación en el mismo son ofrecidos por Amgen Inc. de forma completamente discrecional.

(3) Su participación en el Plan es voluntaria.

(4) Amgen Inc. y sus Afiliados no son responsables de ninguna disminución en el valor de la opción otorgada y/o de las Acciones Comunes emitidas mediante el Plan.

Reconocimiento de la Ley Laboral y Declaración de Política. Al aceptar cualquier Opción bajo el presente, usted reconoce expresamente que Amgen Inc., con oficinas registradas localizadas en One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., es la única responsable de la administración del Plan y que su participación en el mismo y la adquisición de Acciones Comunes no constituyen de ninguna manera una relación laboral entre usted y Amgen Inc., debido a que su participación en el Plan es únicamente una relación comercial y que su único empleador es Amgen Mexico S.A. de C.V. ("Amgen-México"). Derivado de lo anterior, usted reconoce expresamente que el Plan y los beneficios a su favor que pudieran derivar de la participación en el mismo, no establecen ningún derecho entre usted y su empleador, Amgen – México, y no forman parte de las condiciones laborales y/o los beneficios otorgados por Amgen – México, y cualquier modificación del Plan o la terminación del mismo no constituirá un cambio o desmejora de los términos y condiciones de su trabajo.

Asimismo, usted entiende que su participación en el Plan es resultado de la decisión unilateral y discrecional de Amgen Inc., por lo tanto, Amgen Inc. se reserva el derecho absoluto de modificar y/o descontinuar su participación en el Plan en cualquier momento y sin ninguna responsabilidad para usted.

Finalmente, usted manifiesta que no se reserva ninguna acción o derecho que origine una demanda en contra de Amgen Inc., por cualquier compensación o daños y perjuicios, en relación con cualquier disposición del Plan o de los beneficios derivados del mismo, y en consecuencia usted exime amplia y completamente a Amgen Inc. de toda responsabilidad, como así también a sus Afiliadas, accionistas, directores, agentes o representantes legales con respecto a cualquier demanda que pudiera surgir.

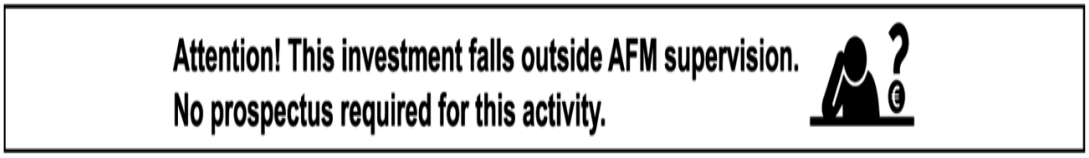
NOTIFICATIONS

Securities Law Information. The Options and the Shares offered under the Plan have not been registered with the National Register of Securities maintained by the Mexican National Banking and Securities Commission and cannot be offered or sold publicly in Mexico. In addition, the Plan, the Agreement and any other document relating to the Options may not be publicly distributed in Mexico. These materials are addressed to you only because of your existing relationship with the Company and your Employer and these materials should not be reproduced or copied in any form. The offer contained in these materials does not constitute a public offering of securities but rather constitutes a private placement of securities addressed specifically to individuals who are present employees of Amgen-Mexico made in accordance with the provisions of the Mexican Securities Market Law, and any rights under such offering shall not be assigned or transferred.

NETHERLANDS

NOTIFICATIONS

Securities Law Information.



NORWAY

NOTIFICATIONS

Foreign Asset/Account Reporting Information. Norwegian residents may be subject to foreign asset reporting as part of their ordinary tax return. Norwegian banks, financial institutions, limited companies etc. must report certain information to the Tax Administration. Such information may then be pre-completed in a Norwegian resident's tax return. However, if the resident has traded, or is the owner of, financial instruments (*e.g.*, Shares) not pre-completed in the tax return, the Norwegian resident must enter this information in Form RF-1159, which is an appendix to the tax return.

Options will be considered assets and are, therefore, subject to wealth tax. An exemption from wealth tax may be available for non-transferrable awards. However, because the wealth tax regulations and the practice of the tax authorities are not well developed, Norwegian residents should provide the tax authorities with information concerning the Options in the annual tax return even if the Norwegian resident maintains that no wealth tax is payable.

Exchange Control Information. In general, Norwegian residents should not be subject to any foreign exchange requirements in connection with their acquisition or sale of Shares under the Plan, except normal reporting requirements to the Norwegian Currency Registry. If any transfer of funds into or out of Norway is made through a Norwegian bank, the bank will make the registration.

POLAND

NOTIFICATIONS

Foreign Asset/Account Reporting Information. Polish residents holding foreign securities (including Shares) and maintaining accounts abroad must file reports with the National Bank of Poland if the aggregate value of cash and securities held in such foreign accounts exceeds a certain threshold (currently PLN 7 million). If required, the reports are due on a quarterly basis by the 20th day following the end of each quarter and must be filed on special forms available on the website of the National Bank of Poland.

Exchange Control Information. In addition, Polish residents are required to transfer funds through a bank account in Poland if the transferred amount in any single transaction exceeds a specified threshold (currently €15,000 (or PLN 15,000 if such transfer of funds is associated with the business activity of a consultant)). You must store all documents connected with any foreign exchange transactions you engage in for a period of five (5) years from the end of the year when such transactions were made. Penalties may apply for failure to comply with exchange control requirements.

PORTUGAL

TERMS AND CONDITIONS

Consent to Receive Information in English. You hereby expressly declare that you have full knowledge of the English language and have read, understood and fully accepted and agreed with the terms and conditions established in the Plan and Agreement.

Conhecimento da Lingua. *Por meio do presente, eu declaro expressamente que tem pleno conhecimento da língua inglesa e que li, compreendi e livremente aceitei e concordei com os termos e condições estabelecidas no Plano e no Acordo.*

PUERTO RICO

There are no country-specific provisions.

ROMANIA

NOTIFICATIONS

Exchange Control Information. Certain transfers of funds may need to be reported to the National Office for Prevention and Control of Money Laundering on specific forms by the relevant bank or financial institution. If you deposit proceeds from the sale of Shares or the receipt of dividends in a bank account in Romania, you may be required to provide the Romanian bank assisting with the transaction with appropriate documentation explaining the source of the income. You should consult with a legal advisor to determine whether you will be required to submit such documentation to the Romanian bank.

RUSSIA

NOTIFICATIONS

Foreign Account Report Information. Russian residents maintaining accounts abroad must disclose such accounts with the Russian tax authorities, as follows: (i) file notifications upon opening (or closing or changing bank details) within 30 days, and (ii) file reports on the movement of cash or financial assets on such accounts by June 1 of the following year. Such notifications and reports must be filed on special forms available on the website of the Russian

tax authorities. Russian residents who are absent from Russia for more than 183 days in a year may be relieved from this reporting.

TERMS AND CONDITIONS

Securities Law Information. The sale of Shares acquired under the Plan is not permitted within Russia. The Shares are currently traded on the Nasdaq Global Select Market in the U.S. under the ticker symbol "AMGN," therefore, the Shares may be sold on this exchange.

You understand that the exchange control rules and regulations in Russia and the legal restrictions impacting your participation in the Plan are subject to frequent change. You should consult with your personal legal advisor to determine the applicability of any requirements or restrictions applicable to any Shares or cash received in connection with the Plan.

SINGAPORE

TERMS AND CONDITIONS

Restriction on Sale and Transferability. You hereby agree that any Shares acquired pursuant to the Option will not be offered for sale in Singapore prior to the six (6)-month anniversary of the Grant Date, unless such sale or offer is made pursuant to one or more exemptions under Part XIII Division 1 Subdivision (4) (other than section 280) of the Securities and Futures Act (Chap. 289, 2006 Ed.) ("SFA"), or pursuant to, and in accordance with the conditions of, any other applicable provisions of the SFA.

NOTIFICATIONS

Securities Law Information. The grant of the Option is being made pursuant to the "Qualifying Person" exemption under section 273(1)(f) of the SFA, on which basis it is exempt from the prospectus and registration requirements under the SFA, and is not made with a view to the Option being subsequently offered for sale to any other party. The Plan has not been, and will not be, lodged or registered as a prospectus with the Monetary Authority of Singapore.

Director Notification Requirement. Directors (including alternate, substitute, associate and shadow directors) of a Singapore Affiliate are subject to certain notification requirements under the Singapore Companies Act, regardless of whether they are resident or employed in Singapore. Directors of a Singapore Affiliate must notify the Singapore Affiliate in writing of an interest (*e.g.*, Options, Shares, etc.) in the Company or any related company within two (2) business days of (i) its acquisition or disposal, (ii) any change in a previously disclosed interest (*e.g.,* when the Shares are sold), or (iii) becoming a director.

SLOVAK REPUBLIC

There are no country-specific provisions.

SLOVENIA

NOTIFICATIONS

Foreign Asset/Account Reporting Information. Slovenian residents may be required to report the opening of bank and/or brokerage accounts to tax authorities within eight (8) days of opening such account. You should consult with your personal tax advisor to determine whether this requirement will be applicable to any accounts opened in connection with your participation in the Plan (*e.g.*, your brokerage account with the Company's designated broker).

SPAIN

TERMS AND CONDITIONS

Nature of Grant. The following provision supplements Section XII of the Agreement:

In accepting this Option, you consent to participation in the Plan and acknowledge that you have received a copy of the Plan.

You understand that the Company has unilaterally, gratuitously and in its sole discretion decided to grant the Option under the Plan to individuals who may be members of the Board or Employees of the Company or its Affiliates throughout the world. The decision is a limited decision, which is entered into upon the express assumption and condition that (i) the Option granted will not economically or otherwise bind the Company or any of its Affiliates on an ongoing basis, other than as expressly set forth in the Agreement, including this Appendix; (ii) Option granted hereunder and any Shares acquired under the Plan shall not become a part of any employment contract (either with the Company or any of its Affiliates) and shall not be considered a mandatory benefit, salary for any purposes (including severance compensation) or any other right whatsoever; and (iii) any unvested Options will be forfeited immediately upon termination of your employment for any reason, as detailed below. Further, you understand and freely accept that there is no guarantee that any benefit whatsoever shall arise from any gratuitous and discretionary grant of the Option since the future value of the Option and the underlying Shares is unknown and unpredictable. In addition, you understand that the Option granted hereunder would not be made but for the assumptions and conditions referred to above; thus, you understand, acknowledge and freely accept that, should any or all of the assumptions be mistaken or should any of the conditions not be met for any reason, then any grant of an Option or right to an Option shall be null and void.

Further, the vesting of the Option is expressly conditioned on your continued and active rendering of service, such that if your employment terminates for any reason whatsoever, the Option may cease vesting immediately, in whole or in part, effective on the date of your termination of employment (unless otherwise specifically provided in Section IV of the Agreement). This will be the case, for example, even if (1) you are considered to be unfairly dismissed without good cause (*i.e.*, subject to a "despido improcedente"); (2) you are dismissed for disciplinary or objective reasons or due to a collective dismissal; (3) you terminate service due to a change of work location, duties or any other employment or contractual condition; (4) you terminate service due to a unilateral breach of contract by the Company or an Affiliate; or (5) your employment terminates for any other reason whatsoever.

Consequently, upon termination of your employment for any of the above reasons, you may automatically lose any rights to Options that were not vested on the date of your termination of employment, as described in the Plan and the Agreement.

You acknowledge that you have read and specifically accept the conditions referred to in Section IV of the Agreement.

NOTIFICATIONS

Securities Law Information. No "offer of securities to the public," as defined under Spanish law, has taken place or will take place in the Spanish territory. The Agreement (including this Appendix) has not been nor will it be registered with the *Comisión Nacional del Mercado de Valores*, and does not constitute a public offering prospectus.

Exchange Control Information. You will be required to declare electronically to the Bank of Spain any security accounts (including brokerage accounts held abroad), as well as the securities (including Shares acquired under the Plan) held in such accounts if the value of the transactions for all such accounts during the prior year or the balances of such accounts as of December 31 of the prior year exceeds a certain threshold (currently, €1,000,000). Different thresholds and deadlines to file this declaration apply. However, if neither such transactions during the immediately preceding year nor the balances / positions as of December 31 exceed the applicable threshold, no such declaration must be filed unless expressly required by the Bank of Spain. If any of such thresholds were exceeded during the current year, you may be required to file the relevant declaration corresponding to the prior year, however, a summarized form of declaration may be available..

Foreign Asset/Account Reporting Information.
To the extent that you hold Shares and/or have bank accounts outside of Spain with a value in excess of €50,000 (for each type of asset) as of December 31 each year, you will be required to report information on such assets in your tax return (tax form 720) for such year. After such Shares and/or accounts are initially reported, the reporting obligation will apply for subsequent years only if the value of any previously-reported Shares or accounts increases by more than €20,000 (for each type of asset) as of each subsequent December 31, or if you sell or otherwise dispose of any previously-reported Shares or accounts. If the value of such Shares and/or accounts as of December 31 does not exceed €50,000, a summarized form of declaration may be presented.

SWEDEN

TERMS AND CONDITIONS

Authorization to Withhold. This provision supplements Section V of the Agreement:

Without limiting the Company's and the Employer's authority to satisfy their withholding obligations for Tax Obligations as set forth in the Agreement, in accepting the Options, you authorize the Company to withhold Shares or to sell Shares otherwise issuable to you upon exercise to satisfy Tax Obligations, regardless of whether the Company and/or Employer have an obligation to withhold such Tax

Obligations, provided that such withholding would not, in the Company's determination, result in adverse accounting consequences to the Company.

SWITZERLAND

NOTIFICATIONS

Securities Law Information. Neither this document nor any other materials relating to the Option (i) constitutes a prospectus according to articles 35 et seq. of the Swiss Federal Act on Financial Services ("FinSA"), (ii) may be publicly distributed or otherwise made publicly available in Switzerland to any person other than an employee of the Company or one of its Subsidiaries or (iii) has been or will be filed with, approved or supervised by any Swiss reviewing body according to article 51 of FinSA or any Swiss regulatory authority, including the Swiss Financial Market Supervisory Authority.

TAIWAN

NOTIFICATIONS

Securities Law Information. Participation in the Plan is available only for select Board members and Employees of the Company and its Affiliates. The grant of Units and participation in the Plan is not a public offer of securities by a Taiwanese company.

Exchange Control Information. You may acquire and remit foreign currency (including proceeds from the sale of Shares or the receipt of dividends) up to US$10,000,000 per year without justification. If the transaction amount is TWD500,000 or more in a single transaction, you must submit a Foreign Exchange Transaction Form. If the transaction amount is US$500,000 or more in a single transaction, you must also provide supporting documentation to the satisfaction of the remitting bank.

THAILAND

NOTIFICATIONS

Exchange Control Information. If you receive funds in connection with the Plan (*e.g.*, dividends or sale proceeds) with a value equal to or greater than a certain threshold (currently US$1,000,000) per transaction, you are required to immediately repatriate such funds to Thailand. Any foreign currency repatriated to Thailand must be converted to Thai Baht or deposited into a foreign currency deposit account opened with any commercial bank in Thailand acting as the authorized agent within 360 days from the date the funds are repatriated to Thailand. You are also required to inform the authorized agent of the details of the foreign currency transaction, including your identification information and the purpose of the transaction. The Employee is responsible for ensuring compliance with all exchange control laws in Thailand.

If you do not comply with the above obligations, you may be subject to penalties assessed by the Bank of Thailand. Because exchange control regulations change frequently and without notice,

you should consult your legal advisor before selling any Shares (or receiving any other funds in connection with the Plan) to ensure compliance with current regulations. It is your responsibility to comply with exchange control laws in Thailand, and neither the Company nor your Employer will be liable for any fines or penalties resulting from failure to comply with applicable laws.

TÜRKIYE

NOTIFICATIONS

Securities Law Information. The sale of Shares acquired under the Plan is not permitted within Türkiye. The sale of Shares acquired under the Plan must occur outside of Türkiye. The Shares are currently traded on the Nasdaq Global Select Market in the U.S. under the ticker symbol "AMGN" and Shares may be sold on this exchange.

Exchange Control Information. You may be required to engage a Turkish financial intermediary to assist with the cash exercise of an Option or the sale of Shares acquired under the Plan. To the extent a Turkish financial intermediary is required in connection with the Option exercise or the sale of any Shares acquired upon exercise of the Option, you are solely responsible for engaging such Turkish financial intermediary. You should consult your personal legal advisor prior to the exercise of Options or any sale of Shares to ensure compliance with the current requirements.

UNITED ARAB EMIRATES

NOTIFICATIONS

Securities Law Information. Options under the Plan are granted only to select Board members and Employees of the Company and its Affiliates and are for the purpose of providing equity incentives. The Plan and the Agreement are intended for distribution only to such Board members and Employees and must not be delivered to, or relied on by, any other person. You should conduct your own due diligence on the Options offered pursuant to this Agreement. If you do not understand the contents of the Plan and/or the Agreement, you should consult an authorized financial adviser. The Emirates Securities and Commodities Authority and the Dubai Financial Services Authority have no responsibility for reviewing or verifying any documents in connection with the Plan. Further, the Ministry of the Economy and the Dubai Department of Economic Development have not approved the Plan or the Agreement nor taken steps to verify the information set out therein, and have no responsibility for such documents.

UNITED KINGDOM

TERMS AND CONDITIONS

Tax Withholding. This provision supplements Section V of the Agreement:

Without limitation to Section V of the Agreement, you agree that you are liable for all Tax Obligations and hereby covenant to pay all such Tax Obligations as and when requested by the Company or your

Employer or by HM Revenue and Customs ("HMRC") (or any other tax authority or any other relevant authority). You also agree to indemnify and keep indemnified the Company and your Employer against any taxes that they are required to pay or withhold or have paid or will pay to HMRC (or any other tax authority or any other relevant authority) on your behalf.

Notwithstanding the foregoing, if you are an executive officer or director within the meaning of Section 13(k) of the Exchange Act, as amended from time to time, you understand that you may not be able to indemnify the Company or your Employer for the amount of income tax not collected from or paid by you, as it may be considered a loan. In the event that you are an executive officer or director and income tax is not collected from you within ninety (90) days after the end of the tax year in which the Taxable Event occurs, the amount of any uncollected income tax may constitute an additional benefit to you on which additional income tax and national insurance contributions ("NICs") may be payable. You acknowledge that you are responsible for reporting and paying any income tax due on this additional benefit directly to HMRC under the self-assessment regime and for paying your Employer for the amount of any NICs due on this additional benefit, which the Company or your Employer may obtain from you by any of the means set forth in Section V of the Agreement.

If the maximum applicable withholding rate is used, any over-withheld amount may be credited to you by the Company or your Employer (with no entitlement to the Common Stock equivalent) or if not so credited, you may seek a refund from the local tax authorities.

Joint Election. If you are a resident of the United Kingdom between the Grant Date and the vesting of the Option, as a condition of the Option granted hereunder, you agree to accept any liability for secondary Class 1 National Insurance Contributions (the "Employer NICs"), which may be payable by the Company or your Employer with respect to the exercise of the Option and issuance of Shares subject to the Option, the assignment or release of the Option for consideration, or the receipt of any other benefit in connection with the Option.

Without limitation to the foregoing, you agree to make an election (the "Election"), in the form specified and/or approved for such election by HMRC, that the liability for your Employer NICs payments on any such gains shall be transferred to you to the fullest extent permitted by law. You further agree to execute such other elections as may be required between you and any successor to the Company and/or your Employer. You hereby authorize the Company and your Employer to withhold such Employer NICs by any of the means set forth in Section V of the Agreement.

Failure by you to enter into an Election, withdrawal of approval of the Election by HMRC or a joint revocation of the Election by you and the Company or your Employer, as applicable, shall be grounds for the forfeiture and cancellation of the Option, without any liability to the Company or your Employer.

UNITED STATES

TERMS AND CONDITIONS

Nature of Grant. The following provision replaces Section IV(B)(1) of the Agreement:

(1) "termination of your employment" shall mean the last date you are either an active employee of the Company or an Affiliate or actively engaged as a Director of the Company or an Affiliate; in the event of termination of your employment (whether or not in breach of local labor laws), your right to exercise the Option and vest under the Plan, if any, will terminate effective as of the date that you are no longer actively employed; provided, however, that such right will be extended by any notice period mandated by law (e.g. the Worker Adjustment and Retraining Notification Act ("WARN Act") notice period or similar periods pursuant to local law) and any paid administrative leave (as applicable), unless the Company shall provide you with written notice otherwise before the commencement of such notice period or leave. Your right, if any, to exercise the Option after termination of employment will be measured by the date of termination of your active employment; provided, however, that such right will be extended by any notice period mandated by law (e.g. the Worker Adjustment and Retraining Notification Act ("WARN Act") notice period or similar periods pursuant to local law) and any paid administrative leave, unless the Company shall provide you with written notice otherwise before the commencement of such notice period or leave. Notwithstanding anything to the contrary herein, in no event shall the term of this Option extend beyond the Expiration Date set forth on the Award Notice and in this Agreement.

Form of Award Notice

[*The information set forth in this Award Notice will be contained on the related pages on Merrill Lynch Benefits Website (or the website of any successor company to Merrill Lynch Bank & Trust Co., FSB). This Award Notice shall be replaced by the equivalent pages on such website. References to Award Notice in this Agreement shall then refer to the equivalent pages on such website.*]

This notice of Award (the "Award Notice") sets forth certain details relating to the grant by the Company to you of the Award identified below, pursuant to the Plan. The terms of this Award Notice are incorporated into the Restricted Stock Unit Agreement (the "Agreement") that accompanies this Award Notice and made part of the Agreement. Capitalized terms used in this Award Notice that are not otherwise defined in this Award Notice have the meanings given to such terms in the Agreement.

Employee:
Employee ID:
Address:
Award Type:
Grant ID:
Plan: Amgen Inc. Second Amended and Restated 2009 Equity Incentive Plan, as amended and/or restated from time to time
Grant Date:
Grant Price: $_____
Number of Shares:
Number of Units
Vesting Date: Means the vesting date indicated in the Vesting Schedule
Vesting Schedule: Means the schedule of vesting set forth under Vesting Details
Vesting Details: Means the presentation (tabular or otherwise) of the Vesting Date and the quantity of Shares vesting

IMPORTANT NOTICE REGARDING ACCEPTANCE OF THE AWARD AND THE REQUIREMENT TO OPEN A BROKERAGE ACCOUNT[1]:

RESIDENTS OF THE U.S. AND PUERTO RICO: Please read this Award Notice, the Plan and the Agreement (collectively, the "Grant Documents") carefully. If you, as a resident of the U.S. or Puerto Rico, do **not** wish to receive this Award and/or you do **not** consent and agree to the terms and conditions on which this Award is offered, as set forth in the Grant Documents, then you must reject the Award by contacting the Merrill Lynch call center at +1 (800) 97AMGEN (+1 (800) 972-6436) within the U.S., Puerto Rico and Canada or +1 (609) 818-8910 from all other countries (Merrill Lynch will accept the charges for your call) no later than the forty-fifth calendar day following the day on which this Award Notice is made available to you,

[1] *This provision is only for use on the form of grant used for the U.S. and Puerto Rico.*

in which case the Award will be cancelled. For the purpose of determining the forty-five calendar days, Day 1 will be the day **immediately** following the day on which this Award Notice is made available to you. Your failure to notify the Company of your rejection of the Award or your refusal of, or disagreement with, all terms and conditions of the Award, as set forth in the Grant Documents, within this specified period will constitute your acceptance of the Award and your agreement with all terms and conditions of the Award, as set forth in the Grant Documents. If you agree to the terms and conditions of your grant and you desire to accept it, then no further action is needed on your part to accept the grant. However, you must still open a brokerage account as directed by the Company, by 1:00 pm Pacific Time on or before the date that is 11 months after the Grant Date specified in this Award Notice. This step is necessary to process transactions related to your equity grant. If you do not open a brokerage account by this deadline, **your grant will be cancelled**.

RESTRICTED STOCK UNIT AGREEMENT

THE SPECIFIC TERMS OF YOUR GRANT OF RESTRICTED STOCK UNITS ARE FOUND IN THE PAGES RELATING TO THE GRANT OF RESTRICTED STOCK UNITS FOUND ON MERRILL LYNCH BENEFITS WEBSITE (OR THE WEBSITE OF ANY SUCCESSOR COMPANY TO MERRILL LYNCH BANK & TRUST CO., FSB) (THE "AWARD NOTICE") WHICH ACCOMPANIES THIS DOCUMENT. THE TERMS OF THE AWARD NOTICE ARE INCORPORATED INTO THIS RESTRICTED STOCK UNIT AGREEMENT.

On the Grant Date specified in the Award Notice, Amgen Inc., a Delaware corporation (the "Company"), has granted to you, the grantee named in the Award Notice, an award under the Amgen Inc. Second Amended and Restated 2009 Equity Incentive Plan, as amended and/or restated from time to time (the "Plan"), for the Number of Units with respect to the number of shares of the $0.0001 par value common stock of the Company (the "Shares") specified in the Award Notice, on the terms and conditions set forth in this Restricted Stock Unit Agreement, any additional terms and conditions for your country set forth in the attached Appendix A and the Award Notice (collectively, the "Agreement") and the Plan. The Units shall constitute Restricted Stock Units under Section 9.5 of the Plan, which is incorporated herein by reference. Capitalized terms not defined herein shall have the meanings assigned to such terms in the Plan.

I. Vesting Schedule and Termination of Units.

a. *General.* Subject to the terms and conditions of this Agreement, on each Vesting Date, the Number of Units indicated on the Vesting Schedule shall vest, provided that you have remained continuously and actively employed with the Company or an Affiliate through each applicable Vesting Date, unless (i) [your employment has terminated due to your Voluntary Termination (as defined in paragraph (d) of this Section I below)]*[2], [(ii)] you experience a Qualified Termination (as defined below), or (iii) [(ii)] as otherwise determined by the Company in the exercise of its discretion as provided in paragraph (f) of this Section I. The Units represent an unfunded, unsecured promise by the Company to deliver Shares. Only whole Shares shall be issued upon vesting of the Units, and the Company shall be under no obligation to issue any fractional Shares to you. If your employment with the Company or an Affiliate is terminated for any reason or for no reason, including if your active employment is terminated by the Company or an Affiliate without Cause (as defined below), or in the event of any other termination of your active employment caused directly or indirectly by the Company or an Affiliate, except as otherwise provided in paragraphs (b), (c), [(d),]*[(1)] (e) or (f) of this Section I below, your unvested Units shall automatically expire and terminate on the date of termination of your active employment. Notwithstanding anything herein to the contrary, the Vesting Schedule

[2] *Paragraph (d) of Section I of this Agreement is not applicable to awards identified by the Administrator as new hire, retention, special or promotion grants and the provisions of such paragraph shall be reserved and references thereto identified by an asterisk (*) shall be omitted from the agreements evidencing such grants.*

may be accelerated (by notice in writing) by the Company in its sole discretion at any time that the Units remain outstanding and unvested (in whole or in part). In addition, if not prohibited by local law, vesting may be suspended by the Company in its sole discretion during a leave of absence as provided from time to time according to Company policies and practices.

b. *Permanent and Total Disability.* Notwithstanding the provisions in paragraph (a) above, if your employment with the Company or an Affiliate terminates due to your Permanent and Total Disability (as defined below), then the vesting of Units granted under this Agreement shall be accelerated, subject to your execution and non-revocation of a general release and waiver in a form provided by the Company (for the purpose of resolving any potential or actual disputes arising from your employment and the termination of your employment with the Company) (a "Release"), to vest in full as of the day immediately preceding such termination of your employment with respect to all Units granted hereunder. Notwithstanding the foregoing, if the Units were granted in the calendar year in which such termination occurs, (i) the Units shall instead be accelerated to vest only with respect to a number of Units equal to (A) the number of Units subject to this Agreement multiplied by (B) a fraction, the numerator of which is the number of complete months you remained continuously and actively employed by the Company or an Affiliate during the calendar year in which your termination occurs, and the denominator of which is twelve (12), and (ii) any Units that remain unvested following the acceleration provided for in clause (i) shall automatically expire and terminate on the date of the termination of your active employment due to your Permanent and Total Disability without consideration therefor.

c. *Death*. Notwithstanding the provisions in paragraph (a) above, if your employment with the Company or an Affiliate terminates due to your death, then the vesting of Units granted under this Agreement shall be accelerated to vest in full as of the day immediately preceding your death. Notwithstanding the foregoing, if the Units were granted in the calendar year in which your death occurs, (i) the Units shall instead be accelerated to vest only with respect to a number of Units equal to (A) the number of Units subject to this Agreement multiplied by (B) a fraction, the numerator of which is the number of complete months you remained continuously and actively employed by the Company or an Affiliate during the calendar year in which your death occurs, and the denominator of which is twelve (12), and (ii) any Units that remain unvested following the acceleration provided for in clause (i) shall automatically expire and terminate on the date of the termination of your active employment due to your death without consideration therefor.

d. *[Voluntary Termination (Retirement)*.

(i) Notwithstanding the provisions in paragraph (a) above, if you terminate your employment with the Company or an Affiliate due to your voluntary termination (and such voluntary termination is not the result of Permanent and Total Disability (as defined below)) after you are at least sixty-five (65) years of age, or after you are at least fifty-five (55) years of age and have been an employee of the Company and/or an Affiliate for at least ten (10) years in the aggregate as determined by the Company in

its sole discretion according to Company policies and practices as in effect from time to time ("Voluntary Termination"), then the Units will continue to vest following your Voluntary Termination pursuant to the Vesting Schedule without regard to the termination of employment prior to the Vesting Date, subject to your execution and non-revocation of a Release. Notwithstanding the foregoing, if the Units were granted in the calendar year in which the Voluntary Termination occurs, (i) the Units will continue to vest pursuant to the Vesting Schedule provided in the Award Notice, provided, that each tranche of Units scheduled to vest upon each remaining Vesting Date in the Vesting Schedule will vest only with respect to (A) the number of Units in such tranche multiplied by (B) a fraction, the numerator of which is the number of complete months you remained continuously and actively employed by the Company or an Affiliate during the calendar in which your termination occurs and the denominator of which is twelve (12), and (ii) any Units in excess of the number of Units which are eligible to vest pursuant to clause (i) shall automatically expire and terminate on the date of termination of your active employment due to your Voluntary Termination without consideration therefor; provided, further, however, that in the event of your death following your Voluntary Termination, any Units that remain outstanding as of the date of your death will become vested (and the Vesting Date with respect to such Units will occur) as of the day immediately preceding your death.

(ii) Notwithstanding the foregoing, in the event your Voluntary Termination occurs on or after the date of a Change of Control, then, to the extent permitted by applicable law, the vesting of Units granted under this Agreement shall be accelerated to vest as of the day immediately prior to the date of your Voluntary Termination.

(iii) Notwithstanding the definition of Voluntary Termination set forth above, if the Company receives an opinion of counsel that there has been a legal judgment and/or legal development in your jurisdiction that would likely result in the favorable treatment upon Voluntary Termination described above being deemed unlawful and/or discriminatory, then the Committee will not apply the favorable treatment described above.][Reserved]*[3]

e. *Qualified Termination after a Change of Control*. Notwithstanding the provisions in paragraph (a) above, in the event of your Qualified Termination (as defined below), then, to the extent permitted by applicable law, the vesting of Units granted under this Agreement shall be accelerated to vest as of the day immediately prior to the date of your Qualified Termination.

f. *Continued Vesting*. Notwithstanding the provisions in paragraph (a) above, the Company may in its sole discretion at any time during the term of this Agreement, in writing, otherwise provide that the Units will vest pursuant to the Vesting Schedule without

[3] *Paragraph(d) of Section I of this Agreement is not applicable to awards identified by the Administrator as new hire, retention, special or promotion grants and the provisions of such paragraph shall be reserved and references thereto identified by an asterisk (*) shall be omitted from the agreements evidencing such grants.*

regard to the termination of employment prior to the Vesting Date, subject to any terms and conditions that the Company may determine.

For purposes of this Agreement:

(i) "termination of your active employment" shall mean the last date that you are either an active employee of the Company or an Affiliate or actively engaged as a Director of the Company or an Affiliate; in the event of termination of your employment (whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are working or the terms of your employment agreement, if any), your right to receive Units and vest under the Plan, if any, will terminate effective as of the date that you are no longer actively providing services and will not be extended by any notice period (*e.g.*, active employment would not include any period of "garden leave" or similar period mandated under employment laws in the jurisdiction where you are employed or the terms of your employment agreement, if any). The Company shall have exclusive discretion to determine when you are no longer actively providing services for purposes of this Agreement (including whether you may still be considered to be providing services while on a leave of absence);

(ii) "Cause" shall mean (i) your conviction of a felony (or similar crime under applicable law, as determined by the Company), or (ii) your engaging in conduct that constitutes willful gross neglect or willful gross misconduct in carrying out your duties, resulting, in either case, in material economic harm to the Company or any Affiliate, unless you believed in good faith that such conduct was in, or not contrary to, the best interests of the Company or any Affiliate. For purposes of clause (ii) above, no act, or failure to act, on your part shall be deemed "willful" unless done, or omitted to be done, by you not in good faith;

(iii) "Permanent and Total Disability" shall have the meaning ascribed to such term under Section 22(e)(3) of the Code and with such permanent and total disability being certified prior to termination of your employment by (i) the U.S. Social Security Administration, (ii) the comparable governmental authority applicable to an Affiliate, (iii) such other body having the relevant decision-making power applicable to an Affiliate, or (iv) an independent medical advisor appointed by the Company in its sole discretion, as applicable, in any such case;

(iv) "Qualified Termination" shall mean

(a) if you are an employee who participates in the Change of Control Plan (as defined below), your termination of employment within two (2) years following a Change of Control (i) by the Company or an Affiliate other than for Cause, Disability, or as a result of your death or (ii) by you for Good Reason (as defined in the Change of Control Plan); or

(b) if you are an employee who does not participate in the Change of Control Plan or the Change of Control Plan is no longer in effect, your termination

of employment within two (2) years following a Change of Control by the Company or an Affiliate other than for Cause, Disability, or as a result of your death;

(v) "Change of Control" shall mean the occurrence of any of the following:

(A) the acquisition (other than from the Company) by any person, entity or "group," within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act (excluding, for this purpose, the Company or any of its Affiliates, or any employee benefit plan of the Company or any of its Affiliates which acquires beneficial ownership of voting securities of the Company), of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of fifty percent (50%) or more of either the then-outstanding Shares or the combined voting power of the Company's then-outstanding voting securities entitled to vote generally in the election of directors; or

(B) the consummation by the Company of a reorganization, merger, consolidation, (in each case, with respect to which persons who were the stockholders of the Company immediately prior to such reorganization, merger or consolidation do not, immediately thereafter, own more than fifty percent (50%) of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then-outstanding voting securities) or a liquidation or dissolution of the Company or of the sale of all or substantially all of the assets of the Company.

Notwithstanding anything herein or in the Agreement to the contrary, if a Change of Control constitutes a payment event with respect to any Unit that is subject to United States income tax and which provides for a deferral of compensation that is subject to Section 409A (as defined below), the transaction or event described in subsection (A) or (B) above must also constitute a "change in control event," as defined in U.S. Treasury Regulation § 1.409A-3(i)(5), in order to constitute a Change of Control for purposes of payment of such Unit.

(vi) "Change of Control Plan" shall mean the Company's change of control and severance plan, including the Amgen Inc. Change of Control Severance Plan, as amended and restated, effective as of December 9, 2010 (and any subsequent amendments thereto), or equivalent plan governing the provision of benefits to eligible employees upon the occurrence of a Change of Control (including resulting from a termination of employment that occurs within a specified time period following a Change of Control), as in effect immediately prior to a Change of Control; and

(vii) "Disability" shall mean your "disability" as determined in accordance with the Company's long-term disability plan as in effect immediately prior to a Change of Control.

II. Form and Timing of Settlement. Subject to satisfaction of Tax Obligations or similar obligations as provided for in Section III, any vested Units shall be settled by the Company delivering to you a number of Shares equal to the number of such vested Units or in a lump sum in cash with a value equal to the Fair Market Value of the number of Shares subject to the vested Units as of the applicable vesting date (without interest thereon), or in a combination of Shares and cash, as determined by the Administrator at any time prior to settlement and in its discretion. Such settlement of any vested Units shall occur on the earlier of (a) the regularly scheduled Vesting Date(s) indicated in the Vesting Schedule or in any case by the end of the calendar year in which such applicable Vesting Date occurs, or (b) the date of the applicable event set forth in paragraph (b), (c), [the last clause of paragraph (d)(i), (d)(ii),]* or (e) of Section I above or as soon as practicable, and in any event within 70 days after the date of such event. [(For the avoidance of doubt, in the event that any Units continue to vest following a Voluntary Termination in accordance with Section I(d)(i) above, the Vesting Date(s) for purposes of settlement pursuant to this Section II shall be the regularly scheduled Vesting Dates following such termination.)]*[4] Notwithstanding the foregoing provisions of this Section II, to the extent that the Units are exempt from or otherwise not subject to Section 409A, the Units shall be settled within the short-term deferral period of Section 409A. Notwithstanding anything to the contrary in the foregoing, in the event that (i) the vesting and settlement of Units is conditioned on your execution, non-revocation and delivery of a Release and (ii) the period over which the Release becomes effective and nonrevocable commences in one calendar year and ends in the next calendar year, the Units will be settled in the second calendar year. Shares issued in respect of a Unit shall be deemed to be issued in consideration of past services actually rendered by you to the Company or an Affiliate or for its benefit for which you have not previously been compensated or for future services to be rendered, as the case may be, which the Company deems to have a value at least equal to the aggregate par value thereof.

III. Tax Withholding; Issuance of Shares. Regardless of any action the Company or your actual employer (the "Employer") takes with respect to any or all income tax (including federal, state and local taxes), social insurance, payroll tax, fringe benefit tax, payment on account or other tax-related items related to your participation in the Plan and legally applicable to you ("Tax Obligations"), you acknowledge that the ultimate liability for all Tax Obligations is and remains your responsibility and may exceed the amount, if any, actually withheld by the Company and/or your Employer. You further acknowledge that the Company and/or your Employer (i) make no representations or undertakings regarding the treatment of any Tax Obligations in connection with any aspect of the Units or the underlying Shares, including the grant of the Units, the vesting of Units, the conversion of the Units into Shares or the receipt of an equivalent cash payment, the subsequent sale of any Shares acquired at vesting and the receipt of any Dividends (as defined in Section IV, below) or Dividend Equivalents, and (ii) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Units to reduce or eliminate your liability for Tax Obligations or achieve any particular tax result. Furthermore, if you become subject to tax in more than one jurisdiction, you acknowledge that the Company and/or your Employer (or former employer, as applicable) may be required to withhold or account for Tax Obligations in more than one jurisdiction.

[4] *Paragraph(d) of Section I of this Agreement is not applicable to awards identified by the Administrator as new hire, retention, special or promotion grants and the provisions of such paragraph shall be reserved and references thereto identified by an asterisk (*) shall be omitted from the agreements evidencing such grants.*

Prior to any relevant taxable or tax withholding event, as applicable, you shall pay or make adequate arrangements satisfactory to the Company or to your Employer (in their sole discretion) to satisfy all Tax Obligations. In this regard, you authorize the Company and/or your Employer or their respective agents, at their discretion, to satisfy all applicable Tax Obligations by one or a combination of the following:

(a) withholding from your wages or other cash compensation paid to you by the Company and/or your Employer; or

(b) withholding from proceeds of the sale of Shares acquired upon vesting or payment of the Units either through your voluntary sale or through a mandatory sale arranged by the Company (on your behalf pursuant to this authorization); or

(c) withholding in Shares issuable, or cash payable, upon vesting or payment of the Units, provided that, if such Shares are withheld, the Company and your Employer shall only withhold an amount of Shares with a fair market value not to exceed the Tax Obligations as determined in the discretion of the Company or your Employer, as applicable.

Depending on the withholding method, the Company may withhold or account for Tax Obligations by considering applicable minimum statutory withholding rates or other applicable withholding rates, including maximum applicable rates. If the Tax Obligations are satisfied by withholding in Shares, for tax purposes you are deemed to have been issued the full number of Shares subject to the vested Units, notwithstanding that a number of the Shares is held back and not actually issued to you solely for the purpose of paying the Tax Obligations due as a result of any aspect of your participation in the Plan (any Shares withheld by the Company hereunder shall not be deemed to have been issued by the Company for any purpose under the Plan and shall remain available for issuance thereunder).

Finally, you shall pay to the Company or your Employer any amount of Tax Obligations that the Company or your Employer may be required to withhold or account for as a result of your participation in the Plan that cannot be or were not satisfied by the means previously described. You agree to take any further actions and execute any additional documents as may be necessary to effectuate the provisions of this Section III. Notwithstanding Section II above, the Company may refuse to issue or deliver the Shares or the proceeds of the sale of Shares if you fail to comply with your obligations in connection with the Tax Obligations.

IV. Dividend Equivalents

(a) Crediting and Payment of Dividend Equivalents. Subject to this Section IV, Dividend Equivalents shall be credited on each Unit granted to you under this Agreement in the manner set forth in the remainder of this Section IV. With respect to each Unit covered by the Award, if the Company declares one or more dividends or distributions (each, a "Dividend") on its Common Stock with a record date which occurs during the period commencing on the Grant Date through and including the day immediately preceding the day the share of Common Stock subject to such Unit is issued to you, whether in the form

of cash, Common Stock or other property, then on the date such Dividend is paid to the Company's stockholders you shall be credited with an amount equal to the amount or fair market value of such Dividend which would have been payable to you if you held a share of Common Stock as of the record date for such Dividend, unless the applicable Unit has been forfeited between the record date and payment date for such Dividend. Any such Dividend Equivalents shall be credited and deemed reinvested in the Common Stock as of the applicable Dividend payment date. Dividend Equivalents shall be payable in full shares of Common Stock, unless the Administrator determines, at any time prior to payment and in its discretion, that they shall be payable in cash. Dividend Equivalents payable with respect to fractional shares of Common Stock shall be paid in cash.

(b) Treatment of Dividend Equivalents. Except as otherwise expressly provided in this Section IV, any Dividend Equivalents credited to you shall be subject to all of the provisions of this Agreement which apply to the Unit with respect to which they have been credited and shall be payable, if at all, at the time and to the extent that the underlying Unit becomes payable pursuant to Section II above. Dividend Equivalents shall not be payable on any Units that do not vest, or are forfeited, pursuant to the terms of this Agreement. Dividend Equivalent rights and any amounts that may become distributable in respect thereof shall be treated separately from the Units and the rights arising in connection therewith for purposes of the designation of time and form of payments required by Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Grant Date, "Section 409A").

V. Transferability. No benefit payable under, or interest in, this Agreement, the Units, or the Shares that are scheduled to be issued to you hereunder shall be subject in any manner to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or charge and any such attempted action shall be void and no such benefit or interest shall be, in any manner, liable for, or subject to, your or your beneficiary's debts, contracts, liabilities or torts; provided, however, nothing in this Section V shall prevent transfer (i) by will or (ii) by applicable laws of descent and distribution.

VI. Notices. Any notices provided for in this Agreement or the Plan shall be given in writing or electronically and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail or equivalent foreign postal service, postage prepaid, addressed to you at such address as is currently maintained in the Company's records or at such other address as you hereafter designate by written notice to the Company Stock Administrator. Such notices may be given using any automated system for the documentation, granting or settlement of Awards, such as a system using an internet website or interactive voice response, as approved by the Company.

VII. Plan. This Agreement is subject to all the provisions of the Plan, which provisions are hereby made a part of this Agreement, including without limitation the provisions of Section 9.5 of the Plan relating to Restricted Stock Units, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. In the

event of any conflict between the provisions of this Agreement and those of the Plan, the provisions of the Plan shall control.

VIII. Governing Law and Venue. The terms of this Agreement shall be governed by the laws of the State of Delaware without giving effect to principles of conflicts of laws. For purposes of litigating any dispute that arises hereunder, the parties hereby submit to and consent to the jurisdiction of the State of Delaware, and agree that such litigation shall be conducted in the courts of the State of Delaware, or the federal courts for the United States for the federal district located in the State of Delaware, and no other courts, where this Agreement is made and/or to be performed.

IX. Code Section 409A. The time and form of payment of the Units is intended to comply with the requirements of Section 409A and this Agreement shall be interpreted in accordance with Section 409A. Accordingly, no acceleration or deferral of any payment shall be permitted if it would cause the payment of the Units to violate Section 409A. In addition, notwithstanding any provision herein to the contrary, in the event that following the Grant Date, the Committee (as defined in the Plan) determines that it may be necessary or appropriate to do so, the Committee may adopt such amendments to the Plan and/or this Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Committee determines are necessary or appropriate to (a) exempt the Plan and/or the Units from the application of Section 409A and/or preserve the intended tax treatment of the benefits provided with respect to this Award, or (b) comply with the requirements of Section 409A; provided, however, that this paragraph shall not create an obligation on the part of the Committee to adopt any such amendment, policy or procedure or take any such other action. For purposes of Section 409A, the right to receive payment of Units at each Vesting Date shall be treated as a right to receive separate and distinct payments. No payment hereunder shall be made to you during the six (6)-month period following your "separation from service" (within the meaning of Section 409A) to the extent that the Company determines that paying such amount at the time set forth herein would be a prohibited distribution under Section 409A(a)(2)(B)(i). If the payment of any such amounts is delayed as a result of the previous sentence, then within thirty (30) days following the end of such six (6)-month period (or, if earlier, your death), the Company shall pay to you (or to your estate) the cumulative amounts that would have otherwise been payable to you during such period, without interest.

X. Acknowledgement. By electing to accept this Agreement, you acknowledge receipt of this Agreement and hereby confirm your understanding that the terms set forth in this Agreement constitute, subject to the terms of the Plan, which terms shall control in the event of any conflict between the Plan and this Agreement, the entire agreement and understanding of the parties with respect to the matters contained herein and supersede any and all prior agreements, arrangements and understandings, both oral and written, between the parties concerning the subject matter of this Agreement. The Company may, in its sole discretion, decide to deliver any documents related to current or future participation in the Plan (including this Agreement) by electronic means. You hereby consent to receive such documents by electronic delivery and agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company.

XI. Acknowledgement of Nature of Plan and Units. In accepting this Agreement, you acknowledge, understand and agree that:

(a) the Plan is established voluntarily by the Company, is discretionary in nature and may be modified, amended, suspended or terminated by the Company at any time, as provided in the Plan;

(b) the Plan is operated and the Units are granted solely by the Company, and only the Company is a party to this Agreement; accordingly, any rights you may have under this Agreement may be raised only against the Company but not any Affiliate (including, but not limited to, the Employer);

(c) no Affiliate (including, but not limited to, the Employer) has any obligation to make any payment of any kind to you under this Agreement;

(d) the grant of the Units is exceptional, voluntary and occasional and does not create any contractual or other right to receive future awards of Units, or benefits in lieu of Units even if Units have been awarded in the past;

(e) all decisions with respect to future awards, if any, will be at the sole discretion of the Company;

(f) your participation in the Plan is voluntary;

(g) the grant of Units, the Shares subject to the Units, and the income from and value of same, are not intended to replace any pension rights or compensation;

(h) neither the grant of Units nor any provision of this Agreement, the Plan or the policies adopted pursuant to the Plan confer upon you any right with respect to employment or continuation of current employment and shall not interfere with the ability of your Employer to terminate your employment or service relationship (if any) at any time;

(i) in the event that you are not an employee of the Company or any Affiliate, the Units shall not be interpreted to form an employment contract or relationship with the Company or any Affiliate;

(j) the future value of the underlying Shares is unknown, indeterminable and cannot be predicted with certainty;

(k) in consideration of the grant of Units hereunder, no claim or entitlement to compensation or damages arises from termination of Units, and no claim or entitlement to compensation or damages shall arise from forfeiture of the Units resulting from (i) the termination of your employment by the Company or an Affiliate (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are employed or the terms of your employment agreement, if any)

and/or (ii) the application of the Clawback Policy as described in Section XVIII below, and you irrevocably release the Company and your Employer from any such claim that may arise; if, notwithstanding the foregoing, any such claim is found by a court of competent jurisdiction to have arisen, you shall be deemed irrevocably to have waived your entitlement to pursue such claim;

(l) unless otherwise agreed with the Company, the Units, the Shares subject to the Units, and the income from and value of same, are not granted as consideration for, or in connection with, the service you may provide as a director of an Affiliate of the Company;

(m) except as otherwise provided in this Agreement or the Plan, the Units and the benefits evidenced by this Agreement do not create any entitlement to have the Units or any such benefits transferred to, or assumed by, another company nor to be exchanged, cashed out or substituted for, in connection with any corporate transaction affecting the shares of the Company;

(n) the following provisions apply only if you are providing services outside the United States:

(i) for employment law purposes outside the United States, the Units, Shares subject to the Units, and the income from and value of same, are not part of normal or expected compensation or salary for any purpose, including but not limited to for purposes of calculating any severance, resignation, termination, redundancy, dismissal, end of service payments, bonuses, holiday pay, long-service awards, pension or retirement benefits or similar mandatory payments; and

(ii) neither the Company, your Employer nor any Affiliate of the Company shall be liable for any foreign exchange rate fluctuation between your local currency and the United States Dollar that may affect the value of the Units or of any amounts due to you pursuant to the settlement of the Units or the subsequent sale of any Shares acquired upon settlement.

XII. No Advice Regarding Award. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan, or your acquisition or sale of the underlying Shares. You should consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

XIII. Compliance with Laws. Notwithstanding any provision of this Agreement to the contrary, if you are employed by the Company or an Affiliate in any of the countries identified in the attached Appendix A (which constitutes a part of this Agreement), are subject to the laws of any foreign jurisdiction, or relocate to one of the countries included in the attached Appendix A, the Units granted hereunder shall be subject to any additional terms and conditions for your country set forth in Appendix A and to the following additional terms and conditions:

(a) the terms and conditions of this Agreement, including Appendix A, are deemed modified to the extent necessary or advisable to comply with applicable foreign laws or facilitate the administration of the Plan;

(b) if applicable, the effectiveness of your award of Units is conditioned upon its compliance with any applicable foreign laws, regulations, rules or local governmental regulatory exemption and subject to receipt of any required foreign regulatory approvals;

(c) to the extent necessary to comply with applicable foreign laws, the payment of any earned Units shall be made in cash or Common Stock, at the Company's election; and

(d) the Company may take any other action, before or after an award of Units is made, that it deems advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals.

Notwithstanding anything to the contrary contained herein, the Company shall not take any actions hereunder that would violate the Securities Act, the Exchange Act, the Code, or any other securities or tax or other applicable law or regulation, or the rules of any Securities Exchange. Notwithstanding anything to the contrary contained herein, the Shares issuable upon vesting of the Unit shall not be issued unless such Shares are then registered under the Securities Act, or, if such Shares are not then so registered, the Company has determined that such vesting and issuance would be exempt from the registration requirements of the Securities Act, and that the issuance satisfied all other applicable legal requirements.

XIV. ***Data Privacy. In order for the Company to facilitate your participation in the Plan, the Company and your Employer must collect and use personal data about you. In accordance with applicable laws, reasonable security measures will be implemented and maintained to protect the security of your personal data; however, you understand that absolute security cannot be guaranteed.***

You understand that the Company and your Employer may hold certain personal information about you, including your name, home address and telephone number, email address, date of birth, social insurance/security number (to the extent permitted under applicable local law), passport or other identification number, salary, nationality, job title/work history/service periods, residency status, citizenship, tax withholding and payroll data, any shares of stock or directorships held in the Company, details of all equity compensation or any other entitlement to Shares awarded, cancelled, vested, unvested or outstanding in your favor, for the purposes of implementing, administering and managing the Plan ("personal data").

You authorize the transfer of your personal data to Merrill Lynch Bank & Trust Co., FSB, or any successor thereto, and any other third parties which may assist the Company (presently or in the future) with implementing, administering and managing your participation in the Plan to receive, possess, use, retain and transfer your personal data, in electronic or other form, for the purpose of implementing, administering and managing your participation in the Plan, including any requisite transfer of such personal data as may be required to any other broker, escrow agent or other third party with whom the Shares received in settlement of the Units may be deposited. You understand that such authorized recipients of your personal data may be located in countries that do not provide the same level of data privacy laws and protections as the country in which your personal data originated. Transfers of personal data among Company and its group entities follow applicable laws and our Binding Corporate Rules (BCRs). For more information on Company's BCRs, please visit http://www.amgen.com/bcr/. You acknowledge that the collection, use and transfer of your personal

data is necessary to facilitate your participation in the Plan, as well as to grant you Units or other equity awards and administer or maintain such awards.

You may correct or update your personal data previously provided to Company, by contacting your local human resources representative. Subject to applicable law, you may have additional rights, including the right to object and/or request destruction of your personal data. To exercise these rights, where applicable, please contact your local human resources representative.

XV. Severability. If one or more of the provisions of this Agreement shall be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and the invalid, illegal or unenforceable provisions shall be deemed null and void; however, to the extent permissible by law, any provisions which could be deemed null and void shall first be construed, interpreted or revised retroactively to permit this Agreement to be construed so as to foster the intent of this Agreement and the Plan.

XVI. Language. By electing to accept this Agreement, you acknowledge that you are sufficiently proficient in English, or have consulted with an advisor who is sufficiently proficient in English, so as to allow you to understand the terms and conditions of this Agreement. Further, if you have received this Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control, unless otherwise required by applicable law.

XVII. Imposition of Other Requirements. The Company reserves the right to impose other requirements on your participation in the Plan, on the Units and on any Shares acquired under the Plan, to the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

XVIII. Compensation Subject to Recovery. The Units subject to and Shares issuable under this Award and all compensation payable with respect to them shall be subject to clawback, recoupment and/or recovery by the Company pursuant to any and all of the Company's policies with respect to the clawback, recoupment or recovery of compensation in effect as of the Grant Date or as may be adopted or maintained by the Company following the Grant Date, including, without limitation, the Company's Policy on Recovery of Erroneously Awarded Compensation (effective October 2, 2023) and Executive Officer Equity Recoupment Policy (effective December 31, 2020), as they shall be in effect and may be amended from time to time (collectively, the "Clawback Policy"), to the maximum extent permitted by applicable law.

XIX. Waiver. You acknowledge that a waiver by the Company of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by you or any other grantee.

XX. Headings. This Agreement's section headings are for convenience only and shall not constitute a part of this Agreement or affect this Agreement's meaning.

Very truly yours,
AMGEN INC.

By:_____
Name:
Title:

APPENDIX A

**ADDITIONAL TERMS AND CONDITIONS OF THE
AMGEN INC. SECOND AMENDED AND RESTATED
2009 EQUITY INCENTIVE PLAN,
AS AMENDED AND/OR RESTATED FROM TIME TO TIME**

**GRANT OF RESTRICTED STOCK UNITS
(BY COUNTRY)**

Certain capitalized terms used but not defined in this Appendix A shall have the meanings set forth in the Plan and/or the Agreement to which this Appendix is attached.

TERMS AND CONDITIONS

This Appendix includes additional terms and conditions that govern any Units granted under the Plan if, under applicable law, you are a resident of, are deemed to be a resident of or are working in one of the countries listed below. Furthermore, the additional terms and conditions that govern any Units granted hereunder may apply to you if you transfer employment and/or residency to one of the countries listed below and the Company shall, in its discretion, determine to what extent the terms and conditions contained herein shall apply to you.

NOTIFICATIONS

This Appendix also includes notifications relating to exchange control and other issues of which you should be aware with respect to your participation in the Plan. The information is based on the exchange control, securities and other laws in effect in the countries to which this Appendix refers as of October 2025. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the notifications herein as the only source of information relating to the consequences of your participation in the Plan because the information may be outdated when you vest in the Units and acquire Shares under the Plan, or when you subsequently sell Shares acquired under the Plan.

In addition, the notifications are general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of any particular result. Accordingly, you should seek appropriate professional advice as to how the relevant laws in your country may apply to your situation. Finally, if you are a citizen or resident of a country other than the one in which you are currently residing and/or working or are considered a resident of another country for local law purposes, the information contained herein may not be applicable to you or you may be subject to the provisions of one or more jurisdictions.

ALL NON-U.S. JURISDICTIONS

TERMS AND CONDITIONS

Tax Withholding; Issuance of Shares. The following provision supplements Section III of the Agreement:

In the event the Company withholds or accounts for Tax Obligations by considering maximum applicable rates in your jurisdiction(s), in the event of over-withholding, you may receive a refund of any over-withheld amount in cash and will not be entitled to the equivalent amount in Shares, or if not refunded, you may seek a refund from the local tax authorities. In the event of under-withholding, you may be required to pay any additional Tax Obligations directly to the applicable tax authority or to the Company and/or your Employer.

NOTIFICATIONS

Insider Trading Restrictions/Market Abuse Laws. You may be subject to insider trading restrictions and/or market abuse laws based on the exchange on which the Shares are listed and in applicable jurisdictions including the United States and your country or your broker's country, if different, which may affect your ability to accept, acquire, sell or otherwise dispose of Shares, rights to Shares (*e.g.*, Units) or rights linked to the value of Shares (*e.g.*, Dividend Equivalents) during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in applicable jurisdictions). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders you place before you possessed inside information. Furthermore, you could be prohibited from (i) disclosing the inside information to any third party, which may include fellow employees (other than on a "need to know" basis) and (ii) "tipping" third parties or causing them otherwise to buy or sell securities. Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. You are responsible for ensuring your compliance with any applicable restrictions and you should speak with your personal legal advisor on this matter.

Foreign Asset/Account, Tax Reporting Information. Your country of residence may have certain foreign asset and/or account reporting requirements which may affect your ability to acquire or hold Shares under the Plan or cash received from participating in the Plan (including from any Dividends or Dividend Equivalents received, or sale proceeds arising from the sale of Shares) in a brokerage or bank account outside of your country. You may be required to report such accounts, assets or transactions to the tax or other authorities in your country. You also may be required to repatriate sale proceeds or other funds received as a result of participating in the Plan to your country within a certain time after receipt. You are responsible for ensuring your compliance with such regulations, and you should speak with your personal legal advisor on this matter.

ALL EUROPEAN ECONOMIC AREA ("EEA") / EUROPEAN UNION ("EU") JURISDICTIONS, UNITED KINGDOM AND SWITZERLAND

TERMS AND CONDITIONS

Data Privacy Notice. This provision replaces Section XIV of the Agreement:

Please refer to the Fair Processing Notice previously provided by your local human resources representative, which notice governs the collection, use and transfer of your personal data necessary for the Company to facilitate your participation in the Plan. If you have any questions or concerns regarding the Fair Processing Notice, including questions about your rights afforded thereunder, you should contact your local human resources representative or send an email to hrconnect@amgen.com.

For purposes of implementing, administering and managing the Plan, Company and your Employer may hold certain personal data about you, including your name, home address and telephone number, email address, date of birth, social insurance/security number (to the extent permitted under applicable local law), passport or other identification number, salary, nationality, job title/work history/service periods, residency status, citizenship, tax withholding and payroll data, any shares of stock or directorships held in the Company, details of all equity compensation or any other entitlement to Shares awarded, cancelled, vested, unvested or outstanding in your favor ("personal data").

You authorize the transfer of your personal data to Merrill Lynch Bank & Trust Co., FSB, or any successor thereto, and any other third parties which may assist the Company (presently or in the future) with implementing, administering and managing your participation in the Plan to receive, possess, use, retain and transfer your personal data, in electronic or other form, for the purpose of implementing, administering and managing your participation in the Plan, including any requisite transfer of such personal data as may be required to any other broker, escrow agent or other third party with whom the Shares received in settlement of the Units may be deposited.

ARGENTINA

TERMS AND CONDITIONS

Labor Law Acknowledgement. The following provision supplements Section XI of the Agreement:

In accepting this Agreement, you acknowledge, understand and agree that the grant of the Units is made by the Company (not your Employer) in its sole discretion and that the value of the Units or any Shares acquired under the Plan shall not constitute salary or wages for any purpose under Argentine labor law including, but not limited to, the calculation of (i) any labor benefits including, without limitation, vacation pay, thirteenth salary, compensation in lieu of notice, annual bonus, disability, and leave of absence payments, etc., or (ii) any termination or severance indemnities or similar payments.

NOTIFICATIONS

Securities Law Information. The Units and the underlying Shares have not been and will not be publicly issued, placed, distributed, offered or listed in the Argentine capital markets, and, as a result, have not been and will not be registered with the Argentina Securities Commission (Comisión Nacional de Valores, "CNV"). Neither this nor any other offering material related to the Units nor the underlying Shares may be utilized in connection with any general offering to the public in Argentina. Any Argentine resident who acquires Shares under the Plan does so under their own responsibility under the terms of a private offering to the Argentine resident from outside Argentina. Any Argentine resident who acquires Shares shall not transfer such Shares to any other person within six (6) months of acquiring the Shares, unless the transaction is conducted outside Argentina.

Exchange Control Information. Exchange control regulations in Argentina are subject to frequent change. You should consult with your personal legal advisor regarding any exchange control obligations that you may have prior to receiving proceeds from Dividend Equivalents, the sale of Shares or dividends. You must comply with any and all Argentine currency exchange restrictions, approvals and reporting requirements in connection with your participation in the Plan.

Foreign Asset/Account Reporting Information. If you are an Argentine resident, you are required to report certain information regarding any Shares you hold as of December 31 each year to the Argentine tax authorities on your annual tax return.

AUSTRALIA

NOTIFICATIONS

Australia Offer Document. This grant of Units is being made under Division 1A, Part 7.12 of the Corporations Act 2001 (Cth).

Tax Information. Subdivision 83A-C of the Income Tax Assessment Act 1997 (Cth) applies to the Units granted under the Plan, such that the Units are intended to be subject to deferred taxation.

Exchange Control Information. If you are an Australian resident, exchange control reporting is required for cash transactions exceeding a certain threshold (currently AUD10,000) and for international fund transfers. If an Australian bank is assisting with the transaction, the bank will file the report on your behalf. If there is no Australian bank involved in the transfer, you will be required to file the report.

AUSTRIA

NOTIFICATIONS

Foreign Asset/Account Reporting Information. If you are an Austrian resident and you hold Shares acquired under the Plan outside of Austria, you may be subject to reporting obligations to the Austrian National Bank.

Exchange Control Information. If the value of Shares meets or exceeds a certain threshold (currently, €5,000,000), you must report the securities held on a quarterly basis to the Austrian National Bank as of the last day of the quarter, on or before the 15th day of the month following the end of the calendar quarter. Further, if you hold cash in accounts outside Austria, monthly reporting requirements will apply, as explained in the next paragraph, if the aggregate transaction volume of such cash accounts meets or exceeds a certain threshold.

A separate reporting requirement applies when you sell Shares acquired under the Plan, receive a cash Dividend paid on such Shares or Dividend Equivalents paid in cash. In that case, there may be exchange control obligations if the cash proceeds are held outside of Austria. If the transaction volume of all cash accounts abroad meets or exceeds a certain threshold (currently €10,000,000), the movements and balances of all accounts must be reported monthly, as of the last day of the month, on or before the 15th day of the following month, on the prescribed forms.

BELGIUM

NOTIFICATIONS

Tax Reporting; Foreign Asset/Account Reporting Information. If you are a Belgian resident, you are required to report any securities (*e.g.*, Shares acquired under the Plan) held and bank accounts (including brokerage accounts) opened and maintained outside of Belgium on your annual tax return. The first time you report the foreign security and/or bank account on your annual income tax return you will have to provide the National Bank of Belgium Central Contact Point with the account details of any such foreign accounts (including the account number, bank name and country in which such account was opened) in a separate form. This report, as well as information on how to complete it, can be found on the website of the National Bank of Belgium, www.nbb.be, under the *Kredietcentrales / Centrales des crédits* caption.

Stock Exchange Tax Information. A stock exchange tax applies to transactions executed by a Belgian resident through a non-Belgian financial intermediary, such as a U.S. broker. The stock exchange tax likely will apply when Shares acquired under the Plan are sold. It is your responsibility to comply with this tax obligation and you should consult your personal tax advisor for additional details on your obligations with respect to the stock exchange tax.

Annual Securities Accounts Tax Information. An annual securities accounts tax may be payable if the total value of securities held in a Belgian or foreign securities account (e.g., Shares acquired under the Plan) exceeds a certain threshold on four reference dates within the relevant reporting period (i.e., December 31, March 31, June 30 and September 30). In such case, the tax will be due on the value of the qualifying securities held in such account. It is your responsibility to comply with this obligation, and you should consult with your personal tax or financial advisor for additional details.

BRAZIL

TERMS AND CONDITIONS

Compliance with Law. By accepting the Units, you acknowledge that you agree to comply with applicable Brazilian laws and pay any and all applicable taxes associated with the vesting of the Units, the sale of Shares acquired under the Plan, the payment of Dividends on such Shares and the receipt of any Dividend Equivalents paid in cash.

Acknowledgement of Nature of Plan and Units. This provision supplements Section XI of the Agreement:

In accepting this Agreement, you acknowledge (i) that you are making an investment decision, (ii) that the Shares will be issued to you only if the vesting conditions are met and any necessary services are rendered by you during the vesting period set forth in the Vesting Schedule, and (iii) that the value of the underlying Shares is not fixed and may increase or decrease in value over the vesting period without compensation to you.

NOTIFICATIONS

Exchange Control Information. If you are resident or domiciled in Brazil, you will be required to submit annually a declaration of assets and rights held outside of Brazil to the Central Bank of Brazil if the aggregate value of such assets and rights on December 31 of each year exceeds US$1,000,000. If such amount exceeds US$100,000,000, the referenced declaration must be submitted quarterly, in the month following the end of each quarter. Assets and rights that must be reported include the following: (i) bank deposits; (ii) loans; (iii) financing transactions; (iv) leases; (v) direct investments; (vi) portfolio investments, including Shares acquired under the Plan; (vii) financial derivatives investments; and (viii) other investments, such as real estate. Please note that foreign individuals holding Brazilian visas are considered Brazilian residents for purposes of this reporting requirement and must declare at least the assets held abroad that were acquired subsequent to the date of admittance as a resident of Brazil. Individuals holding assets and rights outside of Brazil valued at less than US$1,000,000 are not required to submit a declaration.

Tax on Financial Transactions. Payments to foreign countries, repatriation of funds into Brazil, and the conversion associated with such fund transfers into local currency, may be subject to the Tax on Financial Transactions. It is your responsibility to comply with any applicable Tax on Financial Transactions arising from participation in the Plan and you should consult your personal tax advisor for additional details.

BULGARIA

Exchange Control Information. You will be required to file statistical forms with the Bulgarian National Bank annually regarding your receivables in bank accounts abroad as well as securities held abroad (e.g., Shares acquired under the Plan) if the total sum of all such receivables and securities equals or exceeds a certain threshold as of the previous calendar year-end. The reports are due by

March 31. You should contact your bank in Bulgaria for additional information regarding these requirements.

CANADA

TERMS AND CONDITIONS

Termination of Employment. Section I(i) of the Agreement is amended to read as follows:

(i) "termination of your active employment" shall mean the last date that you are either actually providing services to the Company or an Affiliate or actually providing services as a Director of the Company or an Affiliate; in the event of involuntary termination of your employment (regardless of the reason for such termination and whether or not later found to be invalid or unlawful, including for breaching applicable laws in the jurisdiction where you are employed or the terms of your employment agreement, if any), except as explicitly and minimally required under applicable legislation your right, if any, to earn, seek damages in lieu of, vest in or otherwise benefit from or participate in any portion of the Units or the Plan will be measured by and immediately terminate, as of the termination of your employment (the "Termination Date"). Except as explicitly and minimally required under applicable legislation, the Termination Date will exclude and will not be extended by any period during which notice, pay in lieu of notice or related payments or damages are provided or required to be provided under applicable laws (including, but not limited to, statute, contract, common/civil law or otherwise).You will not earn or be entitled to any pro-rated vesting of the Units or other benefits under or participation in the Plan for that portion of time before the Termination Date, nor will you be entitled to any compensation for lost vesting, benefits, or other participation. Subject to applicable legislation, if the date you are no longer actually providing services cannot be reasonably determined under the terms of this Agreement or the Plan, the Company shall have the exclusive discretion to determine when you are no longer actually providing services for purposes of this Agreement (including whether you may still be considered to be providing services while on a leave of absence). Notwithstanding the foregoing, if applicable employment standards legislation explicitly requires continued vesting or other participation during a statutory notice period, your right to vest in the Units or otherwise participate in or benefit from the Units under the Plan, if any, will terminate effective as of the last day of your minimum statutory notice period, but you will not earn or be entitled to pro-rated vesting or other benefits or participation if the vesting date falls after the end of your statutory notice period, nor will you be entitled to any compensation for lost vesting benefits, or participation;

Acknowledgement of Nature of Plan and Units. Sections XI(c), XI(i) and XI(k) of the Agreement are amended to read as follows:

(c) no Affiliate (including, but not limited to, the Employer) has any obligation to make any payment of any kind to you under this Agreement, except to the extent explicitly and minimally required under applicable legislation;

(i) in consideration of the grant of Units hereunder, no claim or entitlement to compensation or damages arises from termination of Units, and no claim or entitlement to compensation or damages shall arise from forfeiture of the Units resulting from (i) the termination of your employment by the Company or an Affiliate (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are employed or the terms of your employment agreement, if any) and/or (ii) the application of the Clawback Policy as described in Section XVIII below, except to the extent explicitly and minimally required under applicable legislation;

(k) for employment law purposes outside the United States, the Units, Shares subject to the Units, and the income from and value of same, are not part of normal or expected compensation or salary for any purpose, including but not limited to for purposes of calculating any severance, resignation, termination, redundancy, dismissal, end of service payments, bonuses, holiday pay, long-service awards, pension or retirement benefits or similar mandatory payments, except to the extent explicitly and minimally required under applicable legislation;

Form of Settlement – Units Payable Only in Shares. Notwithstanding any discretion in Section 9.5 of the Plan or anything to the contrary in the Agreement, the Units do not provide any right for you, as a resident of Canada, to receive a cash payment and shall be paid in Shares only.

The following provision will apply to you if you are a resident of Quebec:

French Language Documents. A French translation of this document and certain other documents related to this Award will be made available to you as soon as reasonably practicable. You understand that, from time to time, additional information related to the Award may be provided in English and such information may not be immediately available in French. However, upon request, the Company will provide a translation of such information into French as soon as reasonably practicable. Notwithstanding anything to the contrary in the Agreement, and unless you indicate otherwise, the French translation of this document and certain other documents related to the Award will govern your participation in the Plan.

Data Privacy Notice. This provision supplements Section XIV of the Agreement:

You hereby authorize the Company and the Company's representative to discuss with and obtain all relevant information from all personnel (professional or not) involved in the administration of the Plan. You further authorize the Company, your Employer and Merrill Lynch Bank & Trust Co., FSB (or any other stock plan service provider) to disclose and discuss your participation in the Plan with their advisors. You also authorize the Company and your Employer to record such information and keep it in your file.

NOTIFICATIONS

Securities Law Information. You are permitted to sell Shares acquired through the Plan through the designated broker appointed under the Plan, if any, provided that the resale of such Shares takes place outside of Canada through the facilities of a stock exchange on which the Shares are listed (*e.g.*, the Nasdaq Global Select Market).

Foreign Asset/Account Reporting Information. Specified foreign property, including Shares, stock options and other rights to receive Shares (*e.g.*, Units) of a non-Canadian company held by a Canadian resident employee generally must be reported annually on a Form T1135 (Foreign Income Verification Statement) if the total cost of the employee's specified foreign property exceeds a certain threshold (currently C$100,000) at any time during the year. Thus, such stock options and Units must be reported – generally at nil cost – if the applicable cost threshold is exceeded because other specified foreign property is held by the employee. When Shares are acquired, their cost generally is the adjusted cost base ("ACB") of the Shares. The ACB ordinarily would equal the fair market value of the Shares at the time of acquisition, but if the employee owns other shares of the same company, this ACB may have to be averaged with the ACB of the other shares.

CHINA

TERMS AND CONDITIONS

The following terms apply only to individuals who are subject to exchange control restrictions in the People's Republic of China (the "PRC"), as determined by the Company in its sole discretion:

Vesting of the Units. [Notwithstanding anything to the contrary in Section I(d) of the Agreement, if your employment with the Company or an Affiliate terminates due to your Voluntary Termination, as defined in Section I(d), then the vesting of Units granted under this Agreement shall be accelerated to vest as of the day immediately preceding such Voluntary Termination with respect to all Units granted hereunder.]*[5]

Sale Requirement. Notwithstanding anything to the contrary in the Agreement, due to exchange control laws in the PRC, you agree that the Company reserves the right to require the immediate sale of any Shares issued upon settlement of the Units. You understand and agree that any such immediate sale of Shares will occur as soon as is practical following settlement of the Units. Alternatively, if the Shares are not immediately sold upon settlement of the Units, the Company will require the sale of any Shares you may then hold within six (6) months (or such other period as may be required under applicable legal or exchange control requirements) following the termination of your employment with the Company, including its Affiliates.

You agree that the Company is authorized to instruct Merrill Lynch Bank & Trust Co., FSB or such other designated broker as may be selected by the Company to assist with the sale of the

[5] *Paragraph (d) of Section I of the Agreement is not applicable to awards identified by the Administrator as new hire, retention, special or promotion grants and the provisions of such paragraph shall be reserved and references thereto identified by an asterisk (*) shall be omitted from the agreements evidencing such grants.*

Shares on your behalf pursuant to this authorization, and you expressly authorize such broker to complete the sale of such Shares. You also agree to sign any agreements, forms and/or consents that may be reasonably requested by the Company (or the Company's designated broker) to effectuate the sale of the Shares (including, without limitation, as to the transfers of the proceeds and other exchange control matters noted below) and to otherwise cooperate with the Company with respect to such matters, provided that you shall not be permitted to exercise any influence over how, when or whether the sales occur. Upon the sale of the Shares, you will receive the cash proceeds from the sale, less any applicable Tax Obligations, brokerage fees or commissions, in accordance with applicable exchange control laws and regulations.

You acknowledge that Merrill Lynch Bank & Trust Co., FSB or such other designated broker as may be selected by the Company is under no obligation to arrange for the sale of the Shares at any particular price. Due to fluctuations in the Share price and/or applicable exchange rates between the settlement date and (if later) the date on which the Shares are sold, the amount of proceeds ultimately distributed to you may be more or less than the market value of the Shares on the settlement date (which is the amount relevant to determining your liability for Tax Obligations). You understand and agree that the Company is not responsible for the amount of any loss that you may incur and that the Company assumes no liability for any fluctuations in the Share price and/or any applicable exchange rate.

Designated Broker Account. If Shares issued upon the settlement of the Units are not immediately sold, you acknowledge that you are required to maintain the Shares in an account with Merrill Lynch Bank & Trust Co., FSB or such other designated broker as may be selected by the Company until the Shares are sold through such Company-designated broker.

Exchange Control Requirements. You understand and agree that, pursuant to local exchange control requirements, you will be required to repatriate the cash proceeds from the sale of the Shares issued to you upon settlement of the Units and from the receipt of any Dividends or Dividend Equivalents to China. You further understand that, under applicable laws, such repatriation of your cash proceeds will need to be effectuated through a special exchange control account established by the Company or any Affiliate, including your Employer, and you hereby consent and agree that any proceeds may be transferred to such special account prior to being delivered to you. You also understand that the Company will deliver the proceeds to you as soon as possible, but that there may be delays in distributing the funds to you due to exchange control requirements in China. Proceeds may be paid to you in U.S. dollars or local currency at the Company's discretion. If the proceeds are paid to you in U.S. dollars, you will be required to set up a U.S. dollar bank account in China so that the proceeds may be deposited into this account. If the proceeds are paid to you in local currency, the Company is under no obligation to secure any particular currency conversion rate and the Company may face delays in converting the proceeds to local currency due to exchange control restrictions. You further agree to comply with any other requirements that may be imposed by the Company in the future in order to facilitate compliance with exchange control requirements in China.

COLOMBIA
TERMS AND CONDITIONS

Labor Law Acknowledgement. The following provision supplements Section XI of the Agreement:

You acknowledge that pursuant to Article 15 of Law 50/1990 (Article 128 of the Colombian Labor Code), the Plan and related benefits do not constitute a component of "salary" for any purpose. Therefore, they are considered to be of an extraordinary nature and will not be included and/or considered for purposes of calculating any and all labor benefits, such as legal/fringe benefits, vacations, indemnities, payroll taxes, social insurance contributions and/or any other labor-related amounts, subject to the limitations provided in Law 1393/2010.

Mandate Letter. In accepting the Units, you agree that – if requested by the Company or the Employer – you will execute a Mandate Letter or such other document (whether electronically or by such other method as requested by the Company or the Employer) that the Company determines is necessary or advisable in order that (i) a sufficient number of Shares to be allocated to you upon vesting can be sold on your behalf to cover Tax Obligations required to be withheld by the Employer and (ii) the proceeds from such sale can be wired directly from the Company to the Employer in Colombia for remittance to the tax authorities.

NOTIFICATIONS

Securities Law Information. The Shares are not and will not be registered with the Colombian registry of publicly traded securities (*Registro Nacional de Valores y Emisores*) and therefore the Shares may not be offered to the public in Colombia. Nothing in this document should be construed as the making of a public offer of securities in Colombia.

Exchange Control Information. Investment in assets located abroad (such as Shares acquired under the Plan) does not require prior approval from the Central Bank (*Banco de la República*). Nonetheless, such investments are subject to registration before the Central Bank as foreign investments held abroad, regardless of value.

Any payments for your investment originating in Colombia (and the liquidation of such investments) must be transferred through the Colombian foreign exchange market (*e.g.*, local banks), which includes the obligation to correctly complete and file the appropriate foreign exchange form (*declaración de cambio*).

Foreign Asset/Account Reporting Notice. An annual information return may need to be filed with the Colombian Tax Office detailing any assets held abroad (including Shares acquired under the Plan). If the individual value of any of these assets exceeds a certain threshold, each asset must be described (*e.g.*, its nature and its value) and the jurisdiction in which it is located must be disclosed. It is your responsibility to comply with this tax reporting requirement.

CROATIA

NOTIFICATIONS

Exchange Control Information. Croatian residents may be required to report any foreign investments (including Shares acquired under the Plan) to the Croatian National Bank for statistical purposes. You should be aware that exchange control regulations in Croatia are subject to frequent change and you are solely responsible for ensuring your continued compliance with current Croatian exchange control laws.

CZECH REPUBLIC

NOTIFICATIONS

Exchange Control Information. If you are a resident of the Czech Republic, you may be required to notify the Czech National Bank ("CNB") of the acquisition of Shares under the Plan or maintenance of a foreign account if (i) you maintain foreign direct investments with a value of 2,500,000 Kč or more in the aggregate, (ii) you maintain a certain threshold of foreign financial assets, or (iii) you are specifically requested to do so by the CNB.

DENMARK

TERMS AND CONDITIONS

Danish Stock Option Act. In accepting the Units, you acknowledge that you have received an Employer Statement translated into Danish, which is being provided to comply with the Danish Stock Option Act. To the extent more favorable to you and required to comply with the Stock Option Act, as amended with effect from January 1, 2019. You also acknowledge any grant of Units under the Plan made on or after January 1, 2019 is subject to the rules of the amended Act. Accordingly, you agree that the treatment of the Units upon the termination of your employment is governed solely by Section I(i) of the Agreement and any corresponding provisions in the Plan. The relevant termination provisions are also detailed in the Employer Statement.

Please be aware that as set forth in Section 1 of the Act, the Act only applies to "employees" as that term is defined in Section 2 of the Act. If you are a member of the registered management of an Affiliate or Subsidiary in Denmark or otherwise do not satisfy the definition of employee, you will not be subject to the Act, and the Employer Statement will not apply to you.

NOTIFICATIONS

Foreign Asset/Account Reporting Information. The requirement to report certain information to the Danish Tax Administration via Form V or K was eliminated effective January 1, 2019. However, you still must report the foreign bank/brokerage accounts and their deposits, and Shares held in a foreign bank or brokerage account in your tax return under the section on foreign affairs and income.

EGYPT

NOTIFICATIONS

Exchange Control Information. If you transfer funds into Egypt in connection with the Units, you are required to transfer the funds through a registered bank in Egypt.

FINLAND

NOTIFICATIONS

Foreign Asset/Account Reporting Information. There are no specific reporting requirements with respect to foreign assets/accounts. However, please note that you must check your pre-completed tax return to confirm that the ownership of Shares and other securities (foreign or domestic) are correctly reported. If you find any errors or omissions, you must make the necessary corrections electronically or by sending specific paper forms to the local tax authorities.

FRANCE

TERMS AND CONDITIONS

Language Consent. By accepting the grant, you confirm having read and understood the Plan and Agreement which were provided in the English language. You accept the terms of these documents accordingly.

Consentement Relatif à la Langue Utilisée. *En acceptant l'attribution, vous confirmez avoir lu et compris le Plan et le Contrat, qui ont été communiqués en langue anglaise. Vous acceptez les termes de ces documents en connaissance de cause.*

NOTIFICATIONS

Foreign Asset/Account Reporting Information. French residents and non-residents must declare to the Customs Authorities the cash and securities they import or export without the use of a financial institution when the value of such cash or securities exceeds a certain threshold (currently €10,000). French residents also must report all foreign bank and brokerage accounts on an annual basis (including accounts opened or closed during the tax year) on Form N° 3916, together with the income tax return. Failure to comply could trigger significant penalties.

GERMANY

NOTIFICATIONS

Foreign Asset/Account Reporting Information. If your acquisition of Shares under the Plan leads to a qualified participation at any point during the calendar year, you will need to report the acquisition

when you file your tax return for the relevant year. A qualified participation is attained only in the unlikely event (i) you own at least 1% of the Company and the value of the Shares acquired exceeds a certain threshold (currently €150,000) or (ii) you hold Shares exceeding 10% of the Company's total Common Stock.

Exchange Control Information. Cross-border payments in excess of a certain threshold (currently €50,000) must be reported monthly to the German Federal Bank (*Bundesbank*). In case of payments in connection with securities (including proceeds realized upon the sale of Shares or the receipt of Dividends or Dividend Equivalents) and/or if the Company withholds Shares with a value in excess of the applicable threshold for any Tax Obligations, the report must be made monthly following the month in which the payment was received and must be filed electronically. The form of report (*Allgemeines Meldeportal Statistik*) can be accessed via the *Bundesbank's* website (www.bundesbank.de) and is available in both German and English. In addition, you may be required to report the acquisition or sale of Shares to the *Bundesbank* if the value of the Shares acquired or sold exceeds the applicable threshold. You are responsible for satisfying any applicable reporting obligation.

GREECE

NOTIFICATIONS

Foreign Asset/Account Reporting Information. The reporting of foreign assets (including Shares and other investments) is your own obligation and takes place through your annual tax return.

HONG KONG

TERMS AND CONDITIONS

Form of Settlement – Units Payable Only in Shares. Notwithstanding any discretion in Section 9.5 of the Plan or anything to the contrary in the Agreement, the Units do not provide any right for you to receive a cash payment and shall be paid in Shares only.

Sale of Shares. Shares received at vesting are accepted as a personal investment. In the event that Shares are issued in respect of the Units within six (6) months of the Grant Date, you agree that you will not offer to the public or otherwise dispose of the Shares prior to the six (6)-month anniversary of the Grant Date.

NOTIFICATIONS

SECURITIES WARNING: *The contents of this document have not been reviewed by any regulatory authority in Hong Kong. You should exercise caution in relation to the offer. If you are in doubt about any of the contents of the Agreement, including this Appendix, or the Plan, you should obtain independent professional advice. The Units and any Shares issued in respect of the Units do not constitute a public offering of securities under Hong Kong law and are available only to members of the Board and Employees. The Agreement, including this Appendix, the Plan and other incidental communication materials have not been prepared in accordance with and are not*

intended to constitute a "prospectus" for a public offering of securities under the applicable securities legislation in Hong Kong. The Units and any documentation related thereto are intended solely for the personal use of each member of the Board and/or Employee and may not be distributed to any other person.

HUNGARY

There are no country-specific provisions.

ICELAND

NOTIFICATIONS

Exchange Control Information. Approval by the Central Bank of Iceland is no longer required to participate in the Plan, regardless of the value of the Shares acquired under the Plan. Despite the recent relaxation of the exchange control requirements, you should consult with your personal advisor to ensure compliance with applicable exchange control regulations in Iceland as such regulations are subject to frequent change. You are responsible for ensuring compliance with all exchange control laws in Iceland.

INDIA

NOTIFICATIONS

Exchange Control Information. You understand that you must repatriate any cash Dividends paid on Shares acquired under the Plan to India or any Dividend Equivalents paid in cash, as well as any proceeds from the sale of Shares acquired under the Plan within such time as may be required under applicable Indian exchange control laws, which may be amended from time to time, unless an exemption applies. You will receive a foreign inward remittance certificate ("FIRC") from the bank where you deposit the foreign currency, and you must maintain the FIRC as proof of repatriation of funds in the event that the Reserve Bank of India or your Employer requests proof of repatriation. It is your responsibility to comply with these requirements. Neither the Company nor the Employer will be liable for any fines or penalties resulting from your failure to comply with any applicable laws. You may be required to provide information regarding funds received from participation in the Plan to the Company and/or the Employer to enable them to comply with their filing requirements under exchange control laws in India.

Foreign Asset/Account Reporting Information. You are required to declare foreign bank accounts and any foreign financial assets (including Shares held outside of India) in your annual tax return. It is your responsibility to comply with this reporting obligation, and you should consult your personal tax advisor in this regard.

IRELAND

TERMS AND CONDITIONS

Acknowledgement of Nature of Plan and Units. This provision supplements Section XI of the Agreement:

In accepting this Agreement, you understand and agree that the benefits received under the Plan will not be taken into account for any redundancy or unfair dismissal claim.

ITALY

TERMS AND CONDITIONS

Acknowledgement of Nature of Agreement. In accepting this Agreement, you acknowledge that (1) you have received a copy of the Plan, the Agreement and this Appendix; (2) you have reviewed the applicable documents in their entirety and fully understand the contents thereof; and (3) you accept all provisions of the Plan, the Agreement and this Appendix.

For any Units granted, you further acknowledge that you have read and specifically and explicitly approve, without limitation, the following sections of the Agreement: Section I; Section II; Section III; Section VIII; Section X; Section XI; Section XVI; Section XVII; and the Data Privacy Notice for All European Economic Area ("EEA") / European Union ("EU") Jurisdictions, United Kingdom and Switzerland in this Appendix.

NOTIFICATIONS

Foreign Asset/Account Reporting Information. Italian residents who, at any time during the fiscal year, hold foreign financial assets (including cash and Shares) which may generate income taxable in Italy are required to report these assets on their annual tax returns (UNICO Form, RW Schedule) for the year during which the assets are held, or on a special form if no tax return is due. These reporting obligations will also apply to Italian residents who are the beneficial owners of foreign financial assets under Italian money laundering provisions.

Foreign Financial Assets Tax. The fair market value of any Shares held outside of Italy is subject to a foreign assets tax at a flat rate. The fair market value is considered to be the value of the Shares on the Nasdaq Global Select Market on December 31 of the applicable year in which you held the Shares (or when the Shares are acquired during the course of the year, the tax is levied in proportion to the actual days of holding over the calendar year). No tax payment duties arise if the amount of the foreign financial assets tax calculated on all financial assets held abroad does not exceed a certain threshold. You should consult with your personal tax advisor about the foreign financial assets tax.

JAPAN

NOTIFICATIONS

Foreign Asset/Account Reporting Information. You will be required to report to the Japanese tax authorities details of any assets held outside of Japan as of December 31st (including any

Shares acquired under the Plan) to the extent such assets have a total net fair market value exceeding a certain threshold (currently ¥50,000,000). Such report will be due by June 30 each year. You should consult with your personal tax advisor as to whether the reporting obligation applies to you and whether you will be required to include in the report details of any Shares or cash that you hold.

KOREA

NOTIFICATIONS

Exchange Control Information. Korean residents who sell Shares acquired under the Plan and/or receive cash Dividends on the Shares must file a report with a Korean foreign exchange bank if the proceeds exceed a certain threshold (currently US$5,000 per transaction) and are deposited into a non- Korean bank account. The report is not required if proceeds are deposited into a non-Korean brokerage account. It is your responsibility to ensure compliance with any applicable exchange control reporting obligations.

Foreign Asset/Account Reporting Information. You are required to declare all foreign financial accounts (*e.g.* non-Korean bank accounts, brokerage accounts holding Shares, etc.) to the Korean tax authority and file a report regarding such accounts if the monthly balance of such accounts exceeds a certain threshold. It is your responsibility to comply with this reporting obligation, and you should consult your personal tax advisor to ensure compliance with this requirement.

LITHUANIA

NOTIFICATIONS

Foreign Asset/Account Reporting Information. If you (i) hold certain job positions established by the law or (ii) donate to political parties or political campaigners, you must file an Annual Asset Return of the Individual (Family) in Form No. FR0001 with respect to assets held outside of Lithuania (*e.g.*, Shares). If you open an account in a foreign financial institution and annual turnover in the account exceeds a certain threshold (currently €15,000), you must file a foreign account report.

MEXICO

TERMS AND CONDITIONS

Acknowledgement of the Agreement. In accepting the Award granted hereunder, you acknowledge that you have received a copy of the Plan, have reviewed the Plan and the Agreement, including this Appendix, in their entirety and fully understand and accept all provisions of the Plan and the Agreement, including this Appendix. You further acknowledge that you have read and specifically and expressly approve the terms and conditions of Section XI of the Agreement, in which the following is clearly described and established:

(1) Your participation in the Plan does not constitute an acquired right.

(2) The Plan and your participation in the Plan are offered by Amgen Inc. on a wholly discretionary basis.

(3) Your participation in the Plan is voluntary.

(4) Amgen Inc. and its Affiliates are not responsible for any decrease in the value of the Units granted and/or Shares issued under the Plan.

Labor Law Acknowledgement and Policy Statement. In accepting any Award granted hereunder, you expressly recognize that Amgen Inc., with registered offices at One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., is solely responsible for the administration of the Plan and that your participation in the Plan and acquisition of Shares do not constitute an employment relationship between you and Amgen Inc. since you are participating in the Plan on a wholly commercial basis and your sole employer is Amgen Mexico S.A. de C.V. ("Amgen-Mexico"). Based on the foregoing, you expressly recognize that the Plan and the benefits that you may derive from participation in the Plan do not establish any rights between you and your Employer, Amgen-Mexico, and do not form part of the employment conditions and/or benefits provided by Amgen-Mexico and any modification of the Plan or its termination shall not constitute a change or impairment of the terms and conditions of your employment.

You further understand that your participation in the Plan is as a result of a unilateral and discretionary decision of Amgen Inc.; therefore, Amgen Inc. reserves the absolute right to amend and/or discontinue your participation in the Plan at any time without any liability to you.

Finally, you hereby declare that you do not reserve to yourself any action or right to bring any claim against Amgen Inc. for any compensation or damages regarding any provision of the Plan or the benefits derived under the Plan, and you therefore grant a full and broad release to Amgen Inc., its Affiliates, stockholders, officers, agents or legal representatives with respect to any claim that may arise.

Spanish Translation

Reconocimiento del Otorgamiento. Al aceptar cualquier Otorgamiento bajo el presente documento, usted reconoce que ha recibido una copia del Plan, que ha revisado el mismo en su totalidad, así como también el Acuerdo de Opción, el Acuerdo, incluyendo este Apéndice, además que comprende y está de acuerdo con todas las disposiciones tanto del Plan y del Otorgamiento, incluyendo este Apéndice. Asimismo, usted reconoce que ha leído y manifiesta específicamente y expresamente la conformidad con los términos y condiciones establecidos en la Sección XI del Acuerdo, en los que se establece y describe claramente que:

(1) Su participación en el Plan de ninguna manera constituye un derecho adquirido.

(2) El Plan y su participación en el mismo son ofrecidos por Amgen Inc. de forma completamente discrecional.

(3) Su participación en el Plan es voluntaria.

(4) Amgen Inc. y sus Afiliados no son responsables de ninguna disminución en el valor de Unidades o de las Acciones Comunes emitidas mediante el Plan.

Reconocimiento de la Ley Laboral y Declaración de Política. Al aceptar cualquier Otorgamiento de Acciones bajo el presente, usted reconoce expresamente que Amgen Inc., con oficinas registradas localizadas en One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., es la única responsable de la administración del Plan y que su participación en el mismo y la adquisición de Acciones Comunes no constituyen de ninguna manera una relación laboral entre usted y Amgen Inc., debido a que su participación en el Plan es únicamente una relación comercial y que su único empleador es Amgen Mexico S.A. de C.V. ("Amgen-México"). Derivado de lo anterior, usted reconoce expresamente que el Plan y los beneficios a su favor que pudieran derivar de la participación en el mismo, no establecen ningún derecho entre usted y su empleador, Amgen – México, y no forman parte de las condiciones laborales y/o los beneficios otorgados por Amgen – México, y cualquier modificación del Plan o la terminación del mismo no constituirá un cambio o desmejora de los términos y condiciones de su trabajo.

Asimismo, usted entiende que su participación en el Plan es resultado de la decisión unilateral y discrecional de Amgen Inc., por lo tanto, Amgen Inc. se reserva el derecho absoluto de modificar y/o descontinuar su participación en el Plan en cualquier momento y sin ninguna responsabilidad para usted.

Finalmente, usted manifiesta que no se reserva ninguna acción o derecho que origine una demanda en contra de Amgen Inc., por cualquier compensación o daños y perjuicios, en relación con cualquier disposición del Plan o de los beneficios derivados del mismo, y en consecuencia usted exime amplia y completamente a Amgen Inc. de toda responsabilidad, como así también a sus Afiliadas, accionistas, directores, agentes o representantes legales con respecto a cualquier demanda que pudiera surgir.

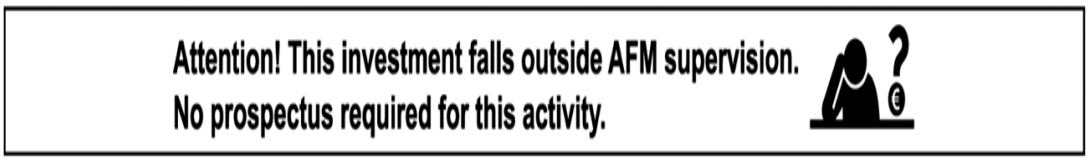
NOTIFICATIONS

Securities Law Information. The Units and the Shares offered under the Plan have not been registered with the National Register of Securities maintained by the Mexican National Banking and Securities Commission and cannot be offered or sold publicly in Mexico. In addition, the Plan, the Agreement and any other document relating to the Units may not be publicly distributed in Mexico. These materials are addressed to you only because of your existing relationship with the Company and your Employer and these materials should not be reproduced or copied in any form. The offer contained in these materials does not constitute a public offering of securities but rather constitutes a private placement of securities addressed specifically to individuals who are present employees of Amgen-Mexico made in accordance with the provisions of the Mexican Securities Market Law, and any rights under such offering shall not be assigned or transferred.

NETHERLANDS

NOTIFICATIONS

Securities Law Information.



NORWAY

NOTIFICATIONS

Foreign Asset/Account Reporting Information. Norwegian residents may be subject to foreign asset reporting as part of their ordinary tax return. Norwegian banks, financial institutions, limited companies etc. must report certain information to the Tax Administration. Such information may then be pre-completed in a Norwegian resident's tax return. However, if the resident has traded, or is the owner of, financial instruments (*e.g.*, Shares) not pre-completed in the tax return, the Norwegian resident must enter this information in Form RF-1159, which is an appendix to the tax return.

Exchange Control Information. In general, Norwegian residents should not be subject to any foreign exchange requirements in connection with their acquisition or sale of Shares under the Plan, except normal reporting requirements to the Norwegian Currency Registry. If any transfer of funds into or out of Norway is made through a Norwegian bank, the bank will make the registration.

POLAND

NOTIFICATIONS

Foreign Asset/Account Reporting Information. Polish residents holding foreign securities (including Shares) and maintaining accounts abroad must file reports with the National Bank of Poland if the aggregate value of cash and securities held in such foreign accounts exceeds a certain threshold (currently PLN 7 million). If required, the reports are due on a quarterly basis by the 20th day following the end of each quarter and must be filed on special forms available on the website of the National Bank of Poland.

Exchange Control Information. In addition, Polish residents are required to transfer funds through a bank account in Poland if the transferred amount in any single transaction exceeds a specified threshold (currently €15,000 (or PLN 15,000 if such transfer of funds is associated with the business activity of a consultant)). You must store all documents connected with any foreign exchange transactions you

engage in for a period of five (5) years from the end of the year when such transactions were made. Penalties may apply for failure to comply with exchange control requirements.

PORTUGAL

TERMS AND CONDITIONS

Consent to Receive Information in English. You hereby expressly declare that you have full knowledge of the English language and have read, understood and fully accepted and agreed with the terms and conditions established in the Plan and Agreement.

Conhecimento da Lingua. *Por meio do presente, eu declaro expressamente que tem pleno conhecimento da língua inglesa e que li, compreendi e livremente aceitei e concordei com os termos e condições estabelecidas no Plano e no Acordo.*

PUERTO RICO

There are no country-specific provisions.

ROMANIA

NOTIFICATIONS

Exchange Control Information. Certain transfers of funds may need to be reported to the National Office for Prevention and Control of Money Laundering on specific forms by the relevant bank or financial institution. If you deposit proceeds from the sale of Shares or the receipt of Dividends or Dividend Equivalents in a bank account in Romania, you may be required to provide the Romanian bank assisting with the transaction with appropriate documentation explaining the source of the income. You should consult with a legal advisor to determine whether you will be required to submit such documentation to the Romanian bank.

RUSSIA

NOTIFICATIONS

Foreign Account Report Information. Russian residents maintaining accounts abroad must disclose such accounts with the Russian tax authorities, as follows: (i) file notifications upon opening (or closing or changing bank details) within 30 days, and (ii) file reports on the movement of cash or financial assets on such accounts by June 1 of the following year. Such notifications and reports must be filed on

special forms available on the website of the Russian tax authorities. Russian residents who are absent from Russia for more than 183 days in a year may be relieved from this reporting.

TERMS AND CONDITIONS

Securities Law Information. The sale of Shares acquired under the Plan is not permitted within Russia. The Shares are currently traded on the Nasdaq Global Select Market in the U.S. under the ticker symbol "AMGN," therefore, the Shares may be sold on this exchange. You understand that the exchange control rules and regulations in Russia, legal restrictions impacting your participation in the Plan, are subject to frequent change. You should consult with your personal legal advisor to determine the applicability of any requirements or restrictions applicable to any Shares or cash received in connection with the Plan."

You understand that the exchange control rules and regulations in Russia and the legal restrictions impacting your participation in the Plan are subject to frequent change. You should consult with your personal legal advisor to determine the applicability of any requirements or restrictions applicable to any Shares or cash received in connection with the Plan.

SINGAPORE

TERMS AND CONDITIONS

Restriction on Sale and Transferability. You hereby agree that any Shares acquired pursuant to the Units will not be offered for sale in Singapore prior to the six (6)-month anniversary of the Grant Date, unless such sale or offer is made pursuant to one or more exemptions under Part XIII Division 1 Subdivision (4) (other than section 280) of the Securities and Futures Act (Chap. 289, 2006 Ed.) ("SFA"), or pursuant to, and in accordance with the conditions of, any other applicable provisions of the SFA.

NOTIFICATIONS

Securities Law Information. The grant of the Units is being made pursuant to the "Qualifying Person" exemption under section 273(1)(f) of the SFA, on which basis it is exempt from the prospectus and registration requirements under the SFA, and is not made with a view to the Units being subsequently offered for sale to any other party. The Plan has not been, and will not be, lodged or registered as a prospectus with the Monetary Authority of Singapore.

Director Notification Requirement. Directors (including alternate, substitute, associate and shadow directors) of a Singapore Affiliate are subject to certain notification requirements under the Singapore Companies Act, regardless of whether they are resident or employed in Singapore. Directors of a Singapore Affiliate must notify the Singapore Affiliate in writing of an interest (*e.g.*, Units, Shares, etc.) in the Company or any related company within two (2) business days of (i) its acquisition or disposal, (ii) any change in a previously disclosed interest (*e.g.,* when the Shares are sold), or (iii) becoming a director.

SLOVAK REPUBLIC

There are no country-specific provisions.

SLOVENIA

NOTIFICATIONS

Foreign Asset/Account Reporting Information. Slovenian residents may be required to report the opening of bank and/or brokerage accounts to tax authorities within eight (8) days of opening such account. You should consult with your personal tax advisor to determine whether this requirement will be applicable to any accounts opened in connection with your participation in the Plan (*e.g.*, your brokerage account with the Company's designated broker).

SPAIN

TERMS AND CONDITIONS

Labor Law Acknowledgement. The following provision supplements Section XI of the Agreement:
By accepting the Units granted hereunder, you consent to participation in the Plan and acknowledge that you have received a copy of the Plan.

You understand that the Company has unilaterally, gratuitously and in its sole discretion decided to grant any Units under the Plan to individuals who may be members of the Board or Employees of the Company or its Affiliates throughout the world. The decision is a limited decision, which is entered into upon the express assumption and condition that (i) any Units granted will not economically or otherwise bind the Company or any of its Affiliates on an ongoing basis, other than as expressly set forth in the Agreement, including this Appendix; (ii) the Units granted hereunder and any Shares acquired under the Plan shall not become a part of any employment contract (either with the Company or any of its Affiliates) and shall not be considered a mandatory benefit, salary for any purposes (including severance compensation) or any other right whatsoever; and (iii) any unvested Units will be forfeited immediately upon termination of your employment for any reason, as detailed below. Further, you understand and freely accept that there is no guarantee that any benefit whatsoever shall arise from any gratuitous and discretionary grant of Units since the future value of the Units and the underlying Shares is unknown and unpredictable. In addition, you understand that any Units granted hereunder would not be made but for the assumptions and conditions referred to above; thus, you understand, acknowledge and freely accept that, should any or all of the assumptions be mistaken or should any of the conditions not be met for any reason, then any grant of Units or right to Units shall be null and void.

Further, the vesting of the Units is expressly conditioned on your continued and active rendering of service, such that if your employment terminates for any reason whatsoever, the Units may

cease vesting immediately, in whole or in part, effective on the date of your termination of employment (unless otherwise specifically provided in Section I of the Agreement). This will be the case, for example, even if (1) you are considered to be unfairly dismissed without good cause (*i.e.*, subject to a "despido improcedente"); (2) you are dismissed for disciplinary or objective reasons or due to a collective dismissal; (3) you terminate service due to a change of work location, duties or any other employment or contractual condition; (4) you terminate service due to a unilateral breach of contract by the Company or an Affiliate; or (5) your employment terminates for any other reason whatsoever. Consequently, upon termination of your employment for any of the above reasons, you may automatically lose any rights to Units that were not vested on the date of your termination of employment, as described in the Plan and the Agreement.

You acknowledge that you have read and specifically accept the conditions referred to in Section I of the Agreement.

NOTIFICATIONS

Securities Law Information. No "offer of securities to the public," as defined under Spanish law, has taken place or will take place in the Spanish territory. The Agreement (including this Appendix) has not been nor will it be registered with the *Comisión Nacional del Mercado de Valores*, and does not constitute a public offering prospectus.

Exchange Control Information. You will be required to declare electronically to the Bank of Spain any security accounts (including brokerage accounts held abroad), as well as the securities (including Shares acquired under the Plan) held in such accounts if the value of the transactions for all such accounts during the prior year or the balances of such accounts as of December 31 of the prior year exceeds a certain threshold (currently €1,000,000). Different thresholds and deadlines to file this declaration apply. However, if neither such transactions during the immediately preceding year nor the balances / positions as of December 31 exceed the applicable threshold, no such declaration must be filed unless expressly required by the Bank of Spain. If any of such thresholds were exceeded during the current year, you may be required to file the relevant declaration corresponding to the prior year, however, a summarized form of declaration may be available.

Foreign Asset/Account Reporting Information. To the extent that you hold Shares and/or have bank accounts outside of Spain with a value in excess of €50,000 (for each type of asset) as of December 31 each year, you will be required to report information on such assets in your tax return (tax form 720) for such year. After such Shares and/or accounts are initially reported, the reporting obligation will apply for subsequent years only if the value of any previously-reported Shares or accounts increases by more than €20,000 (for each type of asset) as of each subsequent December 31, or if you sell or otherwise dispose of previously-reported Shares or accounts. If the value of such Shares and/or accounts as of December 31 does not exceed €50,000, a summarized form of declaration may be presented.

SWEDEN

TERMS AND CONDITIONS

Authorization to Withhold. This provision supplements Section III of the Agreement:

Without limiting the Company's and the Employer's authority to satisfy their withholding obligations for Tax Obligations as set forth in the Agreement, in accepting the Units, you authorize the Company to withhold Shares or to sell Shares otherwise issuable to you upon vesting or settlement to satisfy Tax Obligations, regardless of whether the Company and/or Employer have an obligation to withhold such Tax Obligations, provided that such withholding would not, in the Company's determination, result in adverse accounting consequences to the Company.

SWITZERLAND

NOTIFICATIONS

Securities Law Information. Neither this document nor any other materials relating to the Awards (i) constitutes a prospectus according to articles 35 et seq. of the Swiss Federal Act on Financial Services ("FinSA"), (ii) may be publicly distributed or otherwise made publicly available in Switzerland to any person other than an employee of the Company or one of its Subsidiaries or (iii) has been or will be filed with, approved or supervised by any Swiss reviewing body according to article 51 of FinSA or any Swiss regulatory authority, including the Swiss Financial Market Supervisory Authority.

TAIWAN

NOTIFICATIONS

Securities Law Information. Participation in the Plan is available only for select Board members and Employees of the Company and its Affiliates. The grant of Units and participation in the Plan is not a public offer of securities by a Taiwanese company.

Exchange Control Information. You may acquire and remit foreign currency (including proceeds from the sale of Shares or the receipt of Dividends or Dividend Equivalents) up to US$10,000,000 per year without justification. If the transaction amount is TWD500,000 or more in a single transaction, you must submit a Foreign Exchange Transaction Form. If the transaction amount is US$500,000 or more in a single transaction, you must also provide supporting documentation to the satisfaction of the remitting bank.

THAILAND

NOTIFICATIONS

Exchange Control Information. If proceeds from the sale of Shares or the receipt of any Dividends or Dividend Equivalents exceed a certain threshold (currently US$1,000,000), you must (i) immediately repatriate such funds to Thailand and (ii) report the inward remittance to the Bank of Thailand on a Foreign Exchange Transaction Form. In addition, within three hundred and sixty (360) days of repatriation, you must either convert any funds repatriated to Thailand to Thai Baht or deposit the funds in a foreign exchange account with a Thai commercial bank. Any such commercial bank must be duly authorized by the Bank of Thailand to engage in the purchase, exchange and withdrawal of foreign currency. The Employee is responsible for ensuring compliance with all exchange control laws in Thailand.

TÜRKIYE

NOTIFICATIONS

Securities Law Information. The sale of Shares acquired under the Plan is not permitted within Türkiye. The sale of Shares acquired under the Plan must occur outside of Türkiye. The Shares are currently traded on the Nasdaq Global Select Market in the U.S. under the ticker symbol "AMGN" and Shares may be sold on this exchange.

Exchange Control Information. You may be required to engage a Turkish financial intermediary to assist with the sale of Shares acquired under the Plan. To the extent a Turkish financial intermediary is required in connection with the sale of any Shares acquired under the Plan, you are solely responsible for engaging such Turkish financial intermediary. You should consult your personal legal advisor prior to the sale of Shares to ensure compliance with the current requirements.

UNITED ARAB EMIRATES

NOTIFICATIONS

Securities Law Information. Units under the Plan are granted only to select Board members and Employees of the Company and its Affiliates and are for the purpose of providing equity incentives. The Plan and the Agreement are intended for distribution only to such Board members and Employees and must not be delivered to, or relied on by, any other person. You should conduct your own due diligence on the Units offered pursuant to this Agreement. If you do not understand the contents of the Plan and/or the Agreement, you should consult an authorized financial adviser. The Emirates Securities and Commodities Authority and the Dubai Financial Services Authority have no responsibility for reviewing or verifying any documents in connection with the Plan. Further, the Ministry of the Economy and the Dubai Department of Economic Development have not approved the Plan or the Agreement nor taken steps to verify the information set out therein, and have no responsibility for such documents.

UNITED KINGDOM

TERMS AND CONDITIONS

Tax Withholding. This provision supplements Section III of the Agreement:

Without limitation to Section III of the Agreement, you agree that you are liable for all Tax Obligations and hereby covenant to pay all such Tax Obligations as and when requested by the Company or your Employer or by HM Revenue and Customs ("HMRC") (or any other tax authority or any other relevant authority). You also agree to indemnify and keep indemnified the Company and your Employer against any taxes that they are required to pay or withhold or have paid or will pay to HMRC (or any other tax authority or any other relevant authority) on your behalf.

Notwithstanding the foregoing, if you are an executive officer or director (as within the meaning of Section 13(k) of the Exchange Act, as amended from time to time), you understand that you may not be able to indemnify the Company or your Employer for the amount of income tax not collected from or paid by you, as it may be considered a loan. In the event that you are an executive officer or director and income tax is not collected from you within ninety (90) days after the end of the tax year in which the Taxable Event occurs, the amount of any uncollected income tax may constitute an additional benefit to you on which additional income tax and national insurance contributions ("NICs") may be payable. You acknowledge that you are responsible for reporting and paying any income tax due on this additional benefit directly to HMRC under the self-assessment regime and for paying your Employer for the amount of any NICs due on this additional benefit, which the Company or your Employer may obtain from you by any of the means set forth in Section III of the Agreement.

If the maximum applicable withholding rate is used, any over-withheld amount may be credited to you by the Company or your Employer (with no entitlement to the Common Stock equivalent) or if not so credited, you may seek a refund from the local tax authorities.

Joint Election. If you are a resident of the United Kingdom between the Grant Date and the vesting of the Units, as a condition of the Units granted hereunder, you agree to accept any liability for secondary Class 1 National Insurance Contributions (the "Employer NICs"), which may be payable by the Company or your Employer with respect to the Units and/or payment of the Units and issuance of Shares pursuant to the Units, the assignment or release of the Units for consideration, or the receipt of any other benefit in connection with the Units.

Without limitation to the foregoing, you agree to make an election (the "Election"), in the form specified and/or approved for such election by HMRC, that the liability for your Employer NICs payments on any such gains shall be transferred to you to the fullest extent permitted by law. You further agree to execute such other elections as may be required between you and any successor to the Company and/or your Employer. You hereby authorize the Company and your Employer to withhold such Employer NICs by any of the means set forth in Section III of the Agreement.

Failure by you to enter into an Election, withdrawal of approval of the Election by HMRC or a joint revocation of the Election by you and the Company or your Employer, as applicable, shall be grounds for the forfeiture and cancellation of the Units, without any liability to the Company or your Employer.

UNITED STATES

TERMS AND CONDITIONS

Termination of Employment. The following provision replaces Section I(i) of the Agreement:

(i) "termination of your active employment" shall mean the last date that you are either an active employee of the Company or an Affiliate or actively engaged as a Director of the Company or an Affiliate; in the event of termination of your employment (whether or not in breach of local labor laws), your right to receive Units and vest under the Plan, if any, will terminate effective as of the date that you are no longer actively employed; provided, however, that such right will be extended by any notice period mandated by law (*e.g.*, the Worker Adjustment and Retraining Notification Act ("WARN Act") notice period or similar periods pursuant to local law) and any paid administrative leave (as applicable), unless the Company shall provide you with written notice otherwise before the commencement of such notice period or leave; *provided further*, that notwithstanding the effect of any such extension, in no event will the Units be paid later than the 90th day following your termination of employment;

Form of Award Notice

[*The information set forth in this Award Notice will be contained on the related pages on Merrill Lynch Benefits Website (or the website of any successor company to Merrill Lynch Bank & Trust Co., FSB). This Award Notice shall be replaced by the equivalent pages on such website. References to Award Notice in this Agreement shall then refer to the equivalent pages on such website.*]

This notice of Award (the "Award Notice") sets forth certain details relating to the grant by the Company to you of the Award identified below, pursuant to the Plan. The terms of this Award Notice are incorporated into the Performance Unit Agreement (the "Agreement") that accompanies this Award Notice and made part of the Agreement. Capitalized terms used in this Award Notice that are not otherwise defined in this Award Notice have the meanings given to such terms in the Agreement.

Employee:
Employee ID:
Address:
Award Type:
Grant ID:
Plan: Amgen Inc. Second Amended and Restated 2009 Equity Incentive Plan, as amended and/or restated from time to time
Program Amgen Inc. 2009 Performance Award Program, as amended and/or restated from time to time
Grant Date:
Number of Shares:
Number of Performance Units:
Performance Period: The Performance Period beginning on and ending on .
Resolutions: The Resolutions of the Compensation and Management Development Committee of the Board of Directors of Amgen Inc. establishing the performance goals and Performance Period applicable to this Award.
Vesting Date: Means the vesting date indicated in the Vesting Schedule
Vesting Schedule: Means the schedule of vesting set forth under Vesting Details
Vesting Details: Means the presentation (tabular or otherwise) of the Vesting Date and the quantity of Shares vesting.

IMPORTANT NOTICE REGARDING ACCEPTANCE OF THE AWARD AND THE REQUIREMENT TO OPEN A BROKERAGE ACCOUNT [1]**:**

[1] *This provision is only for use on the form of grant used for the U.S. and Puerto Rico.*

***RESIDENTS OF THE U.S. AND PUERTO RICO*:** Please read this Award Notice, the Plan and the Agreement (collectively, the "Grant Documents") carefully. If you, as a resident of the U.S. or Puerto Rico, do **not** wish to receive this Award and/or you do **not** consent and agree to the terms and conditions on which this Award is offered, as set forth in the Grant Documents, then you must reject the Award by contacting the Merrill Lynch call center at +1 (800) 97AMGEN (+1 (800) 972-6436) within the U.S., Puerto Rico and Canada or +1 (609) 818-8910 from all other countries (Merrill Lynch will accept the charges for your call) no later than the forty-fifth calendar day following the day on which this Award Notice is made available to you, in which case the Award will be cancelled. For the purpose of determining the forty-five calendar days, Day 1 will be the day **immediately** following the day on which this Award Notice is made available to you. Your failure to notify the Company of your rejection of the Award or your refusal of, or disagreement with, all terms and conditions of the Award, as set forth in the Grant Documents, within this specified period will constitute your acceptance of the Award and your agreement with all terms and conditions of the Award, as set forth in the Grant Documents. If you agree to the terms and conditions of your grant and you desire to accept it, then no further action is needed on your part to accept the grant. However, you must still open a brokerage account as directed by the Company, by 1:00 pm Pacific Time on or before the date that is 11 months after the Grant Date specified in this Award Notice. This step is necessary to process transactions related to your equity grant. **If you do not open a brokerage account by this deadline, your grant will be cancelled**.

PERFORMANCE UNIT AGREEMENT

THE SPECIFIC TERMS OF YOUR GRANT OF PERFORMANCE UNITS ARE FOUND IN THE PAGES RELATING TO THE GRANT OF PERFORMANCE UNITS FOUND ON MERRILL LYNCH BENEFITS WEBSITE (OR THE WEBSITE OF ANY SUCCESSOR COMPANY TO MERRILL LYNCH BANK & TRUST CO., FSB) (THE "AWARD NOTICE") WHICH ACCOMPANIES THIS DOCUMENT. THE TERMS OF THE AWARD NOTICE ARE INCORPORATED INTO THIS PERFORMANCE UNIT AGREEMENT.

On the Grant Date specified in the Award Notice, Amgen Inc., a Delaware corporation (the "Company"), has granted to you, the grantee named in the Award Notice, an award under the Amgen Inc. Second Amended and Restated 2009 Equity Incentive Plan, as amended and/or restated from time to time (the "Plan"), for the Number of Performance Units (the "Performance Units") specified in the Award Notice on the terms and conditions set forth in this Performance Unit Agreement, the Award Notice (and any applicable additional terms and conditions for your country set forth in the attached Appendix A (as described in greater detail in Section XIV below)) (collectively, this "Agreement"), the Plan, the Amgen Inc. 2009 Performance Award Program, as amended and/or restated from time to time (the "Program") and the Resolutions (as defined in the Award Notice). Capitalized terms not defined herein shall have the meanings assigned to such terms in the Program.

I. Performance Period. The Performance Period shall have the meaning set forth in the Award Notice.

II. Value of Performance Units. The value of each Performance Unit is equal to a share of Common Stock.

III. Performance Goals. An amount of the Performance Units up to the maximum amount specified in the Resolutions shall be earned, depending on the extent to which the Company achieves the performance goals established by the Committee pursuant to the Resolutions. The Performance Units earned shall be calculated in accordance with the Resolutions and the Program.

IV. Form and Timing of Settlement.

(a) *General*. Subject to Section XIII and the satisfaction of applicable Tax Obligations and similar obligations as provided in Section V, and except as set forth in the Program, any Performance Units earned pursuant to Section III above shall be settled by the Company delivering to you a number of Shares equal to the number of Shares covered by the earned Performance Units or in a lump sum in cash with a value equal to the Fair Market Value of the number of Shares subject to the earned Performance Units as of the last day of the Performance Period (without interest thereon), or in a combination of Shares and cash, as determined by the Administrator at any time prior to settlement and in its discretion, as soon as practicable, and in any event within 90 days, after the last day of the Performance Period. Shares issued in respect of a Performance Unit shall be deemed to be issued in consideration of past services actually rendered by you to the Company or an Affiliate or for its benefit for which you have not

previously been compensated or for future services to be rendered, as the case may be, which the Company deems to have a value at least equal to the aggregate par value thereof.

(b) *Voluntary Retirement*. In the event that your employment with the Company or an Affiliate is terminated prior to the last business day of the Performance Period by reason of your Voluntary Retirement and you are Retirement-Eligible on the date of such termination, the full or prorated amount of your Award, if any, applicable to the Performance Period shall be paid in accordance with paragraph (a) of this Section IV. For purposes of the foregoing, the amount of your Award (rounded down to the nearest whole number) shall be determined based on the Company's performance as compared to the Performance Goals for the Performance Period and (i) if the Award was granted with respect to a Performance Period commencing in a calendar year prior to the calendar year in which your Voluntary Retirement occurs, the full amount of the Award is payable, and (ii) if the Award was granted with respect to the Performance Period commencing in the calendar year in which your Voluntary Retirement occurs, the Award otherwise payable is multiplied by a fraction (rounded to two decimal places), the numerator of which is the number of complete months you remained continuously and actively employed by the Company or an Affiliate during the calendar year in which your termination occurs, and the denominator of which is twelve (12). Notwithstanding the foregoing, you shall not be entitled to such full or prorated amount of your Award pursuant to this paragraph (b) unless either you execute and do not revoke a general release and waiver in a form provided by the Company (for the purpose of resolving any potential or actual disputes arising from your employment and the termination of your employment with the Company) (a "Release") and deliver it to the Company no later than the date specified by the Company, or the Company waives such release requirement in writing; *provided*, *however*, that in no event shall payment of such full or prorated amount of your Award be made later than the specified payment date as set forth in paragraph (a) of this Section IV. This paragraph (b) shall supersede Section 7.1(a) of the Program.

(c) *Death and Disability*. In the event that your employment with the Company or an Affiliate is terminated prior to the last business day of the Performance Period by reason of your death or Permanent and Total Disability, the full or prorated amount of your Award, if any, applicable to such Performance Period shall be paid in accordance with the provisions of paragraph (a) of this Section IV. For purposes of the foregoing, the amount of your Award (rounded down to the nearest whole number) shall be determined based on the Company's performance as compared to the Performance Goals for the Performance Period and (i) if the Award was granted with respect to a Performance Period commencing in a calendar year prior to the calendar year in which such termination occurs, the full amount of the Award is payable, and (ii) if the Award was granted with respect to the Performance Period commencing in the calendar year in which such termination occurs, the portion of the Award payable is determined by multiplying the full amount of the Award by a fraction (rounded to two decimal places), the numerator of which is the number of complete months you remained continuously and actively employed by the Company or an Affiliate during the calendar year in which your termination occurs, and the denominator of which is twelve (12). Notwithstanding the foregoing, if your employment is terminated due to your Permanent and Total

Disability, you shall not be entitled to such full or prorated amount of your Award pursuant to this paragraph (c) unless either you execute and do not revoke a Release and deliver it to the Company no later than the date specified by the Company, or the Company waives such release requirement in writing; *provided*, *however*, that in no event shall payment of such full or prorated amount of your Award be made later than the specified payment date as set forth in paragraph (a) of this Section IV. This paragraph (c) shall supersede Section 7.1(b) of the Program.

(d) *Other*. In the event that your employment with the Company or an Affiliate is terminated prior to the last business day of the Performance Period for any reason other than as specified in paragraphs (b) and (c) above, all of your rights to an Award for the Performance Period shall be forfeited, unless, prior to the payment date set forth in paragraph (a) of this Section IV, the Company, in its sole discretion, makes a written determination to otherwise pay the full or prorated amount of your Award, if any, applicable to the Performance Period, which full or prorated amount shall be paid in accordance with the provisions of paragraph (a) of this Section IV. For purposes of the foregoing, if the payment of your Award is prorated, the amount of your Award (rounded down to the nearest whole number) shall be determined based on the Company's performance as compared to the Performance Goals for the Performance Period and (i) if the Award was granted with respect to a Performance Period commencing in a calendar year prior to the calendar year in which such termination occurs, the full amount of the Award is payable, and (ii) if the Award was granted with respect to the Performance Period commencing in the calendar year in which such termination occurs, the Award otherwise payable is multiplied by a fraction (rounded to two decimal places), the numerator of which is the number of complete months you remained continuously and actively employed by the Company or an Affiliate during the calendar year in which your termination occurs, and the denominator of which is twelve (12). Notwithstanding the foregoing, you shall not be entitled to such full or prorated amount of your Award pursuant to this paragraph (d) unless either you execute and do not revoke a Release and deliver it to the Company no later than the date specified by the Company, or the Company waives such release requirement in writing; *provided*, *however*, that in no event shall payment of such full or prorated amount of your Award be made later than the specified payment date as set forth in paragraph (a) of this Section IV. This paragraph (d) shall supersede Section 7.1(c) of the Program.

V. Issuance of Shares; Tax Withholding. Regardless of any action the Company or your actual employer (the "Employer") takes with respect to any or all income tax (including federal, state and local taxes), social insurance, payroll tax, fringe benefit tax, payment on account or other tax-related items related to your participation in the Plan and the Program and legally applicable to you (the "Tax Obligations"), you acknowledge that the ultimate liability for all Tax Obligations is and remains your responsibility and may exceed the amount, if any, actually withheld by the Company and/or your Employer. You further acknowledge that the Company and/or your Employer (i) make no representations or undertakings regarding the treatment of any Tax Obligations in connection with any aspect of the Performance Units or the underlying Shares, including the grant of the Performance Units, the vesting of the Performance Units, the conversion of the Performance Units into shares or the receipt of an equivalent cash payment, the subsequent sale of any shares acquired at settlement and the receipt of any

Dividends (as defined in Section VI, below) or Dividend Equivalents; and (ii) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Performance Units to reduce or eliminate your liability for Tax Obligations or to achieve any particular tax result. Furthermore, if you become subject to tax in more than one jurisdiction, you acknowledge that the Company and/or your Employer (or former employer, as applicable) may be required to withhold or account for Tax Obligations in more than one jurisdiction.

Prior to any relevant taxable or tax withholding event, as applicable, you shall pay or make adequate arrangements satisfactory to the Company or to your Employer (in their sole discretion) to satisfy all Tax Obligations. In this regard, you authorize the Company and/ or your Employer, or their respective agents, at their discretion, to satisfy all applicable Tax Obligations by one or a combination of the following:

(a) withholding from your wages or other cash compensation paid to you by the Company and/or your Employer; or

(b) withholding from proceeds of the sale of Shares issued upon settlement of the Performance Units, either through your voluntary sale or through a mandatory sale arranged by the Company (on your behalf pursuant to this authorization); or

(c) withholding in Shares issuable, or cash payable, upon settlement of the Performance Units provided that, if such Shares are withheld, the Company and your Employer shall only withhold an amount of Shares with a fair market value not to exceed the Tax Obligations as determined in the discretion of the Company or your Employer, as applicable.

Depending on the withholding method, the Company may withhold or account for Tax Obligations by considering applicable minimum statutory withholding rates or other applicable withholding rates, including maximum applicable rates. If the Tax Obligations are satisfied by withholding in Shares, for tax purposes you are deemed to have been issued the full number of Shares subject to the earned Performance Units, notwithstanding that a number of Shares is held back and not actually issued to you solely for the purpose of paying the Tax Obligations due as a result of any aspect of your participation in the Plan (any Shares withheld by the Company hereunder shall not be deemed to have been issued by the Company for any purpose under the Plan and shall remain available for issuance thereunder).

Finally, you shall pay to the Company or your Employer any amount of Tax Obligations that the Company or your Employer may be required to withhold or account for as a result of your participation in the Plan and the Program that cannot be or were not satisfied by the means previously described. You agree to take any further actions and to execute any additional documents as may be necessary to effectuate the provisions of this Section V. Notwithstanding Section IV above, the Company may refuse to issue or deliver the Shares or the proceeds of the sale of Shares if you fail to comply with your obligations in connection with the Tax Obligations.

VI. Dividend Equivalents

(a) Crediting of Dividend Equivalents. Subject to this Section VI, Dividend Equivalents shall be credited on each Performance Unit granted to you under this Agreement in the manner set forth in the remainder of this Section VI. With respect to each Performance Unit covered by the Award, if the Company declares one or more dividends or distributions (each, a "Dividend") on its Common Stock with a record date which occurs during the period commencing on the Grant Date through and including the day immediately preceding the day the Share subject to each Performance Unit is issued to you, whether in the form of cash, Common Stock or other property, then, on the date such Dividend is paid to the Company's stockholders, you shall be credited with an amount equal to the amount or fair market value of such Dividend which would have been payable to you if you held a number of Shares equal to the number of Performance Units granted to you on the Grant Date (including any previously credited Dividends which have been deemed to have been reinvested in Common Stock as provided by the next succeeding sentence), as of each such record date for each such Dividend (not including on any Performance Units which were previously paid or forfeited) as if each such amount had been reinvested in Common Stock as of the date of the payment of such Dividend (such accumulated dividends, the "Target Accumulated Dividends"). Each such Dividend Equivalent shall be deemed to have been reinvested in Common Stock as of the applicable Dividend payment date. Dividend Equivalents shall be payable in full Shares, unless the Administrator determines, at any time prior to payment and in its discretion, that they shall be payable in cash. Dividend Equivalents payable with respect to fractional Shares shall be paid in cash.

(b) Treatment of Dividend Equivalents. Except as otherwise expressly provided in this Section VI any Dividend Equivalents credited to you shall be subject to all of the provisions of this Agreement which apply to the Performance Units with respect to which they have been credited and shall be payable, if at all, at the time and to the extent that the underlying Performance Unit becomes payable pursuant to paragraph (a) of Section IV above. Dividend Equivalents shall not be payable on any Performance Units that do not vest, or are forfeited, pursuant to the terms of this Agreement. Dividend Equivalent rights and any amounts that may become distributable in respect thereof shall be treated separately from the Performance Units and the rights arising in connection therewith for purposes of the designation of time and form of payments required by Section 409A of the Internal Revenue Code of 1986, as amended (the "Code") (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Grant Date, "Section 409A").

VII. Nontransferability. No benefit payable under, or interest in, this Agreement, the Units, or the Shares that may become issuable to you hereunder shall be subject in any manner to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or charge and any such attempted action shall be void and no such benefit or interest shall be, in any manner, liable for, or subject to, your or your beneficiary's debts, contracts, liabilities or torts; *provided, however*, nothing in this Section VII shall prevent transfer (i) by will or (ii) by applicable laws of descent and distribution.

VIII. No Contract for Employment. This Agreement is not an employment or service contract with the Company or an Affiliate and nothing in this Agreement shall be deemed to create in any way whatsoever any obligation on your part to continue in the employ or service of the Company

or an Affiliate, or of the Company or an Affiliate to continue your employment or service with the Company or an Affiliate.

IX. Nature of Grant. In accepting the grant of Performance Units, you acknowledge, understand and agree that:

(a) the Plan and the Program are established voluntarily by the Company, are discretionary in nature and may be modified, amended, suspended or terminated by the Company at any time, as provided in the Plan and in the Program;

(b) the Plan is operated and the Performance Units are granted solely by the Company, and only the Company is a party to this Agreement; accordingly, any rights you may have under this Agreement may be raised only against the Company but not any Affiliate (including, but not limited to, the Employer);

(c) no Affiliate (including, but not limited to, the Employer) has any obligation to make any payment of any kind to you under this Agreement;

(d) the grant of the Performance Units is exceptional, voluntary and occasional and does not create any contractual or other right to receive future awards of Performance Units, or benefits in lieu of Performance Units, even if Performance Units have been awarded in the past;

(e) all decisions with respect to future awards, if any, will be at the sole discretion of the Company;

(f) your participation in the Plan and the Program is voluntary;

(g) the grant of Performance Units, the Shares subject to the Performance Units, and the income from and value of same, are not intended to replace any pension rights or compensation;

(h) neither the grant of Performance Units nor any provision of this Agreement, the Plan, the Program or the policies adopted pursuant to the Plan or Program confer upon you any right with respect to employment or continuation of current employment and shall not interfere with the ability of your Employer to terminate your employment or service relationship (if any) at any time;

(i) in the event that you are not an employee of the Company or any Affiliate, the Performance Units shall not be interpreted to form an employment contract or relationship with the Company or any Affiliate;

(j) the future value of the Shares that may be earned upon the end of the Performance Period is unknown, indeterminable, and cannot be predicted with certainty;

(k) in consideration of the grant of Performance Units hereunder, no claim or entitlement to compensation or damages arises from termination of Performance Units, and no claim or entitlement to compensation or damages shall arise from forfeiture of the Performance Units resulting from (i) the termination of your employment by the Company or an Affiliate (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are employed or the terms of your employment agreement, if any) and/or (ii) the application of the Clawback Policy as described in Section XXI below, and you irrevocably release the Company and your Employer from any such claim that may arise; if, notwithstanding the foregoing, any such claim is found by a court

of competent jurisdiction to have arisen, you shall be deemed irrevocably to have waived your entitlement to pursue such claim;

(l) in the event of termination of your employment (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are employed or the terms of your employment agreement, if any), your right to receive Performance Units and receive shares under the Plan and the Program, if any, will terminate effective as of the date that you are no longer actively employed and will not be extended by any notice period (*e.g.*, active employment would not include a period of "garden leave" or similar period mandated under employment laws in the jurisdiction where you are employed or the terms of your employment agreement, if any);

(m) unless otherwise agreed with the Company, the Performance Units, the Shares subject to the Performance Units, and the income from and value of same, are not granted as consideration for, or in connection with, the service you may provide as a director of an Affiliate of the Company;

(n) except as otherwise provided in this Agreement or the Plan, the Performance Units and the benefits evidenced by this Agreement do not create any entitlement to have the Performance Units or any such benefits transferred to, or assumed by, another company nor to be exchanged, cashed out or substituted for, in connection with any corporate transaction affecting the shares of the Company; and

(o) the following provisions apply only if you are providing services outside the United States:

(A) for employment law purposes outside the United States, the Performance Units, the Shares subject to the Performance Units, and the income from and value of same, are not part of normal or expected *compensation* or salary for any purpose, including but not limited to for purposes of calculating any severance, resignation, termination, redundancy, dismissal, end of service payments, bonuses, holiday pay, long-service awards, pension or retirement benefits or similar mandatory payments; and

(B) neither the Company, your Employer nor any Affiliate of the Company shall be liable for any foreign exchange rate fluctuation between your local currency and the United States Dollar that may affect the value of the Performance Units or of any amounts due to you pursuant to the settlement of the Performance Units or the subsequent sale of any Shares acquired upon settlement.

X. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan and the Program, or your acquisition or sale of the underlying Shares. You should consult with your personal tax, legal and financial advisors regarding your participation in the Plan and the Program before taking any action related thereto.

XI. Notices. Any notices provided for in this Agreement, the Plan or the Program shall be given in writing or electronically and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail or equivalent foreign postal service, postage prepaid, addressed to you at such address as is currently maintained in the Company's records or at such other address as you hereafter designate by written notice to the Company Stock Administrator. Such notices may be given using any automated system

for the documentation, granting or settlement of Awards, such as a system using an internet website or interactive voice response, as approved by the Company.

XII. Resolutions, Plan and Program. This Agreement is subject to all of the provisions of the Resolutions, the Plan and the Program and their provisions are hereby made a part of this Agreement and incorporated herein by reference, including, without limitation, the provisions of Article 9 of the Plan (relating to Performance Awards) and Section 13.2 of the Plan (relating to adjustments upon changes in the Common Stock), and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of this Agreement and those of the Resolutions, the Plan and the Program, the provisions of the Plan shall control. Notwithstanding any provision of this Agreement or the Program to the contrary, any earned Performance Units paid in cash rather than Shares shall not be deemed to have been issued by the Company for any purpose under the Plan.

XIII. Code Section 409A. The time and form of payment of the Performance Units is intended to comply with the requirements of Section 409A and this Agreement shall be interpreted in accordance with Section 409A. Accordingly, no acceleration or deferral of any payment shall be permitted if it would cause the payment of the Performance Units to violate Section 409A. In addition, notwithstanding any provision herein to the contrary, in the event that following the Grant Date, the Committee determines that it may be necessary or appropriate to do so, the Committee may adopt such amendments to the Plan, Program and/or this Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Committee determines are necessary or appropriate to (a) exempt the Plan, Program and/or the Performance Units from the application of Section 409A and/or preserve the intended tax treatment of the benefits provided with respect to this Award, or (b) comply with the requirements of Section 409A; *provided*, *however*, that this paragraph shall not create an obligation on the part of the Committee to adopt any such amendment, policy or procedure or take any such other action. No payment hereunder shall be made to you during the six (6)-month period following your "separation from service" (within the meaning of Section 409A) to the extent that the Company determines that paying such amount at the time set forth herein would be a prohibited distribution under Section 409A(a)(2)(B)(i). If the payment of any such amounts is delayed as a result of the previous sentence, then within thirty (30) days following the end of such six (6)-month period (or, if earlier, your death), the Company shall pay to you (or to your estate) the cumulative amounts that would have otherwise been payable to you during such period, without interest.

XIV. Provisions Applicable to Participants in Foreign Jurisdictions. Notwithstanding any provision of this Agreement or the Program to the contrary, if you are employed by the Company or an Affiliate in any of the countries identified in the attached Appendix A (which constitutes a part of this Agreement), are subject to the laws of any foreign jurisdiction, or relocate to one of the countries included in the attached Appendix A, your award of Performance Units shall be subject to any additional terms and conditions for such country set forth in Appendix A and to the following additional terms and conditions:

(a) the terms and conditions of this Agreement, including Appendix A, are deemed modified to the extent necessary or advisable to comply with applicable foreign laws or facilitate the administration of the Plan and the Program;

(b) if applicable, the effectiveness of your Award is conditioned upon its compliance with any applicable foreign laws, regulations, rules or local governmental regulatory exemption and subject to receipt of any required foreign regulatory approvals;

(c) to the extent necessary to comply with applicable foreign laws, the payment of any earned Performance Units shall be made in cash or Common Stock, at the Company's election; and

(d) the Committee may take any other action, before or after an award of Performance Units is made, that it deems necessary or advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals.

Notwithstanding anything to the contrary contained herein, the Company shall not take any actions hereunder, and no Award of Performance Units shall be granted, and no Shares payable with respect to an Award shall be issued, that would violate the Securities Act, the Exchange Act, the Code, or any other securities or tax or other applicable law or regulation, or the rules of any Securities Exchange. Notwithstanding anything to the contrary contained herein, no Shares issuable with respect to an Award shall be issued unless such shares are then registered under the Securities Act, or, if such shares are not then so registered, the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act and that the issuance satisfied all other applicable legal requirements.

XV. ***Data Privacy. In order for the Company to facilitate your participation in the Plan and the Program, the Company and your Employer must collect and use personal data about you. In accordance with applicable laws, reasonable security measures will be implemented and maintained to protect the security of your personal data; however, you understand that absolute security cannot be guaranteed.***

You understand that the Company and your Employer may hold certain personal information about you, including your name, home address and telephone number, email address, date of birth, social insurance/security number (to the extent permitted under applicable local law), passport or other identification number, salary, nationality, job title/work history/service periods, residency status, citizenship, tax withholding and payroll data, any shares of stock or directorships held in the Company, details of all equity compensation or any other entitlement to Shares awarded, cancelled, vested, unvested or outstanding in your favor, for the purposes of implementing, administering and managing the Plan and the Program ("personal data").

You authorize the transfer of your personal data to Merrill Lynch Bank & Trust Co., FSB, or any successor thereto, and any other third parties which may assist the Company (presently or in the future) with implementing, administering and managing your participation in the Plan and the Program to receive, possess, use, retain and transfer your personal data, in electronic or other form, for the purpose of implementing, administering and managing your participation in the Plan and the Program, including any requisite transfer of such personal data as may be required to any other broker, escrow agent or other third party with whom the Shares received in settlement of the

Performance Units may be deposited. You understand that such authorized recipients of your personal data may be located in countries that do not provide the same level of data privacy laws and protections as the country in which your personal data originated. Transfers of personal data among Company and its group entities follow applicable laws and our Binding Corporate Rules (BCRs). For more information on Company's BCRs, please visit http://www.amgen.com/bcr/. You acknowledge that the collection, use and transfer of your personal data is necessary to facilitate your participation in the Plan, as well as to grant you Performance Units or other equity awards and administer or maintain such awards.

You may correct or update your personal data previously provided to Company, by contacting your local human resources representative. Subject to applicable law, you may have additional rights, including the right to object and/or request destruction of your personal data. To exercise these rights, where applicable, please contact your local human resources representative.

XVI. Language. By electing to accept this Agreement, you acknowledge that you are sufficiently proficient in English or have consulted with an advisor who is sufficiently proficient in English, so as to allow you to understand the terms and conditions of this Agreement. Furthermore, if you have received this Agreement or any other document related to the Plan and/or the Program translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control, unless otherwise required by applicable law.

XVII. Governing Law and Venue. The terms of this Agreement shall be governed by the laws of the State of Delaware without giving effect to principles of conflicts of laws. For purposes of litigating any dispute that arises hereunder, the parties hereby submit to and consent to the jurisdiction of the State of Delaware, and agree that such litigation shall be conducted in the courts of the State of Delaware, or the federal courts for the United States for the federal district located in the State of Delaware, and no other courts, where this Agreement is made and/or to be performed.

XVIII. Severability. If one or more of the provisions of this Agreement shall be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and the invalid, illegal or unenforceable provisions shall be deemed null and void; however, to the extent permissible by law, any provisions which could be deemed null and void shall first be construed, interpreted or revised retroactively to permit this Agreement to be construed so as to foster the intent of this Agreement and the Plan.

XIX. Electronic Delivery and Participation. The Company may, in its sole discretion, decide to deliver any documents related to current or future participation in the Plan and/or the Program (including this Agreement) by electronic means. You hereby consent to receive such documents by electronic delivery and agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

XX. Imposition of Other Requirements. The Company reserves the right to impose other requirements on your participation in the Plan and the Program, on the Performance Units and on any Shares acquired under the Plan and the Program, to the extent the Company determines it is necessary

or advisable for legal or administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

XXI. Compensation Subject to Recovery. The Performance Units subject to and Shares issuable under this Award and all compensation payable with respect to them shall be subject to clawback, recoupment and/or recovery by the Company pursuant to any and all of the Company's policies with respect to the clawback, recoupment or recovery of compensation in effect as of the Grant Date or as may be adopted or maintained by the Company following the Grant Date, including, without limitation, the Company's Policy on Recovery of Erroneously Awarded Compensation (effective October 2, 2023) and Executive Officer Equity Recoupment Policy (effective December 31, 2020), as they shall be in effect and may be amended from time to time (collectively, the "Clawback Policy"), to the maximum extent permitted by applicable law.

XXII. Waiver. You acknowledge that a waiver by the Company of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by you or any other grantee.

XXIII. Headings. This Agreement's section headings are for convenience only and shall not constitute a part of this Agreement or affect this Agreement's meaning.

Very truly yours,
AMGEN INC.

By:_____
Name:
Title:

APPENDIX A

**ADDITIONAL TERMS AND CONDITIONS OF THE
AMGEN INC. SECOND AMENDED AND RESTATED
2009 EQUITY INCENTIVE PLAN,
AS AMENDED AND/OR RESTATED FROM TIME TO TIME**

**AWARD OF PERFORMANCE UNITS
(BY COUNTRY)**

Certain capitalized terms used but not defined in this Appendix A shall have the meanings set forth in the Plan and/or the Agreement to which this Appendix is attached.

TERMS AND CONDITIONS

This Appendix includes additional terms and conditions that govern any Performance Units granted under the Plan if, under applicable law, you are a resident of, are deemed to be a resident of or are working in one of the countries listed below. Furthermore, the additional terms and conditions that govern the Performance Units granted hereunder may apply to you if you transfer employment and/or residency to one of the countries listed below and the Company shall, in its discretion, determine to what extent the terms and conditions contained herein shall apply to you.

NOTIFICATIONS

This Appendix also includes notifications relating to exchange control and other issues of which you should be aware with respect to your participation in the Plan. The information is based on the exchange control, securities and other laws in effect in the countries to which this Appendix refers as of October 2025. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the notifications herein as the only source of information relating to the consequences of your participation in the Plan because the information may be outdated when you acquire Shares under the Plan, or when you subsequently sell Shares acquired under the Plan and the Program.

In addition, the notifications are general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of any particular result. Accordingly, you should seek appropriate professional advice as to how the relevant laws in your country may apply to your situation. Finally, if you are a citizen or resident of a country other than the one in which you are currently residing and/or working or are considered a resident of another country for local law purposes, the information contained herein may not be applicable to you or you may be subject to the provisions of one or more jurisdictions.

ALL NON-U.S. JURISDICTIONS

TERMS AND CONDITIONS

Issuance of Shares; Tax Withholding. The following provision supplements Section V. of the Agreement:

In the event the Company withholds or accounts for Tax Obligations by considering maximum applicable rates in your jurisdiction(s), in the event of over-withholding, you may receive a refund of any over-withheld amount in cash and will not be entitled to the equivalent amount in Shares, or if not refunded, you may seek a refund from the local tax authorities. In the event of under-withholding, you may be required to pay any additional Tax Obligations directly to the applicable tax authority or to the Company and/or your Employer.

NOTIFICATIONS

Insider Trading Restrictions/Market Abuse Laws. You may be subject to insider trading restrictions and/or market abuse laws based on the exchange on which the Shares are listed and in applicable jurisdictions including the United States and your country or your broker's country, if different, which may affect your ability to accept, acquire, sell or otherwise dispose of Shares, rights to Shares (*e.g.*, Performance Units) or rights linked to the value of Shares (*e.g.*, Dividend Equivalents) during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in applicable jurisdictions). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders you place before you possessed inside information. Furthermore, you could be prohibited from (i) disclosing the inside information to any third party, which may include fellow employees (other than on a "need to know" basis) and (ii) "tipping" third parties or causing them otherwise to buy or sell securities. Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. You are responsible for ensuring your compliance with any applicable restrictions and you should speak with your personal legal advisor on this matter.

Foreign Asset/Account, Tax Reporting Information. Your country of residence may have certain foreign asset and/or account reporting requirements which may affect your ability to acquire or hold Shares under the Plan or cash received from participating in the Plan (including from any Dividends or Dividend Equivalents received, or sale proceeds arising from the sale of Shares) in a brokerage or bank account outside of your country. You may be required to report such accounts, assets or transactions to the tax or other authorities in your country. You also may be required to repatriate sale proceeds or other funds received as a result of participating in the Plan to your country within a certain time after receipt. You are responsible for ensuring your compliance with such regulations, and you should speak with your personal legal advisor on this matter.

ALL EUROPEAN ECONOMIC AREA ("EEA") / EUROPEAN UNION ("EU") JURISDICTIONS, UNITED KINGDOM AND SWITZERLAND

TERMS AND CONDITIONS

Data Privacy Notice. This provision replaces Section XV of the Agreement:

Please refer to the Fair Processing Notice previously provided by your local human resources representative, which notice governs the collection, use and transfer of your personal data necessary for the Company to facilitate your participation in the Plan and the Program. If you have any questions or concerns regarding the Fair Processing Notice, including questions about your rights afforded thereunder, you should contact your local human resources representative or send an email to hrconnect@amgen.com.

For purposes of implementing, administering and managing the Plan, Company and your Employer may hold certain personal data about you, including your name, home address and telephone number, email address, date of birth, social insurance/security number (to the extent permitted under applicable local law), passport or other identification number, salary, nationality, job title/work history/service periods, residency status, citizenship, tax withholding and payroll data, any shares of stock or directorships held in the Company, details of all equity compensation or any other entitlement to Shares awarded, cancelled, vested, unvested or outstanding in your favor ("personal data").

You authorize the transfer of your personal data to Merrill Lynch Bank & Trust Co., FSB, or any successor thereto, and any other third parties which may assist the Company (presently or in the future) with implementing, administering and managing your participation in the Plan and the Program to receive, possess, use, retain and transfer your personal data, in electronic or other form, for the purpose of implementing, administering and managing your participation in the Plan and the Program, including any requisite transfer of such personal data as may be required to any other broker, escrow agent or other third party with whom the Shares received in settlement of the Performance Units may be deposited.

ARGENTINA

TERMS AND CONDITIONS

Labor Law Acknowledgement. The following provision supplements Section IX of the Agreement:

In accepting the grant of Performance Units, you acknowledge, understand and agree that the grant of the Performance Units is made by the Company (not your Employer) in its sole discretion and that the value of the Performance Units or any Shares acquired under the Plan and the Program shall not constitute salary or wages for any purpose under Argentine labor law including, but not limited to, the calculation of (i) any labor benefits including, without limitation, vacation pay, thirteenth salary, compensation in lieu of notice, annual bonus, disability, and leave of absence payments, etc., or (ii) any termination or severance indemnities or similar payments.

NOTIFICATIONS

Securities Law Information. The Performance Units and the underlying Shares have not been and will not be publicly issued, placed, distributed, offered or listed in the Argentine capital markets, and, as a result, have not been and will not be registered with the Argentina Securities Commission (Comisión Nacional de Valores, "CNV"). Neither this nor any other offering material related to the Performance Units nor the underlying Shares may be utilized in connection with any general offering to the public in Argentina. Any Argentine resident who acquires Shares under the Plan does so under their own responsibility under the terms of a private offering to the Argentine resident from outside Argentina. Any Argentine resident who acquires Shares shall not transfer such Shares to any other person within six (6) months of acquiring the Shares, unless the transaction is conducted outside Argentina.

Exchange Control Information. Exchange control regulations in Argentina are subject to frequent change. You should consult with your personal legal advisor regarding any exchange control obligations that you may have prior to receiving proceeds from Dividend Equivalents, the sale of Shares or dividends. You must comply with any and all Argentine currency exchange restrictions, approvals and reporting requirements in connection with your participation in the Plan and the Program.

Foreign Asset/Account Reporting Information. If you are an Argentine resident, you are required to report certain information regarding any Shares you hold as of December 31 each year to the Argentine tax authorities on your annual tax return.

AUSTRALIA

NOTIFICATIONS

Australia Offer Document. This grant of Units is being made under Division 1A, Part 7.12 of the Corporations Act 2001 (Cth).

Tax Information. Subdivision 83A-C of the Income Tax Assessment Act 1997 (Cth) applies to the Performance Units granted under the Plan, such that the Performance Units are intended to be subject to deferred taxation.

Exchange Control Information. If you are an Australian resident, exchange control reporting is required for cash transactions exceeding a certain threshold (currently AUD10,000) and for international fund transfers. If an Australian bank is assisting with the transaction, the bank will file the report on your behalf. If there is no Australian bank involved in the transfer, you will be required to file the report.

AUSTRIA

NOTIFICATIONS

Foreign Asset/Account Reporting Information. If you are an Austrian resident and you hold Shares acquired under the Plan and the Program outside of Austria, you may be subject to reporting obligations to the Austrian National Bank.

Exchange Control Information. If the value of Shares meets or exceeds a certain threshold (currently, €5,000,000), you must report the securities held on a quarterly basis to the Austrian National Bank as of the last day of the quarter, on or before the 15th day of the month following the end of the calendar quarter. Further, if you hold cash in accounts outside Austria, monthly reporting requirements will apply, as explained in the next paragraph, if the aggregate transaction volume of such cash accounts meets or exceeds a certain threshold.

A separate reporting requirement applies when you sell Shares acquired under the Plan and the Program, receive a cash Dividend paid on such Shares or Dividend Equivalents paid in cash. In that case, there may be exchange control obligations if the cash proceeds are held outside of Austria. If the transaction volume of all cash accounts abroad meets or exceeds a certain threshold (currently €10,000,000), the movements and balances of all accounts must be reported monthly, as of the last day of the month, on or before the 15th day of the following month, on the prescribed forms.

BELGIUM

NOTIFICATIONS

Tax Reporting; Foreign Asset/Account Reporting Information. If you are a Belgian resident, you are required to report any securities (*e.g.*, Shares acquired under the Plan and the Program) held and bank accounts (including brokerage accounts) opened and maintained outside of Belgium on your annual tax return. The first time you report the foreign security and/or bank account on your annual income tax return you will have to provide the National Bank of Belgium Central Contact Point with the account details of any such foreign accounts (including the account number, bank name and country in which such account was opened) in a separate form. This report, as well as information on how to complete it, can be found on the website of the National Bank of Belgium, www.nbb.be, under the *Kredietcentrales / Centrales des crédits* caption.

Stock Exchange Tax Information. A stock exchange tax applies to transactions executed by a Belgian resident through a non-Belgian financial intermediary, such as a U.S. broker. The stock exchange tax likely will apply when Shares acquired under the Plan and the Program are sold. It is your responsibility to comply with this tax obligation and you should consult your personal tax advisor for additional details on your obligations with respect to the stock exchange tax.

Annual Securities Accounts Tax Information. An annual securities accounts tax may be payable if the total value of securities held in a Belgian or foreign securities account (e.g., Shares acquired under the Plan and the Program) exceeds a certain threshold on four reference dates within the relevant reporting period (i.e., December 31, March 31, June 30 and September 30). In such case, the tax will be due on the value of the qualifying securities held in such account. It is your responsibility to comply with this obligation, and you should consult with your personal tax or financial advisor for additional details.

BRAZIL

TERMS AND CONDITIONS

Compliance with Law. By accepting the Performance Units, you acknowledge that you agree to comply with applicable Brazilian laws and pay any and all applicable taxes associated with the vesting of the Performance Units, the sale of Shares acquired under the Plan and the Program, the payment of Dividends on such Shares and the receipt of any Dividend Equivalents paid in cash.

Nature of Grant. This provision supplements Section IX of the Agreement:

In accepting the grant of Performance Units, you acknowledge (i) that you are making an investment decision, (ii) that the Shares will be issued to you only if the vesting conditions are met and any necessary services are rendered by you during the vesting period set forth in the Vesting Schedule, and (iii) that the value of the underlying Shares is not fixed and may increase or decrease in value over the vesting period without compensation to you.

NOTIFICATIONS

Exchange Control Information. If you are resident or domiciled in Brazil, you will be required to submit annually a declaration of assets and rights held outside of Brazil to the Central Bank of Brazil if the aggregate value of such assets and rights on December 31 of each year exceeds US$1,000,000. If such amount exceeds US$100,000,000, the referenced declaration must be submitted quarterly, in the month following the end of each quarter. Assets and rights that must be reported include the following: (i) bank deposits; (ii) loans; (iii) financing transactions; (iv) leases; (v) direct investments; (vi) portfolio investments, including Shares acquired under the Plan and the Program; (vii) financial derivatives investments; and (viii) other investments, such as real estate. Please note that foreign individuals holding Brazilian visas are considered Brazilian residents for purposes of this reporting requirement and must declare at least the assets held abroad that were acquired subsequent to the date of admittance as a resident of Brazil. Individuals holding assets and rights outside of Brazil valued at less than US$1,000,000 are not required to submit a declaration.

Tax on Financial Transactions. Payments to foreign countries, repatriation of funds into Brazil, and the conversion associated with such fund transfers into local currency, may be subject to the Tax on Financial Transactions. It is your responsibility to comply with any applicable Tax on Financial Transactions arising from participation in the Plan and you should consult your personal tax advisor for additional details.

BULGARIA

Exchange Control Information. You will be required to file statistical forms with the Bulgarian National Bank annually regarding your receivables in bank accounts abroad as well as securities held abroad (e.g., Shares acquired under the Plan) if the total sum of all such receivables and securities equals or exceeds a certain threshold as of the previous calendar year-end. The reports are due by

March 31. You should contact your bank in Bulgaria for additional information regarding these requirements.

CANADA

TERMS AND CONDITIONS

Termination of Employment. This provision supplements Section IX(l) of the Agreement:

For purposes of the Performance Units and except as explicitly and minimally required under applicable legislation or expressly provided in this Agreement, (i) your employment will termination and (ii) your right, if any, to earn, seek damages in lieu of, vest in or otherwise benefit from or participate in any portion of the Performance Units or the Plan will be measured by and immediately terminate, as of the date you no longer actually providing services to the Company and/or the Employer, regardless of the reason for such termination and whether or not later found to be invalid or in breach of applicable laws in the jurisdiction where your employed or the terms of your employment agreement, if any (the "Termination Date"). Except as explicitly and minimally required under applicable legislation, the Termination Date will exclude and will not be extended by any period during which notice, pay in lieu of notice or related payments or damages are provided or required to be provided under applicable laws (including, but not limited to, statutory law, regulatory law and/or common or civil law). You will not earn or be entitled to any pro-rated vesting for that portion of time before the Termination Date, nor will you be entitled to any compensation for lost vesting, benefits, or other participation. Subject to applicable legislation, if the date you are no longer actually providing services cannot be reasonably determined under the terms of this Agreement or the Plan, the Company shall have the exclusive discretion to determine when you are no longer actually providing services for purposes of this Agreement (including whether you may still be considered to be providing services while on a leave of absence). Notwithstanding the foregoing, if applicable employment standards legislation explicitly requires continued vesting or other participation during a statutory notice period, your right to vest in the Performance Units or otherwise participate in or benefit from the Performance Units under the Plan, if any, will terminate effective as of the last day of your minimum statutory notice period, but you will not earn or be entitled to pro-rated vesting or other benefits or participation if the vesting date falls after the end of your statutory notice period, nor will you be entitled to any compensation for lost vesting;

Acknowledgement of Nature of Plan and Units. Section IX(c), IX(k) and IX(o)(A) of the Agreement are amended to read as follows:

(c) no Affiliate (including, but not limited to, the Employer) has any obligation to make any payment of any kind to you under this Agreement, except to the extent explicitly and minimally required under applicable legislation;

(k) in consideration of the grant of Performance Units hereunder, no claim or entitlement to compensation or damages arises from termination of Performance Units, and no claim

or entitlement to compensation or damages shall arise from forfeiture of the Performance Units resulting from (i) the termination of your employment by the Company or an Affiliate (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are employed or the terms of your employment agreement, if any) and/or (ii) the application of the Clawback Policy as described in Section XXI below, except to the extent explicitly and minimally required under applicable legislation;

(o)(A) for employment law purposes outside the United States, the Performance Units, the Shares subject to the Performance Units, and the income from and value of same, are not part of normal or expected compensation or salary for any purpose, including but not limited to for purposes of calculating any severance, resignation, termination, redundancy, dismissal, end of service payments, bonuses, holiday pay, long-service awards, pension or retirement benefits or similar mandatory payments, except to the extent explicitly and minimally required under applicable legislation; and

Form of Settlement - Performance Units Payable Only in Shares. Notwithstanding any discretion in Section 9.5 of the Plan or the Program or anything to the contrary in the Agreement, the Award does not provide any right for you, as a resident of Canada, to receive a cash payment and shall be paid in Shares only.

The following provision will apply to you if you are a resident of Quebec:

French Language Documents. A French translation of this document and certain other documents related to this Award will be made available to you as soon as reasonably practicable. You understand that, from time to time, additional information related to the Award may be provided in English and such information may not be immediately available in French. However, upon request, the Company will provide a translation of such information into French as soon as reasonably practicable. Notwithstanding anything to the contrary in the Agreement, and unless you indicate otherwise, the French translation of this document and certain other documents related to the Award will govern your participation in the Plan.

Data Privacy Notice. This provision supplements Section XV of the Agreement:

You hereby authorize the Company and the Company's representative to discuss with and obtain all relevant information from all personnel (professional or not) involved in the administration of the Plan and the Program. You further authorize the Company, your Employer and Merrill Lynch Bank & Trust Co., FSB (or any other stock plan service provider) to disclose and discuss your participation in the Plan with their advisors. You also authorize the Company and your Employer to record such information and keep it in your file.

NOTIFICATIONS

Securities Law Information. You are permitted to sell Shares acquired through the Plan through the designated broker appointed under the Plan, if any, provided that the resale of such Shares takes

place outside of Canada through the facilities of a stock exchange on which the Shares are listed (*e.g.*, the Nasdaq Global Select Market).

Foreign Asset/Account Reporting Information. Specified foreign property, including Shares, stock options and other rights to receive Shares (*e.g.*, Performance Units) of a non-Canadian company held by a Canadian resident employee generally must be reported annually on a Form T1135 (Foreign Income Verification Statement) if the total cost of the employee's specified foreign property exceeds a certain threshold (currently C$100,000) at any time during the year. Thus, such stock options and Performance Units must be reported – generally at nil cost – if the applicable cost threshold is exceeded because other specified foreign property is held by the employee. When Shares are acquired, their cost generally is the adjusted cost base ("ACB") of the Shares. The ACB ordinarily would equal the fair market value of the Shares at the time of acquisition, but if the employee owns other shares of the same company, this ACB may have to be averaged with the ACB of the other shares.

CHINA

TERMS AND CONDITIONS

The following terms apply only to individuals who are subject to exchange control restrictions in the People's Republic of China (the "PRC"), as determined by the Company in its sole discretion:

Vesting of the Performance Units. Notwithstanding anything to the contrary in Article 7.1 of the Program, if your employment with the Company or an Affiliate terminates at any time during the Performance Period, you shall forfeit all Performance Units.

Sale Requirement. Notwithstanding anything to the contrary in the Agreement, due to exchange control laws in the PRC, you agree that the Company reserves the right to require the immediate sale of any Shares acquired upon settlement of the Performance Units. You understand and agree that any such immediate sale of Shares will occur as soon as is practical following settlement of the Performance Units. Alternatively, if the Shares are not immediately sold upon settlement of the Performance Units, the Company will require the sale of any Shares you may then hold within six (6) months (or such other period as may be required under applicable legal or exchange control requirements) following the termination of your employment with the Company, including its Affiliates.

You agree that the Company is authorized to instruct Merrill Lynch Bank & Trust Co., FSB or such other designated broker as may be selected by the Company to assist with the sale of the Shares on your behalf pursuant to this authorization, and you expressly authorize such broker to complete the sale of such Shares. You also agree to sign any agreements, forms and/or consents that may be reasonably requested by the Company (or the Company's designated broker) to effectuate the sale of the Shares (including, without limitation, as to the transfers of the proceeds and other exchange control matters noted below) and to otherwise cooperate with the Company with respect to such matters, provided that you shall not be permitted to exercise any influence

over how, when or whether the sales occur. Upon the sale of the Shares, you will receive the cash proceeds from the sale, less any applicable Tax Obligations, brokerage fees or commissions, in accordance with applicable exchange control laws and regulations.

You acknowledge that Merrill Lynch Bank & Trust Co., FSB or such other designated broker as may be selected by the Company is under no obligation to arrange for the sale of the Shares at any particular price. Due to fluctuations in the Share price and/or applicable exchange rates between the settlement date and (if later) the date on which the Shares are sold, the amount of proceeds ultimately distributed to you may be more or less than the market value of the Shares on the settlement date (which is the amount relevant to determining your liability for Tax Obligations). You understand and agree that the Company is not responsible for the amount of any loss that you may incur and that the Company assumes no liability for any fluctuations in the Share price and/or any applicable exchange rate.

Designated Broker Account. If Shares issued upon the settlement of the Performance Units are not immediately sold, you acknowledge that you are required to maintain the Shares in an account with Merrill Lynch Bank & Trust Co., FSB or such other designated broker as may be selected by the Company until the Shares are sold through such Company-designated broker.

Exchange Control Requirements. You understand and agree that, pursuant to local exchange control requirements, you will be required to repatriate the cash proceeds from the sale of the Shares issued upon settlement of the Performance Units and from the receipt of any Dividends or Dividend Equivalents to China. You further understand that, under applicable laws, such repatriation of your cash proceeds will need to be effectuated through a special exchange control account established by the Company or any Affiliate, including your Employer, and you hereby consent and agree that any proceeds may be transferred to such special account prior to being delivered to you. You also understand that the Company will deliver the proceeds to you as soon as possible, but that there may be delays in distributing the funds to you due to exchange control requirements in China. Proceeds may be paid to you in U.S. dollars or local currency at the Company's discretion. If the proceeds are paid to you in U.S. dollars, you will be required to set up a U.S. dollar bank account in China so that the proceeds may be deposited into this account. If the proceeds are paid to you in local currency, the Company is under no obligation to secure any particular currency conversion rate and the Company may face delays in converting the proceeds to local currency due to exchange control restrictions. You further agree to comply with any other requirements that may be imposed by the Company in the future in order to facilitate compliance with exchange control requirements in China.

COLOMBIA

TERMS AND CONDITIONS

Labor Law Acknowledgement. The following provision supplements Section IX of the Agreement:

You acknowledge that pursuant to Article 15 of Law 50/1990 (Article 128 of the Colombian Labor Code), the Plan, the Program and related benefits do not constitute a component of "salary" for any purpose. Therefore, they are considered to be of an extraordinary nature and will not be included and/or

considered for purposes of calculating any and all labor benefits, such as legal/fringe benefits, vacations, indemnities, payroll taxes, social insurance contributions and/or any other labor-related amounts, subject to the limitations provided in Law 1393/2010.

Mandate Letter. In accepting the Performance Units, you agree that – if requested by the Company or the Employer – you will execute a Mandate Letter or such other document (whether electronically or by such other method as requested by the Company or the Employer) that the Company determines is necessary or advisable in order that (i) a sufficient number of Shares to be allocated to you upon vesting can be sold on your behalf to cover Tax Obligations required to be withheld by the Employer and (ii) the proceeds from such sale can be wired directly from the Company to the Employer in Colombia for remittance to the tax authorities.

NOTIFICATIONS

Securities Law Information. The Shares are not and will not be registered with the Colombian registry of publicly traded securities (*Registro Nacional de Valores y Emisores*) and therefore the Shares may not be offered to the public in Colombia. Nothing in this document should be construed as the making of a public offer of securities in Colombia.

Exchange Control Information. Investment in assets located abroad (such as Shares acquired under the Plan and the Program) does not require prior approval from the Central Bank (Banco de la República). Nonetheless, such investments are subject to registration before the Central Bank as foreign investments held abroad, regardless of value.

Any payments for your investment originating in Colombia (and the liquidation of such investments) must be transferred through the Colombian foreign exchange market (*e.g.*, local banks), which includes the obligation to correctly complete and file the appropriate foreign exchange form (*declaración de cambio*).

Foreign Asset/Account Reporting Notice. An annual information return may need to be filed with the Colombian Tax Office detailing any assets held abroad (including Shares acquired under the Plan). If the individual value of any of these assets exceeds a certain threshold, each asset must be described (*e.g.*, its nature and its value) and the jurisdiction in which it is located must be disclosed. It is your responsibility to comply with this tax reporting requirement.

CROATIA

NOTIFICATIONS

Exchange Control Information. Croatian residents may be required to report any foreign investments (including Shares acquired under the Plan) to the Croatian National Bank for statistical purposes. You should be aware that exchange control regulations in Croatia are subject to frequent change and you are solely responsible for ensuring your continued compliance with current Croatian exchange control laws.

CZECH REPUBLIC

NOTIFICATIONS

Exchange Control Information. If you are a resident of the Czech Republic, you may be required to notify the Czech National Bank ("CNB") of the acquisition of Shares under the Plan or maintenance of a foreign account if (i) you maintain foreign direct investments with a value of 2,500,000 Kč or more in the aggregate, (ii) you maintain a certain threshold of foreign financial assets, or (iii) you are specifically requested to do so by the CNB.

DENMARK

TERMS AND CONDITIONS

Danish Stock Option Act. In accepting the Performance Units, you acknowledge that you have received an Employer Statement translated into Danish, which is being provided to comply with the Danish Stock Option Act (the "Act"). To the extent more favorable to you and required to comply with the Act, as amended with effect from January 1, 2019. You also acknowledge any grant of Performance Units under the Plan made on or after January 1, 2019 is subject to the rules of the amended Act. Accordingly, you agree that the treatment of the Performance Units upon the termination of your employment is governed solely by Section I(i) of the Agreement and any corresponding provisions in the Plan. The relevant termination provisions are also detailed in the Employer Statement.

Please be aware that as set forth in Section 1 of the Act, the Act only applies to "employees" as that term is defined in Section 2 of the Act. If you are a member of the registered management of an Affiliate or Subsidiary in Denmark or otherwise do not satisfy the definition of employee, you will not be subject to the Act, and the Employer Statement will not apply to you.

NOTIFICATIONS

Foreign Asset/Account Reporting Information. The requirement to report certain information to the Danish Tax Administration via Form V or K was eliminated effective January 1, 2019. However, you still must report the foreign bank/brokerage accounts and their deposits, and Shares held in a foreign bank or brokerage account in your tax return under the section on foreign affairs and income.

EGYPT

NOTIFICATIONS

Exchange Control Information. If you transfer funds into Egypt in connection with the Performance Units, you are required to transfer the funds through a registered bank in Egypt.

FINLAND

NOTIFICATIONS

Foreign Asset/Account Reporting Information. There are no specific reporting requirements with respect to foreign assets/accounts. However, please note that you must check your pre-completed tax return to confirm that the ownership of Shares and other securities (foreign or domestic) are correctly reported. If you find any errors or omissions, you must make the necessary corrections electronically or by sending specific paper forms to the local tax authorities.

FRANCE

TERMS AND CONDITIONS

Language Consent. By accepting the Award, you confirm having read and understood the Plan and Agreement which were provided in the English language. You accept the terms of these documents accordingly.

Consentement Relatif à la Langue Utilisée. *En acceptant l'prix, vous confirmez avoir lu et compris le Plan et le Contrat, qui ont été communiqués en langue anglaise. Vous acceptez les termes de ces documents en connaissance de cause.*

NOTIFICATIONS

Foreign Asset/Account Reporting Information. French residents and non-residents must declare to the Customs Authorities the cash and securities they import or export without the use of a financial institution when the value of such cash or securities exceeds a certain threshold (currently €10,000). French residents also must report all foreign bank and brokerage accounts on an annual basis (including accounts opened or closed during the tax year) on Form N° 3916, together with the income tax return. Failure to comply could trigger significant penalties.

GERMANY

NOTIFICATIONS

Foreign Asset/Account Reporting Information. If your acquisition of Shares under the Plan leads to a qualified participation at any point during the calendar year, you will need to report the acquisition when you file your tax return for the relevant year. A qualified participation is attained only in the unlikely event (i) you own at least 1% of the Company and the value of the Shares acquired exceeds a certain threshold (currently €150,000) or (ii) you hold Shares exceeding 10% of the Company's total Common Stock.

Exchange Control Information. Cross-border payments in excess of a certain threshold (currently €50,000) must be reported monthly to the German Federal Bank (*Bundesbank*). In case of payments in connection with securities (including proceeds realized upon the sale of Shares or the receipt of Dividends or Dividend Equivalents), and/or if the Company withholds Shares with a value in excess of the applicable threshold for any Tax Obligations, the report must be made monthly following the month in which the payment was received and must be filed electronically. The form of report (*Allgemeines Meldeportal Statistik*) can be accessed via the Bundesbank's website (www.bundesbank.de) and is

available in both German and English. In addition, you may be required to report the acquisition or sale of Shares to the *Bundesbank* if the value of the Shares acquired or sold exceeds the applicable threshold. You are responsible for satisfying any applicable reporting obligation.

GREECE

NOTIFICATIONS

Foreign Asset/Account Reporting Information. The reporting of foreign assets (including Shares and other investments) is your own obligation and takes place through your annual tax return.

HONG KONG

TERMS AND CONDITIONS

Form of Settlement - Performance Units Payable Only in Shares. Notwithstanding any discretion in Section 9.5 of the Plan or the Program or anything to the contrary in the Agreement, the Award does not provide any right for you, as a resident of Hong Kong, to receive a cash payment and shall be paid in Shares only.

Sale of Shares. Shares received at vesting are accepted as a personal investment. In the event that Shares are issued in respect of Performance Units within six (6) months of the Grant Date, you agree that you will not offer to the public or otherwise dispose of such Shares prior to the six (6)-month anniversary of the Grant Date.

NOTIFICATIONS

SECURITIES WARNING: *The contents of this document have not been reviewed by any regulatory authority in Hong Kong. You should exercise caution in relation to the offer. If you are in doubt about any of the contents of the Agreement, including this Appendix, or the Plan, you should obtain independent professional advice. The Performance Units and any Shares issued in respect of the Performance Units do not constitute a public offering of securities under Hong Kong law and are available only to members of the Board and Employees. The Agreement, including this Appendix, the Plan and other incidental communication materials have not been prepared in accordance with and are not intended to constitute a "prospectus" for a public offering of securities under the applicable securities legislation in Hong Kong. The Performance Units and any documentation related thereto are intended solely for the personal use of each member of the Board and/or Employee and may not be distributed to any other person.*

HUNGARY

There are no country-specific provisions.

ICELAND

NOTIFICATIONS

Exchange Control Information. Approval by the Central Bank of Iceland is no longer required to participate in the Plan and the Program, regardless of the value of the Shares acquired under the Plan and the Program. Despite the recent relaxation of the exchange control requirements, you should consult with your personal advisor to ensure compliance with applicable exchange control regulations in Iceland as such regulations are subject to frequent change. You are responsible for ensuring compliance with all exchange control laws in Iceland.

INDIA

NOTIFICATIONS

Exchange Control Information. You understand that you must repatriate any cash Dividends paid on Shares acquired under the Plan to India or any Dividend Equivalents paid in cash, as well as any proceeds from the sale of Shares acquired under the Plan within such time as may be required under applicable Indian exchange control laws, which may be amended from time to time, unless an exemption applies. You will receive a foreign inward remittance certificate ("FIRC") from the bank where you deposit the foreign currency, and you must maintain the FIRC as proof of repatriation of funds in the event that the Reserve Bank of India or your Employer requests proof of repatriation. It is your responsibility to comply with these requirements. Neither the Company nor the Employer will be liable for any fines or penalties resulting from your failure to comply with any applicable laws. You may be required to provide information regarding funds received from participation in the Plan to the Company and/or the Employer to enable them to comply with their filing requirements under exchange control laws in India.

Foreign Asset/Account Reporting Information. You are required to declare foreign bank accounts and any foreign financial assets (including Shares held outside of India) in your annual tax return. It is your responsibility to comply with this reporting obligation, and you should consult your personal tax advisor in this regard.

IRELAND

TERMS AND CONDITIONS

Nature of Grant. This provision supplements Section IX of the Agreement:

In accepting the grant of Performance Units, you acknowledge that the benefits received under the Plan will not be taken into account for any redundancy or unfair dismissal claim.

ITALY

TERMS AND CONDITIONS

Nature of Grant. In accepting the grant of Performance Units, you acknowledge that (1) you have received a copy of the Plan, the Program, the Agreement and this Appendix; (2) you have reviewed the applicable documents in their entirety and fully understand the contents thereof; and (3) you accept all provisions of the Plan, the Program, the Agreement and this Appendix.

You further acknowledge that you have read and specifically and explicitly approve, without limitation, the following sections of the Agreement: Section III, Section IV, Section V, Section IX, Section IV, Section XVI, Section XX and the Data Privacy Notice for All European Economic Area ("EEA") / European Union ("EU") Jurisdictions, United Kingdom and Switzerland in this Appendix.

NOTIFICATIONS

Foreign Asset/Account Reporting Information. Italian residents who, at any time during the fiscal year, hold foreign financial assets (including cash and Shares) which may generate income taxable in Italy are required to report these assets on their annual tax returns (UNICO Form, RW Schedule) for the year during which the assets are held, or on a special form if no tax return is due. These reporting obligations will also apply to Italian residents who are the beneficial owners of foreign financial assets under Italian money laundering provisions.

Foreign Financial Assets Tax. The fair market value of any Shares held outside of Italy is subject to a foreign assets tax at a flat rate. The market value is considered to be the value of the Shares on the Nasdaq Global Select Market on December 31 of the applicable year in which you held the Shares (or when the Shares are acquired during the course of the year, the tax is levied in proportion to the actual days of holding over the calendar year). No tax payment duties arise if the amount of the foreign financial assets tax calculated on all financial assets held abroad does not exceed a certain threshold. You should consult with your personal tax advisor about the foreign financial assets tax.

JAPAN

NOTIFICATIONS

Foreign Asset/Account Reporting Information. You will be required to report to the Japanese tax authorities details of any assets held outside of Japan as of December 31st (including any Shares acquired under the Plan and the Program) to the extent such assets have a total net fair market value exceeding a certain threshold (currently ¥50,000,000). Such report will be due by June 30 each year. You should consult with your personal tax advisor as to whether the reporting obligation applies to you and whether you will be required to include in the report details of any Shares or cash that you hold.

KOREA

NOTIFICATIONS

Exchange Control Information. Korean residents who sell Shares acquired under the Plan and/or receive cash Dividends on the Shares must file a report with a Korean foreign exchange bank if the

proceeds exceed a certain threshold (currently US$5,000 per transaction) and are deposited into a non- Korean bank account. The report is not required if proceeds are deposited into a non-Korean brokerage account. It is your responsibility to ensure compliance with any applicable exchange control reporting obligations.

Foreign Asset/Account Reporting Information. You are required to declare all foreign financial accounts (*e.g.* non-Korean bank accounts, brokerage accounts holding Shares, etc.) to the Korean tax authority and file a report regarding such accounts if the monthly balance of such accounts exceeds a certain threshold. It is your responsibility to comply with this reporting obligation and you should consult your personal tax advisor to ensure compliance with this requirement.

LITHUANIA

NOTIFICATIONS

Foreign Asset/Account Reporting Information. If you (i) hold certain job positions established by the law or (ii) donate to political parties or political campaigners, you must file an Annual Asset Return of the Individual (Family) in Form No. FR0001 with respect to assets held outside of Lithuania (*e.g.*, Shares). If you open an account in a foreign financial institution and annual turnover in the account exceeds a certain threshold (currently €15,000), you must file a foreign account report.

MEXICO

TERMS AND CONDITIONS

Acknowledgement of the Grant. In accepting the Award granted hereunder, you acknowledge that you have received a copy of the Plan and the Program, have reviewed the Plan and the Program and the Agreement, including this Appendix, in their entirety and fully understand and accept all provisions of the Plan, the Program and the Agreement, including this Appendix. You further acknowledge that you have read and specifically and expressly approve the terms and conditions of Section IX of the Agreement, in which the following is clearly described and established:

(1) Your participation in the Plan and the Program do not constitute an acquired right.

(2) The Plan and your participation in the Plan and the Program are offered by Amgen Inc. on a wholly discretionary basis.

(3) Your participation in the Plan and the Program is voluntary.

(4) Amgen Inc. and its Affiliates are not responsible for any decrease in the value of any Shares issued with respect to the Award.

Labor Law Acknowledgement and Policy Statement. In accepting any Award granted hereunder, you expressly recognize that Amgen Inc., with registered offices at One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., is solely responsible for the administration of the Plan and

that your participation in the Plan and acquisition of Shares do not constitute an employment relationship between you and Amgen Inc. since you are participating in the Plan on a wholly commercial basis and your sole employer is Amgen Mexico S.A. de C.V. ("Amgen-Mexico"). Based on the foregoing, you expressly recognize that the Plan and the Program and the benefits that you may derive from participation in the Plan and the Program do not establish any rights between you and your Employer, Amgen-Mexico, and do not form part of the employment conditions and/or benefits provided by Amgen-Mexico and any modification of the Plan or its termination shall not constitute a change or impairment of the terms and conditions of your employment.

You further understand that your participation in the Plan and the Program is as a result of a unilateral and discretionary decision of Amgen Inc.; therefore, Amgen Inc. reserves the absolute right to amend and/or discontinue your participation in the Plan at any time without any liability to you.

Finally, you hereby declare that you do not reserve to yourself any action or right to bring any claim against Amgen Inc. for any compensation or damages regarding any provision of the Plan or the benefits derived under the Plan, and you therefore grant a full and broad release to Amgen Inc., its Affiliates, stockholders, officers, agents or legal representatives with respect to any claim that may arise.

Spanish Translation

Reconocimiento del Otorgamiento. Al aceptar cualquier Otorgamiento de Acciones bajo el presente documento, usted reconoce que ha recibido una copia del Plan y del Programa, que ha revisado el Plan y el Programa, así como también el Apéndice en su totalidad, además que comprende y está de acuerdo con todas las disposiciones tanto del Plan, del Programa y del Otorgamiento, incluyendo este Apéndice. Asimismo, usted reconoce que ha leído y manifiesta específicamente y expresamente la conformidad con los términos y condiciones establecidos en la Sección IX del Acuerdo del Otorgamiento, en los que se establece y describe claramente que:

(1) Su participación en el Plan y en el Programa de ninguna manera constituye un derecho adquirido.

(2) Su participación en Plan y en el Programa son ofrecidos por Amgen Inc. de forma completamente discrecional.

(3) Su participación en el Plan y en el Programa es voluntaria.

(4) Amgen Inc. y sus Afiliados no son responsables de ninguna disminución en el valor de las Acciones Comunes emitidas mediante el Plan.

Reconocimiento de la Ley Laboral y Declaración de Política. Al aceptar cualquier Otorgamiento bajo el presente, usted reconoce expresamente que Amgen Inc., con oficinas registradas localizadas en One Amgen Center Drive, Thousand Oaks, California 91320, U.S.A., es la única responsable de la administración del Plan y que su participación en el mismo y la adquisición de Acciones Comunes no constituyen de ninguna manera una relación laboral entre usted y Amgen Inc., debido a que su

participación en el Plan es únicamente una relación comercial y que su único empleador es Amgen Mexico S.A. de C.V. ("Amgen-Mexico"). Derivado de lo anterior, usted reconoce expresamente que el Plan y el Programa y los beneficios a su favor que pudieran derivar de la participación en el mismo, no establecen ningún derecho entre usted y su empleador, Amgen – México, y no forman parte de las condiciones laborales y/o los beneficios otorgados por Amgen – México, y cualquier modificación del Plan o la terminación del mismo no constituirá un cambio o desmejora de los términos y condiciones de su trabajo.

Asimismo, usted entiende que su participación en el Plan y en el Programa es resultado de la decisión unilateral y discrecional de Amgen Inc., por lo tanto, Amgen Inc. se reserva el derecho absoluto de modificar y/o descontinuar su participación en el Plan en cualquier momento y sin ninguna responsabilidad para usted.

Finalmente, usted manifiesta que no se reserva ninguna acción o derecho que origine una demanda en contra de Amgen Inc., por cualquier compensación o daños y perjuicios, en relación con cualquier disposición del Plan o de los beneficios derivados del mismo, y en consecuencia usted exime amplia y completamente a Amgen Inc. de toda responsabilidad, como así también a sus Afiliadas, accionistas, directores, agentes o representantes legales con respecto a cualquier demanda que pudiera surgir.

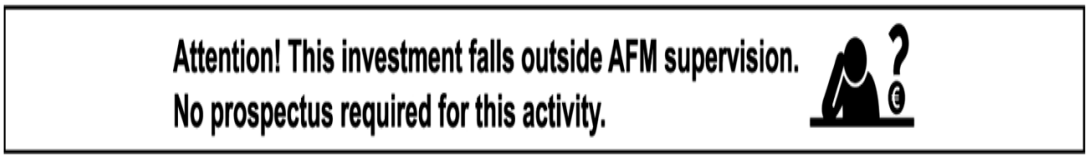
NOTIFICATIONS

Securities Law Information. The Performance Units and the Shares offered under the Plan have not been registered with the National Register of Securities maintained by the Mexican National Banking and Securities Commission and cannot be offered or sold publicly in Mexico. In addition, the Plan, the Agreement and any other document relating to the Performance Units may not be publicly distributed in Mexico. These materials are addressed to you only because of your existing relationship with the Company and your Employer and these materials should not be reproduced or copied in any form. The offer contained in these materials does not constitute a public offering of securities but rather constitutes a private placement of securities addressed specifically to individuals who are present employees of Amgen-Mexico made in accordance with the provisions of the Mexican Securities Market Law, and any rights under such offering shall not be assigned or transferred.

NETHERLANDS

NOTIFICATIONS

Securities Law Information.



NORWAY

NOTIFICATIONS

Foreign Asset/Account Reporting Information. Norwegian residents may be subject to foreign asset reporting as part of their ordinary tax return. Norwegian banks, financial institutions, limited companies etc. must report certain information to the Tax Administration. Such information may then be pre-completed in a Norwegian resident's tax return. However, if the resident has traded, or is the owner of, financial instruments (*e.g.*, Shares) not pre-completed in the tax return, the Norwegian resident must enter this information in Form RF-1159, which is an appendix to the tax return.

Exchange Control Information. In general, Norwegian residents should not be subject to any foreign exchange requirements in connection with their acquisition or sale of Shares under the Plan, except normal reporting requirements to the Norwegian Currency Registry. If any transfer of funds into or out of Norway is made through a Norwegian bank, the bank will make the registration.

POLAND

NOTIFICATIONS

Foreign Asset/Account Reporting Information. Polish residents holding foreign securities (including Shares) and maintaining accounts abroad must file reports with the National Bank of Poland if the aggregate value of cash and securities held in such foreign accounts exceeds a certain threshold (currently PLN 7 million). If required, the reports are due on a quarterly basis by the 20th day following the end of each quarter and must be filed on special forms available on the website of the National Bank of Poland.

Exchange Control Information. In addition, Polish residents are required to transfer funds through a bank account in Poland if the transferred amount in any single transaction exceeds a specified threshold (currently €15,000 (or PLN 15,000 if such transfer of funds is associated with the business activity of a consultant)). You must store all documents connected with any foreign exchange transactions you engage in for a period of five (5) years from the end of the year when such transactions were made. Penalties may apply for failure to comply with exchange control requirements.

PORTUGAL

TERMS AND CONDITIONS

Consent to Receive Information in English. You hereby expressly declare that you have full knowledge of the English language and have read, understood and fully accepted and agreed with the terms and conditions established in the Plan, the Program and Agreement.

Conhecimento da Lingua. *Por meio do presente, eu declaro expressamente que tem pleno conhecimento da língua inglesa e que li, compreendi e livremente aceitei e concordei com os termos e condições estabelecidas no Plano, no Programa e no Acordo.*

PUERTO RICO

There are no country-specific provisions.

ROMANIA

NOTIFICATIONS

Exchange Control Information. Certain transfers of funds may need to be reported to the National Office for Prevention and Control of Money Laundering on specific forms by the relevant bank or financial institution. If you deposit proceeds from the sale of Shares or the receipt of Dividends or Dividend Equivalents in a bank account in Romania, you may be required to provide the Romanian bank assisting with the transaction with appropriate documentation explaining the source of the income. You should consult with a legal advisor to determine whether you will be required to submit such documentation to the Romanian bank.

RUSSIA

NOTIFICATIONS

Foreign Account Report Information. Russian residents maintaining accounts abroad must disclose such accounts with the Russian tax authorities, as follows: (i) file notifications upon opening (or closing or changing bank details) within 30 days, and (ii) file reports on the movement of cash or financial assets on such accounts by June 1 of the following year. Such notifications and reports must be filed on

special forms available on the website of the Russian tax authorities. Russian residents who are absent from Russia for more than 183 days in a year may be relieved from this reporting.

TERMS AND CONDITIONS

Securities Law Information. The sale of Shares acquired under the Plan is not permitted within Russia. The Shares are currently traded on the Nasdaq Global Select Market in the U.S. under the ticker symbol "AMGN," therefore, the Shares may be sold on this exchange.

You understand that the exchange control rules and regulations in Russia and the legal restrictions impacting your participation in the Plan are subject to frequent change. You should consult with your personal legal advisor to determine the applicability of any requirements or restrictions applicable to any Shares or cash received in connection with the Plan.

SINGAPORE

TERMS AND CONDITIONS

Restriction on Sale and Transferability. You hereby agree that any Shares acquired pursuant to the Performance Units will not be offered for sale in Singapore prior to the six (6)-month anniversary of the Grant Date, unless such sale or offer is made pursuant to one or more exemptions under Part XIII Division 1 Subdivision (4) (other than section 280) of the Securities and Futures Act (Chap. 289, 2006 Ed.) ("SFA"), or pursuant to, and in accordance with the conditions of, any other applicable provisions of the SFA.

NOTIFICATIONS

Securities Law Information. The grant of the Performance Units is being made pursuant to the "Qualifying Person" exemption under section 273(1)(f) of the SFA, on which basis it is exempt from the prospectus and registration requirements under the SFA, and is not made with a view to the Performance Units being subsequently offered for sale to any other party. The Plan has not been, and will not be, lodged or registered as a prospectus with the Monetary Authority of Singapore.

Director Notification Requirement. Directors (including alternate, substitute, associate and shadow directors) of a Singapore Affiliate are subject to certain notification requirements under the Singapore Companies Act, regardless of whether they are resident or employed in Singapore. Directors of a Singapore Affiliate must notify the Singapore Affiliate in writing of an interest (*e.g.*, Performance Units, Shares, etc.) in the Company or any related company within two (2) business days of (i) its acquisition or disposal, (ii) any change in a previously disclosed interest (*e.g.,* when the Shares are sold), or (iii) becoming a director.

SLOVAK REPUBLIC

There are no country-specific provisions.

SLOVENIA

NOTIFICATIONS

Foreign Asset/Account Reporting Information. Slovenian residents may be required to report the opening of bank and/or brokerage accounts to tax authorities within eight (8) days of opening such account. You should consult with your personal tax advisor to determine whether this requirement will be applicable to any accounts opened in connection with your participation in the Plan (*e.g.*, your brokerage account with the Company's designated broker).

SPAIN

TERMS AND CONDITIONS

Labor Law Acknowledgement. The following provision supplements Section IX of the Agreement:

By accepting the Award granted hereunder, you consent to participation in the Plan and the Program and acknowledge that you have received a copy of the Plan and the Program.

You understand that the Company has unilaterally, gratuitously and in its sole discretion decided to grant the Award under the Plan and the Program to individuals who may be members of the Board or Employees of the Company or its Affiliates throughout the world. The decision is a limited decision that is entered into upon the express assumption and condition that (i) the Awards granted will not economically or otherwise bind the Company or any of its Affiliates on an ongoing basis, other than as expressly set forth in the applicable Agreement, including this Appendix; (ii) the Awards granted hereunder and any Shares acquired under the Plan shall not be considered a mandatory benefit, salary for any purposes (including severance compensation) or any other right whatsoever; and (iii) any unvested Performance Units will be forfeited immediately upon termination of your employment for any reason, as detailed below. Further, you understand and freely accept that there is no guarantee that any benefit whatsoever shall arise from any gratuitous and discretionary grant of the Award since the future value of the Award and any Shares that may be issued in respect of such Award is unknown and unpredictable. In addition, you understand that the Award granted hereunder would not be made but for the assumptions and conditions referred to above; thus, you understand, acknowledge and freely accept that, should any or all of the assumptions be mistaken or should any of the conditions not be met for any reason, then the grant of the Award or right to the Award shall be null and void.

Further, the vesting of the Performance Units is expressly conditioned your continued and active rendering of service, such that if your employment terminates for any reason whatsoever, the Performance Units may cease vesting immediately, in whole or in part, effective on the date of your termination of employment (unless otherwise specifically provided in Section I of the Agreement). This will be the case, for example, even if (1) you are considered to be unfairly dismissed without good cause (*i.e.*, subject to a "despido improcedente"); (2) you are dismissed for disciplinary or objective reasons or due to a collective dismissal; (3) you terminate service due to a change of work location, duties or any other employment or contractual condition; (4) you terminate service due to a unilateral breach of contract by the Company or an Affiliate; or (5) your employment terminates for any other

reason whatsoever. Consequently, upon termination of your employment for any of the above reasons, you may automatically lose any rights to Performance Units that were not vested on the date of your termination of employment, as described in the Plan and the Agreement.

You acknowledge that you have read and specifically accept the conditions referred to in Section I of the Agreement.

NOTIFICATIONS

Securities Law Information. No "offer of securities to the public," as defined under Spanish law, has taken place or will take place in the Spanish territory. The Agreement (including this Appendix) has not been nor will it be registered with the *Comisión Nacional del Mercado de Valores*, and does not constitute a public offering prospectus.

Exchange Control Information. You will be required to declare electronically to the Bank of Spain any security accounts (including brokerage accounts held abroad), as well as the securities (including Shares acquired under the Plan) held in such accounts if the value of the transactions for all such accounts during the prior year or the balances of such accounts as of December 31 of the prior year exceeds a certain threshold (currently, €1,000,000). Different thresholds and deadlines to file this declaration apply. However, if neither such transactions during the immediately preceding year nor the balances / positions as of December 31 exceed the applicable threshold, no such declaration must be filed unless expressly required by the Bank of Spain. If any of such thresholds were exceeded during the current year, you may be required to file the relevant declaration corresponding to the prior year, however, a summarized form of declaration may be available.

Foreign Asset/Account Reporting Information. To the extent that you hold Shares and/or have bank accounts outside of Spain with a value in excess of €50,000 (for each type of asset) as of December 31 each year, you will be required to report information on such assets in your tax return (tax form 720) for such year. After such Shares and/or accounts are initially reported, the reporting obligation will apply for subsequent years only if the value of any previously-reported Shares or accounts increases by more than €20,000 (for each type of asset) as of each subsequent December 31, or if you sell or otherwise dispose of previously-reported Shares or accounts. If the value of such Shares and/or accounts as of December 31 does not exceed €50,000, a summarized form of declaration may be presented.

SWEDEN

TERMS AND CONDITIONS

Authorization to Withhold. This provision supplements Section III of the Agreement:

Without limiting the Company's and the Employer's authority to satisfy their withholding obligations for Tax Obligations as set forth in the Agreement, in accepting the Performance Units, you authorize the Company to withhold Shares or to sell Shares otherwise issuable to you upon vesting or settlement to satisfy Tax Obligations, regardless of whether the Company and/or Employer have an obligation to

withhold such Tax Obligations, provided that such withholding would not, in the Company's determination, result in adverse accounting consequences to the Company.

SWITZERLAND

NOTIFICATIONS

Securities Law Information. Neither this document nor any other materials relating to the Performance Units (i) constitutes a prospectus according to articles 35 et seq. of the Swiss Federal Act on Financial Services ("FinSA"), (ii) may be publicly distributed or otherwise made publicly available to any person other than an employee of the Company or one of its Subsidiaries in Switzerland or (iii) has been or will be filed with, approved or supervised by any Swiss reviewing body according to article 51 of FinSA or any Swiss regulatory authority, including the Swiss Financial Market Supervisory Authority.

TAIWAN

NOTIFICATIONS

Securities Law Information. Participation in the Plan is available only for select Board members and Employees of the Company and its Affiliates. The grant of Performance Units and participation in the Plan is not a public offer of securities by a Taiwanese company.

Exchange Control Information. You may acquire and remit foreign currency (including proceeds from the sale of Shares or the receipt of Dividends or Dividend Equivalents) up to US$10,000,000 per year without justification. If the transaction amount is TWD500,000 or more in a single transaction, you must submit a Foreign Exchange Transaction Form. If the transaction amount is US$500,000 or more in a single transaction, you must also provide supporting documentation to the satisfaction of the remitting bank.

THAILAND

NOTIFICATIONS

Exchange Control Information. If proceeds from the sale of Shares or the receipt of any Dividends or Dividend Equivalents exceed a certain threshold (currently US$1,000,000), you must (i) immediately repatriate such funds to Thailand and (ii) report the inward remittance to the Bank of Thailand on a Foreign Exchange Transaction Form. In addition, within three hundred and sixty (360) days of repatriation, you must either convert any funds repatriated to Thailand to Thai Baht or deposit the funds in a foreign exchange account with a Thai commercial bank. Any such commercial bank must be duly authorized by the Bank of Thailand to engage in the purchase, exchange and withdrawal of foreign currency.

TÜRKIYE

NOTIFICATIONS

Securities Law Information. The sale of Shares acquired under the Plan is not permitted within Türkiye. The sale of Shares acquired under the Plan must occur outside of Türkiye. The Shares are currently traded on the Nasdaq Global Select Market in the U.S. under the ticker symbol "AMGN" and Shares may be sold on this exchange.

Exchange Control Information. You may be required to engage a Turkish financial intermediary to assist with the sale of Shares acquired under the Plan. To the extent a Turkish financial intermediary is required in connection with the sale of any Shares acquired under the Plan, you are solely responsible for engaging such Turkish financial intermediary. You should consult your personal legal advisor prior to the sale of Shares to ensure compliance with the current requirements.

UNITED ARAB EMIRATES

NOTIFICATIONS

Securities Law Information. Performance Units under the Plan are available only to select Board members and Employees of the Company and its Affiliates and are for the purpose of providing equity incentives. The Plan, the Program and the Agreement are intended for distribution only to such Board members and Employees and must not be delivered to, or relied on by, any other person. You should conduct your own due diligence on the Performance Units offered pursuant to this Agreement. If you do not understand the contents of the Plan and/or the Agreement, you should consult an authorized financial adviser. The Emirates Securities and Commodities Authority and the Dubai Financial Services Authority have no responsibility for reviewing or verifying any documents in connection with the Plan. Further, the Ministry of the Economy and the Dubai Department of Economic Development have not approved the Plan or the Agreement nor taken steps to verify the information set out therein and have no responsibility for such documents.

UNITED KINGDOM

TERMS AND CONDITIONS

Tax Withholding. This provision supplements Section V of the Agreement:

Without limitation to Section V of the Agreement, you agree that you are liable for all Tax Obligations and hereby covenant to pay all such Tax Obligations as and when requested by the Company or your Employer or by HM Revenue and Customs ("HMRC") (or any other tax authority or any other relevant authority). You also agree to indemnify and keep indemnified the Company and your Employer against any taxes that they are required to pay or withhold or have paid or will pay to HMRC (or any other tax authority or any other relevant authority) on your behalf.

Notwithstanding the foregoing, if you are an executive officer or director (as within the meaning of Section 13(k) of the Exchange Act, as amended, from time to time), you understand that you may not be able to indemnify the Company or your Employer for the amount of income tax not collected from or paid by you, as it may be considered a loan. In the event that you are an executive officer or director and income tax is not collected from you within ninety (90) days after the end of the tax year in which the Taxable Event occurs, the amount of any uncollected income tax may constitute an additional benefit to you on which additional income tax and national insurance contributions ("NICs") may be payable. You acknowledge that you are responsible for reporting and paying any income tax due on this additional benefit directly to HMRC under the self-assessment regime and for paying your Employer for the amount of any NICs due on this additional benefit, which the Company or your Employer may obtain from you by any of the means set forth in Section V of the Agreement.

If the maximum applicable withholding rate is used, any over-withheld amount may be credited to you by the Company or your Employer (with no entitlement to the Common Stock equivalent) or if not so credited, you may seek a refund from the local tax authorities.

Joint Election. If you are a resident of the United Kingdom between the Grant Date and the vesting of the Performance Units, as a condition of the Award, you agree to accept any liability for secondary Class 1 National Insurance Contributions (the "Employer NICs") which may be payable by the Company or your Employer with respect to the earning and/or payment of the Performance Units and issuance of Shares in respect of the Performance Units, the assignment or release of the Performance Units for consideration or the receipt of any other benefit in connection with the Performance Units.

Without limitation to the foregoing, you agree to make an election (the "Election"), in the form specified and/or approved for such election by HMRC, that the liability for your Employer NICs payments on any such gains shall be transferred to you to the fullest extent permitted by law. You further agree to execute such other elections as may be required between you and any successor to the Company and/or your Employer. You hereby authorize the Company and your Employer to withhold such Employer NICs by any of the means set forth in Section V of the Agreement.

Failure by you to enter into an Election, withdrawal of approval of the Election by HMRC or a joint revocation of the Election by you and the Company or your Employer, as applicable, shall be grounds for the forfeiture and cancellation of the Performance Units, without any liability to the Company or your Employer.

UNITED STATES

TERMS AND CONDITIONS

Nature of Grant. The following provision replaces Section IX(l) of the Award Agreement:

(l) in the event of termination of your employment (whether or not in breach of local labor laws), your right to receive Performance Units and receive Shares under the Plan and the Program, if any, will terminate effective as of the date that you are no longer actively employed; *provided*, *however*, that such right will be extended by any notice period mandated by law (*e.g.*, the Worker Adjustment and

Retraining Notification Act ("WARN Act") notice period or similar periods pursuant to local law) and any paid administrative leave (as applicable), unless the Company shall provide you with written notice otherwise before the commencement of such notice period or leave. In such event, payment of the Performance Units shall be made in accordance with Section IV; *provided*, *further*, *however*, that notwithstanding the effect of any such extension, subject to Section 4.2 of the Program, in no event will the Performance Units be paid later than the 90th day following the last day of the Performance Period.

Exhibit 10.19.5

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

October 1, 2025

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799
United States
Attention: Corporate Secretary

Re: Waiver of Certain Rights Related to [*]-Targeting Molecules Under the Collaboration Agreement

Dear Sir or Madam:

Reference is made to that certain Collaboration Agreement, dated as of October 31, 2019 (as amended on April 20, 2022 and February 26, 2023, the "Collaboration Agreement"), by and among Amgen Inc. ("Amgen"), BeOne Medicines I GmbH (f/k/a BeiGene Switzerland GmbH) ("BeOne") and, solely with respect to Section 13.6, BeOne Medicines Ltd. (f/k/a BeiGene, Ltd.). Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Collaboration Agreement.

Amgen has notified BeOne that Amgen is undergoing discussions with a potential counterparty ("Counterparty") regarding a [*] combination study with Amgen's IMDELLTRA® and Counterparty's [*] (the "Counterparty [*] Product" and the "Study").

In accordance with Section 15.16 (Waivers and Modifications) of the Collaboration Agreement, this letter serves to document BeOne's and Amgen's agreement that, with respect to the Counterparty [*] Product, the Distracting Program Restrictions under Article IX of the Collaboration Agreement are hereby waived by the Parties in relation to the Study.

Please acknowledge your agreement and consent to the foregoing by counter-signing this letter agreement in the space provided below and returning a copy to us.

[*Signature Page Follows*]

Yours sincerely,
BEONE MEDICINES I GMBH

/s/ Michael Schoen_____
By: Michael Schoen
Title: Managing Director

BEONE MEDICINES LTD.

/s/ Chan Lee_____
By: Chan Lee
Title: SVP, General Counsel and Corporate Secretary

Acknowledged and agreed:
AMGEN INC.

/s/ Rachna Khosla_____
By: Rachna Khosla
Title: SVP, Business Development

BeOne Medicines I GmbH
Aeschengraben 27
4051 Basel, Switzerland
BeOneMedicines.com

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

THIRD AMENDMENT TO COLLABORATION AGREEMENT

This Third Amendment to the Collaboration Agreement ("Amendment") is entered into as of October 31, 2025 (the "Third Amendment Effective Date") by and among Amgen Inc., a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799 ("Amgen"), BeOne Medicines I GmbH (f/k/a BeiGene Switzerland GmbH), a Swiss corporation with a principal place of business at Aeschengraben 27, 4051 Basel, Switzerland ("BeOne"), and BeOne Medicines Ltd. (f/k/a BeiGene, Ltd.), a Swiss corporation with a principal place of business at Aeschengraben 27, 4051 Basel, Switzerland ("BeOne Parent"). BeOne and Amgen are sometimes referred to herein individually as a "Party" and collectively as the "Parties." This Amendment amends that certain Collaboration Agreement, entered into as of October 31, 2019 (as amended from time to time, the "Agreement"), by and between Amgen and BeOne and, solely with respect to Section 13.6 thereof, BeOne Parent. Capitalized terms used but not defined herein have the meanings given to them in the Agreement.

RECITALS

WHEREAS, pursuant to the Agreement, Amgen and BeOne collaborate on the commercialization of certain Products (as defined in the Agreement) in the Collaboration Territory (as defined in the Agreement) and the global development funding and clinical development and commercialization of certain clinical-stage Pipeline Products in the Collaboration Territory; and

WHEREAS, the Parties desire to enter into this Amendment, upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, the Parties, intending to be legally bound hereby, do agree as follows:

AGREEMENT

1. Amendments to Party Names.

   a. All references in the Agreement to "BeiGene Switzerland GmbH" are hereby amended to "BeOne Medicines I GmbH."

   b. All references in the Agreement to "BeiGene, Ltd." are hereby amended to "BeOne Medicines Ltd."

   c. All references in the Agreement to "BeiGene" are hereby amended to "BeOne."

d. All references in the Agreement to "BeiGene Parent" are hereby amended to "BeOne Parent."

2. Amendment to Select Definitions.

a. The defined term "Bo Ao Product" is hereby amended and restated in its entirety as follows:

"Bo Ao Product" means any Product which is approved by the JSC for importation into Hainan Bo Ao prior to Regulatory Approval of such Product."

b. The defined term "Early Access Product" is hereby amended and restated in its entirety as follows:

"Early Access Product" means each of a Bo Ao Product or a Tianjin Product."

c. The defined term "Tianjin Product" is hereby amended and restated in its entirety as follows:

"Tianjin Product" means any Product which is approved by the JSC for importation into Tianjin prior to Regulatory Approval of such Product."

d. The defined term "Tianjin Support Costs" is hereby amended and restated in its entirety as follows:

"Tianjin Support Costs" means all actual and, if reasonably practicable, [*]."

3. The first paragraph of Section 7.2.8 of the Agreement is hereby amended and restated in its entirety as follows:

"Notwithstanding anything to the contrary in this Agreement, the Parties desire to initiate the Profit-sharing arrangement set forth in Section 7.2 for any Bo Ao Product, Tianjin Product or Early Access Product prior to applicable Initiation Date, subject to the following terms and conditions:"

4. Supply Price Schedule. The Supply Price Schedule is hereby amended to include the following as a new row:

[*]	[*]%

5. Miscellaneous.

a. Except as specifically amended above, the Agreement shall continue to be in full force and effect.

b. This Amendment and its effect are subject to and shall be construed and enforced in accordance with the laws of the State of New York, U.S.A.

c. This Amendment may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts will be deemed an original, will be construed together and will constitute one and the same instrument. Signature pages of this Amendment may be exchanged by facsimile or other electronic means without affecting the validity thereof.

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Third Amendment Effective Date.

AMGEN INC.

/s/ Rachna Khosla
Name: Rachna Khosla
Title: Senior Vice President, Business Development

BEONE MEDICINES I GMBH

/s/ Michael Schoen
Name: Michael Schoen
Title: Managing Director

BEONE MEDICINES LTD.

/s/ Chan Lee
Name: Chan Lee
Title: Senior Vice President, General Counsel & Corporate Secretary

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

FOURTH AMENDMENT TO COLLABORATION AGREEMENT

This Fourth Amendment to the Collaboration Agreement ("Amendment") is entered into as of November 11, 2025 (the "Fourth Amendment Effective Date") by and among Amgen Inc., a Delaware corporation having its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799 ("Amgen"), BeOne Medicines I GmbH (f/k/a BeiGene Switzerland GmbH), a Swiss corporation with a principal place of business at Aeschengraben 27, 4051 Basel, Switzerland ("BeOne"), and BeOne Medicines Ltd. (f/k/a BeiGene, Ltd.), a Swiss corporation with a principal place of business at Aeschengraben 27, 4051 Basel, Switzerland ("BeOne Parent"). BeOne and Amgen are sometimes referred to herein individually as a "Party" and collectively as the "Parties." This Amendment amends that certain Collaboration Agreement, entered into as of October 31, 2019 (as amended from time to time, the "Agreement"), by and between Amgen and BeOne and, solely with respect to Section 13.6 thereof, BeOne Parent. Capitalized terms used but not defined herein have the meanings given to them in the Agreement.

RECITALS

WHEREAS, pursuant to the Agreement, Amgen and BeOne collaborate on the commercialization of certain Products (as defined in the Agreement) in the Collaboration Territory (as defined in the Agreement) and the global development funding and clinical development and commercialization of certain clinical-stage Pipeline Products in the Collaboration Territory; and

WHEREAS, the Parties desire to enter into this Amendment, upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, the Parties, intending to be legally bound hereby, do agree as follows:

AGREEMENT

1. Amendment to Section 5.1.5(a) (Retained In-Line Product) of the Agreement. Section 5.1.5(a) of the Agreement is hereby amended and restated in its entirety as follows:

"BeOne shall retain [*] in the Collaboration Territory for so long as such In-Line Product is sold in the Collaboration Territory (each, a "Retained In-Line Product")."

2. Amendment to Section 7.2.1 (BeOne Costs). Section 7.2.1 of the Agreement is hereby amended and restated in its entirety as follows:

""BeOne Costs. Within [*] after the end of each calendar quarter, BeOne will provide to Amgen a final report of its Commercialization and Related Costs, on a Product-by-

Product basis, incurred by BeOne or its Affiliates in accordance with this Agreement (collectively, "BeOne Costs") in such quarter. BeOne will initially incur the portion of the Commercialization and Related Costs attributed to its activities hereunder. In addition to the annual Commercialization Budget approved hereunder, prior to the end of each calendar year, BeOne will provide Amgen with a nonbinding estimate of its Commercialization and Related Costs for the [*] period [*] following the year covered by such approved budgets; *provided* that the Parties will review and discuss such estimated Costs at the JSC. Notwithstanding the foregoing, BeOne's shared portion of the Commercialization and Related Costs incurred in performing any Clinical Studies conducted after Regulatory Approval for In-Line Products in the Collaboration Territory shall be subject to an annual maximum of [*] during each [*] period following the Effective Date and until January 1, 2026 subject to an aggregate maximum of [*]. Within [*] after the end of each calendar quarter, BeOne will provide Amgen with a report of BeOne's product-level profit & loss statements for such calendar quarter, which report will contain a detailed and itemized calculation of Net Revenues for each Product during such calendar quarter. Additionally, within [*] after the end of each calendar quarter, BeOne will provide Amgen with a report of any Recoveries for such calendar quarter.""

3. Amendment to Section 7.10.1 (Pipeline ROW Royalties).

The table in Section 7.10.1(a) is hereby amended and restated in its entirety as follows:

Aggregate Annual Net Revenues of Pipeline Products (excluding AMG 510)	Royalty Rate
For that portion of aggregate annual Net Revenues of Pipeline Products in the ROW less than or equal to [*] U.S. Dollars (US$[*])	[*]%*
For that portion of aggregate annual Net Revenues of Pipeline Products in the ROW greater than [*] U.S. Dollars (US$[*]) and less than or equal to [*] U.S. Dollars (US$[*])	[*]%*
For that portion of aggregate annual Net Revenues of Pipeline Products in the ROW greater than [*] U.S. Dollars (US$[*]) and less than or equal to [*] U.S. Dollars (US$[*])	[*]%*
For that portion of aggregate annual Net Revenues of Pipeline Products in the ROW greater than [*] Dollars (US$[*])	[*]%*
*On and after January 1, 2026, the portion of aggregate annual Net Revenues of Pipeline Products attributed to Net Revenues of AMG 757 (also known as tarlatamab or IMDELLTRA®) for any Royalty Rate tier will be paid at the specified Royalty Rate for such tier reduced by [*]% (specifically [*]). If aggregate annual Net Revenues include Net Revenues from any Pipeline Products other than AMG 757, Net Revenues for each Pipeline Product, including AMG 757, will be distributed proportionately (based on the percentage of Net Revenues attributable to each applicable Pipeline Product) across each Royalty Rate tier. For example, if in a particular calendar year, sales of AMG 757 were $[*] and sales of other Pipeline Products were $[*], then the percentage applicable to AMG 757 would be [*]% and the percentage applicable to the other Pipeline Products would be [*]%. So, total royalties due for that year would be [*]. Quarterly proportions will be determined based on the cumulative year-to-date Net Revenues for each applicable Pipeline Product. Any adjustments to previous quarters resulting from changes in these cumulative proportions will be applied in the current quarter.	

4. Miscellaneous.

a. Except as specifically amended above, the Agreement shall continue to be in full force and effect.

b. This Amendment and its effect are subject to and shall be construed and enforced in accordance with the laws of the State of New York, U.S.A.

c. This Amendment may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts will be deemed an original, will be construed together and will constitute one and the same instrument. Signature pages of this Amendment may be exchanged by facsimile or other electronic means without affecting the validity thereof.

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Fourth Amendment Effective Date.

AMGEN INC.

/s/ Robert A. Bradway
Name: Robert A. Bradway
Title: Chairman of the Board, President and
Chief Executive Officer

BEONE MEDICINES I GMBH

/s/ Michael Schoen
Name: Michael Schoen
Title: Managing Director

BEONE MEDICINES LTD.

/s/ Chan Lee
Name: Chan Lee
Title: Senior Vice President, General Counsel & Corporate Secretary

AMGEN INC.

The following is a list of subsidiaries of the Company as of December 31, 2025, omitting some subsidiaries which, considered in the aggregate, would not constitute a significant subsidiary.

SUBSIDIARY (Name under which subsidiary does business)	STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION
Amgen (Europe) GmbH	Switzerland
Amgen Canada Inc.	Canada
Amgen Fremont Inc.	Delaware
Amgen Global Finance B.V.	Netherlands
Amgen Global Technology Unlimited Company	Ireland
Amgen GmbH Germany	Germany
Amgen Ilaç Ticaret Limited Şirketi	Türkiye
Amgen International Holdings Inc.	Delaware
Amgen K.K.	Japan
Amgen K-A, Inc.	Delaware
Amgen Manufacturing Limited LLC	Puerto Rico
Amgen Rare Disease Holdings Inc.	Delaware
Amgen Research (Munich) GmbH	Germany
Amgen S.A.S.	France
Amgen S.p.A.	Italy
Amgen SF, LLC	Delaware
Amgen Singapore Holding Pte. Ltd.	Singapore
Amgen Singapore Manufacturing Pte. Ltd.	Singapore
Amgen Technology (Ireland) Unlimited Company	Ireland
Amgen Technology, Limited	Bermuda
Amgen USA Inc.	Delaware
Amgen Worldwide Holdings B.V.	Netherlands
Amgen, S.A.	Spain
BioVex LLC	Delaware
ChemoCentryx, Inc.	Delaware
Five Prime Therapeutics, Inc.	Delaware
Horizon Therapeutics Finance S.à.r.l	Luxembourg
Horizon Therapeutics Holdings Limited	Ireland
Horizon Therapeutics Ireland DAC	Ireland
Horizon Therapeutics Limited	Ireland
Horizon Therapeutics Services LLC	Delaware
Horizon Therapeutics U.S. Holding LLC	Delaware
Horizon Therapeutics USA, Inc.	Delaware
HZNP Finance Limited	Bermuda
Immunex Corporation	Washington
Immunex Rhode Island Corporation	Delaware
Onyx Pharmaceuticals, Inc.	Delaware
Onyx Therapeutics, Inc.	Delaware
Pillartree Limited	Ireland
Saga Investments Coöperatief U.A.	Netherlands
TeneoBio, Inc.	Delaware
Viela Bio, Inc.	Delaware

CERTIFICATIONS

I, Robert A. Bradway, Chairman of the Board, Chief Executive Officer and President of Amgen Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Amgen Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and

   (d) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 13, 2026

/s/ ROBERT A. BRADWAY
Robert A. Bradway
Chairman of the Board,
Chief Executive Officer and President

CERTIFICATIONS

I, Peter H. Griffith, Executive Vice President and Chief Financial Officer of Amgen Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Amgen Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and

   (d) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 13, 2026

/s/ PETER H. GRIFFITH
Peter H. Griffith
Executive Vice President and Chief Financial Officer

Certification of Chief Executive Officer

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Amgen Inc. (the "Company") hereby certifies that:

(i) the accompanying Annual Report on Form 10-K of the Company for the period ended December 31, 2025 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 13, 2026

/s/ ROBERT A. BRADWAY

Robert A. Bradway
Chairman of the Board,
Chief Executive Officer and President

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Amgen Inc. and will be retained by Amgen Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Certification of Chief Financial Officer

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Amgen Inc. (the "Company") hereby certifies that:

(i) the accompanying Annual Report on Form 10-K of the Company for the period ended December 31, 2025 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 13, 2026

/s/ PETER H. GRIFFITH
Peter H. Griffith
Executive Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 ("Section 906"), or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Amgen Inc. and will be retained by Amgen Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

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November 2017

Follow the Dollar

Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines

Case
1:25-cv-3452-DDD-STV

Exhibit
31

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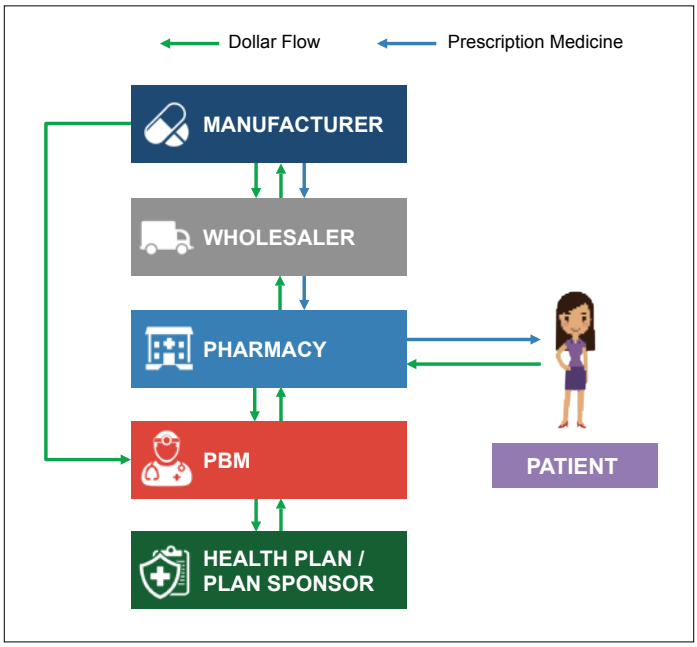
Introduction

Over the past year, increased media and policymaker focus on the price of medicines has led to anger and frustration targeted at pharmaceutical manufacturers, pharmacy benefit managers (PBMs), and health plans. Drug pricing is a complex and often confusing issue, shaped by a pharmaceutical distribution and payment system that involves multiple transactions among numerous stakeholders. A better understanding of the players involved in the pharmaceutical supply chain, and the role each plays in determining what patients utlimately pay for their prescription medicines, can help consumers and policymakers find answers to their questions and concerns about cost and access to medicines.

While there has been significant public discussion about the prices of prescription medicines, it is rarely clear what price is being discussed. As this paper shows, there is no one price for a medicine, as prices paid by wholesalers, pharmacies, PBMs, and health plan sponsors all vary and are determined by negotiations between stakeholders, each with varying degrees of negotiating power. For example, large PBMs that negotiate on behalf of health plan sponsors and manage benefits for covering tens of millions of patients are able to leverage their market power to obtain substantial discounts and rebates on brand medicines.

In 2015, more than one-third of a brand medicine's list price was rebated back to health plans or the government or kept by other stakeholders.

As the supply chain has consolidated and competition among brand medicines has intensified over the past 5 to 10 years, privately negotiated rebates and discounts on brand medicines have also risen sharply. In 2015, more than one-third of a brand medicine's list price was rebated back to health plans or the government or kept by other stakeholders.[1] Continued growth in rebates and discounts—which



now exceed $100 billion each year[1]—has kept payers' prices for brand medicines climbing at modest rates, despite more rapid growth in publicly reported list prices.

After accounting for all discounts, prices for brand medicines have grown at or more slowly than historical rates, yet many patients have experienced rapidly increasing out-of-pocket costs. Over the past 10 years, patient cost-sharing has risen substantially faster than health plan costs. For workers with employer-sponsored health insurance, out-of-pocket spending for deductible and coinsurance payments increased by 230% and 89%, respectively, compared to a 56% increase in payments by health plans.[2]

One reason that it seems as if the costs of medicines are going up dramatically is because discounts and rebates provided by brand manufacturers do not flow directly to the patients taking the medicine. Large deductibles and prescriptions that require coinsurance pose particular challenges, as these types of cost-sharing are typically based on a medicine's full, undiscounted price. In 2015, cost-sharing for nearly one-fifth of brand medications filled in the

commercial market was based on the undiscounted list price, accounting for more than half of patient out-of-pocket spending on brand medicines.[3]

In 2015, cost-sharing for nearly one-fifth of brand medications filled in the commercial market was based on the undiscounted list price, accounting for more than half of patient out-of-pocket spending on brand medicines.[3]

In most cases, negotiated savings flow back to employers and health plans, and rebates are used to reduce premiums. But in recent years, plan sponsors have raised doubts about this process and whether incentives are appropriately aligned across all stakeholders. Although PBMs say they prefer lower list prices, as this paper shows, in many cases, the system creates incentives for PBMs to prefer medicines with higher list prices and higher rebates. As a result, some industry observers and government agencies have questioned whether insurers and PBMs are more focused on the size of rebates than on achieving the lowest possible costs and best outcomes for patients.[3]

The financial arrangements among stakeholders purchasing brand medicines have evolved significantly in the last decade. Transformation has been driven both by growing market consolidation and integration of the roles of PBMs, pharmacies, and wholesalers and by the need to meet new challenges related to storage, handling, administration, and insurance requirements for new medicines. As the system has evolved, the variety and level of administrative and service fees charged by supply chain entities have also increased.

This paper provides a high-level explanation of the financial flows that occur as brand medicines move through the supply chain for retail, mail-order, and specialty drugs. Information on the discounts, rebates, and fees privately negotiated between stakeholders was gathered from a combination of published materials and key informant interviews with industry experts. Because the vast majority of prescriptions are reimbursed under an insurer's pharmacy benefit, we focus on the distribution and financial arrangements for these medicines. The distribution and payment system for generic medicines varies significantly from those for brand medicines and is beyond the scope of this paper.

To help demonstrate the way the system works, we provide several illustrative examples of the financial flows that occur as medicines move along the supply chain. Because payment terms are determined through confidential, private negotiations, the terms of individual contracts are highly variable and may differ from the hypothetical examples presented here.

From the Factory to the Pharmacy

Before a patient can go to the pharmacy (or mailbox) to pick up their prescription, the medicine must make its way from the pharmaceutical manufacturer to the pharmacy.

Each year, nearly 6 billion prescriptions are filled in the United States (US), of which nearly 500 million are for brand medicines.[4] To deliver medicines efficiently to 60,000 pharmacies across the country, manufacturers contract with ***wholesale distributors (wholesalers)***.

- **Wholesale distributors (wholesalers)** take physical possession of prescription medicines once they have been shipped from the manufacturer.
- Wholesalers typically earn a distribution service fee based on a percentage of a medicine's purchase price.
- The wholesaler market is highly consolidated. The 3 largest pharmaceutical wholesalers—McKesson, AmerisourceBergen, and Cardinal Health—account for an estimated 85% to 90% of the market.[5]

Wholesalers serve as the connection between manufacturers and pharmacies. They typically purchase medicines from manufacturers at a price known as the wholesale acquisition cost (WAC). This price is the "list price" of a brand medicine. WAC is the price manufacturers charge to wholesalers or other direct purchasers before any discounts, rebates, or other price reductions are applied.

In return for a wholesaler's distribution services, manufacturers pay wholesalers a distribution service fee. This fee is commonly based on a percentage of the list price (WAC) and is provided in exchange for financial management, inventory management, distribution service, and data processing. Contracts between manufacturers and wholesalers may also include bulk-purchasing discounts and discounts for prompt payment. In total, these fees, discounts, and rebates are negotiated individually between manufacturers and wholesalers and can vary as a percentage of WAC.

Retail and mail-order pharmacies contract with wholesalers to stock their pharmacies with prescription medicines. Pharmacies typically purchase medicines from the wholesaler at a contracted discount off the WAC, and this rate can and does vary based on the size and purchasing power of the pharmacy. Contracts between wholesalers and pharmacies facilitate timely and full payment for product purchases and require pharmacies to meet other contractual obligations in exchange for this discount.

There is no standard definition for "specialty medicines." Many stakeholders define specialty medicines as those that:

- Involve complex treatment regimens, monitoring of side effects, assistance with medication administration, frequent dosing adjustments, and patient follow-up
- Involve special handling (eg, cold chain)
- Are biologics and are delivered to the patient via injection or infusion
- Target chronic or rare diseases with smaller patient populations than traditional medicines
- Exceed a certain price threshold (eg, Medicare Part D defines specialty-tier drugs as costing $670 or more per month)

The distribution and payment flow for ***specialty medicines*** in the outpatient setting can vary from the process described above, as these medicines are often not stocked at retail pharmacies. Instead, because some medicines have special requirements for storage and handling or because utilization needs to be closely managed, patients are more likely to receive specialty medicines from ***specialty pharmacy providers (SPPs)***.

SPPs, which almost exclusively manage specialty medicines, began to play a much larger role in the distribution system over the past decade. Payers often set up a network of SPPs to provide specialty medicines to patients and require them to fill prescriptions at participating SPPs.

Manufacturers may also limit their product's distribution to select SPP network participants for several reasons, such as when only a small population of patients uses a particular medicine (making distribution across broad networks difficult, given the limited supply) or when additional safety monitoring is required by the Food and Drug Administration (FDA) (eg, a Risk Evaluation and Mitigation Strategy [REMS]).[6]

Like retail pharmacies, SPPs typically purchase specialty medicines from wholesalers at a discounted rate off the list price and may be required to pay network access and other fees to PBMs. SPPs also typically charge manufacturers data-processing and administrative fees.

Today, the largest SPPs are owned or affiliated with a PBM, as shown in ***Table 1***.

Table 1. Top Specialty Pharmacies in the US in 2016[7]

Specialty Pharmacy Name	Parent Organization	Share of US Specialty Revenues
CVS Specialty	CVS Health (PBM)	28%
Accredo	Express Scripts (PBM)	19%
AllianceRx Walgreens Prime	Walgreens Boots Alliance/Prime Therapeutics (PBM)	13%
BriovaRx	Optum Rx (PBM)	7%
Diplomat Pharmacy	Diplomat Pharmacy	4%
	TOTAL	**71%**

Who Pays Pharmacies?

To receive compensation for the prescriptions they dispense, pharmacies submit claims to PBMs and are reimbursed based on a negotiated rate. Although the terms of these private negotiations vary, the basis for these negotiations is typically not the WAC, but the average wholesale price (AWP). The AWP is often used as the basis for these negotiations because the underlying data are continuously updated and publicly available.[a]

The pharmacy reimbursement rate is usually a discount from AWP plus a dispensing fee minus any patient cost-sharing collected by the pharmacy.

[a] As typically calculated for brand medicines, the AWP is 20% higher than the WAC.

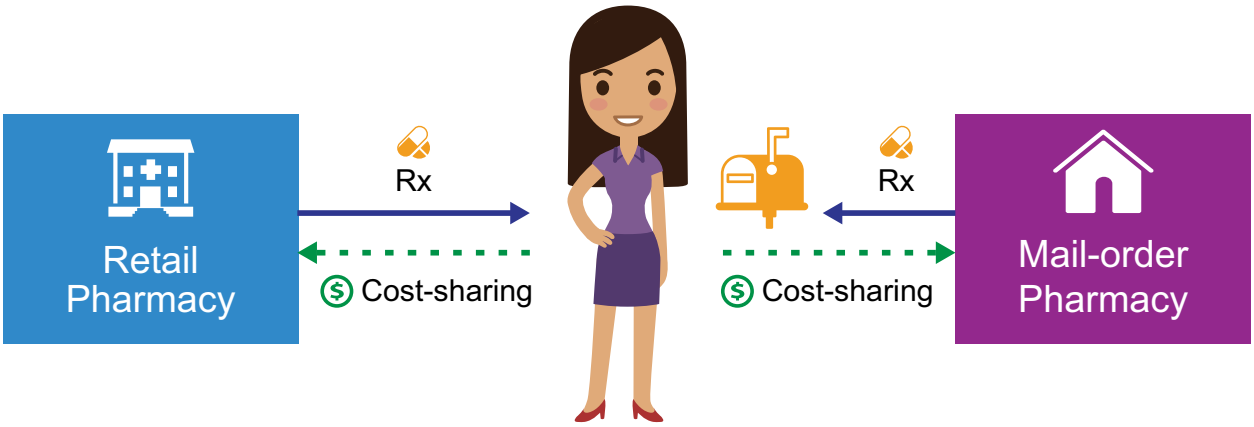
Patient Experience: Understanding Out-of-Pocket Costs

How much a patient pays for a prescription is determined by their insurance coverage. When a patient drops off their prescription, the pharmacy contacts a patient's health plan to obtain certain information on the patient's pharmacy benefits, such as whether the medicine is covered by their plan and what their share of the cost will be. The cost-sharing amount paid to the pharmacy can be any one of the following:

Full, undiscounted price of the medicine, if they haven't met their deductible (ie, a set amount the patient must pay out of pocket each year before their insurance begins paying for their care)[b]

Copayment: A fixed dollar amount for each prescription

Coinsurance: A percentage of the medicine's full, undiscounted price (eg, 20%); in some cases, coinsurance may be capped at a certain amount (eg, $200)



Health plans usually outsource the management of outpatient pharmacy benefits to ***PBMs***, which use a variety of tools to manage drug spending for their health plan clients.

The flow of rebates and discounts is different for prescription medicines than for medical services. Physician and hospital visits, lab tests, and other services are typically billed to patients at prices negotiated between the health plan and provider, as spelled out in the patient's explanation of benefits. The patient thus sees the benefit of that negotiation as soon as they receive their bill.

- **PBMs** contract with manufacturers to **negotiate discounts and rebates** that can benefit their clients. They also negotiate network and administrative fees with pharmacies.
- PBMs offer a range of administrative (eg, enrollment, marketing), clinical (eg, pharmacy and therapeutics committee, appeals support), and other business services to their customers.
- The 3 largest PBMs are estimated to manage prescription drug benefits for about 70% of the market.[8]

[b] Patients without insurance also face the full undiscounted price of the medicine.

For medicines, savings negotiated between manufacturers and PBMs are generally not shared with patients at the time that they fill a prescription. Plan sponsors often use the rebates and discounts they receive to help reduce plan costs or premiums, though they are not required to do so (except in Medicare Part D). That means patients whose cost-sharing is tied to the price of a medicine (ie, patients with coinsurance and those who fill a prescription before meeting their deductible) are typically charged based on the undiscounted list price, even though the PBM may have negotiated a rebate with the manufacturer that significantly lowered the medicine's final net price.

Sometimes a patient's cost-sharing amount may exceed the price the health plan actually pays for a medicine or exceed what the patient would pay at the pharmacy counter without using insurance (ie, by paying in cash). Language in PBM contracts may discourage or prohibit pharmacists from informing insured patients about the lower cash price, at the risk of the pharmacy being excluded from the PBM's network.[9,10]

The Financial Back-end: Understanding Discounts and Rebates

Once a patient receives a medication, the physical journey of that medicine through the pharmaceutical distribution system is complete. The funding flow, however, is not. The funding mechanisms described so far—including payments based on WAC or AWP and cost-sharing payments made by patients—can be said to occur upfront, in the sense that the payment amount is known at the time that the medication is purchased. On the back-end, negotiated rebates, which are typically applied retroactively, after the patient has taken possession of the medication, play a larger role.

Similar to the role of wholesalers in facilitating the distribution of medicines from manufacturers to pharmacies, PBMs play a key role in negotiations among various stakeholders along the supply chain.[c] In exchange for their services, which include managing formularies, processing claims, and negotiating discounts and rebates, PBMs typically retain a percentage of the discounts and rebates paid by manufacturers and/or are paid a fee by health plans.

The PBM industry is highly consolidated. About 70% of all prescription claims are processed by 3 PBMs: Express Scripts, the Caremark business of CVS Health, and the OptumRx business of UnitedHealth.[8] In contrast, in 2011, the top 3 PBMs accounted for just under half of the market.[11] These 3 PBMs have also become more vertically integrated with other parts of the supply chain:

All 3 own large mail-order pharmacies and 3 of the 4 largest specialty pharmacies in the US market

With more than 80 million covered lives, Express Scripts is not only the largest PBM—it is also the third-largest pharmacy in the US as measured by prescription revenues

OptumRx is owned by UnitedHealth, a large health insurer

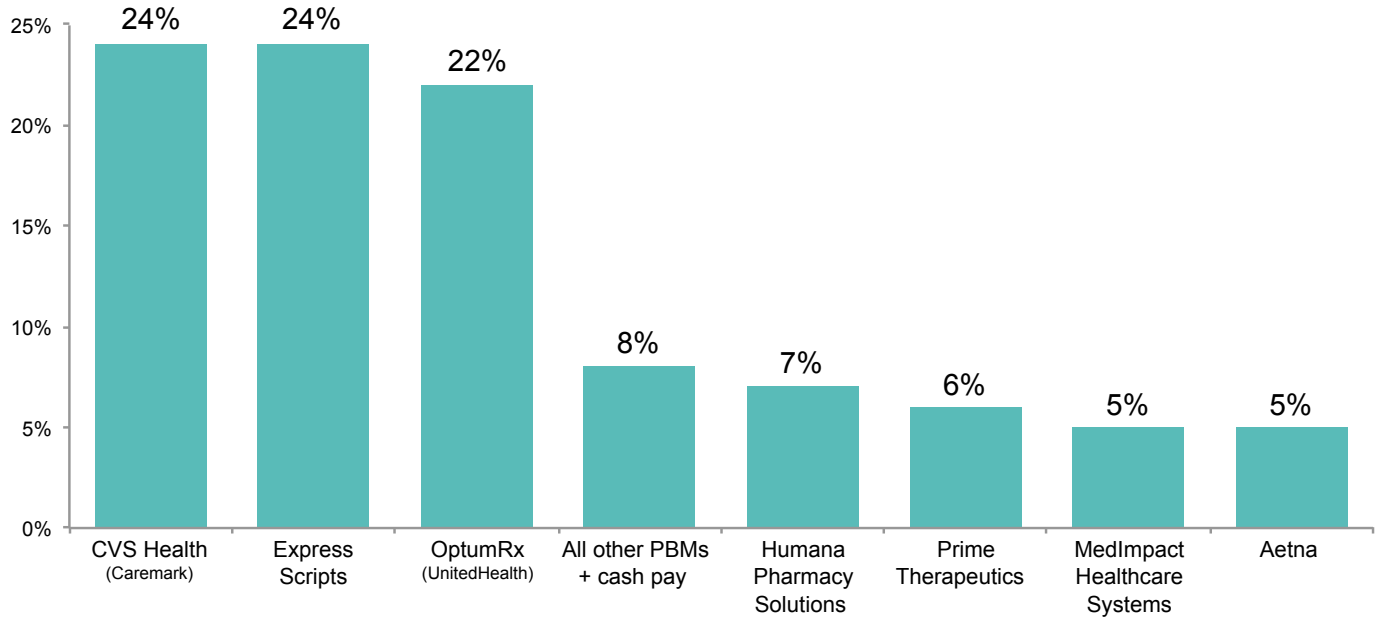
CVS Health owns the largest pharmacy chain nationwide, with more than 9,600 retail pharmacies and $60 billion in annual prescription sales[12]

Negotiation of Prices by PBMs and Manufacturers

PBMs work with insurers to design pharmacy benefits on behalf of their health plan and employer clients. Because PBMs often design formularies for clients, they have significant influence over which medications are covered and how much patients have to pay out of pocket for their prescriptions. In order to increase patients' access to their medicines, pharmaceutical manufacturers may negotiate rebates with PBMs in exchange for a medicine's placement on a lower cost-sharing tier or to avoid restrictions on utilization. The sheer volume of prescription claims managed by large PBMs (***Figure 1***) provides them with significant leverage in these negotiations.

[c] Unlike a wholesaler, a PBM does not take physical possession of a medication (unless the PBM owns a mail-order or specialty pharmacy, in which case they do).

Figure 1. Total Prescription Claims Managed, by PBM, 2016[13]



Total prescription claims include claims at a PBM's network for pharmacies, including prescriptions filled by a PBM's mail-order and specialty pharmacies. Total may not add up to 100 due to rounding.
Source: Pembroke. Consulting estimates.

Rebates negotiated between manufacturers and PBMs are typically calculated as a percentage of the list price. Additional rebates may also be paid if the total number of prescriptions dispensed, relative to other medicines in the therapeutic class, exceeds a predetermined threshold. These market-share rebates are determined retroactively, based on utilization data submitted to the manufacturer from the PBM. Increasingly, PBMs also negotiate price protection provisions with manufacturers as a standard feature of contracts.[14] Under these arrangements, manufacturer price increases in excess of predetermined thresholds result in increased rebates to the PBM.[15]

Manufacturers pay rebates directly to PBMs, which pass them on, in whole or in part, to health plans or employers according to the terms of the client's agreement with the PBM. In addition to rebates, PBMs often require manufacturers to pay administrative service fees for administering, invoicing, and collecting rebate payments. These administrative fees are intended to reimburse the PBM for services provided to the manufacturer and are not generally passed on to the PBM's client. In recent years, however, such fees have increased rapidly, and large employers and health plans have begun to negotiate for a share of the fees to be passed through.[16]

Contracting Between PBMs, Health Plans, and Employers

Services offered by a PBM can include establishment of a community retail pharmacy network, mail-order capabilities, rebate negotiations with manufacturers, formulary development, utilization management, claims adjudication, and eligibility determination. A large health plan with the capacity to perform many of these services internally may contract with a PBM just for claims adjudication services, paying the PBM for those services alone.[17] However, a smaller health plan or an employer directly contracting for PBM services would not likely have such internal capabilities and would pay the PBM a higher fee to provide a broader range of services.

Contractual arrangements between PBMs and plan sponsors include:

Terms of reimbursement for prescription medicines

Total amount of rebates that must be passed through to the health plan or employer

Type of administrative service fees to be paid to the PBM

Health plan sponsors use 2 primary models when contracting with a PBM. The first is a ***spread-pricing model***. With spread pricing, plan sponsors compensate the PBM by permitting the PBM to retain differences, or spreads, between the amount that a PBM charges to a plan sponsor and the amount that the PBM pays to the pharmacy that dispenses the drug to a consumer. Under this model, the amount paid by the plan to the PBM for a prescription can be greater than the amount paid by the PBM to the pharmacy, with the difference retained as revenue by the PBM. An alternative contracting approach is known as a ***pass-through pricing model***. This contracting approach offers additional transparency, as it ensures that the PBM will pass through the price they pay for the medications and earn a negotiated administrative fee.[18]

Health plan sponsors use 2 primary models when contracting with a PBM:

- Spread-pricing model
- Pass-through pricing model

The service fees received by the PBM may vary depending on what share of rebates and fees are passed through to the plan sponsor. For example, while PBMs typically retain an average of 10% to 15% of the rebates they negotiate, some clients choose to have the PBM pass back all of the rebates in exchange for higher flat fees.[19] In the case of smaller employers, who may not have the same level of negotiating sophistication as large employers or health plans, the PBM may retain a greater share of the rebate.[20]

As in any market, some plan sponors are able to negotiate more favorable rates than others. Employer benefit consultants help employer-sponsored health plans negotiate with PBMs for better deals, though asymmetry in information about the level of available discounts often makes it challenging for these plans to compare bids for PBM services effectively.[21] For example, the lack of standardization in the definitions used in PBM contracts (eg, what constitutes a brand vs a generic drug) may appear to be a technical nuance, yet the rebate retained by the PBM may be significantly higher depending on how a medicine is classified.[22] PBMs also may classify fees as separate from rebates, allowing them to retain these payments rather than passing them along to health plans and employers.[22]

With the growing number and scale of administrative and service fees, it is increasingly complex for plan sponsors to assess whether such fees are being passed through to reduce final plan costs or if they may even contribute indirectly to increasing plan costs. The National Pharmaceutical Council (NPC) recently conducted a study of employers' perceptions of the overall value they receive from PBMs. Almost two-thirds (63%) of surveyed employers felt that PBMs lacked transparency in how they make money, and 49% felt that rebates contributed to misaligned incentives that put PBMs' business interests before those of their clients or patients.[22]

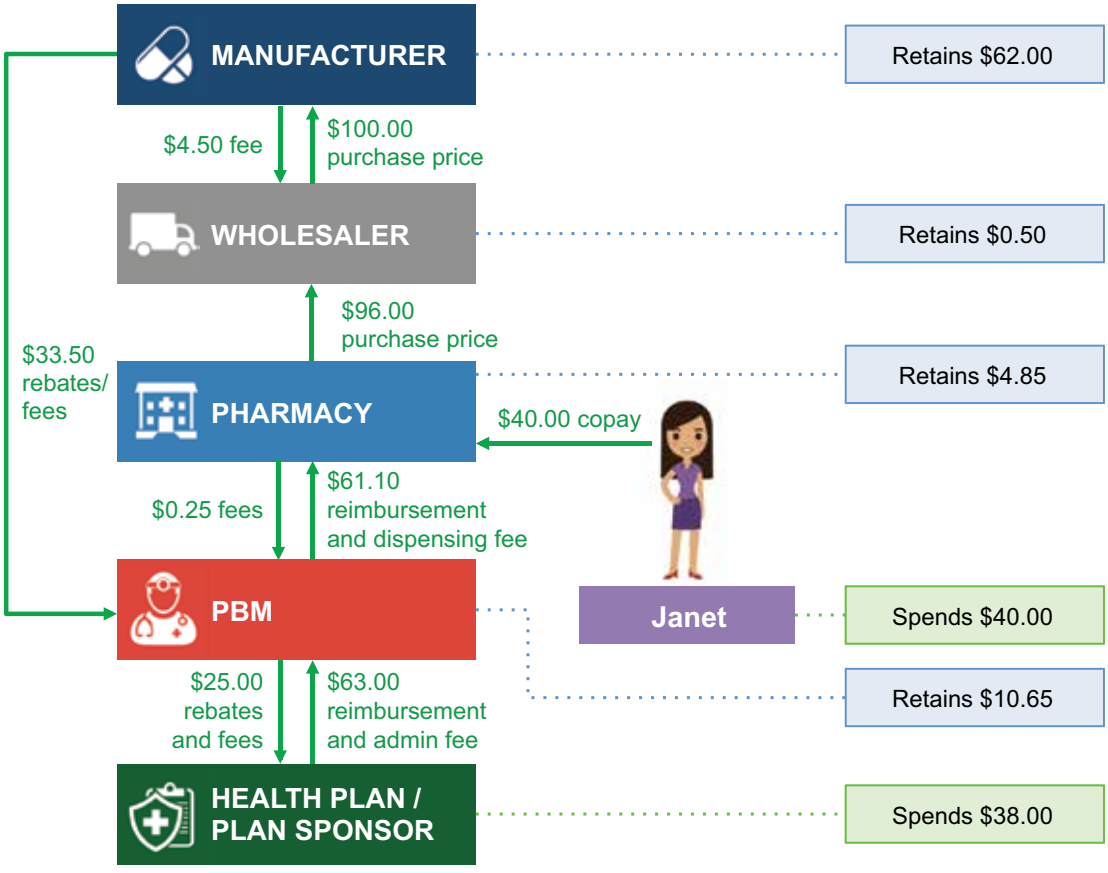
Janet, Scott, and Diane: How the System Works for Patients

Drawing from published materials and interviews with industry experts, the following examples highlight the financial flows that occur as brand medicines move through the supply chain. Illustrative examples are provided for 3 patients: Janet, Scott, and Diane, each of whom has a different chronic condition and faces a different type of cost-sharing (ie, copayment, coinsurance, or deductible). In each example, the rebate negotiated between the manufacturer and the PBM is based on information that has been publicly reported as typical for medicines in that therapeutic class.

Janet is a patient with commercial insurance taking a blood pressure medicine with a list price of $100.00. Her copayment for brand medicines is $40.00. Because Janet's health plan receives a 25% rebate off of the list price of her blood pressure medicine, her copayment of $40.00 is slightly more than the $38.00 net price paid by her health plan. Accounting for rebates and fees, the manufacturer retains $62.00, approximately two-thirds of the medicine's list price.

Flow of Payment for a $100 Blood Pressure Medicine

(Patient Pays a Copayment)



This graphic is illustrative of a hypothetical product with a WAC of $100 and an AWP of $120. It is not intended to represent every financial relationship in the marketplace.

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Flow of Payment for a $100 Blood Pressure Medicine (Copayment Example): Janet

Number		Item	Amount	Computation
[WAC]		Wholesale Acquisition Cost	$100.00	WAC (set by manufacturer)
[AWP]		Average Wholesale Price	$120.00	[WAC] * 1.2 (determined by pricing publications)
Wholesaler:	[1]	Buys product from manufacturer	$100.00	[WAC]
	[2]	Collects distribution fee from manufacturer	$4.50	[1] * 4.5%
	[3]	Sells product to pharmacy	$96.00	[1] - 4.0%
	Wholesaler Retains		**$0.50**	**[2] - [1] + [3]**
Pharmacy:	[4]	Collects cost-sharing from patient	$40.00	Determined by plan
	[5]	Collects dispensing fee from PBM	$1.50	Estimate
	[6]	Collects ingredient cost reimbursement from PBM	$59.60	([AWP] - 17%) -[4]
	Pharmacy Retains		**$4.85**	**[4] + [5] + [6] - [3] - [11]**
PBM:	[7]	Collects base rebate from manufacturer	$25.00	[WAC] * 25%
	[8]	Collects administrative service fee from manufacturer	$4.50	[WAC] * 4.5%
	[9]	Collects price protection rebate from manufacturer	$4.00	[WAC] * 4.0%
	[10]	Collects and retains administrative fee from health plan/plan sponsor	$1.00	Negotiated with health plan/plan sponsor. Per claim fee
	[11]	Collects and retains transaction and E-prescribing fees from pharmacy	$0.25	Transaction ($0.10) + E-prescribing ($0.15) fees
	[12]	Retains share of base rebate and price protection rebate	$5.13	[7] * 12.5% + [9] * 50%
	[13]	Retains share of manufacturer administrative fee	$3.38	[8] * 75%
	[14]	Reimbursed for ingredient cost by health plan/ plan sponsor	$62.00	([AWP] - 15%) - [4]
	PBM Retains		**$10.65**	**[10] + [11] + [12] + [13] + [14] - [6] - [5]**
Health Plan/ Plan Sponsor:	[15]	Payment to PBM	$63.00	[10] + [14]
	[16]	Receives share of rebates and fees	$25.00	([7] + [9] - [12]) + ([8] - [13])
	Final Health Plan/Plan Sponsor Cost		**$38.00**	**[15] - [16]**
Patient Payment Amount			**$40.00**	**[4]**
Manufacturer-retained Payment			**$62.00**	**[WAC] - [2] - [7] - [8] - [9]**

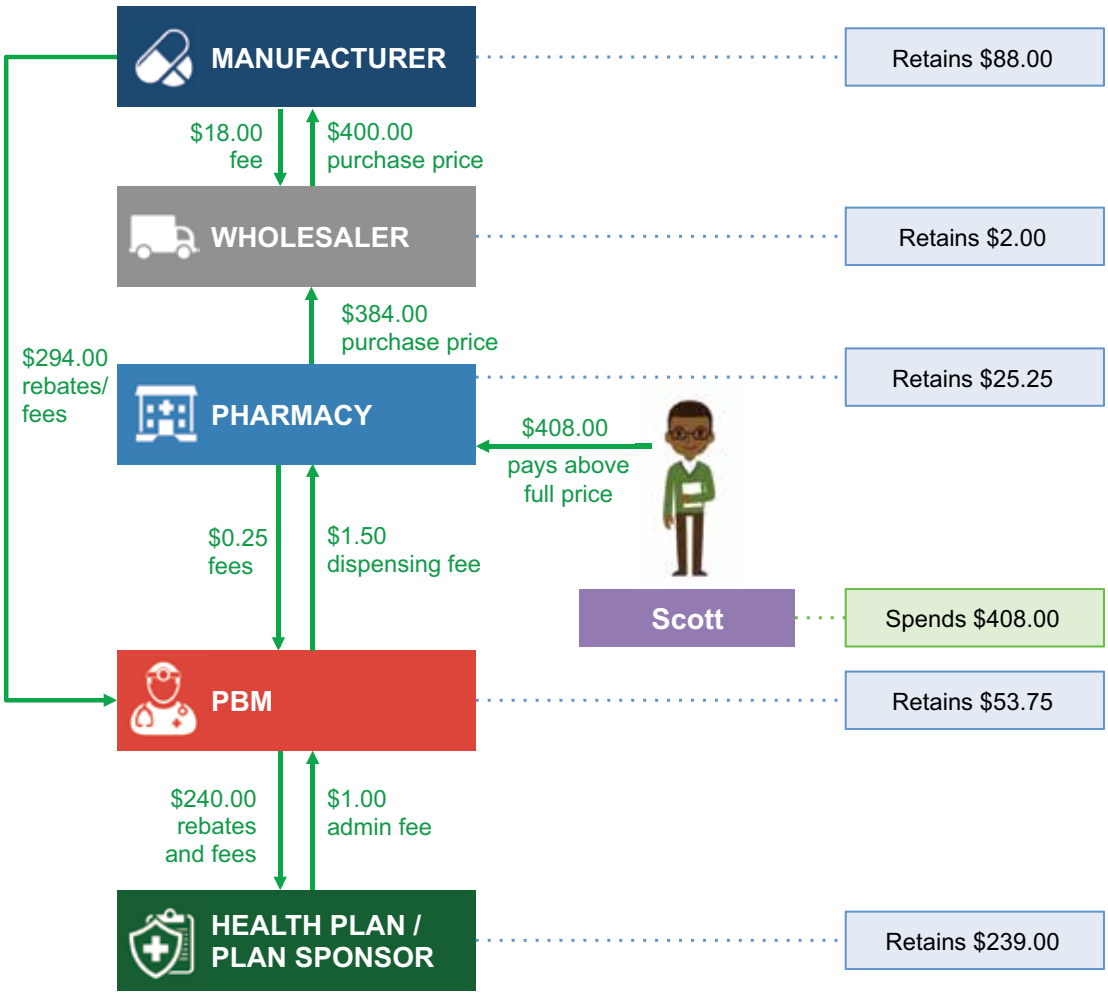
Assumptions

Brand WAC/Rx (30-day supply)	$100.00	PBM rebate pass through to health plan/plan sponsor	87.5%
Wholesaler fees/discounts (WAC discount)	4.5%	Administrative fee to PBM (from manufacturer) (WAC discount)	4.5%
Pharmacy ingredient cost reimbursement (AWP discount)	17.0%	PBM administrative fee pass through to health plan/plan sponsor	25.0%
Pharmacy ingredient acquisition cost (WAC discount)	4.0%	Price protection rebate to PBM (from manufacturer) (WAC discount)	4.0%
Pharmacy dispensing fee	$1.50	Price protection rebate pass through to health plan/plan sponsor	50.0%
PBM base rebate (WAC discount)	25.0%	Patient cost-sharing amount	$40.00

Scott takes insulin for his type 2 diabetes and has health coverage with a high deductible from his employer. Prior to meeting his deductible each year, he has to pay more than the full undiscounted cost of his medicine, $408.00, even though his health plan receives a rebate from the manufacturer that reduces the list price by 65%. Scott is paying the amount that is contracted between the health plan and the PBM which, in this case is higher than the list price of the medicine. Although the health plan does not pay for Scott's insulin while he is in his deductible, it still receives the negotiated rebate and earns $239.00 per prescription. The PBM earns $53.75, including fees and a share of the rebate it negotiated, while the manufacturer retains $88.00.

Flow of Payment for a $400 Insulin

(Patient Is in Deductible Phase)



This graphic is illustrative of a hypothetical product with a WAC of $400 and an AWP of $480. It is not intended to represent every financial relationship in the marketplace.

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Flow of Payment for a $400 Insulin (Deductible Example): Scott

Number		Item	Amount	Computation
[WAC]		Wholesale Acquisition Cost	$400.00	WAC (set by manufacturer)
[AWP]		Average Wholesale Price	$480.00	[WAC] * 1.2 (determined by pricing publications)
Wholesaler:	[1]	Buys product from manufacturer	$400.00	[WAC]
	[2]	Collects distribution fee from manufacturer	$18.00	[1] * 4.5%
	[3]	Sells product to pharmacy	$384.00	[1] - 4.0%
	Wholesaler Retains		**$2.00**	**[2] - [1] + [3]**
Pharmacy:	[4]	Collects cost-sharing from patient	$408.00	[AWP] - 15%
	[5]	Collects dispensing fee from PBM	$1.50	Estimate
	[6]	Reimbursed by PBM for ingredient cost	$0.00	No payment made by PBM
	Pharmacy Retains		**$25.25**	**[4] + [5] - [3] - [11]**
PBM:	[7]	Collects base rebate from manufacturer	$260.00	[WAC] * 65%
	[8]	Collects administrative service fee from manufacturer	$18.00	[WAC] * 4.5%
	[9]	Collects price protection rebate from manufacturer	$16.00	[WAC] * 4.0%
	[10]	Collects and retains administrative fee from health plan/plan sponsor	$1.00	Negotiated with health plan/plan sponsor. Per claim fee
	[11]	Collects and retains transaction and E-prescribing fees from pharmacy	$0.25	Transaction ($0.10) + E-prescribing ($0.15) fees
	[12]	Retains share of base rebate and price protection rebate	$40.50	[7] * 12.5% + [9] * 50%
	[13]	Retains share of manufacturer administrative fee	$13.50	[8] * 75%
	[14]	Reimbursed for ingredient cost by health plan/ plan sponsor	$0.00	No payment made by health plan/plan sponsor
	PBM Retains		**$53.75**	**[10] + [11] + [12] + [13] - [5]**
Health Plan/ Plan Sponsor:	[15]	Payment to PBM	$1.00	[10]
	[16]	Receives share of rebates and fees	$240.00	([7] + [9] - [12]) + ([8] - [13])
	Final Health Plan/Plan Sponsor Retains		**$239.00**	**[16] - [15]**
Patient Payment Amount			**$408.00**	**[4]**
Manufacturer-retained Payment			**$88.00**	**[WAC] - [2] - [7] - [8] - [9]**

Assumptions

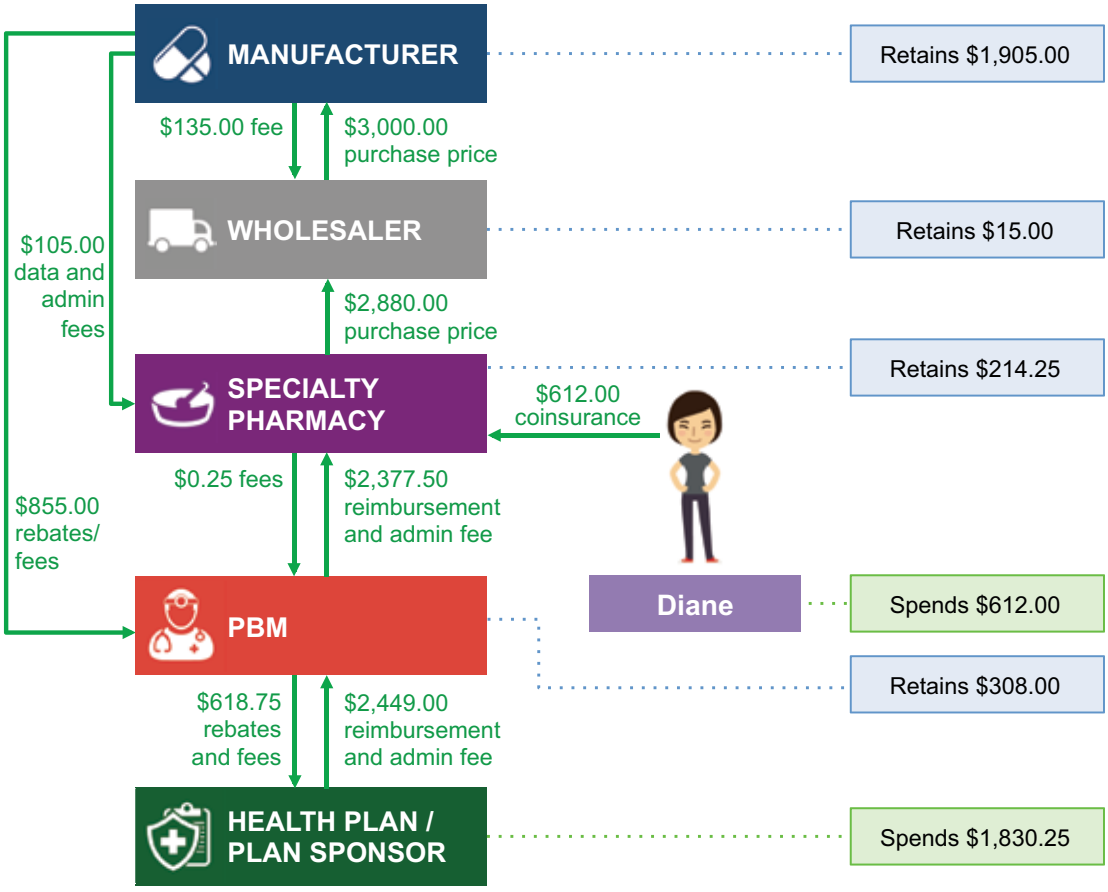
Brand WAC/Rx (30-day supply)	$400	PBM rebate pass through to health plan/plan sponsor	87.5%
Wholesaler fees/discounts (WAC discount)	4.5%	Administrative fee to PBM (from manufacturer) (WAC discount)	4.5%
Pharmacy ingredient cost reimbursement (AWP discount)	17.0%	PBM administrative fee pass through to health plan/plan sponsor	25%
Pharmacy ingredient acquisition cost (WAC discount)	4.0%	Price protection rebate to PBM (from manufacturer) (WAC discount)	4.0%
Pharmacy dispensing fee	$1.50	Price protection rebate pass through to health plan/plan sponsor	50%
PBM base rebate (WAC discount)	65%	Patient cost-sharing amount	$408.00

Diane has commercial coverage that requires her to pay a coinsurance of 20% for her HIV medicine. The manufacturer has negotiated a 20% rebate on the cost of her medicine, but Diane's health plan calculates her coinsurance based on the full undiscounted price. The PBM keeps a share of the rebate it negotiated with the manufacturer and collects additional fees calculated as a percentage of the list price, retaining $308.00. But because the medicine is dispensed by a specialty pharmacy owned by the PBM, the PBM earns a total of $522.25 on Diane's prescription ($308.00 + $214.25). In this example, the PBM also negotiated for "price protection," resulting in an additional rebate being paid to the PBM following an increase in the list price of the medicine. Half of the savings from this price protection rebate are retained by the PBM and half are passed through to the health plan, but Diane does not directly receive any of the benefit.

Note that if the manufacturer of Diane's HIV medicine were to further reduce the medicine's net price through an additional privately negotiated rebate with the PBM, it may not directly reduce Diane's cost unless the health plan moves the medicine to a lower tier or reduces the coinsurance for all medicines on that tier. Additionally, if instead of offering a 20% rebate, the manufacturer were to independently lower the list price of Diane's medicine from $3,000 to $2,400, the PBM would earn $169.65 less on this prescription. Because PBMs determine formularies and patient cost-sharing, and thus hold the keys to patient access to the medicine, reductions in the list price may jeopardize market access and formulary position of a medicine.

Flow of Payment for a $3,000 HIV Medicine

(Patient Pays Coinsurance)



This graphic is illustrative of a hypothetical product with a WAC of $3,000 and an AWP of $3,600. It is not intended to represent every financial relationship in the marketplace.

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Flow of Payment for a $3,000 HIV Medicine (Coinsurance Example): Diane

Number		Item	Amount	Computation
[WAC]		Wholesale Acquisition Cost	$3,000.00	WAC (set by manufacturer)
[AWP]		Average Wholesale Price	$3,600.00	[WAC] * 1.2 (determined by pricing publications)
Wholesaler:	[1]	Buys product from manufacturer	$3,000.00	[WAC]
	[2]	Collects distribution fee from manufacturer	$135.00	[1] * 4.5%
	[3]	Sells product to pharmacy	$2,880.00	[1] - 4.0%
	Wholesaler Retains		**$15.00**	**[2] - [1] + [3]**
Specialty Pharmacy:	[4]	Collects cost-sharing from patient	$612.00	Determined by plan (20% coinsurance) (([AWP] - 15%) * 20%)
	[5]	Collects dispensing fee from PBM	$1.50	Estimate
	[6]	Collects administrative and data fees from manufacturer	$105.00	[WAC] * 3.5%
	[7]	Ingredient cost reimbursement from PBM	$2,376.00	([AWP] - 17%) - [4]
	Specialty Pharmacy Retains		**$214.25**	**[4] + [5] + [6] + [7] - [3] - [12]**
PBM:	[8]	Collects base rebate from manufacturer	$600.00	[WAC] * 20%
	[9]	Collects administrative service fee from manufacturer	$135.00	[WAC] * 4.5%
	[10]	Collects price protection rebate from manufacturer	$120.00	[WAC] * 4.0%
	[11]	Collects and retains administrative fee from health plan/plan sponsor	$1.00	Negotiated with plan sponsor/per claim fee
	[12]	Collects and retains transaction and E-prescribing fees from pharmacy	$0.25	Transaction ($0.10) + E-prescribing ($0.15) fees
	[13]	Retains share of base rebate and price protection rebate	$135.00	([8] * 12.5%) + ([10] * 0.5)
	[14]	Retains share of manufacturer administrative fee	$101.25	[9] * 75%
	[15]	Reimbursed for ingredient cost by health plan/ plan sponsor	$2,448.00	([AWP] - 15%) - [4]
	PBM Retains		**$308.00**	**[11] + [12] + [13] + [14] + [15] - [7] - [5]**
Health Plan/ Plan Sponsor:	[16]	Payment to PBM	$2,449.00	[11] + [15]
	[17]	Receives share of rebates and fees	$618.75	([8] + [10] - [13]) + ([9] - [14])
	Final Health Plan/Plan Sponsor Cost		**$1,830.25**	**[16] - [17]**
Patient Payment Amount			**$612.00**	**[4]**
Manufacturer-retained Payment			**$1,905.00**	**[WAC] - [2] - [6] - [8] - [9] - [10]**

Assumptions

Brand WAC/Rx (30-day supply)	$3,000	PBM rebate pass through to health plan/plan sponsor	87.5%
Wholesaler fees/discounts (WAC discount)	4.5%	Administrative fee to PBM (from manufacturer) (WAC discount)	4.5%
Pharmacy ingredient cost reimbursement (AWP discount)	17.0%	PBM administrative fee pass through to health plan/plan sponsor	25%
Pharmacy administrative and data fees (from manufacturer) (WAC discount)	3.5%	Price protection rebate to PBM (from manufacturer) (WAC discount)	4.0%
Pharmacy ingredient acquisition cost (WAC discount)	4.0%	Price protection rebate pass through to health plan/plan sponsor	50%
Pharmacy dispensing fee	$1.50	Patient cost-sharing amount	$612.00
PBM base rebate (WAC discount)	20.0%		

The Evolution of the Pharmaceutical Market

Over the last decade, as the market for prescription medicines has evolved in response to many changes in the insurance, regulatory, and business landscapes, interactions along the supply chain have evolved as well.

One change is the types of prescription medicines that patients are using. Innovative medicines have revolutionized the treatment of complex and costly diseases, including cancer, hepatitis C, HIV/AIDS, and cardiovascular disease. Breakthroughs in medical research have also yielded a treasure trove of new biologic medicines to treat many of the most serious and life-threatening conditions that have been, until now, without effective therapies.

Innovative medicines have revolutionized the treatment of complex and costly diseases, including cancer, hepatitis C, HIV/AIDS, and cardiovascular disease.

At the same time, the shift in utilization from brand medicines to generic drugs continues. At the end of a brand medicine's patent life, generic medicines enter the market, and the price of treatment plummets. Using tiered cost-sharing and other utilization management tools, PBMs are able to rapidly steer market share away from brand medicines, driving savings from generics. This creates a system of built-in cost-containment that does not exist in other parts of our health care system.

Another change is the rapid rate of horizontal and vertical integration among the various entities along the pharmaceutical supply chain. Through mergers and acquisitions, PBMs and health plans have created even larger companies, increasing their leverage in private drug-pricing negotations. While consolidation may lead to more efficient payment and distribution models, it also raises questions about whether incentives are appropriately aligned across all stakeholders and whether plan sponsors have sufficient expertise and visibility into contractual arrangements to make good purchasing decisions and protect their interests. Health plans and employers count on intermediaries to bargain on their behalf. If, through consolidation, competition among these intermediaries is reduced, these intermediaries may be in a position to keep a bigger share of the savings they negotiate on behalf of their clients.

Finally, through higher deductibles and coinsurance amounts, health plans have increased the amount that many patients pay for their prescription medicines. More employers are also shifting their employees to high-deductible health plans that provide little or no assistance for prescription medicines unless a patient incurs thousands of dollars of costs. These changes mean that to the patient, the cost of prescription medicines seems to be increasing quite rapidly when what is actually changing is that their insurance covers less of the cost.

Patients' cost-sharing is increasingly based on undiscounted prices.[1,3]

As the hypothetical examples in this paper show, patients may be paying more than their insurer for a prescription, and they may not benefit from negotiated rebates. Although many manufacturers are offering larger rebates every year, patients' cost-sharing is increasingly based on undiscounted prices.[1,3] This needs to change. Patients should benefit from negotiated rates in the form of lower out-of-pocket costs at the pharmacy, just like they do for other types of health care services.

The examples in the paper also show that significant revenue streams are tied to medicines' list prices

and that in circumstances when payers do not benefit from negotiated rebates, incentives may not be aligned to produce the lowest costs for patients or the health care system. We should move toward a system in which negotiations focus on rewarding the best value for patients.

What is encouraging is that the market is starting to move in the direction of a system that better aligns the cost of prescription medicines with their value. Biopharmaceutical companies are working with private health insurers to implement new payment arrangements for a variety of diseases. For example, cancer medicines may work better for patients with one type of cancer than those with another approved indication of the medicine. Under these potential new arrangements, prices and rebates for the medicine could differ based on the type of cancer a patient has or how well an individual responds to treatment. Biopharmaceutical companies are also considering new ways to pay for treatment when a patient needs multiple high-priced, innovative medicines and experimenting with money-back guarantees if a medicine does not work as intended. These new types of arrangements offer the potential to increase the choice of therapy, ensure that patients have affordable access to the newest medicines, and enable our health care system to achieve better outcomes at even more affordable prices.

In circumstances when payers do not benefit from negotiated rebates, incentives may not be aligned to produce the lowest costs for patients or the health care system.

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Addendum to the 2023 Affordability Review Summary Report: Enbrel

Drafted: May 6, 2025
Approved: May 23, 2025

Overview of the Data Miscategorization

Prescription Drug Affordability Board ("PDAB", "Board") staff were notified of a data miscategorization during the course of data validation in preparation for the Upper Payment Limit (UPL) rulemaking for Enbrel. Specifically, there was a miscategorization in the All Payer Claims Database (APCD) when a pharmacy benefit manager (PBM) submitted data to the APCD administrator, the Center for Improving Value in Health Care (CIVHC). The payer types examined during the original affordability reviews are: Commercial, Medicaid, and Medicare Advantage. The PBM submitted claims in which they categorized Medicare claims as commercial and commercial claims as Medicare. Staff validated the corrected data and presented the updated information to the Board at its meeting on April 11, 2025. This document focuses on the corrected data for Enbrel.

Impacted Data Points

Due to the miscategorization of payer-type by the PBM, multiple data points were impacted. Staff presented the Board with corrected information for the following data points for Enbrel:

- **Patient Count**: the number of patients utilizing the prescription drug in a year.
- **Average WAC per Course of Treatment**: the average wholesale acquisition (WAC) cost per course/period of treatment. This was presented as a range because the exact number is confidential.
- **Average Paid per Person (APPY)**: the average amount paid for the drug by both (patients and payer) per person per year.
- **APPY - Plan Paid**: the average amount paid for the drug by the payer per person per year.
- **APPY - Out-of-Pocket (OOP)**: the average amount paid for the drug by the patient per year.
- **Total Paid**: total amount paid by payers and patients for the drug within one year.
- **Total Patient Paid**: total amount paid by all patients for the drug within one year.

Corrected Tables and Figures

Following sections are the corrected tables and figures for Enbrel. The table and figure numbers correspond to the original affordability review summary report (ARSR). The corrected tables and figures will not consider outdated data and therefore do not include data from 2018.

Case 1:25-cv-3452-DDD-STV
Exhibit 32

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Table 2

Utilization of Enbrel

Drug Name	Corrected Data			
	2019	2020	2021	2022
Enbrel	2,567	2,508	2,744	2,585

Table 2 shows the number of utilizers of Enbrel by year from 2019 - 2022.

Figure 1

Enbrel Utilization by Payer Type

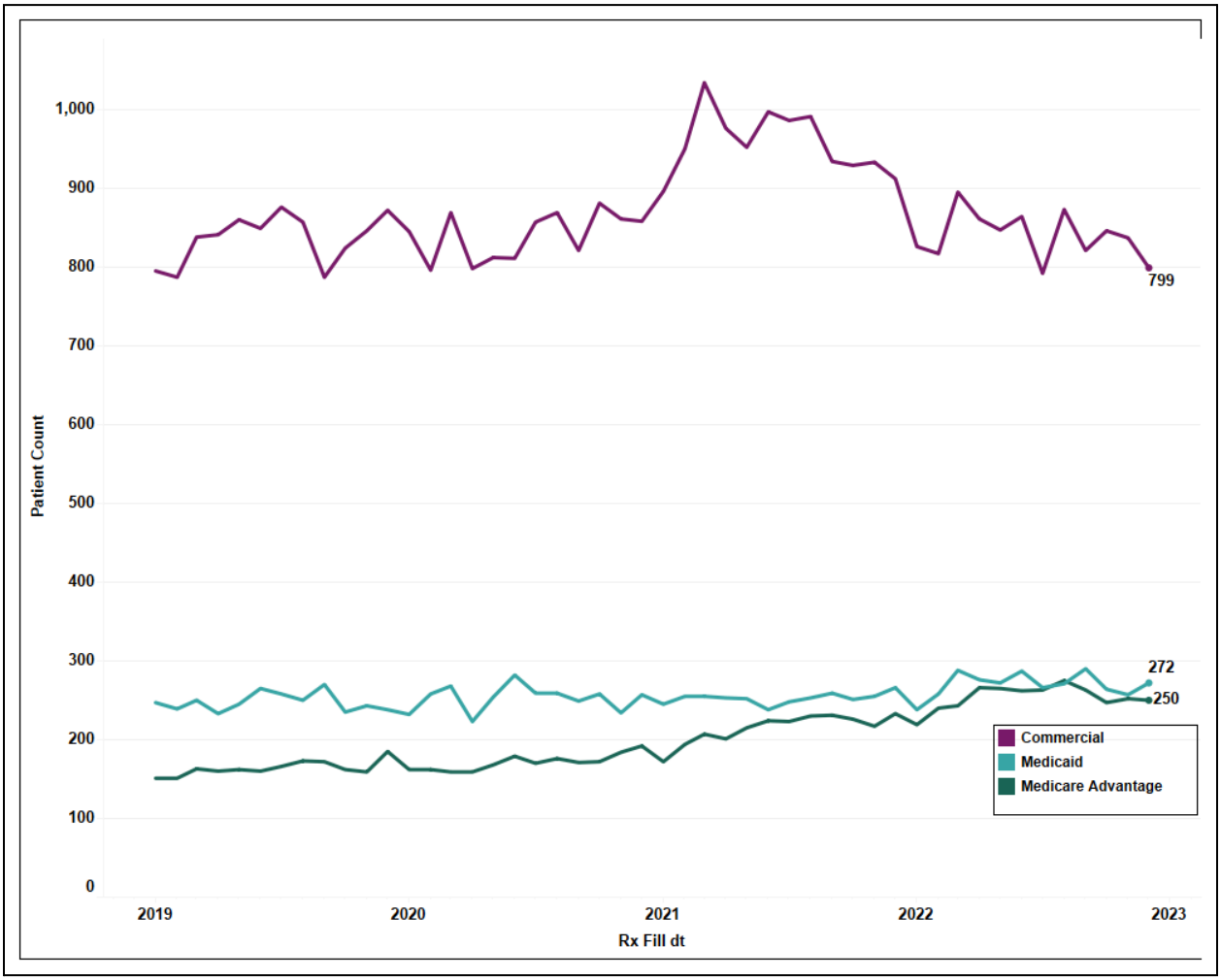


Figure 1 shows the monthly number of patients who filled a prescription for Enbrel each month between January 2019 and December 2022, where the purple line represents the number of commercially insured patients, the teal line shows the number of Medicaid patients, and the green line shows the number of Medicare Advantage patients.

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Figure 2

Insurance Information

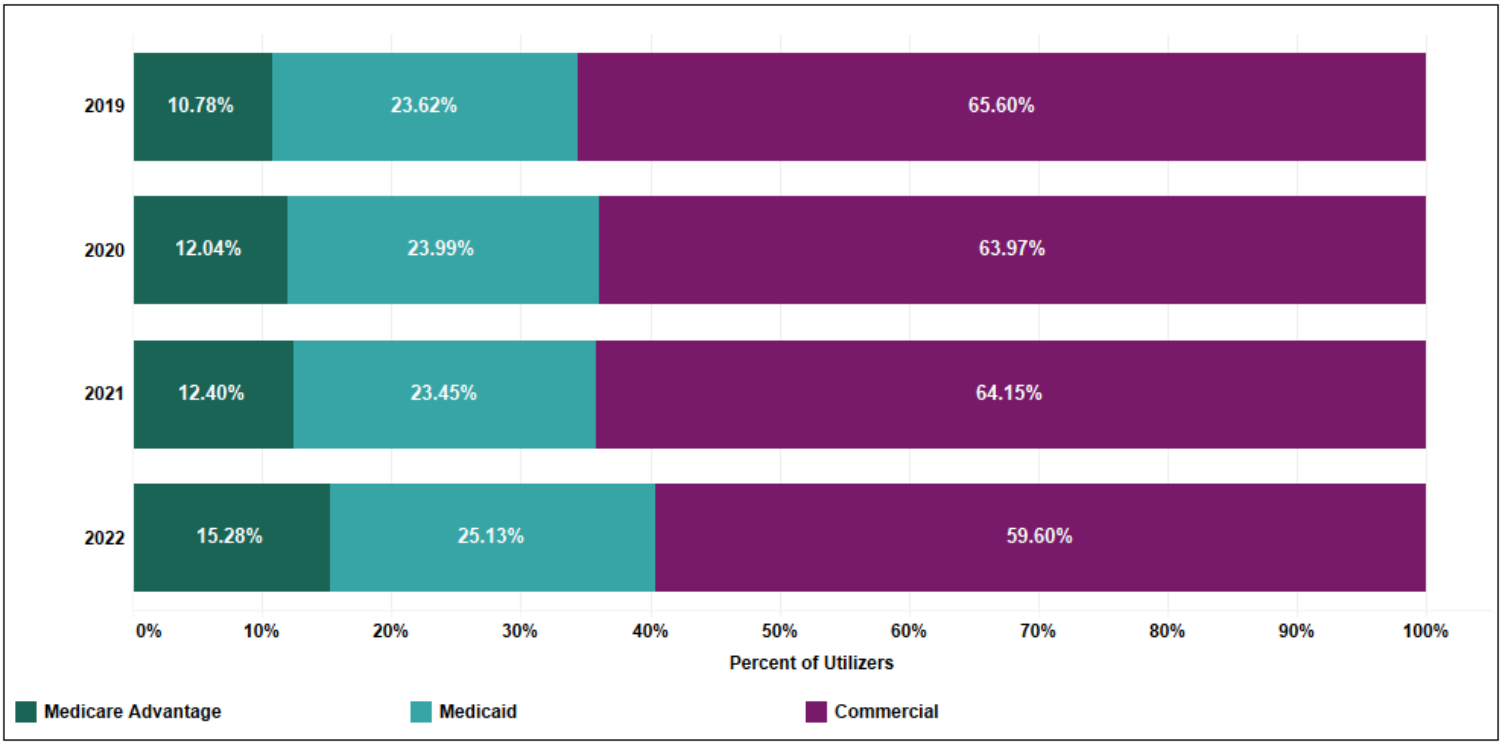


Figure 2 shows Enbrel payer mix percentages from 2019-2022. This figure shows the percent of patients by payer type and year where green represents patients with Medicare Advantage, teal represents patients with Medicaid, and purple represents patients with commercial insurance. From 2019-2022, between 65.60% and 59.60% of Enbrel utilizers were commercially insured.

Table 5

Utilization of Enbrel and Identified Therapeutic Alternatives

Drug Name	Corrected Data			
	2019	2020	2021	2022
Enbrel	2,567	2,508	2,744	2,585
Cimzia	323	351	419	479
Humira	5,504	5,874	7,064	7,290
Remicade	1261	1,134	1,021	635
Simponi	367	394	482	546

Table 5 shows the number of utilizers of Enbrel and therapeutic alternatives by year from 2019 - 2022.

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Figure 4

Insurance Information for Therapeutic Alternatives

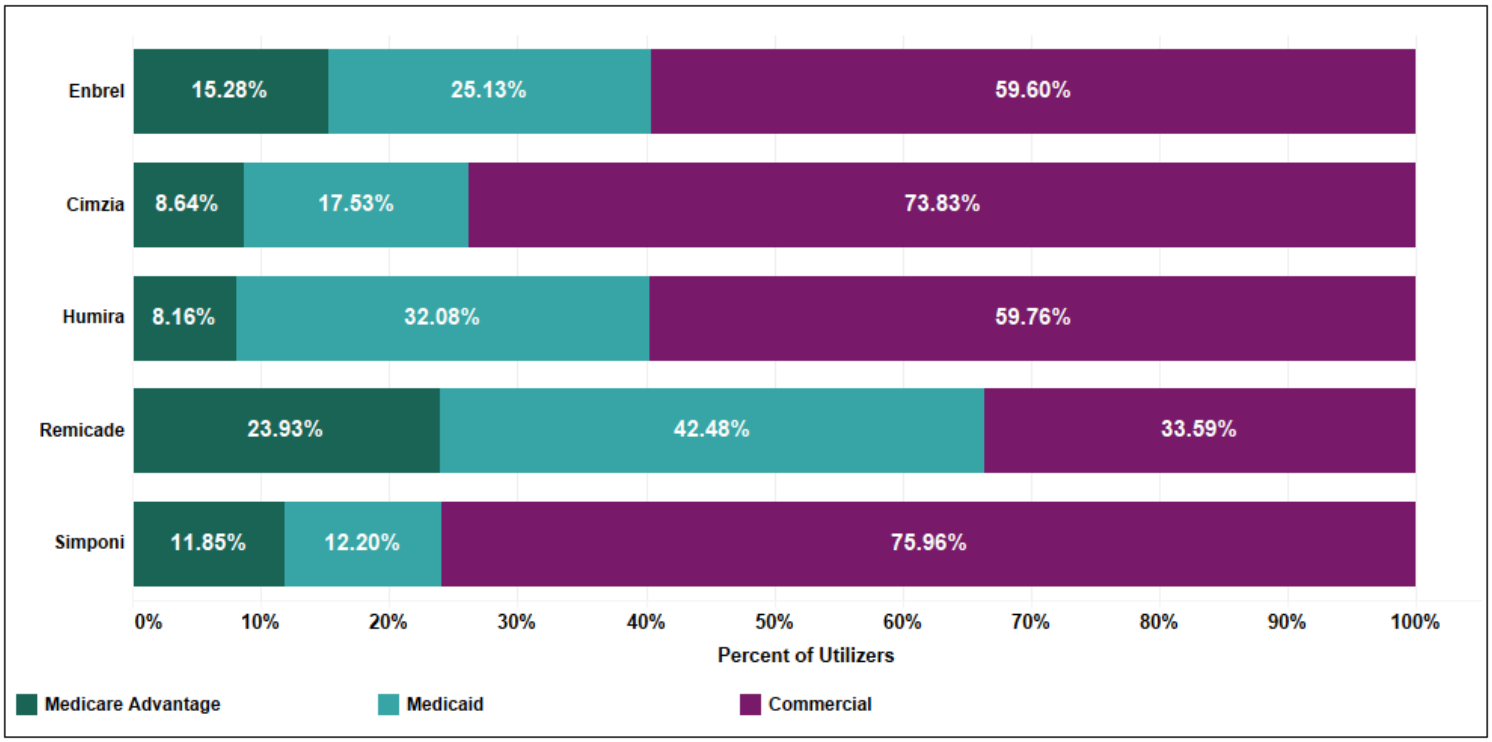


Figure 4 shows the 2022 payer mix for Enbrel and its identified therapeutic alternatives. This figure shows the percent of patients by payer type and year where green represents patients with Medicare Advantage, teal represents patients with Medicaid, and purple represents patients with commercial insurance. Enbrel and Humira had around 60% of patients with commercial insurance while Cimzia and Simoni had higher commercial coverage between 73-76%, and Remicade had lower commercial coverage (33.59%).

Table 6

Enbrel's 2022 Price & Cost Per Person Statistics

	Corrected Data
Price & Cost Per Person Statistics	**Amount**
Average WAC per Course of Treatment Per Person	$50k-$60k
Average Paid per Person	$49,297
APPY - Plan Paid	$46,460
APPY - Out-of-Pocket	$3,536

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Table 7

Enbrel's 2022 Statewide Price & Cost Statistics

Statewide Price & Cost Statistics	Corrected Data Amount
Total Paid Amount	$127,431,855
Total Plan Paid	$120,098,707
Total Medicaid Paid	$23,803,080
Total Patient Paid	$6,921,218

Figure 5

Average Commercial Out-of-Pocket Cost Comparison

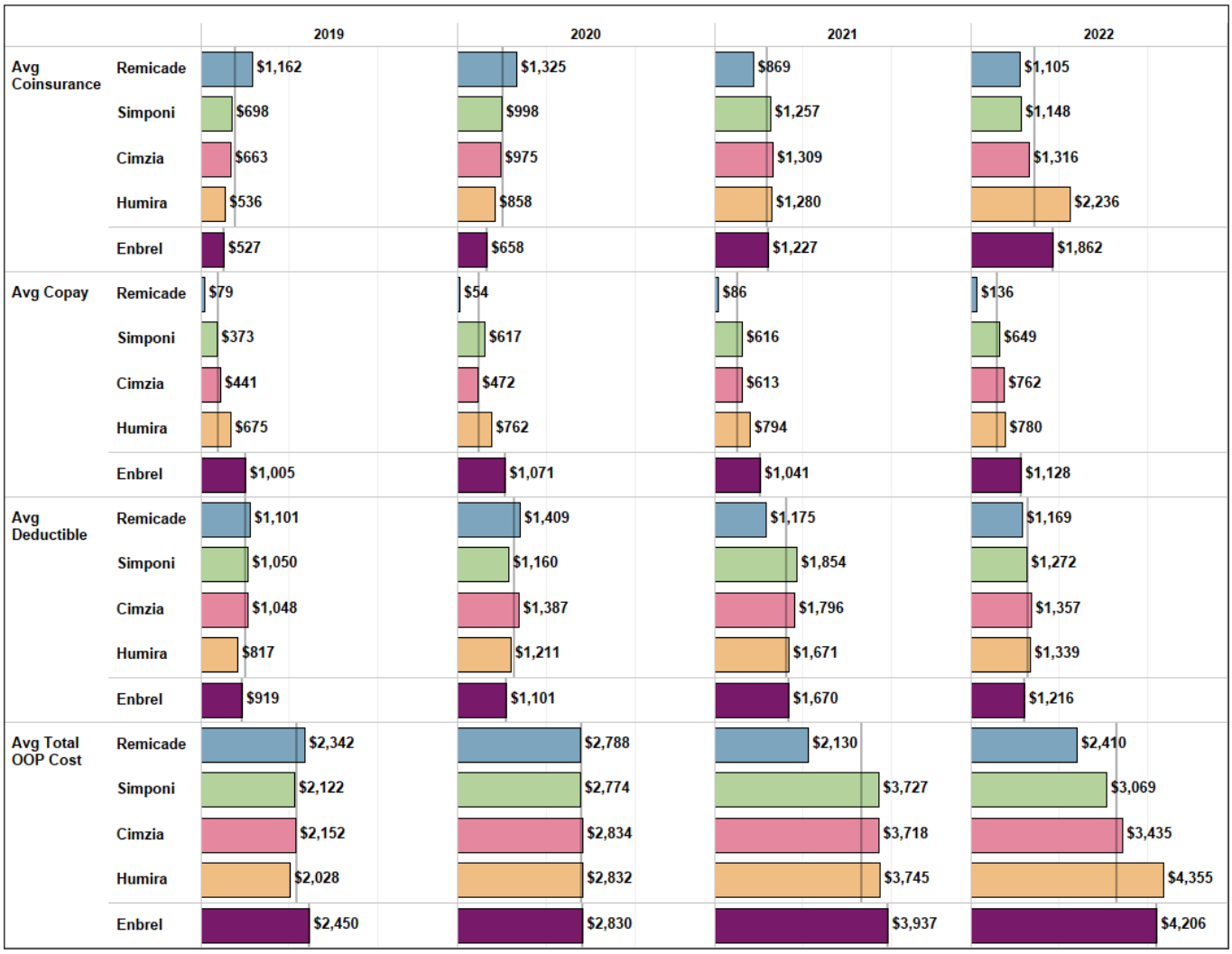


Figure 5 shows each out-of-pocket cost type for commercially insured individuals with Enbrel in dark purple and its therapeutic alternatives by year. There is a light gray line that shows the average of the therapeutic alternatives as a comparison to determine if Enbrel is more or less expensive than the average of its therapeutic alternatives. For example, the bottom right corner

shows the average total out-of-pocket cost in 2022, Enbrel was $4,206, which is higher than the average of the three identified therapeutic alternatives, but lower than one of the therapeutic alternatives.

Table 8

Average Monthly Commercial Out-of-Pocket Cost Information in 2022

	Corrected Data				
	Enbrel	**Cimzia**	**Humira**	**Remicade**	**Simponi**
Average Total OOP Cost	$649	$577	$670	$509	$558
Average Coinsurance Amount	$286	$217	$343	$244	$205
Average Copay Amount	$174	$134	$120	$29	$147
Average Deductible Amount	$189	$226	$207	$236	$206
Days Supply	28	27	28	43	30

Table 8 shows average monthly out of pocket expenditures for individuals who are commercially insured.

Figure 6

Changes in Copay Amounts by Year and Drug 2019-2022

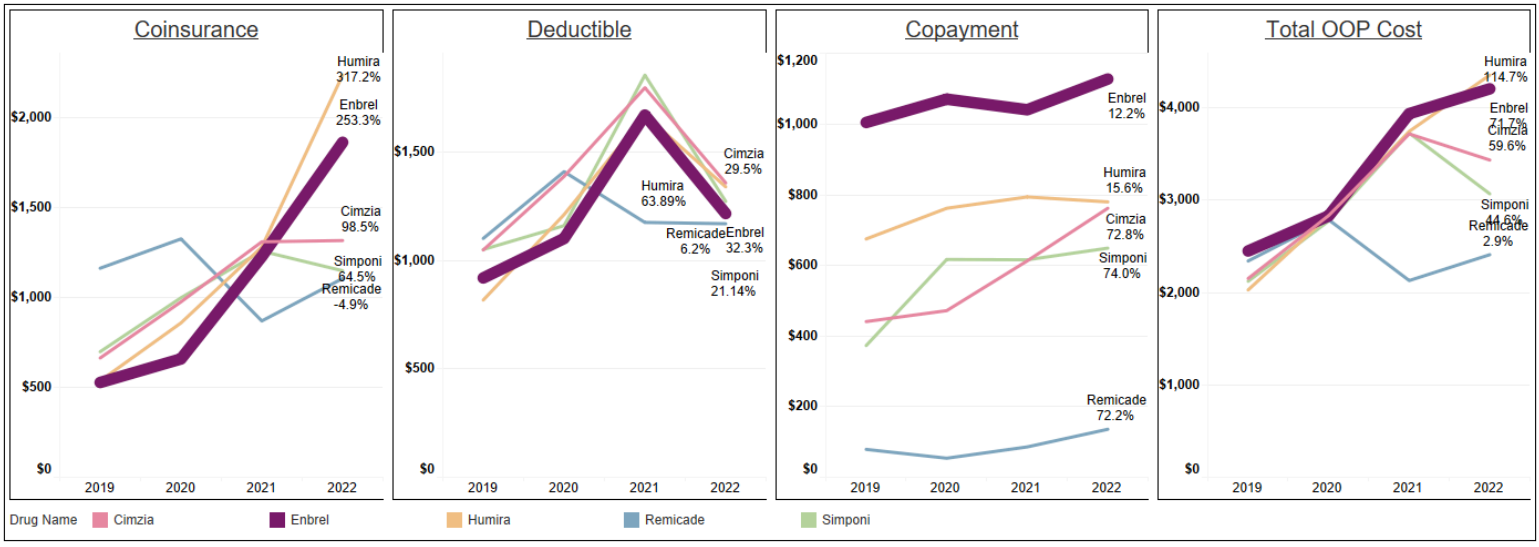


Figure 6 shows the annual change in the annual average OOP amounts comparing Enbrel (dark purple) to its therapeutic alternatives. Each line is labeled with the name of the therapeutic

alternative and the percent change from January 2019 - December 2022. Enbrel had the second highest increase in total out-of-pocket costs with a 71.7% increase.

Table 10

Annual Utilization and Expenditures

	Corrected data			
	2019	**2020**	**2021**	**2022**
Patient Count	2,567	2,508	2,744	2,585
Total Paid	$95,178,318	$103,079,777	$124,248,172	$127,437,778
Average Paid Per Person	$37,077	$41,100	$45,280	$49,299
Total Patient Paid	$4,356,574	$4,831,893	$7,305,304	$6,921,218
Average OOP	$2,207	$2,532	$3,438	$3,536

Table 10 shows the number of patients using Enbrel, the total amount paid for Enbrel, the average paid per person, the total amount that patients paid, and the average amount that each patient paid.

Figure 9

Monthly Utilizers for Enbrel and Therapeutic Alternatives

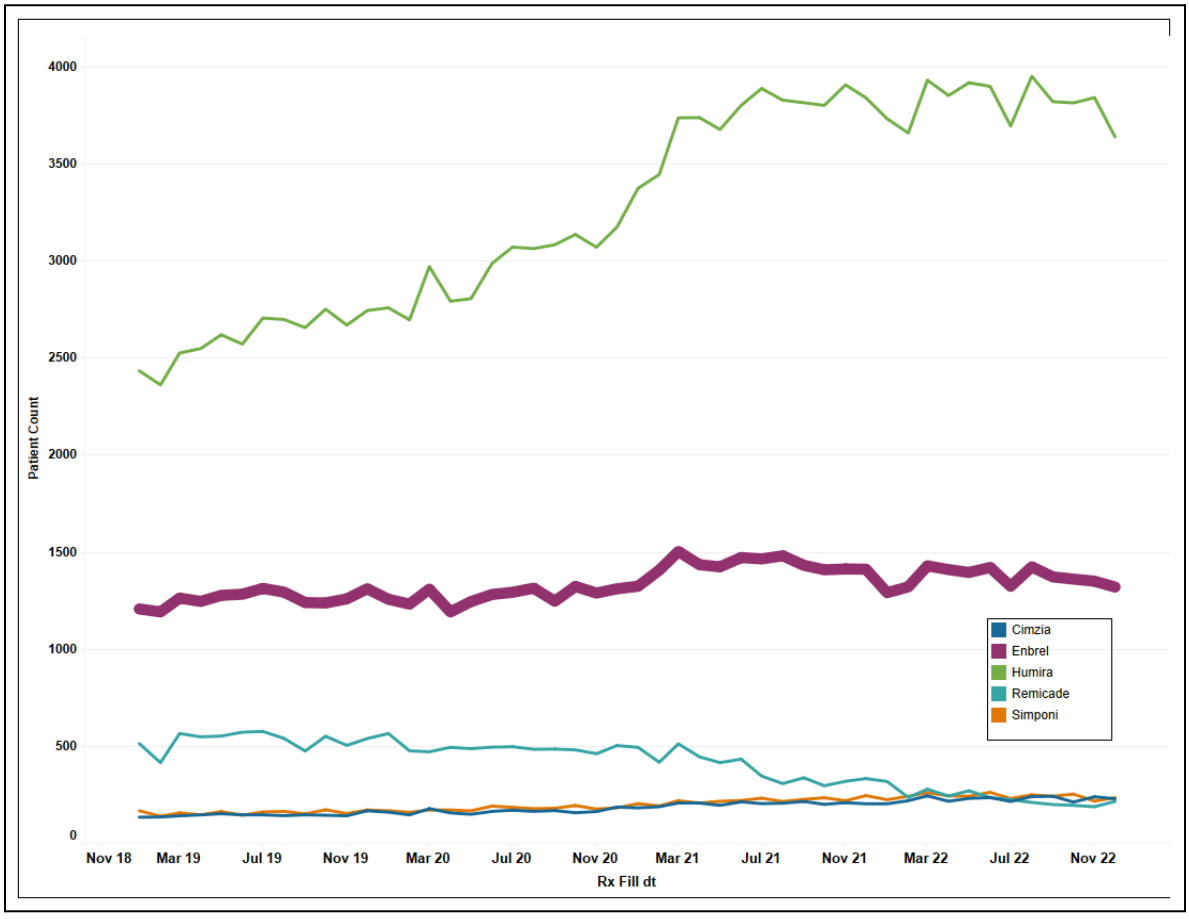


Figure 9 shows the monthly number of utilizers for Enbrel and therapeutic alternatives. Utilization of Enbrel has stayed consistent from January 2019 to December 2022; it is the second highest utilized drug after Humira which has increased significantly in the same timeframe.

Figure 10

Monthly Total Paid and Average Total Paid

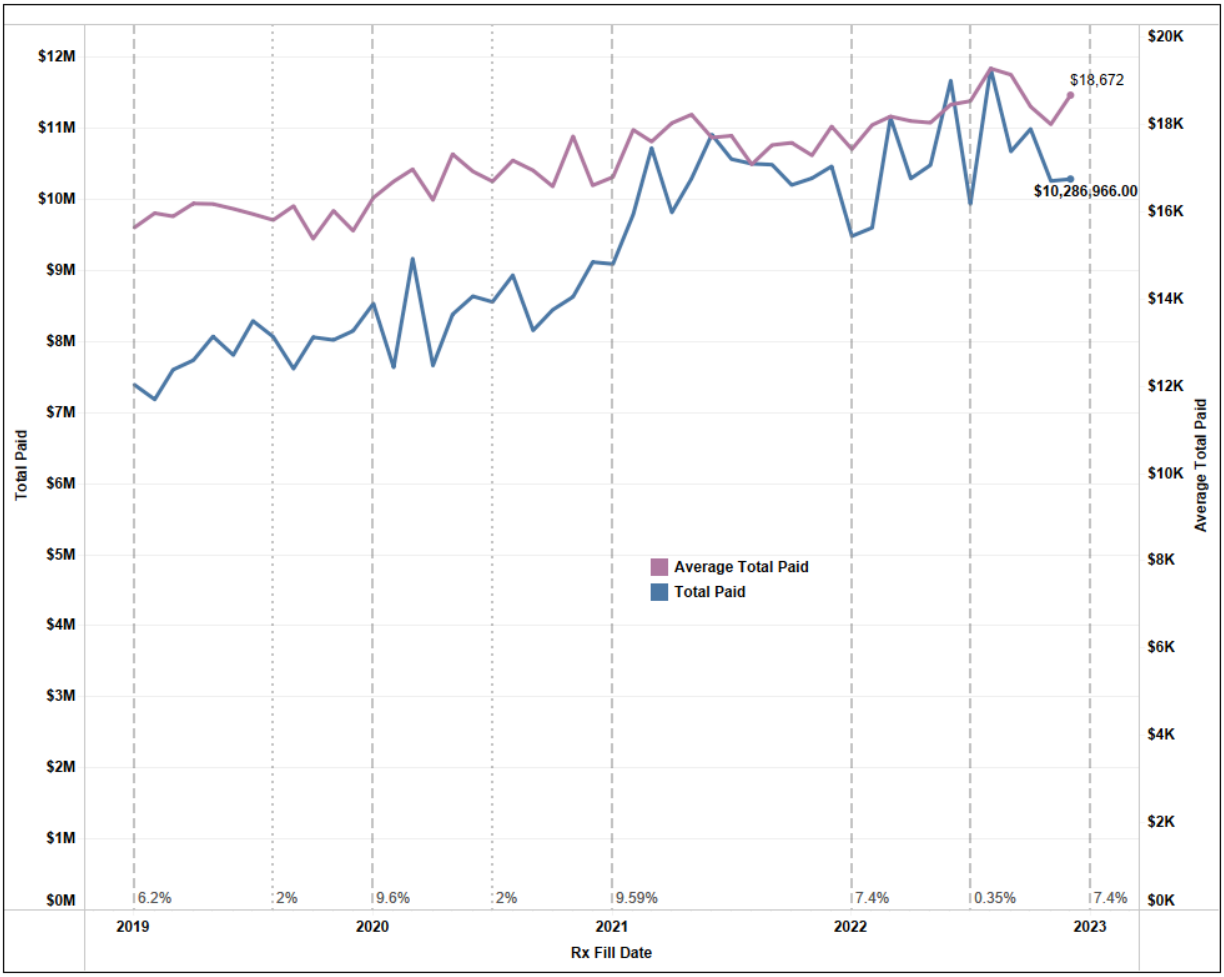


Figure 10 shows the monthly total paid with the blue line (left axis) and the monthly average paid per person with the purple line (right axis) with vertical lines representing changes in WAC with the magnitude of the change written to the right of the line with an arrow up or down indicating an increase or decrease in the WAC. There is no visible correlation between the WAC change and the corresponding change in the APCD paid amounts. During this time frame, the number of patients using Enbrel increased from 2,567 in 2019 to 2,585 in 2022.

COLORADO
Prescription Drug Affordability Board
Division of Insurance

2023 Affordability Review Summary Report: Enbrel

February 23, 2024

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Executive Summary

Affordability Review Summary Report Findings

Enbrel (etanercept), first approved by the United States Food and Drug Administration in 1998, is a tumor necrosis factor (TNF) inhibitor and is used to treat rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, psoriatic arthritis, juvenile psoriatic arthritis, and polyarticular juvenile idiopathic arthritis. The FDA granted orphan drug designation in 1998 for polyarticular-course juvenile rheumatoid arthritis, now referred to as polyarticular juvenile idiopathic arthritis. The relevant professional medical guidelines identify the following in-class therapeutic alternatives for Enbrel: Humira, Cimzia, Simponi/Simponi Aria, and Remicade. Patients and caregivers, as well as individuals with scientific and medical training, provided input that patients need many treatment options to identify the medications that work for them.

When compared to a placebo, Enbrel has shown improvements in symptoms for each indication. For some indications, there is evidence that Enbrel and its in-class therapeutic alternatives are associated with beneficial treatment effects when compared to other prescription drug treatments not in class. Of the few studies evaluating Enbrel compared to in-class therapeutic alternatives for rheumatoid arthritis, most found no difference in treatment, though one study found Enbrel to be inferior to Humira for remission, while another study found Enbrel to be superior to Remicade for different measure of remission.

In passing Senate Bill 21-175, the legislature recognized the importance of evaluating both the effectiveness of a drug, as well as its cost to consumers and the larger health care system. Enbrel's wholesale acquisition cost has increased 1,582.24%, from [redacted] per unit at its launch in November 1998 to [redacted] per unit in January 2024, which is significantly greater than the increase in inflation for the same time period. Over half of insurance carriers who submitted information to the Colorado All Payer Claims Database (APCD) reported that Enbrel was one of the top 15 prescription drugs that raised premiums for all covered lives. Enbrel has also appeared in other states' assessments of the costliest drugs, including contributing to increases in insurance plan spending.

In Colorado in 2022, Enbrel was the second most utilized drug (3,406 patients) compared to its in-class therapeutic alternatives, Humira (7,526), Remicade (698), Simponi (579), and Cimzia (475), and saw relatively steady utilization from 2018 to 2022. According to 2022 APCD data, Enbrel cost $46,772 per patient and over $159,305,653 in total. In that year, the average annual out-of-pocket cost for patients with commercial insurance was $3,980 annually. Though there was evidence in both APCD data and patient and caregiver survey responses that monthly out-of-pocket costs were quite varied, 27 of 38 (71.1%) of Colorado patients and caregivers reported the cost of Enbrel has made it difficult to access the drug. The majority of patients and caregivers surveyed (33 of 38) stated they used some form of assistance program to access Enbrel, with over a quarter of patients (10 of 38) reporting they still had trouble affording Enbrel.

In 2023, it is estimated that [redacted] of Amgen Inc.'s national gross sales for Enbrel was spent on rebates, 340B discounts, manufacturer financial assistance programs, and other price concessions. International net revenue for Enbrel decreased from $4.465 billion in 2021 to $4.177 billion in 2022, which may be partly explained by [redacted].

The following report and its appendices provide detailed evidence necessary for the Board's consideration of whether Enbrel is unaffordable to Coloradans.

Board Deliberation and Vote Summary

After receiving and reviewing evidence in support of the affordability review components set forth in statute and rule, on February 16, 2024, the Colorado Prescription Drug Affordability Board (the Board)

acknowledged there was sufficient evidence to proceed with deliberations for the Enbrel affordability review. The Board then deliberated whether the use of Enbrel was unaffordable for Colorado consumers.

During deliberations, Board members noted that the data concerning out-of-pocket costs and patient and caregiver experience purchasing the drug provided evidence that the drug is unaffordable to patients in Colorado. Deliberation also included discussion of:

- Enbrel is clearly an effective drug that is comparable to therapeutic alternatives;
- Utilization of therapeutic alternatives and availability of biosimilars;
- Average out-of-pocket cost is relatively higher than some therapeutic alternatives;
- Concerns that Colorado patients may be paying higher out-of-pocket costs or have more affordability concerns than survey results from patients outside of Colorado;
- Health equity and patients in rural counties may be going undiagnosed or be unable to access medications; and
- High changes in wholesale acquisition cost (WAC).

After deliberations and hearing public comment from six individuals, the Board voted 4-0 that the use of Enbrel consistent with the labeling approved by the FDA or with standard medical practice is unaffordable for Colorado consumers. Dr. Sami Diab recused himself from the deliberation and vote due to a conflict of interest.

To view the meeting recording in full, see:
https://us06web.zoom.us/rec/share/Qok1gyXB8g_7SJI2Bt4UJSXdHre7F3jgFAdCJnaaxNplnTyuLgc3Vzt4RbyC5xpb.7RBSR3AvYJkCKjjw

Introduction

The Colorado Prescription Drug Affordability Board (the Board) was established in 2021 through the passage of Senate Bill 21-175. Governor Polis appointed five members to the Board in September 2021. Since then, the Board has appointed members to the 15-person Prescription Drug Affordability Advisory Council (the Advisory Council) and hosted a five-part learning series in spring 2022 to provide Board members, Advisory Council members, and interested stakeholders foundational knowledge necessary to implement a successful new prescription drug affordability program. The Board has also promulgated five rules to implement statutory requirements and developed five policies to guide the program.

One of the Board's duties is to perform affordability reviews of prescription drugs as described in section 10-16-1406, C.R.S. This section outlines the Board's four steps in conducting affordability reviews:(1) identification of eligible drugs, (2) selection of drugs for affordability reviews, (3) conducting affordability reviews on selected drugs, and (4) determining if use of the selected drugs are unaffordable for Colorado consumers.

The first step - identification of prescription drugs eligible for affordability reviews - was completed when the Board approved the final list of prescription drugs eligible for affordability reviews on June 9, 2023. The second step - selection of prescription drugs for affordability reviews - was completed when the Board selected five drugs for affordability reviews on August 4, 2023. This report has been prepared by Board staff to assist the Board in completing the third and fourth steps of the affordability review process for the prescription drug, Enbrel.

This report of the affordability review for Enbrel was conducted in accordance with 3 CCR 702-9, Part 3.1.E.6. Additionally, this report contains appendices with detailed information for each of the fifteen criteria the Board shall and may consider as a part of its affordability review, to the extent practicable.

Report Structure

About This Report

The main body of the Affordability Review Summary Report is divided into three profiles: a therapeutic and utilization profile; a cost and price profile; and an access to care profile. The profiles contain information from the fifteen statutory and regulatory components the Board considers as a part of an affordability review. The profiles were identified by Board members and Board staff as a way to present affordability review evidence in a commonsense manner. While these profiles incorporate all fifteen components the Board considers during affordability reviews, additional information is provided for each of the fifteen components in the appendices, with each component having an individual appendix. More information on the structure of each profile and the appendices is provided in the sections below.

While several components lend themselves to inclusion in only one profile, three components inform all profiles contained in the Summary Report. Those components, and information regarding the type and volume of feedback Board staff received, are summarized below:

- Input from patients and caregivers - Board staff gathered input from three patients and caregivers at one public meeting on September 19, 2023. Additionally, 287 patients and caregivers completed surveys regarding the health and financial effects of Enbrel, and many of these patients and caregivers also attended the public meetings.
- Input from individuals with scientific and medical training - Board staff gathered input from two individuals with scientific or medical training at one public meeting on September 19, 2023 as well as five individuals at small-group meetings. Additionally, three individuals with scientific & medical training completed surveys regarding the health and financial effects of Enbrel.
- Voluntarily submitted information - two patients, caregivers, and other entities submitted voluntary information. Amgen Inc., the manufacturer of Enbrel, also voluntarily submitted public and confidential information. Note: no assessment was conducted of accuracy of voluntarily submitted information or the extent to which the information applies to Coloradans.

The Summary Report and Appendices may contain proprietary, confidential, and trade-secret information. Such information is redacted in public reports.

Therapeutic and Utilization Profile

The Therapeutic and Utilization Profile includes information about Enbrel's clinical efficacy and the people who use it. This section provides information regarding Enbrel's indication, utilizer profile, health equity impact, and therapeutic alternatives. Affordability review components present in this profile include information from Appendices B, G, H, I, J, and L.

Price and Cost Profile

The Price and Cost Profile includes information on what different entities on the prescription drug supply chain charge for Enbrel, as well as what different entities pay for Enbrel. This profile also contains information on Enbrel's financial effects on health, medical, and social service costs. Affordability review components present in this profile include information from Appendices A, B, D, E, H, I, J, K, and O.

Access to Care Profile

The Access to Care Profile examines potential access to care concerns related to Enbrel and whether there is evidence that the causes of access to care concerns may be related to Enbrel's price or cost. This profile

includes an examination of potential relationships of changes between utilization, price, and costs as well as information on safety net providers, utilization management requirements, and health benefit plan design. Affordability review components present in this profile include information from Appendices A, B, C, E, F, H, I, J, K, M, and N.

Appendices

This report contains an appendix for each of the fifteen components the Board is to consider as a part of affordability reviews, as well as a last appendix, Appendix P - Data Sources and Limitations. Descriptions of the appendices related to the fifteen affordability review components are outlined below. Some appendices contain data and information specific to one or more of Enbrel's six FDA-approved indications. Those appendices are noted below with an asterisk (*). All other appendices contain data for Enbrel irrespective of indication.

Table 1
Appendices and Relevant Statutory, Rule, and Policy Guidance for Affordability Review Components

Component Name	Component Details
***Appendix A:** Current WAC & Change in WAC	The Board shall consider the wholesale acquisition cost of the drug. C.R.S. § 10-16-1406(4)(a).
***Appendix B:** Therapeutic Alternatives	The Board shall consider the cost and availability of therapeutic alternatives to the prescription drug in the state. C.R.S. § 10-16-1406(4)(b).
Appendix C: Price Effect on Access	The Board shall consider the effect of the price on Colorado consumers' access to the prescription drug. C.R.S. § 10-16-1406(4)(c).
***Appendix D:** Relative Financial Effects	The Board shall consider the relative financial effects on health, medical, or social services costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. C.R.S. § 10-16-1406(4)(d).
Appendix E: Patient Copayment & Other Cost Sharing	The Board shall consider the patient copayment or other cost sharing of the drug. C.R.S. § 10-16-1406(4)(e).
Appendix F: Safety Net Providers	The Board shall consider the impact on safety net providers if the prescription drug is available through section 340B of the federal "Public Health Service Act", Pub.L. 78-410. C.R.S. § 10-16-1406(4)(f).
***Appendix G:** Orphan Drug Status	The Board shall consider orphan drug status. C.R.S. § 10-16-1406(4)(g).
***Appendix H:** Patients & Caregivers	The Board shall consider input from patients and caregivers affected by the condition or disease that is treated by the prescription drug that is under review by the Board. C.R.S. § 10-16-1406(4)(h)(I).
***Appendix I:** Individuals with Scientific & Medical Training	The Board shall consider input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by the Board. C.R.S. § 10-16-1406(4)(h)(II).
Appendix J: Voluntarily Submitted Information	The Board shall consider any other information that a manufacturer, carrier, pharmacy benefit management firm, or other entity chooses to provide. C.R.S. § 10-16-1406(4)(i).

Component Name	Component Details
Appendix K: Rebates, Discounts, and Price Concessions	The Board may consider estimated manufacturer net-sales or net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives; and The Board may consider manufacturer financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, Part 3.1.E.2.j.i.
***Appendix L:** Health Equity	The Board will consider whether the pricing of the prescription drug results in or has contributed to health inequities in priority populations. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, Part 3.1.E.2.j.ii.
***Appendix M:** Information from HCPF	The Board shall consider information from the Department of Health Care Policy and Financing, including additional analyses HCPF conducts relevant to the prescription drug or therapeutic alternative under review; and/or information regarding safety net providers participating in the 340B, including information to assist with gathering input to assess the impact to safety net providers for a prescription drug under review that is available through Section 340B of the Federal "Public Health Service Act", Pub. L. 78-410. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, Part 3.1.E.2.j.iii.
Appendix N: Non-Adherence & Utilization Management	The Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, 3.1.E.2.j.iv.
Appendix O: Pricing Information	The Board may consider any documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug, including documents and information relating to: (a) Life-cycle management; (b) The average cost of the prescription drug in the state; (c) Market competition and context; (d) Projected revenue; (e) The estimated cost-effectiveness of the prescription drug; and (f) Off-label usage of the prescription drug. C.R.S. § 10-16-1406(6). The Board may access pricing information for prescription drugs by: (I) accessing publicly available pricing information from a state to which manufacturers report pricing information; (II) accessing available pricing information from the all-payer health claims database and from state entities; and (III) accessing information that is available from other countries. C.R.S. § 10-16-1406(7)(a).

*Appendix contains information specific to one or more of the six indications Enbrel treats.

Enbrel Therapeutic and Utilization Profile

The Therapeutic and Utilization Profile includes information about Enbrel's clinical efficacy and the people who use it. This section provides information regarding Enbrel's indication, utilizer profile, health equity impact, and therapeutic alternatives.

Indications

Enbrel has six FDA-approved indications:

- Rheumatoid arthritis (RA) - reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active RA (FDA approval in 1998).
- Ankylosing spondylitis (AS) - reducing signs and symptoms in patients with active AS (FDA approval in 2003).
- Plaque psoriasis (PsO) - treatment of patients 4 years or older with chronic moderate to severe PsO who are candidates for systemic therapy or phototherapy (FDA approval in 2004).

- Psoriatic arthritis (PsA) - reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with PsA (FDA approval in 2002).
- Juvenile psoriatic arthritis (JPsA) - treatment of active JPsA in pediatric patients 2 years of age and older (FDA approval in Oct. 2023).
- Polyarticular juvenile idiopathic arthritis (pJIA) - reducing signs and symptoms of moderately to severely active pJIA in patients ages 2 and older (FDA approval in 2016).

For context, all of the FDA-approved indications listed above are autoimmune diseases[1]. RA, AS, PsA, JPsA, and pJIA are forms of arthritis and rheumatic diseases[2], with AS sometimes also called axial spondylitis, and RA being the most common type of rheumatic diseases.[3] Juvenile idiopathic arthritis (JIA) is an umbrella term for chronic arthritis in children,[4] and JPsA, sometimes called psoriasis-related JIA[5], and pJIA are two different types of JIA.[6] Plaque psoriasis is the most common form of the chronic skin condition, psoriasis[7]. Psoriasis is also associated with PsA; the majority of patients who develop PsA already have some form of psoriasis (PsO or another psoriasis)[8], and juvenile patients with JPsA also have some form of psoriasis (PsO or another type of psoriasis).[9]

Enbrel is classified by the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system as a tumor necrosis factor alpha (TNF-α or TNF) inhibitor.[10] Additional information is provided below for each FDA-approved indication.

Rheumatoid Arthritis (RA)

Rheumatoid arthritis (RA) is a chronic, symmetrical, inflammatory autoimmune disease that initially affects small joints, progressing to larger joints, and eventually the skin, eyes, heart, kidneys, and lungs. Often, the bone and cartilage of joints are destroyed, and tendons and ligaments weaken. Damage to joints can cause deformities and bone erosion, which can be painful. Common symptoms of RA include morning stiffness of the affected joints, fatigue, fever, weight loss, joints that are tender, swollen and warm, and rheumatoid nodules under the skin. The onset of this disease is usually from the age of 35 to 60 years, with remission and exacerbation.[11]

Around 1.3 million people in the US have rheumatoid arthritis.[12] The goals of treatment for RA are to reduce joint inflammation and pain, maximize joint function, and prevent joint destruction and deformity. Treatment regimens consist of combinations of pharmaceuticals, weight-bearing exercise, educating patients about the disease, and rest. Treatment regimens take into account factors such as disease progression, the joints involved, age, overall health, occupation, compliance, and education about the disease.[13]

[1] https://autoimmune.org/disease-information/
[2] https://www.niams.nih.gov/health-topics/arthritis-and-rheumatic-diseases
[3] https://www.ncbi.nlm.nih.gov/books/NBK532288/
[4] https://pubmed.ncbi.nlm.nih.gov/31779842/
[5] https://rarediseases.info.nih.gov/diseases/10970/psoriasis-related-juvenile-idiopathic-arthritis
[6] https://www.niams.nih.gov/health-topics/juvenile-arthritis
[7] https://www.niams.nih.gov/health-topics/psoriasis
[8] https://www.niams.nih.gov/health-topics/psoriatic-arthritis
[9] Id.
[10] https://www.whocc.no/atc_ddd_index/?code=L04AB&showdescription=no
[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6422329/
[12] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8348893/
[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6422329/

The Mayo Clinic states that, "RA can be difficult to diagnose in its early stages because the early signs and symptoms mimic those of many other diseases".[14] Individuals with scientific and medical training noted that patients taking Enbrel have moderate to severe RA and may have already tried other prescription drugs and that a patient's medications may depend on how long someone has had RA and the severity of their symptoms. Disease-modifying antirheumatic drugs (DMARDs) are often prescribed for RA, with conventional DMARDs more commonly recommended for DMARD-naive patients with moderate to high disease activity and biologic DMARDs (including TNF inhibitors like Enbrel) are recommended to be added to conventional DMARDs for patients taking maximally tolerated doses of conventional DMARDs.[15]

Ankylosing Spondylitis

Ankylosing spondylitis (AS), a subset of axial spondyloarthritis,[16] is an inflammatory disease that causes inflammation in the joints and ligaments of the spine. Axial spondyloarthritis has two types. When the condition is found on X-ray, it is called ankylosing spondylitis. When the condition can't be seen on X-ray but is found based on symptoms, blood tests and other imaging tests, it is called non-radiographic axial spondyloarthritis.[17]

Ankylosing spondylitis (AS) is a chronic, inflammatory disease primarily affecting the axial spine that can manifest with a range of clinical signs and symptoms. Symptoms typically begin in early adulthood. The hallmark features of AS include chronic back pain and progressive spinal stiffness, though it may also affect peripheral joints and digits.[18] AS often leads to impaired spinal mobility and can result in a hunched posture. In addition to skeletal involvement, AS can affect other body organs, manifesting in inflammatory bowel disease, acute anterior uveitis, and psoriasis. AS is also linked to an increased risk of cardiovascular disease and pulmonary complication.[19]

The exact cause of AS is unknown, but researchers believe that genetics play a role. The HLA-B27 gene is found in most white patients who have AS, but is only found in 50% of Black patients who have AS.[20] There is no cure for ankylosing spondylitis, but treatments can lessen symptoms and possibly slow progression of the disease. The goal of treatment is to ease pain and stiffness, prevent deformities, and maintain as normal a lifestyle as possible.[21]

Plaque Psoriasis

Plaque psoriasis (PsO) is the most common type of psoriasis, accounting for more than 80% of cases. Psoriasis affects both men and women, with earlier onset in women and those with a family history. An estimated 60 million people have psoriasis worldwide, and the condition is more common in high income areas and those with older populations.[22]

The National Psoriasis Foundation describes the appearance of psoriasis plaques as raised, inflamed, and scaly patches of skin that may also be itchy and painful. On white skin, plaques typically appear as raised, red patches covered with a silvery white buildup of dead skin cells or scale. On skin of color, the plaques may appear darker and thicker and more of a purple or grayish color or darker brown. Plaques can appear anywhere on the body, although they most often appear on the scalp, knees, elbows, and torso. Plaques

[14] https://www.mayoclinic.org/diseases-conditions/rheumatoid-arthritis/diagnosis-treatment/drc-20353653
[15] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/acr.24596
[16] https://www.arthritis.org/diseases/ankylosing-spondylitis
[17] https://www.mayoclinic.org/diseases-conditions/ankylosing-spondylitis/symptoms-causes/syc-20354808
[18] https://www.ncbi.nlm.nih.gov/books/NBK470173/
[19] https://www.ncbi.nlm.nih.gov/books/NBK470173/
[20] https://www.hopkinsmedicine.org/health/conditions-and-diseases/ankylosing-spondylitis
[21] https://www.hopkinsmedicine.org/health/conditions-and-diseases/ankylosing-spondylitis
[22] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8140694/

generally appear symmetrically on the body, affecting the same areas of the body on the right and left sides.[23] Patients with psoriasis may also present with other chronic conditions such as Crohn's disease, psoriatic arthritis, psychological disorders, and uveitis.[24]

Treatment options for plaque psoriasis include topicals, phototherapy, oral treatments, and biologics. Recognition and management of comorbidities (such as psoriatic arthritis, psychological, cardiovascular and hepatic diseases) is an essential part of holistic care for individuals with psoriasis.[25]

Plaque psoriasis is also the most common clinical form of psoriasis in children.[26] One article reported that approximately 70% of children with psoriasis present with chronic plaque psoriasis.[27] Nearly 40% of adult patients with psoriasis have reported having the condition in childhood, with at least one-third of the patients showing symptoms of psoriasis before the age of 16 years. [28]

One study states that pediatric patients with psoriasis are also likely to have various comorbidities such as hyperlipidemia, hypertension, diabetes mellitus, rheumatoid arthritis, and Chrohn's disease. The long-term comorbidities associated with psoriasis can place a great burden on the physical and mental wellbeing of children with psoriasis beyond the symptoms of psoriasis itself, therefore it is encouraged to screen patients periodically and receive treatment not only for their skin lesions but also for comorbidities.[29]

Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, inflammatory disease of the joints and entheses, where tendons and ligaments connect to bone.[30] It is a type of arthritis linked with psoriasis, a chronic skin disease. PsA affects men and women almost equally with a peak age at onset of 40 and 50 years[31], though it may also affect children. For many people, it starts about 10 years after psoriasis develops, but some develop PsA first or without ever developing or noticing psoriasis.[32]

PsA affects multiple organ systems including peripheral and axial joints, skin, and nails, and is associated with comorbidities such as osteoporosis, uveitis, subclinical bowel inflammation, and cardiovascular disease.[33] Joint pain, stiffness, and swelling are the main symptoms of PsA, and disease flares can alternate with periods of remission.[34] PsA is similar to RA in symptoms and inflammation but it tends to affect fewer joints than RA.[35]

Diagnosing psoriatic arthritis begins with a physical exam to look for swollen or painful joints, and nail and skin changes. X-rays or scans like ultrasound, MRI or CT can show joint damage. Blood tests may help rule out other diseases, and a skin biopsy can confirm psoriasis.[36] Though there is no cure, a growing range of

[23] https://www.psoriasis.org/plaque/
[24] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4323693/#:~:text=Comorbidities%20classically%20associated%20with%20psoriasis,have%20been%20associated%20with%20psoriasis.&text=Gelfand%20et%20al.
[25] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8140694/
[26] https://www.uptodate.com/contents/psoriasis-in-children-epidemiology-clinical-manifestations-and-diagnosis?topicRef=112983&source=see_link
[27] https://onlinelibrary.wiley.com/doi/full/10.1111/1346-8138.17049#:~:text=International%20studies%20have%20shown%20that,significantly%20higher%20incidence%20in%20men.
[28] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3132900/
[29] https://onlinelibrary.wiley.com/doi/full/10.1111/1346-8138.17049#:~:text=International%20studies%20have%20shown%20that,significantly%20higher%20incidence%20in%20men.
[30] https://www.psoriasis.org/about-psoriatic-arthritis/
[31] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6758836/
[32] https://www.psoriasis.org/about-psoriatic-arthritis/
[33] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6758836/
[34] https://www.mayoclinic.org/diseases-conditions/psoriatic-arthritis/symptoms-causes/syc-20354076
[35] https://www.hopkinsmedicine.org/health/conditions-and-diseases/arthritis/psoriatic-arthritis
[36] https://rheumatology.org/patients/psoriatic-arthritis

treatments are available to help stop the disease progression, lessen pain, protect joints, and preserve range of motion. Early recognition, diagnosis, and treatment of PsA can prevent or limit the extensive joint damage that can occur in later stages of the disease.[37]

Juvenile Psoriatic Arthritis

Juvenile idiopathic arthritis (JIA) is an umbrella-term describing a group of conditions characterized by chronic arthritis beginning before the age of 16 years, persisting for at least 6 weeks, and having no other identifiable cause.[38] Juvenile psoriatic arthritis (JPsA) is a relatively rare condition in childhood as it represents approximately 5% of the entire JIA population.[39] JPsA most often appears between the ages of 11 and 12. Girls are more likely to develop it when they are younger and boys when they are older.[40]

Symptoms can vary considerably but may include stiffness, pain, and swelling in one or more joints, pitted nails, stiffness and limited range of motion, fatigue, swelling, redness and pain in the eyes, and a red itchy rash on the joints, scalp, face, and trunk.[41] Early diagnosis improves the chances of successful treatment and the prevention of joint damage and other complications. Treatment for JPsA aims to relieve pain, reduce swelling, and prevent further damage to the joints.[42]

The literature is inconsistent regarding the features of JPsA, and there is debate among rheumatologists whether it is a distinct entity within JIA.[43] The few studies that have compared the clinical characteristics and genetic determinants of JPsA with those of the other JIA categories have obtained competing findings. The debate on the categorization of JPsA as a distinct entity within JIA classification is still ongoing and has prompted the revision of its current classification.[44] Due to the relatively sparse research and very recent FDA approval of Enbrel for treatment of JPsA, some sections of this summary report and the appendices may have less information for this indication.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Polyarticular juvenile idiopathic arthritis (pJIA) also falls beneath the umbrella of JIA. JIA can affect not only joints, but extra-articular structures, including eyes, skin, and internal organs, leading to disability and even associated fatality.[45] Within this cluster of conditions, the polyarticular form of JIA (involving more than four joints within the first 6 months) is further divided based on the presence of rheumatoid factor. Blood tests for rheumatoid factor (RF) will show if this type is RF-positive or RF-negative.[46] Both RF-positive and negative variants have characteristic clinical features: for RF-negative pJIA, inflammation can be asymmetrical, but for RF-positive pJIA symmetric involvement of the large and small joints of hands and feet is the most prevalent.[47]

Children with pJIA pose unique diagnostic and therapeutic challenges compared to children with involvement of fewer joints. Polyarticular JIA patients tend to be at increased risk for joint damage, resulting in poorer functional outcomes and decreased quality of life.[48] Chronic inflammation leads to cartilage and bone erosions and resulting joint damage. This presents clinically as a painful, red, swollen

[37] https://www.psoriasis.org/about-psoriatic-arthritis/
[38] https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00629-8
[39] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9199423/
[40] https://www.medicalnewstoday.com/articles/322612#causes-and-risk-factors
[41] https://www.medicalnewstoday.com/articles/322612#symptoms
[42] https://www.medicalnewstoday.com/articles/322612#treatment
[43] https://www.jrheum.org/content/94/11
[44] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9821505/
[45] https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00629-8
[46] https://www.tandfonline.com/doi/full/10.2147/CLEP.S53168
[47] https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00629-8
[48] https://www.tandfonline.com/doi/full/10.2147/CLEP.S53168

joint(s) with limited range of movement and, if the arthritis is prolonged, potential for joint deformities and growth disturbances.[49]

The progressive nature of JIA and potential for long-term damage emphasizes the critical need for a prompt and accurate diagnosis. The clinical presentation of JIA may vary depending on JIA sub-type. Children with systemic or polyarticular disease may present with more varied symptoms of fatigue, fever, weight loss or growth failure.[50]

Once diagnosed, the early treatment of JIA is critical to increase the potential for disease remission and to avoid further joint damage.[51] The damage caused by JIA can affect patients into adulthood and cause chronic disability. Up to half of young adults will continue to have active disease, and up to one third will have chronic disability into adulthood. Additionally, RF-positive polyarticular JIA is the least likely to achieve remission[52]

Utilizer Profile

Enbrel's utilization has increased since the FDA approved the drug in 1998. According to Colorado's All Payer Claims Database (APCD), 3,406 individuals utilized Enbrel in 2022. Additionally, data from the APCD indicates that patients who utilize Enbrel are most commonly insured through commercial insurance, followed by nearly equal utilization for patients insured by Medicaid and Medicare Advantage plans.[53] APCD utilization estimates can be viewed as low estimates, since data for some self-insured commercial insurance plans (ERISA) and Medicare FFS enrollees, as well as uninsured individuals, is not included. See Appendix P for more information.

Table 2
Utilization of Enbrel

Drug Name	2018	2019	2020	2021	2022
Enbrel	3,890	3,653	3,440	3,692	3,406

Table 2 shows the number of utilizers of Enbrel by year from 2018 - 2022.

[49] https://www.mdpi.com/2227-9032/9/12/1683
[50] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(07)60363-8/fulltext
[51] https://www.mdpi.com/2227-9032/9/12/1683
[52] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(07)60363-8/fulltext
[53]Utilization information in this section is from the Colorado All Payer Claims Database (APCD). APCD data limitations are outlined in Appendix P.

Figure 1
Enbrel Utilization by Payer Type

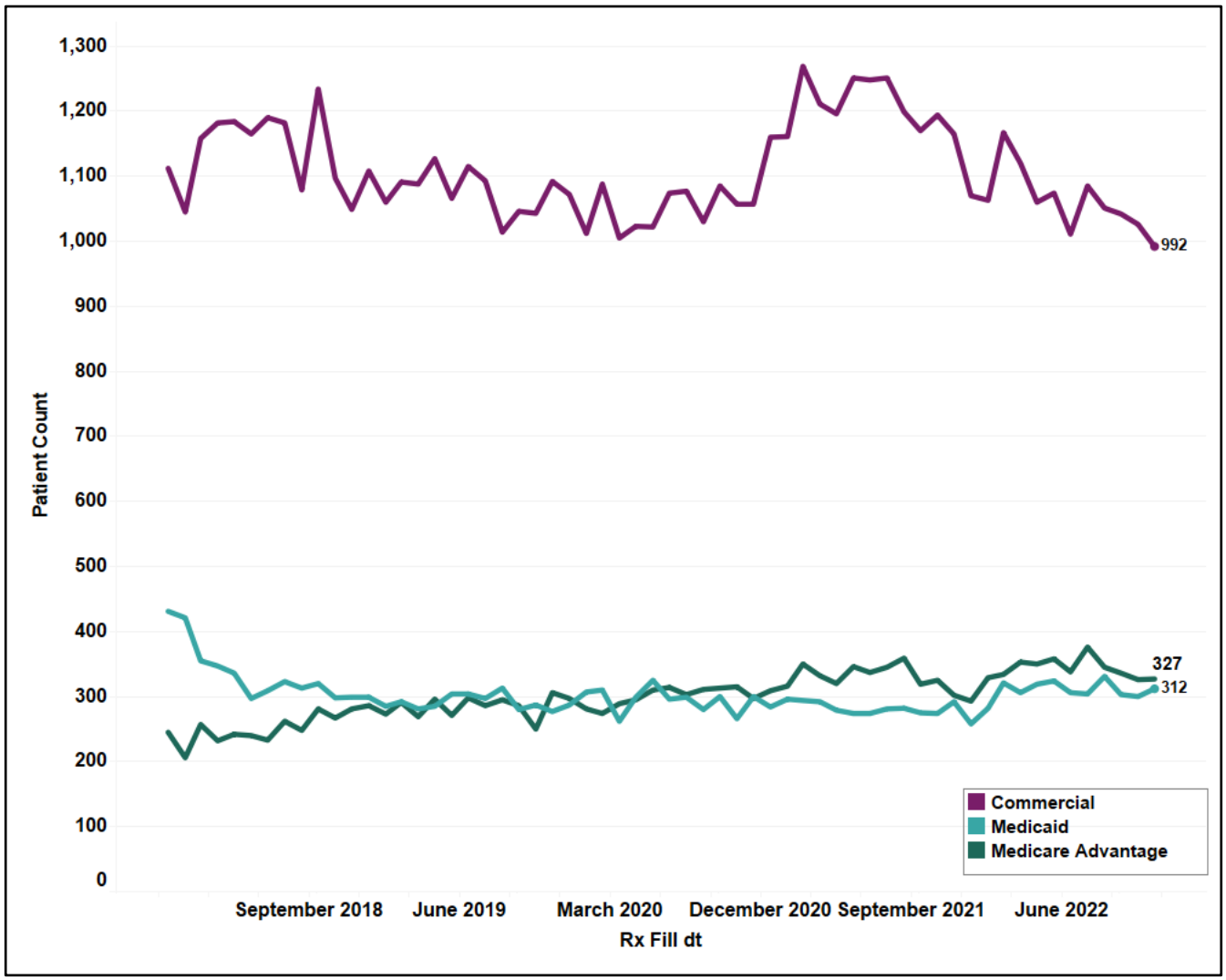


Figure 1 shows the monthly number of patients who filled a prescription for Enbrel each month between January 2018 and December 2022, where the purple line represents the number of commercially insured patients, the teal line shows the number of Medicaid patients, and the green line shows the number of Medicare Advantage patients.

Figure 2
Insurance Information

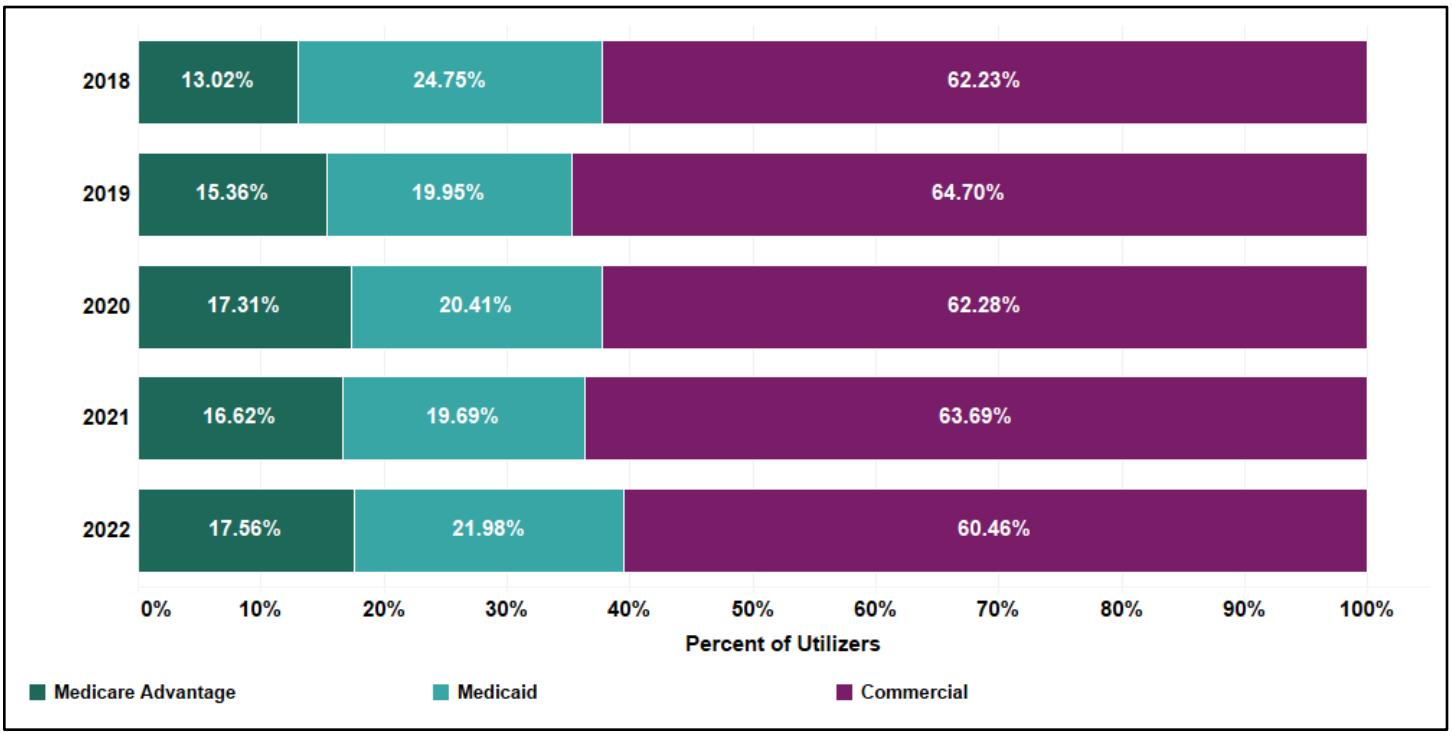


Figure 2 shows Enbrel payer mix percentages from 2018-2022. This figure shows the percent of patients by payer type and year where green represents patients with Medicare Advantage, teal represents patients with Medicaid, and purple represents patients with commercial insurance. From 2018-2022, between 60.46% and 64.70% of Enbrel utilizers were commercially insured.

Health Equity Impact

Obtaining prescription drug-specific information regarding health equity can be a complex task. There is evidence that priority populations[54] experience health inequity associated with their use of medications, which causes an increased risk of adverse outcomes including mortality, morbidity burden, quality of life deficit, and patient safety issues.[55] Further, there may be condition- or disease-specific studies that investigate health inequities, but there are not always studies that investigate the impacts of a specific prescription drug. While there was not significant data regarding Enbrel specifically, there was data regarding indications Enbrel treats. Health equity literature reviews were conducted for five of Enbrel's FDA-approved indications and are summarized in the table below. See Appendix L for more information.

[54] The Board's adopted definition of priority populations is: people experiencing homelessness; people involved with the criminal justice system; black people, indigenous people, and people of color; American Indians and Alaska natives; veterans; people who are lesbian, gay, bisexual, transgender, queer, or questioning; people of disproportionately affected sexual orientations, gender identities, or sex assigned at birth; people who have AIDS or HIV; older adults; children and families; and people with disabilities, including people who are deaf and hard of hearing, people who are blind and deafblind, people with brain injuries, people with intellectual and developmental disabilities, people with other co-occurring disabilities; and other populations as deemed appropriate by the Prescription Drug Affordability Board. 3 CCR 702-9, 1.1.C.
[55] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10037618/#:~:text=In%20comparison%20to%20the%20general,16%2C17%2C18%5D.

Table 3
Enbrel Health Equity Literature Review Highlights by Indication

Indication	Health Equity Literature Review Highlights
RA	• Non-Hispanic African Americans and people with low family income had a significantly higher RA risk, while people with high education levels had a significantly lower RA risk. • Geographic distance from a rheumatologist can increase negative health outcomes by delaying diagnosis and making it difficult for patients to receive the frequent reassessments needed to monitor disease activity. One study found that patients with the longest driving distances to rheumatology providers had approximately 30% decreased odds of receiving an RA diagnosis compared with those located nearest to rheumatology care.
AS	• Ankylosing spondylitis (AS), a subset of axial spondyloarthritis, is historically considered a disease predominantly impacting men and it is often under-recognized or misdiagnosed in women. • Multiple researchers have raised concerns about detection bias with regard to diagnosing AS among people of color. Despite being diagnosed at lower rates than white and Hispanic patients, Black patients reported greater discomfort and impairment, had higher levels of inflammation, and showed more joint damage and deterioration on X-rays and MRIs.
PsO	• Hispanic and Black patients with psoriasis experienced more provider-related bias, stereotyping, misdiagnosis, and delayed diagnosis compared with white patients. Additionally, people with skin of color are underrepresented in clinical trials of psoriasis therapies. • Children with psoriasis are at approximately 20% to –30% higher risk of developing psychiatric disorders, such as depression and anxiety, than children without any psoriasis diagnosis.
PsA	• One study found that white patients were five times more likely to be diagnosed with psoriatic arthritis compared with Black patients. The disparity in prevalence could potentially be due to underdiagnosis in historically marginalized racial/ethnic groups. • One study reported a significantly higher degree of disease severity and lower use of biologics among Black patients compared with white patients. One study found Black patients were 70% less likely to receive biologics than white patients.
pJIA	• One US study showed that Black children with pJIA were nearly twice as likely to have joint damage than their white counterparts. • Lower socioeconomic status was associated with persistent functional disability, race/ethnicity was associated with higher disease activity, and use of public insurance and a guardian's education level of high school or lesser were associated with both functional disability and persistent moderate to severe disease activity across the first year of treatment.

During the selection of eligible prescription drugs for affordability reviews, the Board reviewed a Social Vulnerability Index Score (SVI) for all eligible prescription drugs. The SVI score represents the percent of individuals who use Enbrel who live in a county with a score above the Colorado average score. Individuals residing in counties with SVI scores higher than the statewide average may be more vulnerable to adverse outcomes due to social conditions in their county. The SVI score measurement is not meant to be a comprehensive assessment of Enbrel and health equity. Rather, it is meant to be a contextual snapshot to better understand if the typical patient who uses Enbrel lives in a county that has a higher vulnerability to adverse outcomes due to social conditions than the average Colorado county.

In 2022, 48.65% of patients taking Enbrel lived in a county with a higher SVI score than the statewide average. This means that patients taking Enbrel have a slightly lower likelihood of living in a county with higher vulnerability to adverse outcomes due to social conditions than the average Coloradan. See Appendix L for more information.

Figure 3

Map of Colorado by 2022 SVI Score for Utilizers of Enbrel

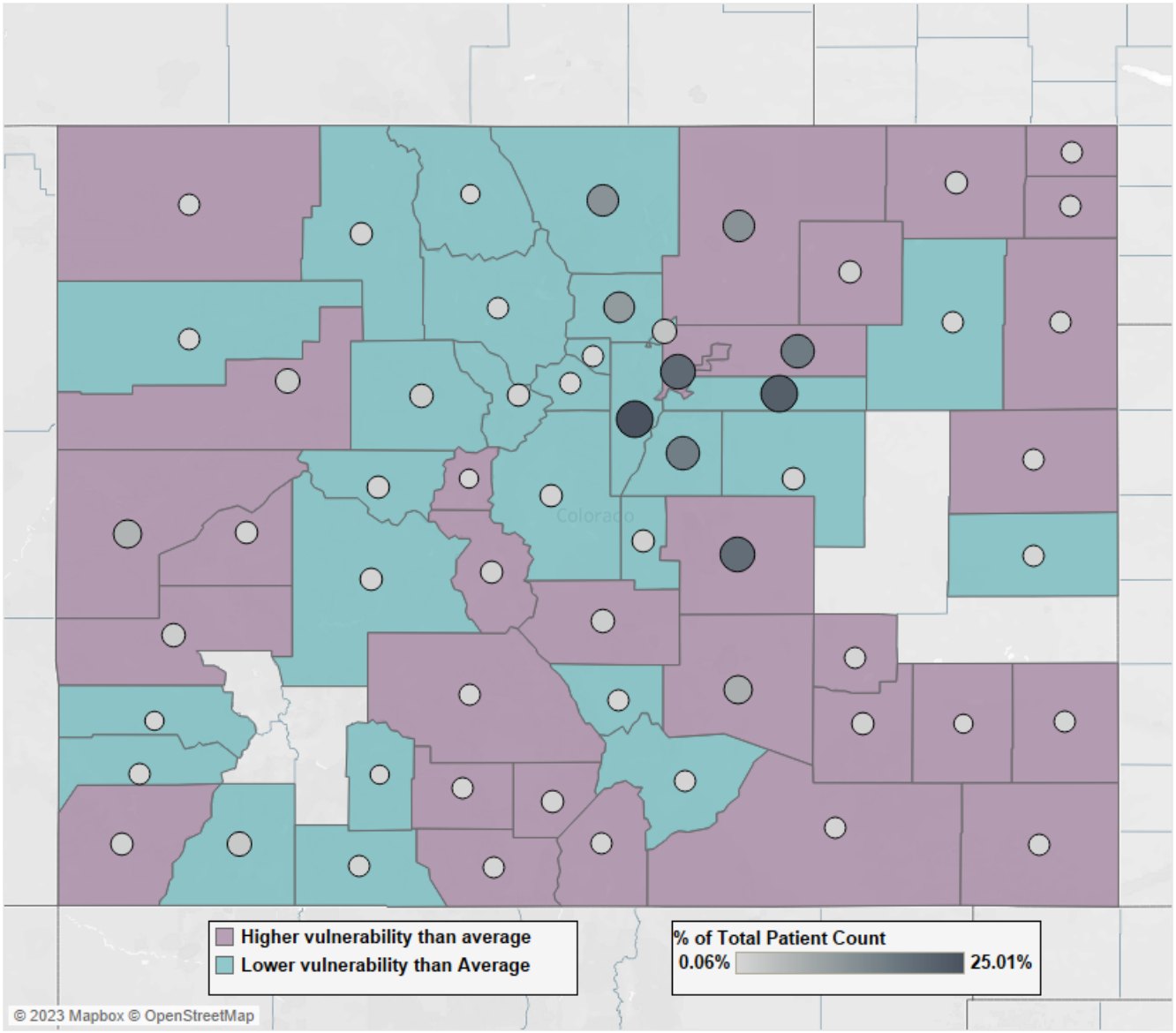


Figure 3 shows a map of Colorado by county, where purple counties indicate higher than average SVI scores and teal counties indicate a lower than SVI score, and counties without color did not have any patients who used Enbrel in 2022 residing in them. The dots on each county show the percent of patients who used Enbrel in 2022 by county where a larger, darker dot represents a higher portion of utilizers and smaller, lighter dots represent a smaller portion of the population.

Board staff received robust patient and caregiver input through an online survey aimed at gathering information regarding the health and financial effects of Enbrel. Survey participants could voluntarily provide information regarding whether they were a member of a priority population. Of the 38 Colorado respondents, eight were children and family members, 15 were older adults, 18 were people with a disability, one was disproportionately affected by sexual orientation, gender, identity, or sex assigned at birth, and six were people who are lesbian, gay, bisexual, queer, or questioning.

Therapeutic Alternatives

The Board adopted a definition of therapeutic alternatives as prescription drugs in the same pharmacological or therapeutic class that have been shown through peer-reviewed studies to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose or prescription drugs recommended as consistent with standard medical practice by medical professional association guidelines (3 CCR 702-9, Part 1.1.C). For the purposes of this affordability review, therapeutic alternatives were identified through the review of medical professional association guidelines. The resulting in-class therapeutic alternatives are summarized in Table 4 below. Information related to Enbrel's therapeutic alternatives is contained throughout this summary report and appendices. Humira and Remicade have FDA-approved biosimilar products. The following biosimilar products are approved for Humira (US market entrance date): Abrilada (11/29/2023), Amjevita (1/31/2023), Cyltezo (7/1/2023), Hadlima (7/6/2023), Hulio (7/6/2023), Hyrimoz (7/6/2023), Idacio (7/1/2023), Yuflyma (7/5/2023), Yusimry (7/6/2023). The following biosimilar products are approved for Remicade (FDA approval date): Avsola (7/6/2020), Inflectra (11/21/2016), Reflexis (8/1/2017).[56]

Table 4
Enbrel Therapeutic Alternatives Details

Non-proprietary name	Brand Name	Mechanism of Action	Approved Indication(s) (FDA Approval Date)
adalimumab	Humira	TNF inhibitor	RA (2002), AS (2006), PsO (2008), PsA (2005), pJIA (2008)
certolizumab pegol	Cimzia	TNF inhibitor	RA (2009), AS (2013), PsO (2018), PsA (2013)
golimumab	Simponi / Simponi Aria	TNF inhibitor	RA (2009), AS (2009), PsA (2009), pJIA (2020)
infliximab	Remicade	TNF inhibitor	RA (1999), AS (2004), PsO (2006), PsA (2005)

Table 4 shows details of Enbrel's therapeutic alternatives and FDA approval dates.

Utilization information for Enbrel and therapeutic alternatives is outlined below.

Table 5
Utilization of Enbrel and identified Therapeutic Alternatives

Brand Name	2018	2019	2020	2021	2022
Enbrel	3,890	3,653	3,440	3,692	3,406
Cimzia	350	337	368	453	475
Humira	4,920	5,557	5,960	7,339	7,526
Remicade	1,172	1,271	1,161	1,087	698
Simponi	337	375	400	501	579

Table 5 shows the number of utilizers of Enbrel and therapeutic alternatives by year from 2018 - 2022.

[56] Analytics were not conducted on biosimilar products due their relatively new introduction and low utilization in 2018-2022 APCD data.

Figure 4

Insurance information for Therapeutic Alternatives

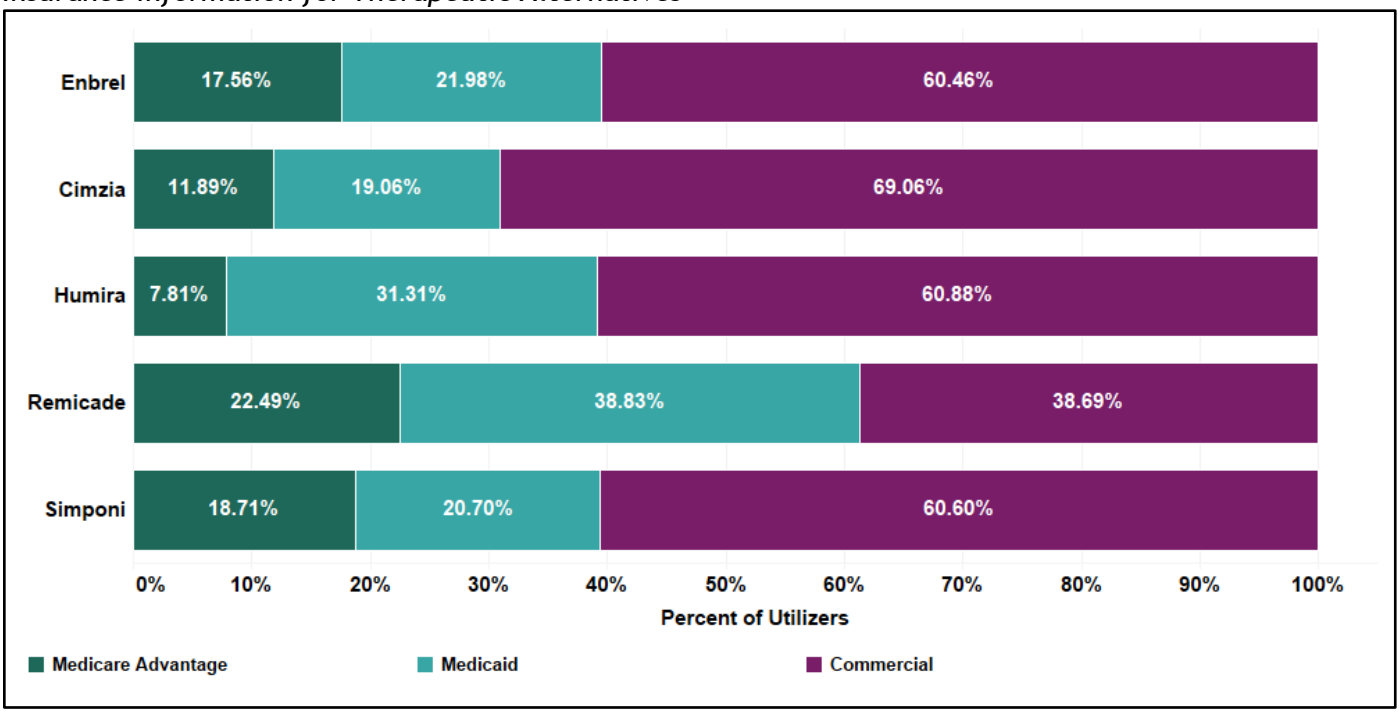


Figure 4 shows the 2022 payer mix for Enbrel and its identified therapeutic alternatives. This figure shows the percent of patients by payer type and year where green represents patients with Medicare Advantage, Teal represents patients with Medicaid, and purple represents patients with commercial insurance. Enbrel, Humira, and Simponi had around 60% of patients with commercial insurance while Cimzia had higher commercial coverage (69.06%) and Remicade had lower commercial coverage (38.69%).

Enbrel Price and Cost Profile

The Price and Cost Profile includes information on what different entities on the prescription drug supply chain charge for Enbrel, as well as what different entities pay for Enbrel. This profile also contains information on Enbrel's financial effects on health, medical, and social service costs.

Table 6

Enbrel's 2022 Price & Cost per Person Statistics

Price & Cost Per Person Statistics	Amount
Average WAC per Course of Treatment per Person[57]	[redacted]
Average Paid per Person	$46,772
APPY - Plan Paid	$41,769

[57] Course of treatment is calculated based on utilization not FDA labeling recommended doses. For course of treatment methodology please see June 9th, 2023 PDAB Board staff memo: https://drive.google.com/file/d/16BFOEB-LMiulmYzhKhxeGjvbFoh88cTs/view?usp=sharing

APPY - Out-of-Pocket[58]	$2,295

Table 7
Enbrel's 2022 Statewide Price & Cost Statistics

Statewide Price and Cost Statistics	Amount
Total Paid Amount	$159,305,653
Total Plan Paid[59]	$142,264,673
Total Medicaid Paid	$24,456,550
Total Patient Paid	$9,860,820
Gross-to-net Estimates	[redacted]

The current WAC for Enbrel is [redacted] per unit, with the most recent update to the WAC in January 2024. The initial WAC was [redacted] in November 1998. This is a 1,582.24% increase from November 1998 to January 2024, a 40.27% increase in the past five years, and a 5% increase from 2023. The average course of treatment is [redacted] units per patient per year, making the current WAC per course of treatment [redacted].[60] See Appendix A for more information.

Pursuant to section 10-16-1405, C.R.S., carriers and pharmacy benefit managers submit data about the highest cost prescription drugs to the APCD, including the fifteen prescription drugs that caused the greatest increase to the carrier's premiums. Ten of the nineteen carriers who submitted data reported Enbrel in the top fifteen drugs that caused the greatest increase to premiums, seven of these submitters reported Enbrel in the top five drugs that caused the greatest increase to premiums. Additionally, prescription drug transparency data from other states indicates Enbrel is among the costliest drugs in the state (Maine, Oregon) and has price increases above certain thresholds (Minnesota). See Appendix O for more information. The SEC requires all public companies to file a Form 10-K each year, and a Form 10-Q each quarter.[61] These forms provide a financial snapshot of the company's revenues, assets, and liabilities for the previous year. Amgen Inc.'s 2022 10-K details that Enbrel's international Product Revenue decreased from approximately $4.465 billion in 2021 to $4.117 billion in 2022 (p.F-17). See Appendix O for more information.

Out-of-Pocket Estimates

Patient copayment and other cost sharing depends on many factors, including: a patient's insurance coverage, how much has already been contributed to out-of-pocket maximum amounts in a benefit year, and whether the patient receives other assistance to pay for their portion of prescription drug. The APCD

[58] Medicaid copayments are $0-$3 for each prescription fill, as a result, Medicaid out of pocket paid amounts are removed from all averages in the data presented below, however, it is included in the statewide totals when reviewing the total amount patients paid. Medicaid copay information: https://www.healthfirstcolorado.com/copay/
[59] Total Plan Paid represents the amount paid by a patient's primary insurance coverage, even though secondary coverage may have paid an amount. Secondary insurance coverage paid amounts are generally captured in Total Paid Amounts.
[60] Course of Treatment methodology outlined in Board Staff Memo from June 6, 2023: https://drive.google.com/file/d/16BFOEB-LMiulmYzhKhxeGjvbFoh88cTs/view?usp=sharing.
[61] United States Securities and Exchange Commission, Form 10-K, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, Transition Report Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934, Amgen Inc., : https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/318154/000031815423000017/amgn-20221231.htm.

provides data on the patient portion of the claim paid for the drug, but does not contain any information on assistance programs. Patients, caregivers, and individuals with scientific or medical training provided input regarding their experiences with assistance programs through public meetings, surveys, and voluntarily submitted information. See Appendices H, I, and J for more information.

The average annual out-of-pocket cost per person per year for individuals with commercial insurance is $3,980. There was wide variation in monthly average out-of-pocket costs, where 57.3% of individuals paid a total amount between $0-$50, though some individuals paid as much as $9,850-9,990.[62] Figure 5 outlines the annual out-of-pocket amounts for commercially insured individuals by type of out-of-pocket expense. See Appendix E for more details.

Figure 5
Average Commercial Out-of-Pocket Cost Comparison



[62] For the vast majority of patients covered by Medicaid, patient prescription drug copayments are between $0-$3 for each prescription drug fill and most individuals with Medicaid coverage do not have deductibles or coinsurance. See Appendix E for more information.

Figure 5 shows each out-of-pocket cost type for commercially insured individuals with Enbrel in dark purple and its therapeutic alternatives by year. There is a light gray line that shows the average of the therapeutic alternatives as a comparison to determine if Enbrel is more or less expensive than the average of its therapeutic alternatives. For example, the bottom right corner shows the average total out-of-pocket cost in 2022, Enbrel was $3,980, which is higher than the average of the four identified therapeutic alternatives, but lower than one of the therapeutic alternatives.

Another snapshot of out-of-pocket costs for individuals with commercial insurance is summarized below for both Enbrel and identified therapeutic alternatives.

Table 8
Average Monthly Commercial Out-of-Pocket Cost Information in 2022

	Enbrel	Cimzia	Humira	Remicade	Simponi
Average Total OOP Cost	**$373**	$305	$356	$303	$263
Average Coinsurance Amount	**$151**	$103	$171	$124	$105
Average Copay Amount	**$78**	$53	$56	$21	$48
Average Deductible Amount	**$132**	$146	$129	$125	$98
Average Days Supply	**34.3**	31.5	32.4	45.5	35.6

Table 8 shows average monthly out of pocket expenditures for individuals who are commercially insured.

In 2022, in an average month, an individual with commercial insurance paid a total of $373, $132 went towards a patient's deductible, $151 was paid towards coinsurance, and $78 was paid via copayment. Similar information is provided for therapeutic alternatives. These averages are calculated based on claims from the APCD, which does not include information about assistance programs that individuals might use when filling their prescriptions.

Figure 6
Changes in Copay amounts by Year and Drug 2018-2022

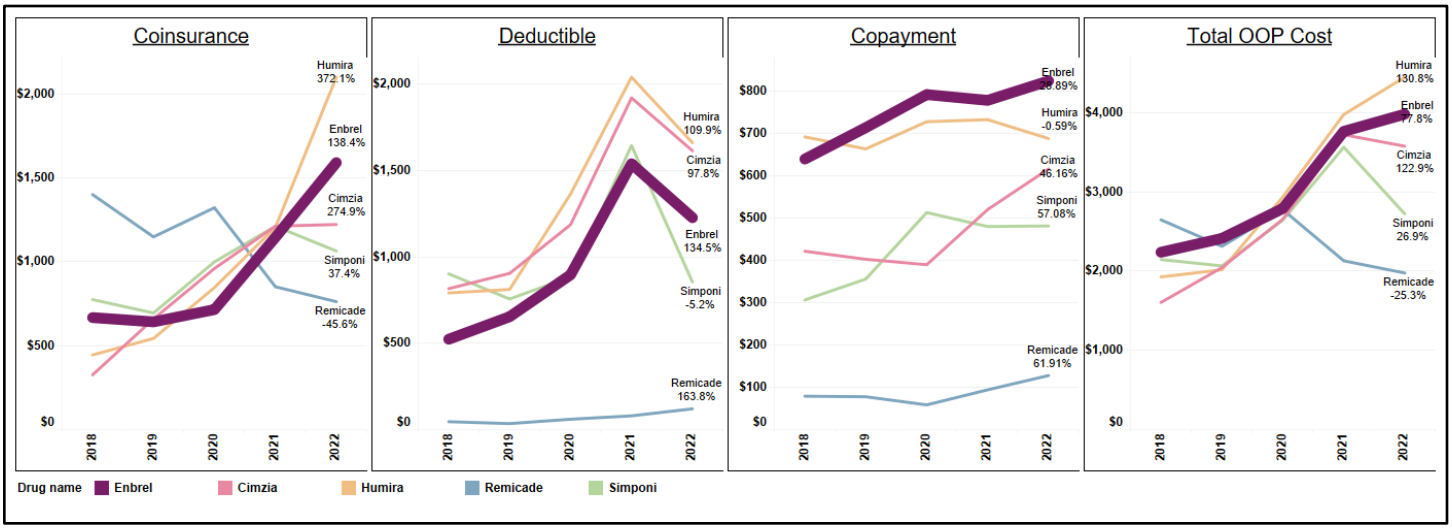


Figure 6 shows the annual change in the annual average oop amounts comparing Enbrel (dark purple) to its therapeutic alternatives. Each line is labeled with the name of the therapeutic alternative and the percent change from January 2018 - December 2022. Enbrel had the third highest increase in total out-of-pocket costs with a 77.8% increase. See Appendix E for more information.

Amgen Inc. provided information on the Enbrel Co-Pay Card program and Amgen Safety Net Foundation, which is available to eligible patients who need additional help and provides free or reduced medicine to patients who do not have insurance and meet certain eligibility criteria. See Appendices J and K for more information. Board staff received information in surveys that as many as 87% (33 of 38) of patients utilize some form of patient assistance program (could be manufacturer or another entity), though 30% (10 of 33) still had trouble affording Enbrel. See Appendices H, I, J, and K for more information.

Rebates, Discounts, and Price Concessions Estimates

The gross-to-net sales estimate is a proprietary estimate where SSR Health estimates all price concessions the manufacturer gives, including rebates, 340B discounts, assistance programs, and other price concessions provided by manufacturers compared to gross sales to get a percentage estimate of all discounts.[63] The gross-to-net sales estimate was [redacted] in the third quarter of 2008 (the earliest SSR Health estimates available), which increased to [redacted] in the third quarter of 2023. Additionally, In 2021, 14 of 25 carriers reported to the APCD that Enbrel was in the top 15 drugs for which the carrier received the largest rebate. See Appendix K for more information.

[63] All gross-to-net estimates are provided on a four quarter moving average.

Figure 7
Estimated Total Gross-to-Net Sales



Figure 7 shows the total gross-to-net sales estimate for Enbrel and identified therapeutic alternatives. The gross-to-net sales estimate for Enbrel has increased to [redacted] in the third quarter of 2023, [redacted]

Enbrel's Health and Financial Effects

One component of affordability reviews is an assessment of the relative financial effects on health, medical, or social service costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. Information regarding Enbrel's relative financial effects on health, medical, or social service costs is summarized here from literature reviews (Appendix D), input from patients and caregivers (Appendix H), input from individuals with scientific and medical training (Appendix I), and voluntarily submitted information (Appendix J). These summaries are structured to focus first on Enbrel's health effects, followed by financial effects.

Enbrel's Health Effects

The FDA label provides information on Enbrel's impact on the health effects on the indications it is approved to treat. See Appendix D for more information. Patients, caregivers, and individuals with scientific and

medical training reported in meetings and surveys regarding health effects. Examples of feedback, including two quotes that summarize common themes, are provided below; see Appendix H and Appendix I for more information.

- *"This drug has given me my life back. My flares are farther apart and Enbrel has allowed me to live my own life with few modifications and compromises"* Survey respondent with rheumatoid arthritis.
- *"We cycle through these drugs because sometimes they lose effectiveness or we just build up an immunity to them. That happened with Enbrel, but it was a glorious remission when I had it."* Public input session attendee.
- Enbrel has reduced pain and symptoms in the majority of patients of all indications, though some rheumatoid arthritis and psoriatic arthritis patients reported no improvements. Other patients stated that Enbrel worked well until it lost its effectiveness and they had to cycle to a new medication. One patient at a public input session liked that Enbrel is self-injectable, which cut down on trips to the doctor to get infusions.
- The most common side effect reported for all indications was pain and bruising at the injection site. Less common symptoms were chills, nausea, lowered immune system, depression, and dry mouth leading to dental issues. One patient reported not caring for the delivery method of self-injection.

Additionally, patients and caregivers provided input regarding therapeutic alternatives. Select answers are summarized below; see Appendix H for more information.

- **Humira:** Many patients reported it to be ineffective, and others reported that it worked well for a time to reduce inflammation and pain before it lost efficacy. One patient stated that it works better than Enbrel for them. Patients reported similar side effects as Enbrel.
- **Remicade**: Patients reported that this worked well but then plateaued and stopped working. One patient stated it gave them no relief.
- **Cimzia**: Effective and pregnancy safe option. One said getting sick too often.
- **Methotrexate:** Some patients said it did not work, others said it reduced inflammation but caused extreme severe side effects leading them to stop taking it. Reported side effects include nausea, blurry vision, severe fatigue and nausea, brain fog, hair loss, sores in mouth, and liver damage.

In addition to gathering information from patients, caregivers, and individuals with scientific and medical training, Board staff conducted literature reviews to compile evidence of the clinical effectiveness of Enbrel. To do this, Board staff examined studies conducted by Health Technology Assessment (HTAs) organizations. HTA organizations, often found within or supporting governmental agencies in other countries, can provide consistent and thorough assessments of a prescription drug's clinical and cost effectiveness. See Appendix D for information compiled from six HTA organizations for Enbrel's FDA-approved indications.

Enbrel's Financial Effects

Understanding a prescription drug's financial effects on health, medical, and social service costs as compared to therapeutic alternatives can be a complex task. HTA organizations conduct evaluations of the effects and impacts of a prescription drug, which may address the direct, intended consequences as well as their indirect, unintended consequences. Though nearly all HTA organizations take into account patient, caregiver, and provider perspectives when determining a prescription drug's cost effectiveness, Board staff were able to gather direct input from those groups on Enbrel's financial effects on health, medical, and social service costs.

Patients, caregivers, and individuals with scientific and medical training were asked in public meetings and in surveys to share any additional information about how Enbrel affects them financially. Participants and

respondents shared experiences related to out-of-pocket costs, assistance programs, and utilization management requirements. Select answers are highlighted below; see Appendix H for more information.

Table 9
National and Colorado Patient Responses: How does Enbrel impact each patient or their family?[64]

Survey Prompt	National Responses	Colorado Responses
This medication reduces the amount of time and money going to the doctor.	110 of 267	14 of 38
This medication reduces the amount of time and money spent going to the hospital or needing surgery.	63 of 267	9 of 38
This medication allows me to work and support my family.	110 of 267	15 of 38
Due to the cost of this medication, I have had to cut costs in other areas of my life.	74 of 267	20 of 38
Out-of-pocket costs have caused me to accrue medical debt.	36 of 267	8 of 38

Additionally, of the 33 of 38 Colorado patients who use assistance programs, 10 patients still had trouble affording Enbrel despite assistance. See Appendix H (input from patients and caregivers), Appendix I (input from individuals with scientific and medical training), and Appendix J (voluntarily submitted information) for more detail.

Board staff conducted literature reviews to compile evidence of the cost effectiveness of Enbrel. A summary of these organizations, the country where they are found, and their conclusions regarding the clinical effectiveness of Enbrel are outlined in Appendix D.

Enbrel Access to Care Profile

The Access to Care Profile examines potential access to care concerns related to Enbrel and whether there is evidence that the causes of access to care concerns may be related to Enbrel's price or cost. This profile includes an examination of potential relationships of changes between utilization, price, and costs as well as information on safety net providers, utilization management requirements, and health benefit plan design.

Price Effect on Access

Enbrel's WAC has increased 36 times since it was approved by the FDA in 1998, increasing a total of 1,582.24% since introduction, an increase that is significantly more than inflation (Figure 8 below). See Appendix A for more information. From 2018 to 2022, APCD data shows fluctuations in Enbrel's average annual patient out-of-pocket costs and total patient paid amounts, but with general increases across the five years and a 35.9% increase in average annual out-of-pocket costs (Table 10 below). See Appendix E for more information. Meanwhile, APCD data shows monthly fluctuations in average utilization of Enbrel, which

[64] 45 out of 267 national survey participants did not answer regarding the impact Enbrel has on the patient or their family. 3 out of 38 Colorado survey participants did not answer regarding the impact Enbrel has on the patient or their family.

appear relatively steady, though there was a decrease in utilization from 2018 to 2022 (See Figure 9 and Table 10 below).

Two of Enbrel's therapeutic alternatives, Humira and Remicade, have recent FDA-approved biosimilar products. While this affordability review does not contain information or analyses related to biosimilar products, there is evidence that biosimilar entry for TNF inhibitors resulted in increased utilization and price reduction in European markets.[65] Currently, Enbrel has patent protection and is protected from biosimilar competition and patents that prevent the introduction of biosimilar products are set to expire in 2029.[66] See Appendix C for more information.

Patient and caregiver survey results provide further insight that patients report the cost of Enbrel has impacted their ability to access the prescription drug (see Table 11 below). While this impact varies by the self-reported out-of-pocket cost per month, over half (10 of 19) of Colorado patients paying between $0-50 per month for Enbrel still reported that cost has at some point impacted their ability to access Enbrel. See Appendices E and H for more information.

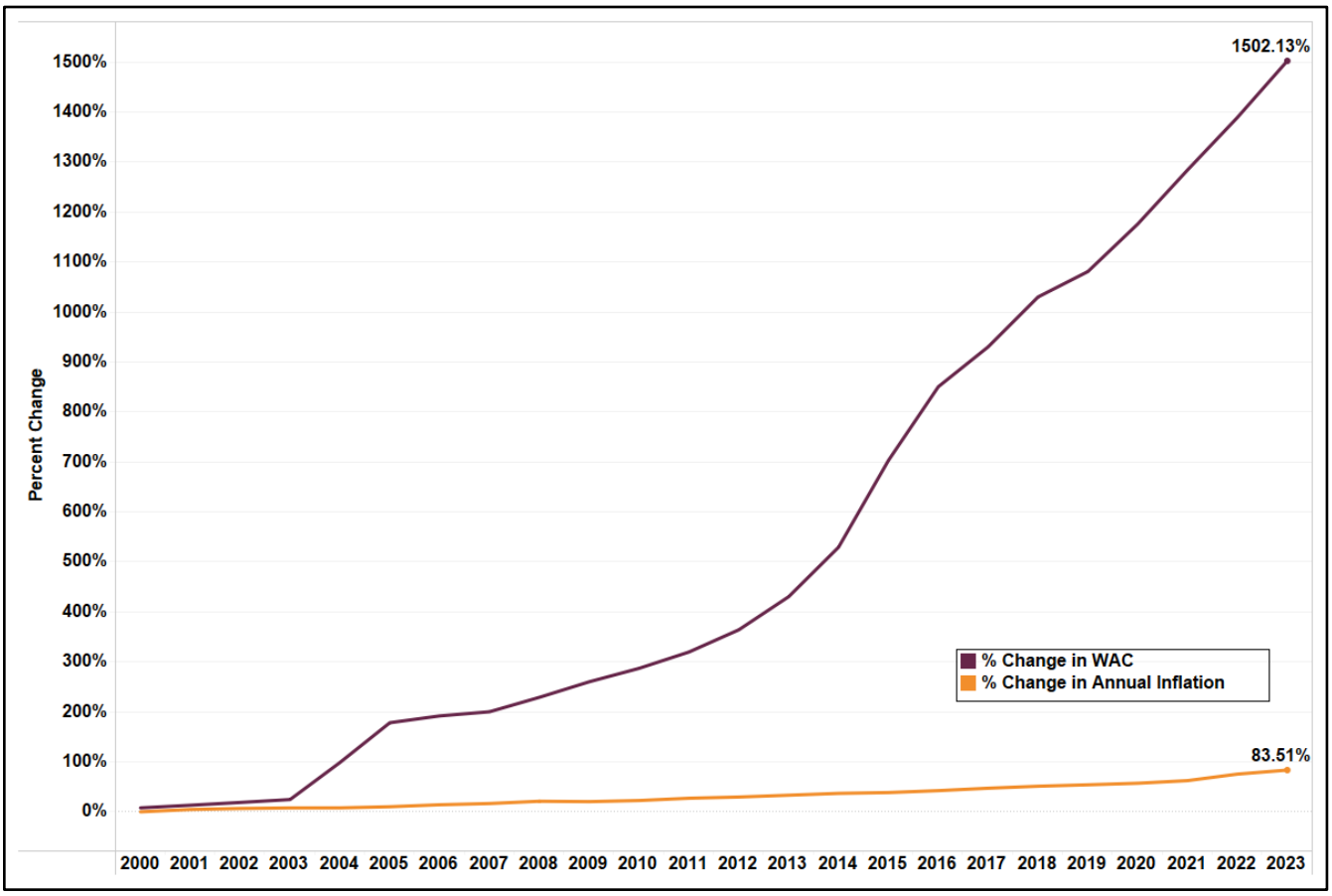
Table 10
Annual Utilization and Expenditures

	2018	2019	2020	2021	2022
Patient Count	3,890	3,653	3,440	3,692	3,406
Total Paid	$129,421,272	$127,959,896	$134,815,241	$161,483,771	$159,305,653
Average Paid Per Person	$33,270	$35,029	$39,190	$43,739	$46,772
Total Patient Paid	$6,720,180	$7,399,691	$7,700,602	$10,524,066	$9,860,820
Average OOP	$1,688	$1,866	$2,189	$2,526	$2,295
WAC Per Unit	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table 10 shows the year-over-year increases in the number of patients using Enbrel, the total amount paid for Enbrel, the average paid per person, the total amount that patients paid, and the average amount that each patient paid.

[65] https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2023.1151764/full
[66] https://www.centerforbiosimilars.com/view/nj-court-decision-means-3-decades-of-product-exclusivity-for-enbrel

Figure 8
Percentage Change in WAC (Enbrel) Compared to Annual Inflation



For additional context, Figure 8 shows the same change in WAC as a percent change (purple) and annual inflation (orange) over the same time frame.[67]

[67] Figure 8 shows a comparison with inflation, which was not calculated for the complete year of 2023 at the time of this report, so the most recent WAC price is not included in this graphic and the percent change in WAC noted here is from 2018 through 2022.

Figure 9

Monthly Utilizers for Enbrel and Therapeutic Alternatives

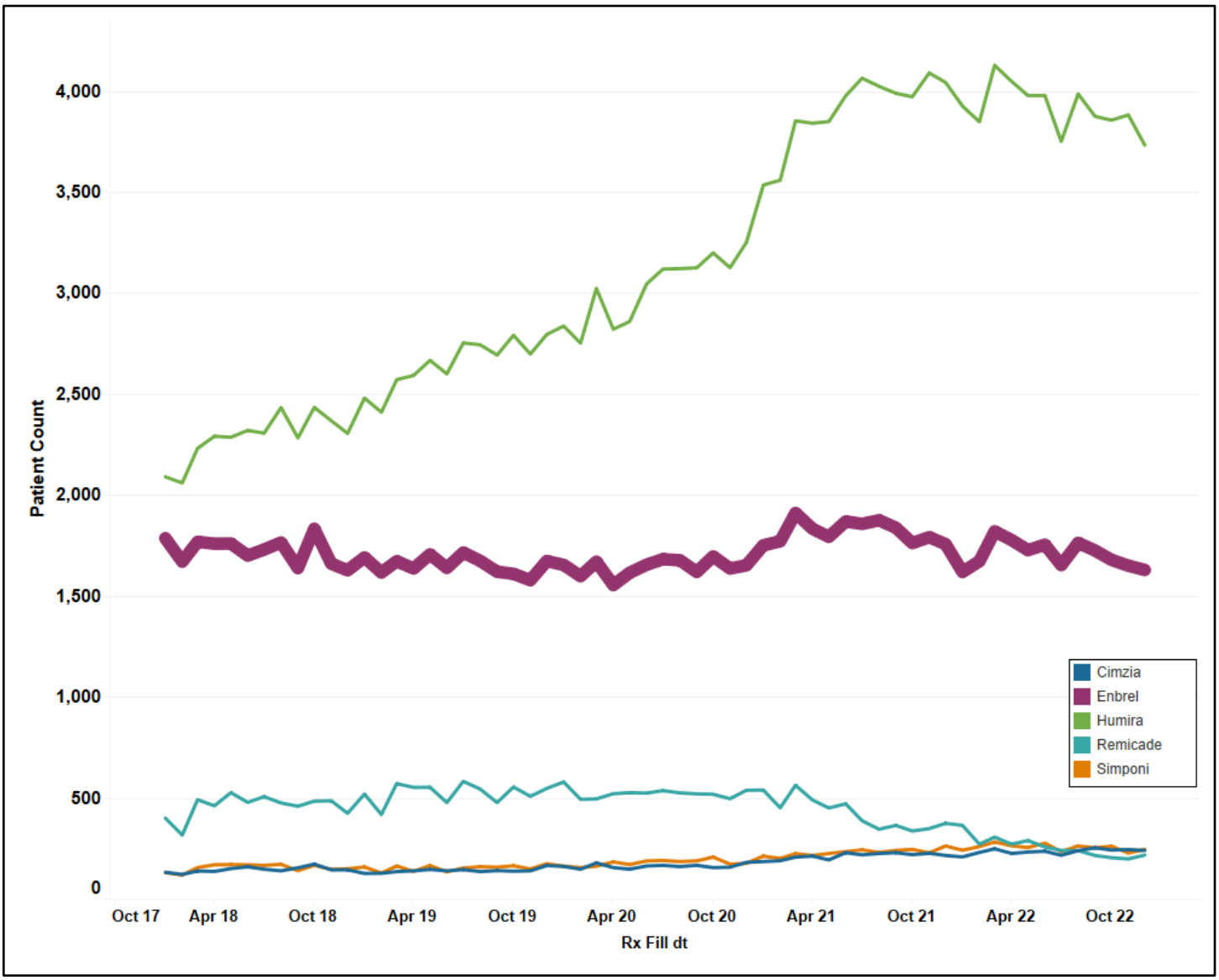


Figure 9 shows the monthly number of utilizers for Enbrel and therapeutic alternatives. Utilization of Enbrel has stayed consistent from January 2018 to December 2022, it is the second highest utilized drug after Humira which has increased significantly in the same timeframe.

Figure 10
Monthly Total Paid and Average Total Paid

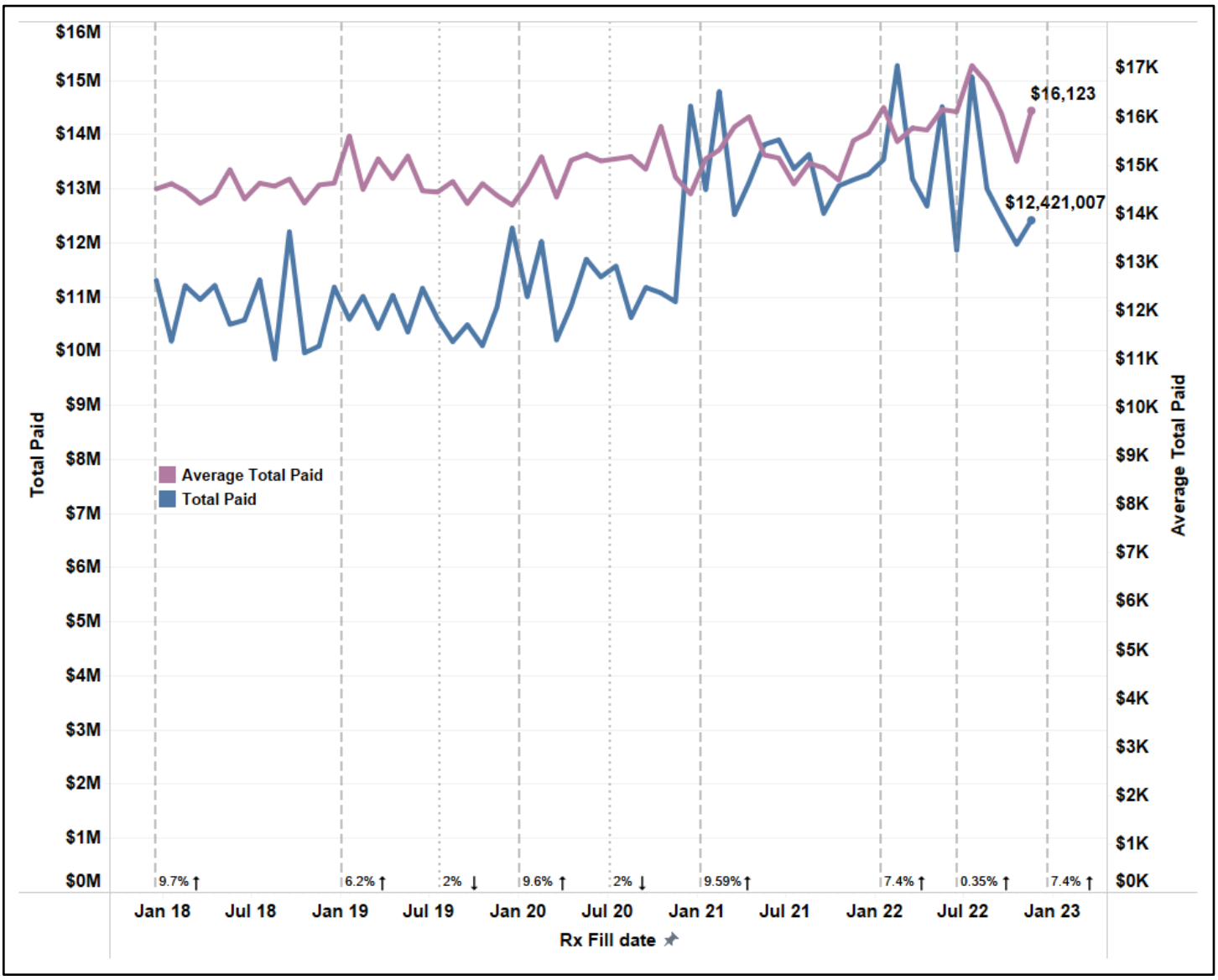


Figure 10 shows the monthly total paid with the blue line (left axis) and the monthly average paid per person with the purple line (right axis) with vertical lines representing changes in WAC with the magnitude of the change written to the right of the line with an arrow up or down indicating an increase or decrease in the WAC. There is no visible correlation between the WAC change and the corresponding change in the APCD paid amounts. During this time frame, the number of patients using Enbrel increased from 3,890 in 2018 to 3,406 in 2022.

Table 11
Colorado Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	Colorado Response	Cost Affects Access
$0 - $50	19 of 38	10 of 19 said cost does affect access.

$50 - 100	4 of 38	2 of 4 said cost does affect access.
$100 - $150	1 of 38	1 of 1 said cost does affect access.
$150 - $250	2 of 38	2 of 2 said cost does affect access.
$250 - $500	1 of 38	1 of 1 said cost does affect access.
$500 - $1000	6 of 38	6 of 6 said cost does affect access.
More than $1000 per month	5 of 38	5 of 5 said cost does affect access.

Safety Net Providers, Utilization Management Requirements, and Health Benefit Plan Design

Individuals with scientific and medical training provided input that safety net providers participate as covered entities in the federal 340B Drug Pricing Program administered by the U.S. Health Resources & Services Administration (HRSA) and dispense Enbrel. See Appendix H for more information. No safety net providers volunteered information regarding Enbrel's utilization in a safety net setting, nor the nature of the 340B discount for Enbrel. See Appendices F, I, and M for more information.

It is difficult to precisely know how many uninsured patients in Colorado have an indication treated by Enbrel. Patients and caregivers who responded to the survey provided some insight. See Appendix H for more information.

Patients and caregivers who completed surveys provided the following information regarding utilization management:

Table 12
Survey response: Utilization management.

Survey Prompt	National Responses	Colorado Responses
I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	23 of 267 (9%)	6 of 38 (16%)
My insurance plan has dropped or switched my drug coverage after the plan year started.	25 of 267 (9%)	2 of 38 (5%)
My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	73 of 267 (27%)	14 of 38 (37%)
My insurance plan requires prior approval to fill the prescription.	183 of 267 (69%)	24 of 38 (63%)
My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	97 of 267 (36%)	18 of 38 (47%)

I worry that the cost of my prescription will raise my insurance premium.	56 of 267 (21%)	8 of 38 (21%)

Table 12 shows both national and Colorado patient responses to a survey question asking if they had experienced any of the listed utilization management practices. See Appendix H for more information.

Utilization management requirements, along with prescription drug formularies, are meant to encourage the use of medically appropriate and cost-effective drug-related products that meet the needs of patient populations.[68] To better understand health benefit plan design coverage and formulary structure, data was accessed by Colorado Division of Insurance (DOI) staff for the affordability review. Data pulled was for carriers in the individual and small group markets for which DOI receives annual rate filings. As such, this data does not describe the entire insurance market in Colorado, but can shed valuable information on benefit plan design and out-of-pocket costs.

Of the ten carriers that submitted filings, eight carriers cover four or more dosage forms of Enbrel. All carriers that cover Enbrel require prior authorization. In total, 576 plans provide coverage for Enbrel and the majority of carriers place Enbrel on the highest two formulary tears, meaning a higher portion of the drug is paid by patients than prescription drugs on lower tiers (until the maximum out-of-pocket amount under the plan is paid by the patient). See Appendix E for more information.

68 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10398227/#:~:text=The%20intent%20of%20a%20formulary,the%20needs%20of%20patient%20populations.

Appendix A

Enbrel: Wholesale Acquisition Cost

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the wholesale acquisition cost of the drug. (C.R.S. § 10-16-1406(4)(a)).

Rule: The Board will consider both the current wholesale acquisition cost of the prescription drug and changes in the prescription drug's wholesale acquisition cost over time. (3 CCR 702-9, Part 3.1.E.2.a).

Policy: Information regarding the initial WAC, the current WAC, and changes to WAC over time. (PDAB Policy 04, p. 6).

Underlying Methodology: Board staff compiled wholesale acquisition cost (WAC) data for Enbrel for the Board's consideration in the following manner:

1. Using AnalySource, staff pulled all effective WAC per unit amounts and dates associated with the drug.
2. Staff calculated the percent change in WAC since launch and in past five years by using the following calculation: (Current WAC - Initial WAC) / Initial WAC
3. Staff calculated annual inflation amounts by identifying the Bureau of Labor Statistics' (BLS) Annual Inflation Numbers using the Denver-Aurora-Lakewood area to compare WAC changes over time to inflation.[1]

Data Source(s):

- AnalySource's WAC amount, representing the manufacturer's published catalog or list price for a drug product to wholesalers as reported to First Databank by the manufacturer.
- U.S. Bureau of Labor Statistics for Denver-Aurora-Lakewood for annual inflation numbers.

Considerations and Data Limitations:

- Precise WAC amounts are confidential and may only be shared with the Board, Board staff, and Board contractors.
- The WAC does not consider rebates, discounts, or actual paid amounts.

[1] https://www.bls.gov/regions/mountain-plains/news-release/ConsumerPriceIndex_Denver.htm. Annual inflation numbers were for all items, not seasonally adjusted, with the current base (1982-40 = 100), and inflation change was calculated on an annual basis.

Enbrel: Wholesale Acquisition Cost Evidence

The current WAC for Enbrel is [redacted] per unit, with the most recent update to the WAC in January 2024. The initial WAC was [redacted] in November 1998. This is a 1,582.24% increase from November 1998 to January 2024, a 40.27% increase in the past five years, and a 5% increase from 2023. The average course of treatment is [redacted] units per patient per year, making the current WAC per course of treatment [redacted].[2]

Table A-1

WAC per unit: Date, Price, and Percent Increase (Enbrel)

Enbrel WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	2.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	104.08%
[redacted]	[redacted]	4.31%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	-3.92%

[2] For course of treatment methodology please see June 6, 2023 PDAB Board staff memo: https://drive.google.com/file/d/16BFOEB-LMiulmYzhKhxeGjvbFoh88cTs/view?usp=sharing

[redacted]	[redacted]	9.18%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	5.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	7.90%
[redacted]	[redacted]	9.90%
[redacted]	[redacted]	7.90%
[redacted]	[redacted]	7.90%
[redacted]	[redacted]	9.90%
[redacted]	[redacted]	8.40%

[redacted]	[redacted]	9.68%
[redacted]	[redacted]	6.20%
[redacted]	[redacted]	-2.00%
[redacted]	[redacted]	9.59%
[redacted]	[redacted]	-2.00%
[redacted]	[redacted]	9.59%
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	0.35%
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	4.99%

Table A-1 shows all historical WAC per unit amounts and the percent difference of each change.

Figure A-1
Change in WAC per Unit Price (Enbrel)

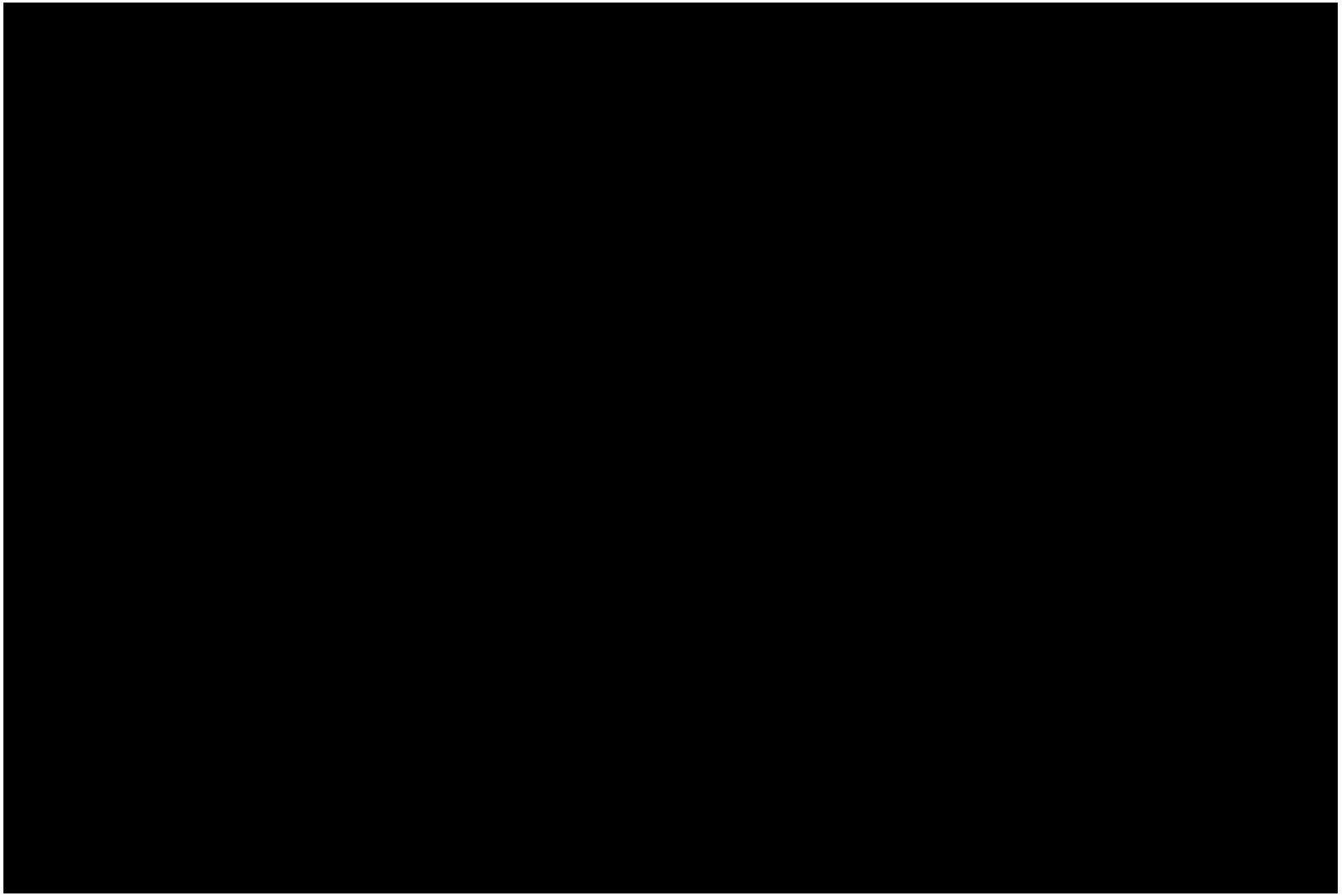
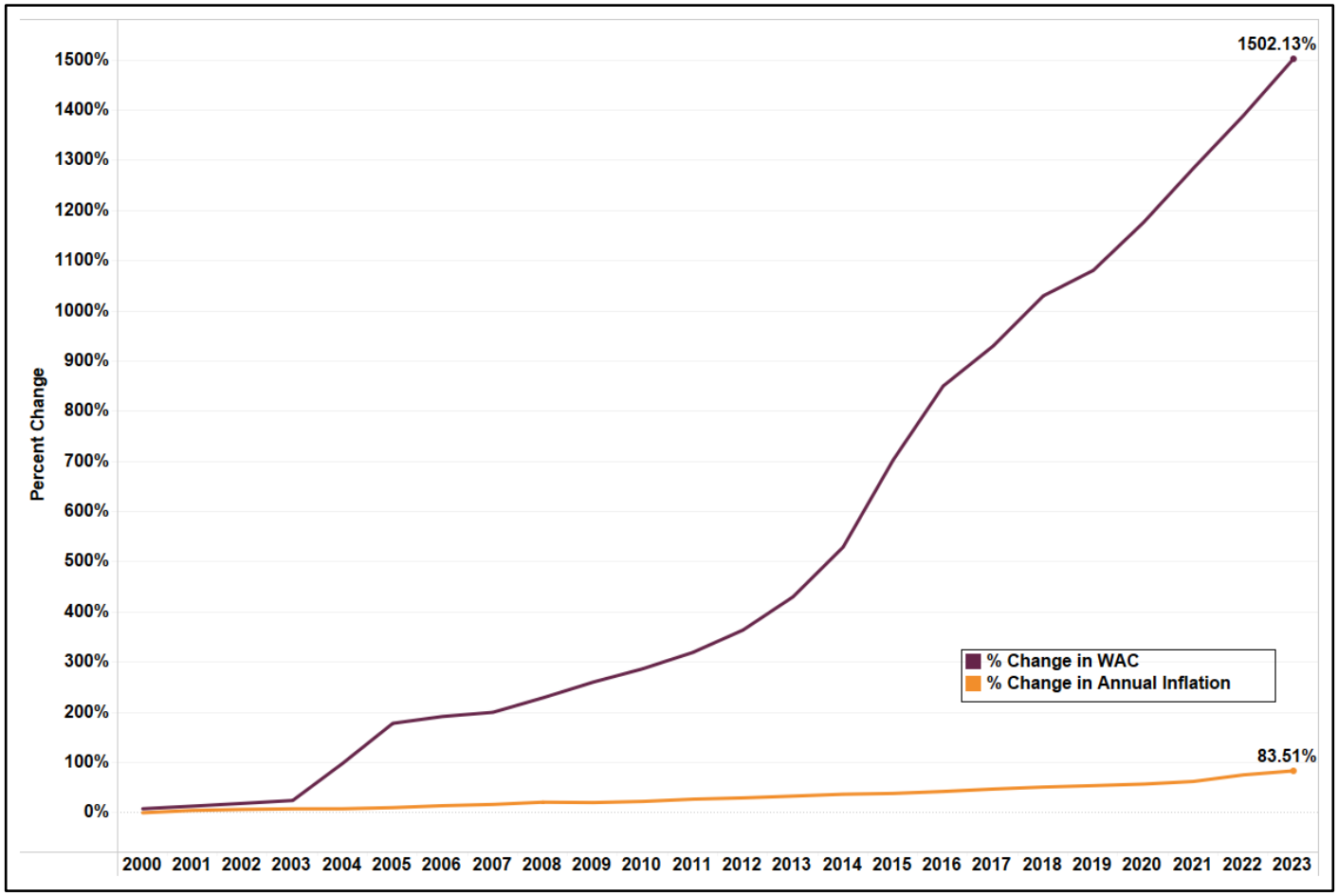


Figure A-1 shows the change in WAC per unit price since its initial WAC price in November 1998.

Figure A-2
Percentage Change in WAC (Enbrel)



For additional context, Figure A-2 shows the same change in WAC as a percent change (purple) and annual inflation (orange) over the same time frame.[3]

[3] Figure A-2 shows a comparison with inflation, which was not calculated for the complete year of 2023 at the time of this report, so the most recent WAC price is not included in this graphic and the percent change in WAC noted here is from 2018 through 2022.

Figure A-3
WAC per Course of Treatment for Enbrel and Therapeutic Alternatives



Figure A-3 shows the changes in WAC per course of treatment for Enbrel and identified therapeutic alternatives.[4] This graphic highlights the changes in WAC for each drug, as listed in table A-2 below, as well as the WAC per course of treatment of each drug as determined by average

[4] The course of treatment calculation used in selecting drugs, calculated from 2021 APCD claims experience was used across all time frames to highlight the changes in WAC relative to each drug. For course of treatment methodology please see June 6, 2023 PDAB Board staff memo: https://drive.google.com/file/d/16BFOEB-LMiulmYzhKhxeGjvbFoh88cTs/view?usp=sharing

utilization in Colorado. If a line does not continue to the end of the figure, it is because the WAC has not changed from the last year displayed. Enbrel has the third highest current WAC per course of treatment after Humira and Simponi.

Table A-2

WAC Changes from Initial and within the Last 5 Years for Therapeutic Alternatives to Enbrel

Cimzia WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	228.90%
[redacted]	[redacted]	7.00%
[redacted]	[redacted]	4.00%
[redacted]	[redacted]	5.90%
[redacted]	[redacted]	5.90%
[redacted]	[redacted]	5.90%

Humira WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	395.00%
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	7.40%

[redacted]	[redacted]	8.00%

Remicade WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	136.74%
[redacted]	[redacted]	4.90%

Simponi WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	205.33%
[redacted]	[redacted]	4.50%
[redacted]	[redacted]	4.80%
[redacted]	[redacted]	5.80%
[redacted]	[redacted]	5.30%
[redacted]	[redacted]	4.00%

Table A-2 shows the initial WAC and any changes in WAC in the last five years for identified therapeutic alternatives.[5]

[5] The first percent increase may cover up to 16 years, which is why some of the initial increases appear to be larger. Where there are multiple WACs per unit for a drug, only one strength and dosage form is included to display the increases in identified therapeutic alternatives.

Analysis of differences in WAC for Enbrel and identified therapeutic alternatives is complex due to the different indications a prescription drug may be used to treat. More information regarding Enbrel and identified therapeutic alternatives' indications and FDA-recommended dosages is provided below for context.

Table A-3
FDA Recommended Dosage by Drug & Indication

Drug Name	Indication	FDA Recommended Dosage
Enbrel[6]	Rheumatoid Arthritis (RA)	50 mg once weekly
	Polyarticular Juvenile Idiopathic Arthritis (JIA)	0.8 mg/kg weekly with a max of 50 mg per week
	Psoriatic Arthritis (PsA)	50 mg once weekly
	Ankylosing Spondylitis (AS)	50 mg once weekly
	Plaque Psoriasis (PsO)	50 mg twice weekly for 3 months, followed by 50 mg once weekly
Therapeutic Alternative	**Indication**	**FDA Recommended Dosage**
Cimzia[7]	Rheumatoid Arthritis (RA)	400 mg initially and at weeks 2 and 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every 4 weeks can be considered
	Psoriatic Arthritis (PsA)	400 mg initially and at weeks 2 and 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every 4 weeks can be considered
	Ankylosing Spondylitis (AS)	400 mg is given as 2 subcutaneous injections of 200 mg each (initially) and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks
	Rheumatoid Arthritis (RA)	40 mg every other week.

[6] https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/103795s5591lbl.pdf
[7] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125160s270lbl.pdf

Humira[8]	Juvenile Idiopathic Arthritis (JIA)	• 10 kg (22 lbs) to <15 kg (33 lbs):10 mg every other week • 15 kg (33 lbs) to < 30 kg (66 lbs):20 mg every other week • ≥ 30 kg (66 lbs):40 mg every other week
	Psoriatic Arthritis (PsA)	40 mg every other week.
	Ankylosing Spondylitis (AS)	40 mg every other week.
	Plaque Psoriasis (Ps)	80 mg initial dose, followed by 40 mg every other week starting one week after the initial dose.
Remicade[9]	Rheumatoid Arthritis (RA)	In conjunction with methotrexate, 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks.
	Psoriatic Arthritis (PsA)	5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
	Ankylosing Spondylitis (AS)	5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks.
	Plaque Psoriasis (Ps)	5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks.
Simponi[10]	Rheumatoid Arthritis (RA)	50 mg administered by subcutaneous injection once a month.
	Psoriatic Arthritis (PsA)	50 mg administered by subcutaneous injection once a month.
	Ankylosing Spondylitis (AS)	50 mg administered by subcutaneous injection once a month.

Table A-3 shows the FDA label's suggested dosing for each indication of Enbrel and identified therapeutic alternatives.

[8] https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125057s410lbl.pdf
[9] https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/103772s5359lbl.pdf
[10] https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125289s0064lbl.pdf

Appendix B

Enbrel: Therapeutic Alternatives

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the cost and availability of therapeutic alternatives to the prescription drug in the state. (C.R.S. § 10-16-1406(4)(b)).

Rule: The Board will consider the cost and availability of therapeutic alternatives to the prescription drug in the state. The Board may review any relevant data regarding costs and expenditures related to the prescription drug and its therapeutic alternatives, as well as any relevant data regarding availability and utilization related to the prescription drug and its therapeutic alternatives. (3 CCR 702-9, Part 3.1.E.2.b).

Therapeutic alternative is defined as a drug product that contains a different therapeutic agent than the drug in question, but is the same pharmacological or therapeutic class and has been shown through peer-reviewed studies to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose or has been recommended as consistent with standard medical practice by medical professional association guidelines. (3 CCR 702-9, Part 1.1.C)

Policy: Information containing a list of therapeutic alternatives for the Board's consideration through review and consultation of sources such as the Orange Book, the Purple Book, World Health Organization's anatomical therapeutic classification code system, and peer-reviewed research. Information prepared for the Board's consideration includes:

- The cost of the therapeutic alternative in the state by examining APCD expenditure data or other data sources relevant to cost of the therapeutic alternatives in the state;
- The availability of the therapeutic alternative in the state by examining APCD utilization data or other data sources relevant to the therapeutic alternatives in the state; and
- Rebate data for the therapeutic alternative(s) by examining external databases. (PDAB Policy 04, p. 6).

Underlying Methodology: Board staff and members of the Program on Regulation, Therapeutics, and Law (PORTAL) have compiled data for Enbrel and identified therapeutic alternatives for the Board's consideration in the following manner:

1. Identified therapeutic alternatives for Enbrel.
2. Presented utilization data from 2018-2022, including both units utilized and the number of patients who utilized the prescription drug.[1]
3. Presented expenditure data from 2018-2022, including total paid amount, total plan paid amount, total patient paid amount, average paid per person per year, and average patient out-of-pocket cost per person per year.[2]
4. Examined rebate estimates, when available, for selected prescription drugs and identified therapeutic alternatives.

Data Source(s): Members of PORTAL assisted Board staff in compiling information on identified therapeutic alternatives of Enbrel. Data sources used to identify therapeutic alternatives include:

- FDA website, which contains information on current FDA labeling for each drug and FDA-approved indication.
- Websites of medical professional organizations for specific disease areas to identify medical association guidelines.

[1] Utilization data for Enbrel's four identified therapeutic alternatives can be found in Appendices C and E.

[2] Expenditure data for Enbrel's four identified therapeutic alternatives can be found in Appendix C and E.

- UpToDate, an online, evidence-based clinical decision support database, to identify therapeutic alternatives that may have been approved since the most recent medical association guidelines.

Considerations and Data Limitations:

- Medical professional association guidelines used in this affordability review component are often unique to a particular indication and authored by different professional associations. As such, these guidelines are not consistently organized or structured.
- Medical professional guidelines may be published every several years. As such, there may be instances where the selected drug or identified therapeutic alternatives are not in the most recent medical professional association guidelines. If this is the case, it will be noted.

Enbrel: Therapeutic Alternatives Evidence

Therapeutic Alternatives Identification

Members of PORTAL identified therapeutic alternatives in the following manner:

1. Identified the Enbrel's therapeutic class as defined under the WHO Anatomical Therapeutic Chemical[3] (WHO-ATC) classification system. Only drugs listed in the same therapeutic class as Enbrel under this system were evaluated as therapeutic alternatives.
2. Reviewed the current FDA labeling for Enbrel and identified each FDA-approved indication. Pediatric and adult indications were reviewed separately if separate medical professional guidelines were available for the respective populations.
3. Identified U.S. medical professional association guideline(s), which rely upon peer-reviewed research, relevant to each FDA-approved indication done via internet search and reviewing the websites of medical professional organizations. If both U.S. and international guidelines were available, use the US guidelines exclusively. If guidelines were available from multiple U.S. organizations, both were included.
4. Located Enbrel in the guidelines to determine how the drug is recommended for use. For example, was the drug recommended as first-line treatment or subsequent line after failure of another treatment? Was it recommended for all patients or specific sub-populations? This was compared to the drug's FDA label, documenting any discrepancies and off-label uses.
5. Summarized the guideline recommendations and how the selected drug fits into those recommendations. This included information about how the treatment of different subpopulations may deviate from the standard pathway.
6. Within the guidelines, identified other drugs in the same WHO-ATC drug class that were recommended to be used similarly to the selected drug. For each in-class therapeutic alternative, identified the drug's non-proprietary name and brand name.
7. To identify in-class alternatives approved after guideline publication, reviewed treatment options for each indication via UpToDate[4], an online evidence-based clinical decision support database. If recently approved in-class drugs were identified that were not included in the guidelines, these drugs' labeling were reviewed and included as alternatives if the drug had an FDA-approved indication that matched that of the selected drug.
8. Used the FDA approval history database via Drugs.com to identify the estimated indication approval date for each therapeutic alternative. This date was verified using the Drugs@FDA database[5]. If drugs

[3] https://www.whocc.no/atc_ddd_index/

[4] https://www.wolterskluwer.com/en/solutions/uptodate

[5] https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases

were recommended in the guidelines but were not FDA-approved for the indication, these will be marked as off-label alternatives.

Board Consideration of Therapeutic Alternatives to Enbrel

During the Board's September 15, 2023 meeting, the Board directed Board staff to narrow data analyses of APCD, WAC, and rebate data for purposes of this component to identify therapeutic alternatives that are in the same class as Enbrel.

Relevant Medical Professional Guidelines

Enbrel's therapeutic class as defined under the WHO-ATC classification system is Tumor necrosis factor alpha (TNF-α) inhibitors.[6] The following guidelines were used to identify in-class therapeutic alternatives for all FDA approved indications in Table B-X.

Table B-1
Enbrel Indications and Relevant Guidelines

[6] https://www.whocc.no/atc_ddd_index/?code=L04AB&showdescription=no

FDA Approved Indications (as of October 2023)[7]	Relevant Guidelines	Guideline Publication Date
Enbrel is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with **moderately to severely active rheumatoid arthritis (RA)**.	Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research [8]	6/8/2021
Enbrel is indicated for reducing signs and symptoms in patients with **active ankylosing spondylitis (AS)**.	Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol.[9]	8/22/2019
Enbrel is indicated for the treatment of **patients 4 years or older with chronic moderate to severe plaque psoriasis (PsO)** who are candidates for systemic therapy or phototherapy.	Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology.[10] Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. Journal of the American Academy of Dermatology. [11]	4/2019
Enbrel is indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in **adult patients with psoriatic arthritis (PsA)**.	Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol.[12]	11/30/2018
Enbrel is indicated for the treatment of **active juvenile psoriatic arthritis (JPsA) in pediatric patients 2 years of age and older**.	Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care Res.[13]	4/25/2019
Enbrel is indicated for reducing signs and symptoms of moderately to severely active **polyarticular juvenile idiopathic arthritis (pJIA)** in patients 2 years of age and older.	Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care Res.[14]	4/25/2019

[7] www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf
[8] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/acr.24596
[9] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.41042
[10] https://pubmed.ncbi.nlm.nih.gov/30772098/
[11] https://pubmed.ncbi.nlm.nih.gov/31703821/
[12] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.40726
[13] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/acr.23870

Table B-1 shows the FDA approved indications for Enbrel and relevant guidelines and guideline publication date.

In-Class Therapeutic Alternatives

The relevant guidelines outlined above identify the following in-class therapeutic alternatives for Enbrel:

- Humira
- Cimzia
- Simponi / Simponi Aria
- Remicade

Humira

- **Non-Proprietary Name:** adalimumab
- **Brand Name:** Humira
- **Mechanism of Action:** TNF Inhibitor

Table B-2
Humira: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Rheumatoid Arthritis (RA)	Yes	12/31/2002
Ankylosing spondylitis (AS)	Yes	7/28/2006
Plaque Psoriasis: Adult and Pediatric	Yes	1/18/2008
Psoriatic arthritis (PsA)	Yes	10/3/2005
Juvenile Psoriatic Arthritis (JPsA)	No	NA
Polyarticular Juvenile Idiopathic Arthritis (pJIA)	Yes	2/21/2008

Cimzia

- **Non-Proprietary Name:** certolizumab pegol
- **Brand Name:** Cimzia
- **Mechanism of Action:** TNF Inhibitor

Table B-3
Cimzia: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Rheumatoid Arthritis (RA)	Yes	5/13/2009
Ankylosing spondylitis (AS)	Yes	10/17/2013
Plaque Psoriasis: Adult and Pediatric	Yes	5/24/2018
Psoriatic arthritis (PsA)	Yes	9/27/2013

[14] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/acr.23870

Juvenile Psoriatic Arthritis (JPsA)	No	N/A
Polyarticular Juvenile Idiopathic Arthritis (pJIA)	No	N/A

Simponi / Simponi Aria

- **Non-Proprietary Name:** golimumab
- **Brand Name:** Simponi / Simponi Aria
- **Mechanism of Action:** TNF Inhibitor

Table B-4
Simponi / Simponi Aria: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Rheumatoid Arthritis (RA)	Yes	4/24/2009
Ankylosing spondylitis (AS)	Yes	4/24/2009
Plaque Psoriasis: Adult and Pediatric	No	N/A
Psoriatic arthritis (PsA)	Yes	4/24/2009
Juvenile Psoriatic Arthritis (JPsA)	Yes	9/29/2020
Polyarticular Juvenile Idiopathic Arthritis (pJIA)	Yes	9/29/2020

Remicade

- **Non-Proprietary Name:** infliximab*
- **Brand Name:** Remicade
- **Mechanism of Action:** TNF Inhibitor

Table B-5
Remicade: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Rheumatoid Arthritis (RA)	Yes	11/10/1999
Ankylosing spondylitis (AS)	Yes	12/17/2004
Plaque Psoriasis: Adult and Pediatric	Yes	9/26/2006
Psoriatic arthritis (PsA)	Yes	5/13/2005
Juvenile Psoriatic Arthritis (JPsA)	No	N/A

Polyarticular Juvenile Idiopathic Arthritis (pJIA)	No	N/A

Utilization and expenditure data for Enbrel and identified therapeutic alternatives is contained in Appendix C and Appendix E.

Appendix C

Enbrel: Price Effect on Consumer Access

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the effect of the price on Colorado consumers' access to the prescription drug. (C.R.S. § 10-16-1406(4)(c)).

Rule: The Board will consider the effect of price on Colorado consumers' access to the prescription drug by reviewing changes in pricing, expenditure, and utilization over time. (3 CCR 702-9, Part 3.1.E.2.c).

Policy: Information regarding changes in pricing compared to changes in expenditure and utilization over the same time period to analyze potential correlation. Information will also be presented from APCD data and subject matter experts to better understand potential confounding variables, such as:

- When therapeutic alternative(s) were available;
- Changes to patents; and
- Changes in rebate amounts for the prescription drug or therapeutic alternative. (PDAB Policy 04, pp. 6-7).

Underlying Methodology: Board staff have compiled data on price effect on consumer access for the Board's consideration in the following manner:

1. From APCD pharmacy claims, Board staff pulled all claims for Enbrel from October 2018 - December 2022.
2. Board staff combined the claims data with WAC data from AnalySource by joining on the month and year of the claim with the effective WAC of the same month and year.
3. Board staff combined the claims and WAC data with the gross-to-net sales estimates from SSR Health by joining the month and year of the claim with the month and year of the quarter estimates in SSR Health.

Data Source(s): Board staff compiled information on price effect on access for the selected prescription drug from the following sources:

- APCD, which provides detail on utilization and expenditure,
- AnalySource for current and historical WAC,
- FDA and Centers for Medicare and Medicaid Services (CMS) for other pricing data,
- FDA website for changes to patents, and
- SSR Health for gross-to-net sales estimates.

Considerations and Data Limitations: Claims-based utilization data shows what health care services were accessed, but this data does not show what health care services were potentially under-accessed or not accessed at all. Qualitative data (such as surveys or anecdotes) may illuminate which health care services were under-accessed or not accessed at all, but there is no validated data source that provides this information.

Enbrel: Price Effect on Access Evidence

This appendix provides more detailed information regarding: utilization, price, out-of-pocket costs, and gross-to-net sales estimates, and patent information.

Table C-1

Changes in Enbrel Utilization, Expenditure, and Gross-to-Net Sales from 2018-2022

	2018	2022	Percent Change
Total OOP Costs	$1,688	$2,295	35.90%
Total Paid Amount	$129,421,272	$159,305,653	23.09%
Patient Count	3,890	3,406	-12.44%
Gross-to-Net Sales	[redacted]	[redacted]	[redacted]

Table C-1 shows the total OOP costs, the total paid amount, the total number of patients utilizing Enbrel, and the gross-to-net sales estimate in 2018 and 2022, with the percent change over that time period. There was a 12.44% decrease in the number of patients utilizing Enbrel, a 23.09% increase in the total paid amount, and a 35.90% increase in total Out-of-Pocket expenses. During this timeframe there was a [redacted] The decrease in the number of patients utilizing Enbrel could be from a number of situations like individuals moving or changing health insurance but it could also indicate that fewer patients are able to access the drug. In the patient and caregiver survey, 71% of Colorado respondents indicated that the cost of Enbrel impacted their adherence. Please see appendices A, E, H, and K for more detail.

Table C-2

Annual Utilization and Expenditures

	2018	2019	2020	2021	2022
Patient Count	3,890	3,653	3,440	3,692	3,406
Total Paid	$129,421,272	$127,959,896	$134,815,241	$161,483,771	$159,305,653
Average Paid Per Person	$33,270	$35,029	$39,190	$43,739	$46,772
Total Patient Paid	$6,720,180	$7,399,691	$7,700,602	$10,524,066	$9,860,820
Average OOP	$1,688	$1,866	$2,189	$2,526	$2,295
WAC Per Unit	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table C-2 shows the year-over-year increases in the number of patients using Enbrel, the total amount paid for Enbrel, the average paid per person, the total amount that patients paid, and the average amount that each patient paid.

Figure C-1

Monthly Total Paid and Average Total Paid

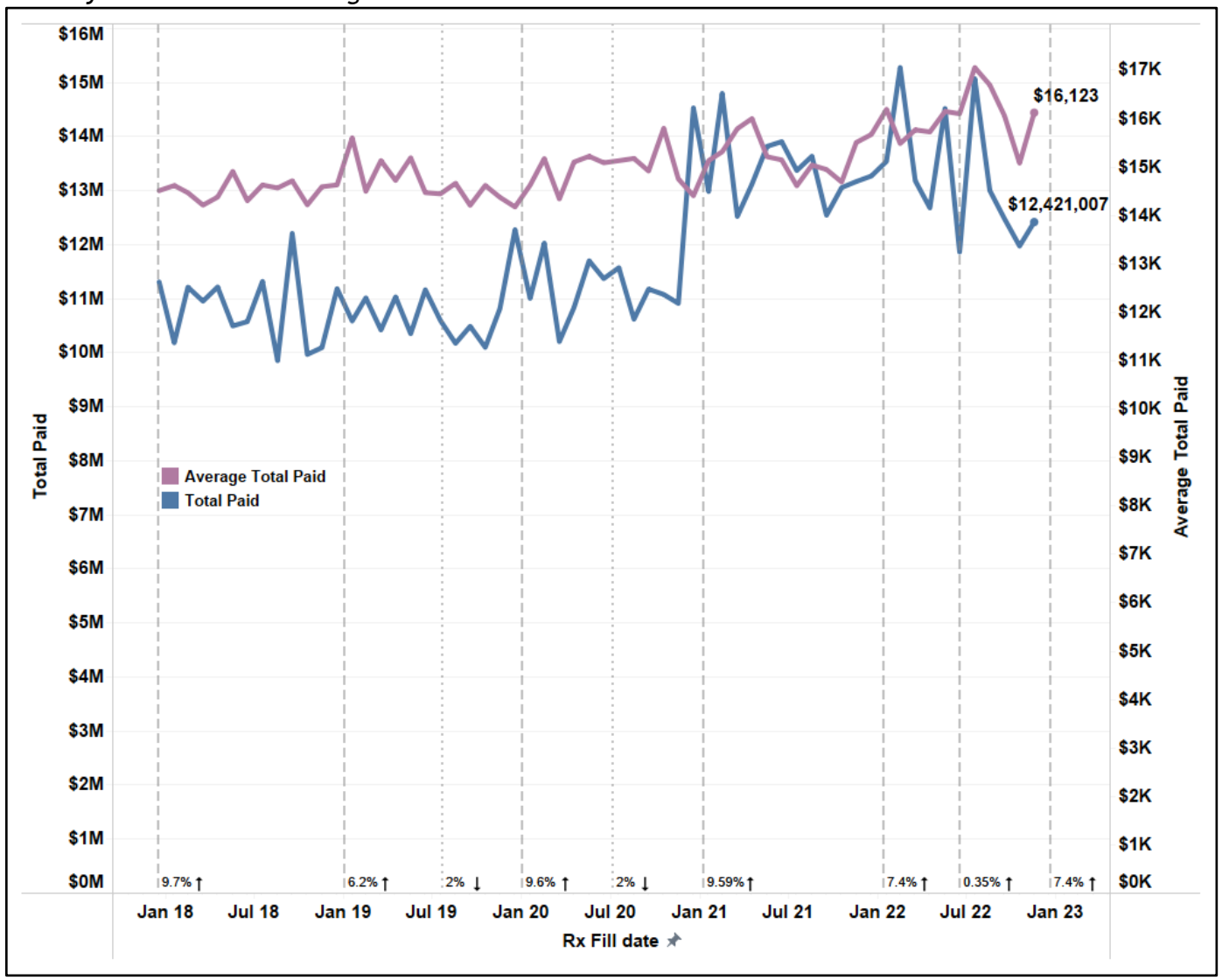


Figure C-1 shows the monthly total paid with the blue line (left axis) and the monthly average paid per person with the purple line (right axis) with vertical lines representing changes in WAC with the magnitude of the change written to the right of the line with an arrow up or down indicating an increase or decrease in the WAC. There is no visible correlation between the WAC change and the corresponding change in the APCD paid amounts. During this time frame, the number of patients using Enbrel decreased from 3,890 in 2018 to 3,406 in 2022.

Table C-3

APCD Utilization and Cost, WAC, and Gross-to-Net Sales Estimates

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	Average OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Jan-18	1,788	[redacted]	[redacted]	$11,311,524	$6,326	$1,579	$553	$589	$282	31
Feb-18	1,672	[redacted]		$10,185,625	$6,092	$1,240	$272	$651	$219	31
Mar-18	1,770	[redacted]		$11,215,634	$6,337	$808	$92	$534	$160	31
Apr-18	1,761	[redacted]	[redacted]	$10,956,773	$6,222	$483	$47	$259	$160	30
May-18	1,762	[redacted]		$11,218,793	$6,367	$563	$48	$373	$135	31
Jun-18	1,702	[redacted]		$10,498,285	$6,168	$456	$44	$277	$133	31
Jul-18	1,732	[redacted]	[redacted]	$10,578,024	$6,107	$649	$35	$478	$113	31
Aug-18	1,767	[redacted]		$11,322,686	$6,408	$521	$45	$292	$178	32
Sep-18	1,640	[redacted]		$9,855,871	$6,010	$555	$30	$388	$126	31
Oct-18	1,835	[redacted]	[redacted]	$12,210,087	$6,654	$472	$44	$304	$124	30
Nov-18	1,662	[redacted]		$9,970,968	$5,999	$430	$42	$289	$103	31

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	Average OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Dec-18	1,629	[redacted]		$10,097,002	$6,198	$383	$32	$230	$119	32
Jan-19	1,693	[redacted]	[redacted]	$11,188,372	$6,609	$1,562	$583	$570	$309	32
Feb-19	1,618	[redacted]		$10,589,531	$6,545	$1,162	$226	$528	$279	32
Mar-19	1,674	[redacted]		$11,017,082	$6,581	$719	$100	$361	$223	33
Apr-19	1,638	[redacted]	[redacted]	$10,423,010	$6,363	$807	$48	$526	$203	30
May-19	1,708	[redacted]		$11,035,221	$6,461	$616	$65	$361	$190	32
Jun-19	1,641	[redacted]		$10,354,192	$6,310	$669	$45	$465	$149	32
Jul-19	1,717	[redacted]	[redacted]	$11,166,931	$6,504	$570	$59	$363	$147	31
Aug-19	1,676	[redacted]		$10,598,839	$6,324	$559	$47	$373	$134	31
Sep-19	1,622	[redacted]		$10,176,518	$6,274	$502	$14	$368	$115	32
Oct-19	1,612	[redacted]	[redacted]	$10,491,164	$6,508	$571	$41	$432	$96	30
Nov-19	1,580	[redacted]		$10,101,495	$6,393	$432	$63	$289	$84	31

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	Average OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Dec-19	1,675	[redacted]		$10,817,543	$6,458	$551	$48	$409	$91	31
Jan-20	1,656	[redacted]	[redacted]	$12,278,737	$7,415	$1,296	$526	$394	$295	31
Feb-20	1,600	[redacted]		$11,007,438	$6,880	$1,007	$218	$470	$235	32
Mar-20	1,672	[redacted]		$12,031,233	$7,196	$798	$130	$436	$202	32
Apr-20	1,556	[redacted]	[redacted]	$10,208,684	$6,561	$641	$92	$348	$183	30
May-20	1,617	[redacted]		$10,838,427	$6,703	$663	$99	$397	$164	33
Jun-20	1,657	[redacted]		$11,703,383	$7,063	$537	$32	$329	$153	32
Jul-20	1,684	[redacted]	[redacted]	$11,373,742	$6,754	$613	$72	$387	$156	32
Aug-20	1,679	[redacted]		$11,575,497	$6,894	$527	$42	$351	$134	32
Sep-20	1,621	[redacted]		$10,622,000	$6,553	$632	$41	$447	$143	31
Oct-20	1,698	[redacted]	[redacted]	$11,179,835	$6,584	$472	$23	$315	$128	32
Nov-20	1,638	[redacted]		$11,080,689	$6,765	$617	$31	$457	$121	33

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	Average OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Dec-20	1,654	[redacted]		$10,915,575	$6,600	$464	$35	$313	$118	32
Jan-21	1,753	[redacted]	[redacted]	$14,532,693	$8,290	$1,262	$522	$471	$242	32
Feb-21	1,773	[redacted]		$12,987,023	$7,325	$928	$278	$428	$195	32
Mar-21	1,913	[redacted]		$14,800,942	$7,737	$931	$253	$481	$166	32
Apr-21	1,835	[redacted]	[redacted]	$12,525,328	$6,826	$729	$202	$385	$144	32
May-21	1,795	[redacted]		$13,120,766	$7,310	$666	$101	$429	$135	33
Jun-21	1,871	[redacted]		$13,821,073	$7,387	$569	$87	$356	$122	31
Jul-21	1,859	[redacted]	[redacted]	$13,908,320	$7,482	$643	$126	$389	$129	33
Aug-21	1,877	[redacted]		$13,374,249	$7,125	$581	$83	$397	$102	32
Sep-21	1,840	[redacted]		$13,638,254	$7,412	$496	$62	$326	$105	31
Oct-21	1,764	[redacted]	[redacted]	$12,546,370	$7,112	$456	$45	$296	$109	31
Nov-21	1,793	[redacted]		$13,058,533	$7,283	$469	$82	$292	$100	31

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	Average OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Dec-21	1,759	[redacted]		$13,170,220	$7,487	$630	$226	$335	$91	32
Jan-22	1,621	[redacted]	[redacted]	$13,272,308	$8,188	$1,390	$560	$540	$270	33
Feb-22	1,674	[redacted]		$13,542,932	$8,090	$1,068	$337	$474	$211	32
Mar-22	1,822	[redacted]		$15,279,699	$8,386	$741	$98	$462	$147	33
Apr-22	1,779	[redacted]	[redacted]	$13,185,263	$7,412	$726	$165	$424	$132	33
May-22	1,729	[redacted]		$12,682,429	$7,335	$578	$65	$376	$135	32
Jun-22	1,756	[redacted]		$14,521,016	$8,269	$662	$80	$452	$122	32
Jul-22	1,655	[redacted]	[redacted]	$11,867,545	$7,171	$617	$68	$412	$125	32
Aug-22	1,765	[redacted]		$15,073,167	$8,540	$619	$63	$451	$104	32
Sep-22	1,727	[redacted]		$13,002,216	$7,529	$516	$33	$371	$108	33
Oct-22	1,681	[redacted]	[redacted]	$12,481,838	$7,425	$615	$114	$405	$105	32
Nov-22	1,652	[redacted]		$11,976,233	$7,250	$412	$33	$296	$86	31

Month, Year of Rx Fill Date	Patient Count	WAC per unit	Gross-to-net-sales estimate	Total Paid	Average Paid	Average OOP Cost	Average Deductible Amount	Average Coinsurance Amount	Average Copay Amount	Average days supply
Dec-22	1,631	[redacted]		$12,421,007	$7,616	$461	$55	$326	$76	33

Table C-3 above shows the monthly amounts of APCD, WAC, and gross-to-net sales estimates for Enbrel. Columns in this table are defined below and all columns are from APCD data unless otherwise noted:

- Month, Year of Rx Fill Date: The month and year the prescription was filled. All data in this table is aggregated to the month and year.
- Patient count: The total number of patients who filled a prescription that month.[1]
- WAC per unit[2]: The per unit WAC amount that was effective that month.
- Gross-to-net sales estimate[3]: The gross-to-net sales estimate of that quarter. Estimates are on a rolling four quarter average, so each estimate covers the previous year. Estimates appear in the first month of each quarter.
- Total Paid: The total amount paid for Enbrel that month, inclusive of payer(s) and patient paid amounts.
- Average Paid: The average paid per person for that month.
- Out-of-pocket Cost: The average out-of-pocket cost (total of copayment, coinsurance, and deductible) per person that month.
- Average Deductible Amount: The average amount that individuals with commercial insurance and Medicare Advantage coverage paid towards their deductible that month. Note the generally higher amounts at the beginning of each year indicating patients contributing to their deductible with lower amounts later in the benefit plan year when the deductible has been met.
- Average Coinsurance Amount: The average amount that individuals with commercial insurance and Medicare Advantage coverage paid towards coinsurance that month. Potential to note that this is increasing.
- Average Copayment Amount: The average amount that individuals with commercial insurance and Medicare Advantage coverage paid in copayments that month.
- Average Days Supply: The average days supply that was filled with prescriptions that month.
- Per Unit Cost: The average per unit cost of the total amount paid per unit distributed. As Enbrel was approved in October 2019, earlier estimates show a ramp of utilization as patients began taking the drug and early estimates may not show an accurate representation of all eligible patients taking the drug.

[1] Patient count in Table C-3 may not add up to the total annual patient count in Table C-2 above it as some patients moved between insurance types throughout a given year

[2] First Databank, AnalySource

[3] SSR Health Estimates

Patents and Exclusivity

There are several ways for prescription drugs to gain exclusivity, which is a period of time when a brand-name drug is protected from generic competition. As of January 29, 2024, there were 75 approved patents for Enbrel with the latest expiration date of 12/31/2039.[4] Thirty-five of these patents expired between 2009 and 2021, while 40 will expire between 2024 and 2039. The Enbrel-related patents that prevent the introduction of biosimilar products are set to expire in 2029.[5] Evaluating patents and exclusivity can be helpful in understanding potential access concerns, because there is evidence that such intellectual property rights can be associated with increased drug prices, delayed availability, and increased costs to consumers and governments.[6]

[4] I-MAK's 'The Drug Patent Book' https://drugpatentbook.i-mak.org/.

[5] https://www.centerforbiosimilars.com/view/nj-court-decision-means-3-decades-of-product-exclusivity-for-enbrel

[6] https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-022-00826-4

Figure C-2

Enbrel Patents and Expiration dates

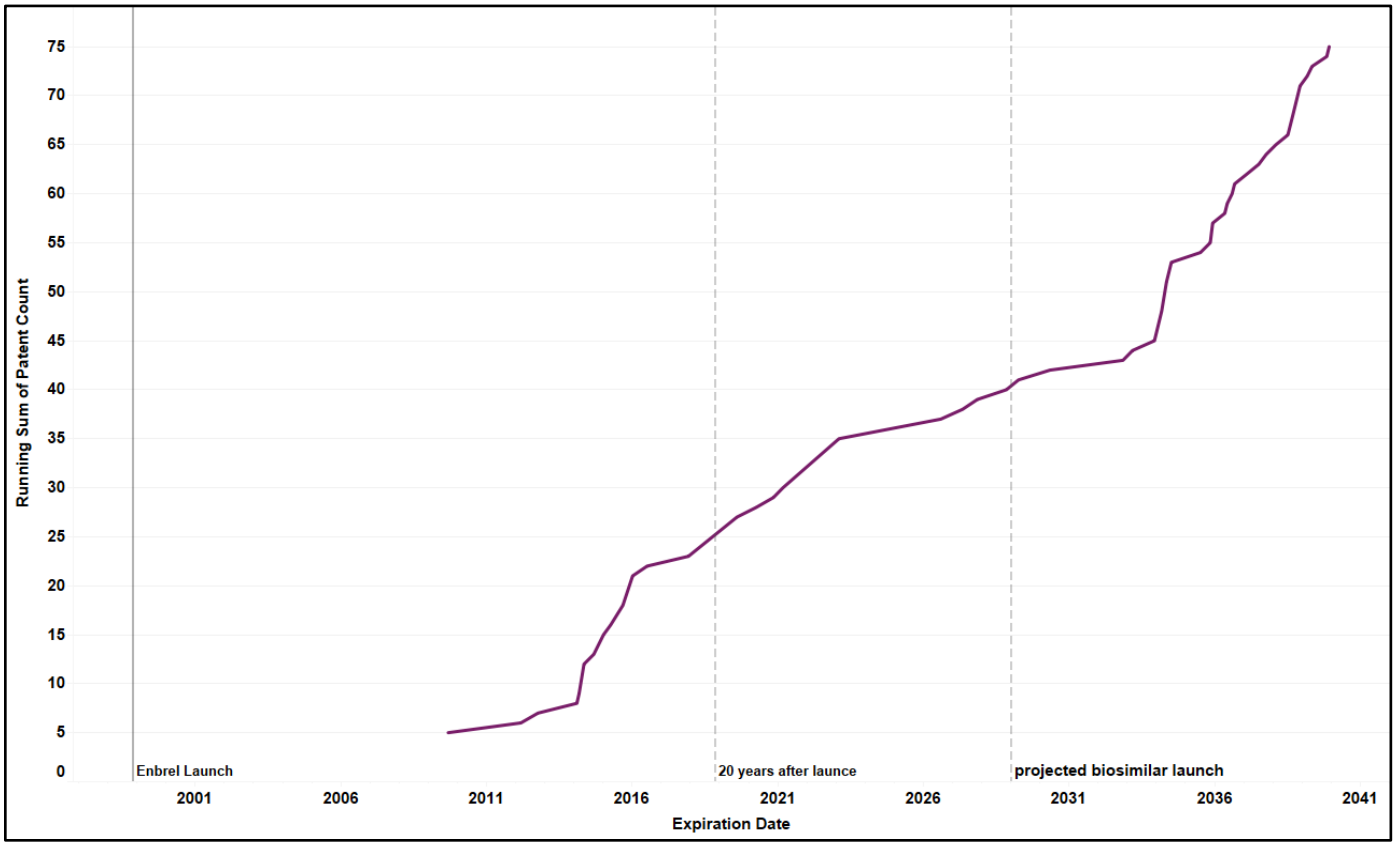


Figure C-2 shows the total number of approved patents for Enbrel based on their expiration date with reference lines highlighting 20 years after launch, the typical patent protection window, and the projected launch of approved biosimilars.

Information about patents for Enbrel contain important public information related to exclusivity of the drug due to litigation around these patents.

A patent for a recombinant protein encoding a receptor for tumor necrosis factor (TNF) was initially issued in 1997 with an expiration date in 2014 under US Patent #5610279.[7] This so-called ‘279 patent is one of several "core" patents that Amgen has used to ensure its U.S. market exclusivity of Enbrel.[8]

In 2011 and 2012, Amgen applied for two additional patents. The granting of these patents (US Patents #8063182 and 8163522) was somewhat unusual in that the ‘182 is a "composition of matter" patents for a larger version of the protein claimed in the ‘279 patent, and the ‘522 patent describes the method to isolate that larger protein version. These “core” patents--which are considered to be quite strong--are usually granted very early in drug development and make the creation of a non-infringing biosimilar drug nearly impossible. The '182 and '522 patents are due to expire in 2028 and 2029, respectively.[9]

Amgen has protected Enbrel through litigation of its patents in U.S. courts. In 2016, Novartis subsidiary Sandoz gained FDA approval for the first etanercept biosimilar, Erelzi. Amgen sued Sandoz later that year, claiming that Erelzi infringed on the '182 and '522 patents. In defense, Sandoz claimed that the 2 patents were invalid. The US District Court of New Jersey decided against Sandoz and found that both patents were valid. In 2019, drug manufacturer Samsung Bioepis gained approval for a second etanercept biosimilar, Eticovo. Amgen again sued claiming that Eticovo would infringe the same two patents and won in 2021. As a result, despite there being two approved biosimilars for Enbrel, both biosimilars are not allowed to enter the market until at least 2029.[10]

[7] https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/

[8] Estimates of the number of patents protecting Enbrel range from around 40 to 68, with at least 57 patent applications included in one analysis. ~40 patents, pg. 126 https://scholarship.kentlaw.iit.edu/cgi/viewcontent.cgi?article=1263&context=ckjip, ~68 patents, https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/, at least 57 patent applications https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.enbrel.report-REVISED-2020-10-06.pdf).

[9] https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/

[10] https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/

Appendix D

Enbrel: Relative Financial Effects of the Prescription Drug on Health, Medical, or Social Service Costs

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the relative financial effects on health, medical, or social services costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. (C.R.S. § 10-16-1406(4)(d)).

Rule: To the extent such information can be quantified, the Board may consider the relative financial effects of the prescription drug on broader health, medical, and/or social services costs, compared with therapeutic alternatives and/or no treatment. This may include considering results from external analyses and modeling studies.

- The Board may identify if the literature uses a quality-adjusted life-year analysis or a similar measure that discounts the value of a life because of an individual's disability or age. The Board may use information that uses a quality-adjusted life year analysis to evaluate relative financial effects, but will not use quality adjusted life year analysis to determine an upper payment limit or other appropriate costs of a prescription drug. If quality-adjusted life year analysis is used during affordability review, the Board will acknowledge any health equity impacts to priority populations. (3 CCR 702-9, Part 3.1.E.2.d).

Policy: Information providing an overview of the research regarding the relative financial effects of the prescription drug on health, medical, or social services costs. This will be done by reviewing research that is:

- Publicly available;
- To the extent the Board has funding, data accessible from the Drug Effectiveness Review Project; or
- Is voluntarily provided by manufacturers. (PDAB Policy 04, p. 7).

Underlying Methodology: Board staff compiled data for Enbrel for the Board's consideration in the following manner:

1. Staff reviewed the current FDA labeling for each selected drug and identified each FDA-approved indication.
2. Identified relevant medical professional guidelines and manufacturer's purported benefits by indication.
3. Found evidence supporting the purported benefits by indication and compared the clinical effectiveness of identified therapeutic alternatives to each drug under review.[1]
4. Assessed the financial effects of a drug compared to identified therapeutic alternatives. This was completed for this appendix by examining studies with cost effectiveness analyses. Staff will note when studies use a quality-adjusted-life-year (QALY) or similar measure. The Affordability Review Summary Report may incorporate additional information of a prescription drug's financial effects that

[1] Staff will note when studies evaluate the clinical effectiveness of a therapeutic alternative that is not being considered by the Board in Appendix B. Further, staff will note when studies compare the clinical effectiveness of each drug under review to a placebo (i.e., when there is not a comparison to a therapeutic alternative).

is not reported in this appendix, but was gathered from patients and caregivers, individuals with scientific and medical training, or provided in voluntarily submitted information.

Considerations and Data Limitations: Staff provided citations for any literature utilized to compile evidence for this component, but some studies may need a subscription for the public to access. Additionally, studies frequently outline limitations. Staff will note these limitations and also note any differences in the specific strengths and dosage forms utilized in studies.

Enbrel: Relative Financial Effects Evidence

Background

One component of affordability reviews is an assessment of the relative financial effects on health, medical, or social services costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. This sort of assessment is commonly referred to as a health technology assessment (HTA), which may be used by organizations or governments to systematically evaluate the effects and impacts of health care technology, or, relevant to this work, prescription drugs.[2] HTAs may address the direct, intended consequences of a prescription drug as well as a drug's indirect, unintended consequences. While some other countries (e.g., the United Kingdom, Canada) use governmental HTAs to guide prescription drug coverage and reimbursement policies, the United States does not have a government-run HTA body.

While the FDA is the primary federal regulator of prescription drugs in the United States, the agency does not take a significant role in regulating HTA activities. The focus of FDA approvals for new drugs and biological products is the result of Phase III human trials, which are aimed at determining the dose at which a drug is effective. In general, there is not typically a requirement for a manufacturer to demonstrate that a new drug is superior to existing treatments in order to be approved.

FDA Approved Indication

Enrbel has six FDA-approved indications:

- Rheumatoid Arthritis (RA)
- Ankylosing Spondylitis
- Plaque Psoriasis: Adult and Pediatric
- Psoriatic Arthritis
- Juvenile Psoriatic Arthritis
- Polyarticular Juvenile Idiopathic Arthritis (JIA)

Information below is provided by indication when appropriate.

[2] https://www.nlm.nih.gov/nichsr/hta101/ta10103.html

Supporting Evidence, Clinical Effectiveness, and Cost Effectiveness

Supporting evidence, clinical effectiveness information, and cost effectiveness information was compiled from the sources below. These resources allowed for an efficient review of HTA reports, meta-analyses, and secondary resources developed by established domestic and international organizations. This approach allows for consistent review and leveraging established methodologic processes to assess quality and conclusion of evidence.

- **Cochrane Library**[3]: an organization that prepares systematic reviews and meta-analyses for a range of clinical areas, drug classes, and diseases/conditions. Literature in this appendix was pulled by searching Cochrane Reviews for "etanercept" and indication and reviewing "Cochrane Reviews" (i.e., not compiling information from Cochrane Protocols, Trials, Editorials, Special Collections, or Clinical Answers). "Etanercept" and indication.
- **Institute for Clinical and Economic Review** (ICER)[4]: a U.S.-based independent non-profit organization that seeks to place a value on medical care by providing comprehensive clinical and cost-effectiveness analyses of treatments, tests, and procedures. Literature in this appendix was pulled by searching ICER Research Assessments for "etanercept" and indication. ICER cost-effectiveness recommendations are non-binding for any U.S. federal, state, and local governments.
- **National Institute for Health and Care Excellence** (NICE)[5]: a United Kingdom-based governmental institute that provides national guidance and guidelines based on evaluations of efficacy, safety, and cost-effectiveness. Literature in this appendix was pulled by searching published NICE guidance for "etanercept" and indication.
- **Canadian Agency for Drugs and Technologies in Health** (CADTH)[6]: a Canada-based not-for-profit organization responsible for providing health care decision makers with objective evidence to help make informed decisions about the optimal use of health technologies, including providing advice, recommendations, and tools. Literature in this appendix was pulled by searching Health Technology Assessment and Reimbursement Reviews for "etanercept" and indication. CADTH's recommendations are non-binding for federal, provincial, and territorial public drug plans and provincial cancer agencies (with the exception of Quebec).[7]
- **Institute for Quality and Efficiency in Health Care** (IQWiG)[8]: a Germany-based governmental agency responsible for assessing the quality and efficiency of medical treatments, including drugs, non-drug interventions, diagnostic and screening methods, and treatment and disease management. Literature in this appendix was pulled by searching Drug Assessment Projects and Reports for "etanercept" and indication.
- **International Network of Agencies for Health Technology Assessment** (INAHTA)[9]: maintains an **international HTA database** that compiles assessments across jurisdictions. Studies and benefit assessments not already identified from ICER, NICE, CADTH, and IQWiG may be pulled for the Board's review. Only studies with robust English summaries will be summarized in this appendix.

[3] https://www.cochranelibrary.com/
[4] https://icer.org/
[5] https://www.nice.org.uk/
[6] https://www.cadth.ca/
[7] https://www.cadth.ca/cadth-reimbursement-reviews
[8] https://www.iqwig.de/en/
[9] https://database.inahta.org/

Literature that met the above criteria are displayed below and quoted directly, with page numbers for reference, to summarize clinical effectiveness conclusions and cost-effectiveness conclusions. Additional information beyond these conclusions can be found in the literature itself, which is cited.

Priority Populations and QALYs: The Board considered health equity impacts to priority populations of Enbrel. Please see Appendix H, Appendix J, and Appendix L for more information. Acknowledging that QALYs may discount the value of life because of an individual's disability or age, the Board has noted when studies utilize QALYs below.

Input from Patients and Caregivers, Input from Individuals with Scientific and Medical Training, and Voluntarily Submitted Information

The FDA released an updated Benefit-Risk Assessment for New Drug and Biological Products: Guidance for Industry on October 20, 2023.[10] This guidance states (pp.12-13):

"FDA recognizes the importance of enabling meaningful patient input to inform drug development and regulatory decision-making, including in the context of FDA's benefit-risk assessment. Patients are experts in the experience of their disease or condition, and they are the ultimate stakeholders in the outcomes of medical treatment. Different types of patient experience data can inform nearly every aspect of FDA's benefit-risk assessment…"

- This appendix provides a robust overview of the scientific studies of clinical and cost effectiveness of Enbrel, with many of the HTA organizations including patient perspectives in some manner. There is additional information contained in Appendix H: Input from Patients and Caregivers, Appendix I: Input from Individuals with Scientific and Medical Training, and Appendix J: Voluntarily Submitted information which may contain additional patient perspectives of the relative financial effects of Enbrel on health, medical, and social costs not captured in this appendix. The Board may want to weigh information from all four appendices when evaluating the relative financial effects of Enbrel.

Rheumatoid Arthritis

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis.[11]

[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/benefit-risk-assessment-new-drug-and-biological-products

[11] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/acr.24596

Manufacturer-Reported Benefits

Information contained in Enbrel's FDA label, Section 14 Clinical Studies, reports on the following four studies and the resulting primary and key secondary efficacy analyses.[12]

Figure D-1
Study I, II, and III Summary (Table 6)

Table 6. ACR Responses in Placebo- and Active-Controlled Trials (Percent of Patients)

	Placebo-Controlled				Active-Controlled	
	Study I		Study II		Study III	
Response	Placebo N = 80	Enbrel* N = 78	MTX/Placebo N = 30	MTX/Enbrel* N = 59	MTX N = 217	Enbrel* N = 207
ACR 20						
Month 3	23%	62%†	33%	66%†	56%	62%
Month 6	11%	59%†	27%	71%†	58%	65%
Month 12	NA	NA	NA	NA	65%	72%
ACR 50						
Month 3	8%	41%†	0%	42%†	24%	29%
Month 6	5%	40%†	3%	39%†	32%	40%
Month 12	NA	NA	NA	NA	43%	49%
ACR 70						
Month 3	4%	15%†	0%	15%†	7%	13%‡
Month 6	1%	15%†	0%	15%†	14%	21%‡
Month 12	NA	NA	NA	NA	22%	25%

* 25 mg Enbrel SC twice weekly.

† $p < 0.01$, Enbrel versus placebo.

‡ $p < 0.05$, Enbrel versus MTX.

Figure D-1 above outlines the percentage of RA patients who reached a 20% (ACR 20), 50% (ACR 50), and 70% (ACR 70) level of improvement in their American College of Rheumatology (ACR) response score after three, six, and 12 months in the clinical trials. The three studies compare patients using Enbrel to patients using a placebo (Study I), patients using Enbrel and methotrexate in combination to patients using methotrexate and a placebo (Study II), and patients using Enbrel to patients using methotrexate (Study III). Footnotes b and c indicate that differences in ACR between the Enbrel and control groups are statistically significant. Therefore, all ACR groups for participants using Enbrel in months three and six of Study I and months 3-12 of Study II are significantly higher than the control groups. In Study III (comparing Enbrel to methotrexate), differences in ACR scores are only statistically significant for participants at months 3 and 6 of the study, suggesting less certainty of differences in comparative value between Enbrel and methotrexate.

[12] https://www.accessdata.fda.gov/spl/data/29187b7c-d166-45e4-bc8c-4cbf71a67702/29187b7c-d166-45e4-bc8c-4cbf71a67702.xml#section-13

Figure D-2
Study IV Summary (Table 7)

Table 7. Study IV Clinical Efficacy Results: Comparison of MTX versus Enbrel versus Enbrel in Combination with MTX in Patients with Rheumatoid Arthritis of 6 Months to 20 Years Duration (Percent of Patients)

Endpoint	MTX (N = 228)	Enbrel (N = 223)	Enbrel/MTX (N = 231)
ACR N*, †			
Month 12	40%	47%	63%‡
ACR 20			
Month 12	59%	66%	75%‡
ACR 50			
Month 12	36%	43%	63%‡
ACR 70			
Month 12	17%	22%	40%‡
Major Clinical Response§	6%	10%	24%‡

* Values are medians.

† ACR N is the percent improvement based on the same core variables used in defining ACR 20, ACR 50, and ACR 70.

‡ $p < 0.05$ for comparisons of Enbrel/MTX versus Enbrel alone or MTX alone.

§ Major clinical response is achieving an ACR 70 response for a continuous 6-month period.

Figure D-2 depicts the major results of Study IV, which included patients with RA for 6 months-20 years who had failed use of a different disease modifying RA drug (a DMARD other than methotrexate) before the start of the trial. 43% of participants had used methotrexate before the trial without stopping use due to insufficiency. The ACR 20, 50, and 70 rows show the percentage of patients who reached these marks of improvement within 12 months of the study. The use of methotrexate in combination with Enbrel was statistically significant for all categories but this significance was for “Enbrel/MTX versus Enbrel alone or MTX alone.” The “Major Clinical Response” category (defined as patients who reached ACR70 for 6 months, continuously) also outlines a statistically significant difference between Enbrel in combination with methotrexate and one of the two comparator groups. Finally, “ACR N" outlines the median ACR score for each study group, demonstrating a statistically significant difference for the Enbrel/methotrexate group.

Voluntarily Submitted Manufacturer Information

- “The introduction of Enbrel® effectively redefined the clinical course of moderate to severe rheumatoid arthritis (RA). Many patients who previously would have endured progressive and painful deformities and immobility now live for years or decades with lower pain, less progression, and greater function.”
- “Enbrel® monotherapy in moderate to severe RA has shown greater efficacy than methotrexate monotherapy, the previous standard treatment, in achieving American College of Rheumatology (ACR) criteria, low disease activity (LDA) response, and reduced radiographic progression.”
- “In RA, Enbrel® patients experience fewer adverse reactions, including infections, compared to those on methotrexate (MTX).”

- "Finally, Enbrel® improves PROs and productivity in adults with moderate to severe RA, PsA, and PsO, boosting patient wellbeing and reducing costs for employers."

Confidential Information

[redacted]

See Appendix J for more information, including Amgen Inc.'s citations for reported benefits.

Clinical Effectiveness and Cost Effectiveness

Table D-1
Rheumatoid Arthritis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library	*Etanercept for the treatment of rheumatoid arthritis, published May 2013:*[13] Etanercept 25 mg administered subcutaneously twice weekly together with MTX was more efficacious than either etanercept or MTX monotherapy for ACR50 and it slowed joint radiographic progression after up to three years of treatment for all participants (responders or not). There was no evidence of a difference in the rates of infections between groups. *Biologics for rheumatoid arthritis: an overview of Cochrane reviews, published October 2009:*[14] Based upon indirect comparisons, anakinra seemed less efficacious than etanercept and adalimumab. Etanercept seemed to cause fewer withdrawals due to adverse events than adalimumab, anakinra and infliximab. Significant heterogeneity in characteristics of trial populations imply that these findings must be interpreted with caution. These findings can inform physicians and patients regarding their choice of biologic for treatment of RA.	Not applicable.
ICER - Rheumatoid Arthritis[15]	*Targeted Immune Modulators for Rheumatoid Arthritis: Effectiveness & Value - Evidence Report, published April 2017 (pp. 47-48):*[16] One head-to-head trial of etanercept and adalimumab (primarily in combination with concomitant conventional DMARDs) reported similar changes in disease activity and quality of life; observational data suggest no difference in remission or ACR response between etanercept and adalimumab. We identified one head-to-head trial that compared etanercept with	*Targeted Immune Modulators for Rheumatoid Arthritis: Effectiveness & Value - Evidence Report, published April 2017 (pp. 79-81):*[17] While TIMs have been highly effective in improving outcomes in comparison to conventional DMARDs, there is uncertainty around the comparative effectiveness of the different types of TIMs and the most effective sequence of TIM therapy. This review focuses on the comparative clinical effectiveness and value of TIMs currently used in RA treatment, as well as TIMs currently under review by the Food and

[13] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004525.pub2/full?highlightAbstract=etanercept
[14] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD007848.pub2/full?highlightAbstract=arthriti%7Carthritis%7Cetanercept%7Crheumatoid
[15] https://icer.org/assessment/rheumatoid-arthritis-2017/#overview - QALY used in this literature.
[16] https://icerorg.wpengine.com/wp-content/uploads/2020/10/NE_CEPAC_RA_Evidence_Report_FINAL_040717.pdf - QALY used in this literature.
[17] https://icerorg.wpengine.com/wp-content/uploads/2020/10/NE_CEPAC_RA_Evidence_Report_FINAL_040717.pdf - QALY used in this literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	adalimumab added to existing conventional DMARD therapy in TIM-naïve patients. In addition, we identified three observational studies that compared the three TNFα inhibitors adalimumab, infliximab and etanercept. Disease Activity and Remission: In the one trial that directly compared etanercept with adalimumab primarily in combination with existing conventional DMARDs in TIM-naive patients, the rates of clinical remission and low disease activity were not reported. The mean change from baseline in disease activity (based on DAS28CRP) showed a similar level of change between adalimumab and etanercept at week 24. In addition to the RCT, we reviewed three observational studies for disease activity. In the first observational study based on data from the CORRONA registry in the US, no statistically significant difference was found in rates of clinical remission among the three TNFα inhibitors evaluated (infliximab, adalimumab and etanercept). The second study, based on the Hellenic Registry of Biologic Therapies in Greece, found no statistically-significant difference in remission between the three agents using the DAS28-ESR definition, but found adalimumab to be superior to both infliximab and etanercept based on CDAI and SDAI defined remission (15% vs. 8% vs. 7%, p=0.022 using CDAI; and 17% vs. 8% vs. 8% using SDAI, p=0.009). The third study, based on the DANBIO registry in Denmark, did not find a significant difference between etanercept and adalimumab. ACR20/50/70: We identified head-to-head evidence of ACR response for etanercept in two observational studies. In one study from the CORRONA registry, significant differences were not demonstrated between adalimumab, etanercept, or infliximab for any level of response. Another observational study of the same TIMs used data from the Danish DANBIO registry and found no differences between adalimumab and etanercept in ACR70 response but found etanercept to be superior to infliximab (adjusted OR 1.78; 95% CI 1.28-2.50). Radiographic Progression: We did not identify any studies of etanercept in comparison to another TIM that reported on radiographic progression. HAQ-DI: We did not identify any head-to-head studies of etanercept that reported on HAQ-DI. Other Patient-Reported Outcomes: Comparable improvements in quality of life were observed among patients in the adalimumab and etanercept arms of the RED-SEA trial using the EuroQol-5 domain health state profile (EQ-5D).	Drug Administration (FDA). All 11 TIMs evaluated in combination with conventional DMARDs significantly improved outcomes in disease activity, remission, and ACR response compared to conventional DMARDs alone. Radiographic progression was also significantly reduced with most TIMs in comparison to conventional DMARDs, but differences in the progression measures used made comparisons across studies difficult. Improvements in function and disability as measured on the HAQ-DI were statistically superior for all TIMs compared to conventional DMARDs. Findings were much more limited for TIM monotherapy. We have high certainty that all FDA-approved TIMs provide a substantial net health benefit relative to conventional DMARD therapy alone. Although the long-term effectiveness and safety of the two investigational TIMs (baricitinib and sarilumab) is less clear, we have moderate certainty of an incremental or better net health benefit with these two agents compared to conventional DMARDs. Head-to-head comparisons of TIMs: • Among monotherapy regimens, there is moderate certainty of an incremental or better net health benefit for sarilumab and intravenous tocilizumab compared to adalimumab. • Combination (i.e., with conventional DMARDs) regimens involving tofacitinib, subcutaneous abatacept, certolizumab pegol, and etanercept have been compared to adalimumab + methotrexate in single trials. Comparisons yielded comparable net health benefits. In a single trial, combination therapy with baricitinib provided statistically-significant but modest benefits over adalimumab, yielding a “comparable or better” rating. For TIMs that have never been compared head to head in a randomized setting, we judge there to be insufficient evidence to differentiate among therapies, including intra-class comparisons of the remaining TNFα inhibitors, IL-6 inhibitors, and JAK inhibitors.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
NICE	*Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed, published January 2016:*[18] Three of the trials reported that ACR response rates were similar for both of the biological DMARDs included in the trial: adalimumab and subcutaneous abatacept (AMPLE), etanercept and infliximab (De Filippis) and intravenous abatacept and infliximab (ATTEST). However, in the ADACTA study, ACR response rates were statistically significantly higher with tocilizumab monotherapy than with adalimumab monotherapy. Three trials provided EULAR response data for the population who had had methotrexate before. Two of the trials reported that EULAR response rates were similar for both of the biological DMARDs included in the trial: adalimumab and etanercept (RED-SEA) and abatacept and infliximab (ATTEST). The results showed that all interventions except for adalimumab monotherapy were associated with beneficial treatment effects compared with conventional DMARDs. The credible intervals for all the interventions, both biological and non-biological, tended to overlap with each other. There was a trend for higher estimated probability of achieving ACR20, 50 or 70 response for the biological DMARD combination therapy than for biological monotherapy. *Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor, published August 2010:*[19] For etanercept, the Assessment Group identified seven uncontrolled studies with durations of follow-up ranging from 3 months to over 9 months. Sample sizes ranged from 25 to 201. The results were not pooled because of substantial clinical and statistical heterogeneity between studies. Four studies reported ACR 20, 50 and 70 response rates ranging from 38% to 72%,	*Adalimumab, etanercept, infliximab and abatacept for treating moderate rheumatoid arthritis after conventional DMARDs have failed, published July 2021:*[20] Therefore, the committee recommended adalimumab and infliximab as first-line biological treatments for moderate active rheumatoid arthritis that has had an inadequate response to intensive therapy with 2 or more conventional DMARDs. Although the assessment group's ICER for etanercept was higher than those for adalimumab and infliximab, it was below £30,000 per QALY gained. In response to consultation, it was highlighted that there are some people for whom etanercept would be a particularly useful treatment option. For example, etanercept has a much lower risk of reactivating latent tuberculosis, which has a higher prevalence in people with a South Asian family background. In addition, compared with some of the other biologicals, etanercept does not need to be stopped as far in advance by people wishing to conceive. The committee recognised that these groups would likely only represent a small number of people with moderate rheumatoid arthritis. The committee noted that the recommendations state that if more than 1 biological is an appropriate treatment option, treatment should start with the least expensive. So it also recommended etanercept as an option. *Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed, published January 2016:*[21] Most studies were of etanercept, infliximab and adalimumab, with no studies found for certolizumab pegol or golimumab. The studies had a wide range of model methods, time horizons, price years, currencies and discount rates. The Assessment Group stated that a detailed analysis of the parameters used in each study was not feasible, and that drawing strong conclusions on the cost effectiveness of individual

[18] https://www.nice.org.uk/guidance/ta375/resources/adalimumab-etanercept-infliximab-certolizumab-pegol-golimumab-tocilizumab-and-abatacept-for-rheumatoid-arthritis-not-previously-treated-with-dmards-or-after-conventional-dmards-only-have-failed-pdf-82602790920133

[19] https://www.nice.org.uk/guidance/ta195/resources/adalimumab-etanercept-infliximab-rituximab-and-abatacept-for-the-treatment-of-rheumatoid-arthritis-after-the-failure-of-a-tnf-inhibitor-pdf-82598558287813

[20] https://www.nice.org.uk/guidance/ta715/resources/adalimumab-etanercept-infliximab-and-abatacept-for-treating-moderate-rheumatoid-arthritis-after-conventional-dmards-have-failed-pdf-82611135252421 - QALY used in this literature.

[21] https://www.nice.org.uk/guidance/ta375/resources/adalimumab-etanercept-infliximab-certolizumab-pegol-golimumab-tocilizumab-and-abatacept-for-rheumatoid-arthritis-not-previously-treated-with-dmards-or-after-conventional-dmards-only-have-failed-pdf-82602790920133 - QALY used in this literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	18% to 21% and 8% to 20% respectively. Four studies reported mean improvements in DAS28 score ranging from 0.47 to 1.80 when compared with pre-treatment values. Three studies reported mean improvements in HAQ score ranging from zero to 0.45 when compared with pre-treatment values. None of the studies assessed joint damage or quality of life.	therapies was not possible. The results of the Assessment Group's systematic review indicated that, in people who had previously had DMARD therapy, many biological DMARDs had incremental cost-effectiveness ratios (ICERs) close to £30,000 per quality-adjusted life year (QALY) gained in both directions, and that the ICERs were often higher for those people not previously treated with DMARDs. No individual biological DMARD was seen to be consistently more cost effective than any other biological DMARD.
CADTH	*Drugs for the Management of Rheumatoid Arthritis (March/April 2018)*[22] The analysis came to the following conclusions: In general, in the patient population included in the review (i.e., those with an inadequate response to MTX), most treatments appear to be more effective than MTX alone. Compared with double-csDMARD therapy, triple-csDMARD therapy appears to be more effective regarding disease response and equally effective for improved function. Compared with biologics in combination with MTX, triple-csDMARD therapy appears to be comparable regarding disease response. Combining MTX with a biologic, a biosimilar, or a tsDMARD appears to be more effective than biologic or tsDMARD monotherapy. The review could not indicate if any one treatment has greater benefits than the others because not all treatments had data available for each of the outcomes and there were often no important differences in the head-to-head comparison results of these treatments.	Not applicable.
IQWiG	*Benefit assessment of biotechnologically produced drugs for the treatment of rheumatoid arthritis (September 17, 2019)*[23] In the combination therapy with MTX without MTX pretreatment, the following biologics were compared with each other in the present benefit assessment: abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, and tocilizumab. A direct comparative study was not available for any comparison of biologics.	Not applicable.

[22] https://www.cadth.ca/drugs-management-rheumatoid-arthritis

[23] https://www.iqwig.de/en/projects/a16-70.html

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	For the combination therapy with MTX without MTX pretreatment, the evidence base is as follows. there is no hint of greater or lesser benefit of any biologic versus another biologic for clinical remission (which particularly in this subquestion is the primary treatment goal to be achieved); there is a hint of greater benefit of adalimumab and etanercept versus certolizumab pegol and tocilizumab for low disease activity; there is no hint of greater or lesser benefit of any further biologic versus another biologic for low disease activity; there is no hint of greater or lesser benefit or harm of any biologic versus another biologic for further patient-relevant outcomes. For the combination therapy with MTX after MTX failure, the evidence base is as follows: there is a hint of greater benefit of adalimumab, certolizumab pegol and golimumab versus anakinra for the primary treatment goal of clinical remission; there is a hint of greater benefit of abatacept, adalimumab, infliximab, and tocilizumab versus anakinra for low disease activity; there is hint of greater benefit of abatacept and tocilizumab versus anakinra for pain; there is a hint of greater benefit of golimumab versus anakinra for health-related quality of life (physical component summary score of the Short Form 36 - Health Survey); there is a hint of greater harm of certolizumab pegol versus all other biologics for 1 or more of the following 3 outcomes: serious adverse events, infections, serious infections. In addition, there is a hint of greater harm of golimumab and tocilizumab versus infliximab for serious infections; there is a hint of greater harm of anakinra versus abatacept, adalimumab, etanercept and infliximab as well as of tocilizumab versus abatacept for discontinuations due to adverse events For monotherapy after MTX intolerance, the evidence base is as follows: there is no hint of greater or lesser benefit or harm of any biologic versus another biologic for the primary treatment goal of clinical remission or other outcomes. For the combination therapy with MTX after biologic failure, the evidence base is as follows: there is no hint of greater or lesser benefit or harm of any biologic versus another biologic for the primary treatment goal of clinical remission or other outcomes. *Biologic medications as second-line therapy for rheumatoid arthritis, published August 2013:*[24]	

[24] https://www.iqwig.de/download/a10-01_biologics-second-line-therapy-for-rheumatoid-arthritis_executive-summary.pdf

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	Etanercept + MTX - At study level both studies showed a low risk of bias. The risk of bias of the results at outcome level was generally high, except for the results for the outcome “remission” in Study 0881A1-308-EU/AU (TEMPO). One of the reasons that applied in most cases and to both studies was that under placebo + MTX substantially more patients discontinued the studies prematurely due to lack of efficacy. Although statistical replacement procedures were used for the patients who discontinued, relevant bias could still occur. If possible, in these cases sensitivity analyses were conducted for the present benefit assessment to investigate the impact of bias. A statistically significant effect with a low risk of bias was shown for the outcome “remission” in the larger of the two studies. The result of the smaller study with a high risk of bias was not statistically significant, but the effect was in the same direction. There is therefore an indication of a benefit of etanercept + MTX for the outcome “remission”. Etanercept versus sulfasalazine - Results were available from one study with a low risk of bias at study level. However at outcome level, the risk of bias was consistently assessed as high. With the exception of remission, this was because of the lack of information as to how many patients from the treatment groups discontinued the study because of lack of efficacy and whether or how these patients were taken into account in the analysis. Accordingly, no sensitivity analyses could be conducted either. For the outcome “remission” it was unclear whether the outcome assessors were blinded. Statistically significant results were shown or an irrelevant effect could be excluded for the outcomes “painful joints”, “swollen joints”, “pain”, “global assessment of disease activity by the patient”, “general health”, “morning stiffness” and “status of physical functioning”. For each of these outcomes there was a hint of an added benefit of etanercept compared with sulfasalazine in patients with intolerance of MTX. Etanercept versus MTX - Results of one study with a low risk of bias at study level were available. However at outcome level, the risk of bias was consistently assessed as high. With the exception of remission, the reason was the lack of information as to how many patients from the treatment groups discontinued the study because of lack of efficacy and whether or how these patients were taken into account in the analysis. For the outcome “remission” it was unclear whether the outcome assessors were blinded. Statistically significant results were shown or an irrelevant effect could be excluded for the outcomes “remission”, “painful joints”, “swollen joints”, “pain”, “global assessment of disease activity by the patient”, “general health” and “morning stiffness”. For each of these outcomes there was a hint of an added benefit of etanercept compared with MTX in	

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	patients with severe active and progressive RA.	
INAHTA	Not applicable.	*Adalimumab, etanercept, infliximab,certolizumab pegol, golimumab, tocilizumab and abatacept for the treatment of rheumatoid arthritis not previously treated with disease-modifying antirheumatic drugs and after the failure of conventional disease-modifying antirheumatic drugs only: systematic review and economic evaluation, published 2016:*[25] Conclusion: bDMARDs appear to have cost per QALY values greater than the thresholds stated by the National Institute for Health and Care Excellence for interventions to be cost-effective. Future research priorities include: the evaluation of the long-term HAQ trajectory while on cDMARDs; the relationship between HAQ direct medical costs; and whether or not bDMARDs could be stopped once a patient has achieved a stated target (e.g. remission).

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available. For Enbrel, there were no applicable results in the following studies found on ClinicalTrials.Gov:

- Study To Evaluate The Response To Enbrel And The Impact Of Rheumatoid Factor(RF) And Anti-Cyclic Citrullinated Peptide(Anti-CCP) In Rheumatoid Arthritis(RA) Patients[26]
- A Study Comparing LBEC0101 to Enbrel® in Subjects With Active Rheumatoid Arthritis Despite Methotrexate Therapy[27]
- Study of Enbrel in Rheumatoid Arthritis (RA) Subjects With Comorbid Disorders[28]
- Randomized Double-blind Parallel Trial to Evaluate Equivalence in Efficacy and Safety of HB203 and Enbrel in RA Patients[29]

[25] https://njl-admin.nihr.ac.uk/document/download/2003416 - QALY used in this literature.
[26] https://clinicaltrials.gov/study/NCT04428424?cond=Rheumatoid%20Arthritis&intr=Etanercept%20%5C(Enbrel%5C)&rank=2
[27] https://clinicaltrials.gov/study/NCT02357069?cond=Rheumatoid%20Arthritis&intr=Etanercept%20%5C(Enbrel%5C)&rank=3
[28] https://clinicaltrials.gov/study/NCT00132418?cond=Rheumatoid%20Arthritis&intr=Etanercept%20%5C(Enbrel%5C)&rank=6
[29] https://clinicaltrials.gov/study/NCT01270997?cond=Rheumatoid%20Arthritis&intr=Etanercept%20%5C(Enbrel%5C)&rank=8

Ankylosing Spondylitis

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Non Radiographic Axial Spondyloarthritis[30]

Manufacturer-Reported Benefits

Information contained in Enbrel's FDA label, Section 14 Clinical Studies, reports on studies in patients between 18 and 70 years of age with active ankylosing spondylitis. Compared with placebo, treatment with Enbrel resulted in improvements in measures of disease activity.[31]

Figure D-3
Study I (Table 12)

Table 12. Components of Ankylosing Spondylitis Disease Activity

	Placebo N = 139		Enbrel[a] N = 138	
Median values at time points	Baseline	6 Months	Baseline	6 Months
ASAS response criteria				
Patient global assessment [b]	63	56	63	36
Back pain [c]	62	56	60	34
BASFI [d]	56	55	52	36
Inflammation [e]	64	57	61	33
Acute phase reactants				
CRP (mg/dL) [f]	2.0	1.9	1.9	0.6
Spinal mobility (cm):				
Modified Schober's test	3.0	2.9	3.1	3.3
Chest expansion	3.2	3.0	3.3	3.9
Occiput-to-wall measurement	5.3	6.0	5.6	4.5

[a] $p < 0.0015$ for all comparisons between Enbrel and placebo at 6 months. P values for continuous endpoints were based on percent change from baseline.
[b] Measured on a Visual Analog Scale (VAS) with 0 = "none" and 100 = "severe".
[c] Average of total nocturnal and back pain scores, measured on a VAS with 0 = "no pain" and 100 = "most severe pain".
[d] Bath Ankylosing Spondylitis Functional Index (BASFI), average of 10 questions.
[e] Inflammation represented by the average of the last 2 questions on the 6-question Bath Ankylosing Spondylitis Disease Activity Index (BASDAI).
[f] C-reactive protein (CRP) normal range: 0-1.0 mg/dL.

30 https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/blt74558fbe6f37b611/6328a49019c64564c313f918/axial-spa-guideline-2019.pdf
31 https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf

Figure D-3 above shows the clinical responses of patients with ankylosing spondylitis who received Enbrel versus placebo.

Voluntarily Submitted Manufacturer Information

Confidential Information

[redacted]

See Appendix J for more information, including Amgen Inc.'s citations for reported benefits.

Clinical Effectiveness and Cost Effectiveness

Table D-2
Ankylosing Spondylitis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library	*TNF-alpha inhibitors for ankylosing spondylitis, 2015*[32] Compared with placebo, there was high quality evidence that patients on an anti-TNF agent were three to four times more likely to achieve an ASAS40 response (assessing spinal pain, function, and inflammation, as measured by the mean of intensity and duration of morning stiffness, and patient global assessment) by six months (adalimumab: risk ratio (RR) 3.53, 95% credible interval (CrI) 2.49 to 4.91; etanercept: RR 3.31, 95% CrI 2.38 to 4.53; golimumab: RR 2.90, 95% CrI 1.90 to 4.23; infliximab: RR 4.07, 95% CrI 2.80 to 5.74, with a 25% to 40% absolute difference between treatment and placebo groups. The number needed to treat (NNT) to achieve an ASAS 40 response ranged from 3 to 5. There was high quality evidence of improvement in physical function on a 0 to 10 scale (adalimumab: mean difference (MD) -1.6, 95% CrI -2.2 to -0.9; etanercept: MD -1.1, 95% CrI -1.6 to -0.6; golimumab: MD -1.5, 95% CrI -2.3 to -0.7; infliximab: MD -2.1, 95% CrI -2.7 to -1.4, with an 11% to 21% absolute difference between treatment and placebo groups. The NNT to achieve the minimally clinically important difference of 0.7 points ranged from 2 to 4. Compared with placebo, there was moderate quality evidence (downgraded for imprecision) that patients on an anti-TNF agent were more likely to achieve an ASAS partial remission by six months (adalimumab: RR 6.28, 95% CrI 3.13 to 12.78; etanercept: RR 4.24, 95% CrI 2.31 to 8.09; golimumab:	Not applicable.

[32] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD005468.pub2/full?highlightAbstract=spondyl%7Cspondylitis%7Cankylos%7Cankylosing%7Cetanercept

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	RR 5.18, 95% CrI 1.90 to 14.79; infliximab: RR 15.41, 95% CrI 5.09 to 47.98 with a 10% to 44% absolute difference between treatment and placebo groups. The NNT to achieve an ASAS partial remission response ranged from 3 to 11.	
ICER	Not applicable.	Not applicable.
NICE	*TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis, 2016*[33] For BASDAI 50 the RRs of a response were 3.16 with adalimumab, 3.17 with etanercept, 3.57 with golimumab, 3.60 with certolizumab pegol, and 4.86 with infliximab. The additional reduction in BASDAI and BASFI scores achieved with adalimumab, certolizumab pegol, etanercept and infliximab compared with placebo were all statistically significant and clinically important. Additional reductions in BASDAI scores compared with placebo were 1.46 units with certolizumab pegol, 1.55 units with adalimumab, 1.75 units with etanercept and 2.28 units with infliximab. Additional BASFI reductions were 1.1 units with certolizumab pegol, 1.25 units with adalimumab, 1.43 units with etanercept, 1.45 units with golimumab and 2.16 units with infliximab. This conclusion was based on results from a trial by Giardina et al. that compared infliximab with etanercept. In the Giardina et al. trial, the BASDAI and BASFI outcomes at week 12 favoured treatment with infliximab, but by week 48 the results for infliximab and etanercept were almost identical.	*TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis, 2016*[34] For ankylosing spondylitis, the companies compared the 5 TNF-alpha inhibitors that have a marketing authorisation for this indication (adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) with each other, and with conventional care. For non-radiographic axial spondyloarthritis, the companies compared the 3 TNF-alpha inhibitors that have a marketing authorisation in this indication (adalimumab, certolizumab pegol and etanercept) with each other and with conventional therapy (except for AbbVie, which did not include etanercept in its model). All evaluations adopted an NHS perspective. Costs and benefits in all cases were discounted at 3.5%. Based on recommendations in NICE's technology appraisal guidance on adalimumab, etanercept and infliximab for ankylosing spondylitis, all models included response criteria to decide whether TNF-alpha inhibitors were continued or stopped. The criteria were ASAS 20, ASAS 40 or BASDAI 50 at week 12, except for UCB Pharma which used response criteria at week 24, in its base-case model for the ankylosing spondylitis population.
CADTH	Not applicable.	Not applicable.
IQWiG	Not applicable.	Not applicable.
INAHTA	*[Adalimumab, etanercept, infliximab and golimumab for the treatment of*	*Adalimumab, etanercept and infliximab for the treatment of*

[33] https://www.nice.org.uk/guidance/ta383/resources/tnfalpha-inhibitors-for-ankylosing-spondylitis-and-nonradiographic-axial-spondyloarthritis-pdf-82602848027077 - QALY used in this literature.
[34] https://www.nice.org.uk/guidance/ta383/resources/tnfalpha-inhibitors-for-ankylosing-spondylitis-and-nonradiographic-axial-spondyloarthritis-pdf-82602848027077 - QALY used in this literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	ankylosing spondylitis and reactive arthritis][35] Anti-TNF-alpha therapy has proved to better control ankylosing spondylitis inflammatory symptoms when compared to placebo or DMDs.	*ankylosing spondylitis: a systematic review and economic evaluation*[36] The review of clinical data related to the three drugs (including conventional treatment) compared with conventional treatment plus placebo indicates that in the short term (12;24 weeks) the three treatments demonstrate clinical and statistical effectiveness in relation to assessment of ASAS, BASDAI and BASFI. Indirect comparisons of treatments were limited and were not able to determine a significant difference in effectiveness between the three agents. The short-term economic assessment indicates that none of the three anti-TNF-a agents is likely to be considered cost-effective at current acceptability thresholds, with infliximab consistently the least favourable option. Analyses carried out by the assessment group over the longer term challenge the assumptions made in the company submissions that costs will decrease over time. Owing to these large and sustained costs, the impact on the NHS budget is likely to be considerable.

Plaque Psoriasis: Adult and Pediatric

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *Journal of the American Academy of Dermatology*[37].

Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. *Journal of the American Academy of Dermatology*.[38]

35 https://database.inahta.org/article/14348
36 https://database.inahta.org/article/6962
37 https://pubmed.ncbi.nlm.nih.gov/30772098/
38 https://pubmed.ncbi.nlm.nih.gov/31703821/

Manufacturer-Reported Benefits

Information contained in Enbrel's FDA label, Section 14 Clinical Studies, reports on the following two studies in adults with plaque psoriasis. The studies generally show that more subjects randomized to Enbrel than placebo achieved at least a 75% reduction from baseline Psoriasis Area and Severity Index (PASI) score.[39]

Figure D-4
Study I (Table 13)

Table 13. Study I Outcomes at 3 and 6 Months

	Placebo/Enbrel 25 mg BIW (N = 168)	Enbrel/Enbrel 25 mg QW (N = 169)	Enbrel/Enbrel 25 mg BIW (N = 167)	Enbrel/Enbrel 50 mg BIW (N = 168)
3 Months				
PASI 75 n (%)	6 (4%)	23 (14%)[a]	53 (32%)[b]	79 (47%)[b]
Difference (95% CI)		10% (4, 16)	28% (21, 36)	43% (35, 52)
sPGA, "clear" or "minimal" n (%)	8 (5%)	36 (21%)[b]	53 (32%)[b]	79 (47%)[b]
Difference (95% CI)		17% (10, 24)	27% (19, 35)	42% (34, 50)
PASI 50 n (%)	24 (14%)	62 (37%)[b]	90 (54%)[b]	119 (71%)[b]
Difference (95% CI)		22% (13, 31)	40% (30, 49)	57% (48, 65)
6 Months				
PASI 75 n (%)	55 (33%)	36 (21%)	68 (41%)	90 (54%)

[a] p = 0.001 compared with placebo.
[b] p < 0.0001 compared with placebo.

Figure D-4 shows the efficacy of Enbrel versus placebo in adult patients with plaque psoriasis.

[39] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf

Figure D-5
Study II (Table 14)

Table 14. Study II Outcomes at 3 Months

	Placebo (N = 204)	Enbrel 25 mg BIW (N = 204)	Enbrel 50 mg BIW (N = 203)
PASI 75 n (%)	6 (3%)	66 (32%)[a]	94 (46%)[a]
Difference (95% CI)		29% (23, 36)	43% (36, 51)
sPGA, "clear" or "minimal" n (%)	7 (3%)	75 (37%)[a]	109 (54%)[a]
Difference (95% CI)		34% (26, 41)	50% (43, 58)
PASI 50 n (%)	18 (9%)	124 (61%)[a]	147 (72%)[a]
Difference (95% CI)		52% (44, 60)	64% (56, 71)

[a] $p < 0.0001$ compared with placebo.

Figure D-5 shows the efficacy of Enbrel versus placebo in adult patients with plaque psoriasis.

Information contained in Enbrel's FDA label, Section 14 Clinical Studies, reports on the following study in pediatric subjects 4 to 17 years of age with moderate to severe plaque psoriasis.[40]

Figure D-6
Study 1(Table 15)

Table 15. Pediatric Plaque Psoriasis Outcomes at 12 Weeks

	Placebo (N = 105)	Enbrel 0.8 mg/kg Once Weekly (N = 106)
PASI 75, n (%)	12 (11%)	60 (57%)
PASI 90, n (%)	7 (7%)	29 (27%)
sPGA "clear" or "almost clear" n (%)	14 (13%)	55 (52%)

Figure D-6 shows efficacy of Enbrel when compared to placebo in pediatric patients with plaque psoriasis.

[40] www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf

Voluntarily Submitted Manufacturer Information

Public Information

- "Across moderate to severe RA, psoriatic arthritis (PsA), and plaque psoriasis (PsO), Enbrel® has demonstrated clinically meaningful improvements in outcomes, such as reductions in joint pain and damage, improved physical functioning, and reduction in skin-related Symptoms."
- "In PsO, where safety of systemic treatments is particularly important in the risk-benefit calculation, Enbrel® improves multiple measures of skin signs and symptoms, as well as a number of patient reported outcome (PRO) measures. Improvements in disease activity and PROs with Enbrel® were maintained long-term (up to 96 weeks).
- "Enbrel® improves PROs and productivity in adults with moderate to severe RA, PsA, and PsO, boosting patient wellbeing and reducing costs for employers."

Clinical Effectiveness and Cost Effectiveness

Table D-3
Adult and Pediatric Plaque Psoriasis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library	*Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis. 2023*[41] For reaching PASI 90, the most effective drugs when compared to placebo were (SUCRA rank order, all high-certainty evidence): infliximab (risk ratio (RR) 49.16, 95% CI 20.49 to 117.95), bimekizumab (RR 27.86, 95% CI 23.56 to 32.94), ixekizumab (RR 27.35, 95% CI 23.15 to 32.29), risankizumab (RR 26.16, 95% CI 22.03 to 31.07). Clinical effectiveness of these drugs was similar when compared against each other. Bimekizumab and ixekizumab were significantly more likely to reach PASI 90 than secukinumab. Bimekizumab, ixekizumab, and risankizumab were significantly more likely to reach PASI 90 than brodalumab and guselkumab. Infliximab, anti-IL17 drugs (bimekizumab, ixekizumab, secukinumab, and brodalumab), and anti-IL23 drugs except tildrakizumab were significantly more likely to reach PASI 90 than ustekinumab, three anti-TNF alpha agents, and deucravacitinib. Ustekinumab was superior to certolizumab. Adalimumab, tildrakizumab, and ustekinumab were superior to etanercept. *Anti-TNF agents for paediatric psoriasis. 2015*[42]	Not applicable.

[41] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011535.pub6/full?highlightAbstract=plaque%7Cplaqu%7Cetanercept
[42] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010017.pub2/full?highlightAbstract=plaque%7Cplaqu%7Cetanercept

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	We can conclude, based on this single included study, that etanercept seems to be efficacious and safe (at least in the short term) for the treatment of paediatric psoriasis.	
ICER	Not applicable.	*Targeted Immunomodulators for the Treatment of Moderate-to-Severe Plaque Psoriasis: Effectiveness and Value. 2016*[43] Third, the newer IL-17A targeted agents provide good economic value in relation to etanercept. The lower initial effectiveness of etanercept, high long-term discontinuation rates, and the need for more expensive second-line therapy decrease its overall value despite lower initial drug cost. In summary, our analyses suggest that if health care payers are able to achieve significant drug rebates, the most effective (and most expensive) targeted drugs provide the greatest benefit to psoriasis patients at a reasonable economic value.
NICE	Not applicable.	Not applicable.
CADTH	*Biologics in Plaque Psoriasis: A Summary. 2021*[44] Health Canada has approved 11 biologics for plaque psoriasis. Biologics for plaque psoriasis can be divided into 2 groups based on mechanisms of action and market authorization dates: Old-generation biologics (5): include anti-TNF drugs (etanercept, adalimumab, infliximab, and certolizumab pegol) and an anti-IL-12/IL-23 inhibitor (ustekinumab), which were approved in Canada before 2010 New-generation biologics (6): include anti-IL-17 inhibitors (secukinumab, ixekizumab, and brodalumab) and anti-IL-23 inhibitors (guselkumab, tildrakizumab, and risankizumab), which were approved in Canada in 2015 or later. *Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people. 2017* Adalimumab (Humira), etanercept (Enbrel) and ustekinumab (Stelara) are all available on the NHS as possible treatments for plaque psoriasis. Adalimumab is for children and young people 4 years or older, etanercept for those 6 years or older and ustekinumab for those 12 years or older. They are only available if the psoriasis:is severe and has not improved with other treatments, for example, ciclosporin, methotrexate or phototherapy, or these can't be used.	Not applicable.

[43] https://icerorg.wpengine.com/wp-content/uploads/2020/10/NE_CEPAC_Psoriasis_Evidence_Report_FINAL_012317.pdf - QALY used in this literature.
[44] https://www.cadth.ca/biologics-plaque-psoriasis-summary

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	If the psoriasis doesn't improve enough, treatment with etanercept should be stopped after 12 weeks and with adalimulab and ustekinumab treatments after 16 weeks.	
IQWiG	Not applicable.	Not applicable.
INAHTA	Not applicable.	*Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people: systematic review and economic evaluation. 2017* [45] The paucity of clinical and economic evidence to inform the cost-effectiveness of biological treatments in children and young people imposed a number of strong assumptions and uncertainties. Health-related quality-of-life (HRQoL) gains associated with treatment and the number of hospitalisations in children and young people are areas of considerable uncertainty. The findings suggest that biological treatments may not be cost-effective for the management of psoriasis in children and young people at a willingness-to-pay threshold of £30,000 per quality-adjusted life-year, unless a number of strong assumptions about HRQoL and the costs of BSC are combined. Registry data on biological treatments would help determine safety, patterns of treatment switching, impact on comorbidities and long-term withdrawal rates. Further research is also needed into the resource use and costs associated with BSC. Adequately powered randomised controlled trials (including comparisons against placebo) could substantially reduce the uncertainty surrounding the effectiveness of biological treatments in biologic-experienced populations of children and young people, particularly in younger children. Such trials should establish the impact of biological therapies on HRQoL in this population, ideally by collecting direct estimates of EuroQol-5 Dimensions for Youth (EQ-5D-Y) utilities.

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. For Enbrel, there were no applicable results in the following studies found on ClinicalTrials.Gov:

[45] https://www.journalslibrary.nihr.ac.uk/hta/hta21640/#/abstract - QALY used in this literature.

- Study Evaluating Etanercept for the Treatment of Moderate to Severe Psoriasis (PRISTINE)[46]
- Study to Evaluate the Efficacy of Enbrel as a Biological Treatment in Moderate to Severe Plaque Psoriasis Patients[47]
- Pediatric Open-Label Extension Study of Etanercept in Patients With Plaque Psoriasis[48]
- Etanercept (Enbrel®) in Psoriasis - Pediatrics[49]
- Pediatric Study in Children and Adolescents With Severe Plaque Psoriasis[50]

Psoriatic Arthritis

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis[51]

Manufacturer-Reported Benefits

Information contained in Enbrel's FDA label, Section 14 Clinical Studies, reports on studies in patients between 18 and 70 years of age with active psoriatic arthritis. Compared to placebo, treatment with Enbrel resulted in significant improvements in measures of disease activity.[52]

46 https://clinicaltrials.gov/study/NCT00663052?cond=Plaque%20Psoriasis&term=etanercept&rank=4
47 https://clinicaltrials.gov/study/NCT04398732?cond=Plaque%20Psoriasis&term=etanercept&rank=8
48 https://clinicaltrials.gov/study/NCT00141921?cond=Pediatric%20Plaque%20Psoriasis&intr=Etanercept&rank=1
49 https://clinicaltrials.gov/study/NCT00078819?cond=Pediatric%20Plaque%20Psoriasis&intr=Etanercept&rank=2
50 https://clinicaltrials.gov/study/NCT02471144?cond=Pediatric%20Plaque%20Psoriasis&intr=Etanercept&rank=3
51 https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.40726
52 https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf

Figure D-7
Study I (Table 11)

Table 11. Components of Disease Activity in Psoriatic Arthritis

	Placebo N = 104		Enbrel[a] N = 101	
Parameter (median)	Baseline	6 Months	Baseline	6 Months
Number of tender joints[b]	17.0	13.0	18.0	5.0
Number of swollen joints[c]	12.5	9.5	13.0	5.0
Physician global assessment[d]	3.0	3.0	3.0	1.0
Patient global assessment[d]	3.0	3.0	3.0	1.0
Morning stiffness (minutes)	60	60	60	15
Pain[d]	3.0	3.0	3.0	1.0
Disability index[e]	1.0	0.9	1.1	0.3
CRP (mg/dL)[f]	1.1	1.1	1.6	0.2

Figure D-7 above shows… the clinical responses of patients with psoriatic arthritis who received Enbrel versus placebo.

Voluntarily Submitted Manufacturer Information

Public Information

- "Across moderate to severe RA, psoriatic arthritis (PsA), and plaque psoriasis (PsO), Enbrel® has demonstrated clinically meaningful improvements in outcomes, such as reductions in joint pain and damage, improved physical functioning, and reduction in skin-related symptoms."
- "Amgen has invested capital studying Enbrel® for additional indications and introduced new, more patient-friendly formulations and administration methods, such as the easy-to-use, self-injection device specifically designed to meet the needs of moderate-to-severe rheumatoid arthritis patients and psoriatic arthritis patients."
- "Finally, Enbrel® improves PROs and productivity in adults with moderate to severe RA, PsA, and PsO, boosting patient wellbeing and reducing costs for employers."

See Appendix J for more information, including Amgen Inc.'s citations for reported benefits.

Clinical Effectiveness and Cost Effectiveness

Table D-5
Psoriatic Arthritis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library	Not applicable.	Not applicable.
ICER	Not applicable.	Not applicable.
NICE	*Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis, 2010*[53] At 24 weeks the treatment effect on psoriasis favoured etanercept with RRs for PASI 75 of 7.05 (95% CI 1.68 to 29.56), PASI 50 of 2.65 (95% CI 1.46 to 4.80) and PASI 90 of 1.88 (95% CI 0.36 to 9.90). At 1 year the mean annualised rate of progression on the Total Sharp Score for all people was −0.03 (standard deviation [SD] 0.87), indicating that on average there was no clinically significant progression of joint erosion based on uncontrolled follow-up data.	*Backsback et al., 2007*[54] The study by Bansback et al. (2007) compared etanercept with ciclosporin and leflunomide. The economic model focused on response according to PsARC and associated HAQ score, with changes in HAQ and further withdrawals modelled over 10 years. Mease 2004 was the source of evidence for response rates and HAQ. The base-case results showed an ICER of around £28,000 per QALY gained for etanercept compared with ciclosporin and £38,000 per QALY gained for etanercept compared with leflunomide. *Bravo Vergel, 2006*[55] The study by Bravo Vergel (2006) compared etanercept with infliximab and palliative care. The model included response according to PsARC and associated HAQ score. Changes in HAQ and further withdrawals were modelled over 40 and 10 years. Evidence from Mease 2000, Mease 2004 and IMPACT was used to model the PsARC response. The ICER for etanercept was between £26,361 and £30,628 per QALY gained compared with palliative care depending on the assumptions made about the deterioration in HAQ score at treatment withdrawal (rebound). Infliximab was the most effective strategy, and generated the highest number of QALYs. *NICE, 2004* A published cost-effectiveness model originally used to support a submission to NICE in 2004 was adapted to incorporate additional effectiveness evidence and new comparators. The adjusted model

[53] https://www.nice.org.uk/guidance/ta199/resources/etanercept-infliximab-and-adalimumab-for-the-treatment-of-psoriatic-arthritis-pdf-82598565006277 - QALY used in this literature.
[54] https://www.nice.org.uk/guidance/ta199/resources/etanercept-infliximab-and-adalimumab-for-the-treatment-of-psoriatic-arthritis-pdf-82598565006277 - QALY used in this literature.
[55] https://www.nice.org.uk/guidance/ta199/resources/etanercept-infliximab-and-adalimumab-for-the-treatment-of-psoriatic-arthritis-pdf-82598565006277 - QALY used in this literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
		compared the costs and benefits associated with etanercept, infliximab, adalimumab and best supportive care over a lifetime horizon. Best supportive care was assumed to be ciclosporin because the population considered in the model were assumed to have already tried other DMARDs (leflunomide, sulfasalazine and methotrexate).[56]
CADTH	Not applicable.	Not applicable.
IQWiG	Not applicable.	Not applicable.
INAHTA	*Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis: a systematic review and economic evaluation, 2011*[57] Pooled estimates of effect demonstrated a significant improvement in patients with PsA for all joint disease and functional status outcomes at 12-14 weeks' follow-up. The biologic treatment significantly reduced joint symptoms assessed by PsARC for etanercept [relative risk (RR) 2.60, 95% confidence interval (CI) 1.96 to 3.45], infliximab (RR 3.44, 95% CI 2.53 to 4.69) and adalimumab (RR 2.24, 95% CI 1.74 to 2.88). This was consistent with the results from the pooled estimates of ACR 20. Furthermore, the statistically significant reduction in HAQ score also indicated a beneficial effect of these biologic therapies on patients' functional status. Significant heterogeneity was observed only in the outcome of PsARC in infliximab. The 24-week data for all three biologics demonstrated that the treatment effects are maintained. Trial data demonstrate a significant effect of all three biologics on skin disease in terms of PASI response, at 12 or 24 weeks. The results of evidence synthesis found that infliximab appears to be the most effective of the three biologics. Across all outcomes of joint and skin disease at 12 weeks, infliximab is associated with the highest probabilities of response. The response in joint disease (PsARC and ACR) is greater with etanercept than with adalimumab, whereas the response in skin disease (PASI) is greater with adalimumab than with etanercept, although these differences are not statistically significant. In those patients who achieve a PsARC response to treatment the highest mean reductions in the functional and psychological impact of the disease, measured by HAQ, are seen with	*Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis: a systematic review and economic evaluation, 2011*[58] The published models estimated that the incremental cost-effectiveness ratio (ICER) for etanercept versus palliative care was between £26,000 and £38,000 per QALY, but did not consider the impact of biologics on the skin component of PsA. The de novo York Assessment Group model evaluated the cost-effectiveness of the three biologic therapies and palliative care only. Under base-case assumptions, for patients with PsA and mild-to-moderate skin disease, the ICER etanercept versus palliative care is about £18,000 per QALY, and the ICER of infliximab versus etanercept is about £44,000 per QALY. Adalimumab is extendedly dominated. The probability that etanercept is cost-effective is 0.436 at a threshold of £20,000 per QALY and 0.475 at a threshold of £30,000 per QALY. The expected lifetime prescription costs of biologic therapies is considerably greater than offset cost savings elsewhere in the NHS. For patients with PsA and moderate-to-severe skin disease who continue on biologics after 3 months if they respond for skin or joints, the ICER of adalimumab versus palliative care is about £16,000 per QALY, the ICER of etanercept versus adalimumab is about £21,000 per QALY and the ICER for infliximab versus etanercept is about £26,000 per QALY. If the cost-effectiveness threshold were £20,000 per QALY then all biologics have a similar probability of being cost-effective.

[56] https://www.nice.org.uk/guidance/ta199/resources/etanercept-infliximab-and-adalimumab-for-the-treatment-of-psoriatic-arthritis-pdf-82598565006277 - QALY used in this literature.
[57] https://www.ncbi.nlm.nih.gov/books/NBK56827/
[58] https://www.ncbi.nlm.nih.gov/books/NBK56827/ - QALY used in this literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	infliximab and etanercept (-0.657 for infliximab and -0.630 for etanercept). For all three biologics the changes in HAQ for those patients who did not respond to treatment were below the minimum clinically significant threshold (-0.3).	For patients with PsA with negligible skin involvement, the ICER of etanercept versus palliative care is about £18,000 per QALY, and the ICER of infliximab versus etanercept is about £65,000 per QALY. Adalimumab is extendedly dominated in this group.

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available. For Enbrel, there were no applicable results in the following studies found on ClinicalTrials.Gov:

- REPArE: Rating Evaluations in Psoriatic Arthritis (PsA) With Etanercept (Enbrel®)[59]
- Etanercept and Methotrexate in Combination or as Monotherapy in Psoriatic Arthritis[60]
- Study Evaluating Etanercept on Skin and Joint Disease in Psoriatic Arthritis[61]

Juvenile Psoriatic Arthritis

The FDA approved Enbrel for the treatment of active juvenile psoriatic arthritis in patients 2 years of age and older in October, 2023. Due to the relatively recent approval, some information may not be available.

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

Manufacturer-Reported Benefits

Information contained in Enbrel's FDA label states that the safety and effectiveness of Enbrel have been established in pediatric patients 2 years to 17 years old with JPsA. Use of Enbrel in JPsA is supported by evidence from adequate and well controlled studies of Enbrel in adults with PsA; pharmacokinetic data from adult patients with psoriatic arthritis, rheumatoid arthritis, and psoriasis; and pharmacokinetic data from pediatric patients with active juvenile idiopathic arthritis and psoriasis.[62]

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[59] https://clinicaltrials.gov/study/NCT00127842?cond=Psoriatic%20Arthritis&term=etanercept&rank=1
[60] https://clinicaltrials.gov/study/NCT02376790?cond=Psoriatic%20Arthritis&term=etanercept&rank=2
[61] https://clinicaltrials.gov/study/NCT00245960?cond=Psoriatic%20Arthritis&term=etanercept&rank=3
[62] www.accessdata.fda.gov/drugsatfda_docs/label/2023/103795s5595lbl.pdf

Voluntarily Submitted Manufacturer Information

No voluntary information was submitted by Amgen Inc. for JPsA. This may be due to the fact that Enbrel received FDA approval for treatment of JPsA after the voluntarily submitted information deadline.

Confidential Information

[redacted]

Clinical Effectiveness and Cost Effectiveness

Table D-7
Juvenile Psoriatic Arthritis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library	*Two-year Efficacy and Safety of Etanercept in Pediatric Patients with Extended Oligoarthritis, Enthesitis-related Arthritis, or Psoriatic Arthritis*[63] The main objective was to determine the 2-year clinical benefit and safety of etanercept (ETN) in children with the juvenile idiopathic arthritis (JIA) categories of extended oligoarthritis (eoJIA), enthesitis-related arthritis (ERA), or psoriatic arthritis (PsA). Over 96 weeks of therapy, ETN demonstrated sustained efficacy at treating the clinical symptoms of all 3 JIA categories, with no major safety issues. *LONG-TERM SAFETY AND EFFICACY OF ETANERCEPT IN PAEDIATRIC SUBJECTS WITH EXTENDED OLIGOARTICULAR JUVENILE IDIOPATHIC ARTHRITIS, ENTHESITIS-RELATED ARTHRITIS, OR PSORIATIC ARTHRITIS*[64] Aim: To assess the long-term safety and clinical benefit of etanercept (ETN) in paediatric subjects with the extended oligoarticular (eo), enthesitis-related (ERA), and psoriatic (PsA) JIA subtypes. Conclusions: ETN treatment for 96 weeks was well-tolerated and effective in treating subjects with the JIA subtypes, eoJIA, ERA, or PsA, as expected from the previous data from polyarticular JIA.	Not applicable.
ICER	Not applicable.	Not applicable.
NICE	Not applicable.	Not applicable.

[63] https://www.jrheum.org/content/43/4/816
[64] https://onlinelibrary.wiley.com/doi/10.1111/imj.12426

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
CADTH	Not applicable.	Not applicable.
IQWiG	Not applicable.	Not applicable.
INAHTA	Not applicable.	Not applicable.

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available. For Enbrel, there were no applicable results in the following studies found on ClinicalTrials.Gov:

- Study Evaluating Etanercept in Patients With Rheumatoid Arthritis(RA), Juvenile Idiopathic Arthritis (JIA), or Psoriatic Arthritis (PsA) in Spain[65]
- Study Evaluating Etanercept in 3 Subtypes of Childhood Arthritis[66]

Polyarticular Juvenile Idiopathic Arthritis (JIA)

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis[67]

Manufacturer-Reported Benefits

Information contained in Enbrel's FDA label, Section 14 Clinical Studies, reports on the following two-part study in children with polyarticular JIA who had a variety of JIA onset types. In part 1, all patients received 0.4mg/kg Enbrel twice weekly. In part 2, patients with a clinical response at day 90 were randomized to remain on Enbrel or receive placebo for 4 months and assessed for disease flare. In part 1, 74% of

[65] https://clinicaltrials.gov/study/NCT00195377?cond=Juvenile%20Psoriatic%20Arthritis&term=etanercept&rank=2
[66] https://clinicaltrials.gov/study/NCT00962741?cond=Juvenile%20Psoriatic%20Arthritis&term=etanercept&rank=1
[67] https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/bltea21f1baaea35cf3/63321ee13df1404a8501fc67/jia-guideline-2019.pdf

patients demonstrated a clinical response and entered part 2. In part 2, 24% of patients remaining on Enbrel experienced disease flare compared to 77% of patients receiving placebo. The median time to flare was 116 days for patients receiving Enbrel and 28 days for patients who received placebo. Of patients who entered part 2 of the study, some patients remaining on Enbrel continued to improve from month 3-7, while those who received placebo did not improve.[68]

Voluntarily Submitted Manufacturer Information

Confidential Information

[redacted]

Clinical Effectiveness and Cost Effectiveness

Table D-8
Juvenile Idiopathic Arthritis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane Library	*Etanercept in Children with Polyarticular Juvenile Rheumatoid Arthritis. 2000*[69] At the end of the open-label study, 51 of the 69 patients (74 percent) had had responses to etanercept treatment. In the double-blind study, 21 of the 26 patients who received placebo (81 percent) withdrew because of disease flare, as compared with 7 of the 25 patients who received etanercept (28 percent) (P=0.003). The median time to disease flare with placebo was 28 days, as compared with more than 116 days with etanercept (P<0.001). In the double-blind study, there were no significant differences between the two treatment groups in the frequency of adverse events. Treatment with etanercept leads to significant improvement in patients with active polyarticular juvenile rheumatoid arthritis. Etanercept is well tolerated by pediatric patients. *Etanercept improves linear growth and bone mass acquisition in MTX-resistant polyarticular-course juvenile idiopathic arthritis. 2011*[70] Baseline patient and disease characteristics were similar in both groups. Clinical disease activity (Pediatric ACR30) was equally well controlled in both groups. Growth velocity increased significantly allowing catch-up	Not applicable.

68 https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf
69 https://www.nejm.org/doi/full/10.1056/NEJM200003163421103
70 https://academic.oup.com/rheumatology/article/49/8/1550/1790206?login=false

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	growth in the etanercept + MTX group only. BMD (lumbar spine Z-score) improved significantly in both groups. A significant increase of bone mineral content and lean : fat mass ratio was seen in the etanercept + MTX group, but not in the MTX group.	
ICER	Not applicable.	Not applicable.
NICE	Not applicable.	Not applicable.
CADTH	Not applicable.	Not applicable.
IQWiG	Not applicable.	Not applicable.
INAHTA	*The clinical effectiveness and cost-effectiveness of abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis: a systematic review and economic evaluation. 2016*[71] Biologic DMARDs are superior to placebo (with methotrexate where permitted) in children with (predominantly) polyarticular course JIA who have had an insufficient response to previous treatment. Randomised comparisons of biologic DMARDs with long-term efficacy and safety follow-up are needed to establish comparative effectiveness. RCTs for JIA subtypes for which evidence is lacking are also required.	*The clinical effectiveness and cost-effectiveness of abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis: a systematic review and economic evaluation. 2016*[72] Four economic evaluations of biologic DMARDs for patients with JIA were identified but all had limitations. Two quality-of-life studies were included, one of which informed the cost-utility model. The incremental cost-effectiveness ratios (ICERs) for adalimumab, etanercept and tocilizumab versus methotrexate were £38,127, £32,526 and £38,656 per quality-adjusted life year (QALY), respectively.

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available. For Enbrel, there were no applicable results in the following studies found on ClinicalTrials.Gov:

- Treatment Tapering in JIA With Inactive Disease (AJIBIOREM)[73]

[71] https://database.inahta.org/article/16252
[72] https://database.inahta.org/article/16252
[73] https://clinicaltrials.gov/study/NCT02840175?cond=Polyarticular%20Juvenile%20Rheumatoid%20Arthritis&term=etanercept&rank=2

- Etanercept Plus Methotrexate Alone in Children With Polyarticular Course Juvenile Rheumatoid Arthritis[74]

[74] https://clinicaltrials.gov/study/NCT03781375?cond=Polyarticular%20Juvenile%20Rheumatoid%20Arthritis&term=etanercept&rank=1

Appendix E

Enbrel: Patient Copayment and Other Cost Sharing

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the patient copayment or other cost sharing that is associated with the prescription drug and typically required pursuant to health benefit plans issued by carriers in the state. (C.R.S. § 10-16-1406(4)(e)).

Rule: The Board will consider the copayment and other cost sharing data, across different health benefit plan designs, to the degree such information is available in the APCD, including copayment, coinsurance, deductible, and/or any other copayment and cost sharing data. (3 CCR 702-9, Part 3.1.E.2.e).

Policy: Information from ACPD data, in aggregate and by payer, for out-of-pocket costs; other data sources that approximate out-of-pocket costs not captured in APCD data; and out-of-pocket analyses will examine up to five years of data and will be consistent across all prescription drugs. (PDAB Policy 04, p. 7).

Underlying Methodology: Board staff have compiled data on patient copayment and other cost sharing for the Board's consideration in the following manner:

1. From APCD pharmacy claims, board staff pulled all claims for Enbrel and relevant insurance coverage information for the patients on those claims for five years from January 2018 - December 2022.
2. Using this claims data and insurance plan information, reviewed out-of-pocket amounts by deductible, copay, and coinsurance.
3. Using this claims data and insurance plan information, reviewed the out-of-pocket cost amounts by payer type (commercial, Medicare Advantage, or Medicaid) and plan type (high deductible plans or not)
4. Using information from the Colorado Division of Insurance (DOI), summarized DOI-regulated plans rate filings relevant to Enbrel.

Data Source(s): Board staff compiled information on patient copayment and other cost sharing for the selected prescription drug from the following sources:

- APCD for patient out-of-pocket cost amounts from January 2018 - December 2022,
- Publicly available information on manufacturer assistance programs, and
- Colorado Division of Insurance (DOI) rate filing information for Colorado health benefit plans, which aggregates data including from plans and benefits and prescription drug templates.

Considerations and Data Limitations: Variation in commercial out-of-pocket costs might reflect different plan designs more than differing costs of the drug, which could impact certain patient's affordable access to the selected drug. Additionally, publicly available manufacturing assistance program information is limited.

APCD data limitations include, in regards to out-of-pocket spending, claims data includes the amount the patient was charged, it does not include how the patient paid for their portion of the drug. Data sources do not contain information on patients' use of an assistance program.

Enbrel: Patient Copayment and Other Cost Sharing Evidence

Background

Patients typically pay for covered prescription drugs in three different ways, all of which are considered patient out-of-pocket (OOP) payment types:

- Copayment: a fixed amount paid for a covered health care service.
- Coinsurance: a percentage of costs paid for a covered health care service.
- Deductible: a total amount paid for covered health care services by a patient, after which insurance pays for the majority of remaining health care services in the remaining plan year.

Health benefit plan design can have a significant impact on both the amount a patient pays for prescription drugs and when in the plan year a patient may pay more for a prescription drug. For example, a patient's cost sharing for prescription drugs might be higher during the beginning of their plan year and then drop significantly after the patient has met their deductible amount.

Health benefit plan designs typically have the most flexibility, and therefore most variability, in the commercially insured market. While there is some variability in plan design for Medicare Advantage and Medicaid, there is very limited variability in patient copayment and cost sharing for patients covered by Medicaid. For the vast majority of patients covered by Health First Colorado (Colorado's Medicaid Program) administered by the Colorado Department of Health Care Policy and Financing, patient prescription drug copayments are between $0-$3 for each prescription drug fill and most individuals with Medicaid coverage do not have deductibles or coinsurance.[1] Since this patient out-of-pocket cost amount is very small relative to individuals with other types of insurance, it has the potential to skew the average Coloradan's out-of-pocket costs much lower than what a typical individual with commercial insurance might pay. As such, Medicaid patient out-of-pocket amounts are removed from estimates of the average out-of-pocket dollar amounts. Medicaid patient out-of-pocket amounts are included in total spend estimates, and Medicaid patients are included in utilization estimates.

Lastly, as previously mentioned, the APCD contains claims data regarding how much a patient was charged for a prescription drug; it does not include information on how the patient paid.If a patient utilized an assistance program that information would not be evident in the APCD. While there is no database that routinely and consistently collects information about patient assistance programs, patients, caregivers, and Enbrel's manufacturer provided some information. See Appendices H and J for more information.

[1] https://www.healthfirstcolorado.com/copay/

Average Patient Payments

Information regarding the average patient payment is provided below in a variety of ways to better understand the different types of patient payments (i.e., copayment vs deductible vs coinsurance) and different amounts over time.

Figure E-1

Changes in Patient Out-of-Pocket Amounts from January 2018 - December 2022

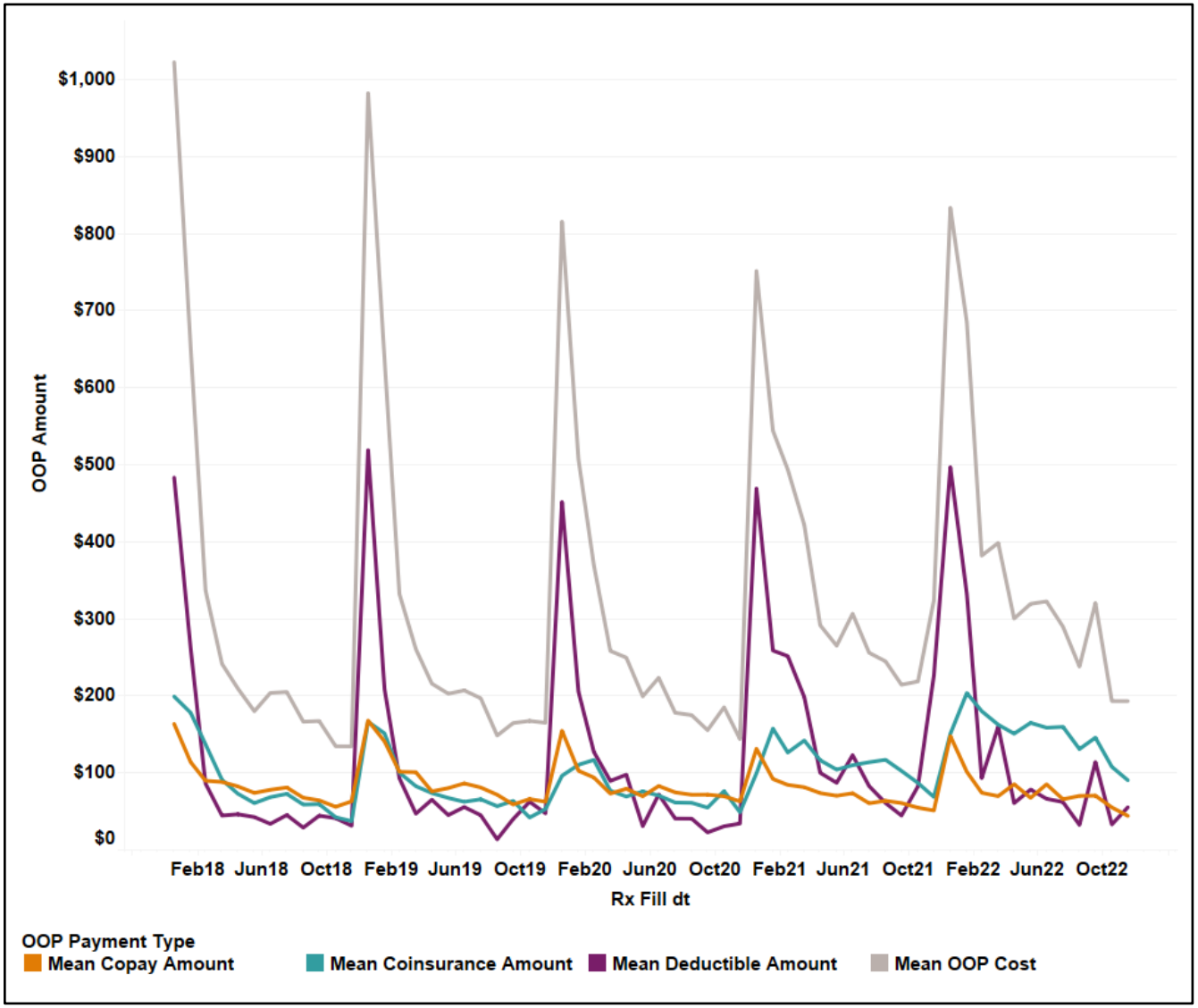


Figure E-1 shows the average out-of-pocket amount for commercially insured patients, where the orange line shows the monthly average copayment amount, the purple line shows the monthly average deductible amount, the teal line shows the monthly average coinsurance amount, and the gray line shows the monthly average total out-of-pocket amount. The deductible has a clear increase at the beginning of each plan year as patients pay more to hit their deductible.

Figure E-2

Average Commercial Out-of-Pocket Cost Comparison



Figure E-2 shows each out-of-pocket cost type for commercially insured individuals with Enbrel in dark purple and identified therapeutic alternatives by year. There is a light gray line that shows the average of identified therapeutic alternatives as a comparison to determine if Enbrel is more or less expensive than the average of identified therapeutic alternatives. For example, the bottom right corner shows the average total out-of-pocket cost in 2022, Enbrel was $3,980, which is higher than the average of the identified therapeutic alternatives, but lower than one of the identified therapeutic alternatives.

Table E-1

Average Annual Totals and Year-Over-Year Changes for Out-of-Pocket Amounts for Commercial Payers from 2018-2022

Drug name	Out of Pocket Cost Type	2018	2019	2020	2021	2022
Enbrel	**Avg Copay**	$639	$713	$791	$777	$823
	Percent Difference		*11.62%*	*10.94%*	*-1.72%*	*5.90%*
	Avg Coinsurance	$667	$642	$715	$1,145	$1,591
	Percent Difference		*-3.81%*	*11.39%*	*60.18%*	*38.89%*
	Avg Deductible	$523	$653	$896	$1,539	$1,226
	Percent Difference		*24.93%*	*37.14%*	*71.70%*	*-20.29%*
	Avg Total OOP Cost	$2,238	$2,413	$2,790	$3,763	$3,980
	Percent Difference		*7.79%*	*15.66%*	*34.87%*	*5.77%*
Cimzia	**Avg Copay**	$421	$402	$389	$519	$615
	Percent Difference		*-4.50%*	*-3.20%*	*33.46%*	*18.48%*
	Avg Coinsurance	$326	$659	$960	$1,212	$1,222
	Percent Difference		*102.32%*	*45.55%*	*26.27%*	*0.82%*
	Avg Deductible	$816	$904	$1,186	$1,920	$1,614
	Percent Difference		*10.84%*	*31.20%*	*61.86%*	*-15.96%*

Drug name	Out of Pocket Cost Type	2018	2019	2020	2021	2022
	Avg Total OOP Cost	$1,604	$2,045	$2,655	$3,721	$3,576
	Percent Difference		*27.44%*	*29.86%*	*40.14%*	*-3.89%*
Humira	**Avg Copay**	$691	$662	$727	$732	$687
	Percent Difference		*-4.12%*	*9.70%*	*0.67%*	*-6.12%*
	Avg Coinsurance	$445	$543	$846	$1,205	$2,100
	Percent Difference		*22.11%*	*55.78%*	*42.45%*	*74.22%*
	Avg Deductible	$791	$811	$1,364	$2,040	$1,661
	Percent Difference		*2.56%*	*68.13%*	*49.56%*	*-18.59%*
	Avg Total OOP Cost	$1,927	$2,017	$2,937	$3,977	$4,447
	Percent Difference		*4.68%*	*45.61%*	*35.41%*	*11.83%*
Remicade	**Avg Copay**	$79	$78	$58	$94	$128
	Percent Difference		*-1.62%*	*-24.76%*	*60.83%*	*36.00%*
	Avg Coinsurance	$1,400	$1,148	$1,322	$851	$762
	Percent Difference		*-17.99%*	*15.13%*	*-35.62%*	*-10.44%*
	Avg Deductible	$46	$35	$60	$80	$120
	Percent Difference		*-24.16%*	*73.68%*	*32.50%*	*51.15%*
	Avg Total OOP Cost	$2,647	$2,313	$2,775	$2,130	$1,976
	Percent Difference		*-12.62%*	*19.96%*	*-23.24%*	*-7.21%*

Drug name	Out of Pocket Cost Type	2018	2019	2020	2021	2022
Simponi	**Avg Copay**	$306	$355	$512	$479	$481
	Percent Difference		*16.12%*	*44.16%*	*-6.42%*	*0.27%*
	Avg Coinsurance	$774	$695	$999	$1,212	$1,064
	Percent Difference		*-10.31%*	*43.88%*	*21.22%*	*-12.18%*
	Avg Deductible	$902	$756	$884	$1,644	$854
	Percent Difference		*-16.15%*	*16.92%*	*86.03%*	*-48.05%*
	Avg Total OOP Cost	$2,146	$2,065	$2,644	$3,564	$2,722
	Percent Difference		*-3.73%*	*28.01%*	*34.80%*	*-23.63%*

Table E-1 shows the average annual coinsurance, copayment, deductible, and total out-of-pocket amounts for Enbrel and identified therapeutic alternatives, as well as the year-over-year percent change across all commercial payers from January 2018 though December 2022. Enbrel, Cimzia, and Humira had consistent increases in total OOP cost, while Remicade and Simponi had some decreases. This is further illustrated in Figure E-3 below.

Figure E-3
Changes in Copay Amounts by Year and Drug 2018-2022

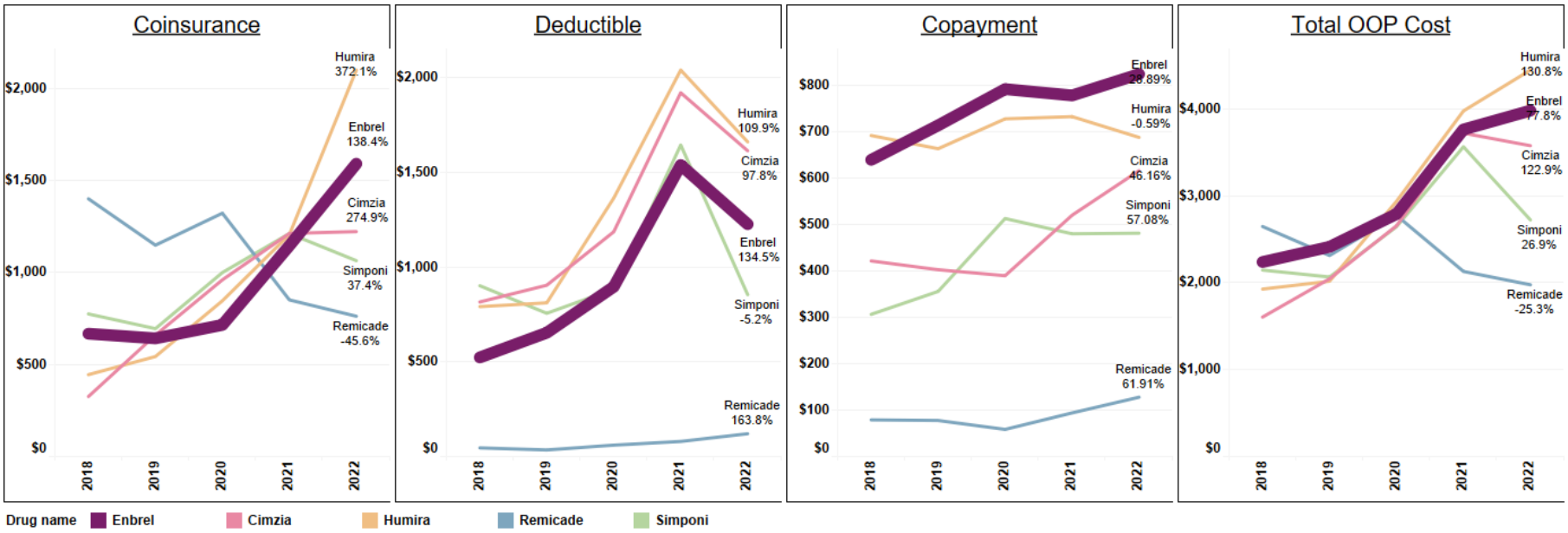


Figure E-3 shows the annual change in the annual average oop amounts comparing Enbrel (dark purple) to identified therapeutic alternatives. Each line is labeled with the name of the identified therapeutic alternative and the percent change from January 2018 to December 2022. Enbrel had the third highest increase in total out-of-pocket costs with a 77.8% increase.

Table E-2
Average Monthly Commercial Out-of-Pocket Cost Information in 2022

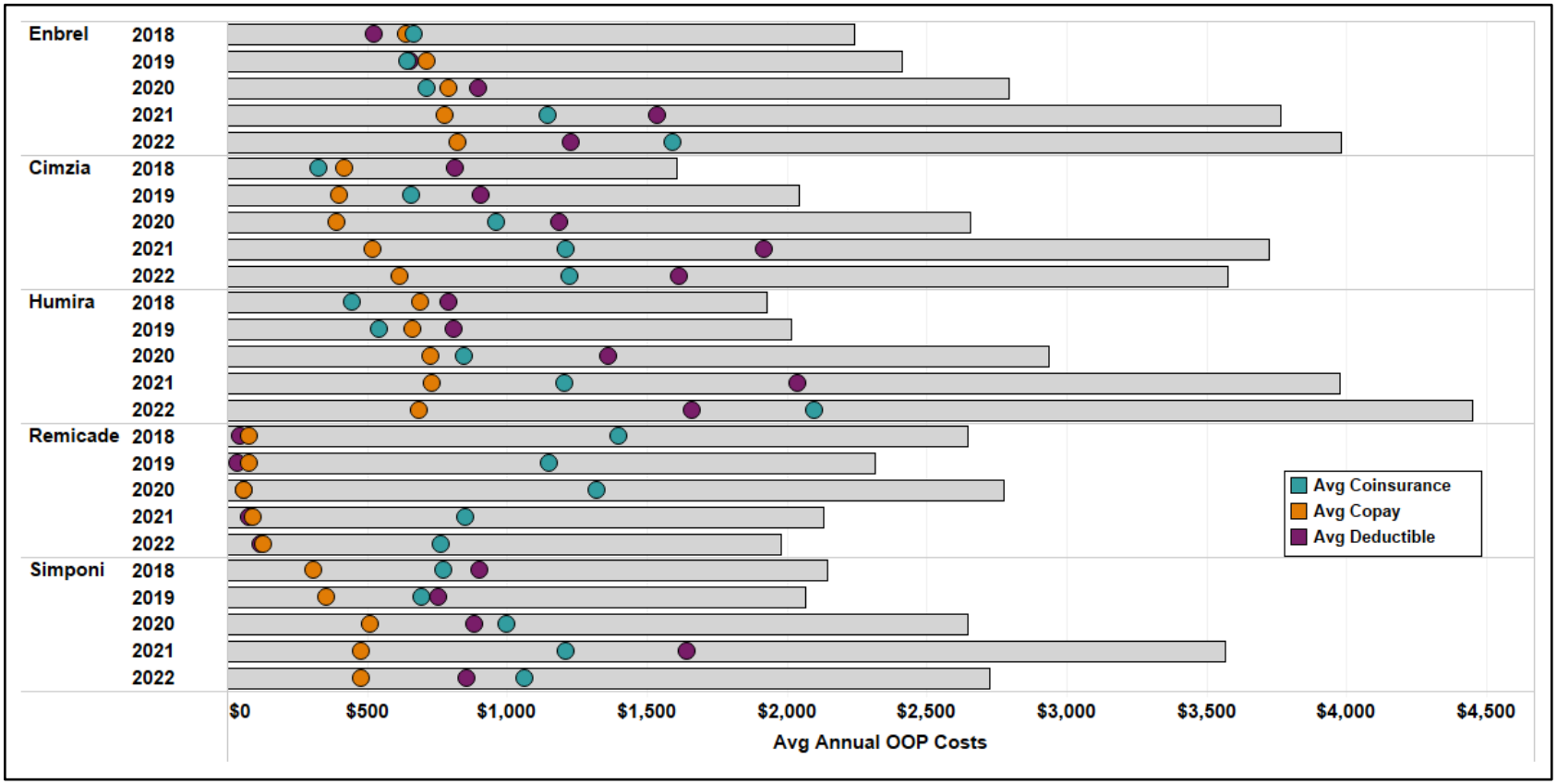
	Enbrel	Cimzia	Humira	Remicade	Simponi
Average Total OOP Cost	**$373**	$305	$356	$303	$263
Average Coinsurance Amount	**$151**	$103	$171	$124	$105
Average Copay Amount	**$78**	$53	$56	$21	$48

Average Deductible Amount	**$132**	$146	$129	$125	$98
Average Days Supply	**34.3**	31.5	32.4	45.5	35.6

Table E-2 shows that in 2022, in an average month an individual with commercial insurance paid a total of $373, $132 went towards a patient's deductible, $151 was paid towards coinsurance, and $78 was paid via copayment. These payments were for an average of 34.3 days. Enbrel is higher than Cimzia, Remicade, and Simponi in all out-of-pocket payments and is lower than Humira in all out-of-pocket payments except the average copay, where it is the highest of all drugs presented.

Figure E-4

Average Total Out-of-Pocket Cost and by Cost Sharing Type from 2018-2022



In Figure E-4, the gray bar displays the annual total out-of-pocket cost and out-of-pocket amounts are displayed as circles, with copayment in amounts in orange, coinsurance amounts as teal, and deductibles amounts as purple. This graphic shows an annual increase in total out of pocket costs for Enbrel with large increases in coinsurance and deductible amounts. These increases are similar to those seen with Cimzia and Humira though Remicade and Simponi show more variation from year to year.

Figure E-5

Patient Out-of-Pocket Payment as a Percentage of Plan Payment from 2018 - 2022

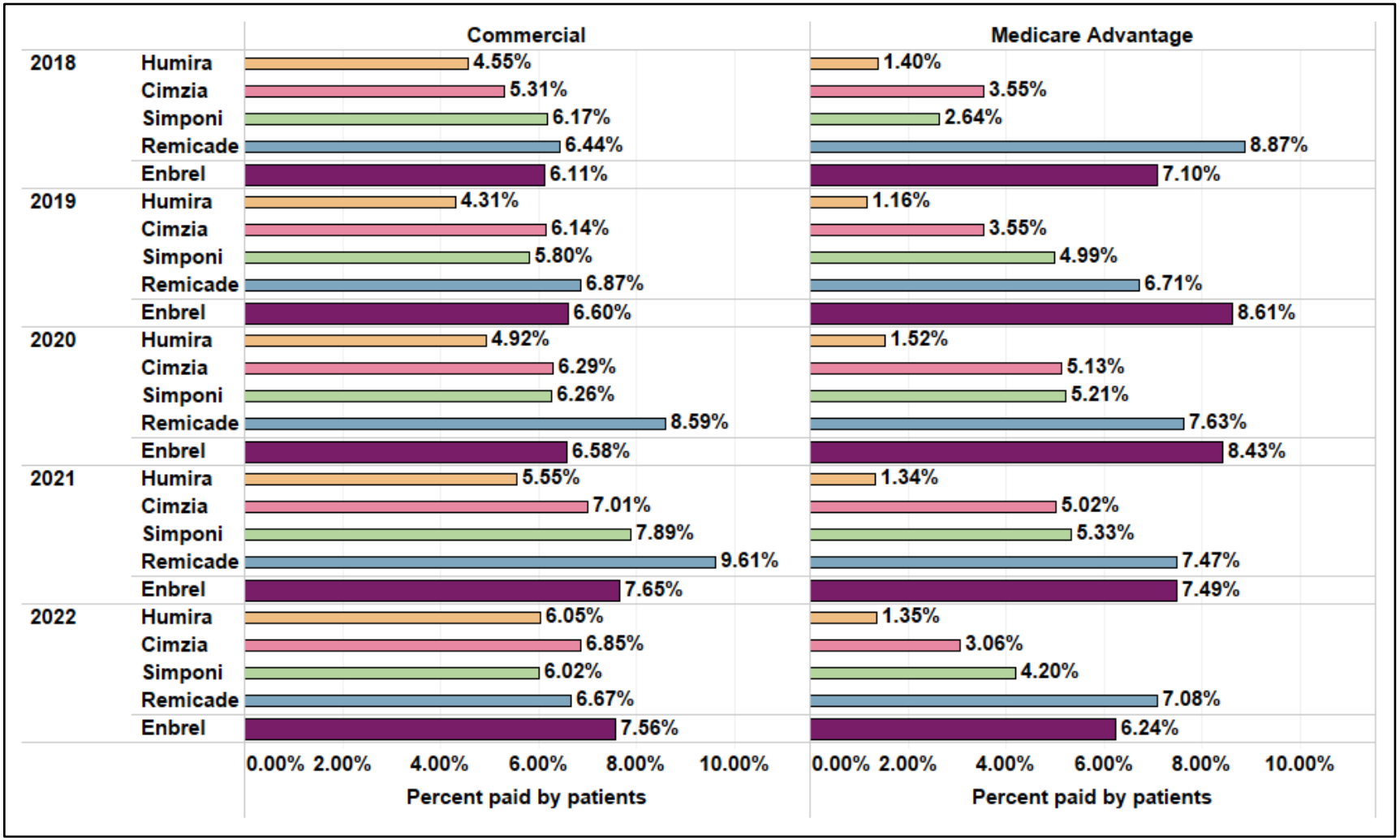


Figure E-5 provides context for what patients paid, as compared to their insurance plan, for Enbrel or its identified therapeutic alternatives from 2018 through 2022. In 2022, commercial patients paid for 7.56% of the total paid for Enbrel, a higher portion than any of identified

therapeutic alternatives. Whereas patients with Medicare Advantage coverage paid for 6.24% of the total paid amount for Enbrel, higher than three of the therapeutic alternatives, but lower than Remicade.

Figure E-6
Total Out-of-Pocket Cost Histogram for Enbrel and Therapeutic Alternatives for 2022

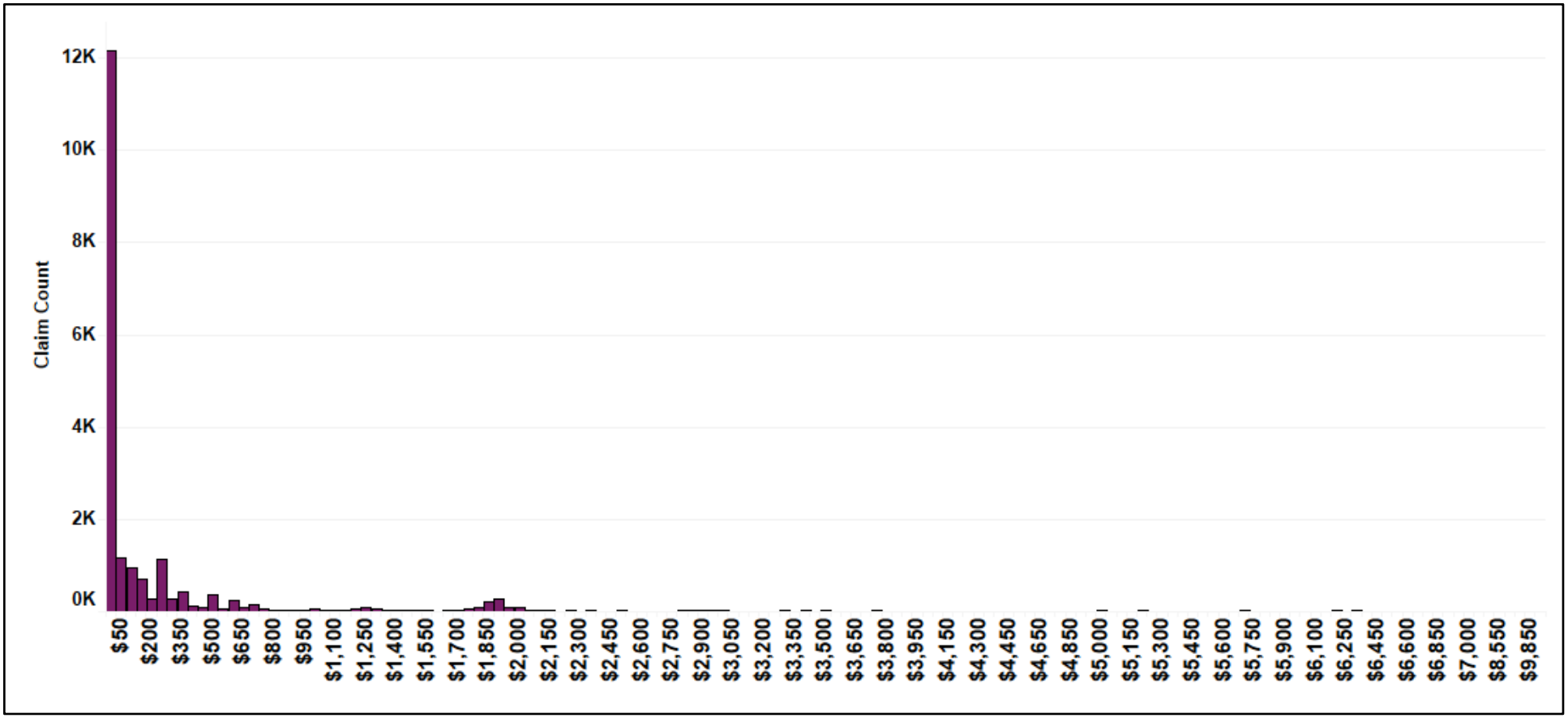


Figure E-6 shows a histogram of annual total out-of-pocket costs for individuals with commercial insurance in 2022 for utilizers of Enbrel. It shows the variation of the total out-of-pocket costs, where 57.3% of Enbrel utilizers paid between $0-$50, though some individuals paid as much as $9,850- $9,900.

Health Benefit Plan Design

A patient's insurance benefit design impacts how much of the health care service cost a patient is responsible for paying. In high deductible health plans (HDHP), a patient or family has a higher deductible that must be met before the insurance company will contribute to claims. When reviewing patient out-of-pocket costs on claims, differentiating between a high deductible benefit plan and a different benefit plan provide some indication of why a patient's out-of-pocket cost was different at different prescription fill points throughout the benefit year. For some individuals on a high deductible plan, they may share in more of the total costs of the drug due to the higher deductible. Below is a table

outlining what portion of the patients using Enbrel on commercial health plans were enrolled in high deductible health plans. In 2021 and 2022, fewer than 6% of patients using Enbrel were enrolled in a high deductible health plan, which means that the out-of-pocket costs presented in this report do incorporate deductibles, but are not necessarily skewed by a large portion of patients on HDHPs.

Table E-3

Percent of patients on HDHP 2018 - 2022

Drug name	2018	2019	2020	2021	2022
Enbrel	9.32%	9.26%	6.33%	4.86%	6.59%
Cimzia	8.37%	7.00%	5.80%	6.09%	7.42%
Humira	7.67%	7.11%	5.51%	4.79%	5.79%
Remicade	5.99%	7.22%	6.58%	7.60%	11.55%
Simponi	7.11%	7.01%	6.69%	5.23%	4.64%

Table E-3 shows the percent of patients on high deductible health plans in the APCD for Enbrel and identified therapeutic alternatives from 2018 to 2022.

Colorado Division of Insurance Regulated Plans Rate Filing Analysis

As part of its rate review processes and enforcement of Regulation 4-2-58, the Colorado Division of Insurance (DOI) receives filings from carriers in the individual and small group markets.[2] Rate filings are filed on an annual basis for compliance reviews by DOI. The following information was pulled by DOI staff for the affordability review and does not describe the entire market in Colorado, but can shed valuable information on benefit plan design and out-of-pocket costs.

Of the ten carriers that submitted filings, eight carriers cover four or more dosage formulas of Enbrel. All Carriers that cover Enbrel require Prior Authorization. In total, 576 Plans provide coverage for Enbrel. In general, the majority of carriers place Enbrel on the highest two tiers, meaning a higher portion of the drug is paid by patients than drugs on lower tiers until the maximum out-of-pocket amount under the plan is paid by the insured.

[2] Regulation 4-2-58: https://drive.google.com/file/d/1_1iwkGf_vI_jxMeUKOmuYVKfc79WtS-K/view

In order to summarize the cost sharing attributes of DOI-regulated plans, they are split into three parts:

- Percent Coinsurance after deductible: the amount of money that a consumer pays for each claim submitted
- Copayment after deductible: the copayment associated with each visit or prescription fill once the deductible is met, and
- Copayment only.

Some of the plans that apply the copayment may apply the deductible, whereas the coinsurance plans always apply the deductible.

Table E-4

DOI-Regulated plans Enbrel Out-of-Pocket Costs Overview

	Total Number of Plans	Minimum	Maximum	Average	Mode
% Coinsurance after Deductible	188	0.00%	50.00%	27.57%	50.00%
Copayment after Deductible	93	$0.00	$150.00	$121.13	$125.00
Copayment	295	$110.00	$775.00	$286.97	$125.00
Total Plans	**576**				

Table E-4 shows a summary of different types of cost sharing and their applicable ranges for DOI regulated plans for Enbrel. The data included in this summary was taken from the Master Review Tool.[3] This tool is distributed through CMS and gathers information from the plans data submitted to the Division through SERFF for the Plan Year 2024.[4]

Patients survey responses showed 27 of 38 Colorado patients reported that cost has affected their access. See Appendix H for more information.

Input from Patient and Caregivers

Table E-5

Colorado Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	Colorado Response	Cost Affects Access
$0 - $50	19 of 38	10 of 19
$50 - 100	4 of 38	2 of 4
$100 - $150	1 of 38	1 of 1
$150 - $250	2 of 38	2 of 2

[3] https://www.qhpcertification.cms.gov/s/Review%20Tools

[4] The information was collected and organized through Excel to calculate the minimum, maximum, average, and mode. The minimum, maximum, average, and mode were calculated.

$250 - $500	1 of 38	1 of 1
$500 - $1000	6 of 38	6 of 6
More than $1000 per month	5 of 38	5 of 5

Appendix F

Enbrel: Impact on Safety Net Providers

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the impact on safety net providers if the prescription drug is available through section 340B of the federal "Public Health Service Act", Pub.L. 78-410. (C.R.S. § 10-16-1406(4)(f)).

Rule: When the prescription drug is available through section 340B of the Federal "Public Health Service Act", Pub.L. 78-410, the Board will evaluate:

- The utilization of the prescription drug by the safety net provider's patients;
- Whether the safety net provider receives a 340B discount for the prescription drug;
- Where the safety net provider does not receive a discount, whether access to the prescription drug is impeded; and
- Any other topics identified by safety net provider stakeholders for discussion. (3 CCR 702-9, Part 3.1.E.2.f).

Policy: As part of the Board's obligation to consider the impact of an affordability review of the cost of a prescription drug on safety net providers, Staff will request all safety net providers to voluntarily provide information to the Board. To facilitate gathering the information from safety net providers, Staff may request a list of 340B approved safety net providers from HCPF. (PDAB Policy 04, p. 7).

Underlying Methodology: Board staff compiled data for the Board's consideration in the following manner:

1. Documented information provided during the stakeholder sessions to gather input from individuals with scientific or medical expertise, specifically the portion of those meetings dedicated to safety net providers. Staff attempted to compile information directly related to the information outlined in rule during stakeholder meetings, as well as a survey.
2. Compiled relevant information provided by entities who submitted information voluntarily.

Data Source(s): Board staff compiled information on safety net provider impact from the following sources:

- Input from safety net providers gathered during stakeholder meetings with individuals with scientific or medical expertise, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations: Information provided to the Board by safety net providers may be confidential. Input provided both via stakeholder meetings and surveys is voluntary. Such qualitative data may not capture information from all safety net providers.

Enbrel: Impact on Safety Net Providers Evidence

Background

The 340B Drug Pricing Program is a means for certain hospitals and clinics to stretch scarce federal resources by buying outpatient prescription drugs at a discount (typically 25-50%), while receiving typical reimbursement from payers. This is intended to allow safety net providers to stretch their financial resources to reach more financially vulnerable patients and deliver comprehensive services.

Eligible health care organizations (called covered entities) are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers.[1]

Evidence

HRSA maintains a database of covered entities and contract pharmacies, including the number of unique covered entities and addresses by covered entity type.[2] In Colorado, there are 108 unique active covered entity names, with an associated 536 unique addresses. Additionally, there are approximately 2,974 approved and participating contract pharmacies. Table F-1 provides information on the number of unique address in Colorado designated by covered entity type:

Table F-1
340B Covered Entity Types and Number of Unique Addresses

340B Entity Type	Unique Addresses[3]
Critical Access Hospital (CAH)	68
HRSA-Funded Health Center (CH)	212
Disproportionate Share Hospital (DSH)	160
Family Planning - Title X (FP)	38
Tribal Contract/Compact with HIS (FQHC638)	1
Health Center Program Look-Alike (FQHCLA)	1
Comprehensive Hemophilia Treatment Center (HM)	1
Ryan White Part C (HV)	1
Children's Hospital (PED)	21
Rural Referral Center (RRC)	6
Ryan White Part A (RWI)	2
Ryan White Part B (RWII)	6

[1] https://www.hrsa.gov/opa
[2] https://340bopais.hrsa.gov/SearchLanding
[3] Table F-1 sums to more than 536 because several covered entities have the same unique name and address but are designated as multiple 340B covered entity types.

340B Entity Type	Unique Addresses[3]
Ryan White Part B ADAP Direct Purchase (RWIID)	1
Ryan White Part B ADAP Rebate Option (RWIIR)	1
Sole Community Hospital (SCH)	6
Sexually Transmitted Diseases (STD)	39
Tuberculosis (TB)	2
Urban Indian Health Center (UI)	1

Due to the differences in the form and manner in which information is submitted to HRSA and the Colorado All Payer Claims Database (APCD), Board staff did not analyze how many of these covered entities dispense Enbrel.

In accordance with HHS 340B Drug Pricing Program Ceiling Price, prescription drug manufacturers are only allowed to charge $0.01 for a prescription drug when its quarterly 340B ceiling price calculation results in an amount less than a penny. This “penny pricing” occurs when a manufacturer raises the price of a drug substantially more quickly than the rate of inflation.[4] While Figure 8 (also Figure A-2) does not display the rate of inflation, the fact that Enbrel’s wholesale acquisition cost (WAC) has risen significantly higher than inflation since its launch, suggests that Enbrel may be, at times, subject to the 340B “penny pricing” policy.

Board staff and HCPF discussed that there was no readily available list or email listserv of 340B covered entities maintained by HCPF that could be used to facilitate Board staff outreach.

There is additional information contained in Appendix I and Appendix J which may contain additional information on impact to safety net providers not captured in this appendix. The Board may want to weigh information from all three appendices when evaluating the impact to safety net providers.

[4] https://www.govinfo.gov/content/pkg/FR-2017-01-05/pdf/2016-31935.pdf

Appendix G

Enbrel: Orphan Drug Status

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider orphan drug status. (C.R.S. § 10-16-1406(4)(g)).

Rule: The Board will identify whether the prescription drug is an orphan drug, as designated by the FDA pursuant to the Orphan Drug Act (Pub.L. 97-414).

The Board may further consider:

- The use of the prescription drug for indications with an orphan drug designation as compared to the use of the prescription drug for other indications; and/or
- The extent to which the drug addresses an unmet need or treats a rare or serious disease for which limited therapeutic alternatives are available. (3 CCR 702-9, Part 3.1.E.2.g).

Policy: The Board will compile evidence and information regarding the prescription drug's orphan drug status as designated by the FDA pursuant to the Orphan Drug Act (Pub.L. 97-414), including:

- Reviewing the Orphan Drug List for the quarter during which the affordability review begins.
- Designation date of the prescription drug on the orphan drug list.
- Treatment designation of the prescription drug on the orphan drug list as an indicator of the population the orphan drug serves.
- Reviews of literature and patient, caregiver, and clinical expertise to understand the extent to which the prescription drug addresses an unmet need or treats a rare or serious disease for which limited therapeutic alternatives are available (PDAB Policy 04, p. 7).

Underlying Methodology: Board staff compiled data regarding orphan drug status for the Board's consideration in the following manner:

- Analyzed listed indications for the selected drug, and using the FDA website, identified if any of the selected drugs treat active orphan drug indications.
- To identify if the drug meets an unmet need or treats a rare condition, Board staff reviewed information received from patient/caregiver and scientific medical training public input sessions and surveys.

Data Source(s): Board staff obtained information regarding the selected drug's orphan drug status from the following sources:

- FDA website, which contains information on current FDA labeling for each drug, FDA-approved indication, and orphan drug status,
- Results from public input sessions and surveys from patients and caregivers and individuals with scientific or medical training, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations: Orphan drug designations are related to the condition or indication being treated. There may be prescription drugs that treat multiple indications, but not all of those indications may be a rare disease. Data limitations that apply broadly to APCD data may apply here.

Enbrel: Orphan Drug Status Evidence

Background

The Orphan Drug Act, passed by Congress in 1983, incentivizes the development of drugs to treat rare diseases. A rare disease is defined as a disease or condition that affects less than 200,000 people in the United States.[1] The FDA does not maintain an exhaustive list of rare diseases, but rather, prescription drug manufacturers submit disease prevalence estimates and other documentation to the FDA in a request for orphan drug designation, which the FDA then assesses.[2]

An orphan drug is defined in the United States as one used for the treatment of a disease or condition affecting fewer than 200,000 people. The FDA has authority to grant orphan drug designation to a drug or biological product to prevent, diagnose or treat a rare disease or condition. Companies and other drug developers can request orphan drug designation and FDA will grant such designation if the drug meets specific criteria. While an orphan drug can be designated prior to the FDA approving the drug, it is not a guarantee that the drug will be approved for orphan drug status. Orphan drug designation provides incentives such as tax credits, fee exemptions, and a potential seven years of market exclusivity after approval.[3]

Orphan Drug Status

Table G-1
Enbrel Orphan Drug and Rare Disease Status

Indication	Orphan Drug Status	Rare Disease
Reduction in signs and symptoms of moderately to severely active **polyarticular-course juvenile rheumatoid arthritis** in patients who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.	Designated/Approved 10/27/1998	Yes

Table G-1 shows Enbrel's FDA approved orphan drug status[4] and rare disease status.

Polyarticular juvenile idiopathic arthritis (pJIA) was formerly called polyarticular-onset juvenile rheumatoid arthritis[5] and is a subset of juvenile idiopathic arthritis (JIA) and is included in the group termed "childhood polyarthritis.[6] Two subgroups of the disease can be distinguished, based on the presence or absence of rheumatoid factor.[7] Polyarticular juvenile idiopathic arthritis comprises 20 to 30 percent of the approximately 300,000 children and adolescents in the US that live with JIA.[8][9]

[1] https://www.fda.gov/patients/rare-diseases-fda
[2] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-316/subpart-C/section-316.21
[3] https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products
[4] https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=116198
[5] https://www.uptodate.com/contents/polyarticular-juvenile-idiopathic-arthritis-treatment
[6] https://www.uptodate.com/contents/polyarticular-juvenile-idiopathic-arthritis-clinical-manifestations-diagnosis-and-complications
[7] https://www.orpha.net/consor/cgi-bin/OC_Exp.php?lng=EN&Expert=404580
[8] https://www.uptodate.com/contents/polyarticular-juvenile-idiopathic-arthritis-treatment/print#:~:text=In%20the%20revised%20nomenclature%2C%20this,of%20juvenile%20idiopathic%20arthritis%22
[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3970916/

Table G-2
Enbrel Orphan Drug Designations and Approvals

Generic Name	etanercept
Trade Name	Enbrel
Date Designated	10/27/1998
Orphan Designation	Reduction in signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.
Orphan Designation Status	Designated/Approved
First Marketing Approval Date	05/27/1999
Approved Labeled Indication	Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients ages 2 and older.

Table G-2 shows Enbrel's orphan drug designations and approvals.[4]

Utilization data was not pulled for Enbrel and identified therapeutic alternatives for the specific indication of polyarticular JIA because diagnoses are not listed on pharmacy claims (see Appendix P for more information). Board staff did hear from patients, caregivers, and individuals with scientific and medical training that Enbrel meets an unmet need for polyarticular JIA, though some stakeholders provided input that access to a variety of medications, including Enbrel and identified therapeutic alternatives is important. See Appendices H, I, and J for more information.

Appendix H

Enbrel: Input from Patients and Caregivers

Affordability Review Statute, Rule, and Policy

Statute: The Board shall consider input from patients and caregivers affected by the condition or disease that is treated by the prescription drug that is under review by the Board (C.R.S. § 10-16-1406(4)(h)(I)).

Rule: The Board will seek input from patients and caregivers affected by a condition or disease that is treated by the prescription drug by gathering information related to:

- The impact of the disease,
- Patient treatment preferences,
- Patient perspective on the benefits and disadvantages of using the prescription drug,
- Caregiver perspective on the benefits and disadvantages of using the prescription drug, and/or
- Available patient assistance in purchasing the prescription drug.

In seeking additional information, the Board will attempt to gather a diversity of experience among patients from different socioeconomic backgrounds (3 CCR 702-9, Part 3.1.E.2.h.i).

Policy: Staff will gather input from patients and caregivers through outreach and holding a public meeting(s).

- Patients and caregivers may continue to provide input via verbal public comment and written public comment.
- During the following Board meeting(s), staff will present input provided by patients and caregivers and will report such information in their final report (PDAB Policy 04, p. 8).

Underlying Methodology: Board staff compiled information from patients and caregivers for the Board's consideration in the following manner:

1. Documented information provided during public input sessions to gather input from patients and caregivers being treated with Enbrel. Staff attempted to compile information directly related to the information outlined in rule during stakeholder meetings and from a publically-available online survey.
2. After the survey deadline and public input sessions concluded, Board staff aggregated responses, identified high-level themes, and compiled findings for the Board.

Data Source(s): Board staff compiled input from patients and caregivers for selected prescription drugs from the following sources:

- Results from public input sessions and surveys completed by patients and caregivers.

Considerations and Data Limitations: Input provided both via stakeholder meetings and surveys is voluntary. Such qualitative data may not capture information from all patients and caregivers.

Enbrel: Input from Patients and Caregivers Evidence

Background

Board staff gathered input from patients and caregivers in two ways: meetings and surveys. Input was gathered from 3 patients and caregivers at public meetings on September 19, 2023. These meetings were structured to be a focus-group style meeting to gather information on the health and financial effects of

Enbrel, and largely followed the survey questions. In addition to input gathered through public meetings, 279 patients and caregivers completed surveys regarding the health and financial effects of Enbrel.

At the initial time of survey release, the Board received 12 responses from patients and caregivers, 11 of whom are Colorado residents. At the December 15th PDAB meeting, Board members requested more information from patients and voted to reopen the surveys until January 21, 2024. After reopening, the Board received a total of 267 responses from Enbrel patients from across the United States, 38 of whom are Colorado residents.

To qualify to participate in patient and caregiver stakeholder meetings or surveys, respondents had to have been prescribed the prescription drug under review or be caregiver for an individual prescribed the drug under review. Outreach was conducted via the public listserv and website, as well as communicating with patient advocacy organizations who reached out to their patient and caregiver populations. Board staff attempted to gather a diversity of patient experiences by holding meetings in the evenings and conducting outreach to multiple consumer organizations.

Input summaries are presented below in a manner similar to how meetings and the survey were conducted: patient information, health effects of Enbrel, and financial effects of Enbrel. Specifically, staff collected information in a manner that encompassed the categories required by Board rule, including the impact of the disease, patient treatment preferences, patient perspective on the benefits and disadvantages of using the prescription drug, caregiver perspective on the benefits and disadvantages of using the prescription drug, and/or available patient assistance in purchasing the prescription drug. This appendix also contains links to the two public meetings audio recordings, the survey, and survey results.

There is additional information contained in Appendix J which may contain additional input from patients and caregivers not captured in this appendix. The Board may want to weigh information from both appendices when evaluating input from patients and caregivers.

Patient Profile

The Board received a total of 267 responses from Enbrel patients from across the United States, 38 of whom are Colorado residents.[1] Three patients attended public input sessions for Enbrel, and one of the three patients also filled out a survey. Themes from survey responses and public input sessions are summarized below.

Oftentimes individuals with autoimmune disorders present with more than one diagnosis. Many survey respondents selected multiple conditions for which they were being treated by Enbrel.

- Of the 267 total respondents, 184 were being treated for rheumatoid arthritis, 56 were being treated for psoriatic arthritis, 19 were being treated for psoriasis, 8 were being treated for juvenile idiopathic arthritis, and 14 were being treated for ankylosing spondylitis.
- Of the 38 Colorado specific respondents, 25 were being treated for rheumatoid arthritis, 8 were being treated for psoriatic arthritis, 2 were being treated for psoriasis, 3 were being treated for juvenile idiopathic arthritis, and 1 was being treated for ankylosing spondylitis.
- Of the three patients who attended the public input session, two were being treated for rheumatoid arthritis, and one patient was being treated for ankylosing spondylitis.

Complete survey results are contained at the bottom of this appendix. This appendix highlights both national trends and Colorado-specific trends for the Board's consideration.

The 38 Colorado specific respondents were insured via:

- Individual/ACA Marketplace: 6

[1] The survey was also completed by a computer who submitted approximately 30,000 identical responses. These responses were identified by staff during the survey review and removed from the data in this report.

- Employer: 14
- Kaiser/Peracare: 1
- Medicaid/Health 1st: 3
- Medicare: 16

The 38 Colorado specific respondents identified as one or more of the following priority populations:

- Children and families: 8
- Older Adults: 15
- People with Disabilities: 18
- People of disproportionately affected sexual orientation, gender, identity, or sex assigned at birth: 1
- People who are lesbian, gay, bisexual, transgender, queer, or questioning: 6

Board staff reviewed survey results and meeting recording transcripts to identify common themes about patient and caregiver experience. The word cloud below was created as a visual representation of the shared experiences of many patients prescribed Enbrel. The greater the number of patients and caregivers who shared an experience is correlated with the size of the word or phrase in the following word cloud. Patients and caregivers with one or more of the following conditions (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and juvenile idiopathic arthritis) stated that their conditions affect their daily lives in the following ways:

Figure H-1
Word Cloud: Patient Experience



Figure H-1 shows a word cloud of common patient experiences heard in public meetings and surveys. Patients being treated for psoriasis reported itchy inflamed skin, sores and plaques and skin cancer as a result of previous treatment.

Patients at public input sessions were able to provide more detail about their conditions. They stressed the physical and emotional toll that the unpredictability of their condition has on them, and the immense fatigue that accompanies the condition. Patients also discussed the difficulty of living with an invisible disease and how each condition presents uniquely in each individual patient. In addition to physical symptoms, patients all agreed that navigating the logistics of their condition, their care team, medications, and insurance felt like a full time job.

- *"My main health outcome is to slow the progression and to possibly have long periods of remission."* Survey respondent.
- *"I want to be able to have something that resembles a normal life." Public input session attendee.*

Patients and caregivers were also asked about the health outcomes that are most important to them when being treated for their conditions. Patients and caregivers with one or more of the following conditions (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and juvenile idiopathic arthritis) stated that

the health outcomes that were most important to them are reduction in pain, discomfort, and inflammation, fewer flares, and management of chronic pain and fatigue to improve their quality of life. Patients being treated for psoriasis indicated that the health outcomes that were most important to them were reduced inflammation, scalp irritation, and reduction in plaques.

Health Effects of Enbrel

When it came to the health effects of Enbrel, patients and caregivers provided a significant amount of input. Some of the more common themes are outlined below. More detailed information regarding each of the themes is found in meeting recordings and survey results.

- *"This drug has given me my life back. My flares are farther apart and Enbrel has allowed me to live my own life with few modifications and compromises"* Survey respondent with rheumatoid arthritis.
- *"We cycle through these drugs because sometimes they lose effectiveness or we just build up an immunity to them. That happened with Enbrel, but it was a glorious remission when I had it."* Public input session attendee.

Common themes regarding the health effects of Enbrel included:

- Enbrel has reduced pain and symptoms in the majority of patients of all indications, though some rheumatoid arthritis and psoriatic arthritis patients reported no improvements. Other patients stated that Enbrel worked well until it lost its effectiveness and they had to cycle to a new medication. One patient at a public input session liked that Enbrel is self-injectable, which cut down on trips to the doctor to get infusions.
- The most common side effect reported for all indications was pain and bruising at the injection site. Less common symptoms were chills, nausea, lowered immune system, depression, and dry mouth leading to dental issues. One patient reported not caring for the delivery method of self-injection.

Therapeutic Alternatives

Of all 267 survey respondents, 176 reported that they cycled through another medication to get to Enbrel. Three of 267 respondents reported not trying another treatment, 27 had tried one other treatment, 42 had tried two other treatments, 35 had tried three other treatments, and 158 had tried three or more treatments.

The experiences of the 38 Colorado patients using other treatments for their conditions is summarized below.

- **Methotrexate:** Some patients said it did not work, others said it reduced inflammation but caused extreme severe side effects leading them to stop taking it. Reported side effects include nausea, blurry vision, severe fatigue and nausea, brain fog, hair loss, sores in mouth, and liver damage.
- **Humira:** Many patients reported it to be ineffective, and others reported that it worked well for a time to reduce inflammation and pain before it lost efficacy. One patient stated that it works better than Enbrel for them. Patients reported similar side effects as Enbrel.
- **Cosentyx:** Patients reported that this works well for them at the moment and report similar side effects to Enbrel.
- **Remicade**: Patients reported that this worked well but then plateaued and stopped working. One patient stated it gave them no relief.
- **Xeljanz**: One patient stated their symptoms worsened and they worried about heart issues linked to the medication. One patient reported side effects of nausea and rash.
- **Rituxan:** Effective but safety data for pregnancy was not available.
- **Cimzia**: Effective and pregnancy safe option. One said getting sick too often.
- **Hydroxychloroquine**: One said works best for them.
- **Taltz**: currently working the best to reduce pain and flares. One said gets sick too often.

- **Plaquenil**: Not strong enough.
- **Diclofenac**: Not safe for long term use.
- **Amitriptyline**: No benefit, lowered seizure threshold leading to my first seizure incident.
- **Gabapentin**: Some pain relief but caused sensory issues.
- **Light treatments for psoriasis:** Resulted in precancerous or cancerous skin.

Other prescriptions patients reported taking include Sulfasalazine, Orencia, Meloxicam, Sulindac, Cymbalta, Stelara, Simponi Aria, Naproxen, meloxicam, Indocin, and Mobic. Patients also reported taking topical and oral steroids, NSAIDs, and muscle relaxants.

- *"I've literally tried them all. I'm kind of old school."* Public input session attendee.

Financial Effects of Enbrel

Patients and caregivers were asked three types of questions related to the financial effects of Enbrel. Some survey questions and meeting discussions focused on better understanding patient out-of-pocket (OOP) costs for Enbrel, while other survey questions and meeting discussions focused on better understanding the relative financial effects of Enbrel on health, medical, or social services costs, and a third type of question aimed to better understand patient experience with utilization management requirements. Information from all types of questions are summarized below.

Patient Out-of-Pocket Cost, Access, and Adherence

There is additional information contained in Appendix E, Appendix J, and Appendix K related to patient costs not captured in this appendix. The Board may want to weigh information in all four appendices when evaluating patient costs.

Patients were asked about their monthly out-of-pocket cost for Enbrel and if the cost of Enbrel has ever affected their access. 122 of 267 national patients and 27 of 38 Colorado patients reported that cost has affected their access.

Table 1
National Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	National Response[2]	Cost Affects Access
$0 - $50	174 of 267	51 of 174
$50 - 100	29 of 267	18 of 29
$100 - $150	8 of 267	5 of 8[3]
$150 - $250	9 of 267	8 of 9
$250 - $500	14 of 267	9 of 14
$500 - $1000	19 of 267	19 of 19
More than $1000 per month	12 of 267	12 of 12

Table 1 shows the number of national patients who self-reported their monthly out-of-pocket costs and the number of patients within each cost bracket who reported that cost affected their access.

[2] 2 out of 267 national survey participants did not answer regarding their out-of-pocket cost per month for Enbrel.

[3] 1 national survey participant whose out-of-pocket cost per month equaled $100-$150 did not respond regarding if cost affected their access to Enbrel.

Table 2
Colorado Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	Colorado Response	Cost Affects Access
$0 - $50	19 of 38	10 of 19
$50 - 100	4 of 38	2 of 4
$100 - $150	1 of 38	1 of 1
$150 - $250	2 of 38	2 of 2
$250 - $500	1 of 38	1 of 1
$500 - $1000	6 of 38	6 of 6
More than $1000 per month	5 of 38	5 of 5

Table 2 shows the number of Colorado patients who self-reported their monthly out-of-pocket costs and the number of patients within each cost bracket who reported that cost affected their access.

Table 3
Survey Response: How does Enbrel impact each patient or their family?[4]

Survey Prompt	National Responses	Colorado Responses
This medication reduces the amount of time and money going to the doctor.	110 of 267	14 of 38
This medication reduces the amount of time and money spent going to the hospital or needing surgery.	63 of 267	9 of 38
This medication allows me to work and support my family.	110 of 267	15 of 38
Due to the cost of this medication, I have had to cut costs in other areas of my life.	74 of 267	20 of 38
Out-of-pocket costs have caused me to accrue medical debt.	36 of 267	8 of 38

Table 3 shows both national and Colorado patient responses to a survey question asking how Enbrel impacts each patient and their family.

[4] 45 out of 267 national survey participants did not answer regarding the impact Enbrel has on the patient or their family. 3 out of 38 Colorado survey participants did not answer regarding the impact Enbrel has on the patient or their family.

Table 4
Survey Responses: Has the cost of Enbrel ever affected your adherence to it?[5]

Survey Prompt	National Responses	Colorado Responses
I have skipped doses of the drug in order to save money	44 of 267	9 of 38
I have reduced the dose of the drug in order to save money.	9 of 267	0 of 38
I have stretched time between doses of the drug in order to save money.	52 of 267	9 of 38
I have changed prescription drugs to treat my condition due to cost.	53 of 267	10 of 38

Table 3 shows both national and Colorado patient responses to a survey question asking if the cost of Enbrel has ever affected adherence.

Assistance Programs

Patients were asked if they use copay assistance programs, discount cards, or savings provided by prescription drug manufacturers or non-profit organizations to help with out-of-pocket costs. Of 267 national patients, 49 did not use manufacturer assistance programs. 216 of 267 patients reporting using patient assistance, and 61 still had trouble affording Enbrel despite assistance.

Of the 38 Colorado respondents, four patients did not use assistance programs, and one did not answer. Of the 33 of 38 Colorado patients who use assistance programs, 10 patients still had trouble affording Enbrel despite assistance.

Patients at public input sessions stated that assistance programs were not difficult to find, but that it was nearly impossible to understand how insurance would be applied, particularly when copay accumulators were involved.

Utilization Management Requirements

Table 5
Survey response: Utilization management.[6]

Survey Prompt	National Responses	Colorado Responses
I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	23 of 267	6 of 38

[5] 89 out of 267 national survey participants did not answer regarding if the cost of Enbrel has affected their adherence to it. 10 out of 38 Colorado survey participants did not answer regarding if the cost of Enbrel has affected their adherence to it.

[6] 36 out of 267 national survey participants did not answer regarding utilization management of Enbrel. 1 out of 38 Colorado survey participants did not answer regarding utilization management of Enbrel.

My insurance plan has dropped or switched my drug coverage after the plan year started.	25 of 267	2 of 38
My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	73 of 267	14 of 38
My insurance plan requires prior approval to fill the prescription.	183 of 267	24 of 38
My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	97 of 267	18 of 38
I worry that the cost of my prescription will raise my insurance premium.	56 of 267	8 of 38

Table 5 shows both national and Colorado patient responses to a survey question asking if they had experienced any of the listed utilization management practices.

When talking about cycling through a drug and having to wait due to prior authorizations and step therapy, one patient at a public input session said “When you have to go through all of that, you deteriorate in the process. As a result of those things, I’ve lost an incredible amount of functioning.”

Additional Financial Effects

Patients and caregivers were asked in public meetings and in surveys to share any additional information about how Enbrel affects them financially. The most common theme from patients was that their condition led to absence from work, inability to work, or loss of productivity due to mobility issues. Patients also reported transportation costs and time lost from having to travel hours to a rheumatologist or pick up medicines. Other patients stated that they will save money because they will no longer require surgeries.

Patients in surveys and in public input sessions reported that the administrative burden of their condition cost them time and money:

- *“Yes, I spend so much time on the phone. Mostly dealing with meds that aren't covered. It's exhausting being a full time patient. Insurance is usually the reason. I went Bankrupt thanks to my condition.”*
- *“Another cost was the many, many hours I had to spend on the phone with insurance, specialty pharmacies, and copay assistance programs to figure out how to afford the medication I needed.”*

Other patients said that they will struggle without copay assistance.

- *“The max annual costs covered through the Enbrel financial assistance program has decreased over the years……The Enbrel program only works if you have good health insurance and it is stable throughout the calendar year, which is sometimes not feasible.”*
- *“The copay assistance runs out before end of year and then insurance does not cover so cost can be near $5000.00.”*

- *"The entirety of our financial issue is from medical debt. Without access, my body shuts down and I slowly start to die. My RA is one of the most aggressive forms and I've had to stop medication several times because we can't afford it unless there is coverage assistance. During those times, I become unable to work, unable to walk, and unable to care for myself at all."*
- *"The copay assistance runs out before end of year and then insurance does not cover so cost can be near $5000.00."*

There is additional information contained in Appendix D and Appendix J related to the relative financial effects of Enbrel not captured in this appendix. The Board may want to weigh information in all three appendices when evaluating patient costs.

Audio from Public Patient and Caregiver Meetings

The audio from the September 19, 2023 public Zoom meeting is found via the following link: https://zoom.us/rec/play/yGLW2uq6iAHgGdal-qnkHGgvidk87SLmmHZoqw3Up3Fdc5PzOqGm_l-tPoskL_5rvCrGVSdU6y-ac27Q.ji5NBubFa-H1gZ6M?autoplay=true.

Patient and Caregiver Survey

The Patient and Caregiver Survey was initially live on the Prescription Drug Affordability Board website from September 12 to October 12, 2023. At the December 15th PDAB meeting, Board members requested more information from patients and voted to reopen the surveys until January 21, 2024. Though survey results are not a representative sample of the experience of all Coloradans taking Enbrel, the results can provide important input from patients and caregivers for the Board to consider.

Survey results are sometimes highlighted in the Summary Report and in appendices. A sample of the survey is below, and full survey results are contained in the next section of this appendix. To protect patient and caregiver privacy, all names and other identifying information are redacted.

Figure H-2
Patient and Caregiver Survey (begins on next page).

Name *

Your answer

Email address *

Your answer

Have you attended, or do you plan to attend, a public input session for patients and caregivers? *

- ◯ Yes
- ◯ No

After you complete this survey, Board staff may have follow up questions for you. Do you consent to staff reaching out to you via email after you complete this survey?

- ◯ Yes
- ◯ No

Zip code

Your answer

If you have health insurance, what type of health insurance do you have? *

- ○ I do not have health insurance
- ○ Insured through employer
- ○ Individual (private) insurance
- ○ Medicare
- ○ Medicaid/Health First Colorado
- ○ Unsure
- ○ Other:

I am responding to this survey as: *

- ☐ A patient living with a condition which is currently or formerly being treated by Enbrel, Genvoya, Cosentyx, Stelara, or Trikafta.
- ☐ A caregiver for someone living with a condition which is currently or formerly being treated by Enbrel, Genvoya, Cosentyx, Stelara, or Trikafta.

If you are a patient, please answer this survey based on your personal experience. If you are a caregiver, please answer the survey based on the experience of the person for whom you are caring.

Which prescription drug are (you/the person you are caring for) taking currently or previously? *

Choose ▾

Health Effects

What condition does this drug treat for you?

Your answer

How does the condition affect your daily life, or the life of person you are caring for? (Consider mobility, self care, usual activities like work, study, housework, family, leisure activities, pain/discomfort, any anxiety/depression).

Your answer

What health outcomes are most important to you when being treated for your condition?

Your answer

What beneficial health effects have you experienced from using this prescription drug, if any?

Your answer

What adverse health effects have you experienced from using this prescription drug, if any?

Your answer

What factors led you to the prescription drug you are currently taking? Select all that apply:

- [ ] It's the only one designated for my condition.
- [ ] I cycled through other medications that didn't work before finding this one.
- [ ] It's the drug my provider prescribed and it works for me.
- [ ] It was required by my insurance company.
- [ ] The method of delivery or injection works best for me.
- [ ] Other:

Have you tried taking other prescription drugs to treat your condition? If so, how many?

- ○ None
- ○ Yes, one other treatment.
- ○ Yes, two other treatments.
- ○ Yes, three other treatments.
- ○ Yes, more than three other treatments.
- ○ Unsure

If you have tried other prescription drugs to treat your condition, what were they? Were there any beneficial or adverse health effects of these other prescription drugs?

Your answer

Financial Effects

How much do you pay out-of-pocket each month for the prescription drug? By out-of-pocket, we mean after insurance or any patient assistance program used to cover the cost of the medication.

- ○ $0-$50 per month
- ○ $50 - $100 per month
- ○ $100 - $150 per month
- ○ $150 - $250 per month
- ○ $250 - $500 per month
- ○ $500- $1000 per month
- ○ More than $1000 per month

Has the cost of this drug ever made it difficult for you to access it?

- ○ Yes
- ○ No

Has the cost of this drug ever affected your adherence to it? Select all that apply.

- ☐ I have skipped doses of the drug in order to save money.
- ☐ I have reduced the dose of the drug in order to save money.
- ☐ I have stretched time between doses of the drug in order to save money.
- ☐ I have changed prescription drugs to treat my condition due to cost.
- ☐ Other:

How does this drug impact you and/or your family? Select all statements that are true for you.

- [ ] This medication reduces the amount of time and money spent going to the doctor.
- [ ] This medication reduces the amount of time and money spent going to the hospital or needing surgery.
- [ ] This medication allows me to work and help support my family.
- [ ] Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.
- [ ] Out-of-pocket costs have caused me to accrue medical debt.

The following questions are centered around any financial assistance you may have received to help purchase the prescription drug. Many patients requiring ongoing treatments for chronic diseases receive financial assistance from drug manufacturers and non-profit organizations in the form of copay assistance programs, discount cards, or savings cards. These help patients pay their out-of-pocket costs (such as deductibles, copays, etc.) for their prescription drugs.

Do you/the person you are caring for use, or have ever used, any copay assistance programs, discount cards, or savings that are provided by prescription drug manufacturers, or non-profit organizations to help with out-of-pocket costs (such as deductibles, copays, etc.) for this drug?

- ○ Yes
- ○ No

If you replied "yes" to the question above, how did you hear about the financial assistance?

- ○ Friend or family member
- ○ My provider
- ○ My pharmacist
- ○ My insurance company
- ○ Prescription drug manufacturer
- ○ Internet search
- ○ Other:

Do you have difficulty affording the drug despite using a patient assistance program?

- ○ Yes
- ○ No

If you are insured, please select any of the following statements that are true for you. Select all that apply.

- ☐ I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.
- ☐ My insurance plan has dropped or switched my drug coverage after the plan year started.
- ☐ My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.
- ☐ My insurance plan requires prior approval to fill the prescription.
- ☐ My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.
- ☐ I worry that the cost of my prescription will raise my insurance premium.

Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?

Your answer

Patient and Caregiver Survey Results

Survey results are provided first for Personal Information, then Health Effects, followed by Financial Effects.

Table H-1

Patient and Caregiver Survey Results

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
1	Patient	Enbrel	Yes	80204	Medicare	People with disabilities	Psoriatic Arthritis	If I am not on a biological I am bedridden. Cannot go up/down stairs, walk, etc.	Can do daily life activities and exercise	Can live daily life and exercise
2	Patient	Enbrel	Yes	80130	Insured through employer		psoriatic arthritis	pain in joints, changes in ability to work	limited joint pain/stiffness, no development of further issues	limited joint pain/stiffness, no development of further issues
3	Patient	Enbrel	Yes	80503	Insured through employer	Children and families	juvenile idiopathic arthritis	for years it restricted my mobility and caused extreme pain and discomfort that was associated with inflammation.	pain relief and reduced inflammation	reduced inflammation and pain for years until Embrel stopped having a significant effect on my knees.
4	Caregiver	Enbrel	No	65689	Insured through employer	Children and families, People with disabilities	Juvenile Arthrits	Loss of mobility, unable to work sustainable hours. Interferes with learning.	Mobility	Full medicated remission. Was able to attend school, exercise and not use wheelchair.
5	Patient	Enbrel	Yes	80109	Medicare	Older adults, People with disabilities	Rheumatoid Arthritis	Mobility, housework pain anxiety quality of life	Mobility	My first medication for RA when it came out

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
										had great experience with it.
6	Patient	Enbrel	No	84057	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning	Rheumatoid Arthritis	Severely limits physical abilities	Less pain, become more able bodied	None
7	Patient	Enbrel	No		Medicare	People involved in the criminal justice system, Children and families, People with disabilities	Rheumatoid Arthritis	I am completely disabled at the age of 38. I am a mom of 4 small children and my RA has robbed them of so much either due to my physical symptoms or not being able to afford things because of the high costs of my treatment and medication. I am unable to cook or clean so that all falls on my husband to do on top of working a full time job.	Stopping the progression of the disease and preventing the pain	

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
8	Patient	Enbrel	No	75571	Insured through employer	Black people, indigenous people, and people of color	Psoriatic Arthritis	PsA takes a toll on my joints and skin. Untreated, I have pain in my knees and hips. I had degeneration of those joints while I was not yet being treated. Work and school were both affected by these condition. I was a poker dealer that couldn't deal poker because my thumbs were swollen. In school, I couldn't sit long enough to be in class. I couldn't get help because at the time I wasn't diagnosed with PsA. My skin drew looks and perpetual self consciousness that is still present.	I needed pain relief and joint damage to slow	My pain and swelling was greatly decreased. So much so that I was able to attend college. I was also able to resume dealing poker when I was on Enbrel
9	Patient	Enbrel	No	56007	Insured through employer	Older adults	RA	It makes it hard for me to accomplish all that needs to be done on a daily basis. It also makes my job difficult.	Pain relief, relief from fatigue	
10	Patient	Enbrel	No	26378	Medicaid/Health First Colorado	People with disabilities	Rheumatoid	Significantly	Treatment	Stopped working after 2 years

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
11	Patient	Enbrel	Yes	80122	Insured through employer	People with disabilities	Rheumatoid Arthritis	It can absolutely paralyze me and self care can seem impossible. I no longer work because of my condition. Pain can truly be unbearable at times and can lead to depression	Little to no pain	This drug has given me my life back. My flares are farther apart and Enbrel has allowed me to live my own life with few modifications and compromises
12	Patient	Enbrel	No	55337	Insured through employer	People with disabilities	RA	Pain, fatigue and lack of sleep make everything more difficult. It's hard not to miss work. You miss fun plans hopefully being able to go to work. Being stiff and in constant pain makes an unhappy person full of fear and anxiety.	Less inflammation side effects. Less pain . Getting better sleep. Relief is a great thing to survive.	I have been on many RX, Enbrel was the best working I've experienced in 14 years.
13	Patient	Enbrel	No	32712	Insured through employer	People with disabilities	Rheumatoid Arthritis	Hard to move around, and painful. Housework tends to fall by the wayside as I just can't do it some days. The pain definitely increases my anxiety and depression.	Less pain	none

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
14	Patient	Enbrel	No	15825	Insured through employer	Older adults, People with disabilities	Rheumatoid Arthritis	Ra makes everything harder to accomplish(pain, fatigue, stiffness, etc). RA has caused me to have multiple conditions or comorbidities. When Ra is controlled these comorbidities are likely to be as well. When Ra rages so do my comorbidities. Multiple specialists have said if I only could ra under control then _____would be in control	I want pain and stiffness to be lessened but in the last few years I've learned that I need my inflammation from ra to be controlled for overall health	My pain and stiffness is reduced. My inflammation control is better which has improved many of my comorbidities
15	Patient	Enbrel	No	19026	Insured through employer	People with disabilities	Rheumatoid arthritis	Hinders all Aspects of my life, financial, physical, Emotional, social	Pain and fatigue reduction	Decrease in pain

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
16	Patient	Enbrel	No	87121	Medicare	Black people, indigenous people, and people of color, American Indians and Alaska natives, People who are lesbian, gay, bisexual, transgender, queer, or questioning, People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth, People with disabilities	Rheumatoid arthritis	I no longer am independent… I need help daily doing things most can do without assistance.. causing depression and anxiety to heighten.	Being more independent	It allowed better movement
17	Caregiver	Enbrel	Yes	80916	Medicaid/Health First Colorado	Children and families, People with disabilities	JIA	Limited her ability to walk	Less pain	Helped with my pain
18	Patient	Enbrel	Yes	81432	Individual (private) insurance		Rheumatoid arthritis	Some days I'm "normal", some days I am in so much that I can't do anything.	Reduce inflammation	Allowed me to live a normal life

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
19	Patient	Enbrel	No	28625	Insured through employer	Older adults	Rheumatoid arthritis	Constant stiffness especially in hands, currently affects simple everyday tasks, Strength in hands and fingers are already compromised, feet, knees, elbows and shoulders are affected on a smaller scale at this time.	To eliminate the “major flares” that stop me in my tracks….unable to function at all.	Enbrel is controlling the flares and helping to maintain my ability to function everyday.
20	Patient	Enbrel	No	61270	Medicare	People with disabilities	Juvenile Rheumatoid Arthritis & Iritis	It makes doing everyday tasks more difficult. Opening bottles, putting on socks, tying shoe laces, brushing hair are all made much more difficult. Preparing my own meals is not possible. Showering is impossible some days. Every single task throughout the day takes thought and more time and effort than it takes an able bodied person. I have been unable to work for 20 years. The pain is chronic and never goes away, it’s a constant buzz that’s always there, just some days the buzzing	To be able to keep the ability to walk as long as possible, to stop more deterioration, and to just be comfortable and not in constant pain.	When I was on it, I missed less school and work days, I was able to walk longer distances, go hiking, and keep up with others.

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
								isn't as loud as others. Walking is sometimes impossible and a wheelchair or cane are needed.		

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
21	Patient	Enbrel	No	76133	Medicare	Older adults, People with disabilities	PsA	I have 2-plus hours of stiffness every morning. I live with chronic joint and tendon pain daily. I suffer from joint swelling. I have moderate difficulty performing basic household tasks most days. Walking for an “extended” amount of time is severely difficult. Standing for extended time is extremely difficult. I have anxiety about shopping because of mobility difficulties and pain. I can’t enjoy family time because of chronic pain.	To lessen joint damage and to lessen chronic pain.	I had about 1 year of decreased stiffness, decreased daily pain, and mobility improvement while on Enbrel. Sadly it stopped working at about the 12-14 month mark.
22	Caregiver	Enbrel	Yes	80401	Insured through employer		RA	pain/discomfort	less pain & discomfort	less pain & discomfort

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
23	Patient	Enbrel	No	45236	Medicare	Children and families	Juvenile Rheumatoid Arthritis/Rheumatoid Arthritis	Unable to complete activities of daily living, on bad days unable to get out of bed experience extreme fatigue as well as systemic symptoms comparable to Mono/COVID body aches, sore throat rash fever in addition to joint pain in flare or with over exertion	Ability to function at the very minimum not be in excruciating pain for the entirety of the day	When first used I was in drug induced remission of JRA for several years when enbrel first came out was able to go to college with Accomodations however my body became used to medication stopped working took long break came back to it and it did not work again
24	Patient	Enbrel	No	19703	Medicare	Older adults	Rheumatoid arthritis	Without medication, I would not be able to walk or use my hands.	That the disease is kept under control to avoid more damage to my body.	I used it in the past, and had absolutely no beneficial effects.
25	Patient	Enbrel	Yes	80026	Medicare	Older adults	psoriasis	itcy body, inflamed areas, sores, plaques on my body, skin cancer as a result of previous treatments	reduced inflamation, scalp irritation, plaques on the body	reduction of all symptoms

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
26	Patient	Enbrel	Yes	80126	Individual (private) insurance	Older adults	Rheumatoid Arthritis	I'm not sure if this question reflects when I have good treatment or without treatment? Without treatment, I need care and cannot work. With treatment, I can function with some difficulty, depends on if I'm dealing with a flare up or not, weather, etc. I can say that I struggle to find and keep work due to my RA. It's very easy to have anxiety/depression when dealing with a chronic condition with many factors out of my control.	That I can function without assistance and be employed full-time in a job that meets my educational and skill level and to maintain that mob. I have not been able to do so due to my RA, yet I don't qualify for disability benefits.	This was the most effective drug for me that I took for my RA until it no longer worked for me. I was able to live very normally, and most normal since being diagnosed with RA in 2007. No other drug has had the same therapeutic effects for my RA as Enbrel.

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27	Patient	Enbrel	Yes	80920	Affordable Care Act (the Exchange/Marketplace)	Older adults, People with disabilities	Rheumatoid Arthritis	Movement is slow, always feel exhausted with no energy and tired, unable to work, random pain and discomfort most severe in hands and feet, experience anxiety and depression throughout the day. Housework is difficult. Unable to participate in many leisure activities. Strength has been affected. Unable to lift and hold objects over 10 pounds safely.	Pain and discomfort management, strength, anxiety and depression.	Less pain and discomfort in joints.
28	Patient	Enbrel	No	93313	Insured through employer	People with disabilities	Psoriatic Arthritis	The psoriasis and psoriatic arthritis just seemed to get worse as I age and the inflammation made it harder to exercise and keep up with daily activities. The pain just seemed to increase and/or take longer to subside. I've since graduated from the Psoriasis and Psoriatic Arthritis and am now being treated for Rheumatoid Arthritis.	Mobility, less pain and discomfort and less stress and anxiety.	The Enbrel worked for almost a uear then stopped working at all.

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29	Patient	Enbrel	No	97067	Medicare	Older adults	Rheumatoid arthritis	Currently - minimally	Pain and fatigue management with minimal side effects	Both pain and fatigue management
30	Patient	Enbrel	No	14120	Medicare	Older adults	Psoriatic arthritis	It would affect all of the above if it weren't for Enbrel	Mobility and comfort	I am just about back to normal. Much more tolerable to have this condition with Enbrel
31	Patient	Enbrel	No	75034	Medicare	Older adults	Rheumatoid Arthritis	exhaustion, anxiety, depression, suppressed immunity	Pain	Pain has been under control the entire time.
32	Patient	Enbrel	No	70403	VA Healthcare System	Veteran	Rheumatoid Arthritis	Pain/discomfort, fatigue, leisure activities, work, housework, exercise, recreation	Reducing fatigue and pain so I can participate in day to day life	It worked for me for a couple months and then my body stopped responding and we switched to xeljanz after 9 months on enbrel

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33	Patient	Enbrel	No	22901	Insured through employer		Initially, I was diagnosed with Psoriatic Arthritis and Sjorgrens but recently that was changed to Covid Vaccine Injury. My symptoms present just like the above autoimmune disorders but I do not have any of the markers for them. This all started directly following an anaphylaxis response to my first Moderna vaccine.	HORRIBLY affected. Pain in joints, trigger fingers on both hands, feet hurt all the time, back cracks also no saliva or tears. Very fatigued all the time.	To get back to "doing"....	I went from about 25% of myself to 75%
34	Patient	Enbrel	No	98230	Medicare	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	Rheumatoid Arthritis	I have issues with using my hands, walking, brushing hair and teeth, sleep and overall health	to be able to dress myself, brush my teeth, get in and out of tub, go to bathroom, walk to mailbox, get in and out of a vehicle	it has helped me dress myself, brush my teeth, walk, do errands, button clothes, tie shoes
35	Patient	Enbrel	Yes	80014	Medicare	Older adults	Rheumatoid arthritis	I no longer take it	less pain and swelling with no bad side effects	I had very bad site reactions, so took it a short time

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36	Patient	Enbrel	No	23180	Insured through employer		Rheumatoid Arthritis	Fatigue is the biggest factor for me. Mostly, I am able to do the things I want to do.	Avoid joint damage, avoid pain, and help with fatigue.	Enbrel did not work for me. I needed to switch to another medication in order to achieve treatment goals.
37	Patient	Enbrel	No	98375	Tricare	Veteran, Children and families	Psoriasis	It affects every aspect of my life. I have young children , I work a full time job in healthcare and my spouse is deployed often which leaves the responsibility of the home and stress on myself. Being military I don't have a support system either and all of these aspect affect my personal health which flairs my psoriasis. My skin affects everything from pain/comfort in my clothing , to safety of infection at work, to being able to physically care for my disabled 5 year old. It has caused me as piety and depression through my life and social circumstances due to the visibility of my condition.	Less fatigue, skins clearness , mental health improvements and the ability to be without pain.	Improvements in skin lesions , joint pain and tenderness

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38	Patient	Enbrel	No	07060	Insured through employer	Older adults	RA	Chronic fatigue and joint pain	Remission	None
39	Patient	Enbrel	No	08535	Medicare	Older adults	RA	Requires biologic to function	Quality of life	Quality of life for 7 yrs
40	Patient	Enbrel	No	34275	Medicare	Older adults	ankylosing spondylitis	It limits the range of motion of my spine and sacroiliac joints. Because in my specific case it targets my cartilage, I cannot do strenuous exercises because that much motion will inflame the cartilage all over my body. So this type of inflammation will make me feel like I have the flu.	The ability to walk and perform the daily activities of life. I must also be hyper aware of my eyes (which have a lot of cartilage in them) because there is a specific chance that my eyes could also become inflamed and limit my vision.	It completely erased the low level pain I endured for several decades. The morning after Enbrel was injected at the doctor's office I felt no pain upon wakening. It was a miracle. This drug, Enbrel, also allowed me to eat. The only other drug that I took and was effective - Feldene, generic name Piroxicam - eroded my stomach so much that I was unable to eat. It literally burned a hole in my stomach. I went on Enbrel so I could eat again. I AM NOT EXAGGERATING!
41	Patient	Enbrel	No	48167	Medicare	Older adults	Rheumatoid arthritis	Limits what I used to be able to do - definitely have had to restructure my lifestyle	Less pain -less swelling-more mobility	Less pain -less swelling-more mobility for about a year than benefits faded

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42	Patient	Enbrel	No		Medicare	People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth, Older adults, People with disabilities	Rheumatoid arthritis	Mobility, pain, ability to engage socially	To stay alive	Keeps me alive, reduces pain, helps me to walk, move
43	Patient	Enbrel	No	37922	Insured through employer	People with disabilities	Rheumatoid Arthritis and Sjrogrens	Can't do much and have panic attacks now, anxiety and depression	More mobility	Less pain
44	Patient	Enbrel	No	98513	Insured through employer	People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth, Children and families, People with disabilities	Rheumatoid Arthritis	Unable to work, daily activities very limited. High levels of pain daily. Anxiety about being in pain and being unable to do already limited activities. Anxiety that I will get viral illnesses because my medication suppresses my immune system. Depression over being unable to lead the life I was living before.	Being able to care for and play with my kids, care for my family and household. Being able to do at least some hobbies that bring me joy. I have already given up on being able to work (in the medical field) or do most hobbies (hiking, camping, kayaking, jogging)	Less pain in my joints.

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45	Patient	Enbrel	No	91355	Medicare	Older adults	Rheumatoid Arthritis	Enbrel gave me an almost normal life for 20 years	No pain and enjoying life	Stopped the progression of the disease. I have deformities from living with RA before enbrel.
46	Patient	Enbrel	No	78633	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	My condition forced me to go on disability. My physical and mental health have been and will continue to be affected by this diagnosis. I am gradually losing my ability to do a number things. I need to consider what activities I need to limit or not do at all. I am learning to ask for help — not an easy task for someone who has been independent all of her life.	Maintain my ability to feel like I still have something to offer this world and be as pain free as possible.	My initial inflammatory numbers were significantly high. Once I started Enbrel, those markers dropped to low levels
47	Patient	Enbrel	No		Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	Rheumatoid arthritis	Daily stiffness and pain, struggle to use hands for tasks, chronic fatigue, mobility limited, cognitive effects- "brain fog"	Decrease pain, decrease fatigue, increase ability to use hands	Enbrel was not that helpful and I continued to decline while on it

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48	Patient	Enbrel	No	59405	Medicare	People with disabilities	Rheumatoid arthritis	Every aspect of my life it affects. I can't hold a job because of flare up, pain walking, lifting, carrying anything, climbing ladders, the fatigue is unrelenting. I can't enjoy doing many things with family, I can't run after my grandchildren or lift them much because after repeated tasks like that pain will start in my back and shoulders and the tiredness kicks in. My feet feel like they are breaking when I walk especially on flat surfaces, my neck shoulders and back are so painful to even wash dishes, my jaw hurts so I can't smile as much as I used to which makes me sad because now I just look grumpy all the time.	To be able to live life as pain free as possible.	It helped kick my disease from the pain for about a year.
49	Patient	Enbrel	No	50613	TRICARE	People with disabilities	Rheumatoid Disease	Allows my joints to move.	Long term protection of my joints.	More mobility.

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50	Patient	Enbrel	No	33611	Insured through employer		Rheumatoid Arthritis	Dec 2019, I woke up one day completely crippled. A year later being put on Enbrel made me feel completely pain-free with no physical limitations.	No pain. No physical limitations. I have to work for a living fulltime.	I am no longer crippled. I can sleep. I can walk. I can use my hands again.
51	Patient	Enbrel	No	47421	Insured through employer	American Indians and Alaska natives, Older adults, Children and families, People with disabilities	Psoriatic Arthritis and Psoriasis	Decreased mobility, pain everywhere, itching, extreme fatigue, multiple comorbidities, decreased immune system., isolation.	No itching, stops progression of joint damage.	Treated Psoriasis well. It did nothing for my psoriatic arthritis.
52	Patient	Enbrel	No	95608	Medicare	People with disabilities	Psoriatic arthritis	Pain, limited mobility, disability	Decreased pain, increased mobility	Decreased pain, increased mobility, less days at home - more days out in the world
53	Patient	Enbrel	No	94124	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning	Rheumatoid Arthritis	I have to carefully manage my energy use and commitment. Needing to change my entire lifestyle to minimise disease activity.	Prevent flair and promote a minimum amount of disease activity.	I am able to live my life..
54	Patient	Enbrel	Yes	80537	Medicare	Older adults	Rheumatoid Arthritis		Stop progressing	Reducing Flares

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55	Patient	Enbrel	No	46060	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	Due to RA, I am mobility limited, cannot do most housework, have given up most hobbies and pastimes, and my bones are moving around.	Less pain and stiffness, prevention of further joint damage.	Enbrel has been a life saver. As long as I am able to stay on the drug, pain and stiffness are considerably reduced.
56	Patient	Enbrel	No	02176	Insured through employer		Rheumatoid Arthritis	frequent pain, and fatigue. Many things are more difficult than they should be	Reduce pain, ability to do normal day to day activities	reduction in pain
57	Patient	Enbrel	No	33433	Insured through employer		Rheumatoid Arthritis	At times, soreness in my joints (specifically hands), exhaustion at times	That I can live my life normally and like I did before this chronic illness	I am back to living life (relatively) normally. I can exercise, work, socialize - generally without pain
58	Patient	Enbrel	No	90740	Cobra	Older adults	Psoriatic Arthritis	Pain discomfort mobility of my hands is compromised	Functionality of daily tasks and lower pain	More flexibility and less pain
59	Patient	Enbrel	No	92057	Medicare	Black people, indigenous people, and people of color, American Indians and Alaska natives, Older adults, People with disabilities	RA	It is a dynamic disease that changes from day to day and has impacted every aspect of my life mentioned above. My constant and salvation has ben my steadfast and loyal loving family and spouse.	pain management and stopping further damage	none that I know of with the exception of managing my RA pain

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60	Patient	Enbrel	No	78373	Medicare	Older adults	Rheumatoid Arthtitis	Tremendous impact in relation to mobility, pain, quality of life, and mental health.	Mobility and pain reduction.	Enbrel was the first biologic I tried. It worked well and I felt the impact immediately.
61	Patient	Enbrel	No	55410	Individual (private) insurance		Rheumatoid Arthritis	I have more pain and fatigue. I have painful joints. I have had to have my big toe fused. I can no longer do many of the physical things I used to do before (e.g. running, downhill skiing, rigorous exercises).	Reduce pain, increase energy and slow or ideally stop the progression of the disease.	Hard to know what exactly to attribute to which drug (I am on multiple) but I believe it has helped slow the progression of the disease and reduced my pain significantly.
62	Patient	Enbrel	No	92675	Medicare	Older adults, People with disabilities	Psoriatic arthritis	I'm limited in how I can do anything. Arthritis 50+ years	Pain relief and slowing progression	
63	Patient	Enbrel	No	19015	Individual (private) insurance		rheumatoid arthritis	I have constant pain and fatigue, it makes it hard to work but I generally pushed through	I know there's no cure, I just want to prevent my condition from getting worse	It helped reduce the pain for several years, then it just stopped working so I switched
64	Patient	Enbrel	No	98136	Medicare	Older adults	Rheumatoid arthritis	Fatigue and joint pain	Less pain	Less pain

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65	Patient	Enbrel	Yes	80031	Medicare	Older adults	Rheumatoid Arthritis	My main symptoms are pain and swelling in several joint in my hands. This affects using my hands in most Dailey activities; I work part time and it affects me at work too. So far it has not affected me internally however that's a possibility in the future. No knowing how RA might affect me in the future is always there and causes some anxiety.	RA is a progressive disease that gets worse as time goes on. My main health outcome is to slow the progression and to possibly have long periods of remission.	Enbrel is the 4th RA drug that I have used so far and is the only one that has slowed the progression.
66	Patient	Enbrel	No	33701	Medicare	Older adults	Rheumatoid arthritis	Difficulty working, pain, significant fatigue especially in the morning	Risk versus benefit of improving lifestyle.	Improvement and in some cases elimination of my symptoms.
67	Patient	Enbrel	No	02818	Insured through employer	Older adults	Rheumatoid Arthritis	Joint deformaties	Relief of symptoms, few side effects, long term or slowing of disease process	Taken yrs ago, it was positive in effects but after 2 yrs it was not as effective
68	Patient	Enbrel	No	55076	Insured through employer	Children and families	Rheumatoid arthritis	Few flares, sometimes sore joints	No flares, no soreness	Only a few flares a year

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69	Patient	Enbrel	No	44129	medicare and tricare for life	Older adults, People with disabilities	rheumatoid arthritis	i had to retire at age 40 because this illness, combined with seven others made working full time impossible. i am a lawyer. my career demanded more than i had. today RA makes housework difficult. i am always behind. i live in constant pain, and more joints are becoming affected. i sew, draw, and crochet. it's hard to accomplish those. but i am a constant optimist!	less pain and fatigue. chronic pain consumes a ton of energy as i work to keep it in the background and move forward.	i took enbrel with methotrexate. enbrel helped alleviate morning stiffness in my knees and elbows.

70	Patient	Enbrel	No	12523	Insured through employer	Older adults, People with disabilities	RA	This condition has stolen my life. Mobility, Daily Non-Stop Pain/Discomfort, causes anxiety and depression, melancholy-as it was once referred to. Overall ability to be as independent and self reliant as I once was has diminished and I've become limited in all parts of my life due to RA-Now I believe due to ongoing remnants of CoVSARs virus that grabbed ahold of my immune system, while I was experiencing a major Break in treatment /causing a systemic Flare of disease, my immune system went haywire and now I've had several other issues infections and have been diagnosed with RA & Lupus, also experiencing Big changes in my blood pressure , and my Overall decline in ability to live a normal life without the pain and discomfort from inflammation and my body continues to be out of control, I feel as though everything has gone completely	SUBSTANTIAL NOTICEABLE GAINs QUICKLY- for Overall increase in mobility without constant Discomfort and pain, stiffness, and stop or block the disease(s), progression so I can return to a "normal" functioning person and live a somewhat normal less painfully consumed life.	None

								awry since becoming infected with Covid 19. Nothing works! And yet my physician (s) continue to say that the medications I'm on are helping, my daily life is diminishing and I feel as though this is what I will have to live with or worse from here on out….(?) .		

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71	Patient	Enbrel	Yes	80004	Medicare	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV	Rheumatoid arthritis	Limited joint mobility	Relief from pain and joint damage	Joint pain relief and strong progression of joint damage
72	Patient	Enbrel	No	60056	Medicare	Older adults	Rheumatoid Arthritis	If the condition is active, my mobility is very poor and I would be in almost constant pain.	Living life to the fullest, mental health, doing my volunteer work., included in family activities.	Very little pain if any. Doing what I want to do.
73	Patient	Enbrel	No	89441	Insured through employer		Psoriasis, Psoriatic Arthritis	On this drug, I did not have joint pain nor did I have flares while I was on it. It also cleared my skin.	Reduction of pain, independence, increased mobility and ability to do ADLs	Significantly clearer skin, reduced joint flares, significantly reduced pain and swelling in joints leading to more indepence, return to near normal activities.
74	Patient	Enbrel	No	92371	Medicare	Older adults	Rheumatoid Arthritis	I do experience some pain/discomfort mostly in my hands and feet but I am still able to do what I want to do.	To be able to feel well enough I don't think much about my condition.	Enbrel has controlled the pain and stiffness Rheumatoid Arthritis causes. It has made my quality of life much better.
75	Patient	Enbrel	Yes	80228	Medicare	Older adults	Rheumatoid arthritis (RA)	affect my life a lot.	mobility, less pain	quit working after a year and half

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76	Patient	Enbrel	No	02360	Insured through employer	Older adults	Psoriasis and Psoriatic Arthritis	Limited mobility in all aspects of life, extreme fatigue, reduced work schedule.	Ability to be active in all daily functions. Less pain and fatigue.	I was on Enbrel for about 2 years 10 years ago and it worked well to reduce my psoriasis and psoriatic pain for about the first year then it started losing efficacy so had to switch to another biologic.
77	Patient	Enbrel	No	46307	Insured through employer		Ankylosing spondylitis	Difficulty daily but manageable 75% of time	Ability to work and care for family	Better manages my symptoms
78	Patient	Enbrel	No	85007	Insured through employer	People with disabilities	Rheumatoid Arthritis	Self care, work, housework, family and leisure activities, chronic pain, anxiety and depression	Less pain, more mobility, affordability of drugs	Increased mobility, less pain
79	Patient	Enbrel	No	56001	Medicare	People with disabilities	PsA & RA	Very much	Be able to live some sort of life	Less joint damage less pain meds needs
80	Patient	Enbrel	No		Insured through employer	Children and families	Plaque Psoriasis	Impacted daily life esp with work and self care. Painful to commute in car, personal outlook and household chores	no side effects.	initially, it was able to control the psoriasis and clear the skin
81	Patient	Enbrel	No	83716	Insured through employer		Psoriatic Arthritis/Spondylitis	Constant pain, mobility issues	Less pain	When I used Enbrel, I felt amazing

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82	Patient	Enbrel	Yes	80015	Insured through employer	People with disabilities	Rheumatoid arthritis	Pain when flares occur, need thumb fusion due to dislocation from RA, difficult to walk at times, typing can be difficult frustration from not being able to do what I want and dropping things	No inflammation, no pain	None
83	Patient	Enbrel	No	13905	Individual (private) insurance	Children and families	Psoriasis and Psoriatic arthritis	Mobility, ability to work, housework, leisure activities, pain, anxiety and depression	Clear skin and less pain and stiffness	I had no bad side effects and it helped my skin a little but did not do anything for my pain and stiffness.
84	Patient	Enbrel	No	28540	Medicare	Older adults	Rheumatoid arthritis	Fatigue, mobility, pain/discomfort, housework	Less pain and fatigue	Less pain
85	Patient	Enbrel	No	29671	Medicare	People with disabilities	Rheumatoid arthritis, and several other autoimmune illnesses	I was mostly bedridden before enbrel. I lived in horrific bone pain. I had no quality of life.	Living with decreased pain and inflammation.	This drug calms my disease activity- stops my body from attacking its own healthy tissues. I have greatly decreased pain and inflammation. I can work my farm and go to the gym. It's a miracle drug for me.
86	Patient	Enbrel	No	17552	Individual (private) insurance		Psoriasis and psoriatic arthritis	Both of my conditions are painful. Enbrel helped reduce the	Decrease in pain	It reduce the pain and swelling in my joints. It cleared my skin of plaques.

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								pain so I can live my life with less pain.		
87	Caregiver	Enbrel	No	23050	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning	Juvenile Idiopathic Arthritis	Occasional joint pain and stiffness, fatigue	Control of inflammation and joint damage prevention	Decreased joint inflammation and decreased pain
88	Patient	Enbrel	No	48910	Insured through employer	People with disabilities	Rheumatoid arthritis	Housework, leisure activities depending on the day I may or may not have the energy, have pain in my hips, legs and feet.	To have the best quality of life possible	Just being able to work and enjoy time with my family
89	Patient	Enbrel	Yes	81611	Insured through employer		Rheumatoid Arthritis	Moderately ++	Continue to have an active life with minimal pain.	I did not do well on Enbrel, I am using a different medication.
90	Patient	Enbrel	No		Insured through employer		rheumatoid arthritis	It impacts every aspect of my life (work, rest, cooking, cleaning, walking, attending events, cleaning myself, etc.)	Reduced symptoms	None
91	Patient	Enbrel	Yes	80015	Insured through employer	Children and families	Rheumatoid arthritis	Pain, limits activity	Less pain and more mobility	Joint pain improvement

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92	Patient	Enbrel	No	62935	Medicaid/Health First Colorado	Children and families	Rheumatoid Disease	Limited mobility, self care, usual activities like work can't work anymore, limited housework, limited family activities, leisure activities, daily pain/discomfort, all anxiety/depression all the time, barely leave the house.	No pain so I can enjoy life again.	Lowered the pain sometimes
93	Patient	Enbrel	No	28081	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	Rheumatoid arthritis	It makes my entire body hurt terribly, and depending on the day I may have issues with one of all of my major joints. My hips are so bad I have to use a cane at times, and I've had surgery on both of them (as well as a knee, an elbow, an ankle, and 11 others)	Better quality of life	Relief from symptoms to a higher degree than existing treatments
94	Patient	Enbrel	No	68521	BCBS	People with disabilities	Rheumatoid Arthritis The pain,	The pain & weakness are debilitating. Taking care of myself is taxing and there are a lot of days I am unable to care for myself.	Accurate diagnoses the first time I see the doctor for the latest problem. Also, it is hard when the doctors keep referring me to other doctors.	None. It didn't work for me.

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95	Patient	Enbrel	No	55304	Insured through employer	Older adults, People with disabilities	Rheumatoid arthritis	Constant pain, unable to work, now require a wheelchair, unable to do household	Stop progression of the disease	It worked. I felt much better and was able to work.
96	Patient	Enbrel	No	78616	I do not have health insurance	Children and families	Psa, RA	Affects alot	Being able to have quality of life	Reduced some issues
97	Patient	Enbrel	No	54220	Medicare	Older adults	Rheumatoid arthritis	Joint pain and swelling	Decreased pain and swelling	Decrease in pain
98	Patient	Enbrel	Yes	80232	Medicare	Older adults, People with disabilities	Psoriatic Arthritis	Constant pain = Depression. I don't like to make plans with people because I don't know how I'm going to feel day to day. Some days are so bad, I just stay in bed. I am limited in what activities I can pursue. If I overdo, I pay. I had to stop working and claim disability due to the discomfort I feel at a computer. I can't do much housework so have to hire someone to help.	Pain relief, fatigue relief	I did not get enough relief from enbrel

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99	Patient	Enbrel	No	44203	Medicare	Older adults, People with disabilities	RA	Without medicine every joint in my body hurt from head to toes. Including jaw, shoulder, wrist , fingers, hips, knees, feet and toes, plus spine. So just moving can cause a constant painsitting to long, standing too long even laying down. I am able to do self care but household chores, to watching grandkids play. I do have better days that I can be more active but then I could be down for a few days.	Pain, swelling and movement	It did help with pain some swelling so I could move more
100	Patient	Enbrel	No	31650	Insured through employer	Older adults	Arthritis AS	Yes	A better range of motion and less daily pain.	It is helping with both.
101	Patient	Enbrel	No	19963	Medicare	Black people, indigenous people, and people of color	Rheumatoid Arthritis	I'm in pain all day. I suffer from insomnia. I have pain in my hips, toes, calf, Achilles tendon. I'm unable to lift the simplest weight or pull and push. I am mildl depressed about my health.	To alleviate my pain. And get a good nights rest sleep. Feel happy about my life	I did not see any improvement so my Rheumatologist discontinued my prescription

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102	Patient	Enbrel	No	68104	Medicare	People with disabilities	Rheumatoid arthritis	I've had the disease for about 40 years. I have had 13 orthopedic surgeries, including 4 joint replacements. I have become unable to work, and require a cane to walk. Household chores have become difficult.	Quality of life. Full stop.	When I started taking it in 1998, it was as if a faucet had been turned on, and my energy came back. In time, my joint inflammation was greatly reduced. Those were hugely important benefits,because at the time I had 3 young children. I continue to experience those benefits, even though my disease is severe. I think I'd have been complete disabled by age 45 if Enbrel hadn't come on the market when it did.
103	Patient	Enbrel	No	44212	Insured through employer	Children and families, People with disabilities	RA	I struggle to complete most daily tasks	be more functioning	not much for me unfortunately
104	Patient	Enbrel	No	306	Individual (private) insurance	People who are lesbian, gay, bisexual, transgender, queer, or questioning, Children and families, People with disabilities	Arthritis	Effects all aspects of daily life	Less pain and stiffness	Less pain

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105	Patient	Enbrel	No	30028	Insured through employer		Rheumatoid Arthritis	With the current treatment of using Enbrel and Hydroxychloriquin, I am very minimally affected. Some days I have pain in my hands and fingers but mostly, as long as I don't over do things, I'm pretty good.	Keep joint damage to a minimum and pain level tolerable for as long as possible.	Enbrel has made my RA symptoms minimal and I am able to mostly function in all of my daily activities.
106	Patient	Enbrel	No	64118	Insured through employer		Rheumatoid Arthritis	Pain	Less pain and reduction of joint damage	None
107	Patient	Enbrel	No	35758	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	Affects mobility, self care, social life, professional career, pain and discomfort, and family relationships	Increased mobility and reduced pain and discomfort	Reduced pain and discomfort. Increased mobility
108	Patient	Enbrel	No	37748	Insured through employer	People with disabilities	Rheumatoid arthritis	Daily activities, leisure activities, anxiety, home duties, ability to work, social activities,	Less pain, less fatigue, quality of life	Some pain relief, better quality of life,
109	Patient	Enbrel	No	27312	Individual (private) insurance		Rheumatoid Arthritis	Pain, swelling, fatigue. Hard to maintain a full time job	To eliminate flare ups	None long term.

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110	Patient	Enbrel	No	93428	Individual (private) insurance	Older adults, People with disabilities	Rheumatoid Arthritis	Affects my mobility and ability to move to exercise, care for self, enjoy life activities. I am retired. But I was a teacher of students who are deaf. It affected my work tremendously as I used sign language. It was very difficult to sign. I retired early. I was not but on Enbrel until after retirement. Enbrel has made a huge difference iny functioning. it is a game changer. I am able to resume about 70 percent of my former activities due to Enbrel.	To be able to be mobile and independent as long as possible.	It helps me tremendously. It is has reduced my flare ups and I am able to do most activities.
111	Patient	Enbrel	No	06085	Medicare	Older adults	Psoriatic arthritis	Chronic pain in base joint of big toes. Mobility compromised.	Mobility and pain reduction	The spread of psoriasis has been slowed

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112	Patient	Enbrel	No	47150	Medicare	Older adults, People with disabilities	Rheumatoid Arthritis	I am on disability now, it became effective last year. I struggle with fine motor use, which made working impossible it seemed and some of my favorite hobbies.	Improved hand function, without serious medication side effects and infections.	I did not feel improved, however I have been off Enbrel since June of 2022. I have declined since then, so perhaps it was doing something. I am seronegative and it is challenging. My doctor thought it caused my uveitis and insisted I stop it.
113	Patient	Enbrel	No	27502	Medicaid/Health First Colorado	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	Ankylosing Spondylitis	Limits my mobility and ability to do house hold chores as well as increase pain and decreased energy.	Joint mobility	None
114	Patient	Enbrel	No	14206	Medicare	People with disabilities	Psoriatic Arthritis	Constant pain, loss of mobility, weight gain, anxiety, loss of job and wages, isolation, strain on relationships	To increase basic function in order to live a more socially acceptable life	None
115	Patient	Enbrel	No	92260	Insured through employer	Older adults, People with disabilities	Ankylosing Spondylitis	Wouldn't be able to live without it. Would need full time care and suffer unbearable pain.	Less pain and be able to move	I am able to maintain a full time job. I still have a lot of pain but it's mostly manageable with other meds. I couldn't work and would be completely disabled

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										without it. Probably wouldn't want to live.
116	Patient	Enbrel	No	79602	Insured through employer		Rheumatoid Arthritis	slight mobility, activites, housework	relief of pain and more mobility	none
117	Patient	Enbrel	No	08083	Medicare	People with disabilities	Psoriatic arthritis	I'm 100% disabled	Lessen the pain and swelling in my joints and slow the damage.	None. I no longer take it.
118	Patient	Enbrel	Yes	80452	Medicare and Medicaid for disabled adults under 65	People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth, People with disabilities	Ankylosing spondylitis and axial psoriatic arthritis	Constant intractable pain and fatigue; Unable to work or perform common chores and errands; severely limited social and recreational activities; unable to do my usual hobbies; had to give up my lifelong career as a dancer and dance educator; not working to my potential as someone with an MFA; lost most of my friends; creates unique challenges in relationships	Management of chronic pain and fatigue so that I can have some quality of life	Pain is more manageable so that I'm not totally bedridden and screaming in agony

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								especially romantic partnerships		
119	Patient	Enbrel	No	17406	Medicare	People with disabilities	RA	Drastically	Being able to do things	Temporary Improved symptoms
120	Patient	Enbrel	No	95205	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	Effects my mobility, painful discomfort of my body along with swelling of feet,hands making it unable to do my job and enjoy life with my family.	Stop or minimize deformity of my hands and feet and help with the rheumatoid arthritis getting any worse.. The Ariel helped with the swelling	The Embrel helped somewhat with the swelling and painful discomfort in my hands and feet.
121	Patient	Enbrel	No	76137	Medicare	People with disabilities	Rheumatoid arthritis	Effects everything I do. There are days when I can't even get out of bed.	The pain and stiffness	Being able to move around

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122	Patient	Enbrel	No	86314	Medicare	Older adults, People with disabilities	Psoriatic disease	I am considered disabled as I have very limited mobility. I suffer from depression as well. Most days my pain level is a 7.	Having clear skin is a plus. No cracking and bleeding. Having less joint pain is a must!	I experienced clear skin and much less joint pain.
123	Patient	Enbrel	No	94015	MediCal	Older adults, People with disabilities	Rheumatoid arthritis and Ulcerative colitis	Both conditions cause pain. RA causes stiffness and make tasks difficult and confine me to my home 95% of the time	Symptom alleviation	i did not respond to this medication
124	Patient	Enbrel	No	85387	United Health Care Medicare Adv	Older adults	Psoriatic arthritis	Housework, family, friends, leisure activities , pain, anxiety.	Less pain, ability to enjoy regular activities	Beneficial for 3-4 yrs then had to switch to a different injectable
125	Patient	Enbrel	No	96161	Insured through employer		Rheumatoid Arthritis	Mobility, housework, family activities, exercise, pain and discomfort	Reduction of pain and inflammation	Taking Enbrel worked for me for about 2 years and then my symptoms of RA came back and I had to change medications.
126	Patient	Enbrel	No	63656	Insured through employer	Older adults	Psoriatic arthritis	Pain/discomfort, no longer able to work, mobility issues, anxiety	Less pain, more mobility	All around results for my health
127	Patient	Enbrel	No	05450	Medicare	Older adults	Rheumatoid Arthritis	Have daily pain in joints and have trouble doing daily things.	Less pain	Always helped with my pain

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128	Patient	Enbrel	No	98366	Tricare	People with disabilities	Psoriatic arthritis	I'm wheelchair bound	Slowing of progression and pain	None
129	Patient	Enbrel	No	33815	Spouse's employer insurance (I am on disability)	People with disabilities	Psoriatic Arthritis	Mobility, activities of daily life, pain, self care, housework, hobbies, career, driving	Movement, joint pain	At first, I had instant relief, I was able to bend over and walk freely and turn my head
130	Patient	Enbrel	No	60097-9172	Medicare	Older adults	Psoriasis & psoriatic arthritis	I have mobility issues & pain/discomfort	At that time, I was amidst a flare-up. I wanted clear skin.	My skin cleared up.
131	Patient	Enbrel	No	98030	Insured through employer		Psoriatic arthritis	Joint pain, cardiovascular disease	Pain reduction, no inflammation	Reduce inflammation
132	Patient	Enbrel	No	75211	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	Rheumatoid Arthritis and Antiphospholipid Disorder	Every part of my life is affected.	Less pain, better mobility, quality of life	Better quality of life, less pain, more social and family time
133	Patient	Enbrel	No	02360	Insured through employer		Psoriatic arthritis	Limits mobility, depression	Resolution of symptoms	Increase in mobility compared to prior. Almost complete resolution of deformed digits. Almost complete clearing of skin lesions.

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134	Patient	Enbrel	No	30720	Medicare	People with disabilities	Rheumatoid arthritis	Makes it very hard to do normal activities	Getting the right medication for me	It helped a lot
135	Patient	Enbrel	No	30728	Medicare	Older adults, People with disabilities	rheumatoid arthritis	I have limited accessibility in all walks of life because of distance necessary to walk. uneven paths, lack of handicap facilities, including grocery stores, restaurants and retail stores, activities including learning and spiritual renewal, recreation facilities,	My functionality as an older adult. Sometimes, being functional includes access to pain management.	Enbrel keeps the action of the RA from causing more deterioration of bones and helps me not feel so fatigued.
136	Patient	Enbrel	No	27705	Insured through employer	Children and families	Psoriatic Arthritis	This disease weakens tendons and has led to me rupturing my tendon with little to no symptoms. It causes multiple area joint stiffness and low level discomfort that impacts mood and sleep. Occasional increases in pain level at random times	The ability to get on the ground to play with kids, squat and bend over without stiffness to do my job. Sleep well to prevent other health issues, and exercise consistently to help with weight and healthy behaviors	When on Embral, I have been able To workout consistently with weights and walk daily up to 6 miles. I have hiked 27 miles in a day, and I have not had to seek care for any orthopedic problems over the past 8 years

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137	Patient	Enbrel	No	34689	Medicare	Older adults, People with disabilities	Rheumatoid Arthritis	Mobility limitations using walker, Unable to drive, Require assistance household chores & cooking meals, Chronic Pain, Depression & Unable to participate in outside activities, Depression.	Management of symptoms. Increased mobility, Adequate nutrition.	Management of symptoms, better mobility, pain management.
138	Patient	Enbrel	No	72070	Individual (private) insurance	Older adults, People with disabilities	Ankylosing Spondylitis	Pain, mobility, housework, recreation, work	Being able to have some semblance of a normal life	Less pain, somewhat improved mobility
139	Patient	Enbrel	No	28752	Medicaid/Health First Colorado	Older adults, Children and families, People with disabilities	Rheumatoid arthritis	It affects every aspect of my life I can't play with my grandchildren work or even leave the house very often	To keep my rheumatoid arthritis under control	It controlled my rheumatoid arthritis for 10 years

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140	Patient	Enbrel	No	43229	Medicaid/Ohio		Rheumatoid Arthritis	BEFORE Enbrel, I was unable to dress, bathe, eat, brush my teeth, lift my arms, work... do ANY normal activities (due to excruciating joint pain). I was pretty depressed and had involuntary suicidal thoughts. I couldn't even imagine living the rest of my life in so much pain. I knew I was a burden on my family, and that it would get worse. Now on Enbrel, I hope to live and enjoy a long life. My pain is manageable most days, with a rare "flare up" of extreme pain. Mobility and pain improved 90%+.	Good mobility and minimal pain.	Good mobility and minimal pain.
141	Patient	Enbrel	No	77868	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning	Psoriatic Arthritis	painful joints, problems moving etc	relief of pain and stopping arthritis from shortening my life	none
142	Patient	Enbrel	No	34453	Insured through employer	People with disabilities	RA	Pain, exhaustion and disability	Function	Clearing of brain fog some easing of pain

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143	Patient	Enbrel	No	49079	Medicare	Veteran, Older adults, People with disabilities	Rheumatoid arthritis	Difficulty with household chores, daily living, walking, lifting, carrying.	Reduction of PAIN and fatigue	It reduced my pain and fatigue and allowed me to work.
144	Patient	Enbrel	No	02081	Insured through employer	Black people, indigenous people, and people of color, People who are lesbian, gay, bisexual, transgender, queer, or questioning	Rheumatoid arthritis	Daily fatigue making it hard to concentrate at work and home and remember things, hard time putting clothes on in the morning and getting out of bed from stiffness, random flares make it hard to schedule get togethers because I might not feel well	Reduced pain and slowed progression of disease	Less pain and reduced flares
145	Patient	Enbrel	No	37013	Insured through employer		Rheumatoid arthritis	It's very difficult.	Less pain and fatigue	It helped alleviate swelling and pain
146	Patient	Enbrel	No	74743	Medicare	Older adults, People with disabilities	Rheumatory Arthritis	Limits all daily living activities moderately	Lower pain, slow down progression	Increased energy, greater flexibility
147	Patient	Enbrel	No	97055	Medicare	Older adults, People with disabilities	rheumatoid arthritis	It affects all of the things listed! In cold weather they are even worse.	independence	Enbrel did not help me.

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148	Patient	Enbrel	No	14580	Medicare	Older adults	Psoriasis. Psoriatic ArthrInterferesitis	Interferers with all aspects of daily living.	to be free of constant pain	less joint pain, less embarrassment over large patches of ugly skin and flaking hair debris
149	Patient	Enbrel	No	53511	Medicare	Older adults	Rheumatoid Arthritis	Stiffness in hands on occasion makes housework difficult at times	Relieve pain and stiffness	Didn't help me that much
150	Patient	Enbrel	No	58501	Insured through employer		Rheumatoid Arthritis	Fatigue	Less pain and swelling of joints	More mobility
151	Patient	Enbrel	No	60201	Insured through employer		Ankylosing spondylitis	This condition affects me in every way possible. Cronic pain affecting my mobility and mental health. I am so tired after a simple day of work and unable to do housework or socialize with friends and family. I often need help from my aging parents for simple things because I am so tired from working all day and have pain from just sitting at my desk. I need to work to afford health insurance and I still can't afford the cost	Reduction of chronic pain, more energy and lowered inflammatory markers (which means inflammation is doing less damage to my body).	Decreased pain, more energy and increased mobility.

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								of medication so my parent help me out financially.		
152	Patient	Enbrel	No	76087	Insured through employer	Older adults	Rheumatoid Arthritis	Mobility	Anti inflammatory and mobility	Anti inflammatory and mobility
153	Patient	Enbrel	Yes	80602	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning	Rheumatoid Arthritis	Occasional pain and discomfort, daily fatigue.	Remission	Reduction in symptoms for the very brief period I was on it.
154	Patient	Enbrel	No	53045	Medicare	Older adults, People with disabilities	Arthritis	Mobility, balance in selfcarek	Improved balance and flexibility	Balance and strength for employment

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155	Patient	Enbrel	No	02668	Insured through employer		Psoriatic Arthritis	Currently is under control	Better mobility, reduced joint swelling, less pain.	Almost complete remission
156	Patient	Enbrel	No	98338	Medicare	People with disabilities	Rheumatoid arthritis	I had to quit working I have a hard time with my daily activities of life and sometimes I get depressed	To stop the progression of the disease and to not have to use my cane for walking	I haven't had to use my cane for Almost a year and a half It just better Mobility and it's disease is not progressing very fast at all
157	Patient	Enbrel	No	61072	Insured through employer	Older adults	Rheumatoid arthritis	Low level content pain and fatigue interfere with high activity levels.	Comfort and control of progression	None
158	Patient	Enbrel	No	33762	Medicare		Rheumatoid arthritis	Somewhat	Relief	It helped for a year
159	Patient	Enbrel	No	85716	Insured through employer	Black people, indigenous people, and people of color	Rheumatoid arthritis	Brain fog/ Short term memory loss. Flair unable to be mobile. Vacation causes fatigue.	Fatigue, and flair pain management	Slowing progress of disease, prolonged in between flairs.
160	Patient	Enbrel	No	63119	Medicare	Older adults	Rheumatoid arthritis	Currently in remission. Rarely affects me lately.	Pain relief and range of motion increases	Moderate improvement in te condition.

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161	Patient	Enbrel	No	15717	Insured through employer	People with disabilities	Rheumatoid Arthritis	Some days I am bed-bound. Other days I can go to the store. I am always in pain.	Less pain, less joint damage.	none
162	Patient	Enbrel	No	28712	Insured through employer	People with disabilities	Rheumatoid arthritis	Condition limits life very much without medication.	Functioning as close to normal as possible.	Decrease in symptoms.
163	Patient	Enbrel	No	47126	Medicare	People with disabilities	Rheumatoid arthritis	Disabled with poor mobility, pain, swelling, and exhaustion. Unable to work, difficult to complete housework, cooking, unable to sleep for more than three hours at a time. Seldom leave the house for leisure activities. Had depression and anxiety when first diagnosed.	Lessening of pain, swelling, and sleep disturbances.	Only had a moderate improvement from it.
164	Patient	Enbrel	No	78735	Insured through employer		Psoriatic arthritis and psoriasis	Pain, limited use of joints, itching and burning	Control pain and long term damage to my joints. Control or eliminate psoriasis lesions	Less pain, psoriasis free slowing down progression of permanent joint damage
165	Patient	Enbrel	No	85611	I do not have health insurance	Older adults	Rheumatoid Arthritis	Moderately affected	less pain	Less pain, Increased mobility

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166	Patient	Enbrel	No	73012	Insured through employer		Rheumatoid Arthritis	My condition affected my daily life including mental physical ability to conduct daily activities including work.	To be pain-free, and able to conduct daily activities	Embrel dramatically change my life. It helped me get my life back.
167	Patient	Enbrel	No	23059	Insured through employer	Older adults	Psoriasis and psoriatic arthritis	Pain, fatigue	Mobility, mental health	Skin improvement, Mobility
168	Patient	Enbrel	No	48823	Medicare	Older adults, People with disabilities	Psoriasis, psoriatic arthritis	Mobility, self conscious of appearance, extremely painful, can not work	Mobility, gaining some pain relief	Did work for a while to clear up psoriasis
169	Patient	Enbrel	No	47392	Medicare	Older adults	Psorasis	Pain/discomfort	Pain free	Ability to do daily activities
170	Patient	Enbrel	No	34480	Medicare	Older adults, People with disabilities	Rheumatoid Arthritis	A lot	Reversal and less pain	More mobility
171	Patient	Enbrel	No	55114	Individual (private) insurance	People with disabilities	Rheumatoid arthritis	Pain, depression, fatigue	Less pain	Less pain and flareups

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172	Patient	Enbrel	No	95215	Through the school	People with disabilities	Rheumatoid arthritis	Always in pain especially with the continuous progression which affects other joints. I have depression. Some activities are difficult for me and when I have flare-ups, I would need assistance. Walking is difficult and standing is even worse.	Less pain or at least more manageable to be able to work.	Less flare ups and swelling especially on my hands
173	Patient	Enbrel	No	74036	Medicare		RA		Slow progression	
174	Patient	Enbrel	No	03104	Medicare	People with disabilities	Rheumatoid Arthritis	Moderately	Mobility	Mobility, Pain, Stiffness
175	Patient	Enbrel	No	52803	Insured through employer	Black people, indigenous people, and people of color, Older adults, Children and families, People with disabilities	RA	unable to do simple daily living task, unable to walk more than a block, unable to stand for 10 min or longer, pain level is always between a 6-9, unable to participate in leisure or exercise. suffer from anxiety and depression	improvement in mobility	not much of anything
176	Patient	Enbrel	No	83655	Medicare	Older adults, People with disabilities	RA, polyarthritis	Limits activities, fatigue, insomnia, depression, pain	Pain, mobility	Pain lessening, more mobility

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177	Patient	Enbrel	No		Individual (private) insurance		Rheumatoid Arthritis	Condition cause daily pain, episodes of extreme fatigue, difficulty dressing myself and preforming routine, daily tasks.	Decreased pain, limited or no fatigue, increased mobility	Decreased pain, limited or no fatigue, increased mobility
178	Patient	Enbrel	No	46835	Insured through employer	Older adults, People with disabilities	Rheumatoid arthritis	Affects every aspect of my life, at work and home. Any physical task is more difficult and often accomodations must be made.	To continue to be active, independent, able to work and pursue other activities	Enbrel allowed me to.vontinue to work at a demanding full-time for 22 more years until retirement.
179	Patient	Enbrel	No	33065	Individual (private) insurance	Older adults	Rheumatoid Arthritis	When I have flare ups, my mobility can be limited, i.e., limited use of hands or shoulder. Most often it is for limited timeframe. This can impact work, housework, cooking meals, and is usually associated with a moderate level of pain/discomfort.	The ability to lead a fully productive life. Ability to handle normal household activities, moderate exercise and full self care.	I have been on this drug for 20+ years. It has greatly limited the progression of my disease and I've lead a fully productive life. From the first day after taking Enbrel, my life improved dramatically.
180	Patient	Enbrel	No	73554	Insured through employer		RA	pain/sleep	lessen pain and sleep more restfully	none - I quite taking it because it did nothing.

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181	Patient	Enbrel	No	38555	Medicare	Older adults, People with disabilities	Rhumatoid Arthritis	Affects me greatly, even in minor everyday activities. I have to use a rollater to ambulate.	Less pain and more mobility.	None - allergic due to having Alpha gal syndrome.
182	Patient	Enbrel	No	93063	Insured through employer	People with disabilities	Rheumatoid Arthritis	Yes	Easing my symptoms so I can function day to day, prevention of further damage caused by my illness, remission would be the ultimate dream.	Less inflammation in my body, ability to walk easier, ability to start to enjoy my life again.
183	Patient	Enbrel	No	19081	Individual (private) insurance	People with disabilities	Psoriatic arthritis	Daily pain that limits the ability to do PT, function, work, recreation, and social aspects	Reducing pain to be able to help myself and be less dependent on others. Including being able to go to PT.	The disease has not progressed to permanently destroy my joints which is what my Dr said would happen if untreated.
184	Patient	Enbrel	No	98329	Insured through employer	People experiencing homelessness, People with disabilities	post streptococcal reactive arthritis	I am much less active and mobile.	Being able to work and keep food on the table.	It reduced flares, but I had to switch a couple years ago because it was no longer affecting me. I did take it while pregnant, though.
185	Patient	Enbrel	No	95747	Insured through employer	People with disabilities	psoriasis and psoriatic arthritis	Constant chronic pain in the joints. Loss of flexibility and mobility. Psoriasis puts a crimp on social activities.	Less pain and more flexibility. A lower visual observance of psoriasis scales.	Some degree of pain relief. Some relief from psoriasis.

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186	Patient	Enbrel	No	92126	Medicate Advantage	Black people, indigenous people, and people of color, People with disabilities	Psoriatic Arthritis	Enabled me to lead a somewhat normal life with less pain	To reduce pain and inflammation, no visible signs of psoriasis, to live life with a greater degree of independence	Same as above
187	Patient	Enbrel	No	67648	Medicare	People with disabilities	Rheumatoid Arthritis	Rheumatoid Arthritis for me is a painful disease. Many of my joints are inflamed and painful. It is difficult for me to do normal activities as basic as standing from a seated position and walking. I am no longer able to work.	Stop bone erosion. Reduce swelling.	My health benefits experienced from using this drug were limited so I was only on it for a short time before moving on to a different medication.
188	Patient	Enbrel	No	29356	Veteran's Health & Medicare	Veteran, People with disabilities	Rheumatoid Arthritis	In all aspects from cooking, cleaning to dressing & sleeping. It affects every tiny part of my life.	mobility - the ability to move without extreme pain	I have mobility back. From the time i took the first shot till now - I am able to walk
189	Patient	Enbrel	No	77433	Medicare	Black people, indigenous people, and people of color, Older adults, People with disabilities	Rheumatoid Arthritis	It affects my mobility, my ability to do housework and ability to focus due to pain.	The health outcome most important to me is reduced pain and inflammation.	Enbrel did help reduce pain. I was able to function almost normally.

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190	Patient	Enbrel	Yes	81413	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, Older adults, People with disabilities	Rheumatoid Arthritis	This condition reduces my mobility, requires me to be on oxygen, causes pain and anxiety/depression. It creates an overwhelming fatigue that is mostly persistent.	Ability to carry out ADLs by myself and to do my hobbies (like gardening).	None
191	Patient	Enbrel	No	05477	Insured through employer	Older adults, People with disabilities	Rheumatoid arthritis	Pain, limitations of joint usage, difficulty in self-care and mobility	Reduce pain, reduce joint damage, increase joint mobility and strength	Enbrel greatly increased my joint mobility and strength, and reduced pain immensely
192	Patient	Enbrel	No	72076	Medicare	People with disabilities	Rheumatoid Arthritis	It affects every part of my daily life and I am currently disabled due to it.	Remission	None
193	Patient	Enbrel	No	10990	Insured through employer	Older adults, People with disabilities	Psoriatic arthritis	24 hrs a day 7 days a week for over 40 years	Reduced inflammation and disease progression	Slowed disease progression and clearing of psoriasis

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194	Patient	Enbrel	No	34491	Medicare	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	Rheumatoid arthritis	I have constant pain, depression, anxiety, guilt, fatigue, brain fog. I have trouble sleeping due to pain. I have trouble doing stuff like cleaning my home, especially the shower and floors. I usually order stuff online and either do drive up or have it shipped to me because going to the store is exhausting.	Manage pain and fatigue	Enbrel did not work for me, but I had to try it because my new insurance wouldn't approve the drug that I was already taking until I failed 2 of 4 drugs they preferred.
195	Patient	Enbrel	No	95125	Medicare	Older adults	RA	pain/discomfort; disruptive to daily living	Remission, if not cure	Was not effective
196	Patient	Enbrel	Yes	81007	Medicare	Older adults, People with disabilities	Psoriatic arthritis	Unable to engage in meaningful work due to mobility, pain and anxiety issues	Decreased pain	None

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197	Patient	Enbrel	No	37931	Insured through employer	People with disabilities	It was prescribed for Rheumatoid Arthritis	I have pain/aches 24/7. I have limited grip strength and arthritis in my knuckles so opening doors, cabinets, bottles, medications, and packaging are difficult. I am only able to stand for about 10 minutes. My walking is only indoors due to balance issues. My toes, ankles, hips, shoulders are all affected by RA. I have to use a stool to cook. I rarely am able to go out for fun. I am being treated for depression. I just don't have the stamina I used to have.	Being able to work and have a little energy when I get home.	It helped some. Pain relief was good.
198	Patient	Enbrel	No	20109	Medicare		arthritis	mobility but it didn't work well enough	mobility, pain	

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199	Patient	Enbrel	No	75009	Insured through employer	Black people, indigenous people, and people of color, Children and families	Rheumatoid arthritis	I have mild to moderate RA so I am able to complete all of my daily activities. If I am in a flare I am less likely to do those activities even if I could do them with some discomfort. I try to prioritize rest during flare ups so I may cancel plans etc. RA has affected me the most mentally and emotionally. I feel out of control and helpless sometimes.	Minimize pain and joint damage.	Greatly reduced pain and inflammation
200	Patient	Enbrel	No	60085	Medicare	Older adults	rheumatoid arthritis	It is slowly taking away my ability to physically care for myself. I have suffered severe pain, depression and considered suicide.	Reasonable mitigation of the limitations the disease has brought on. See above answer	The drug over the course of two years showed no health benefit and I had to add a second injectable which also left me without symptomatic relief or health benefit.
201	Patient	Enbrel	No	75006	Individual (private) insurance	People with disabilities	Rheumatoid arthritis	Pain, limited mobility, reduced motor skills, fatigue	Reduction of disease activity	None

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202	Patient	Enbrel	Yes	80021	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	psoriatic arthritis	severely limits my ability to move regularly, in constant pain from joint inflammation	reduction of pain and arthritic flares	reduction in some pain (from a 9 to a 5-6)
203	Patient	Enbrel	No	56258	Medicare	People who are lesbian, gay, bisexual, transgender, queer, or questioning	Psoriatic Arthritis and Psorisis	Stiff and painful joints, patches of skin scales and patches and itching	Able to move and control skin patches	Able to move, swelling has gone down, able to live without pain and use of arms hands legs
204	Patient	Enbrel	No	14607	Medicare	Older adults, People with disabilities	RA	Decreased mobility, chronic pain, anxiety, difficulty doing normal activities	Stop deformities in hands.feet, reduce pain	Reduced pain, stopped new deformeties
205	Patient	Enbrel	No	19446	Insured through employer	Older adults	rheumatoid arthritis, reactive arthritis	causes pain & discomfort and prevents participation in some activities	pain relief, better sleep	

206	Patient	Enbrel	No	38134	Insured through employer	Black people, indigenous people, and people of color, Older adults, People with disabilities	Ankylosing spondylitis	This condition significantly affects my physical, mental, emotional, and financial abilities. Physically I struggle with doing every day tasks that most are able to perform effortlessly. I have difficulty just getting out of bed independently. I struggle with showering and dressing. I still work but can only work part-time because the work I do as a nurse are long hours and physically demanding. It takes me 2 days to recover from working 1 12- hour shift which impacts my physical and financial well-being. I can't plan house cleaning activities unless I am not working for at least 2 days before or after a work shift, so my home is not as clean as I would like it to be which again impacts me emotionally. I suffer with the ability to focus my mind, because most things like reading and performing tasks are exhausting. I am not able to get restorative	Decreased pain, the ability to think clearly and focus, perform and complete tasks in a timely manner. To just feel productive and like a normal person.	For the time I used Enbrel it helped to slow the progression of the disease process which I didn't know at the time, but having not used it in a while I now know that Enbrel was very effective at allowing me to continue with living my life as normal as possible.

								sleep when I rest because I am in pain all the time. I could continue with how this dis- ease in my body impacts me and my life, but you get the picture.		

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207	Patient	Enbrel	No	20688	Insured through employer	Older adults	Undifferentiated Spondyloarthopathies-RA,PA & AS	Each day is unpredictable, but I am affected each day in some way, physically. Most parts of my body is affected by arthritis in one way or another and weather is a huge contribution to overall symptoms. Dont handle winter well, nor summer due to barometric pressures and humidity.	How much pain means more to me rhan I'm my ability to do things. I no longer carry expectations for activity.	Started in 2013 after an unsuccessful year with Humira and MTX. I'd like to think my weekly use of Enbrel is helping to control deterioration to a point. I'm certainly in more pain without it. It's also kept the ankylosing of my spine to a minimum so far. It did stop my chronic urinary tract infections.
208	Patient	Enbrel	No	23112	Insured through employer	Black people, indigenous people, and people of color	Rheumatoid Arthritis		being free from pain)	Just started but I'm starting to feel better.
209	Patient	Enbrel	No	86004	Insured through employer	Older adults, People with disabilities	Rheumatoid Arthritis	Fatigue, limited mobility, pain/soreness, anxiety and depression, flares prevent any activities.	Less fatigue, slowing down disease progression, preventing heart and lung damage caused by inflammation, less frequency of flares.	Less fatigue, caring for myself and family, exercising (low impact) improved mental health.
210	Patient	Enbrel	No	54452	Individual (private) insurance		Rheumatoid arthritis	Pain, stiffness, fatigue	Less pain and fatigue	Partial relief of symptoms

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211	Patient	Enbrel	No	01801	Insured through employer		Rheumatoid arthritis	Helps me do my everyday tasks	No pain	No or little pain less fatigue
212	Patient	Enbrel	No	43560	Insured through employer		Psoriatic arthritis	It affects all aspects of my daily life when I'm in a flare. I find most tasks difficult to get through.	Quality of life, getting back to as close to normal as possible.	I've experienced less overall flares, it's the closest to normal I've felt.
213	Patient, Caregiver	Enbrel	No	59750	Insured through employer	Older adults, Children and families, People with disabilities	Rheumatoid arthritis	Daily pain, inability to completely clean my house, I don't run anymore, or hike or hunt. Showers and baths are a major undertaking and exhausting.	I want less pain, more energy, ability to walk more.	For sometime, it worked with pain and inflammation. Then it stopped working for me.
214	Patient	Enbrel	No	77355	Husband retired from Shell Oil	Older adults	Rheumatoid Arthritis	Much better now, more energy, less achy-ness, full mobility	Less achy-ness and fatigue	Less achy-ness and fatigue, slowed joint damage
215	Patient	Enbrel	No	20852	Kaiser and Medicare Advantage	Older adults	Rheumatoid Arthritis	Until recently, I functioned fairly well.	Being able to live a relatively normal life.	Kept most of the RA issues controlled.

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216	Patient	Enbrel	No	84043	Medicare	Older adults	Rheumatoid arthritis	Fatigue painful hand joints and loss of grip	To prevent more joint involvement	I had a severe reaction which immobilized me in bed with a headache which was the most severe I had ever experienced. I reported to Enbrel pharmacy
217	Patient	Enbrel	No	55119	Medicare	Older adults	Psoriasis/Psoriatic arthritis	Pain and discomfort, itchiness, inflammation	Being able to move more easily, reduce the scales and itchiness of lesions	At the time it mostly cleared my skin and somewhat slowed the progression of the arthritis.
218	Patient	Enbrel	No	87507	Medicare	Older adults	rheumatoid arthritis	Painful joints restricting usage of hands.	remission of disease or at least slow progression	slowed disease progression

219	Patient	Enbrel	No	94110	Insured through employer	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People with disabilities	rheumatoid arthritis	I don't have as much energy as other people my age. I can't walk as far as most people my age. I can't work as many hours as most people my age (because of both fatigue and pain from sitting at a computer). I don't make as much money as I would if I could work more hours. I struggle with a lot of household tasks, and my husband has to pick up the slack. I have to carefully decide what to do with my free time because my energy is so limited. When it comes to doing physical activities for fun, I am limited to walking (slowly), tai chi, and swimming. I've had both knees replaced; each surgery entailed months of not being able to work and only being able to work a little as I rehabbed, resulting in major income loss. With the ups and downs of RA and being immune compromised because of medications (and thus getting sick more often and for longer than my able-bodied	Reduction of pain; increased mobility; reduction of fatigue.	Enbrel worked really well for me for a few years. It reduced my pain, gave me more energy, and increased my mobility. Then, it just stopped working.

								peers), I experience income loss. RA has affected every single aspect of my life, including my choice of career (I quit classroom teaching because it was too physically tiring), my choice of where to live (in a temperate climate), and my social circle (people who are willing to be patient and understanding with my limitations). I experience some level of pain every day, all the time. It fluctuates, and I'm pretty good at blocking it out unless it's really acute. I often feel like a failure because I am not able to live up to society's standards of what someone my age should be able to do. Society doesn't see me as disabled because I often look able-bodied and healthy, and even people who know me well often seem to expect that I'll be able to function as if I don't have RA. That makes me stressed and depressed. I feel like I'm constantly disappointing others. I		

								feel like I'm constantly scrambling to just try to keep up. I have near-constant anxiety about my health and about my ability to earn enough money.		

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220	Patient	Enbrel	No	24382	Insured through employer		Rheumatoid arthritis	Before taking Enbrel, RA significantly affected all aspects of my life…walking was difficult, self care (washing & brushing my hair), housework was difficult, working as a teacher was increasingly difficult.	Quality of life.	I am able to move, care for myself and do everything I want to without pain.
221	Patient	Enbrel	No	78633	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	All the ways listed. I have numerous problems and they get progressively worse.	Control the debilitating effects, relieve pain and help maintain ways to improve health.	It has helped to control or slow the symptoms of my disease
222	Patient	Enbrel	No	11704	Insured through employer		Rheumatoid	Pain	Limiting pain	Limited benefit
223	Patient	Enbrel	No	15229	Insured through employer	American Indians and Alaska natives, People with disabilities	Spondyloarthritis	Severe fatigue (affects work and all aspects of personal life), increased anxiety and depression, Difficulty engaging in social activities due to mobility, fatigue and pain.	Consistent pain/inflammation management and manageability of the fatigue	Consistent pain management, decreased fatigue, more independence in self care and housework.

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224	Patient	Enbrel	No	36305	Medicare/United Health Care for retired state employees	Older adults, People with disabilities	Rheumatoid Arthritis	Pain/discomfort - mobility - depression	Decrease in pain and increased mobility	This medication did not help me
225	Patient	Enbrel	No	19609	Medicare	Older adults	Rheumatoid arthritis	Fatigue and pain	Prevent damage	Pain relief
226	Patient	Enbrel	No	91304	Medicare		Rheumatoid arthritis	I have pain and swelling in the joints in my hands and feet. I have limited strength and flexibility of my fingers. My right hand is worse with my fingers deviating laterally.	Prevention of further joint destruction, less pain and increased mobility	Enbrel has decreased my finger/hand swelling and improved mobility
227	Patient	Enbrel	No	61822	Medicare	Older adults	Rheumatoid Arthritis	On a good day I do well but during flare ups I can hardly walk. (I use paper plates all the time because I tend to drop things and I use a rollator.)	Being able to stay in my home and not getting to the point where I have to rely on my children to take care of me.	I have experienced fewer flare ups and have not had much joint damage. This is important to me because I play piano and violin and would like to keep doing so.

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228	Caregiver	Enbrel	No	03842	Insured through employer		Juvenile Arthritis	The disease causes my child to experience profound fatigue and joint pain that causes them to miss school and fall behind in their academics. It also prevents them from working full time and interferes with their ability to eat.	Prevention of symptoms and protecting joints from irreversible damage.	Remission of all symptoms
229	Patient	Enbrel	Yes	81001	Medicare	Older adults, People with disabilities	R.A.	Work, leisure activities, pain and discomfort	To not be in pain and discomfort	Don't have pain and no swollen joints
230	Patient	Enbrel	No	63367	Insured through employer	People with disabilities	Ankylosing Spondylitis	Constant pain causes me to lose sleep, be in a bad mood, and have difficulty moving,	Better energy and more ability to function	Short term lower pain and mobility
231	Patient	Enbrel	No	38305	Insured through employer		rheumatoid arthritis	Before RA, I ran 6-8 miles daily and had multiple other hobbies alongside working full time as a professor, wife, and mother. Now, I do well to complete daily tasks in online teaching and some household chores.	prevention of further disability and accidents (especially falls because of risk from co-morbidities associated with RA)	decrease in RA symptoms - fatigue, pain, swelling, stiffness

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232	Patient	Enbrel	No	47802	Medicare	Older adults, People with disabilities	Rheumatoid Arthritis	My arthritis has greatly affected my mobility. I am very limited to all activities, in my life. My wife has become my caretaker.	I would say that the best thing I could hope for, is that the medicine. Would help me achieve at least 30 to 40 percent of my comfort.	This drug greatly helped relieve my discomfort and mobility.
233	Patient	Enbrel	No	24538	Medicare	Older adults	Psoriatic arthritisYrs and psoriasis	Y es	Pain relief and Mobility	Decreased psoriasis and some pain
234	Patient	Enbrel	No	78260	Medicare	Older adults	RA and Ankylosing Spondylitis	Yes	Reduced pain, stop progression of diseases, increase daily living activities	It did stop progression and helped reduce pain
235	Patient	Enbrel	No	08021	Medicare	Older adults, People with disabilities	Psoriatic Arthritis, psoriasis	Mobility, self-care, housework, leisure activities, pain, discomfort, depression	Less pain, more activity	It helped with my pain and cleared my psoriasis
236	Patient	Enbrel	No	30504	Medicare	Older adults	psoriatic arthritis	During flares, there is low back pain plus several peripheral locations of pain and inflammation. It can limit my activities during the flare.	pain reduction/elimination and non-serious side effects	pain reduction/low inflammation activity
237	Patient	Enbrel	No	44216	Insured through employer		Rheumatoid arthritis	Not able to work, pain, discomfort, limited mobility	Slowing the progression of the disease	It didn't work as well as my rheumatologist has hoped

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238	Patient	Enbrel	No	49426	Insured through employer	Older adults	Phsoriatic arthritis [8]	Pain gave up water-skiing, ice skating and tubing behind a boat. Daily life I tire quicker but still excell in my job.	Less pain, stop joint damage, and hopefully remission.	Much less pain, less fatigue, able to do my job and also yard work.
239	Patient	Enbrel	No	61114	Insured through employer	People with disabilities	RA	Mobility	More mobility	Sinus infections
240	Patient	Enbrel	No	28752	Medicare	People with disabilities	Rheumatoid Arthritis	I am affected in my everyday living activities. I struggle with physical & mental limitations such as no longer being able to work (I was a nurse) bathing, cleaning my house, doing errands outside of home, (the going out part), fixing my food, doing laundry, etc. This is difficult due to being in constant varying degrees of pain & the constant struggle with fatigue, & the mental aspects of both of those - depression etc. Everything as a whole varies day to day & does not always seem to have a rhyme	What is most important to me is to be in less pain overall, leading to less damage occurring & possible reversal, which leads to less fatigue, less mental issues, & I can then do more for myself & feel better doing it.	Less overall pain & inflammation

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								or reason to it which is difficult to overcome & cope with.		
241	Patient	Enbrel	No	32789	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	In constant pain cannot do daily activities	Pain control, mobility	None

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242	Patient	Enbrel	No	72103	I do not have health insurance		Rheumatoid arthritis	I causes me daily pain and stiffness in various degrees, a lot of fatigue, which decreases my mobility some days to the point I have to be in bed. Other days it just slows me down in my daily activity. But it's enough to stop me from working and to require help on basic daily things. It has caused me a great deal of anxiety for the future, something I'm working on at the moment.	Increased mobility and less pain, less flares.	Slightly less "bad" days (flare days); I believe it has slowed down the progression, since I don't feel worse than before, even if I don't feel better.
243	Patient	Enbrel	No	77807	Insured through employer	People with disabilities	Rheumatoid Arthritis	Constant pain, lack of strength in hands, eye issues, digestive issues, mobility issues, skin irritation.	Reduced pain and increased mobility	Reduced pain
244	Patient	Enbrel	No	91362	Insured through employer	Older adults, Children and families, People with disabilities	Rheumatoid Arthritis	Deal with daily fatigue and occasional flares	Improve symptoms or reduce inflammation of joints	Medication reduced inflammation and has help decrease other symptoms
245	Patient	Enbrel	No	98102	Medicare	People who have AIDs or HIV, Older adults	Psoriasis	Uncomfortable and embarrassing but not truly disabiling	Clear skin	Initially total clearing almost miraculous

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
246	Patient	Enbrel	No	38068	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	Pain, fatigue, anxiety, depression, loss of mobility, inability to work, to do housework,inability to engage in leisure activities, inability to make commitments about any physical activity	Reduction of pain, fatigue, and joint deformity.	Reduction of pain and fatigue
247	Patient	Enbrel	No	04357	Medicaid	Older adults, People with disabilities	PsA	It effects all parts of my life quite a bit.	Pain	Pain, inflammation, sleep, rash, gastro issues, and mental health
248	Patient	Enbrel	No	38018	Insured through employer	People with disabilities	Psoriatic Disease	I'll try not to let it affect my life as much as possible but it's dibilitating days I can't get out of bed.	Not having joint damage	It worked for me for about two years and did a decent job
249	Patient	Enbrel	No	87005	Individual (private) insurance	People with disabilities	Rheumatoid Arthritis	This disease attacks more than just joints. Mobility from joint pain & damage does limit basic daily living, but so does the connective tissue damage, the pain and blurriness of severe dry eye, and most importantly, the debilitating chronic fatigue. Feeding oneself, let alone	Reduce/slow down the damage and, hopefully, ease the fatigue and pain.	It reduced some of the swelling, pain and fatigue.

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								working, can be impossible.		
250	Patient	Enbrel	No	34286	Medicare	People with disabilities	Rheumatoid Arthritis	Caring for myself in most aspects as my hands, shoulders, back, legs, feet, and vascular systems are all affected	At this point in time...pain	None...my lungs filled with fluid & was hospitalized twice in 4 months

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251	Patient	Enbrel	No	12413	Insured through employer		Rheumatoid arthritis	I have daily joint pain and stiffness. I am more tired and have less stamina and strength, and drop things a lot. I need to rest more and take breaks during many activities. I'm unable to do things I enjoyed such as hiking and volunteering as a firefighter. I've had to modify how I do things or ask for help because I'm not strong enough. Many activities cause pain, like walking or standing for extended periods. My anxiety and depression have become worse, I believe, because of the limitations I have. I worry about the changes in my body that I can't see, such as joint damage and the effects of RA on my heart. I also think about becoming a burden on my family because of my limitations. When the pain, stiffness and swelling are bad I	The most important outcomes for me are relief/reduction of pain, swelling, and stiffness and longer term prevention of damage to my body.	I have seen a reduction in pain and stiffness and fatigue along withfewer flares since being on Enbrel.

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								have to rest for days and take more medication to get through the flares. I fear becoming trapped in my own body someday because of RA.		

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
252	Patient	Enbrel	No	23322	Insured through employer	Children and families	Rheumatoid Arthritis	pain/discomfort, work, leisure activities, some mobility	to lesson pain and discomfort and allow me to live a regular life	I only used drug for 3 weeks because I developed allergic reaction to injection and had raised hives and itching at injection sites. The drug was working on condition though.
253	Patient	Enbrel	No	24184	Individual (private) insurance	Older adults, People with disabilities	rheumatoid arthritis	my mobility is affected, as are housework, family and leisure activities.	To be pain-free, and to enjoy life much more.	I didn't think there were any until I had to forego one weekly dose of my Enbrel. The difference was terrible, as the pain was greatly increased, as was the necessity to limit my life and leisure activities due to the pain and inflammation. My life enjoyment was severely impacted.
254	Patient	Enbrel	Yes	80004	Medicare	Older adults	Rheumatoid Arthritis	Affects usual activities	Relief from pain of	Some relief from pain
255	Patient	Enbrel	No	10036	Insured through employer	Older adults, People with disabilities	Rheumatoid arthritis	I am now disabled	Having my condition under control	It didn’t help me
256	Patient	Enbrel	Yes	80207	Individual (private) insurance	People who are lesbian, gay, bisexual, transgender, queer, or questioning,	rheumatoid arthritis	periodic flares that keep me from moving my limbs freely or without pain, depending on severity	lack of pain and inflammation and protecting the long term health of my joints	Keeps my flares to a minimum

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						Children and families				
257	Patient	Enbrel	Yes	80907	Insured through employer	Children and families, People with disabilities	Rheumatoid arthritis	It is completely debilitating affecting mobility (ambulatory wheelchair driver), limited use of arms/hands, organ damage, multiple reconstructive surgeries, extreme care needs.	The ability to work and function.	The ability to work again.
258	Caregiver	Enbrel	Yes	80121	Insured through employer	Children and families	Juvenile arthritis	She has mild pain daily but mostly does everything she wants to do.	Getting to remission	Massive pain reduction, full range of motion w affected joints
259	Patient	Enbrel	Yes	80004	ACA Plan		RA and switched when I developed UC as well	Chronic, Pain and fatigue	Living a more normal	Remission
260	Patient	Enbrel	Yes	80130	Individual (private) insurance	Older adults, Children and families	Psoriatic arthritis	Unsightly skin condition that affects mental health and perception by others. The sore stiffness in joints is also debilitating at times	A more normal lifestyle free from ridicule or pain	Actually I have taken Humeria, Enbrel, Cosentyx, Stelera and Tremfya at one time or another for various periods of time with varying results. Enbrel the longest. It helped

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
										me manage the negative effects of my condition.
261	Patient	Enbrel	Yes	80524	Medicare	Older adults, People with disabilities	Rheumatoid arthritis	It affects my physical abilities. It can be difficult to exercise or play any kind of sport. I also fight fatigue.	Painlessness, no fatigue and more energy would be great!	Less pain, less fatigue & more stamina.
262	Patient	Enbrel	Yes	80122	Insured through employer	People with disabilities	rheumatoid arthritis	Enbrel was one of the drugs that I have been on to treat my RA. This biologic did help me to continue to function and work, care for my family. I have had been on a lot of biologics and know that this one makes a huge difference for many. In my situation, I had burned through all of the drugs in that class and it was time to move onto a different class of biologics.	The ability to function daily with decreased to no pain and slowing or stopping of the disease progression. Remission is the goal.	Ability to live a normal life due to decrease inflammation and pain

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263	Patient	Enbrel	Yes	80027	For most of the time I was on Enbrel, I had student insurance through the University of Colorado. This is when I encountered the most difficulties affording the medication. After I was married and on my husband's private insurance, it was easier.	Children and families	rheumatoid arthritis	When my rheumatoid arthritis is not well controlled, I have extreme difficulty functioning in my daily life. Depending on which joints are impacted, I can have difficulty walking, doing housework, sitting at my desk, typing (which is extremely problematic as I work as a writer), driving, sometimes even lifting a mug to my mouth to drink. Uncontrolled RA can also come with intense fatigue, which makes it very difficult to care for myself and my three children. All of this can come with a great deal of guilt and anxiety. Uncontrolled RA impacts not just me, but my entire family.	I need to be able to function in my daily life. Pain and fatigue need to be minimized so that I can complete my work, take care of my family, and enjoy my life.	I am a working mom of three small children, and an effective biologic is essential for me to be able to function well enough to care for myself and my family. Enbrel was the first biologic that ever got my RA under control after my diagnosis. It allowed me to finish my dual degree graduate program and earn a law degree and a masters, which would not have been possible with uncontrolled RA. Enbrel was also the medication that eventually got my postpartum flare under control after my first son was born, and allowed me to experience being a new mom without the added burden of pain and fatigue from RA (on top of pain and fatigue from just being a new mom!). Enbrel also controlled a terrible flare during my difficult second pregnancy, allowing me to care for my first toddler son and significantly reducing

ID #	Patient/Caregiver?	Drug?	CO Resident?	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for?	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
										the uncontrolled inflammation that my second son was exposed to in utero.
264	Caregiver	Enbrel	Yes	80920	Insured through employer and Medicaid	People with disabilities	Psoriasis	Extreme skin breakdown/itching, capacity to attend school, pain in joints	Consistent management of symptoms to minimize breakthrough episodes	Psoriasis is fully managed - instead of plaques head to toe my son experiences very few outbreaks now

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265	Patient	Enbrel	Yes	80246	Medicare	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People who have AIDs or HIV, People with disabilities	Rheumatoid Arthritis	All areas asked to considered are all daily challenges I face with this and other health challenges I have: TBI, HIV, post hip replacement and fusions due to the condition treated.	Remission! Ability to be mobile with least amount of pain	I have had no flares or major events while on Enbrel. I have tried 4 or 5 other brand names which produced no results that Enbrel has. I changed many years ago from enbrel to attempt to get the best results and returned to enbrel for the best I've experienced results.
266	Patient	Enbrel	No	82801	Insured through employer		Ankylosing Sponylitis	Quit job due to lack of accommodation, stiff joints, light sensitivity, more fatigue, anxiety	Being able to live a fulfilled life	Less joint pain, less occurrences of uveitis
267	Patient	Enbrel	Yes	80204	Medicare	People with disabilities	Psoriatic arthritis	I am bedridden without it	No pain equals healthier lifestyle	My joints are helped to the point I can work out

Survey Responses Continued

ID#	What adverse health effects have you experienced from using this prescription drug, if any?	What factors led you to the prescription drug you are currently taking? Select all that apply:	Have you tried taking other prescription drugs to treat your condition? If so, how many?	If you have tried other prescription drugs to treat your condition, what were they? Were there any beneficial or adverse health effects of these other prescription drugs?
1	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira and Enbrel worked well when I was on corporate insurance or Obamacare. but are absolutely unaffordable on Medicare (between $4,000-$7,000/MONTH WITH insurance!!). Not an option on a fixed budget. Or any normal person's budget. It is ridiculous that Medicare patients cannot go through the manufacturers copay assistance program. And that Medicare cannot negotiate drug prices. This is putting all the cost burden on the most vulnerable populations - elderly and disabled people. I am on Remicade now which isn't as effective and I have a lot of joint pain. Also my veins are getting scar tissue from Remicade IV infusions and it's getting difficult if not impossible to give me an IV. Remicade is currently THE ONLY afford and arthritis medication other than methotrexate which made all my hair fall out. But soon I will no longer be able to take Remicade

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				due to my veins. And I will be bedridden again.
2	injection site reactions	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira, Enbrel, Taltz, Stelara, Cosentyx. All but Stelara worked for me. Currently on Cosentyx and have seen the most improvement from it.

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3	none, aside from the fact that it only worked for me for about 2 years.	I cycled through other medications that didn't work before finding this one., i started on methotrexate (which made me too sick) and then transitioned to embrel which stopped working. I am now on Humaria.	Yes, two other treatments.	Methotrexate and Humaria. Both work(ed) very well to reduce inflammation and pain. Methotrexate just made me too sick. Humaria is my current drug.
4	None	It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, two other treatments.	Methotrexate and humira
5		first one available in 1990	Yes, three other treatments.	Atonel,
6	Stomach issues first few doses	It was required by my insurance company.	Yes, one other treatment.	Humira. Not effective, no adverse effects
7		It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Remicade, Humira, cimzia, Xeljanz, Rinvoq
8	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, two other treatments.	Methotrexate caused liver damage. I took Enbrel for 10 years before it stopped working for me. That was 10 years of relief though.

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9	Local swelling and itching	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Simponi, humira, Avsola, Xelzanj
10	None	It was required by my insurance company.	Yes, more than three other treatments.	Methotrexate, humaria, hydroxycortaquine
11	Injection site bruising and temporary pain after administration	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Methotrexate- didn't work Plaquenel - didn't work Humira - didn't work and I broke out in a rash over my entire body
12	Lower immune system. That's with all the Biologics I've taken.	The 1st home given Biologic and I had done some research on it. My Rheumatologist thought it was a good decision.	Yes, three other treatments.	MTX(still taking) Remicage- it didn't work well Orencia-worked for a while Plaquenil- bad stomach upset I'm currently on Rutuxin which is working, I've had to raise my dose. Fir all of them, a shot at home(if it works, is stomach easier and you'd think cheaper. My GI track is done with pills.

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13	none	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira, Enbrel, Remicade, Cosentyx, Xeljanz, Rinvoq, Otezla, Orencia, and now Simponi Aria
14	I have not noticed anything more than occasional injection site redness or itchiness which fades after a few hours	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Methratrexate(kidney issues),avara (allergic), humerus (anaphylactic reaction), Orencia, Rituxan, Actemra(too low white blood cells)Rinvog (too low white blood cells)Several other drugs I can't try because of other drug allergies or they work with similar mechanism so rheumy won't try them. Xeljam worked well until it didn't and then I tried rinvog and rheumy won't let me go back to it because of rinvog low white blood cell and they are similar(Jak)
15	Decreased ability to fight infextions	It was required by my insurance company.	Yes, more than three other treatments.	Humira, cimzia
16		I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	

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17	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Naproxen, meloxicam, and other nsaids
18	Chills	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Humira-stopped working after 1 year. Xelganz - didn’t work very well Actemra-on this one now. It’s only been 3 weeks
19	None.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, more than three other treatments.	Don’t remember all the names. I had allergic reactions with my skin, itching, pigmentation reaction, skin peeling.
20	N/A	I went through all of the medications and now we’re retrying previous medications.	Yes, more than three other treatments.	Gold Injections, Methotrexate, Weekly Solumedrol IV’s, Humira, Actemra, Orencia, Remicade, Rituxin

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21	None	I'm currently not on a medication for my PsA due to insurance and affordability	Yes, three other treatments.	Stelara, it worked quite well but my insurance changed and it was no longer covered. Otezela, could not tolerate due to it causing SEVERE depression. Taltz, by far the best medication so far in decreasing my stiffness, my chronic pain, joint swelling, and helping my mobility. Unfortunately I became severely ill with an antibiotic resistant pneumonia and had to stop Taltz to treat it. My rheumatologist decided it was no longer good for me to take due to risk of severe infections/antibiotic resistant infection.
22	Chance of MS	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Actermra

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23	None	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me., Affordability	Yes, more than three other treatments.	Methotrexate, Orencia, Humira, Symponi, Benlysta, Rituxan, Actemera. Extreme side effects to all of these I can only do Actemra at home not IV infusions developed hives immediately as well as to Benlysta IV, anaphylaxis reaction to one treatment had to have epinephrine shots given then had re bound episode at home the following day, Methotrexate made me extremely nauseated still can't take it since taking as child
24	My RA doctor had me take Embrel for a very limited time, I believe for 2 weeks and took me off it quickly as I had a bad reaction. Within a day of the shot, I would get a pain in an area on my back and then a large whelt would pop up. It last for a few hours and would then disappear. The whelts were the size of a lemon. I am currently taking Xeljanz for my RA.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Methotrexate-heart side effects, sulfasalizine-dr. decided to try another drug, hydroxychloraquin-eye issues, Embrel-whelts with pain, Humira-injection site reactions, Orencia-headaches, Cimzia-did not work at all, Xeljanz-seems to work to keep the RA under control.

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25	none	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	puva and light treatments resulted now in numerous precancer or cancerous skin
26	none	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Orencia, Remicade, Humira, and a couple of others I don't remember their names. Had anaphylaxis reactions to Orencia and Remicade. Humira was ineffective.
27	Not sure if the depression is from this medication.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, one other treatment.	Methotrexate. After 9+ years on this medication non reversible, untreatable blurry eyes occurred
28	None that I can remember.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Enbrel, Arava, Otezla and others I can't remember anymore
29	Multiple skin cancers, including two melanomas	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Aspirin, methotrexate, Humera, gold shots, Remicade, Enbrel, Orencia

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30	Initially a rash at injection site that went away the longer I used it	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate and leflunomide, methotrexate just made me feel ill, leflunomide did help some, but not enough
31		It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Hydroxychloroquine, steroids. Still take half the lowest dose of hydroxychloroquine . Steroids helped but addictive, side effects and hard to stop.
32	None	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Plaquenil, methotrexate (still take these) added enbrel. Now I added xeljanz and discontinued enbrel.
33	Immune suppression	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, Enbrel, Methotrexate, and now on double dose of Cosentyx
34	none	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate (caused liver issues needing hospital stay), minocycline (ineffective), Actemra (blood counts went crazy, had to stop), Humira (ineffective), Remicade (anaphylaxis), Orencia (ineffective), Simponi (increased serious infections), Cimzia (increased infections), Prednisone,

ID#	What adverse health effects have you experienced from using this prescription drug, if any?	What factors led you to the prescription drug you are currently taking? Select all that apply:	Have you tried taking other prescription drugs to treat your condition? If so, how many?	If you have tried other prescription drugs to treat your condition, what were they? Were there any beneficial or adverse health effects of these other prescription drugs?
				works but causes other health issues
35	Large black and blue area at injection site, which took more than two weeks to heal	It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Methotrexate injections work well with a little nausea; malaria meds weren't effective; other injection type gave me lung infection-don't remember the name.
36	Nothing beyond it not working for me.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Sulfasalazine, plaquenil, methotrexate, prednisone, enbrel, humera, symponi, orencia. Currently taking orencia which has worked the best.
37	Stomach related pains/ infection/ headaches/ dizziness	It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, more than three other treatments.	Topical steroids / oral steroids/ other injectables and methotrexate- all of which caused me severe adverse reactions such as anaphylactic
38	None	It did not work as well as desired	Yes, more than three other treatments.	Humira, actemra, Rinvoq, orencia, kevzara

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39	Need to monitor liver	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Enbrel, humira and ACTEMRA currently
40	None.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me., It made me feel like I had no disease at all - a small miracle	Yes, more than three other treatments.	Feldene (the generic name is piroxicam) - severely eroded my stomach making it impossible for me to eat. I am taking Lansoprazole for decades because of this. Lansoprazole is expensive. I still cannot drink a quarter cup of regular coffee or anything high in acid or any type of alchoholic beverage. In the late 1990's I tried 2 other NSAID drugs, Celebrex and another one I can't remember. I immediately had heart palpitations. I was screened by my internal medicine doctor who then sent me to a heart specialist who did a stress test which came up with no indications that needed to be treated, which left me very puzzled. UNTIL I saw a TV report on 60 Minutes which discussed the heart related death of a healthy 33 year old woman from these same drugs. The pharmaceutical companies hid the evidence. I also

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				tried several other NSAID's which did absolutely nothing except take money from me. Tylenol and ibuprofen did not help much.
41	None	It's the only one designated for my condition., I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira, Embrel, Orencia, Xeljanz, Simponi Aria, Rituxan (current). Methotrexate, Leflunomide, Placquenil (current). Prednisone (current). Aleve and Arthritis strength Tylenol (current). Most stopped benefits after a period of time-Methotrexate and Leflunomide caused hair loss.

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42	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, more than three other treatments.	Methotrexate alone, clinical trial meds
43	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	
44	Chronic diarrhea, fatigue.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate- headaches, fatigue, nausea, hair loss. Enbrel was next. Then Xeljanz, experienced fatigue, stomach pain, and painful rashes. Then Humira- only fatigue, but stopped it stopped helping my condition after 2 years. Currently on Cimzia, where I experience episodes of fatigue. All medications have caused me to contract viral and bacterial illnesses MUCH more easily.
45	Lymphoma - my rheumatologist had me stop enbrel. I am on prednisone and rituximab infusions	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Gold injections and sulfasalizine- broke out in a rash after 6 months with each

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46	I needed to give myself the injections. Not terrible, just something new. Once I went onto Medicare, I needed to switch to a different drug since Medicare required me to pay around $1000/month. I'm now taking something else. That requires me to drive an hour there and back once a month for the treatment. My markers are okay, but I am losing more function in joints gradually. I know that may happen regardless of drug choice, but it sometimes makes me question the change.	It's the drug my provider prescribed and it works for me., Cost was a factor in change of drug choice	Yes, one other treatment.	
47	None specifically from the drug but my disease got worse while on it	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	Plaquinel, steroids, enbrel, humira, actemra, xeljanz. Now currently on rinvoq and methotrexate. Actemra helped somewhat. Xeljanz worked well but abruptly stopped working after about a year and half- have been on rinvoq since (~3yrs) and it

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				is working well. Have been on methotrexate since 2017.
48	None	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Xeljanz, Humana, orensia, kevzara, symphoni Aria, methotrexate, luflunamide, hydroxychloroquine, Prednisone and a few others I can't remember right now. They all had kick started my disease back down instead of full flare up till they stopped working and had to switch. I had an allergic reaction to a couple of them that caused an itchy rash.
49	None.	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Prednisone; methotrexate; kineret;

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50	I have experienced no adverse affects thus far.	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	In the first year until I could get into the RA doctor, my PCP put me on Etodolac. I had to take it morning and night and it allowed me to walk like I was very old, but I could walk. I could use my hands, even if only like claws. My doctor said due to the dangers of staying on that med they wanted me to see the RA doctor to get me on another more effective with less ill heath effects.
51	Increased blood pressure and glucose.	It was chosen by my doctor. I had to switch though due to the side effects of the blood pressure and glucose.	Yes, three other treatments.	Cosentyx, Tremfya, Humira
52	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Only a series of anti inflammatories then methotrexate then another I can’t recall the name of
53	None	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	MTX
54	Bruising at injection site	Affordability on Medicare, I had to change to a new biologic therapy	Yes, two other treatments.	Inflectra once I had an eye detachment from hydrochloride

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55	None that I know of.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Prednisone, methotrexate, Celebrex, Naproxysn,
56	immuno compromised	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Leflunimide, Methotrexate,
57	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Sulfasalazine (rash), Prednisone (for a year and a half - I had many odd side effects), I tried a few other pills that I can’t recall (but didn’t work as I tried to stage off steroids)
58	Sometimes it doesn’t go far enough to reduce pain and lack of function	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	I used methotrexate for a few years after first diagnosed but it made me tired and prevented me working to my best capacity
59	unknown	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	methotrexate, quinine, NSAIDS, goldsalts injections, Humira, Remicade

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60	None but it stopped working after six weeks.	It's the drug my provider prescribed and it works for me., No longer taking it.	Yes, more than three other treatments.	Methotrexate-(MTX) initial drug I took. Didn't offer symptom relief by itself. When dosage increased and paired with Enbrel, had good results. When Enbrel stopped working, came off MTX. Later had to switch from pills to shots for better symptom control. After achieving remission, took MTX shots only, but didn't hold back the disease. Dosage was increased but caused gastric distress so had to be reduced. Had to pair with another biologic. Leflunomide- worked well but had an allergic reaction (rash). Steroid shots- worked well for short term symptom relief but negatively impacted eye pressure and sped up cataract development Humira- did not control symptoms until paired with MTX. Reached remission in symptoms but then

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				immune system became too depressed and began having infections. Had to discontinue. Orencia- current medication. Works very well paired with MTX. Beginning to reduce MTX.
61	None besides occasional injection site reaction.	It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Methotrexate, an antibiotic, and Humira.

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62	Didn’t have but it lost it’s effectiveness so I changed my meds	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Limited benefit, Otezla caused a dangerous high fever 6 months after starting. Rare issue
63	very few, just mild injection site reactions	It was the first we tried beyond methotrexate and it worked well for several years. I no longer take it	Yes, more than three other treatments.	I tried humira but it never worked for me. I tried Cimzia and it worked for a while, then I got cancer and was taken off it. I tried planquenil for a while, but I worried about my eyes. I currently take methotrexate and simponiaria
64	None	It's the drug my provider prescribed and it works for me.		Predisone
65	I have not had any adverse effects using Enbrel so far. The only downside is that using Enbrel means any vaccines I get might not provide as much protection as others. I am always up to date on vaccines as Enbrel does	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, three other treatments.	I have used Humira, Orencia and Xeljanz previously. I was on Humira when I got MERSA and then went to Orencia. My symptoms got worse and then tried Xeljanz. My doctor said new studies showed Xeljanz could worsen heart issues; my brother and sister have Afib so I’m now on Enbrel.

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	compromise my immune system.			
66	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate, prednisone, leflunomide, sulfasalazine, hydroxychloroquine. Nausea/vomiting with sulfasalazine; severe diarrhea lasting months after stopping leflunomide; infections with prednisone; and none worked even close to as well as Enbrel for my symptoms. With Enbrel I was able to get off of disability (both my employer disability policy and social security disability)and go back to work as a physician.
67	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Several biological- respiratory side effects

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68		It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, one other treatment.	Sulfasalazine, I am allergic
69	no adverse effects except it just didn't do anything to stop or slow RA progression.	I cycled through other medications that didn't work before finding this one., i tried everything available. some did nothing. some i was allergic to.	Yes, more than three other treatments.	cimzia, simponi, orencia caused allergic reactions. kevzara adversely affected my white blood cells. the rest didn't help enough: humira, xeljanx, and i don't recall the others.
70	Discomfort from injections- I DO NOT LIKE NEEDLES (of ANY sort),& therefore these medications are NOT a good fit for me overall, without QUICKLY NOTICEABLE& SUBSTANTIAL RESULTS- in How I Feel.	At the time it was newer and a main trial or fail drug, I was on for a bit of time it did not help my disease.	Yes, more than three other treatments.	I am a longtime RA patient who tends to be unique in a sense that it seems Nothing has worked for all of my issues, I tend to have these meds work for a time and then they just DONT, and so I've tried and failed Many medications for this diese over my many torturous years of living with RA- but grateful for every trial, hopeful there with be one that works… someday! Too many to list.
71	None	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, three other treatments.	Methotrexate, Humira, they stopped working

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72	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	prednisone, methotrexate, others I can't remember the names
73	Reduced immune response and sicker longer.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Plaquenil, never saw improvement, Otezla, worked great for multiple years but significant GI issues impacting life, Methotrexate, increased liver enzymes, Humira, worked well for years but got sick and had to stop short term and never worked after, Cimzia, developed Palmar Plantar Pustular Psoriasis and had to stop.
74	Just mild itching at the injection site.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Orencia wasn't beneficial at all. Hydroxychloroquine, Azathioprine, Arava was prescribed prior to Enbrel. I have taken methotrexate since 2007 when I was first diagnosed with RA and haven't had any adverse health effects.
75	RA flares	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Methotrexate - caused liver damage

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76	Weight gain and difficulty sleeping.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Several biologics (Humira, Orencia, Cosentyx, Otezla, Remicade, Simponi, Tremfya) that all lost efficacy quickly and any oral drug have adverse effects on my liver. Currently on Taltz.
77	None	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Humira, remicade, symzia,
78	Infections	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira made me worse, Orencia made me worse, Actemra made me worse, Hizentra is the only drug that has helped but is on the bottom of the “fail first” list
79	Redness at injection site	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	I don't remember the pills
80	dont know!	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, one other treatment.	Light therapy, homepathy and Naturopathy

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81	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, Stelara, Otezla, Remicade, Tremfya. I had anaphylaxis with Remicade, infections with Stelara and Humira. I also have had several skin cancers.
82	Painful injection site	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, three other treatments.	Methotrexate (currently taking), Orencia (by infusion, currently taking), Humira (didn't work, Enbril (didn't work), Remicade(infusion, worked well at first and then plateaued and stopped working) The combination on orencia and methotrexate is working best currently
83	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Diclofenec, lyrica, Gabapentin, Humira, Enbrel, now taking Skyrizi and it's working for me. Humira worked for almost 3 years and t then started making my symptoms worse. Enbrel didn't do anything really. The others helped a little but not enough.

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84	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Enbrel, Orencia, actemra, kevzara all worked for months then lost their effectiveness. I had an allergic reaction to Orencia
85	None that I know of.	It was one of the few biologics that my rheumatologist could get free samples of. At the time I started the drug I could not afford it. This was before the drug company “charities”.	Yes, more than three other treatments.	Methotrexate made me feel like I got hit by a bus. Orencia didn’t work. Simponi gave me an anaphylactic reaction. Cinzia worked if I took more of the drug than was prescribed, but it didn’t work well. And I took a whole host of older drugs which the insurance company required before I could try a biologic, but I don’t remember their names. I want to say that one was Arava. They didn’t work for me.
86	None	It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Humira, methotrexate, taltz
87	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate: no benefit, caused nausea; prednisone: worked well, but caused weight gain; steroid joint injection: worked very well, but can’t have repeatedly

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88	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Mtx, Humira, xeljanz, remicade and simponi
89	I had significant injection site reactions and little benefit from the medication at the time I was taking it.	I cycled through other medications that didn't work before finding this one., Only one approved with a history of cancer.	Yes, more than three other treatments.	Sulfasalazine, Methotrexate, Plaquenil, Orencia, Enbrel, Humira, Rituxan, Celebrex, Prednisone, Meloxicam, Sulindac, Cymbalta
90	Suppressed immune system	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate, humira, orencia, sulfasalazine, Rituxan. The only medication I have EVER responded to is Rituxan. (I took Enbrel for 3 months and then stopped because it didn't work for me.)
91	Sick more often	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, three other treatments.	Plaquenil, methotrexate, humira. Plaquenil and humira stopped working, methotrexate made me nauseous
92	It stopped working.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Avera, methotrexate, enbrel, xeljanz, plaquenil, none of these worked.

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93	Migraines	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Celebrex, Otezla, Cosentyx, Skyrizi
94	Continuing pain when the medication did not work for me.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira, Enbrel, Remicade, Rituxiban, and a couple more
95	Extreme neuropathy in feet and legs, and loss of balance both continue after stopping the drug more than 10 years ago. The slurred speech, clouded thinking and visual disturbances cleared up fairly quickly after stopping the drug.	I cycled through other medications that didn't work before finding this one., I am not taking a biologic, just methotrexate and prednisone	Yes, one other treatment.	Orencia-no effects at all
96	None	I cycled through other medications that didn't work before finding this one.	Yes, one other treatment.	Humira, organ shutdown

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97	None	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Methotrexate no adverse effects, Hydrochlorothyazide noadverse effects
98	None that I know of however I have to be tested several times a year to be sure my kidneys aren't being compromised by a biologic	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Methotrexate = severe fatigue and nausea Remicade = no relief Enbrel = was effective for a brief period then no longer worked on my condition. Xeljanz = nausea, rash Cosentyx = current med
99	I had injection site redness and huge hives and itching	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Rutuxan-throat and eyes closed, itching, it worked but wasn't with the side effects Xeljanz worked the best with no side effects. Cost too much Humira same as enbrel for side effects Methotrexate cause upset stomach and nausea Many more but can't fermenter the names

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100	No bad effects	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Celebrate, methotrexate, meloxicam
101	None that im aware of	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me., I get the medication free due to my income	Yes, three other treatments.	Methotrexate, Humira and packwanil
102	None	It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, three other treatments.	My health insurance dictated that I also try Remicade (no effect); Kineret (intolerable GI side effects), and Cimzia (worked well, but insurance company took it off approved drug list).
103	none	It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, three other treatments.	humira, infusions,
104	None	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Meloxicam, Robaxin, ibuprofen,

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105	None.	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Methotrexate, Leflunomide, Prednisone, and also Hydroxychloriquin (which I take with the Enbrel)
106	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	
107	Makes me more at risk for things like COVID, flu, and other diseases	It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	Plaquinal and methotrexate
108	Allergic reaction at injection site, issues taking them with other drugs for other conditions	It was required by my insurance company.	Yes, more than three other treatments.	Humira, Enbrel, Cimzia, Rutixan, xeljanz, Rinvoq, olumiant, orencia. Some were not covered by insurance after a year, many didn't work at all.
109	It stopped being effective.	It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Humira, methotrexate
110	None.		Yes, two other treatments.	Arava, methotrexate

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111	None that I know of	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Benefit was modest at best. No adverse reactions.
112	I had infections and felt ill. Several starts and stops. It was the pharmacist who suggested we try the pediatric dose because of my body weight. The 25mg injections were better. After a long bit of those I was able to tolerate 2 of the 25 mg injections per week.	I am only taking prednisone now as I refused Humira and I had tried a number of others. Now there is dispute between my specialists.	Yes, more than three other treatments.	Methotrexate, Leflunomide, Sulfasalazine, Enbrel. Infections, weight loss, GI issues, headaches.
113	Migraine, nausea	It was required by my insurance company.	Yes, two other treatments.	Humira - adverse migraine reaction, Rinvoq - benefits of decreased pain
114	Permanent damage to and decreased function of my lungs	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, two other treatments.	Cosentyx and Skyrizi
115	Bad nasal congestion daily.	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Diclfenac sodium. Then Enbrel when pain & stiffness got worse.

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				Muscle relaxers and other anti inflammatory meds too.
116	n/a	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Humira, Orencia
117	NA	Tried it but it didn't work.	Yes, more than three other treatments.	Many.
118	Get sick easily due to suppressed immune system, dry mouth leading to dental issues, frequent painful infections on my fingertips	It's the drug my provider prescribed and it works for me., Enbrel was the first drug I was prescribed for my condition, after about a year is lost efficacy and I changed to a different medication	Yes, more than three other treatments.	Humira (had benefit until it stopped working after a year or two, same adverse effects as enbrel), Cosentyx (have been taking this for years and it seems to still work, same adverse effects as enbrel), Indocin (some pain relief, coffee ground stools), Mobic (some pain relief), amitryptaline (no benefit, lowered seizure threshold a leading to my first seizure incident), gabapentin (some pain relief but caused sensory issues and had to lie down on with eyes closed all the time), various muscle relaxants (tend to make pain

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				worse, very unpleasant side effects) etc etc
119	none	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	
120	The only effects that I had was that it stopped working for me, and I needed something stronger or different.	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Humira injections was not effective for me
121	The pain and being able to get up and move around	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Steroids

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122	After using for about 4 years ot stopped working for me.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	I've tried many and they work very well, until they don't. While using I did get many infections as these meds inhibit your immune system.
123	none	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Orencia, Simponi, Remicade, methotrexate, Xeljanz and others, both IV and oral
124	It stopped being effective	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	Humira, Tremfya
125	None	trying to find a medication that works for me	Yes, more than three other treatments.	Orencia, Xeljanz, Rinvoq, Intracept, Humira, plus more
126	Stopped working	Provider suggested & worked for 2 years	Yes, more than three other treatments.	Methotrexate, simponi, otezla, xeljanz
127	None	It was required by my insurance company.	Yes, two other treatments.	Hummers, Orencia

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128	Pneumonia bruising flu symptoms	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Humira cosentyxmotrin celebrex
129	The effects of the drug ended cold turkey after around 8 weeks	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Enbrel was the 1st, I'm on Cosentyx, I've done otezla, Remicade, Skyrizi, and many others (21 yrs)
130		I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Methotrexate
131	Injection site reaction	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	Enbrel, Humera, methotrexate, xeljanz, Otezla
132	More cautious during pandemic and if exposed to sick people	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company., The method of delivery or injection works best for me.	None	Oral and injections of Methotrexate

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133	Pain during injection. Not from the needle, but a burning sensation from the drug.	It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	NSAIDS, sulfasalazine, methotrexate alone
134	I didn't have any jus couldn't afford it	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	They seem to help for awhile and then stopped helping
135		I developed Giant Cell Arteritis and Enbrel was one drug that addressed that condition.	Yes, more than three other treatments.	methotrexate caused long term adverse GI conditions, Humira, Cimsys, several more
136	Occasional discomfort at injection site	I cycled through other medications that didn't work before finding this one.	Yes, one other treatment.	Methyltrexate It caused me to have severe Anemia at the dose that was effective and it is a severe immune system suppressor
137	Immune suppression	It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	
138	None	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Methotrexate, other biologics

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139	I got infections very easily I had a couple that was pretty serious	It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, three other treatments.	Remicade gold treatments orencia
140	None.	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Methotrexate - still use it along with Enbrel. Methotrexate pills made me very nauseous - switched to injectable and that solved the problem. Methotrexate gave me some relief, but only some (better than nothing). The Enbrel changed my life: it made life worth living again.
141	I am unsure of how or if I suffered any negative effects from Enbrel	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Otezla
142	6hr headache and fatigue	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Don't remember all 7 of them
143	None	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira-worked but developed cancer, rituxan-didn't help, Orencia-allergic,

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144	Possibly fatigue, diarrhea day after injection	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Methotrexate (no benefit, severe nausea), Humira (benefited for a week only but only a biweekly injection was approved), Rinvoq (no benefit)
145	Recurrent sinus infections	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Prednisone , methotrexate, meloxican
146	None	It was required by my insurance company.	Yes, more than three other treatments.	Lots of bad side effects. Plaquenil seems to be helping some
147	none it just didnt help.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Enbrel didnt work, Humera, angioedema , one I dont remember, Xeljanz works!, Xeljanz XR works
148	none	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	most recent is Cosentyx which is causing thrush

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149	None	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Remicade,Cimzia,Cellcept,Orencia, Leflunomide and Methotrexate currently taking Hydroxychloroquine only it works well for me initially gave me GI problems but have since resolved.Remicade worked well but developed a rash and so had to stop the medication.Got a UTI from Cimzia had to stop that medication too.Had a adverse reaction to Cellcept had some abnormal blood tests while on it.
150		I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate chronic nausea, sinus issues
151	Localized swelling at the injection site, swelling of the tongue and hives.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, enbrel, cimzia and rinvoq

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152	Brain fog - diarrhea- non reduction of inflammation.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Rinvoq and Ibuprofen is my current drug and is working great to treat my symptoms of RA, with minimal adverse effects. These drugs I have used in the past- Enbrel, Plaquenil, methotrexate, steroids, Humira, Cimzia, Orencia, Celebrex, hydroxychloroquine, meloxicam, sulfasalazine, - Adverse effects with all of these past drugs.
153	None.	It was required by my insurance company.	Yes, one other treatment.	Methotrexate. I experienced extremely severe side effects and could not continue.
154	None	It's the drug my provider prescribed and it works for me.	None	None
155	Problems with my teeth	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Gold, plaquinal, methotrexate, humira, Enbrel
156	Sometimes I have a hard time falling asleep on the day of injection	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	I first tried Humira but I kept getting sick all the time on it

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157	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	
158	Pain at injection site	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	
159	Reaction at injection sight, and it made me sleepy like taking a sleeping pill.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Humira, kezvara (reaction)simponi, xeljanz, (effective 1yr)paquil methotrexate orencia(current)
160	Injection site reaction.	Transferred to Remacade Then stopped treatment all together.	Yes, more than three other treatments.	Prednisone Plaqunil. Reaction to sunlight. Methotrexate. Made me very nauseated for days didn’t help Enbril. Injection site reactions moderate improvement of symptoms Remicade.suspended use due to cancer diagnosis. Worked well though.
161	none	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Actemra helped, but it gave me heart palpitations and made me

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				tired. Rinvoq did not help. Humira did not help.
162	esinophilia cellulitis	It was required by my insurance company.	Yes, more than three other treatments.	Remicade, Arava, Olumiant, Xeljanz, plaquenil, orencia, rynvoq, etc Improve condition for awhile.
163	None.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Orencia, Remicade, Rituxan, Renvoq, Methotrexate. Mild increase in liver function, flushing of face, mild stomach upset, mouth ulcers.
164	Overall none but knowing it decreases body to fight infection especially when COVID was bad just had to be real careful about who or what I was around.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	I've tried a lot since I was 23 when I was diagnosed but enbrel was one that I used for many years before having to switch. It was the best one to control my overall pain and cleared my skin 100% outside of the one I'm currently using.
165	none	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate, Plaquenil, major side affects

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166	None	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	I tried methotrexate, was on Embrel for a year, then took Humira and now I'm on Orencia.
167		It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate, Cosentyx - I prefer medications that don't have documented adverse effects
168	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, cosyntex, remicade, simponi aria, talts
169	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	It was several years ago and I don't remember what they were.
170	None	It's the drug my provider prescribed and it works for me.	Unsure	?
171	None	It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, one other treatment.	Methotrexate

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172	Pain at the injection site	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	Methotrexate - nausea Hydroxychloroquine - worse nausea
173		It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	
174	After about 18 months it stopped working	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Many! At least 8. Most worked well at first then stopped.
175	increased UTI	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Remicade, Leflunomide-gave me Auto-immune Hepatitis, Methotrexate, Humira, currently taking Azathiopine. will be evaluated in a month to start a new RA drug because nothing is working for me
176		I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Arava-hair loss; methotrexate-not effective enough:sulfasalazine-not effective: hydroxychloroquine-not effective

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177	Minor bruising at the injection site. Lack of appetite 24-48 hours after injection. Occasional upset stomach or loose stool 24-48 hours after injection.	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Rinvoq, humeria, methotrexate. Similar side effects. Methotrexate also caused blisters on the tongue.
178	None		Yes, three other treatments.	Methotrexate was ineffective and caused intense nausea and side effects. When I lost prescription coverage for enbrel I switched to simponi and then remicade, which have not been quite as effective as enbrel..
179	I have to be very careful when I get sick. I got Covid in July 2022. I didn't recognize the initial symptoms and took my normal dose of Enbrel which suppressed my immune system. I think I got sicker as a result requiring monoclonal antibody treatment.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Methotrexate - potential lung issues. Initially worked well in conjunction with Enbrel. Currently taking Sulfasalazine in conjunction with Enbrel. Naproxen didn't work. I took Celebrex but stopped due to potential heart risks. Currently take prednisone as needed when addressing flare ups. Cortisone shots in joints when needed during on-going flare ups. Arava didn't work after about 9-12 months and

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				created increased liver enzymes over a few consecutive months.
180	none	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Simponia Aria, Methotrexate, I can't remember the others
181	Allergic signs at second does.	My rheumatologist went through several medications before finding one that I was not allergic to.	Yes, more than three other treatments.	I honestly don't remember as my treatment has been going on for 5+ years now.
182	Headaches first few injections, after maybe two months they stopped. Had on-site rash reactions, waiting to inject until after I showered helped limit the rash.	My dr wanted to provide me relief without damaging my body with harsher options	Yes, one other treatment.	Humira, yes it was beneficial. Had stomach issues the first few injections, after that was ok.

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183	Zero	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., Biologics stop working after a while and need to be switched. I've been on one for 18 years	Yes, more than three other treatments.	Methotrexate, Enbrel, Humira, Simponi, Stelera. No notable side effects. They work until they don't and need to change. Only exception was switching from Humira to Simponi was insurance motivated not drug effect.
184	No immune system.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	They work until they don't. Overall they're all the same.
185	Sick too often before the pandemic.	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Humira and methotrexate along with a bunch of different topical creams and shampoos.
186	None, as far as I know	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	Prednisone tabs, Xeljanz, Humira injections. Health effects were mostly beneficial, except for Prednisone - made me put on weight and also weakened my bones

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187	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Plaquenil, methotrexate, arrava, sulfasalazine, humira, motrin. Adverse health effects with both methotrexate and arrava. I continue n sulfasalazine and motrin as they have both been beneficial. Humira worked for a long time as I was able to use it for seven years and it reduced inflamed joints and was slowing bone erosion.
188	There are side effects, most manageable so far.	The method of delivery or injection works best for me.	Yes, more than three other treatments.	sulfasalazine, hydroquarline ? sp, celebrex, methotrexate, + more i can't recall at mo
189	Continuous sinus infections, colds and pneumonia.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Since I've been living with RA since age 5, I've tried most of the common anti-inflammatory drugs, such as Gold Injections, Arava, Ibuprofen, Methotrexate, Humira and more.
190	Injection site inflammation controlled with allergy medication.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, Enbrel, hydroxychloroquine, methotrexate, Actemra, Orencia, Kevzara (with reaction of blisters at the injection site). Actemra and Orencia worked well until they didn't. Currently I am on azathioprine orally and

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				Rituxan infusions which are working well.
191	After many years of normal lab results, my neutrophils dropped dramatically. I had to stop Enbrel due to this. I waited several months and restarted it, but the issue persisted so I had to stop permenantly.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Methotrexate, prednisone, Plaquenil - all beneficial, just not adequate.
192	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate works but caused pancytopenia. Sulfasalazine was stopped due to kidney failure. Plaquenil didn't work. Enbrel worked a few months and then stopped same with Humira. I am now on Rinvoq which worked for 2 months and seems to be not working anymore.

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193	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Gold, asulfadine, methotrexate many others
194	It was extremely painful to inject. I have been on several medications that I had to inject so it wasn't giving the injection that I had a problem with. Enbrel felt like I was injecting fire.	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	Rituxan, methotrexate, plaquenil, arrava, Simponi(both the IV version and the injection version),sulfasalazine, orencia and xeljanz. I am currently taking xeljanz, methotrexate, and plaquenil. I had digestive issues with sulfasalazine. Rituxan worked really well for several years, but stopped working. A few years ago, I was taking several medications for my RA and got an infection that they couldn't get to clear up, but I don't remember what those meducations were. The other medications either didn't work, stopped working, or the insurance company refused to approve.
195	N/a	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate, 2 others and Embrel

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196	Didn’t work	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Stelara, Simponi Aria,
197	I had to stop Enbrel at 3 months, because I felt like bugs were crawling all over me. I reported this to the pharmacist at Enbrel.	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Sulfasalazine-no improvement. Methotrexate-no improvement, severe fatigue. Humera-minimal improvement, severe leg cramps. Xeljanz-amazing improvement for 4.5 years, then it quit working. Olumiant-minimal improvement, headache, chest pain, leg cramps. Leflunomide-numbness/tingling in fingers, increased blood pressure, balance issues. Rinvoq-worked moderately well for a short time then quit working. Orencia-currently taking. Noted improvement.
198	do not remember since it was years ago	dr prescribed when other meds did not work. when it didn't work well enough moved on to other drugs	Yes, more than three other treatments.	methotrexate- mouth sores, orencia- difficult to find veins, xyljenz- quite due to cost, cimzia taking primarily because of cost in the medicare system

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199	No adverse effects with the exception of site injection minor irritation	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate and hydroxychroquine. Both had several adverse effects like hair loss, headaches, dizziness and nausea.
200	The medication absolutely failed to remediate any of my sequelae of rheumatois srthritis.	It's the drug my provider prescribed and it works for me., My sed rate improved	Yes, more than three other treatments.	opiod pain medication, NSAIDS, sleeping medication
201	Frequent infections, increased fatigue, injection site inflammation	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	Methotrexate, remicade, rituxan, humira, arava, actemra, orencia- medications did not work and caused various side effects including nausea, vomiting, frequent infections, hives, extreme fatigue, diarrhea, muscle pain, injection site inflammation. I have also taken xeljanz and Olumiant. Neither caused side effects and did reduce disease activity.

ID#	What adverse health effects have you experienced from using this prescription drug, if any?	What factors led you to the prescription drug you are currently taking? Select all that apply:	Have you tried taking other prescription drugs to treat your condition? If so, how many?	If you have tried other prescription drugs to treat your condition, what were they? Were there any beneficial or adverse health effects of these other prescription drugs?
202	pain at injection site, did not work as effectively as I had hoped	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	methotrexate (was unable to live on this - severe adverse health effects, including severe nausea and fatigue, constant sores in mouth); Humira (worked well to reduce my arthritic pain and psoriasis but stopped working after a year); Taltz (current biologic - working the best of the four meds to reduce my pain and number of flares)
203	None	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Methotrexate liver test were not good discontinued it
204	Prone to infections unless I'm very careful	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Methotrexate, hydroxychloroquin, Arava, Imuran, sulfasalazine, Humira
205	none	I cycled through other medications that didn't work before finding this one., Enbrel works for me. Humira did not work. Enbrel worked for daughter, so I gave it a try.	Yes, more than three other treatments.	Steroids caused depression, NSAIDS didn't work, oral drugs did not work or caused a rash

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206	I began to have allergic reactions to the medicine over time, I guess from the autoimmune aspect of the disease as I used it more over time my body began to reject it.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, more than three other treatments.	Remicade- I eventually began having unmanageable allergic reactions to the medicine so I was switched by my provider. Humira- also began having unmanageable allergic reactions to this medication. Prednisone has always been a part of my medication regime. Leflunomide- has been a mainstay medication for my treatment also.I tried Otezla but the nausea was to difficult to tolerate.
207	My hair did get a litter thinner, but whether that's the Enbrel I cant say for sure	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Humira and methotrexate
208	None	It's the only one designated for my condition., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate, predine zone,Humira and Leuflafidid.
209	None so far.	It's the drug my provider prescribed and it works for me.	None	None
210	None	It was required by my insurance company.	Yes, three other treatments.	Orencia, Xeljanz XR, Humira

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211	None	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate and plaquennel
212	Slight rash at the injection site and mild hair loss.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate and Humira
213	More infections.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira, Kineret, Orencia, Actemra,
214	None	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Did take Methotrexate but have stopped taking it about 3 months ago
215	None when it was working.	I cycled through other medications that didn't work before finding this one., It stopped working after 23 years.	Yes, two other treatments.	Azulfidine and methotrexate. Alergeric to sulfa and methotrexate made me very sick.
216	Severe headache, nausea and vomiting. Have reacted the same to other biologics	Using rinvoq methotrexate and leflunomide	Yes, more than three other treatments.	Rinvoq Methotrexate inj, prednisone leflunomide. Tried humira not able to tolerate

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217	I was more susceptible To colds, pneumonia.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Orencia, Humira, Remicade, Taltz
218	none	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Cimzia and 1 other. Cimzia works the best for me. Am not taking Embrel or the other injectible (can't remember the name). No adverse health effects.
219	Nausea, diarrhea, tingling in extremities, hot flashes.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira (same deal as Enbrel; it worked really well for several years, then just stopped working); Xelganz (I had an anaphylactic reaction to it and couldn't take it); methotrexate (I currently take it; it's the only thing that's reliably helped me over the years; terrible side effects: nausea and diarrhea, exhaustion...but it's the only thing that really keeps the RA under control); Orencia (I currently take it and it works about as well as Enbrel did before Enbrel stopped working); Nabumetone (I currently take it; it helps with pain and inflammation).

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220	I know it makes me more prone to infections, but I have not experienced any change. I am careful to boost my immune system regularly.	It's the drug my provider prescribed and it works for me.	Yes, one other treatment.	Prednisone…elevated my pain and inflammation, but I didn't like the side effects.
221	The weekly injection is painful and since it requires refrigeration it is difficult to travel.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Kiniret, humira, orencia, all we not controlling the progress of the disease. Remicade caused hives. Methotrexate, meloxicam, tramadol, metrol.
222	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, Actemra, Orencia , Simponi, Rinvoq, Kevzara and others. Had stomach issues with Rinvoq.
223	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate (both injection and pills) - Adverse effects: Digestive issues, headaches, inflammation not well managed). Humira injection - didn't manage pain and inflammation well enough. Celebrex - only assists in the management of inflammation and some pain.

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224	None	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Methotrexate - severe nausea. / Currently taking Humira and Leflunomide without problems.
225	None	I researched it	Yes, one other treatment.	Methotrexate, I still take
226	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	I could not tolerate methotrexate as the starting dose gave me severe abdominal pain and diarrhea for 24 hours after taking it. It wasn't even the dosage that I would eventually be on and it was not worth it to me to be that sick once a week for the rest of my life. I took methotrexate twice. I was on hydrocholoquin which was stopped by the rheumatologist because it was hard to know if it had any benefit. It was the first drug I was started on for my RA. I took Orencia weekly for about two years and it stopped working and was the. Started on Enbrel and Leflunamide. I started to get basal cell carcinomas every three months. I had a stage 1 melanoma on my ear and I stopped the medication. I also had a lot of

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				loose stool and stool urgency with the Leflunamide. I have been on Enbrel weekly for about 10 years
227	I suspect that this affects my immune system and therefore I still mask when out in public.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, two other treatments.	I tried Humira and prednisone. Humira worked for a while. Steroids also worked and I took them for about two years. My doctor and I both wanted to stop steroids and we reduced the dose until I no longer needed them. At this time, I cannot take steroids at all because it makes my wet macular degeneration worse.

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228	None	It's the only one designated for my condition., I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Plaquenil (didn’t work), methotrexate (caused liver inflammation), OTC and prescription NSAIDS (liver inflammation).
229	The shots was very painful to take	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira it works better than enbral
230	Doesn’t last as long	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Too many to list! Maybe 30 in all. Short of some not working well, no real side effects
231	periodic infections at injection site and not anywhere as much benefit to reducing RA symptoms as I would've liked and increased frequency of migraines on injection days	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	plaquenil, methotrexate, orencia, rinvoq, colchicine

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232	N/A	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., It was required by my insurance company.	Yes, more than three other treatments.	Methotrexate, Humira, Voltarin, Azthropiren, Skyrizi.I am currently taking Rinvoc. All worked for periods of time them didn't. The above list of drugs I have taken is a partial list I have taken.
233	None	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Methotrexate and Cosentyx
234	Because of the mice DNA or whatever my body rejected Enbrel after 10 months	I cycled through other medications that didn't work before finding this one., Purely human	Yes, three other treatments.	Cimzia, Cosentyx, Taltz and now I am on Simponi Aria
235	none, however after several years it ceased to help	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Remicade, Humera and now Cosentyx
236	none	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira and Cosentyx, methotrexate and imuran
237	None other than it didn't work for me	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	Methotrexate, Humira

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238	None	I cycled through other medications that didn't work before finding this one.	Yes, one other treatment.	Some help, but fell short 2-4 day's before the next injection.
239	More sinus infections	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Humira, 3difderent types pills.
240	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Arava, methotrexate, prednisone, humira, kevzara, meloxicam, opioid pain medication, plaquenil. I cont to take plaquenil (just started) & prednisone which works well for me, but the side effects are less than ideal & harmful in its own way but my RA is more harmful tho. The goal is to need to take the least amt of prednisone possible or even not at all & still function. The rest of the meds have either helped to a point then stopped helping or didn't help at all with only the Arava giving me undesirable side effects.
241	Gained weight	It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	Cimzia no good Orencia worked

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242	Weight gain, infections are hard to clear.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Methotrexate, leflunomide, hidroxicloroquine, and humira
243	digestive issues, increased liver enzymes	Initial drug provider put me on	Yes, one other treatment.	Methotrexate
244	No real adverse effects	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Humuria, Cimza, Xeljanz, Rinvoq, plaquenil, and others; I dealt with rashes on Plaquenil, some medication caused racing heartbeat but can’t remember which ones
245	None	It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Donovan, clobetasol
246	None known	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., Severe side effect to previous medication	Yes, more than three other treatments.	I’ve had my condition for approximately 40 years. I have not kept a list of all the Rx I’ve tried over the years. The worst side effects were to Remicade. It reduced my immune system to a life threatening level so that I required hospitalization and surgery and high levels of antibiotic and anti fungal medication.

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247	None	I cycled through other medications that didn't work before finding this one.	Yes, one other treatment.	Humera, it didn't work well, and I got a cancer
248	As With any biological medication, I get sick a lot easier my body hurts constantly but my joints are kind of okay	I cycled through other medications that didn't work before finding this one., It is working better than the rest of the meds I have tried	Yes, more than three other treatments.	Methotrexate (still on it) puked everyday for 6 months, but I lost 60 lbs. Humira 4 yrs (then Enbrel for 2) Humira, worked about as well as the Enbrel. Then Rinvoq for 6 mths. Didn’t work and caused major shingles outbreaks for the entire 6 months! Now I’m on Cimzia, and it’s working better than anything so far. I’m also (still and have been since 2014): Diclofinac sodium, prednisone , folic acid(for the MXT), amitriptyline , Duloxitine (1yr now)
249	Unfortunately, I think it was the latex in the pen that ended up causing really bad injection site reactions.	I cycled through other medications that didn't work before finding this one., It was required by my insurance company., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Step therapy starting with hydroxychloroquine, helped a tiny bit. Sulfasalazine, made me desperately ill. Methotrexate, helped a little more, but fatigue got worse. Humira, helped a lot, almost felt back to normal, but efficacy was waning before a year had passed. Prednisone, helps the

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				most, but not allowed to use it long term.
250	See above	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Cimzia, orencia, rituxin, humira, xeljanz, stelara(?), Arava, etc. I failed all due to not working or affected lungs.
251	The only adverse effect I have had is itching and redness at my injection site the day I take Enbrel.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira worked well for about 2 years and unfortunately lost its effectiveness. I also tried Rinvoq and Xeljanz which did help at all. I was on sulfasalzine and plaquinil but didn't see any results.
252	Only used for 3 weeks due to allergic reaction at injection site of raised hives and itching.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Remicade- it worked for more than 10 years before it suddenly no longer worked, Orencia- it never worked for me, Rituxin- it never worked for me, Simponi- it worked for me for 2 to 3 years and then stopped working. I now take Actemra infusions, Plaquenil pills

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				and Methetrexate injections and they seem to be working.
253	None that I am aware of.	It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Gabapentin. I am also taking methotrexate in addition to my Enbrel.
254	Drowsiness, nausea	I no longer use Embrel	Yes, one other treatment.	Hydroxychloroquine works the best
255	None	It was part of a long list of meds tried for my condition that didn’t work	Yes, more than three other treatments.	Some drugs helped for a time but then stopped. One drug made my condition worse but most did nothing.
256	none	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, two other treatments.	Plaquenil wasn't strong enough, and diclofenac is not safe for long term use
257	Slight increase in sinus infections	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	I’ve literally been on all of them.

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258	Site injection reaction	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Methotrexate, meloxicam, humira, arava & naproxen. As well as steroid injections. Adverse Health effects: nausea, headaches, injection pain/burning, tiredness, liver inflammation.
259	Infections	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Stelara, Humira, Rinvoq and now Infelctra
260	None. Some worked better than others, but all of these biologicals worked way better than pills or creams.	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humeria, Enbrel Cosentyx Stellera. Tremfya
261	Just the delivery system. A shot.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	NSAIDs, Humira, rinvoq, xeljanz, plaquenil, methotrexate
262	none, really. It just wasn't as effective for me as it could be.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Remicaid, Humira, Cimzia, Simponi, Orencia, methotrexate, arava, plaquenil

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263	None. I was disappointed when Enbrel lost its effectiveness shortly after my second son was born, because it had been a miracle medication for me for many years by then.	I cycled through other medications that didn't work before finding this one., It was required by my insurance company.	Yes, more than three other treatments.	Methotrexate - not effective on its own. I hate the side effects of this medication. While on this medication, I usually had to dedicate an entire day each week to feeling gross (fatigue, nausea, blurry mind) after my dose. It also caused hair loss. I eventually reached a point where the negatives outweighed the positives. Remicade - never worked for me Orencia - never worked for me Rituxan - probably the most effective treatment I was ever on. The only reason I moved on from this medication was that I wanted a third pregnancy and there wasn't enough safety data for this medication Cimzia - was very effective for me and was a pregnancy-safe option for my third pregnancy. Being able to be on a medication for the entirety of my third pregnancy resulted in a vastly different experience than my first two pregnancies, one of which was completely untreated and one that

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				was only treated at the end. I had a much better pregnancy and no postpartum flare, which was an amazing blessing as a mom of three including a newborn. Arava - currently taking concurrently with the Truxima. Truxima - I wanted to go back to Rituxan after the Cimzia stopped being effective, but my insurance wouldn't approve the name brand medication.

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264	Cellulitis and more prone to infections	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Topical steroids, oral steroids, other biologics as injections
265	None that I'm aware of	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, more than three other treatments.	Remicade, humira, methotrexate, forgot two more names
266	Injection site lumps, lowered immune system so able to catch contagious illness often, longer recovery time	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Sulfasalazine - no improvement in symptoms. Humira - stopped working. Taltz - was getting sick too often. Cimzia - was getting sick too often
267	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Remicade, Humira, Methotrexate, sulfasalazine, Otezla, others

Survey Responses Continued

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
1	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	No			My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	
2	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								supply option) or number of refills I am able to get.	
3	$500-$1000 per month	Yes						My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
4	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Had to fundraise to cover costs so we could pay mortage. Missed work at least twice a month.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
5	$500-$1000 per month	Yes	double dosed and still not helping	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	I'm off all bios and needing a ligament replacement, knee, and foot and ankle fusion
6	$0-$50 per month	No			Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	No
7	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			money., I have changed prescription drugs to treat my condition due to cost.					raise my insurance premium.	
8	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	I have had reduced impact to my life from my condition because of Embrel. It allowed me to support my family mostly unhindered.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
9	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	Yes	Prescription drug manufacturer	Yes	My insurance plan requires prior approval to fill the prescription.	Absence from work which my employer doesn't like
10	$0-$50 per month	No	None	Out-of-pocket costs have caused me to accrue medical debt.	Yes	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
11	$0-$50 per month	No			Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I can no longer work

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
12	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	Yes, I spend so much time on the phone. Mostly dealing with meds that aren't covered. It's exhausting being a full time patient. Insurance is usually the reason. I went Bankrupt thanks to my condition. Yes, on co-pays
13	$0-$50 per month	No		Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription.	Not for Enbrel. It was taken at home.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
14	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Husband switched jobs and thus new insurance this year. I don't know if they will approve but my copay will be 2600 a month until I use up the copay card amount and then I will have to worry about whether they use accumulators and will have to pay the full copay amount or worry about being approved for Patient assistance if they haven't run out of funds. If I have to pay the full copay I will not be able to afford a medication that works for me and doesn't cause reactions, side effects or allergic reactions. It's also on my insurances formulary and that limits my options further. That's why it's important to have several types of drugs from which a doctor and patient to choose from
15	$0-$50 per month	Yes	I have reduced the dose of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	Yes

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
16	$50 - $100 per month	No			Yes	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	
17	$250 - $500 per month	Yes	I have skipped doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Ho mc

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
18	$0-$50 per month	Yes	Dealing with insurance I've had to jump through many hoops. Sometimes there is a delay because the insurance company takes a while to approve new meds. It's stressful!	This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	I miss work for pain, appointments, and my rheumatologist is over 2 hours away.
19	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day	Once I am off my commercial insurance, I am terrified at the expense of this drug. I will NOT be able to afford without the current Assistance Program that is offered. Why does that have to stop?

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								supply option) or number of refills I am able to get.	
20	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	No		No		

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
21	$50 - $100 per month	Yes	I have stretched time between doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	No
22	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	denial of other medications that would help my disease!

23	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost., Still paying on a credit card from a biologic I took several years ago when you are on Medicare you cannot use co pay assistance cards even	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Unable to work, unable to pay back student loans not yet fully disabled hoping to get better some day but still at this time can't function and debt is just piling up for our family because of my medical condition, traveling to appts, medications, husband taking time off work taking me to infusions taking, when I have to go to the hospital etc.

			if you have spouses private health insurance for RX benefits so you are being asked to pay astronomical co pays						

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
24	$0-$50 per month	No			Yes	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	Not necessarily, but I worry about the pharmaceutical company changing the rules for the Patient Assistance Program that would make me ineligible to receive the drug at no cost to me. The older RA drugs are generic and out of pocket costs, at least for me, would be OK, cost wise, but I can't take them due to side effects and basically, because they wouldn't work for me now. The "newer" drugs are very expensive and would be difficult for me to affort without the PAP from the drug company. I also worry that Xeljanz will stop working for me. What is available after that? I rely on the meds to help me live a realtively normal life.
25	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	none

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
26	$0-$50 per month	Yes	I received this drug with a special drug manifacturer patient assistance program. Had to jump through hoops with the drug manufacturer and dr office in order to qualify. Otherwise it was close to $6,000/month for this medication that of course no one can afford.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	Absolutely!! Especially when I was caring full-time for a daughter with a rare disease and disability herself.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
27	$0-$50 per month	No	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My doctor provided a brochure	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Unable to work, no income. Please help with Compound Drugs (eye serum) not on drug formulary. Out of pocket is 100% with no assistance from anywhere.
28	$50 - $100 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription	This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will	Yes, my whole cost of living and supporting my family.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			drugs to treat my condition due to cost.					raise my insurance premium.	
29	$250 - $500 per month	No		This medication reduces the amount of time and money spent going to the doctor.	No		No	My insurance plan requires prior approval to fill the prescription.	No
30	$0-$50 per month	No			Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	
31	More than $1000 per month	Yes			Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	Manufacturer assistance was great, but stopped five years ago when I started on Medicare.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
32	$0-$50 per month	No	I am 100% disabled veteran and all my care/preacriptions are covered by VA		No		No		
33	$500-$1000 per month	Yes		Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	It costs a fortune!! Definitely impacts our thoughts on retirement as the prescription assistance programs do not apply when you switch to Medicare.

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34	$150 - $250 per month	Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	No	Prescription drug manufacturer	Yes	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	as a person on medicare, I am not eligible for financial assistance, which is very difficult
35	$0-$50 per month	No	insurance covered		No				no

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			complete cost						
36	$0-$50 per month	No	No	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
37	$0-$50 per month	No	I have skipped doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	Friend or family member	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
38	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	All of the above
39	$500-$1000 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Friend or family member	No	My insurance plan requires prior approval to fill the prescription.	Fortunate that i can afford $6K annually now that I have retired

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
40	$500-$1000 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	When I was re-ordering the drug from Accredo (which is part of Express Scripts which is part of CIGNA) I asked if financial help was available & they gave me a list of groups to contact. I spent days contacting them and Amgen came through with substantial assistance last year (2023).	Yes	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I have always been single and always worked for over 40 years to support myself. I was extremely aware that I could not be seen walking with a limp out of fear of being fired or not hired. I spent a LOT of time hiding my pain and indeed working overtime to convince my employers to keep me. Upon retirement I moved to a hot climate (southern Florida) to help with my movement and it has really worked. The hot weather is easier on my body than the cold weather and I can swim more easily (the only exercise which does not hurt my body) because of the climate. I got this disease at 30 years old. I asked my rheumatologist about having children. He said I might be OK with taking prednisone. I researched it on my own and decided having children would negatively affect my body and general overall health and I might pass along the possibility of this disease to my children so I decided not to have children. Since most men want a family I also decided not to get married. And I have heard much worse from people in groups where we discuss the impacts of the disease on our personal lives. It only took me 15 months and 5 doctors to get the first diagnosis which was ALMOST correct. Several years later after having more severe symptoms I was given another

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
									diagnosis which was ALMOST correct. And several years after that I finally got a correct diagnosis and Enbrel. In Support Group sessions I have heard much worse from many other people so I consider myself lucky.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
41	$0-$50 per month	No	Not applicable	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My insurance company	No	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Not at this time
42	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Transportation costs

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
43	$250 - $500 per month	No		This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	Expensive disease
44	$0-$50 per month	No			Yes	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	Well, the drug and all subsequent drugs have not worked well enough to allow me go return to work. This drug was inexpensive after insurance AND the manufacturers assistance program. However, my current drug is prohibitively expensive and I have had to spend months on phone calls and paperwork to get assistance from the prescription drug company for it. In general, these types of drugs are expensive, only somewhat effective, and have horrible side effects. I feel strongly that better medications can be developed, but more immediately it needs to be easier for patients to access these medications and any assistance programs to get help paying for them.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
45	$0-$50 per month	No	Always affordable with Kaiser	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	No		No		No
46	$500-$1000 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	No		Yes	My insurance plan requires prior approval to fill the prescription.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
47	$150 - $250 per month	Yes		Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My pharmacist	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Unable to work due to disability from conditions since 2021; prior to that was missing a lot of work and was not getting paid for sick days. One year my salary was cut about $15k due to unpaid sick time. Copay assistance cards limit yearly benefits, so most months copay for rinvoq is $5/mo, but at the end of the year is $180-200/mo, which we cut other costs to cover. Even though enbrel didn't work for me, insurance at the time dictated we try another TNF inhibitor (humira) before moving on to other drug classes. Both had to be >4 months before moving on, so that was about a year of treatment that didn't work at all, in which my disease got significantly worse (2017-2018.)

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48	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Absentee from work, cutting groceries and other essential bills or household necessities, not able to marry my fiancee or they won't cover my medication, not able to fill up my car with gas due to outrageous medication costs.
49	$50 - $100 per month	No	None	This medication reduces the amount of time and money spent going to the doctor.	Yes	Friend or family member	No	My insurance plan requires prior approval to fill the prescription.	No.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
50	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started.	My employer changed health insurance effective 1/1/2024. The new insurance company never sent the memo that our company agreement covers Enbrel as well as other medications to their partner Rx company. Since the RX company said Enbrel is not covered, despite me insisting that it is, they sent my RX to a pharmacy in Minnesota and charged my $10,000 copay card $3,500 which is much more costly than the past copays which range from $50 to $80.The rep at Veracity RX told me if I don't like that and I want to keep picking my Enbrel up in Tampa I will have to pay for it myself. I did let her know she is wrong that Enbrel is covered and asked her once she gets that memo, how shall we now proceed now that we are in the middle of this debacle? In Florida, we refer to this as a real Cluster Fxxk. I am waiting for all of this to be straightened out by my HR team.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
51	$0-$50 per month	No	My insurance perpetually asks for prior authorizations during the year which causes delays in my medication delivery.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	I can no longer work as a nurse due to my condition.
52	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	No		No	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
53	$150 - $250 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	No		No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
54	More than $1000 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	When I qualified for Medicare and I investigated the cost on Medicare I had to go off Enbrel due to cost and no longer qualified for help.	Yes	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I've switched drugs and my co-pay is currently affordable.
55	$0-$50 per month	No	None	This medication reduces the amount of time and money spent going to the hospital or needing surgery.	No		No		No. I have Tricare for Life which provides my prescriptions at a reasonable cost.
56	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	

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57	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	My provider	No		
58	$0-$50 per month	Yes		This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	I'm nervous that when I have to change insurance that it won't be covered like it is now.
59	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	No		No	My insurance plan requires prior approval to fill the prescription.	Yes. I have comorbidities like Shogrens and COPD and have been unable to access due to the co-pay cost which are in the hundreds of dollars each.
60	$0-$50 per month	No	None		No		No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No- retired. I have excellent insurance (Medicare Advantage Plan) which has kept the medication affordable. I would be lost without it's

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
61	$0-$50 per month			This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No		I retired early because of my health but I fortunately can afford private insurance and have two co-pay assistance programs that pay for my Enbrel so that I don't have to.
62	$0-$50 per month	No	Insurance has covered	This medication reduces the amount of time and money spent going to the doctor.	Yes	My insurance company	No		No
63	$0-$50 per month	No	no, I was on the program from the manufacturer that reduced my copay to $10 a month		Yes	my rheumatologist, the one who proscribed the medication told me about it	No		no
64	$250 - $500 per month	No	I can afford my medication but only because I saved my money	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	No		No	My insurance plan requires prior approval to fill the prescription.	None

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65	$50 - $100 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	No		No	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
66	$250 - $500 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	Yes	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	To clarify- when I was on disability, the only way I could afford my Enbrel was through their patient assistance program. When able to work, I then still needed good insurance coverage to keep using it. It gave me back my life and continues to make a huge difference in my life.
67	$0-$50 per month	No	None of the above	This medication allows me to work and help support my family.	No		No	My insurance plan requires prior approval to fill the prescription.	No

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68	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	
69	$0-$50 per month	No	no		No			My insurance plan requires prior approval to fill the prescription.	no

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70		Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost., I have refused medication due to costs&	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	I have since disease flare and then Covid now lupus and ongoing issues with “post covid”, Lulus, and inability to calm my system, lost my ability to work, due to loss of physical mobility/strength, as well as the emotional and mental health issues and challenges I’ve had to endure, accept that I would be fired or retire- and so I have retired due to employers refusal to accept my disability as documented.

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			coverages, I have had to pay completely out of pocket for costs with no coverage and I have been denied several.						

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71	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	Forced to choose between prescriptions sometimes
72	$50 - $100 per month	No	I had to change drug due to bloodwork changes	This medication allows me to work and help support my family.	No			I worry that the cost of my prescription will raise my insurance premium.	

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73	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	My pharmacist	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	My only impact is when the specialized pharmacy can't seem to get their act together and acknowledge the active order they have and send it on time. This has caused significant joint flares and then takes time to get it under control again.
74	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	No				No
75	$500-$1000 per month	Yes	had to limit my budget to afford it once on Medicare	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	I worry that the cost of my prescription will raise my insurance premium.	I had assistance from drug company until I was on Medicare and then all assistance stopped.

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76	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	No
77	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	Numerous surgeries taking me out of work. Occasionally days I am unable to work due to pain/inability to move

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
78	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
79	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	Damage become so severe I'm disabled now fully

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			prescription drugs to treat my condition due to cost.						

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
80	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Had to be on short term disability before using Enbrel.

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81	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	I can't work like I need to.
82	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	

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83	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., Needed to find patient assistance plans to cover copays ranging from $1500 - $18,000	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My pharmacist	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	Inability to work Fulltime and sometimes not able to work at all.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
84	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	Unable to work
85	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	
86	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My provider	No		No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
87	$0-$50 per month	No	None	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
88	$0-$50 per month	No	No	This medication allows me to work and help support my family.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	Yes. Missing work due to my condition
89	$150 - $250 per month	Yes	I have changed prescription drugs to treat my condition due to cost., I no longer take Enbrel, but the cost of all of these medications is high and challenging.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., I worry that the cost of my prescription will raise my insurance premium.	I currently use Rituxan, which require me to drive 4+ hours away (each direction), get a hotel and take time off of work several times a year.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
90	$150 - $250 per month	Yes			No			My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	
91	$500- $1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription.	
92	$0-$50 per month	No			No		No	My insurance plan requires prior approval to fill the prescription.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
93	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My pharmacist	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	Yes - it makes it extremely difficult to manage when something that worked well for me is $1600 a month AFTER insurance and assistance 😣

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
94	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	I'm no longer able to work due to my condition causing a financial burden on my family and all of the meds & doctor appointments also cause financial burdens in & of themselves.
95	$0-$50 per month	No	I'm not taking an expensive biologic. But when I was taking Embrel my insurance covered it.	This medication allows me to work and help support my family.	No		No	My insurance plan requires prior approval to fill the prescription.	No financial impact
96	$50 - $100 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			doses of the drug in order to save money.						
97	$0-$50 per month	No	None	This medication reduces the amount of time and money spent going to the doctor.	No		No		No
98	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost., My doctor has given me samples to	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or	I am now on disability. The cost of these meds take away from my retirement savings. The copay card paid my copay when I had private insurance. This payment even applied to my deductible. However, once I recieved disability, and went on Medicare, I am no longer eligible foe the copay card. This is so wrong. When I was working my deductible was paid but now that I'm on a fixed income, I'm required to pay $2000/month for treatment until I meet my ridiculous deductible amount. Medicare drug coverage is so confusing and seriously awful

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			help with cost					number of refills I am able to get.	
99	$50 - $100 per month	Yes	I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	Being on Medicare prevents medicine to be free of charge or using company coupons/cards for discount

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
100	$0-$50 per month	No	Not applicable	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My pharmacist	No		Yes
101		No	I get my medicine free	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	I'm retired
102	$100 - $150 per month	Yes		This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g.	The drug itself became more expensive to me when I turned 65, because the manufacturer's copay assistance is not available to Medicare subscribers.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
103	$500-$1000 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My pharmacist	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			treat my condition due to cost.						
104	$0-$50 per month	No	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	Internet search	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	None

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
105	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My insurance company	No	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
106	$0-$50 per month	No			Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	
107	$50 - $100 per month	Yes	have always been able to afford the meds but have done with other things	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My pharmacist	Yes	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
108	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	
109	$100 - $150 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	no

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
110	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	
111	$0-$50 per month	No	No	This medication reduces the amount of time and money spent going to the doctor.	No		No		No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
112	$0-$50 per month	No	I was on Indiana Medicaid previously and they paid 100% for my medications. It is a big factor now on Medicare. I would not be able to afford any RA biologics. I looked at the cost and thought maybe it was a blessing the doctor discontinued Enbrel as no way could I have continued this drug.		No				Yes RA issues made working no longer possible. Prescription drug costs on Medicare are very high. I don't think I can afford anything except Prednisone now. It is very cheap. Continuing to go to specialists costs co-pays, more tests and no one agrees. The specialists don't communicate with each other leaving me and probably others without answers. It just costs me more time and money, both of which are running out. Then if they did prescribe a medication I wouldn't be able to afford it. What a broken system we have. I wish it were improved and the road had not led me to being disabled. I would much like to find the answers that would lead me back to life. Thank you.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
113	$0-$50 per month	No			Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	

114	$0-$50 per month	Yes	I have had to deal with specialty pharmacies that cannot deliver medications reliably. I have spent hours and hours in the phone chasing down medication shipments and renewals and repeating the same information over and over again to multiple people and being told my medication will be shipped or that my account is accurate and fine only to find out it wasn't and have to do it all over again over and over again. Specialty	Out-of-pocket costs have caused me to accrue medical debt.	Yes	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Disabled so no living wage income.

			pharmacies are useless. There are too many layers in our healthcare system and it only makes access to care more difficult for people who truly need it.						

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
115	$0-$50 per month	Yes	I've been very lucky but it came very close to me not being able to afford it.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I am just changing to a plan where I need to rely on patient assistance program. Not 100% sure what I'll end up paying. Already struggling with copays for Dr visits and other meds. It's very hard & scary!
116	$0-$50 per month	No			Yes	My provider	No		no
117	$0-$50 per month	No			Yes	My insurance company	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
118	$0-$50 per month	No			No			My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Unable to work more than 10 hours per week, meaning I'm not doing jobs in my potential as a person with an advanced degree because it's hard to find anything like that with such few hours or accommodations for my spine condition; unable to drive on highways due to neck fusion which severely limits my transportation; can't afford my own car so have to borrow partners or rely on medical rides which severely limits my independence
119	$250 - $500 per month	Yes	I have reduced the dose of the drug in order to save money.	Out-of-pocket costs have caused me to accrue medical debt.	No			My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
120	$50 - $100 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Internet search	No		Inability to do my job caused lack work, returned to school to learn a new type of job.
121	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	No		Yes		No
122	$0-$50 per month	No	I have stretched time between doses of the drug in order to save money.		Yes	Doctor	No		I'm blessed that my husband is a disabled vet. In addition to Medicare I have CHAMPVA which pays for my medication otherwise I would not be able to afford it!

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
123	$0-$50 per month	Yes	I cannot afford to pay out of pocket for medications so do not take a drug if it's not insurance paid	This medication reduces the amount of time and money spent going to the doctor., Out-of-pocket costs have caused me to accrue medical debt.	Yes	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	My social security income is small and my constant illnesses make it impossible to work
124	$150 - $250 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
125	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My pharmacist	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	It's very difficult to deal with insurance with medications that cost this much and there are times when I have a lapse in medication due to insurance issues.
126	$0-$50 per month	No			Yes	My provider	No		No
127	$0-$50 per month	No	None of the above		Yes	Prescription drug manufacturer	No		No. But I want to say that I loved Embrel and how it helped me but Medicare made me take a different drug by infusion. I would go back to Embrel if I could!

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
128	$50 - $100 per month	Yes	No	This medication reduces the amount of time and money spent going to the hospital or needing surgery.	No		No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
129	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	I used to - before I retired I had to miss an increasing amount of work due to the pain and stiffness/fatigue that comes with autoimmune diseases. I was a professor and my employer worked around the morning stiffness but I did have to take early retirement.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
130	$0-$50 per month	No	My cost was minimal: a $20 copay	This medication reduces the amount of time and money spent going to the doctor.	No	Friend or family member	No	My insurance plan requires prior approval to fill the prescription.	no
131	$0-$50 per month	No	I used copay assistance. Would not be able to afford without it	This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Internet search	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Specialty pharmacy process can be challenging for delivery of medication

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
132	$50 - $100 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	My employer wanted me to quit or fire me to remove me from their insurance plan in case it raised his costs, and me obtain my own plan. I ended up quitting to work for another company that never questioned my illness.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
133	$0-$50 per month	Yes	Blue Cross/ Blue Shield of MA decided that my copay would be over $2600.00 unless I joined a shady copay assistance thing. (1 star Google rating). It took several months without Enbrel to clear that mess up.	This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Forced to participate by insurance company	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
134	$250 - $500 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	All expenses are hard now can't afford to live and take care of my self for all the medical bills

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
135	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.		No				I no longer drive and I live in a rural area. A relative must take time off work to take me to my infusion.
136	$0-$50 per month	Yes	I had to change pharmacies in order to have it covered and that has caused me to delay doses	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
137	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
138	$0-$50 per month	No	I applied for help through the manufacturer in order to afford this treatment	This medication allows me to work and help support my family.	Yes	Internet search	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., I worry that the cost of my	I had to stop working a full time job

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								prescription will raise my insurance premium.	
139	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	If I didn't have Medicaid to pay for this medicine I couldn't even begin to describe what my disease would do to me Medicaid pays for most but you have to get prior approval and you're only limited to so much a month but I have help through the department of Social Services North Carolina

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
140	$0-$50 per month	Yes	I have skipped doses in order to accumulate it in case of being denied medicaid: I could never afford it without that.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	No			My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I need to keep my income low enough to qualify for medicaid: there's never been a time in my life that I could have afforded the cost ($6-7000 per month last I checked), copays, etc.
141	$50 - $100 per month	Yes	I feel the whole prescription was cost prohibitive but I received help from the company that makes Enbrel		Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number	no

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	
142	$50 - $100 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., I worry that the cost of my prescription will raise my insurance premium.	No
143	$150 - $250 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
144	$0-$50 per month	No			Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	
145	$0-$50 per month	No	None	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	Unplanned flare ups , pain , fatigue affect my work schedule
146	$50 - $100 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started.	All of the above

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
147	$250 - $500 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Internet search	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	no
148	More than $1000 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	Yes	I worry that the cost of my prescription will raise my insurance premium.	My Enbrel treatment was in a clinical trial so the financial hit did not hit for a while. I have been on biological drugs for over 20 years. The financial picture changed several times depending from free (clinical trials) to $1100/mo. since I lost NYS EPIC this month. I am choosing to go off Cosentyx due to finances.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
149	$50 - $100 per month	No	None	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	I worry that the cost of my prescription will raise my insurance premium.	No
150	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription.	No
151	$250 - $500 per month	Yes		Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	Absences from work, being restricted to what jobs I am able to do for work (not a lot of lifting and can't be on my feet all day), having to afford multiple medications to manage my condition, paying more co-pays for seeing multiple specialists, paying out of pocket for treatments and tests that aren't covered by medical insurance.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
152	$0-$50 per month	No	Held the drug only when sick and on antibiotics	This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	Retired and have not had any financial impacts yet
153	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	
154	$50 - $100 per month	No	I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family.	Yes	Drug study	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
155	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	
156	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
157	$50 - $100 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
158	$0-$50 per month	Yes	RX help		Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	
159	$50 - $100 per month	Yes	I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	Yes, have been terminated due to call out with no FMLA available due to being with company less than a year.
160	$250 - $500 per month	No	None	This medication allows me to work and help support my family.	No		No	My insurance plan requires prior approval to fill the prescription.	I no longer take Enbrel

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
161	$0-$50 per month	No			Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	no
162	$0-$50 per month	No	no	This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	Missing work.
163	$500-$1000 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	I became disabled and am no longer able to work. Had to pay for insurance and all related medicines without help until I could access Medicare plans. Wouldn't have been able to access medical care if I hadn't had savings accounts to use during this transition. No one should have to live in pain because they lack access to medical treatment due to costs. I urge you to help those in need of these drugs due to lack of funds.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
164	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	Gals in getting prescriptions due to changing coverage for medications like these however once It was sorted out was able to get the medication at no cost through help with RX help centers.
165	More than $1000 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	No				Do not have insurance due to cost so have had to discontinue using Enbrel

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
166	$0-$50 per month	No		Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	No
167	$50 - $100 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	No		No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	No
168	$0-$50 per month	No	I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family.	No		No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g.	None

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
169	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family.	Yes	My pharmacist	Yes	My insurance plan requires prior approval to fill the prescription.	No
170	More than $1000 per month	Yes	I have skipped doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	N/A

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
171	$0-$50 per month	No		This medication allows me to work and help support my family.	No			My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
172	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance plan requires prior approval to fill the prescription.	No
173	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	Yes	Prescription drug manufacturer	No		

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
174	$0-$50 per month	Yes	None	This medication reduces the amount of time and money spent going to the doctor.	Yes	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	Can't work & on SSDI. Income is minimal. Very thankful for assistance program so at least my symptoms are lessened.
175	$50 - $100 per month	Yes	I have skipped doses of the drug in order to save money., I have reduced the dose of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my	This medication allows me to work and help support my family., Out-of-pocket costs have caused me to accrue medical debt.	Yes	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	yes, unable to work as much as I would like which affects my paycheck, and I am to young mentally for Disability so I just suffer through it financially and make the best of it

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			condition due to cost.						

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
176	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
177	$0-$50 per month	No	No	This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
178	$250 - $500 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my	This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance plan has dropped or switched my drug coverage after the plan year started., I worry that the cost of my prescription will raise my insurance premium.	Was locked in to a low paying job because I was afraid of losing coverage for the drug if I switched employers. Then my employer eliminated coverage for it anyway and I had to search for a payment grant from the manufacturer.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			condition due to cost.						
179	$500-$1000 per month	Yes	No	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	In recent years, financial assistance has not been available from the manufacturer since the manufacturer required it to be applied to my out of pocket and the insurance company denied that. This includes both regular financial assistance as well as need based financial assistance.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
180	$0-$50 per month	No			Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	There are no rhuematologists within an hour of my location. Most are 2+ hours away.
181	$0-$50 per month	No	My specific allergies are the major concern in all of my healthcare treatments.		Yes	My case manager.	No	My insurance plan requires prior approval to fill the prescription.	Not at this time.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
182	$100 - $150 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	
183	$0-$50 per month	No	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Internet search	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to	NA

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								get., I worry that the cost of my prescription will raise my insurance premium.	
184	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	I miss a lot of work and have to travel a ton because of my condition, but it's not Enbrel's fault.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			treat my condition due to cost.						
185	$0-$50 per month	No			No		No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	no
186	$0-$50 per month	No	Cost has not been a problem for me	This medication allows me to work and help support my family.	No		No	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
187	$0-$50 per month	No	I have had to go thru the process of signing up and using a patient assistance program.		Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	Financial impact is that I can no longer work so have lost a fair amount of our families annual income.
188	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	No		No		none. because of my service-connected diseases Enbrel is paid for
189	$50 - $100 per month	Yes	I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries,	No			My insurance plan requires prior approval to fill the prescription.	The biggest impact is to my finances, as I receive SSDI.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			condition due to cost.	vacations, etc.) to pay for the medication.					
190	$0-$50 per month	No	Not affected adherence.	Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
191	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	
192	$0-$50 per month	No			Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription.	No
193	$0-$50 per month	No	No because i qualify for amgen copay program. This will stop with change to medicare and i will need to find a new drug. It will be too costly.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No		Yes, grocery delivery charges because I can't lift heavy items.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
194	$0-$50 per month	No			Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I am no longer able to work as a result of my illnesses.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
195	$50 - $100 per month	Yes			Yes	RN		I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	
196	$150 - $250 per month	Yes	None	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	No
197	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day	Yes. My co-insurance is 20%, and I am behind. I do miss work frequently and am fatigued all the time. If I did not have patient assistance, I would not be able to afford my medication.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
				me to work and help support my family.				supply with no 90 day supply option) or number of refills I am able to get.	
198	$100 - $150 per month	No							
199	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	
200	$0-$50 per month	No	I have not had any difficulties financially to take asn prescribed.	This medication reduces the amount of time and money spent going to the doctor.	No			My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I am retired, initially medically now based on my age. Financial impact has not been an issue in my rheumatologist and my choice of biologic therapies.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
201	$100 - $150 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	No
202	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My insurance company	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day	absences from work - have had to go on FMLA before to reduce the amount of time I could work in a day + required regular breaks; have difficulty working in an office setting because of the pain, which limits which jobs I can get

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								supply option) or number of refills I am able to get.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
203	$0-$50 per month	No	I receive my medication by yearly applying for free meds at Amgen Saftey net and attend of year change does age to every two weeks instead of weekly due to being not enough med to use as prescribed. This year went for nearly a month without medication due to application process I started in Novemebrt		Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
204	$50 - $100 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	Prescription drug manufacturer	Yes	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	
205	$250 - $500 per month	No	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No		no
206	$0-$50 per month	No	I am no longer using this med, but not due to finances.	This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Yes, the provider I see which is a specialist is not covered/ paid by my insurance company. All costs I incure out of pocket because prior to finding this physician I was not getting any relief from any of the other doctors I saw total number of 12 from 1997-2004. I have been a patient of this physician since 2004, my insurance stopped covering my doctor visits to see him in 2018 when my employer

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
									changed to our current insurance plan.
207	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the hospital or needing surgery.	No				
208	$100 - $150 per month			This medication allows me to work and help support my family.	Yes	Myself	Yes	My insurance plan requires prior approval to fill the prescription.	Yes if it wasn't for will my meds I would not be able to afford my medication. Thank GOD
209	$0-$50 per month	No	No	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
210	$0-$50 per month	No	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	Internet search	No	My insurance plan requires prior approval to fill the prescription.	No
211	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No		No
212	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My provider	No		

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
213	$0-$50 per month	No	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Prescription plan changed so that patient assistance copay assistance can no longer be counted towards deductible or out of pocket. One they use the copay money up, I'm responsible for the entire amount. Also they reclassified specialty meds to require a 30% copay no matter what.
214	$0-$50 per month	No	I have assistance from Enbrel	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription.	Not right now but worried when I turn 65 years of age
215	$0-$50 per month	No	No	This medication reduces the amount of time and money spent going to the doctor.	No		No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
216	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes		No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	Live frugally on fixed income
217	$100 - $150 per month	No	No	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
218	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
219	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No		I estimate that if I didn't have RA, I could probably earn twice the amount of money I actually do.
220	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	No.
221	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.		Yes	Physician	No	My insurance plan requires prior approval to fill the prescription., I worry that the cost of my prescription will raise my insurance premium.	I have retired early because of my disability. I think that is the ultimate impact.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
222	$0-$50 per month	No	No	This medication allows me to work and help support my family.	No			My insurance plan requires prior approval to fill the prescription.	No
223	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
224	$50 - $100 per month	No	N/A	This medication reduces the amount of time and money spent going to the doctor.	Yes	My pharmacist	No	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
225	$0-$50 per month	No	None of above		Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
226	$0-$50 per month	No	No	This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	I used the Enbrel co pay card when I had private insurance through my employer. When I turned 65 and went to Medicare I was dropped from the co pay assistance through Amgem and paid more out of pocket. I have a close friend on Medicare who said that her plan considered Enbrel a category 5 drug and her co pay would be over $2,000 and she can't afford that. She has failed other drugs
227	$0-$50 per month	No	I have never done any of the above but I did go without it for about six weeks to see if I still needed it. Yes, I discussed it with my doctor and yes I still need it.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My insurance company	No		Not Embrel. I did experience a shortage of Sulfasalazine in our area and going without it for a few weeks sent me into a particularly bad flare up that lasted six month!

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
228	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Our family had experienced significant financial impacts of the condition of our child. Specifically, my husband and I were self employed but we could not afford the estimated copay for Enbrel if we used an ACA health insurance policy. So we had to shutter our small business and take jobs that offered private health insurance plans because our copay assistance program could not be used with a ACA policy, only with private employers offered policy. In doing so, my husband took a significant pay cut to get a job that offered health insurance coverage.
229	$50 - $100 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Missed some work
230	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								supply option) or number of refills I am able to get.	
231	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	no

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
232	$500-$1000 per month	Yes	I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Yes, cost of transportation to Doctors, Pharmacy etc.
233	$0-$50 per month	Yes		This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	While working.PSA was a large factor in choosing to retire

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
234	$0-$50 per month	No	Medicare covers this however when I first started with Cimzia, Cosentyx and Taltz I paid $5000 per month for the first 3 months to meet deductible	This medication reduces the amount of time and money spent going to the doctor.	No		No	My insurance plan requires prior approval to fill the prescription.	I did retire early because of absences from work
235	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription.	No
236	$0-$50 per month	Yes	no, because I had a copay assistance program at the time	This medication allows me to work and help support my family.	Yes	Prescription drug manufacturer	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day	This drug was used by me in the past, and as long as I had the copay assistance program, it did not impact me financially. My current situation is quite different on Medicare.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								supply with no 90 day supply option) or number of refills I am able to get.	
237	$0-$50 per month	No			Yes	Internet search	No	I worry that the cost of my prescription will raise my insurance premium.	No
238	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My insurance company	No		No
239	$250 - $500 per month	Yes	I have skipped doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes	My pharmacist	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No. Just sick days from the condition of my RA.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
240	$0-$50 per month	Yes	None, only its more of a hassle to jump thru the hoops to obtain it, which greatly adds to my stress which I don't need cause it's bad enough already	This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I can no longer work and it took 2 & a half years to get disability at which I had zero income for me & my husband, furthermore now that I'm on disability the income amount is less than half of what it was while I could still work. That is extremely hard to cope with as well.
241	$0-$50 per month	Yes			Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
242	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No		I had to quit my office job because the long hours sitting down in front of the computer were causing me a lot of pain and flares.
243	$50 - $100 per month	No		This medication allows me to work and help support my family.	Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I have two days a week when I'm exhausted and can't do much and require a nap.
244	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	No
245	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost., I had to stop when I	This medication reduces the amount of time and money spent going to the doctor.	No		Yes	My insurance plan has dropped or switched my drug coverage after the plan year started.	I just have live with uncontrolled psoriasis

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			entered Medicare						
246	$150 - $250 per month	Yes	No, but sacrifices were made by me and my family in order to purchase the drug.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	Dr.'s nurse	Yes	My insurance plan requires prior approval to fill the prescription.	
247	$0-$50 per month	No			No		No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
248	$0-$50 per month	No	I'm very fortunate to have the needed funds for my condition. My job and occupation help with that greatly!	This medication allows me to work and help support my family.	Yes	My provider, insurance co. And the drug mfg.	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Yes, I have to go to my rheumatologist qtly and monthly, I'm on more meds than I can remember, the monthly cost of meds, proper diet for my condition also, somehow ridiculously more expensive, and on top of that, the otc's I have to take on top of the prescriptions, is just so much fun…
249	$500-$1000 per month	Yes	Missed doses because insurance didn't want to pay anymore, which would have left me paying $7k out of pocket each month.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Can't work full-time, if at all. Travel to see the rheumatologist or other specialists requires a 80+ mile drive, sometimes requiring a hotel room ($200+ a night if you need somewhere with an elevator). Lots of doctor visits, imaging and lab work due to the medication. I count on hitting my max out-of-pocket each year. Then I get to argue for hours with insurance to get the remaining costs covered as they should be.
250	$0-$50 per month	No	Have always used as directed		No		No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
251	$0-$50 per month	No		This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	I am unable to work full time because of RA. I have to be careful about my spending because of this and unfortunately am behind in some bills because of lost time at work.
252	$0-$50 per month	No	I am able to get financial assistance from the drug company	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
253	$250 - $500 per month	Yes	I have purchased the medication, but it put a definite financial strain on my life.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes		If my copay card were to go away, I would not be able to get this medication at all.
254	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My pharmacist	Yes	I worry that the cost of my prescription will raise my insurance premium.	Cannot use this prescription because of costs and side effects
255	$0-$50 per month	No	I have had to wait to start a drug while my doctor appealed the declination from	This medication allows me to work and help support my family.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	I have been very fortunate in that my insurance and the copay program made it financially possible to take the medication. It is frustrating that the insurance companies have a say in what drug I try first.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			insurance company.						
256	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	Yes	My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
257	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication., Out-of-pocket costs have caused me to accrue medical debt.	Yes	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	The entirety of our financial issue is from medical debt. Without access, my body shuts down and I slowly start to die. My RA is one of the most aggressive forms and I've had to stop medication several times because we can't afford it unless there is coverage assistance. During those times, I become unable to work, unable to walk, and unable to care for myself at all.
258	$50 - $100 per month	No	No	This medication reduces the amount of time and money spent going to the doctor.	Yes	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance plan requires prior approval to fill the prescription.	No

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
259	$100 - $150 per month	Yes		Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	No	I worry that the cost of my prescription will raise my insurance premium.	Yes no access to private insurance and I'm paying 1200 a month for a plan that had good prescription coverage
260	$0-$50 per month	Yes	I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost., Costs did vary by prescription and some had copay assistance but when that runs out my costs	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	As noted the copay assistance runs out before end of year and then insurance does not cover so cost can be near $5000.00

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
			were in the thousands						
261	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication allows me to work and help support my family.	Yes	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	I only take what I can afford. That does limits me at times.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
262	$50 - $100 per month	Yes		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes	My insurance company	No	My insurance plan requires prior approval to fill the prescription.	
263	$500-$1000 per month	Yes	My rheumatologist provided me with samples so I wouldn't miss doses while I figured out how to cover the cost of the medication.	This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	When I was a student at the University of Colorado and on Enbrel, I had a $750-800 copay per month. I also had a $5,000 annual cap on ALL prescription medications under my insurance, and the cap would be easily reached prior to the end of the year, leaving me without prescription coverage from my insurance. Another cost was the many, many hours I had to spend on the phone with insurance, specialty pharmacies, and copay assistance programs to figure out how to afford the medication I needed.
264	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor.	Yes	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not	Yes, transportation costs, absence from work

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
								recommended by my doctor.	
265	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	None that I'm aware of, although a 90 day supply would help with running back n forth from my doctor and pharmacy. I can no longer drive due to health and pay Uber ti get me everyehere
266	$0-$50 per month	No	No		Yes	Originally my provider but now i just know to look for a co-pay card be my current dr does not mention it	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Loss of second income When I was working I was missing a lot of days which lead to resentment in the workplace and added anxiety.

ID #	Monthly OOP?	Has cost ever made difficult to access ?	Has the cost of this drug ever affected your adherence to it?	How does this drug impact you and/or your family?	Used any assistance programs?	How did you hear about the financial assistance?	Difficulty affording despite assistance?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
267	More than $1000 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes	My provider	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	Cannot do copay assistance with Medicare.

Appendix I

Enbrel: Input from Individuals with Scientific or Medical Training

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by the Board. (C.R.S. § 10-16-1406(4)(h)(II)).

Rule: Individuals with Scientific or Medical Training: The Board will seek input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by the Board, including:

- The impact of the disease,
- Perspectives on benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist, and/or
- Input regarding the prescription drug utilization in standard medical practice, as well as input regarding off label usage. (3 CCR 702-9, Part 3.1.E.2.h.ii).

Off-label usage means the use of a prescription drug for a disease or medical condition that is outside the FDA-approved indication(s) (3 CCR 702-9, 1.1.C).

Policy: Staff will gather input from individuals who possess scientific or medical training through outreach and holding a public meeting(s).

- Individuals who possess scientific or medical training with respect to the condition or disease may continue to provide input via verbal public comment and written public comment.
- During the following Board meeting(s), Staff will present input provided by individuals with scientific or medical training and will report such information in their final report. (PDAB Policy 04, p. 8).

Underlying Methodology: Board staff compiled data for Enbrel for the Board's consideration in the following manner:

1. Documented information provided during the stakeholder sessions to gather input from individuals with scientific and medical training specific to Enbrel. Staff attempted to compile information directly related to the information outlined in rule during stakeholder meetings and from the survey.
2. After the survey deadline and public input sessions have concluded, Board staff aggregated responses, identified high-level themes, and presented findings to the Board in the form of a short report.

Data Source(s): Board staff compiled information from individuals with scientific or medical training for selected prescription drugs from the following sources:

- Results from public input sessions and surveys from individuals with scientific or medical training.

Considerations and Data Limitations: Input provided both via stakeholder meetings and surveys is voluntary. Such qualitative data may not capture information from all individuals with scientific and medical expertise.

Enbrel: Input from Individuals with Scientific or Medical Training Evidence

Background

Board staff gathered input from individuals with scientific or medical training in two ways: meetings and surveys. Input was gathered from two individuals at a public meeting on September 19, 2023. In addition to input gathered through the public meeting, three individuals completed surveys regarding the health and financial effects of Enbrel. Additional input was gathered from five individuals with scientific or medical training via three additional small group meetings.[1]

At the initial time of survey release, the Board received three responses from individuals with scientific or medical training. Board members requested more information from patients and voted to reopen the surveys at the December 15th meeting. After reopening, the Board received zero responses from individuals with scientific or medical training.

To qualify to participate in meetings or surveys, respondents had to have scientific or medical experience with Enbrel. Outreach was conducted via the public listserv and website.

Input summaries are presented below in a manner similar to how meetings and the survey were conducted: health effects of Enbrel and financial effects of Enbrel. Specifically, staff collected information in a manner that encompassed the categories required by Board rule, including the impact of the disease, perspective on the benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist, and/or input regarding the prescription drug utilization in standard medical practice, as well as input regarding off label usage. This appendix also contains links to the public meeting audio recording, the survey, and survey results.

There is additional information contained in Appendix F and Appendix J which may contain additional input from individuals with scientific or medical training not captured in this appendix. The Board may want to weigh information from all three appendices.

Health Effects of Enbrel

Individuals with scientific or medical training stated in public meetings and in survey responses that Enbrel is an anti-TNF biologic therapy that has been used to treat more than a million people with serious inflammatory diseases. It's been studied in more than 100 clinical trials and has a well established safety profile. Enbrel is approved for treatment of the following five indications: severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), ankylosing spondylitis (AS), and moderate to severe juvenile idiopathic arthritis (JIA).

Individuals with scientific and medical training reported in public meetings and surveys that Enbrel provides the following beneficial health effects:

- Reduction in signs and symptoms of approved indications
- Improved overall function and quality of life
- Potentially lowered risk of developing other comorbid health conditions
- Prevention of irreversible joint damage
- Improvement of inflammatory arthritis and inflammatory back pain
- Skin improvement
- Flexibility in managing conditions with or without methotrexate
- User-friendly, prefilled syringe

[1] The referenced small group meetings included discussion of multiple drugs currently undergoing affordability reviews by the Board, including Enbrel.

- Enbrel does not need to be stopped as far in advance by people wishing to conceive

Participants stated that Enbrel is primarily used for patients with RA, which causes functional impairments and deformities of the joint and has major impacts on quality of life. Treatment is necessary to improve physical function and slow the progression of joint damage. When treating for RA, participants often begin by prescribing an agent like methotrexate. If that does not produce a full response, the combination of Enbrel and methotrexate has shown to be optimal for the management of RA, as well as prevention of structural joint damage. One participant stated that with methotrexate, there is a risk of incomplete response which leads to triple therapy, a complicated all-pill regimen. Given the side effects of triple therapy, the participant claims that anti-TNFs like Enbrel become a safer alternative.

When prescribing Enbrel to patients with psoriasis, participants noted that patients not only suffer from itchy, painful skin, but psoriasis can be embarrassing for patients, affecting overall wellbeing and leading to depression and anxiety. Comorbidities include metabolic syndrome, cardiovascular disease, and psoriatic arthritis. Psoriasis is also a chronic condition, so long-term management is necessary to keep disease activity under control and to lower the risk of developing other comorbid health conditions.

Participants also discussed treating pediatric patients for JIA, polyarticular JIA, and other JIA subtypes. Complications that come with JIA include not being able to go to school, play sports, or move without a wheelchair. Participants reported that some infants with JIA are unable to crawl, and some children get arthritis of the jaw or contract uveitis, which left untreated can cause a child to lose their eyesight. Providers stated that there is a lack of pediatric rheumatologists in the nation and that families will fly or drive long distances to be seen. Participants discussed the continuum of patients with JIA into adulthood, where patients are diagnosed with RA and gain access to more FDA approved medications for 18 and older.

Though Enbrel is approved for a broad population with multiple indications, some participants described off-label usage. One participant stated that Enbrel is frequently used off-label in pediatrics, particularly in rarer conditions such as Behcet's disease and Chronic Non-bacterial Osteomyelitis (CNO). Enbrel has also been prescribed for Lupus with inflammatory arthritis.

Side Effects

Individuals with scientific and medical training reported that the most common side effect of Enbrel was increased risk of serious infections compared to synthetic disease-modifying antirheumatic drugs (DMARDs). Survey respondents also stated that side effects could include risk of developing skin cancer and lymphoma and risk of flare of Multiple Sclerosis (MS) or congestive heart failure (CHF).

Therapeutic Alternatives

The most common therapeutic alternatives to Enbrel include other anti-TNFs, such as Humira, Remicade, Cimzia, and Simponi. Participants discussed the development in monoclonal antibodies and loss of response to particular drugs, resulting in TNF cycling or secondary failure. Because patients will often cycle off these medications over time, several participants emphasized the importance of patient access to multiple anti-TNF agents. One participant specifically highlighted that both physicians and patients need access to multiple options over time, as the manifestations and outcomes of these diseases vary among patients and each treatment has its unique benefits.

One participant stated that some providers are comfortable switching between the same drug class as Enbrel because they are more concerned that the patient has no delay in medication versus the patient being without medication. Another participant stated that intravenous infusions are a good TNF alternative, though transportation issues are often a barrier to patients.

When speaking specifically of psoriasis, one participant stated that many topical and systemic treatment options exist and the individual patient must be taken into consideration. Individuals may not be candidates for therapeutic alternatives due to age, systemic medical diseases or history of malignancy, mental health

conditions, other medications/medication interactions, allergies, lifestyle habits, and prior treatment failures or experiences with other psoriasis medications. Common therapeutic alternatives may or may not exist for the patient, depending on these factors.

Financial Effects of Enbrel

Individuals with scientific and medical training were asked three types of questions related to the financial effects of Enbrel: (1) patient out-of-pocket (OOP) costs for Enbrel; (2)relative financial effects of Enbrel on health, medical, or social services costs; and (3) patient and provider experience with utilization management requirements. Information from all types of questions are summarized below.

Patient Cost and Relative Financial Effects

Participants were asked if patients raise concerns about the cost of Enbrel. One participant stated that patients are paying up to $3,000 to $4,000 out of pocket without insurance, and many times the co-pays are as high as $1,000 per month. Another participant emphasized that with Medicaid, self injectables like Enbrel, are almost inaccessible. There are a variety of high copayments with commercial insurance, especially if a patient has multiple comorbidities.

One participant stated they are not seeing huge out-of-pocket costs for patients that are commercially insured due to the robust savings program through the manufacturer. They stated that they rely heavily on manufacturer and patient assistance programs, but patients aren't always aware of assistance programs or have difficulty navigating the process. Some providers stated that they employ patient navigators who connect patients with resources in the community. One participant stated that the annual maximum copay amount that is awarded decreased significantly in the last couple of years. One provider stated this is due to copay maximizers, and another stated that Amgen has decreased their Enbrel copay amount because they are allocating resources for their other medicines.

Participants stated that people who are undocumented can access financial assistance programs despite not being a US citizen. 70 to 80 percent of the drug companies do not request US citizenship, and only request a US address for the last six months to get access to a free drug. For infusions, providers end up taking on the cost because the 340B program helps offset the cost and serve that patient population.

Utilization Management

Utilization management issues reported by participants include step therapy, denials for off-label usage due to the very few FDA medications, and appeals to insurance companies. Participants also stated that patients have so many hurdles when it comes to disease management, navigating insurance, and patient assistance, that they become overwhelmed and want to give up. One participant also stated that once a patient is doing exceptionally well on a medication like Enbrel, having to switch to a different medication due to insurance changes runs the risk of them having uncontrolled disease, effectively worsening their condition.

Audio from Public Meetings with Individuals with Scientific or Medical Training

The audio from the October 10, 2023 public Zoom meeting is found via the following link: https://us06web.zoom.us/rec/play/hwZNw_NQ10uRLT-f0n8YrihtCZQ0roOSO_5hc5gtw076I8rN4GkSt9Zh0BmIH9Hd-72b2OPDkfac5Yte.T2SBIB-NSYozncnS

Individuals with Scientific or Medical Training Survey

The Scientific or Medical Training Survey was initially live on the Prescription Drug Affordability Board website from September 12 to October 3. At the December 15th PDAB meeting, Board members requested more information from patients and voted to reopen the surveys until January 21, 2024. Though survey results are not a representative sample of all individuals with scientific or medical training, the results can still provide important input from individuals with scientific and medical training.

Figure I-1
Individuals with Scientific and Medical Training Survey

Personal Information

I am answering this survey as an individual with scientific or medical training who mainly utilizes my expertise: *

- [ ] In research of this drug for prescription drug development for a manufacturer.
- [ ] In research of this drug in an academic setting.
- [ ] As a prescriber of this drug to patients.
- [ ] As a prescriber of this drug to patients in a safety net setting.
- [ ] Other:

My expertise directly relates to patients who live: *

- [ ] In Colorado
- [ ] Nationally
- [ ] Other:

Health Effects

Please list the conditions that are treated by the prescription drug for which you are providing expertise.

Your answer

Please list the conditions that are treated by the prescription drug for which you are providing expertise.

Your answer

From your experience, how is this drug used in standard medical practice?

Your answer

From your experience, describe any off-label usage of this drug.

Your answer

In your experience, what are the health benefits of this drug?

Your answer

In your experience, what are the health disadvantages of this drug?

Your answer

From your experience, are there any common therapeutic alternatives to this prescription drug? If so, please list them.

Your answer

In your experience, what are the benefits or disadvantages between therapeutic alternatives and this prescription drug?

Your answer

Financial Effects

In your experience, do patients raise financial concerns when being prescribed this prescription drug?

Your answer

Do you discuss this drug's expense with patients when prescribing?

- ◯ Yes
- ◯ No
- ◯ Not applicable

When do you discuss financial effects with patients related to this drug?

- ◯ At the point of prescribing.
- ◯ After the appointment, before the patient reaches the pharmacy.
- ◯ After the patient has been to the pharmacy.
- ◯ Someone else in my organization discusses financial effects with patients.
- ◯ I do not discuss financial effects with patients.
- ◯ Other:

At the point of prescribing, do you discuss any of the following with your patients related to this prescription drug? Select all that apply.

- [ ] Plan specific cost of the drug
- [ ] Patient deductible information
- [ ] Plan formulary alternatives
- [ ] Cost for uninsured patients
- [ ] Pharmacy specific pricing
- [ ] Manufacturer assistance programs
- [ ] Other:

In your experience, have utilization management policies (e.g., insurance requirements related to step therapy or prescription drug formulary tiers) impacted your patients' ability to access this drug?

- ○ Yes
- ○ No
- ○ Other:

If you are a safety net provider, does your clinic/facility provide this prescription drug to patients? If not, why?

Your answer

Individuals with Scientific and Medical Training Results

Survey results are provided for Personal Information, then Health Effects, followed by Financial Effects.

Table I-1
Individuals with Scientific and Medical Training Survey Results

Personal Information, Health Effects and Financial Effects

ID#	I am answering this survey as an individual with scientific or medical training who mainly utilizes my expertise:	My expertise directly relates to patients who live:	Please list the conditions that are treated by the prescription drug for which you are providing expertise.
1	Pharmacist	In Colorado	Psoriatic arthritis, rheumatoid arthritis
2	As a prescriber of this drug to patients.	In Colorado	Psoriasis
3	As a prescriber of this drug to patients., As a prescriber of this drug to patients in a safety net setting.	In Colorado, Nationally	Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis
ID#	What is the impact of this condition(s) on your patients?	From your experience, how is this drug used in standard medical practice?	From your experience, describe any off-label usage of this drug.
1	Can be debilitating	Treatment of psoriatic or rheumatoid arthritis in combo with other meds	N/A
ID#	What is the impact of this condition(s) on your patients?	From your experience, how is this drug used in standard medical practice?	From your experience, describe any off-label usage of this drug.

2	The appearance of psoriasis can be embarrassing. The symptoms associated with psoriasis, including itch, pain, flaking skin, can directly impact patient wellbeing, patient sleep, and ability to complete activities of daily living. Psoriasis is also well known to have systemic medical associations including metabolic syndrome, cardiovascular disease, mental health conditions like depression and anxiety, and psoriatic arthritis, a potentially debilitating inflammatory arthritis. Having active psoriasis can lead to decreased work productivity, decreased interpersonal relationships, and impact emotional wellbeing. Patients often feel the need to hide their skin with clothing or other accessories. In addition, psoriasis is a chronic condition, there is no cure, so long-term management to keep disease activity under control is necessary. Treatment can improve skin disease and it can also potentially lower the risk of developing other comorbid health conditions. Psoriasis treatment is highly individualized and dependent on many factors including disease severity, location of active disease, and the presence of other comorbid medical conditions such as psoriatic arthritis, inflammatory bowel disease, history of malignancy, and depression and/or anxiety. Not all psoriasis patients respond to the same medications and oftentimes trying multiple different treatments before finding the one that works is needed. In addition, patients may lose response to a medication over time, and because again psoriasis is a chronic condition, they need to switch to another therapy. These situations can be frustrating to the patient, but we can also provide hope that multiple treatment options are FDA-approved and available (others are also being researched), and our goal is to find that one that works to control their disease.	Enbrel is an effective medication to treat moderate to severe psoriasis. Enbrel is also approved for pediatric psoriasis down to age four and psoriatic arthritis, so it can be used to manage patients who have both skin and joint psoriatic disease.	(No response)
3	Huge quality of life, morbidity and mortality	RA: second line after methotrexate and PSA and AS: first line drug	RA: second line after methotrexate and PSA and AS: first line drug
ID#	In your experience, what are the health benefits of this drug?	In your experience, what are the health disadvantages of this drug?	From your experience, are there any common therapeutic alternatives to this prescription drug? If so, please list them.

1	Reduces signs and symptoms of the conditions	Increased risk of serious infections	Humira
2	The health benefits include improved psoriasis disease control which often leads to improved quality of life, amelioration of symptoms, and as above, psoriasis disease control can also potentially lower the risk of developing other comorbid health conditions. When treating psoriasis patients with psoriatic arthritis, it can prevent irreversible joint damage and destruction.	As with many systemic medications to treat psoriasis (biologic and traditional systemic medications), there is an increased risk of infections. Enbrel also carries a risk of developing skin cancer and lymphoma.	This is a challenging question to answer because while many topical and systemic treatment options exist for psoriasis, the individual patient must be taken into consideration. Psoriasis factors to consider include body surface area involved, skin locations affected, special site involvement, nail involvement, other psoriasis subtypes, and whether there is concurrent psoriatic arthritis. Individuals may not be candidates for therapeutic alternatives due to age, systemic medical diseases or history of malignancy, mental health conditions, other medications/medication interactions, allergies, lifestyle habits, and prior treatment failures or experiences with other psoriasis medications. Common therapeutic alternatives may or may not exist for the patient, depending on these factors.
3	Significant improvement of inflammatory arthritis and inflammatory back pain along with skin improvement	Increased infection risk, risk of MS or cHF flare in the wrong patient population	All other TNFs, third line drugs
ID#	In your experience, what are the benefits or disadvantages between therapeutic alternatives and this prescription drug?	In your experience, do patients raise financial concerns when being prescribed this prescription drug?	Do you discuss this drug's expense with patients when prescribing?
1	Biosimilars are available for Humira	Yes	N/A
2	As above, this is a challenging question to answer. All medications have risks and benefits but whether the benefits outweigh the risks for the therapy I choose, and their alternatives, depends on the psoriasis patient in front of me.	Yes	Yes
3	I like the weekly prescription as patients can sometimes remember better than every other week or once monthly	Yes. 3000-4000+ out of pocket without insurance and many times co pays are $1000 per month	Yes

ID#	When do you discuss financial effects with patients related to this drug?	At the point of prescribing, do you discuss any of the following with your patients related to this prescription drug? Select all that apply.	In your experience, have utilization management policies (e.g., insurance requirements related to step therapy or prescription drug formulary tiers) impacted your patients' ability to access this drug?
1	Usually when prescription has been processed	Assistance programs, plan formulary alternatives	Yes
2	At the point of prescribing.	Plan formulary alternatives, Manufacturer assistance programs	(No response)
3	At the point of prescribing.	Patient deductible information, Plan formulary alternatives, Cost for uninsured patients, Manufacturer assistance programs	Yes
ID#	If you are a safety net provider, does your clinic/facility provide this prescription drug to patients? If not, why?	If you are a safety net provider, do you receive a 340B discount for this prescription drug?	In your experience, are there any other financial effects of the condition and prescription drug you think the Board should consider?
1	(No response)	(No response)	No
2	(No response)	(No response)	(No response)
3	I work at the dawn clinic and work closely with stride pharmacy to get drugs like this for our patients	Yes	Co pay coverage is really lacking for these meds!

Appendix J

Enbrel: Voluntarily Submitted Information

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other information that a manufacturer, carrier, pharmacy benefit management firm, or other entity chooses to provide. (C.R.S. § 10-16-1406(4)(i)).

Rule: Information Voluntarily Submitted from a Manufacturer, Carrier, Pharmacy Benefit Management Firm, or Other Entity:

- The Board will consider information voluntarily provided by a manufacturer, carrier, pharmacy benefit management firm, or other entity.
- Manufacturers, carriers, pharmacy benefit management firms, or other entities shall have 60 days from the date of selection to provide such information to the Board for its consideration. (3 CCR 702-9, Part 3.1.E.2.i).

Policy: Staff will prepare information voluntarily provided by a manufacturer, carrier, pharmacy benefit management firm, or other entity for the Board's consideration.

- After selection of a prescription drug for affordability review, the Board will notify interested parties, including members of the PDAAC, using its listserv and by posting on its website, of the ability to submit information pursuant to section 10-16-1406(4)(i), C.R.S., if such interested parties are manufacturers, carriers, pharmacy benefit management firms, or other entities. (PDAB Policy 04, p. 8).

Underlying Methodology: None.

Data Source(s): All information that is voluntarily provided to the Board by Oct. 3, 2023 will be provided to the Board for consideration during affordability reviews. Board staff plan to summarize which entities submitted information and the nature of the submitted information.

Considerations and Data Limitations: Some voluntarily submitted information may be confidential, proprietary, or trade secret. Such data will not be made public and can only be discussed by the Board in executive session. Though the deadline for voluntarily submitted information is 60 days after selection (October 3, 2023), the Board voted to extend the voluntarily submitted information for patients and caregivers until October 12, 2023.

This component's information is voluntary. While the Board may request clarification of voluntarily submitted information, there will not be an assessment of the accuracy of voluntarily submitted information or the extent to which it applies to Coloradans. To the degree that voluntarily submitted information is different from information presented in other affordability review components, the Board will need to decide how to evaluate such discrepancies.

Enbrel: Voluntarily Submitted Information Evidence

In compliance with Board policy, on August 10, 2023, Board staff emailed a listserv announcement to subscribers to the PDAB listserv and posted on an announcement on the PDAB website that interested parties had the ability to voluntarily submit information related to Enbrel for 60 days following selection of Enbrel for an affordability review.

Information from Manufacturer

Submissions from Amgen Inc.	Page #s
Affordability Review of Enbrel	J3-J11

Information from Other Entities

Submissions from Other Entities	Pages #s
AiArthritis	J12-J17
Arthritis Foundation	J18-J22

Proprietary Information

Confidential Submissions	Page #s
[redacted]	J23-J49

Amgen Inc.
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October 2, 2023

Via email (*dora_ins_pdab@state.co.us*)

Colorado Department of Regulatory Agencies
Division of Insurance
ATTN: Colorado Prescription Drug Affordability Review Board
1560 Broadway, Suite 850
Denver, CO 80202

Enbrel® Submission Pursuant to 3 Colo. Code Regs. § 702-9-3.1(E)(2)(i)

Amgen is a company that is committed to improving the lives of patients by discovering and developing treatments and cures for serious diseases. **Amgen understands that the cost of prescription drugs is a concern for many Coloradans and has programs in place to ensure affordability, while avoiding access hurdles from pharmacy benefit managers (PBM) and others to the extent possible**. Amgen is committed to the responsible pricing of our medicines, and we price products based on the value they deliver, while aiming to employ flexible pricing approaches to ensure patient access. The list price of a medicine is only one potential factor in determining the ultimate cost to the patient, and all parts of the supply chain have a role in ensuring the affordability of medicines like Enbrel® to Colorado consumers.

The introduction of Enbrel® effectively redefined the clinical course of moderate to severe rheumatoid arthritis (RA). Many patients who previously would have endured progressive and painful deformities and immobility now live for years or decades with lower pain, less progression, and greater function. Since introduction, Enbrel® has been approved in four more disease areas, owing to the broad utility of tumor necrosis factor (TNF) inhibition in transforming the clinical course of many inflammatory diseases.

Across moderate to severe RA, psoriatic arthritis (PsA), and plaque psoriasis (PsO), Enbrel® has demonstrated clinically meaningful improvements in outcomes, such as reductions in joint pain and damage, improved physical functioning, and reduction in skin-related symptoms. Enbrel® is effective for long-term control of disease and has demonstrated these benefits in head-to-head as well as standalone studies. For example, Enbrel® monotherapy in moderate to severe RA has shown greater efficacy than methotrexate monotherapy, the previous standard treatment, in achieving American College of Rheumatology (ACR) criteria, low disease activity (LDA) response, and reduced radiographic progression. Looking at head-to-head performance in PsA, combining methotrexate with Enbrel® did not improve Enbrel® efficacy, distinguishing the TNF pathway as uniquely important and Enbrel® as an effective monotherapy.

In PsO, where safety of systemic treatments is particularly important in the risk-benefit calculation, Enbrel® improves multiple measures of skin signs and symptoms, as well as a number of patient reported outcome (PRO) measures. Improvements in disease activity and PROs with Enbrel® were maintained long-term (up to 96 weeks). Finally, looking at Enbrel® compared with other TNF agents and non-TNF systemic therapies, numerous claims analyses using a validated algorithm have consistently shown Enbrel® to have the highest proportion of "effectively" treated patients compared to adalimumab and infliximab. This has been confirmed in three network meta-analyses (NMA) in RA, helping to differentiate Enbrel® from other biologics.

Enbrel® achieves disease transforming efficacy while also offering an established safety profile. There is not a single therapeutic alternative for Enbrel. Although there are number of biologicals that are indicated for the treatment of moderate to severe RA and other autoimmune disorders treated by Enbrel, **Enbrel and its competitor products do not provide the same response in all patients and they are not simply interchangeable**. More than 600 distinct therapy sequences have been observed for the course of care for moderate to severe RA. This underscores the vital importance of having a wide range of therapeutic choices for patients in this population. The therapeutics most similar to Enbrel are TNF inhibitors – adalimumab, certolizumab pegol, golimumab and infliximab. In RA, Enbrel® patients experience fewer adverse reactions, including infections, compared to those on methotrexate (MTX). Enbrel® may also require less MTX supplementation than other biologics, which could reduce the additional side effects. Real-world evidence (RWE) has shown Enbrel® to have fewer adverse reactions than infliximab and adalimumab as well, with Enbrel® patients having higher adherence as a result. Finally, Enbrel® improves PROs and productivity in adults with moderate to severe RA, PsA, and PsO, boosting patient wellbeing and reducing costs for employers.

Looking beyond Enbrel®, in reviewing the information reflected in the "CO PDAB 2023 Eligible Drug Dashboard" and the criteria to be considered by the Board in assessing the affordability of medicines to Colorado consumers, three elements are critical to developing a more complete picture of innovators' impact on consumer affordability.

- **First,** list prices have become increasingly misleading as the gap between list prices and net prices, known as the "gross-to-net bubble," has become significantly wider in recent years.
- **Second,** in fueling this gross-to-net bubble, the complex system around paying for medicines has not led to corresponding improvements in patient affordability. The extent to which each player in this system may influence a particular medicine's affordability to the patient can vary significantly.
- **Finally,** Amgen has a deep interest in supporting access to life-changing therapies for patients. To this end, Amgen provides financial support information and resources, regardless of a patient's current financial situation or type of insurance they have, to help eligible patients access their prescribed Amgen medication.

Net Prices Declined as List Prices Increased

Much of the public debate about the cost of medicines has been largely focused on list prices. Pharmaceutical companies set the Wholesale Acquisition Cost (known as "WAC"), which is often referred to as the "list price." While the WAC for each of Amgen's products is in part anchored to a medicine's value-driven price, which represents the value a medicine is likely to deliver to patients, to payers, and to society, the price is frequently established against a competitive backdrop. The list price is the price Amgen charges to wholesalers and distributors who purchase medicines, but it does not reflect the true price of the medicine after the rebates and discounts are negotiated with the complex web of wholesalers, distributors, hospitals, providers, pharmacies, pharmacy benefit managers (PBMs), health plans, and other entities in the supply chain. Such price concessions are often necessary to ensure a medicine's appropriate formulary placement and otherwise facilitate patient access without burdensome utilization management hurdles, such as requiring a patient to complete a course of therapy with a drug that may not be the best suited for his or her particular condition.

Since 2019, Amgen's aggregated net prices have declined by 4.7 percent. Amgen is also taking steps to address patient affordability, including providing $19.9 billion in discounts, fees, and rebates to supply chain intermediaries in 2021. Since 2019, these payments to intermediaries have grown by 65 percent. Again, the list prices of Amgen's medicines reflect, among other things, the economic value delivered to patients, providers and payers, the unmet medical need, the size of the patient population, the investment and risk undertaken, and the need to fund continued scientific innovation.

Because of the way PBMs structure relationships with pharmacies and patient-enrollees, increases in list prices generally have a limited impact on net prices, while significantly increasing total rebates paid to the PBMs. In light of this environment, Amgen has increased list prices over the years in response to competitor list price increases to remain available as a choice on PBM formularies. If Amgen had not done so, a likely outcome would have been the removal of Enbrel® from formularies in favor of a competitor who provided a higher rebate to the PBM. Since Enbrel® and its competitor products do not provide the same response in all patients, they are not simply therapeutically equivalent. If taken off formulary, many Enbrel® patients would not have access to the medicine that they and their doctor had determined worked best for them.

For Enbrel®, as of January 4, 2023, the list price is $1,762.34 per weekly 50 mg dose, but, as previously discussed, this does not reflect price concessions. In addition to price concessions, Amgen has invested capital studying Enbrel® for additional indications and introduced new, more patient-friendly formulations and administration methods, such as the easy-to-use, self-injection device specifically designed to meet the needs of moderate-to-severe rheumatoid arthritis patients and psoriatic arthritis patients.

Again, a significant factor for increases in the list price of Enbrel® is that the market for innovative products is structured in a way to benefit intermediaries and not in a way to get lower prices to patients. Enbrel® is in a highly competitive marketplace that includes a number of other medications that are competing for formulary position with PBMs to enable patient access,

including the largest pharmaceutical product in the world Humira®. In such highly competitive marketplaces, companies are forced to simultaneously compete both on lowest net price (i.e., the "all in" price to the PBM) and highest total rebate. In a competitive market, Amgen often must pay increasingly higher rebates to remain on the formulary, even as list prices rise and the net price to the PBM often decreases.

Patient Affordability is a Result of Numerous Inputs in a Complex System

Unlike other categories of healthcare, the list price serves as a primary basis of determining patient out-of-pocket costs for prescription medicines. As a result, the negotiated savings of the market-based healthcare system do not reach patients at the pharmacy counter, especially as co-payments and deductibles on medicines have increased and as high-deductible health plans become more prevalent. The problem is not that the market-based negotiations are not effective at generating savings, it is that the savings never make their way to patients in the form of reduced out-of-pocket costs.

Payers, including healthcare insurers, PBMs, integrated healthcare delivery systems (e.g., vertically-integrated organizations built from consolidations of healthcare insurers and PBMs) and group purchasing organizations, increasingly seek ways to reduce their costs. With increasing frequency, payers are adopting benefit plan changes that shift a greater proportion of drug costs to patients. Such measures include more limited benefit plan designs, high deductible plans, higher patient co-pay or coinsurance obligations and more significant limitations on patients' use of manufacturer commercial co-pay assistance programs.

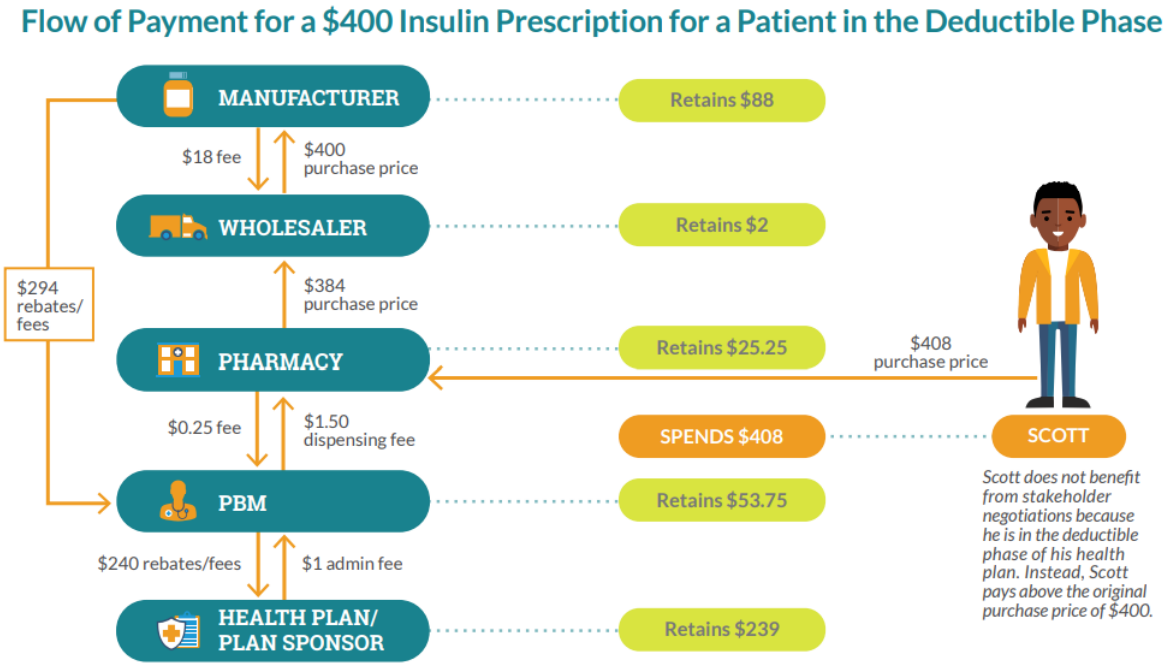
This structure facilitates the current rebate system in the United States, in which companies like Amgen pay billions of dollars in rebates to insurers and PBMs based on the list price, creating a situation in which remaining on-formulary often requires counterintuitive pricing behavior. As discussed later, PBMs can receive lower net prices while consumers see prices increase with little relief at the pharmacy counter, as these savings from the PBMs are rarely, if ever, passed on to any significant extent. While Amgen disapproves of a system where one can lower a medicine's net price and patients pay more and is advocating to change it, this is, unfortunately, the system as it now stands, and Amgen must operate within it to stay competitive and ensure patients have access to Enbrel®.

Despite these structural barriers to reducing patient out-of-pocket costs, due to Amgen's patient assistance programs, commercially insured Coloradans may pay as little as $0 out-of-pocket for each dose with no income eligibility requirements. In fact, roughly two-thirds, or 67 percent, of prescriptions nationally, including those where the Enbrel® Co-Pay Card[1] was used, cost $10 or

[1] Eligibility criteria program maximums apply. For more information about this program, visit www.AmgenSupportPlus.com.

less per month.[2] The remaining one-third of prescriptions cost an average of $341 per month. Overall, only 14 percent of prescriptions cost more than $100 per month.[3]

Exhibit 1. Flow of Payment for Medicines in a Competitive Drug Class in the U.S. Commercial Biopharmaceutical Supply Chain[4]



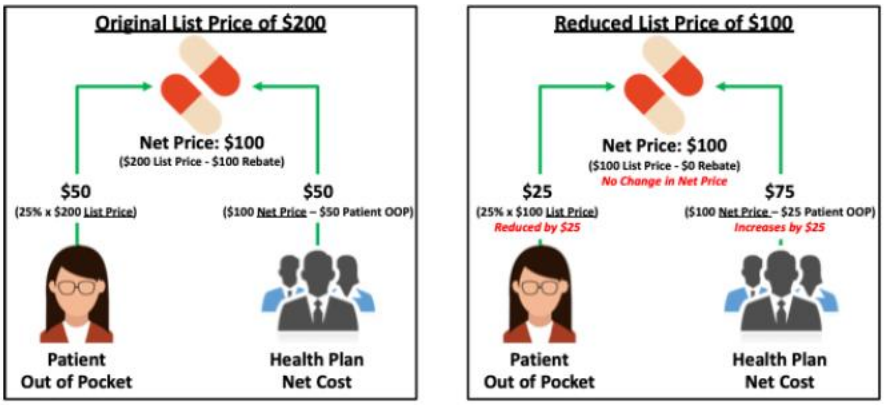
This graphic is illustrative of a hypothetical product with a wholesale acquisition cost (WAC) of $400 and an average wholesale price (AWP) of $480. It is not intended to represent every financial relationship in the marketplace. The payment amounts do not add up to $400 due to markups and discounts along the supply chain.

Furthermore, barriers to reducing list prices are created by the manner in which a PBM determines a drug's "net cost," which serves as an important figure for a PBM's current and potential payer-clients. PBMs calculate plan "net cost" by taking the net price of the drug (e.g., the list price reduced by all applicable rebates) then reducing it further by the patient's out-of-pocket cost. Thus, the more the patient pays out of pocket, the greater the reduction in the net price, meaning a more desirable "net cost" figure for the PBM's client. Because patient out-of-pocket cost is increasingly based on list price, higher list price drugs often result in higher patient out-of-pocket costs and, consequently, even lower "net cost" figures. This means a list price reduction that results in a corresponding reduction in the patient's copayment may be viewed negatively by a PBM as

[2] These data are based on Enbrel® Co-Pay Card paid claims data and paid claims data from national data providers for the period 1/1/2019–12/31/2019. A 1-month supply of ENBREL is typically 4 weekly 50 mg doses.
[3] These data are based on Enbrel® Co-Pay Card paid claims data and paid claims data from national data providers for the period 1/1/2019–12/31/2019, but an individual patient's actual cost may vary depending on the dose, insurance coverage, and eligibility for support programs.
[4] Pharmaceutical Research and Manufacturers of America. *Follow the Dollar: Flow of Payment for a $400 Insulin*. Nov. 29, 2017. Available at: https://phrma.org/en/resource-center/Cost-and-Value/Follow-the-Dollar-Flow-of-Payment-for-a-400-Insulin.

increasing plan "net cost." In other words, where net price to the healthcare system remains constant, a lower list price drug may be viewed by a PBM or payer as increasing plan "net cost" if the patient pays less out of pocket at the pharmacy counter.

Exhibit 2: A Fifty Percent Reduction in List Price Can Result in an Increase in the Net Cost, Contrary to PBMs' and Plan-sponsors' Interests.



One source of client savings increasingly relied on is a rebate guarantee, a fixed dollar amount that is paid to the PBM's clients for each prescription. PBMs receive these rebates from manufacturers. The rebates are based on eligibility criteria, depending on access, utilization management controls and product placement on formulary. The goal for manufacturers with these rebates is to secure a favorable formulary placement, which may lower patients' out-of-pocket costs. Rebate guarantees put pressure on manufacturers to increase list prices, since rebates are based on the difference between list and net prices. However, because patients' out-of-pocket costs are often a percentage of the list price, not net price, all the rebates provided by manufacturers may not actually help patients pay a lower price for their medicines.

PBMs have also introduced new administrative fees to generate revenue, in addition to rebates. New analyses published by Nephron Research found that while the value of rebates paid to PBMs continues to grow, fees and specialty pharmacy now drive a greater share of PBM profits.[5] This is because PBMs have faced criticism for keeping a portion of rebates as revenue for themselves. As a result, they may now pass nearly all rebates on as savings to many clients. As with rebates, however, PBMs base administrative and other fees on drug list price. Due to this dynamic, similar to rebates, manufacturers provide more dollars to PBMs, but these fees are not necessarily passed on to plans, client groups or patients. The Nephron Research found that fees that PBMs charge biopharmaceutical companies doubled in the commercial market over the past five years and were

[5] Eric Percher, Nephron Research. *Trends in Profitability and Compensation of PBMs and PBM Contracting Entities*. Sept. 18, 2023. Available at: https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/.

fueled by increases in traditional administrative fees as well the emergence of new data and PBM contracting entity fees (referred to as "vendor fees").[6]

Some in the healthcare system may assert that these factors are applied to keep health insurance premiums low. Understanding the proportion of rebate dollars, however, applied to maintain more affordable premiums versus other uses has become an increasingly difficult task. This dynamic essentially results in sick patients, who take innovative medicines, subsidizing the healthy patients, which is counter to the purpose of insurance. As you can see in the below illustration, without changing the net price to the healthcare system, the lower list price drug is viewed as increasing plan "net cost" because the patient pays less out of pocket at the pharmacy counter. If the PDAB seeks to address this and similar incentives impacting list prices, more information from PBMs will be necessary, though legislative policy interventions may include mandates on passing through rebates to patients and, among other things, addressing the link between list prices and PBM revenue.

Finally, despite these challenges, maintaining patient access to Enbrel® provides benefits to the broader system, including health, medical, and social services systems.

Amgen's Assistance to Patients Addresses Affordability Challenges

Amgen strives to ensure that every patient who needs our medicine can get access to it. We understand that the dynamics that exist in today's supply chain, such as high coinsurance and deductible levels, can make needed therapies expensive for patients. This is why we sponsor industry leading patient support programs that provide medicine for free to those who cannot afford their medicine. In addition, Amgen offers generous copay assistance to reduce out-of-pocket costs for commercially insured individuals regardless of income.

As previously noted, the out-of-pocket costs commercially insured patients pay for Amgen medicines, like Enbrel®, have changed very little over the decades. Through Amgen's co-pay card programs, out-of-pocket expenditures for our advanced medicines are significantly reduced – **as little as $0 out-of-pocket for each dose with no income eligibility requirements**. In fact, **roughly two-thirds, or 67 percent, of prescriptions, including those where the Enbrel® Co-Pay Card[7] was used, cost $10 or less per month**.[8] The remaining one-third of prescriptions cost an average of $341 per month. Overall, **only 14 percent of prescriptions cost more than $100 per month**.[9]

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[6] *Id*. at pg. 11.

[7] Eligibility criteria program maximums apply. For more information about this program, visit www.AmgenSupportPlus.com.

[8] These data are based on Enbrel® Co-Pay Card paid claims data and paid claims data from national data providers for the period 1/1/2019–12/31/2019. A 1-month supply of ENBREL is typically 4 weekly 50 mg doses.

[9] These data are based on Enbrel® Co-Pay Card paid claims data and paid claims data from national data providers for the period 1/1/2019–12/31/2019, but an individual patient's actual cost may vary depending on the dose, insurance coverage, and eligibility for support programs.

Although Medicare beneficiaries are not eligible for co-pay cards, approximately three-quarters, or 76 percent, of prescriptions cost $50 or less out-of-pocket per month, and the remaining quarter, or 24 percent, of prescriptions cost an average of $395 per month.[10] **For Medicaid beneficiaries, 93 percent of prescriptions cost $10 or less out-of-pocket per month**, and the remaining 7 percent of prescriptions cost an average of $293 per month.[11]

We also recognize that many uninsured and vulnerable patients need extra help affording their medicines. For that reason, Amgen established the Amgen Safety Net Foundation to provide access to Amgen medicines at no cost to qualifying patients in the U.S. (including Puerto Rico) who have a financial need and are uninsured or have an insurance plan that excludes the prescribed Amgen medicine.[12] Since 2008, the Amgen Safety Net Foundation (ASNF) has provided nearly $13 billion worth of Amgen medicines to help hundreds of thousands of qualifying patients gain access to their therapy in the United States.

Amgen Efforts Have Achieved Both Access to and Affordability of Enbrel® for Patients

The leading driver of healthcare costs is the underlying burden of disease, and innovative biopharmaceuticals are part of the solution to addressing this disease burden through lifechanging treatments. What we need is more innovation, not less. Changes are needed to encourage innovation while ensuring patients have access to these innovative medicines.

As our experiences with Enbrel® show, Amgen has implemented reforms to address affordability for our patients. Significantly increasing the rebates paid for a medicine to lower the net price, as was done with Enbrel®, will still leave cost-sharing hurdles for patients, requiring structural reforms to address.

These challenges are not something a single manufacturer or even an industry can make happen. Transforming this system requires the collaboration of all stakeholders, and such broad-based solutions must move beyond a focus on a medicine's list price or else risk unintended consequences for access and innovation. A credible starting point for reform would be to change how PBMs operate in the US marketplace. Specifically, we support policy reforms that would ensure manufacturer rebates are reaching patients at the pharmacy.

The need for innovative medicines has never been greater, driven by a rapidly-aging global population. Industry's ability to innovate and treat patients with medical breakthroughs has never

[10] These data are based on paid claims data from national data providers for the period 1/1/2019–12/31/2019. A particular patient's out-of-pocket costs may vary throughout the year, depending on the Part D benefit phase. Medicare Part D drug coverage is divided into four phases, each with a different cost sharing amount. Such amounts may vary depending on Extra Help program eligibility. For more information, please visit Extra Help with Medicare Prescription Drug Plan Costs from the Social Security Administration (SSA) at https://www.ssa.gov/benefits/medicare/prescriptionhelp.

[11] These data are based on paid claims data from national data providers for the period 1/1/2019–12/31/2019, and any individual patient's out-of-pocket costs may vary throughout the year and be dependent on individual circumstances.

[12] For more information, please visit the Amgen Safety Net Foundation at https://www.amgensafetynetfoundation.com/.

been greater, driven by remarkable advances in science and technology. Stakeholders must partner to drive policy solutions to help improve access and affordability for patients without sacrificing innovation.

Amgen appreciates and shares Colorado's interest in ensuring medications are affordable. Though we have concerns about the delegation to the Review Board of the ability to make a determination on affordability, as well any resulting upper price limit, and we do not release any positions on which we may later rely with respect to the scheme overall, we recognize the importance of dialogue on this topic and remain driven by our mission to serve patients.

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

"We don't represent the patient voice, we *are* the patient voice."

September 30th, 2023

Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

RE: Colorado Prescription Drug Affordability Board (CO PDAB) Voluntary Information Submission - Patient/Caregiver and Patient Organization Engagement for Consideration During Affordability Reviews

Dear Prescription Drug Affordability Board Members,

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient organization led by people affected by AiArthritis diseases, is excited about the opportunity to participate in your drug affordability reviews. As such, we had patient representatives participate in all three public comments sessions relevant to our community (Enbrel, Stelara, and I - as a person on Cosentyx - was a participant) and shared the survey with many in Colorado and nationwide.

We appreciate how much the PDAB worked to include patients and associated testimony. As people who did participate, we would like to take this opportunity to provide feedback for the Board to review prior to your review. We hope you will consider our suggestions as you continue navigating this process.

About AiArthritis. We are the only patient organization in the world focusing solely on this group of diseases, whose leadership consists of those diagnosed with or caring for persons with our diseases, and who specialize in designing innovative, patient-inspired solutions. Our leaders are also public policy, education, and research experts. Given the evolving landscape of health affordability and economic assessments to request direct patient voice participation, in conjunction with the need to fine tune the associated processes, AiArthritis feels positioned to help.

The following comments are divided into two sections: Participation Feedback and General Process Comments.

Participation Feedback

- **Preparation Assistance.** Given new processes breed confusion and questions, there is no surprise Patient Organizations (who were largely responsible for getting the word out to potential patient participants) were unclear about participation (i.e., "Can patient organizations representing the patient voice participate, or only those diagnosed/care partners?" or "How would a patient prepare for participation in an online session?"). The Office Hours, hosted by Callie Shelton and Lila Cummings, were exceptionally helpful addressing these questions. They were equally available and willing to answer additional questions via email outside of scheduled office hours.

Recommendations: Continue the open office hours. Create and publish a FAQ document based on inquiries this initial round.

- **Participation of patients and care partners.** AiArthritis, as an organization who connects patients/care partners to opportunities to have a voice in matters that impact their health,[1] is excited about the evolving landscape to bring more people with lived experience to the conversation. In saying this, our organization is led by those affected by these diseases. We also understand challenges associated with inviting community participation *(i.e., they may feel uncertain they are answering the question correctly, uncertain how their perspectives will be interpreted, not fully clear of the purpose for participation/broader issue, fine line between wanting help developing speaking points and feeling 'scripted')*. While this is not the case with advocates, who are used to speaking publicly, there is a push to bring additional patients 'to the table,' including those who historically are not accustomed to sharing their stories or perspectives.

  Identifying patients/care partners who reside in Colorado, and taking or have taken a specific drug for an indicated disease, has proved difficult. AiArthritis and other organizations struggled to locate people to participate, particularly in online sessions. While part of the challenge likely involves known participatory barriers (as outlined above), there is concern how patient/care partner data will be included if the representation was small. *Note: We are uncertain how many patients/care partners participated via survey or email, but this information will be important to understand when planning for future reviews.*

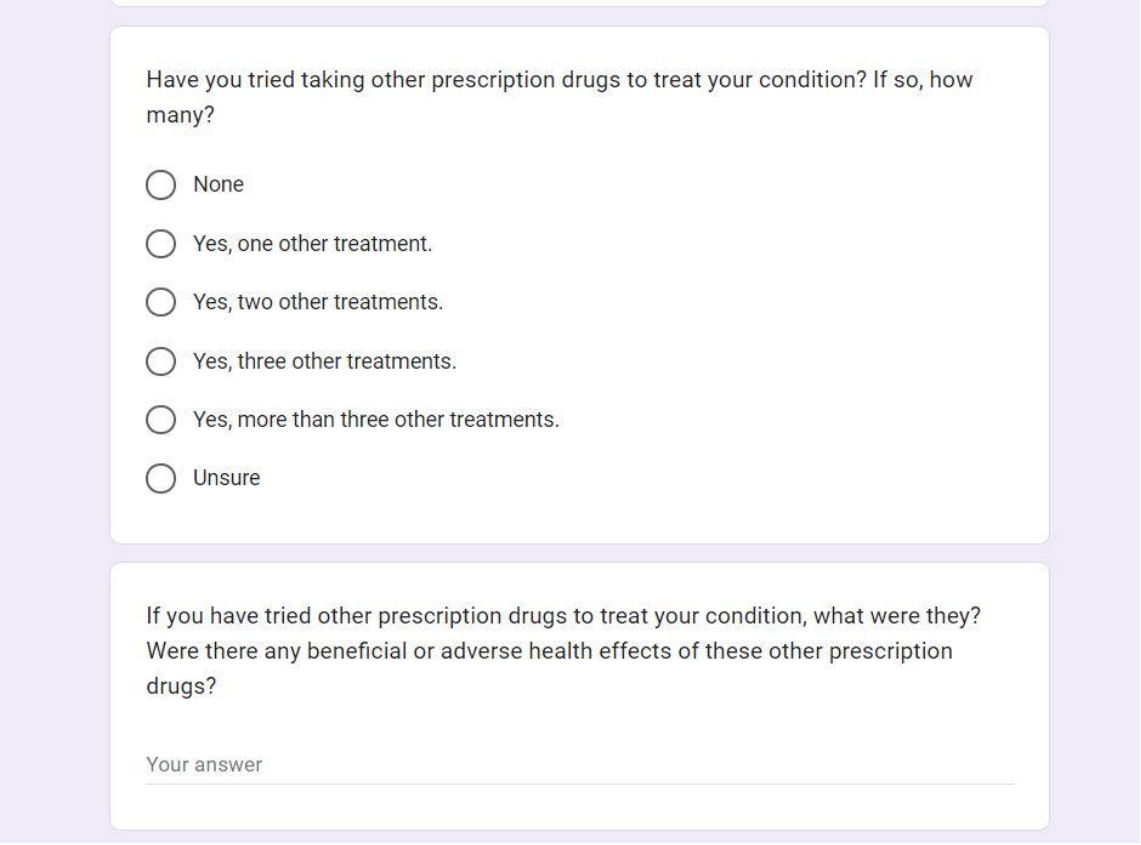
  - **Colorado residents versus those not residing in Colorado**. We appreciate the Board's willingness to permit non-Colorado residents to participate, particularly given that identifying Colorado participants was challenging. However, how their testimony will be weighted is unclear.

  Recommendations: We encourage the Board to release data collected from surveys and email participation, including demographic information, to access participatory challenge and guide efforts to recruit patient/care partner participants. If the percentage of CO participants is low (and additionally, what is considered 'low' should be established), future PDABs should increase outreach efforts to ensure sufficient participation.. Examples may include designing brochures or invitations to share with patients/care partners, Patient Organizations, clinics, or health practitioners.

- **Survey and associated polling design.** AiArthritis is pleased the Board considered many ways to capture patient/care partner perspectives. However, we are concerned about the question design, which may have resulted in inaccurate data collection.

[1] https://www.aiarthritis.org/aiarthritisvoices

- For example, one series of questions asks if a patient ever skipped a dose or stretched out a dose *due to drug affordability issues*. Patients may answer 'yes' to this question if they have skipped a dose or stretched out a dose, dismissing the 'why' at the end of the sentence. *However, as heard several times in the online sessions, this often occurs due to disruption in care caused by utilization management practices (i.e., prior authorization, step therapy) or formulary changes (including non-medical switching).* This is particularly true if the patient participates in the drug manufacturer's assistance plan.
- The following questions were asked in the survey version and discussed in the online sessions:



For those living with AiArthritis diseases and on biologic treatments, answering these questions could cause Board reviewers to feel, "Well, this person has done well on other drugs, so there is no real reason this one drug they are doing well on (or did well on for years) is that valuable." *That is not what Board reviewers should take away from this data.*

What the Board needs to understand is that the current practice of finding the treatment that will work best for us is often a long process. When it works, our disease is not progressing, comorbidities are not forming, and we are living our best lives. The number of times we tried another drug is irrelevant. The number of times it worked or did not work is irrelevant. What matters is finding one that works and, if it fails naturally - not if the

insurance company pulls a patient off of it for company gain - finding another one that works. This is the only way to avoid unnecessary disease activity and potentially permanent damage.

It may take between 1 and 9 years for a patient to get diagnosed, depending on several factors (failure to be referred to a specialist, dismissed due to negative blood work, etc.). After 6-12 months from onset, the window of opportunity to achieve remission closes without proper treatment. Once on a biologic, it can take three months or longer to realize if it will work. If not, the trial-and-error process continues. In the meantime, the patient is dealing with pain, fatigue, brain fog and other symptoms that compromise their ability to lead full, functional lives. But then it happens - the one drug that works. Suddenly, the patient may be able to work full time again, go to school regularly, or do simple things like carry their child or attend a ballgame

Biologics will not work for all people with a shared diagnosis. The goal is to find the right one, and hang on to it until it stops working on its own - as it may be years before another works. So whether a person tried and failed three and two worked or failed five and three worked, the data does not matter. *The only data that matters is if a patient is stable now and, if so, don't disrupt it.*

Recommendations: The Board should consider recruiting patients during the development of questions to identify potential issues prior to publication. Patients can identify issues that a person not living with the condition would not realize. The Board should consider the uniqueness of AiArthritis diseases and the associated challenges patients face to find the right treatments (outside of affordability factors).

- **Lack of other stakeholder participation.** Similar to our concerns regarding lack of patient/care partner participation (particularly from the state of Colorado), we are equally concerned regarding the lack of physician/health professional participation.

  Additionally, while we understand the movement towards involving the voices of only those diagnosed with diseases and who have real world experience using the treatments in review, Patient Organization's bring a perspective that could help ensure data collected is viewed with the proper context. For example, the average patient/care partner may not have supplemental references that show how long on average it takes to be diagnosed or how subgroups within diagnoses matter.

  Recommendations: AiArthritis suggests polling healthcare specialists who prescribe the drugs under review to inquire why they would or would not participate (in the case of our diseases, this could be led by groups like the Coalition of State Rheumatology Organizations/CSRO). We also suggest inviting representatives from Patient Organizations to the listening sessions and then offering them an

opportunity to meet with Board representatives to weigh in on patient/care partner comments, specifically to add context or supplemental information.

- **Disclosures and clarification**. AiArthritis understands there is concern from certain parties that involvement of Patient Organizations who are funded by the manufacturers of the drugs in review could be biased in their testimony, guidance, or feedback. While it is true that organizations, including AiArthritis, obtain financial support from pharmaceutical companies, they are not permitted to (nor do they try to) influence our voice.

  Recommendations. If there is any question regarding who influences Patient Organization perspectives, as clearly outlined in these submitted comments, the people affected by the conditions we serve- who are at the heart of our missions - influence our words.

General Process Comments

- **Regarding upper limit payments.** We understand the Board has the authority to review prescription drug costs and evaluate their impact on Coloradans through affordability reviews of prescription drugs. As a result of these reviews, the Board may then recommend ways to address those costs, which may set an upper payment limit for certain prescription drugs.
  - We question how this process may deter innovation and the development of new pharmacologic therapies. There are many people affected with AiArthritis diseases who have exhausted all current medications and are waiting for new treatments to surface.
  - We also are unclear how this will impact the introduction of biosimilars to the market and how the reference drugs may be impacted.
  - We question how precision medicine will be factored into this process, as we are beginning to identify which types of biologics may or may not work best for different subgroups.
- **How much will patient/care partner perspectives be considered in determining affordability?**
  - In the introduction to the survey, it states, "The PDAB will use the information you provide as part of the affordability review process to determine if a prescription drug is unaffordable for Colorado consumers." At least during the live sessions (as we have not viewed the survey data), patients overwhelmingly agreed Enbrel, Cosentyx, and Stelara were affordable if accessed with help from the manufacturer; but could be inaccessible and even cause harm as a result of insurance practices. How will these perspectives be counted and weighted?
    - Given the difficulty to recruit patients/care partners in Colorado, we are grateful the Board opened comments to a broader population. However, how will the data collected outside of the state be considered during the review?

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

"We don't represent the patient voice, we *are* the patient voice."

In closing, I would like to extend gratitude again on behalf of AiArthritis, and all persons living with our diseases, for this opportunity to participate in your review process and to provide comments that we hope can help as you evolve it. Thank you for considering our suggestions and do not hesitate to reach out to me at tiffany@aiarthritis.org with any questions.

Sincerely,

Tiffany Westrich-Robertson

Tiffany Westrich-Robertson
Chief Executive Officer
Person living with non-radiographic axial spondyloarthritis
International Foundation for Autoimmune & Autoinflammatory Arthritis

Arthritis Foundation®

Yes

October 12, 2023

Colorado Prescription Drug Affordability Board
Department of Regulatory Agencies
Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

Dear Members of the CO Prescription Drug Affordability Board and Advisory Council:

On behalf of the Arthritis Foundation, representing the nearly 60 million Americans and nearly 950,000 Coloradans living with doctor-diagnosed arthritis, we appreciate the opportunity to comment on the ongoing work of the Colorado Prescription Drug Affordability Board (PDAB) to conduct affordability boards for five drugs, including three indicated for various forms of arthritis.

We thank the PDAB for holding opportunities for patients to provide input on their experiences taking these drugs, including listening sessions, surveys, and small group meetings. We also appreciate that PDAB staff have provided ample opportunities for stakeholders to ask questions and provide feedback, including through weekly office hours and individual calls. We would like to provide feedback on the following:

1. The process of soliciting patient feedback
2. Our data and insights on the patient experience taking biologic medicines
3. Examples of our work with value assessment to inform your methodological considerations for determining affordability

Patient Engagement Process

We were able to recruit two patients to participate in the Enbrel stakeholder meeting, and though we disseminated the survey through our state newsletter channels, it is unknown how many patients completed it. We found it difficult to generate a significant number of patients to participate in either the PDAB staff-led stakeholder meetings or a small group meeting. We do not know definitively why this was the case, but through internal conversations with our CO-based staff and state advocate leaders, we speculate it was likely due to a combination of limited scope (i.e., CO residents with experience on those specific drugs); difficulty relating to or understanding the purpose or process; a lack of time or bandwidth; or limited scope in our outreach. These are questions we would like to explore further in concert with the PDAB to improve response rates for future patient participation opportunities. In the meantime, we encourage PDAB staff to prioritize the following for future efforts:

- Coordinating with the patient advocacy community well in advance so we can collectively determine effective outreach practices.
- Working closely with the health care provider community to recruit patients; providers have the most consistent and wide-reaching touchpoints with patients and are in a unique position to communicate with patients on those specific

drugs. Providers have limited time, so having pamphlets or even a QR code they can give patients could make a substantial difference in recruitment efforts.

For immediate next steps we recommend that you combine the survey data with the focus group insights to form a more holistic picture of the patient experience. In our experience surveys can provide critical insights but often lead to more questions as to why a patient may have answered a question a certain way or about the outcome of their experience. We hope the focus group insights help fill in those gaps, but if there are remaining gaps in understanding what leads to affordability and accessibility challenges for patients, we urge the PDAB to collaborate with patient advocacy organizations to conduct follow-up patient stakeholder opportunities.

AF Data and Insights

We regularly collect survey and focus group data from patients on their experiences with prescription drugs, including impacts of out-of-pocket costs, impacts of step therapy and prior authorization, and general experiences finding the right treatment.

Out-of-pocket Costs

The list price of Rheumatoid Arthritis (RA) biologics ranges from $5,000 to $8,000+ per dose, and patient cost-sharing varies depending on their plan type. These drugs are typically placed on specialty tiers with either co-insurance or higher co-pays. For those paying co-insurance, costs can reach into the thousands for one fill. Many patients with commercial insurance rely on some sort of copay assistance to help afford their cost-sharing, which can cause significant problems when they enroll in Medicare or experience restrictions in the use of copay assistance.

In a survey conducted by the Arthritis Foundation in 2021, patients cited out-of-pocket costs as one of the top three barriers to accessing care. Of all surveyed, 37% have had trouble affording their out-of-pocket costs this past year. Of those, 54% say they have incurred debt or suffered financial hardship because of it. Out-of-reach costs can lead to non-adherence which results in myriad negative impacts to health. In our survey, trouble affording out-of-pocket medical expenses had negative impacts on care: 45% delayed refilling a prescription, 41% say their health care worsened, and 41% switched medications as a result.

Utilization Management

Arthritis Foundation data demonstrates that inappropriate use of utilization management (UM) such as step therapy and prior authorization can lead to delays in care, resulting in negative financial, emotional, and physical consequences. Patients living with arthritis are particularly susceptible to these kinds of insurance practices, and many utilization management protocols tend to apply policies that do not adequately align with clinical guidelines or what the provider deems is in the patient's best interest. Inappropriate use of UM practices can lead to treatment delays and disease worsening. When inappropriately used, step therapy can undermine the clinical judgment of health care

providers and put patients' health at unnecessary risk. Many patients must try multiple drugs before finding one that works for them, so the ability to remain on a drug that works is critical.

A 2023 Arthritis Foundation survey on utilization management issues found the following:

- Nearly 60% of patients reported having difficulty getting their doctor-prescribed medication.
- Over 70% of patients surveyed have experienced step therapy multiple times, with 12% having experienced it 5 or more times.
- Nearly half of patients indicated they experienced joint damage due to the step therapy protocols,
    - 25% developed non-joint related health complications, and
    - 70% of patients reported suffering from stress, depression, and anxiety as a result.
- More than half of patients indicated their arthritis was at least somewhat well-managed prior to step therapy.
- While more than half of patients requested an exception to the step therapy requirement, it was only granted about 1/3rd of the time with the most likely reason cited for the exemption request was due to having already tried and failed the drug the health plan was requiring.

Over 70% of patients had to go through prior authorization process because their health plan required it.

Value Assessment Examples

The Arthritis Foundation has engaged in two RA-specific value assessment-related efforts since 2016:

Institute of Clinical and Economic Review (ICER) RA Review 2017

The Arthritis Foundation participated in an Institute of Clinical and Economic Review (ICER) review of RA drugs in 2016-2017 and as part of this effort we conducted a survey of RA patients' experience with taking biologics. Among the findings: a majority had taken multiple biologics over the course of their RA and many switched early in treatment, including 56% of respondents who had been on or taken Enbrel for less than two years. The most cited reason across all biologics was the drug did not work. Specific to Enbrel, 48% cited it did not work, 19% had bad side effects, and 9% had insurance changes. 35% of respondents indicated challenges accessing their medications and when asked the impact of insufficient treatment, 57% cited they had to take additional medications for things like pain, depression, and anxiety; 42% missed work or school; 40% experienced joint damage or worsening of disease; 22% developed non joint-related symptoms related to their disease; 19% had to leave their job or school; and 11% had to be hospitalized.

As a result of this survey, ICER took into consideration the high level of variability in treatment efficacy and the consequences of disruptions of treatment and indicated in the final report that step therapy is not appropriate in all cases.

Innovation and Value Initiative (IVI) RA Model and White Paper 2021
In its update to its RA model in 2019, IVI worked with the Arthritis Foundation to identify RA patients with whom to conduct a focus group in order to better incorporate patient experience data into their modeling. The focus group yielded important and invaluable insights and as a result we co-authored a white paper highlighting the key themes and best practices for this patient-centered approach. From the paper:

- Traditional clinical trials and research do not always capture the full complexity of living with RA, including comorbid conditions, fatigue, mental health, and the impact of hormonal changes.
- Access to effective treatment may be driven by insurance coverage or haphazard testing of treatments rather than by clinical guidelines.
- Costs related to RA include far more than direct medication costs and need to be captured.
- While RA is a progressive disease, people living with it are seeking independence and normalcy versus just symptom management.

The focus groups revealed a diverse range of experiences. From the paper:

- While severity of RA and response to treatment vary among individuals, commonly experienced symptoms include significant joint pain and weakness, stiffness, and fatigue.
- Most participants described fatigue as a largely unaddressed impact of RA, and a factor further exacerbated by many of the RA treatments as a side effect.
- Multiple individuals pointed to hormonal changes (puberty, pregnancy, menopause, etc.) as “triggers” to the onset of symptoms or treatment failures.
- Nearly every participant described significant psychological impacts of the disease, including depression, anxiety, and social isolation.
- Co-occurring conditions are common, and when present, complicate outcomes. Multiple participants reported co-occurring health conditions, including type 1 diabetes, fibromyalgia, spondyloarthropathy, lupus, anxiety, and depression.

The paper noted that even with only 14 participants, there was wide diversity in time to diagnosis (between 6 months and 5 years) and time to finding an effective treatment (between 1 year and never); treatment experiences from the paper:

- Participants reported that treatment choices appeared to be based on trial and error or insurance coverage, rather than clinical guidelines or assessment by their clinician.
- Many had difficulty finding effective treatment over time. Most were concerned about the durability of treatment and the lack of clarity about what might trigger sudden change or failure of a treatment. Several reported never finding a fully effective treatment option despite extensive regimen testing.

- Multiple individuals were concerned about running out of treatment options; there was a sense that each treatment had a "shelf life" or limited time horizon.
- Participants reflected a common experience or understanding that insurance coverage, socioeconomic status, and race impact the quality of and access to treatment.
- Participants described the impact of treatment on choices to have children, how having children impacts treatment options, and the ability to have children.

Also from the paper:
Other areas of less frequently measured costs that have high impact on patients' experiences and outcomes include:

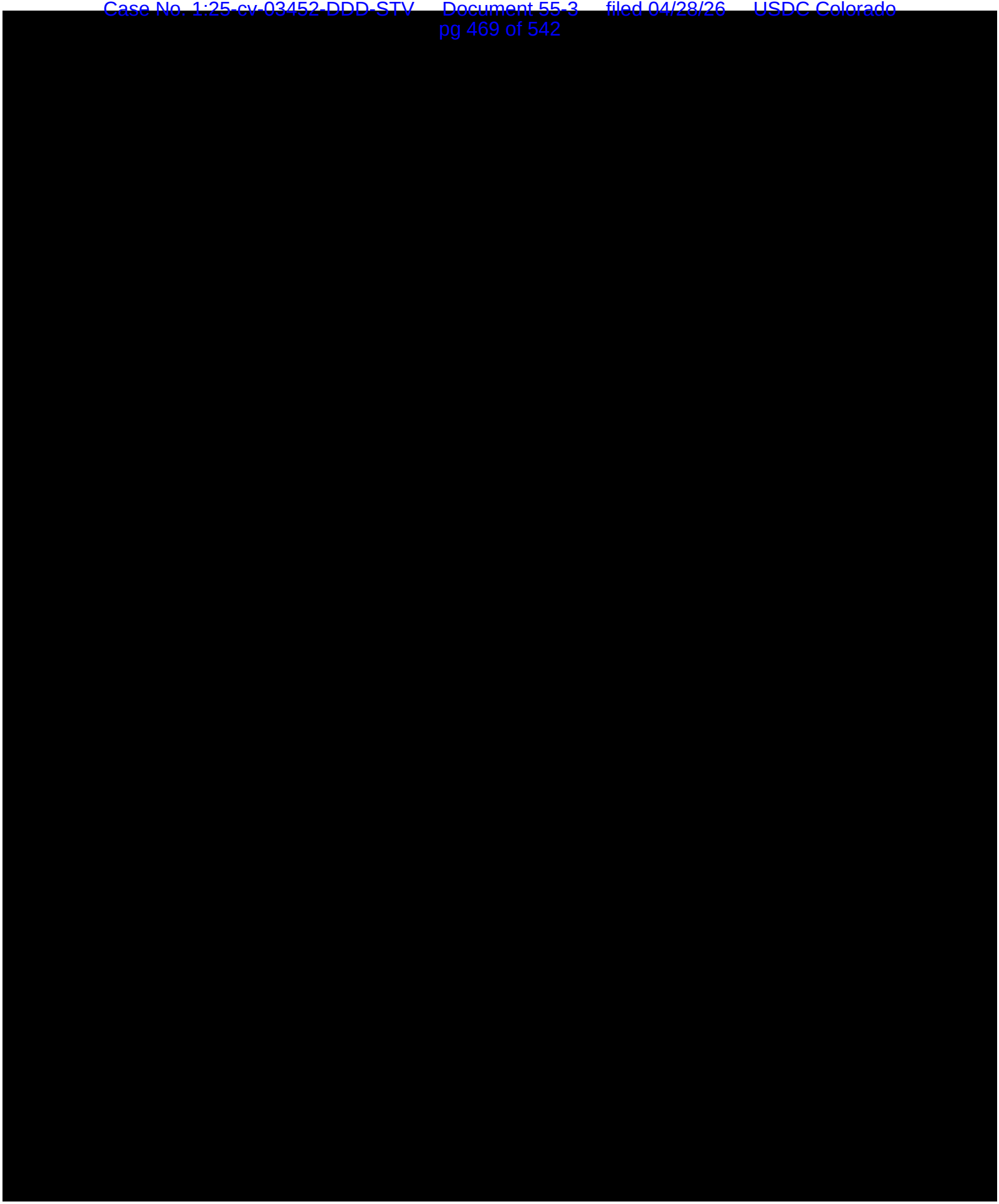
- Time spent in seeking, receiving, and recovering from treatment, with some calculating this cost to be upwards of a month a year.
- Diminished ability to work and lost wages due to early retirement or career impact, including choosing lower paying jobs to ensure health insurance access.
- Heavy burden of RA on caregivers (spouses, parents, and siblings), such as anxiety, missed work time, childcare, and job choice based on health insurance.
- Ancillary costs of seeking and receiving treatment, including transportation costs, non-medical supportive expenses (e.g., assistive devices), and non-covered benefits.

We hope these insights and examples will be valuable to the PDAB as it embarks upon the next phase of affordability reviews. We welcome the opportunity to provide further insights and to serve as a resource to the PDAB in the coming weeks and months. Thank you for your consideration, and we look forward to engaging with you in the future.

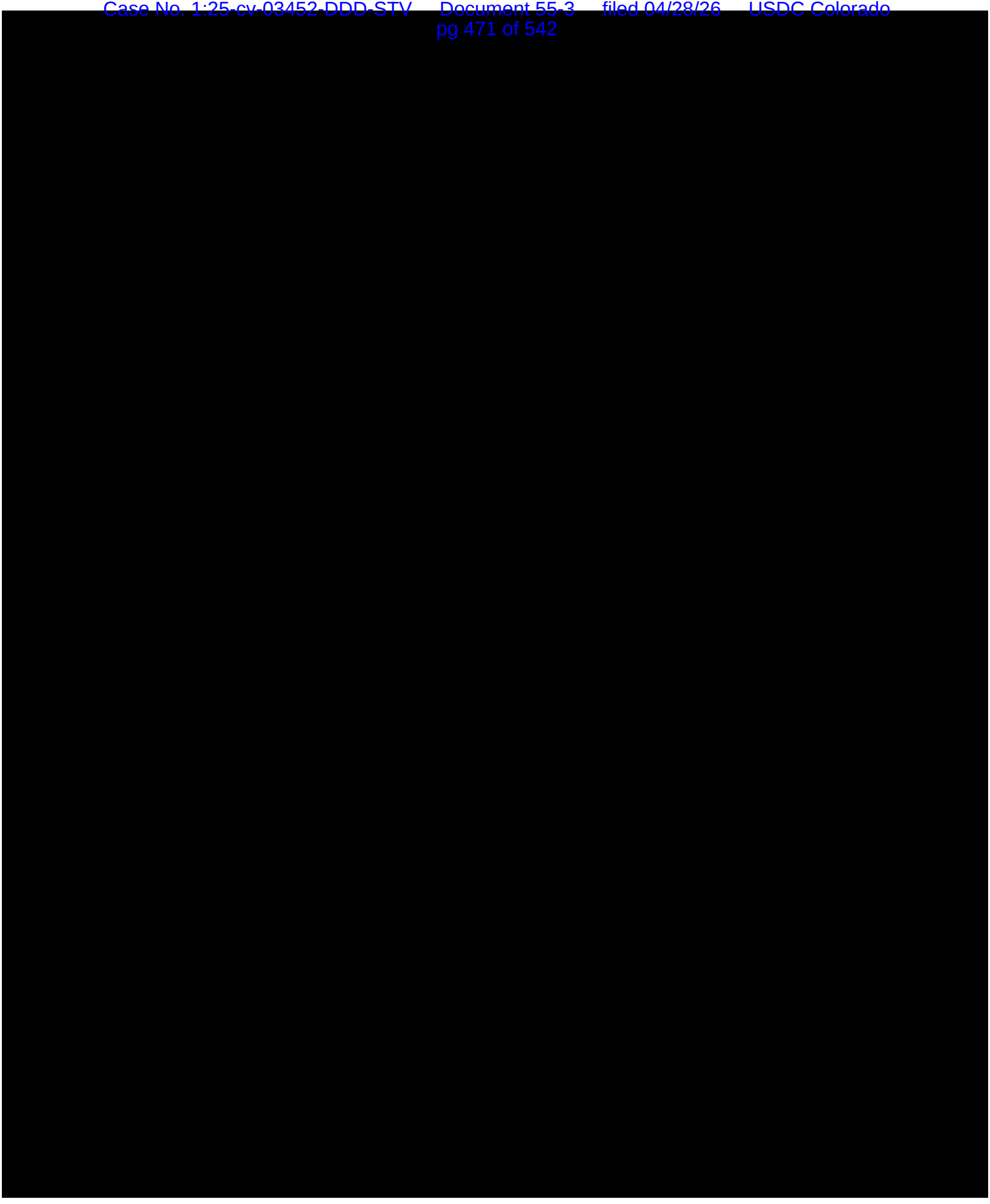
Sincerely,

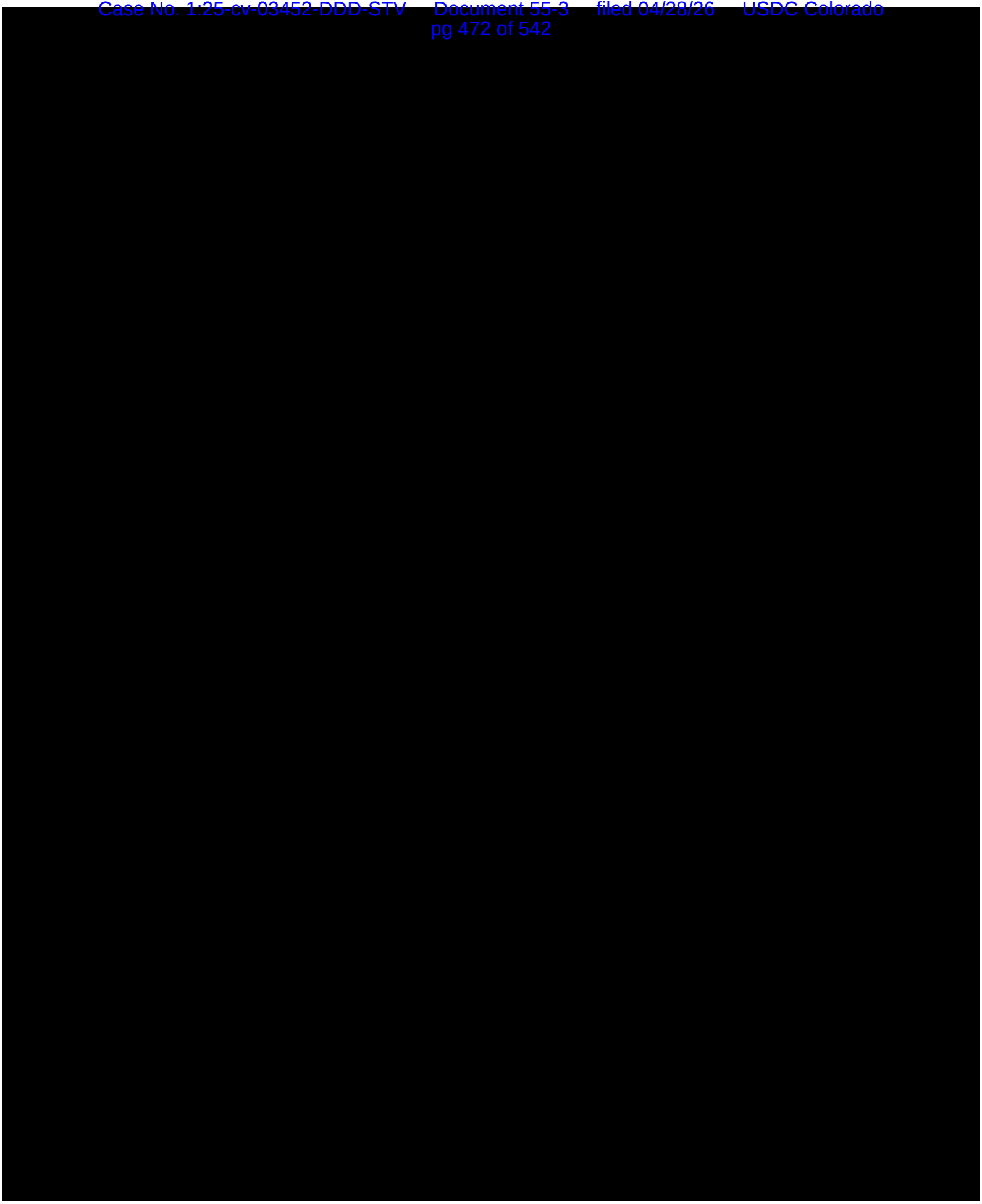
Anna Hyde

Anna Hyde
Vice President of Advocacy and Access
Arthritis Foundation



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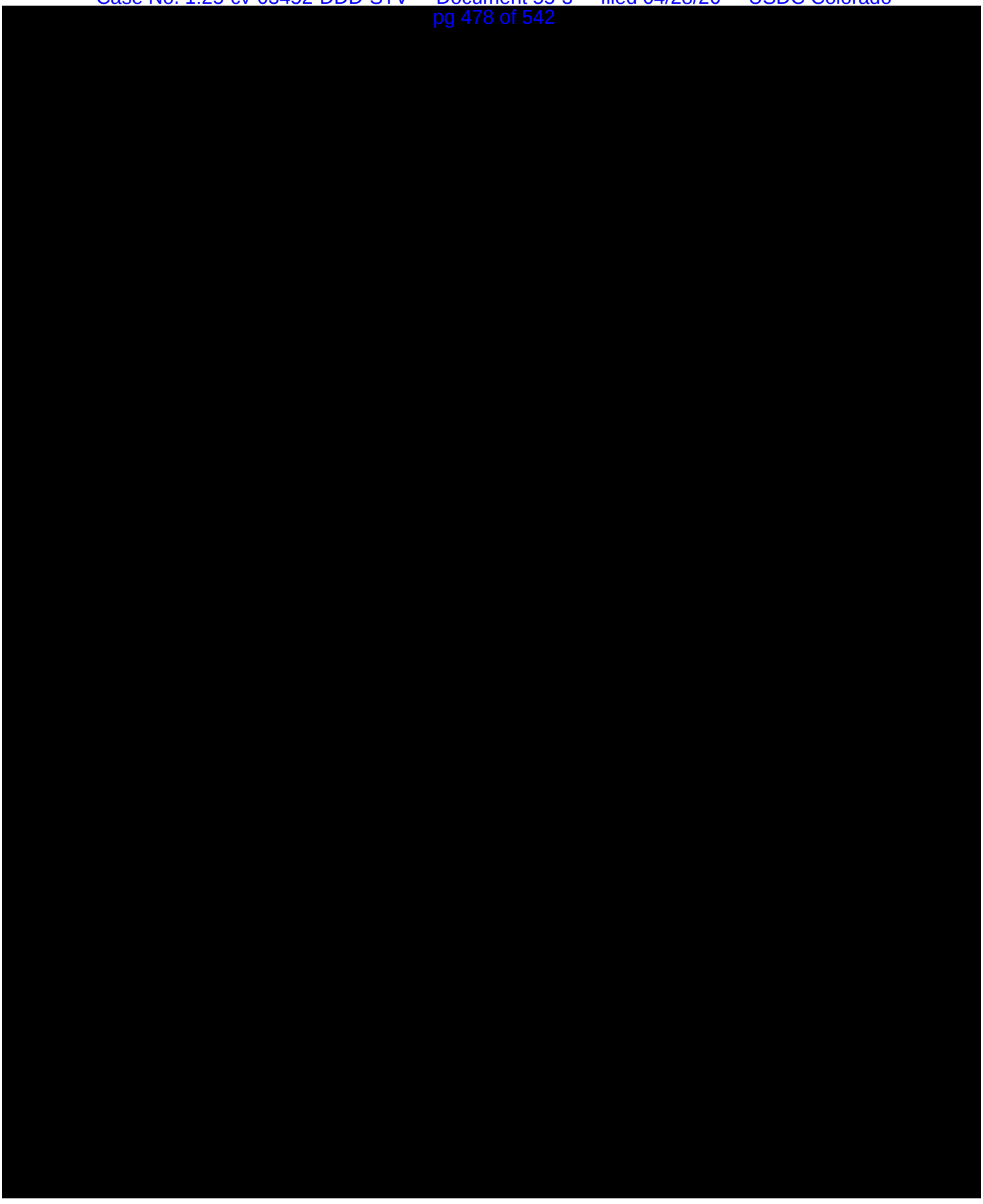


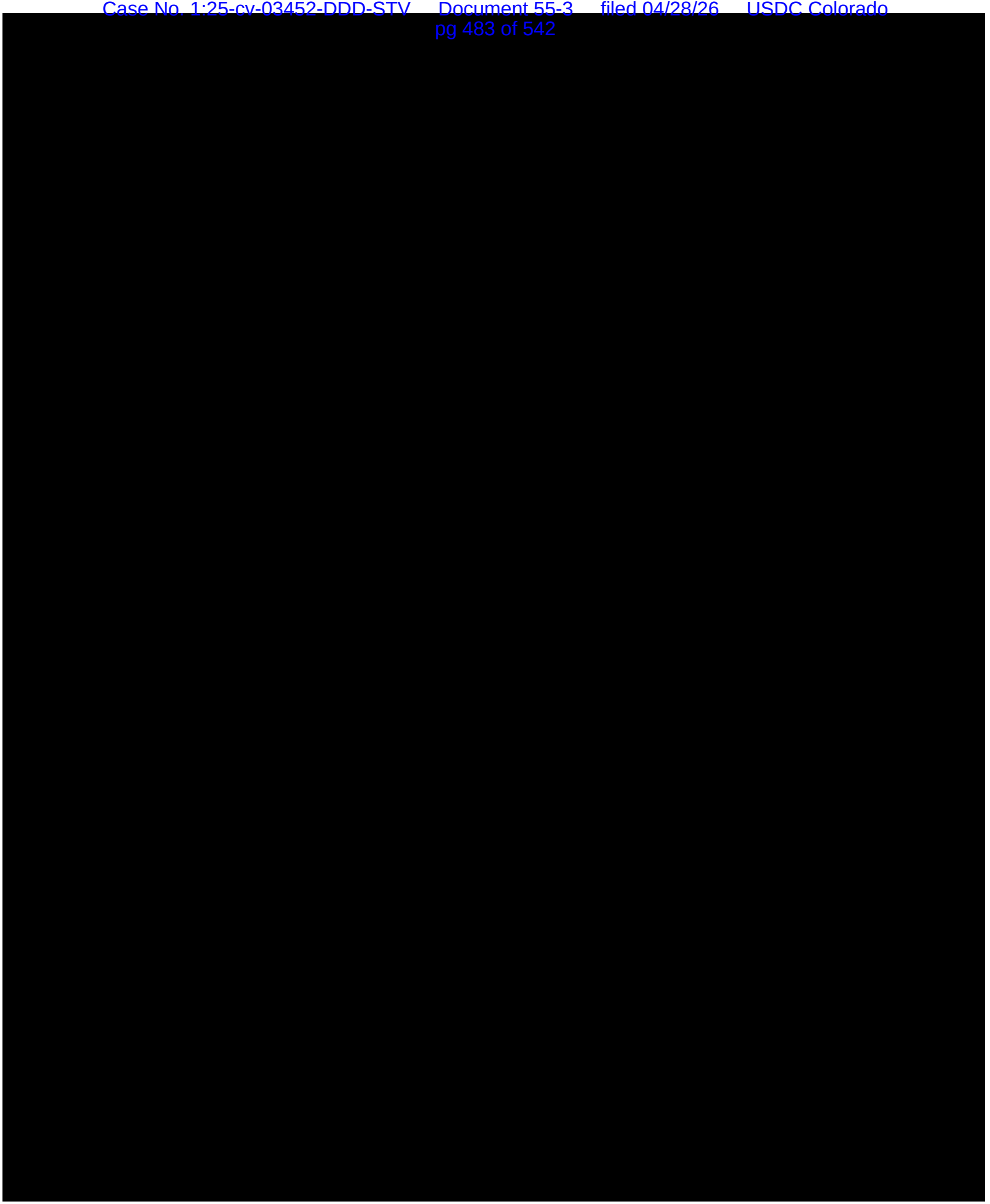




COLORADO
Prescription Drug
Affordability Board
Division of Insurance

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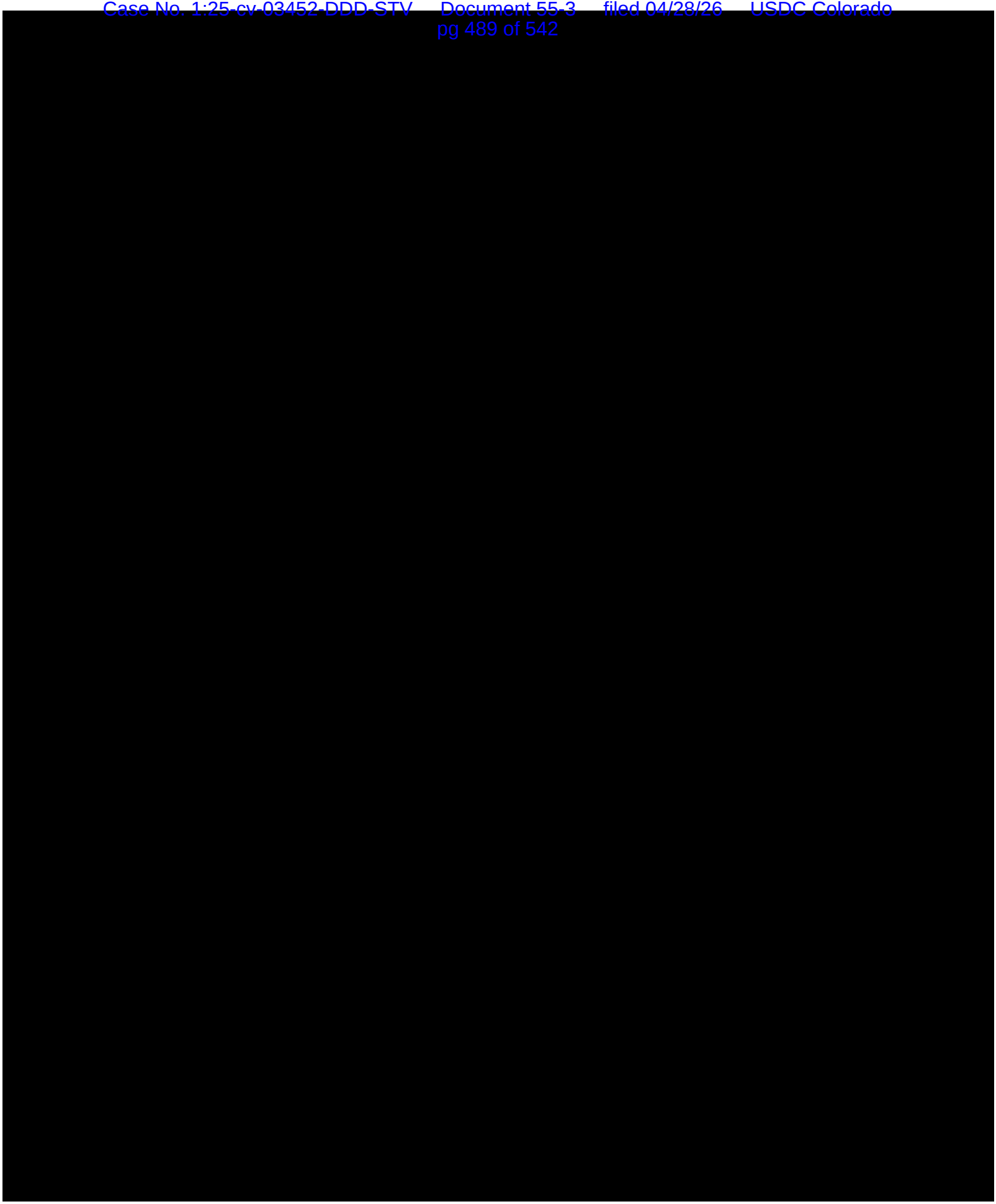




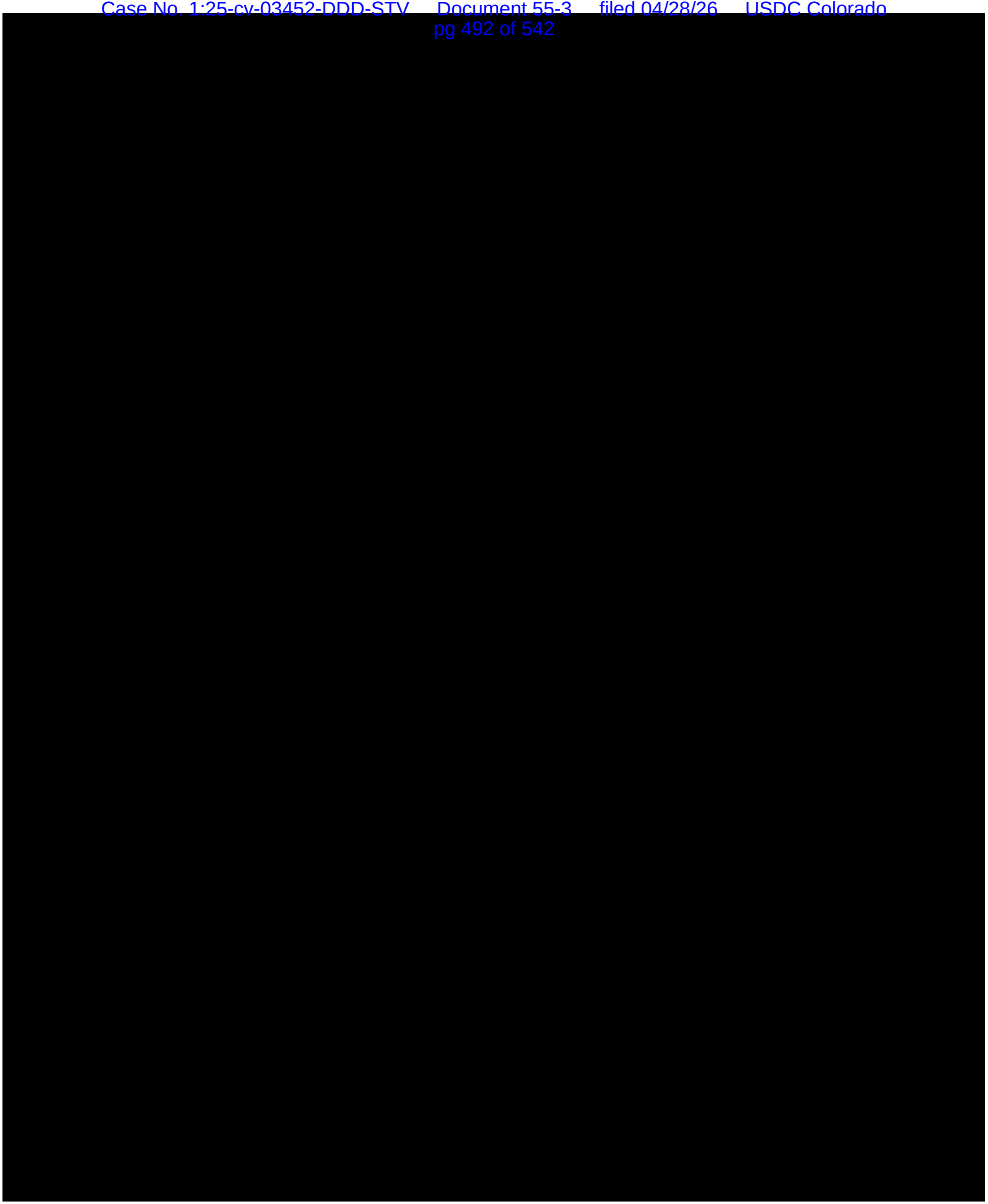
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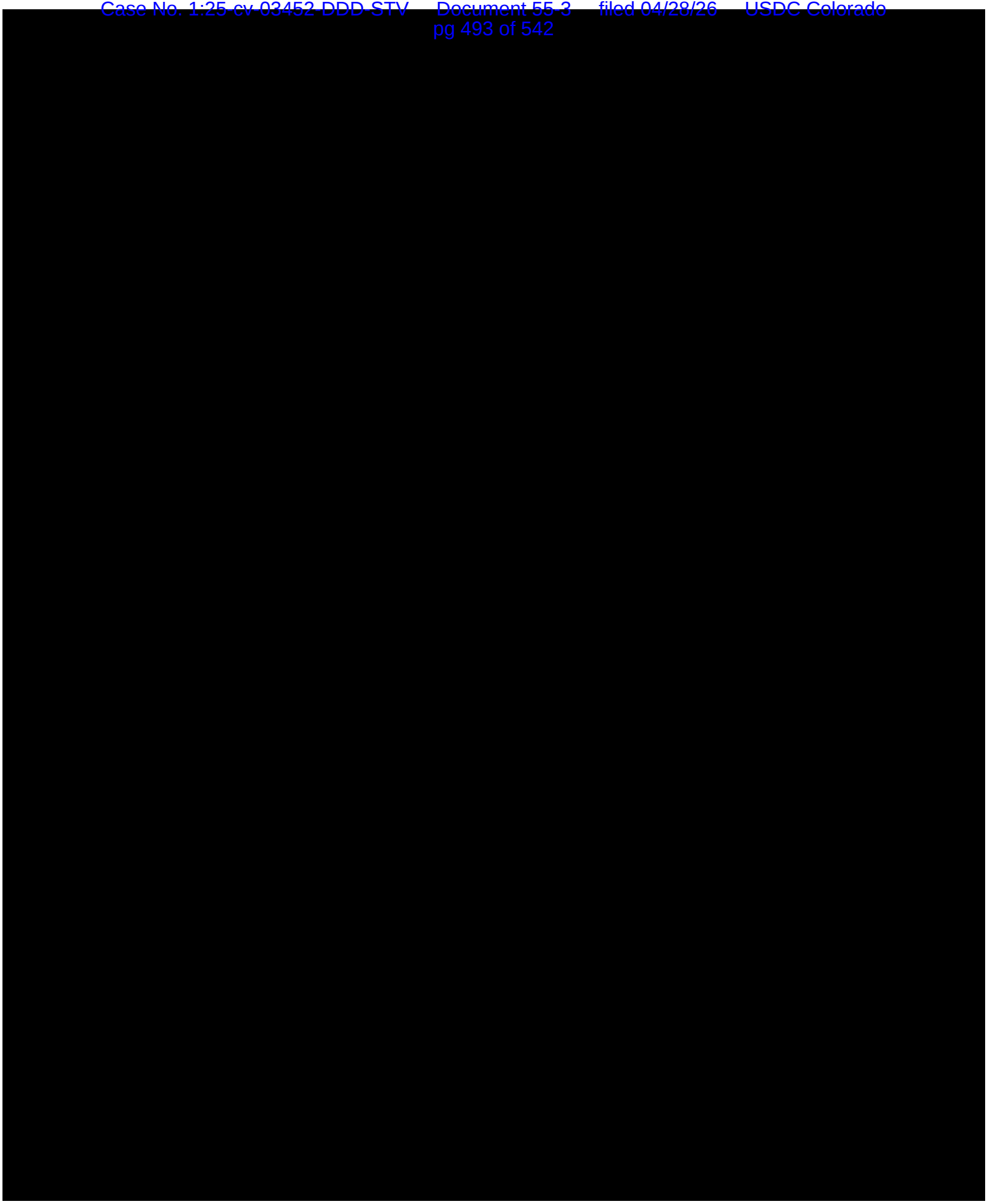
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Appendix K

Enbrel: Rebates, Discounts, and Price Concessions

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule: To the extent practicable, the Board may consider estimated manufacturer net-sales or net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives.

The Board may consider manufacturer financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities. (3 CCR 702-9, Part 3.1.E.2.j.i).

Policy: To the extent the Board has funding, information may be prepared from an external database regarding estimated manufacturer net sales and net costs (including rebates, discounts, and price concessions) for the prescription drug under review and, to the extent practicable, for therapeutic alternatives under review. Staff may also prepare information regarding manufacturer coupons to pharmacies and/or consumers. (PDAB Policy 04, p. 8).

Underlying Methodology: Board staff compiled data for the selected prescription drug for the Board's consideration in the following manner:

- Board staff contracted with SSR Health[1] to receive their proprietary U.S. prescription brand drug pricing and analytics database, which provides total net revenue and volume estimates for the majority of active brand name prescription drugs in the United States. SSR Health uses net revenues from publicly-available SEC Form 10-K financial reports from drug makers or other public sources to develop a net-sales and gross-to-net estimates quarterly for all drugs.[2] The gross-to-net estimates provide a quarterly estimated gross-to-net percent that is inclusive of all concessions and discounts that manufacturers deduct from gross sales. This is inclusive of all rebates, 340B discounts, and point of sale copayment support. SSR Health provides these estimates on a total, statutory Medicaid, and total less statutory Medicaid basis.
- Board staff gathered these estimates for Enbrel, which are presented below. The estimates are on a rolling four quarter basis.
- Board staff used publicly available information on patient assistance programs to identify manufacturer coupons and discount programs available to patients.

Data Source(s): Board staff compiled information on rebates, discounts, and price concessions for Enbrel from the following sources:

- SSR Health for estimated gross-to-net sales,
- Results of public input sessions and surveys for patients and caregivers, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations:

- SSR Health data is proprietary and confidential. Estimates are national and do not necessarily reflect rebates, discounts, and price concessions in Colorado.

[1] SSR Health: https://www.ssrhealth.com/

[2] "Best Practices Using SSR Health Net Drug Pricing Data", Health Affairs Forefront, March 10, 2022. DOI: 10.1377/forefront.20220308.712815: https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data

- Publicly available patient assistance program information is limited and does not reflect the number of patients who qualify and regularly receive assistance and the process for patients to receive assistance.

Enbrel: Rebates, Discounts, and Price Concessions Evidence

Background

This appendix includes information on gross-to-net estimates, net-sales estimates, and manufacturer financial assistance programs information. For the purposes of this appendix, these terms mean:

- Gross-to-net Sales Estimate means the proprietary estimate as a percentage where SSR Health estimates all price concessions the manufacturer gives, including rebates, 340B discounts, and coupons provided by manufactures compared to gross sales to get a percentage estimate of all discounts. All gross-to-net sales estimates are provided on a four quarter moving average to provide full annual estimates and smooth quarter to quarter variation.
- Net-sales Estimate means the proprietary estimate of net sales based on sales information from 10-K financial reports and other publically available sources including earnings calls, press releases, and investor presentations.[3]
- Manufacturer financial assistance program Estimate. This is different from the broader “patient assistance program” or “assistance program” terminology used in the Summary Report and in other appendices. While those later terms cover any patient assistance programs, information in this summary just pertains to financial assistance programs offered by the prescription drug manufacturer.

Information for gross-to-net estimates and net-sales estimates are provided first, followed by manufacturer financial assistance program estimates.

[3] "Best Practices Using SSR Health Net Drug Pricing Data", Health Affairs Forefront, March 10, 2022. DOI: 10.1377/forefront.20220308.712815: https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data

SSR Health Estimates

Figure K-1
Enbrel Net-Sales and Gross-to-Net Estimates



Figure K-1 shows the net- sales and gross-to-net estimates for Enbrel in 2008. The total gross-to-net estimate in April 2008 was [redacted], which increased to [redacted] in the third quarter of 2023.

Table K-1
Estimated Gross-to-Net for the Third Quarter of 2023

Gross-to-Net Measure	Enbrel	Cimzia	Humira	Remicade	Simponi
Total	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Statutory Medicaid	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total less Statutory Medicaid	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table K-1 shows the gross-to-net estimates broken out by total (all), statutory Medicaid (reflects most Medicaid rebates, but not all such as best price), and total less statutory Medicaid (commercial and Medicare Part D plans). The statutory Medicaid estimate is likely derived from the base 23.1% rebate required under statute[4] and not the Medicaid best price requirement that generates greater discounts. This means that the Medicaid discounts for Enbrel should actually exceed those provided to non-Medicaid entities. Strength and dosage forms of prescription drugs may be associated with different rebate amounts. What is represented in this table is for all strengths and dosage forms.

[4] 42 CFR § 447.509 Medicaid drug rebates (MDR)

Figure K-2
Estimated Total Gross-to-Net Sales



Figure K-2 shows the total gross-to-net sales estimate for Enbrel and identified therapeutic alternatives. The gross-to-net sales estimate for Enbrel has increased to [redacted] in the third quarter of 2023, [redacted]

Table K-2
Gross-to-Net Estimate (Enbrel and Therapeutic Alternatives)

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
April 2008	[redacted]		[redacted]	[redacted]	
July 2008	[redacted]		[redacted]	[redacted]	
October 2008	[redacted]		[redacted]	[redacted]	
January 2009	[redacted]	[redacted]	[redacted]	[redacted]	

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
April 2009	[redacted]	[redacted]	[redacted]	[redacted]	
July 2009	[redacted]	[redacted]	[redacted]	[redacted]	
October 2009	[redacted]	[redacted]	[redacted]	[redacted]	
January 2010	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2010	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2010	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2010	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
July 2013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2015	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2016	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2016	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2016	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2016	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2017	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2017	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2017	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2017	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
January 2018	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2018	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2018	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2018	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2019	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Quarter Date	Enbrel	Cimzia	Humira	Remicade	Simponi
July 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2023	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2023	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2023	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table K-2 lists the quarterly total gross-to-net estimates from April 2008 to July 2023 for Enbrel and identified therapeutic alternatives. If a cell is left empty, there were no estimates for that drug during that quarter.

Figure K-3
Enbrel Net-Sales Estimate as a percent of Amgen Total Net-Sales Estimate



Figure K-3 shows Enbrel net sales estimates (in purple) as a percent of Amgen total net sales from the first quarter of 2018 through the third quarter of 2023. In the third quarter of 2023, Enbrel accounted for an estimated [redacted] of Amgen's total net sales. Additional information of manufacturer-reported information of Enbrel's share of Amgen Inc.'s total sales is contained in Appendix O.[5]

Table K-3
Quarterly Net-Sales Estimate

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2008	Q1	[redacted]		[redacted]	[redacted]	

[5] Appendix O contains information of Enbrel's net sales for national and international sales, whereas this appendix contains estimates for national sales only.

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2008	Q2	[redacted]		[redacted]	[redacted]	
2008	Q3	[redacted]	[redacted]	[redacted]	[redacted]	
2008	Q4	[redacted]	[redacted]	[redacted]	[redacted]	
2009	Q1	[redacted]	[redacted]	[redacted]	[redacted]	
2009	Q2	[redacted]	[redacted]	[redacted]	[redacted]	
2009	Q3	[redacted]	[redacted]	[redacted]	[redacted]	
2009	Q4	[redacted]	[redacted]	[redacted]	[redacted]	
2010	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2010	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2010	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2010	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2011	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2011	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2011	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2011	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2012	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2012	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2012	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2012	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2013	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2013	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2013	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2013	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2014	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2014	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2014	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2014	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2015	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2015	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2015	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2015	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2016	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2016	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2016	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2016	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2017	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2017	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2017	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2017	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2018	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2018	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2018	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2018	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Year	Quarter	Enbrel	Cimzia	Humira	Remicade	Simponi
2021	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2021	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2021	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2021	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2022	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2022	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2022	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2022	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2023	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2023	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2023	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table K-3 lists the quarterly estimates in net sales for Enbrel and identified therapeutic alternatives from January 2008 to July 2023.[6] These amounts are the same reflected in Figure K-1 above.

Pursuant to section 10-16-1405(1)(a)(VII), C.R.S., each carrier and PBM must report the fifteen prescription drugs for which the carrier received the largest rebates. In 2021, 14 of 25 carriers indicated that Enbrel was in the top 15 drugs for which the carrier received the largest rebate.

Figure K-4
Carrier's Rank of Enbrel Rebates

[6] Any cells without values do not have estimates in SSR Health

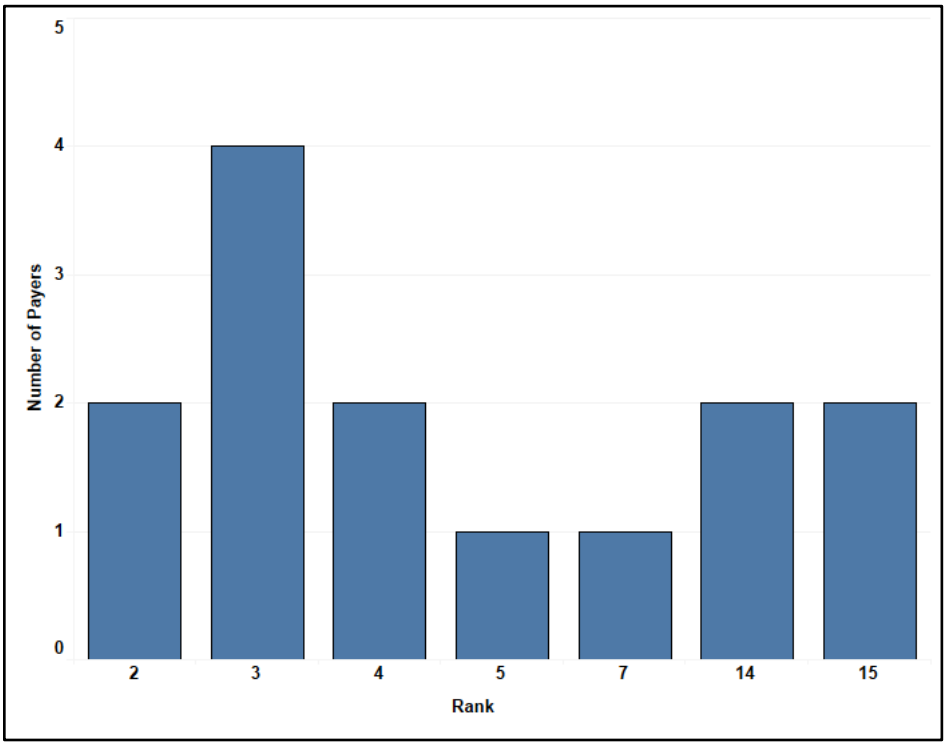


Figure K-4 shows the number of carriers who ranked Enbrel in the top 15 rebated drugs. The x-axis shows the rank and the y-axis shows the number of carriers who ranked Enbrel in that position, for example, two carriers ranked Enbrel as the second highest rebated drug and four carriers ranked it as the third highest drug.

Manufacturer Financial Assistance Programs

As part of voluntarily submitted information from Amgen Inc., the following statement regarding patient assistance was submitted: “Despite these structural barriers to reducing patient out-of-pocket costs, due to Amgen’s patient assistance programs, commercially insured Coloradans may pay as little as $0 out-of-pocket for each dose with no income eligibility requirements. In fact, roughly two-thirds, or 67 percent, of prescriptions nationally, including those where the Enbrel® Co-Pay Card was used, cost $10 or less per month. The remaining one-third of prescriptions cost an average of $341 per month. Overall, only 14 percent of prescriptions cost more than $100 per month.”[7] Additionally, the statement said, “As previously noted, the out-of-pocket costs commercially insured patients pay for Amgen medicines, like Enbrel®, have changed very little over the decades. Through Amgen’s co-pay card programs, out-of-pocket expenditures for our advanced medicines are significantly reduced – as little as $0 out-of-pocket for each dose with no income eligibility requirements. In fact, roughly two-thirds, or 67 percent, of prescriptions, including those where the Enbrel® Co-Pay Card was used, cost $10 or less per month. The remaining one-third of prescriptions cost an average of $341 per month. Overall, only 14 percent of prescriptions cost more than $100 per month.” Amgen Inc. stated the following about uninsured and vulnerable patients: “We also recognize that many uninsured and vulnerable patients need extra help affording their medicines. For that reason, Amgen established the Amgen Safety Net Foundation to provide access to Amgen medicines at no cost to qualifying patients in the U.S. (including Puerto Rico) who have a financial need and are uninsured or have an insurance plan that excludes the prescribed Amgen medicine. Since 2008, the Amgen Safety Net Foundation (ASNF) has provided nearly $13 billion worth of Amgen medicines to help hundreds of thousands of qualifying patients gain access to their therapy in the United States.”[8]

[7] https://drive.google.com/file/d/1wjNIBWWQoOQe0ufBRWkl0GmqOe381WN2/view?usp=drive_link
[8] https://drive.google.com/file/d/1wjNIBWWQoOQe0ufBRWkl0GmqOe381WN2/view?usp=drive_link

Board staff gathered further information on the Enbrel Co-Pay Program via the drug's public website.[9] According to the website, the co-pay program is open to patients with commercial insurance that covers an Amgen SupportPlus product, regardless of financial need. While there is no income requirement for participation, the maximum program benefit and patient total program benefit are determined by the patient's plan coverage. A patient must meet eligibility criteria for the Amgen Safety Net Foundation assistance including that they: lived in the U.S. or its territories for six months or longer, satisfy income eligibility requirements, and are uninsured or on an insurance plan that excludes the Amgen medicine or its generic/biosimilar. While certain Medicare Part D patients may be eligible, they have to demonstrate inability to afford the medicine and have satisfied all payer guidelines and Prior Authorization (PA) requirements. Patients using Enbrel are able to check if they qualify for assistance through ASNF from their website.[10]

Board staff heard from patients, caregivers, and individuals with scientific and medical training that there are patient assistance programs in addition to the Enbrel Co-Pay Program. See Appendices H, I, and J for more information on both manufacturer financial assistance programs and other patient assistance programs.

[9] https://www.amgensupportplus.com/copay-card-program-terms-and-conditions

[10] https://www.amgensafetynetfoundation.com/eligibility.html

Appendix L

Enbrel: Health Equity Factors

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule: The Board will consider whether the pricing of the prescription drug results in or has contributed to health inequities in priority populations. (3 CCR 702-9, Part 3.1.E.2.j.ii).

Policy: Staff will prepare information regarding changes in utilization as compared to changes in WAC and changes in expenditures as identified in APCD data, attempting to understand changes in utilization by:

- People experiencing homelessness;
- People involved in the criminal justice system;
- Black people, indigenous people, and people of color;[1]
- American Indians and Alaska natives;
- Veterans;
- People who are lesbian, gay, bisexual, transgender, queer, or questioning;
- People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth;
- People who have AIDs or HIV;
- Older adults;
- Children and families;
- People with disabilities, including people who are deaf and hard of hearing, people who are blind and deafblind, people with brain injuries, people with intellectual and developmental disabilities, people with other co-occurring disabilities;
- Other populations as deemed appropriate by the Prescription Drug Affordability Board. (PDAB Policy 04, pp. 8-9).

Underlying Methodology: Board staff have compiled data on health equity factors for the Board's consideration in the following manner:

1. Staff conducted an analysis into the Social Vulnerability Index (SVI) score of counties where individuals who used Enbrel live.
2. Staff conducted a literature review to understand if the indications for the selected prescription drug disproportionately impact priority populations.

Data Sources: Board staff compiled information on health equity factors for the selected prescription drug from the following sources:

- The Social Vulnerability Index (SVI), created by the U.S. Center for Disease Control (CDC) Geospatial Research, Analysis and Services Program, which uses 16 U.S. census variables to determine the social vulnerability of counties. This program defines social vulnerability as factors, including poverty, lack of access to transportation, and crowded housing that may weaken a community's ability to prevent suffering and financial loss in a disaster.[2]
- APCD data to identify the county of residence of patients who took Enbrel in 2022.
- Peer-reviewed journals pertaining to the indications treated by the selected prescription drugs and potential impacts on priority populations.

[1] When referring to racial and ethnic groups, Board staff applies the language used in the study being referenced.

[2] https://www.atsdr.cdc.gov/placeandhealth/svi/index.html

Considerations and Data Limitations: The SVI is calculated on a county basis, and does not necessarily reflect the circumstances of the utilizers of the prescription drug. County of residence at the time each prescription was used, if individuals moved during 2022, so their utilization factors into the percent of total patients from each county where they resided throughout the year.

Enbrel: Health Equity Factors Evidence

Social Vulnerability Index (SVI) Information

Board staff calculated SVI scores for patients who utilized Enbrel in the following manner:

1. Staff used 2020 Social Vulnerability Index (SVI) data by county in Colorado and calculated the straight statewide average overall SVI score of 49.95%.
2. Counties with an SVI score higher than 49.95% were classified as higher than the statewide average, meaning that individuals residing in these counties may be more vulnerable to adverse outcomes due to social conditions in their county.
3. Counties with an SVI score lower than 49.95% were classified as lower than the statewide average, meaning that individuals residing in these counties may be less vulnerable to adverse outcomes due to social conditions in their county.
4. Staff aggregated APCD data based on the county of residence of utilizers of Enbrel and calculated a percent of total patients who resided in each county in Colorado in 2022.
5. Staff combined these two data sources to determine the percent of patients who used Enbrel in 2022 who resided in Colorado counties with SVI scores above the statewide average.

Following the methodology outlined above, staff calculated that in 2022, 48.65% of patients who filled a prescription for Enbrel lived in a county with an SVI score above the statewide average of 49.95%, meaning that 48.65% of Enbrel patients lived in a county with higher social vulnerability. This could indicate that patients who utilize Enbrel are located in counties that are more vulnerable to adverse outcomes due to social conditions in their county than patients in the average Colorado county.

Figure L-1

Map of Colorado by 2022 SVI Score for Utilizers of Enbrel

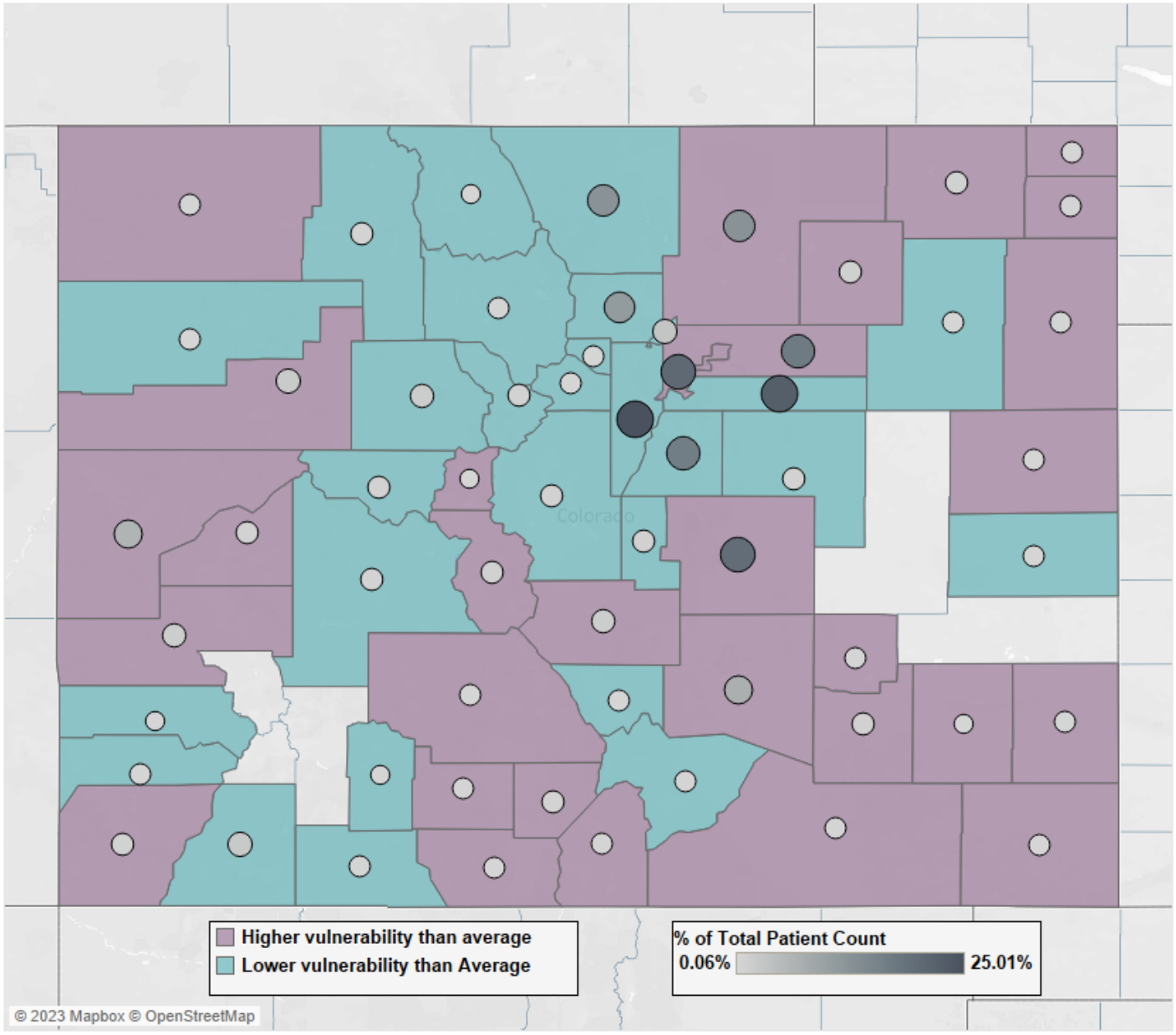


Figure L-1 shows the state of Colorado by county, where purple counties indicate higher than average SVI scores and teal counties indicate a lower than average SVI score, and counties without color did not have any patients who used Enbrel in 2022 residing in them. The dots on each county show the percent of patients who used Enbrel in 2022 by county where a larger, darker dot represents a higher portion of utilizers and smaller, lighter dots represent a smaller portion of the population.

Table L-1

Percent of Patients of Enbrel and Therapeutic Alternatives by County

	County	County SVI Score	Enbrel	Cimzia	Humira	Remicade	Simponi
	ADAMS	80.95%	8.54%	7.16%	8.18%	6.16%	7.43%
	ALAMOSA	100.00%	0.23%		0.35%	0.14%	

Counties with Higher Vulnerability Than Average	BACA	52.38%	0.09%	0.21%	0.07%	0.14%	0.17%
	BENT	82.54%	0.03%		0.04%	0.14%	
	CHAFFEE	63.49%	0.50%	0.63%	0.29%	1.00%	0.17%
	CONEJOS	93.65%	0.06%	0.21%	0.04%	0.29%	
	COSTILLA	95.24%	0.15%	0.21%	0.04%	0.14%	
	CROWLEY	77.78%	0.09%		0.04%	0.14%	0.17%
	DELTA	79.37%	0.35%	1.26%	0.49%	0.43%	0.35%
	DENVER	73.02%	10.31%	10.53%	12.12%	11.89%	10.36%
	EL PASO	53.97%	9.86%	8.84%	10.38%	11.32%	7.43%
	FREMONT	60.32%	0.79%	0.84%	1.00%	0.43%	0.52%
	GARFIELD	61.90%	1.06%	1.26%	1.32%	0.57%	0.86%
	KIT CARSON	69.84%	0.06%		0.12%		0.17%
	LAKE	57.14%	0.03%		0.11%		0.17%
	LAS ANIMAS	85.71%	0.15%		0.32%		0.35%
	LINCOLN	55.56%			0.04%		0.17%
	LOGAN	71.43%	0.47%	0.42%	0.52%	0.29%	0.17%
	MESA	74.60%	3.02%	5.47%	3.23%	2.44%	2.42%
	MOFFAT	90.48%	0.21%	0.42%	0.15%		0.52%
	MONTEZUMA	58.73%	0.38%	0.63%	0.54%	0.72%	0.17%
	MONTROSE	68.25%	0.79%	2.74%	0.69%	0.29%	0.35%
	MORGAN	92.06%	0.53%		0.50%	0.29%	0.35%
	OTERO	87.30%	0.44%		0.41%	0.57%	0.17%

	PHILLIPS	50.79%	0.15%	0.21%	0.07%		0.17%
	PROWERS	98.41%	0.12%		0.21%	0.14%	0.17%
	PUEBLO	84.13%	3.49%	1.89%	4.36%	1.15%	3.63%
	RIO GRANDE	96.83%	0.18%	0.21%	0.39%		0.17%
	SAGUACHE	88.89%	0.06%		0.08%		
	SEDGWICK	76.19%	0.06%		0.03%		0.17%
	WELD	66.67%	6.25%	5.68%	8.08%	8.45%	5.70%
	YUMA	65.08%	0.21%		0.19%	0.29%	
	Total		***48.65%***	***48.84%***	***54.37%***	***47.42%***	***42.49%***
Counties with Lower Vulnerability Than Average	ARAPAHOE		11.30%	9.26%	9.78%	14.76%	12.61%
	ARCHULETA	41.27%	0.21%		0.12%	0.14%	
	BOULDER	39.68%	5.46%	8.42%	5.06%	2.87%	8.12%
	BROOMFIELD	9.52%	1.56%	1.47%	1.33%	1.00%	1.73%
	CHEYENNE	14.29%	0.06%		0.07%		
	CLEAR CREEK	19.05%	0.09%	0.21%	0.15%	0.29%	0.17%
	CUSTER	6.35%	0.06%		0.08%	0.14%	
	DOLORES	12.70%	0.09%				
	DOUGLAS	1.59%	8.28%	5.89%	5.87%	8.02%	8.98%
	EAGLE	44.44%	0.88%	0.63%	0.56%	0.57%	0.35%
	ELBERT	0.00%	0.41%	0.21%	0.23%	0.43%	0.52%
	GILPIN	4.76%	0.12%	0.21%	0.03%	0.29%	
	GRAND	28.57%	0.21%	0.63%	0.17%		
	GUNNISON	25.40%	0.23%	0.63%	0.25%		0.17%

	HINSDALE	38.10%			0.04%		
	HUERFANO	42.86%	0.18%		0.09%		
	JACKSON	31.75%	0.03%				
	JEFFERSON	20.63%	12.51%	16.00%	10.75%	11.03%	19.00%
	LA PLATA	36.51%	1.17%	1.47%	1.38%	0.43%	0.35%
	LARIMER	33.33%	6.19%	3.79%	7.49%	11.03%	3.45%
	MINERAL	22.22%	0.03%		0.03%		
	OURAY	6.35%		0.21%	0.04%		
	PARK	3.17%	0.32%	0.42%	0.21%	0.14%	0.17%
	PITKIN	15.87%	0.41%	0.21%	0.27%	0.14%	
	RIO BLANCO	47.62%	0.06%	0.21%	0.12%	0.29%	0.35%
	ROUTT	11.11%	0.26%	0.21%	0.52%	0.14%	0.52%
	SAN JUAN	44.44%			0.01%		
	SAN MIGUEL	26.98%	0.03%	0.21%	0.13%	0.14%	
	SUMMIT	30.16%	0.41%	0.21%	0.35%	0.43%	0.69%
	TELLER	17.46%	0.44%	0.21%	0.43%	0.14%	0.52%
	WASHINGTON	34.92%	0.09%		0.13%	0.14%	
	Total		***51.09%***	***50.74%***	***45.68%***	***52.58%***	***57.69%***

Table L-1 shows a breakdown of the SVI score of each county, with higher than average vulnerability counties listed first, with the percent of utilizers in each county for Enbrel and identified therapeutic alternatives in 2022. Please note the percent of utilizers may not equal 100% as some patients may have moved throughout the year and might be counted in each location where they lived while filling a prescription.

Figure L-2
SVI Score for Enbrel and Therapeutic Alternatives

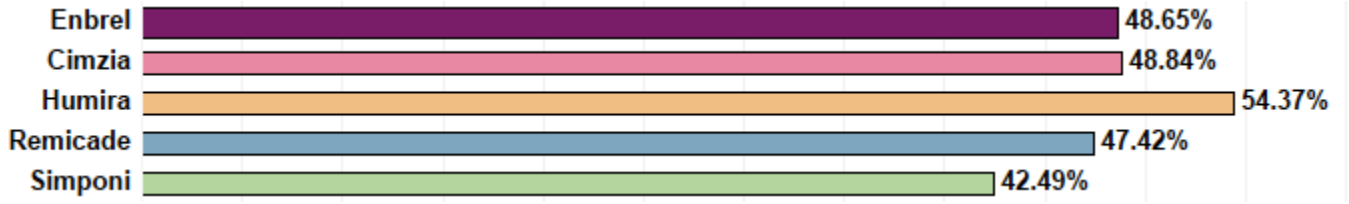


Figure L-2 shows the percent of utilizers of Enbrel and identified therapeutic alternatives that lived in a county with a higher social vulnerability index score than the statewide average.

Health Equity Literature Review

Literature reviews were conducted for each of Enbrel's FDA-approved indications and are meant to provide a broad overview of potential health equity impacts related to the disease or condition. Citations are provided for more information regarding the specific study populations, locations, timeframes, and categories or subcategories of the indication being studied.

Rheumatoid Arthritis (RA)

According to major treatment guidelines, the standard of care for rheumatoid arthritis (RA) includes early assessment, frequent reassessment, and aggressive adjustment of therapy to achieve remission and reduce disease progression.[3] RA therapy is dependent on access to specialty care, insurance coverage, and management of associated comorbidities.[4] One study found that non-Hispanic African Americans and people with low family income had a significantly higher RA risk, while people with high education levels had a significantly lower RA risk.[5]

Delay in diagnosis of RA can lead to more severe disease manifestations and irreversible bone destruction, disability, and loss of function.[6] Geographic distance from a rheumatologist can increase negative health outcomes by delaying diagnosis and making it difficult for patients to receive the frequent reassessments needed to monitor disease activity.[7] One study found that patients with the longest driving distances to rheumatology providers had approximately 30% decreased odds of receiving an RA diagnosis compared with those located nearest to rheumatology care.[8] Remote distance from providers was also associated with a 70% reduction in continuity of care in the first year of disease onset.[9] Additionally, decreased access to RA services can result in accumulation of RA damage, leading to increased need for surgeries.[10]

Type of insurance is also associated with RA disease activity and burden. Some studies have shown that Medicaid coverage can be associated with less access to care. One study found that fewer than 20% of rheumatology practices were caring for more than 50% of RA patients with Medicaid.[11] Another study of patients aged 18 to 64 years found that uninsured and Medicaid patients were 17% and 13% less likely to visit a rheumatologist, respectively.[12]

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[3] https://www.rheumatic.theclinics.com/article/S0889-857X(20)30077-6/fulltext

[4] https://acrabstracts.org/abstract/the-distribution-of-social-deprivation-distance-to-care-and-disease-burden-in-rheumatoid-arthritis-patients-in-the-united-states/

[5] https://www.mdpi.com/2077-0383/10/15/3289

[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8009304/

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8009304/

[8] https://onlinelibrary.wiley.com/doi/abs/10.1002/acr.22333

[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3913026/

[10] https://www.jrheum.org/content/42/3/429.short

[11] https://acrabstracts.org/abstract/the-distribution-of-social-deprivation-distance-to-care-and-disease-burden-in-rheumatoid-arthritis-patients-in-the-united-states/

[12] https://www.tandfonline.com/doi/abs/10.1080/03007995.2016.1227775

Currently, there are multiple therapeutic options for patients with RA, but the availability of biological therapy to groups with lower socioeconomic status is a concern given the cost of these therapies to payers.[13] Medicaid patients aged 18 to 64 years had just 9% odds of receiving biological therapy compared with patients with private insurance.[14] Those with Medicaid were more likely than those with private insurance to be unable or delayed in getting prescription drugs, to experience cognitive, social, and physical limitations, and also reported significantly lower general health and health-related quality of life.[15]

Rheumatoid arthritis is associated with progressive disability, and with limitations in work and physical activity. One study revealed that 39% of RA patients were unable to work 10 years after early-stage rheumatoid arthritis. About 30% of RA patients were more likely to need help with personal care and were twice as likely to have a health-related activity limitation.[16] One study found that patients with RA are more susceptible to mental health disorders such as anxiety, depression, or cognitive impairment, which may be contributing to higher disease activity and lower treatment responsiveness.[17]

Ankylosing Spondylitis (AS)

Ankylosing spondylitis (AS), a subset of axial spondyloarthritis,[18] is historically considered a disease predominantly impacting men. However, increasing evidence suggests that it is often under-recognized or misdiagnosed in women. One study found that, on average, women wait about 8 years for an AS diagnosis while men wait about 6 years, and women may have more active disease because of a delay in diagnosis. In addition, men are more likely to receive a correct first diagnosis of AS (30%) compared with women (11%). Many factors are thought to contribute to this longer diagnostic delay, including inadequate healthcare professional knowledge, historical biases, and poor communication between providers, resulting in a lack of awareness of potential gender differences in disease manifestation, leading to misdiagnosis.[19]

Studies have found that white people are more often diagnosed with ankylosing spondylitis when compared with Black and Hispanic people.[20] Multiple researchers have raised concerns about detection bias with regard to diagnosing AS among people of color. Since it has been believed that white people are at higher risk for AS, health care providers may tend to suspect AS more often when treating white people while missing symptoms of spondylitis in people of color.[21] Some researchers have noted that reduced access to diagnostic tests and specialists may also affect the numbers of people of color diagnosed with rheumatic diseases.[22]

Despite being diagnosed at lower rates than white and Hispanic patients, Black patients reported greater discomfort and impairment, had higher levels of inflammation, and showed more joint damage and deterioration on X-rays and MRIs.[23] A study in the Journal of Rheumatology found that Black patients with AS have both higher disease activity and comorbidities compared to white patients.[24] This is further complicated by the fact that people of color are underrepresented in clinical trials for inflammatory arthritis and genetic research as a whole.[25]

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13 https://www.jmcp.org/doi/abs/10.18553/jmcp.2014.20.11.1110
14 https://www.tandfonline.com/doi/abs/10.1080/03007995.2016.1227775
15 https://www.tandfonline.com/doi/abs/10.1080/03007995.2016.1227775
16 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9677290/
17 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9677290/
18 https://www.arthritis.org/diseases/ankylosing-spondylitis
19 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9568456/
20 https://www.jrheum.org/content/jrheum/47/6/835.full.pdf
21 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8475338/
22 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693696/
23 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693696/
24 https://www.jrheum.org/content/47/6/835.long
25 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4082969/

As with many other inflammatory diseases, research suggests Black patients are not offered biologics as early on as white patients.[26] One study found that Black patients tended to undergo less treatment with biologic agents, despite having more severe disease.[27]

Plaque Psoriasis

Psoriasis is an immune-mediated disease that affects 3.0% of the US adult population, or more than 7.5 million adults. Plaque psoriasis is the most common subtype of psoriasis, affecting up to 80 percent of those with psoriasis.[28] Psoriasis has higher prevalence among white individuals (3.6%) compared with Asian (2.5%), Hispanic (1.9%), and Black (1.5%) individuals.[29]

Lack of culturally competent care was identified as a key unmet need for psoriasis among people with skin of color. One study reported that Hispanic and Black patients with psoriasis experienced more provider-related bias, stereotyping, misdiagnosis, and delayed diagnosis compared with white patients. The clinical presentation of psoriasis is different in people with darker skin tones compared to those with lighter skin tones and contributes to delayed diagnosis in historically marginalized populations. Additionally, people with skin of color are underrepresented in clinical trials of psoriasis therapies.[30]

Compared with white patients with psoriasis, individuals with skin of color may be less familiar with and have different rates of treatment with biologic therapies for psoriasis, are more likely to be hospitalized for psoriasis, and their access to physicians may differ. One study demonstrated significantly higher odds of hospitalization for psoriasis among Black, Hispanic, and Asian individuals. The same study also found higher rates of hospitalization for psoriasis among Medicare and Medicaid recipients, and uninsured patients compared with privately insured patients.[31] Black patients were less likely to receive biologic treatment or effective medications for their psoriasis compared with white patients. One study found that 8.3% of Black patients received a disease-modifying antirheumatic drug (DMARD) for their psoriasis, and 28% received a biologic therapy. In comparison, 13.3% of White individuals received a DMARD and 46.2% received a biologic therapy for their psoriasis. Additionally, patients of color reported high costs of care as a significant barrier to seeking and receiving treatment. Black, Asian, and other non-Hispanic historically marginalized populations are approximately 40% less likely to see a dermatologist for psoriasis compared with white patients.[32]

Nearly one-third of psoriasis patients are in the pediatric age group. With an annual prevalence of up to 0.71%, childhood psoriasis can be regarded as a frequently seen chronic inflammatory skin disorder having a significant impact on the quality of life. Incidence of pediatric psoriasis varies between different ethnic groups, being highest in white and Black children. International studies have shown that pediatric psoriasis is more common in girls than in boys, but the difference is not always significant.[33]

Children with psoriasis require treatment until adulthood, and prolonged treatment may increase the risk of complications and adverse events, therefore it is crucial to adopt an effective treatment approach that reduces this risk. Long-term comorbidities associated with psoriasis may place a great burden on the physical and mental health of children with psoriasis beyond the effects of psoriasis itself. Pediatric patients with moderate-to-severe plaque psoriasis demonstrated significantly impaired health-related quality of life in relation to physical, emotional, social, and school functioning compared with healthy children, and pediatric psoriasis was associated with significantly worse quality of life than other skin diseases. Children

[26] https://www.ajmc.com/view/black-patients-with-ra-less-likely-than-white-counterparts-to-be-prescribed-a-biologic
[27] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693696/
[28] https://www.psoriasis.org/locations-and-types/
[29] https://www.sciencedirect.com/science/article/abs/pii/S0733863522000961?via%3Dihub
[30] https://www.sciencedirect.com/science/article/abs/pii/S0733863522000961?via%3Dihub
[31] https://www.sciencedirect.com/science/article/abs/pii/S0733863522000961?via%3Dihub
[32] https://www.sciencedirect.com/science/article/abs/pii/S0733863522000961?via%3Dihub
[33] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5683294/

with psoriasis are at approximately 20% to –30% higher risk of developing psychiatric disorders, such as depression and anxiety, than children without any psoriasis diagnosis. Anxiety or depression may stem from experiences of shame, behavior avoidance, bullying, decreased self-confidence, and social isolation caused by psoriasis.[34]

Psoriatic Arthritis

Often, patients with psoriasis are also diagnosed with psoriatic arthritis (PsA). Up to 30% of psoriasis patients initially present with a skin condition and then eventually progress into joint pain over 10 years following the initial psoriasis diagnosis.[35] The condition typically begins between the ages of 30 and 50, but children with psoriasis may also develop psoriatic arthritis. Though all races can get psoriasis and psoriatic arthritis, it is diagnosed more often in white people than people of other races and ethnicities.[36] One study found that white patients were five times more likely to be diagnosed with psoriatic arthritis compared with Black patients.[37] The disparity in prevalence could potentially be due to underdiagnosis in historically marginalized racial/ethnic groups.[38]

Though psoriatic arthritis is less frequent in Black patients compared to white patients, Black patients had more severe skin involvement, and greater psychological impact and impaired quality of life. One study reported a significantly higher degree of disease severity and lower use of biologics among Black patients compared with white patients.[39] One study found Black patients were 70% less likely to receive biologics than white patients.[40]

Insurance coverage may also impact diagnosis and treatment for psoriatic arthritis. One study found that Medicaid patients were less likely to be diagnosed with psoriatic arthritis, and only 12% of those with Medicaid saw a doctor who specializes in treating arthritis, compared to more than 50% of patients with other types of insurance. Those with private insurance or Medicare were more likely to get a correct diagnosis, see a specialist, and have targeted treatments.[41]

Juvenile Psoriatic Arthritis

In children, psoriatic arthritis is a form of juvenile idiopathic arthritis (JIA). It affects 1-7% of children with JIA. Juvenile Psoriatic Arthritis (JPsA) and its definition has been a matter of debate among pediatric rheumatologists for many years. The few studies that have compared the clinical characteristics and genetic determinants of JPsA with those of the other JIA categories have obtained contrasting findings. The debate on the categorization of JPsA as a distinct entity within JIA classification is still ongoing and has prompted the revision of its current classification.[42]

No research on health equity and JPsA is currently available.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Juvenile idiopathic arthritis (JIA) is an umbrella-term describing a group of conditions characterized by chronic arthritis beginning before the age of 16 years, persisting for at least 6 weeks, and having no other

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[34] https://onlinelibrary.wiley.com/doi/full/10.1111/1346-8138.17049#:~:text=International%20studies%20have%20shown%20that,significantly%20higher%20incidence%20in%20men.

[35] https://link.springer.com/article/10.1007/s40744-023-00580-y

[36] https://www.webmd.com/arthritis/psoriatic-arthritis/disparities-psoriatic-arthritis-diagnosis-treatment

[37] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8475338/

[38] https://link.springer.com/article/10.1007/s40744-023-00580-y

[39] https://link.springer.com/article/10.1007/s10067-014-2763-3

[40] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9045033/#:~:text=Another%20study%20found%20that%20Black,worse%20disease%20severity%20%5B10%5D

[41] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8475338/

[42] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9821505/

identifiable cause.[43] Studies suggest that disparities are prevalent among children with polyarticular juvenile idiopathic arthritis (pJIA) and impact different timepoints of disease. Disparities in polyarticular JIA were evident before establishing care with a pediatric rheumatologist, with statistically significant delays among those living in poverty, but disparities exist even for children in the care of a rheumatologist across the first year of treatment.[44]

Children with pJIA are more likely than those with other categories of JIA to experience prolonged periods of active disease.[45] One US study showed that Black children with pJIA were nearly twice as likely to have joint damage than their white counterparts.[46] Studies have also shown that at the initial visit to a rheumatologist, Black children had significantly higher disease activity compared with white children and to all other children combined. Black children also showed significantly higher pain scores and lesser mobility than their white counterparts.[47]

Multiple social determinants were identified as contributing to disparities in pJIA. Lower socioeconomic status was associated with persistent functional disability, race/ethnicity was associated with higher disease activity, and use of public insurance and a guardian's education level of high school or lesser were associated with both functional disability and persistent moderate to severe disease activity across the first year of treatment.[48] In a study of children with new JIA diagnoses, publicly insured children had significantly higher active joint counts and were more likely to have polyarticular arthritis compared to children with private insurance. Prompt escalation to TNF inhibitors is recommended for children with JIA and ongoing disease activity despite treatment with conventional disease-modifying antirheumatic drugs (cDMARDs). Overall TNFi use did not differ between children with different insurance types, but publicly insured children were escalated from cDMARDs to TNFis more quickly, consistent with their increased disease severity.[49]

While selected information has been pulled above, there is additional information contained in Appendix Appendix H: Input from Patients and Caregivers, Appendix I: Input from Individuals with Scientific and Medical Training, and Appendix J: Voluntarily Submitted Information which may contain additional information on health equity effects not captured in this appendix. The Board may want to weigh information from all four appendices when evaluating the health equity of Enbrel.

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43 https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00629-8

44 https://www.rheumatologyadvisor.com/home/topics/pediatric-rheumatology/disparities-impacting-delays-in-care-and-disease-outcomes-in-polyarticular-juvenile-idiopathic-arthritis/

45 https://pubmed.ncbi.nlm.nih.gov/36521922/

46 https://www.jrheum.org/content/40/6/936

47 https://www.jrheum.org/content/40/6/936

48 https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00610-5

49 https://pubmed.ncbi.nlm.nih.gov/36521922/

Appendix M

Enbrel: Information from the Department of Health Care Policy and Financing (HCPF)

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule: The Board shall consider information from HCPF as follows:

- Additional analyses HCPF conducts relevant to the prescription drug or therapeutic alternative under review; and/or
- Information regarding safety net providers participating in the 340B, including information to assist with gathering input to assess the impact to safety net providers for a prescription drug under review that is available through Section 340B of the Federal "Public Health Service Act", Pub.L. 78-410. (3 CCR 702-9, Part 3.1.E.2.j.iii).

Policy: Staff will review any additional analyses conducted by HCPF relevant to the prescription drug or therapeutic alternative under review for presentation to the Board. (PDAB Policy 04, p. 9).

Underlying Methodology: None.

Data Source(s): Board staff sought to compile information for the selected prescription drugs from the following sources:

- Publicly available reports from the Colorado Department of Health Care Policy and Financing (HCPF).

Considerations and Data Limitations: If any selected prescription drugs or therapeutic alternatives were mentioned in public HCPF reports, Board staff noted any differences in definitions, the period of time being analyzed, or general characteristics of the prescription drugs or analytics being conducted.

Enbrel: Information from the Department of Health Care Policy and Financing Evidence

Board staff requested any publicly available reports with quantitative or qualitative data related to Enbrel from HCPF and were informed that there are no publicly available reports.

HCPF maintains a preferred drug list (PDL) with prior authorization requirements for self-administered drugs and Appendix P with prior authorization requirements for physician-administered drugs.[1] These lists are developed with recommendations from HCPF's Drug Utilization Review Board.[2]

HCPF's PDL outlines the following information effective as of January 1, 2024:[3]

- For rheumatoid arthritis, all other arthritis (except psoriatic arthritis), and ankylosing spondylitis: Enbrel is a preferred agent with no prior authorization required if diagnosis is met. Of identified therapeutic alternatives, Humira is also a preferred agent, while Cimzia and Simponi are non-preferred agents and require a prior authorization.

[1] https://hcpf.colorado.gov/pharmacy-resources.

[2] https://hcpf.colorado.gov/drug-utilization-review-board.

[3] https://hcpf.colorado.gov/sites/hcpf/files/01-01-24%20PDL-V8.1.pdf.

- For psoriatic arthritis: Enbrel is a preferred agent with no prior authorization required if diagnosis is met. Of identified therapeutic alternatives, Humira is also a preferred agent, while Cimzia and Simponi are non-preferred agents and require a prior authorization.

HCPF's Appendix P outlines the following information effective January 1, 2024:[4]

- Remicade may be approved if certain criteria are met, including a requirement that a Medicaid member has tried and failed one preferred TNF inhibitor.

Additionally, Board staff and HCPF discussed that there was no readily available list or email listserv of 340B covered entities that could be used to facilitate Board staff outreach.

[4] https://hcpf.colorado.gov/sites/hcpf/files/Appendix%20P%2001.01.24%20V2.1.pdf.

Appendix N

Enbrel: Non-Adherence and Utilization Management

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the Board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule: The Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug. (3 CCR 702-9, 3.1.E.2.j.iv).

Policy: To the extent such information is available, the Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug. (PDAB Policy 04, p. 9).

Underlying Methodology: Board staff have compiled data for the selected prescription drug for the Board's consideration in the following manner:

1. Document information provided during the stakeholder sessions to gather input from patients and caregivers and individuals with scientific or medical expertise. Staff attempted to compile information directly related to the information outlined in rule during stakeholder meetings, as well as a survey.
2. Relevant information provided by entities who submitted information voluntarily.

Data Source(s): Board staff compiled information on non-adherence and utilization management for Enbrel from the following sources:

- Results of public input sessions and surveys by patients and caregivers and individuals with scientific and medical training, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations: Input provided both via stakeholder meetings and surveys is voluntary. Such qualitative data may not capture information from all patients and caregivers.

Enbrel: Non-Adherence and Utilization Management Evidence

See Appendix M for more information regarding the Department of Health Care Policy & Financing's (HCPF's) prior authorization requirements for Enbrel and identified therapeutic alternatives.

Stakeholder Input

Through public input sessions and surveys, patients and caregivers disclosed information about non-adherence of Enbrel due to cost. Of the 38 Colorado patients and caregivers surveyed:

- Twenty two participants indicated that cost impacted their adherence to Enbrel and nine respondents indicated that they skipped or stretched doses of the drug to save money.
- Twenty-four participants said their insurance plan requires prior approval to fill the prescription, eighteen said their insurance plan limits the supply of the drug, eight worried that the cost of the prescription will raise their premium, and fourteen said their insurance required them to try a medication they had previously failed.

See Appendices H and I for more information.

Voluntarily Submitted Information

Amgen Inc. voluntarily submitted the following information related to utilization management and adherence:

Utilization management:

- “Net Prices Declined as List Prices Increased: Such price concessions are often necessary to ensure a medicine’s appropriate formulary placement and otherwise facilitate patient access without burdensome utilization management hurdles, such as requiring a patient to complete a course of therapy with a drug that may not be the best suited for his or her particular condition.” (Amgen Inc. Voluntarily Submitted Information, p. 3)
- “Patient Affordability is a Result of Numerous Inputs in a Complex System: The rebates are based on eligibility criteria, depending on access, utilization management controls and product placement on formulary.” (Amgen Inc. Voluntarily Submitted Information, p. 6)

Adherence:

- “Enbrel achieves disease transforming efficacy while also offering an established safety profile: Real-world evidence (RWE) has shown Enbrel® to have fewer adverse reactions than infliximab and adalimumab as well, with Enbrel® patients having higher adherence as a result.” (Amgen Inc. Voluntarily Submitted Information, p. 2)
- [redacted]

See Appendix J for more information.

Appendix O

Enbrel: Pricing Information

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board may consider any documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug, including documents and information relating to: (a) Life-cycle management; (b) The average cost of the prescription drug in the state; (c) Market competition and context; (d) Projected revenue; (e) The estimated cost-effectiveness of the prescription drug; and (f) Off-label usage of the prescription drug. (C.R.S. § 10-16-1406(6)).

The Board may access pricing information through publicly available pricing information from state entities, the APCD, and other countries. (C.R.S. § 10-16-1406(7)(a)). Pricing information is defined as information about the price of a prescription drug, including information that explains or helps explain how the price was determined. (C.R.S. § 10-16-1401(20)).

To the extent that there is no publicly available information with which to conduct an affordability review, the Board may request that a manufacturer, carrier, or pharmacy benefit management firm provide pricing information for any prescription drug identified. (C.R.S. § 10-16-1406(7)(b)).

Rule: The Board may also consider documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug including information related to:

- Life cycle management;
- Average cost of the prescription drug in Colorado;
- Market competition;
- Projected revenue;
- Estimated cost-effectiveness of the prescription drug; and/or
- Off-label usage of the prescription drug.

The Board may access pricing information for prescription drugs by:

- Accessing publicly available pricing information from a state to which manufacturers report pricing information;
- Accessing available pricing information from the APCD and from state entities; and/or
- Accessing information that is available from other countries.

To the extent there is no publicly available information with which to conduct an affordability review, the Board may request that a manufacturer, carrier, or PBM provide pricing information for any prescription drug eligible for an affordability review.

- Such interested parties shall have 30 days from the date of the request of a prescription drug for affordability review to provide such information to the Board for its consideration.
- Failure of an entity to provide pricing information to the Board for an affordability review does not affect the authority of the Board to conduct the affordability review, as described in this section. (See 3 CCR 702-9, Parts 3.1.E.3, 4).

Policy: The Board may also consider documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug including information related to:

- Life-cycle management;
- Average cost of the prescription drug in Colorado;
- Market competition;
- Projected revenue;
- Estimated cost-effectiveness of the prescription drug; and/or
- Off-label usage of the prescription drug.

The Board may access pricing information for prescription drugs by:

- Accessing publicly available pricing information from a state to which manufacturers report pricing information. Staff will review other state programs and provide such information to the extent it is available.
- Accessing available pricing information from the APCD and from state entities.
- Staff will review pricing information in the APCD and, to the extent such data has not already been utilized in the affordability review, provide such information.
- Staff will review pricing information available from state entities and provide such information to the Board.
- Accessing information that is available from other countries. Staff will review pricing information from other countries and provide such information to the extent it is available. (PDAB Policy 04, pp. 9-10).

Underlying Methodology: None.

Data Sources: Board staff obtained pricing information through public reports and the following data sources:

- APCD data, including APCD data gathered pursuant to C.R.S. § 10-16-1405.
- Other state prescription drug transparency reports.
- U.S. Security and Exchange Commission (SEC) Form 10-K Filings.

Considerations and Data Limitations: Board staff did not recommend the Board specifically request pricing information from manufacturers, carriers, and PBMs since information is already both publicly available and available through the Division of Insurance's contract with AnalySource.[1] However, entities were able to choose to provide information related to the following components by submitting such information through the "Voluntarily Submitted Information" path by October 3, 2023:

- Life-cycle management;
- Average cost of the prescription drug in Colorado;
- Market competition
- Projected revenue;
- Estimated cost-effectiveness of the prescription drug; and/or
- Off-label usage of the prescription drug.

The Division of Insurance did not receive any voluntarily submitted information from entities with additional pricing information.

Information accessed through searches for public reports and data may not always match exactly the type of data being compiled for other affordability review components. Board staff will note when publicly available data cannot be vetted for exact comparability.

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[1] AnalySource data contains information on Enbrel's price - See Appendix A for more information.

Enbrel: Pricing Information Evidence

Other State Transparency Reports

Board staff reviewed prescription drug transparency reports from six other states, summarized below.

West Virginia

The West Virginia legislature passed Senate Bill 689 in 2020, requiring all pharmaceutical manufacturers that sell drugs directly or to wholesalers in West Virginia to submit pricing information to the State Auditor's Office for it to be visualized and transparent for the everyday consumer.[2] In 2023, this resulted in four published reports:

- Pharmaceutical Manufacturers WAC Report - Annual information from 2020 through 2022 is provided in a searchable database for both Enrbel and Amgen Inc., specifically introductory prices and weighted average costs for multiple strengths and dosage forms of Enbrel as reported by the manufacturer in 2020 and 2022.
- Patent Exclusivity Report - Information regarding Amgen Inc., but not Enbrel, is contained in this report.
- WAC Increases - No information regarding Enbrel or Amgen Inc. is contained in this report.
- Research and Development Costs - Information regarding Amgen Inc. is contained in this report, specifically that Amgen Inc.'s 2022 research and development costs were $4.819 billion.

Minnesota

The Minnesota legislature passed a law creating the Prescription Drug Price Transparency Data and Dashboards.[3] In the Reporting Snapshot of data reported by June 2023, the Minnesota Department of Health (MDH) outlined 47 expected reports from Amgen, Inc. with 60 reports received.[4]

The Price Increase - Five Year Price Analysis Dashboard[5] provided the following information regarding Enbrel's price increases:

Table O-1
Information from Minnesota

[2] https://stories.opengov.com/westvirginia/published/kFdN-WMxm.
[3] https://www.health.state.mn.us/data/rxtransparency/dashboards/index.html.
[4] https://www.health.state.mn.us/data/rxtransparency/dashboards/reporting.html.
[5] https://www.health.state.mn.us/data/rxtransparency/dashboards/fiveyear.html

Manufacturer	NDC	Item Description	% Current Change	% Prior Year 1 Change	% Prior Year 2 Change	% Prior Year 3 Change	% Prior Year 4 Change	% Prior Year 5 Change	Prior Year 1 WAC	Prior Year 2 WAC	Prior Year 3 WAC	Prior Year 4 WAC	Prior Year 5 WAC	WAC After Current Change	WAC Effective Date
Amgen Inc.	58406001001	Etanercept 25 MG/0.5ML Solution Prefilled Syringe 0.500 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$820	$746	$695	$647		$881	1/4/2023
Amgen Inc.	58406001001	Etanercept 25 MG/0.5ML Solution Prefilled Syringe 0.500 ML UD	2.40%	10.00%	7.40%	7.40%			$746	$695	$647			$820	7/1/2022
Amgen Inc.	58406001004	Etanercept 25 MG/0.5ML Solution Prefilled Syringe 0.500 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$3,282	$2,984	$2,778	$2,587		$3,525	1/4/2023
Amgen Inc.	58406001004	Etanercept 25 MG/0.5ML Solution Prefilled Syringe 0.500 ML UD	2.40%	10.00%	7.40%	7.40%			$2,984	$2,778	$2,587			$3,282	7/1/2022
Amgen Inc.	58406002101	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$1,641	$1,492	$1,389	$1,294		$1,762	1/4/2023
Amgen Inc.	58406002101	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	2.40%	10.00%	7.40%	7.40%			$1,492	$1,389	$1,294			$1,641	7/1/2022
Amgen Inc.	58406002104	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$6,564	$5,968	$5,557	$5,174		$7,049	1/4/2023

Manufacturer	NDC	Item Description	% Current Change	% Prior Year 1 Change	% Prior Year 2 Change	% Prior Year 3 Change	% Prior Year 4 Change	% Prior Year 5 Change	Prior Year 1 WAC	Prior Year 2 WAC	Prior Year 3 WAC	Prior Year 4 WAC	Prior Year 5 WAC	WAC After Current Change	WAC Effective Date
Amgen Inc.	58406002104	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	2.40%	10.00%	7.40%	7.40%			$5,968	$5,557	$5,174			$6,564	7/1/2022
Amgen Inc.	58406003201	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$1,641	$1,492	$1,389	$1,294		$1,762	1/4/2023
Amgen Inc.	58406003201	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	2.40%	10.00%	7.40%	7.40%			$1,492	$1,389	$1,294			$1,640	7/1/2022
Amgen Inc.	58406003204	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$6,564	$5,968	$5,557	$5,174		$7,049	1/4/2023
Amgen Inc.	58406003204	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	2.40%	10.00%	7.40%	7.40%			$5,968	$5,557	$5,174			$6,563	7/1/2022
Amgen Inc.	58406004401	Etanercept 50 MG/ML Solution Cartridge 1.000 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$1,641	$1,492	$1,389	$1,294		$1,762	1/4/2023
Amgen Inc.	58406004401	Etanercept 50 MG/ML Solution Cartridge 1.000 ML UD	2.40%	10.00%	7.40%	7.40%			$1,492	$1,389	$1,294			$1,641	7/1/2022

Manufacturer	NDC	Item Description	% Current Change	% Prior Year 1 Change	% Prior Year 2 Change	% Prior Year 3 Change	% Prior Year 4 Change	% Prior Year 5 Change	Prior Year 1 WAC	Prior Year 2 WAC	Prior Year 3 WAC	Prior Year 4 WAC	Prior Year 5 WAC	WAC After Current Change	WAC Effective Date
Amgen Inc.	58406004404	Etanercept 50 MG/ML Solution Cartridge 1.000 ML UD	7.40%	7.40%	10.00%	7.40%	7.40%		$6,564	$5,968	$5,557	$5,174		$7,049	1/4/2023
Amgen Inc.	58406004404	Etanercept 50 MG/ML Solution Cartridge 1.000 ML UD	2.40%	10.00%	7.40%	7.40%			$5,968	$5,557	$5,174			$6,564	7/1/2022
Amgen Inc.	58406005501	Etanercept 25 MG/0.5ML Solution 0.500 ML UD	7.40%	7.40%	10.00%	7.40%			$820	$746	$695			$881	1/4/2023
Amgen Inc.	58406005501	Etanercept 25 MG/0.5ML Solution 0.500 ML UD	2.40%	10.00%	7.40%				$746	$695				$820	7/1/2022
Amgen Inc.	58406005504	Etanercept 25 MG/0.5ML Solution 0.500 ML UD	7.40%	7.40%	10.00%	7.40%			$3,282	$2,984	$2,778			$3,525	1/4/2023
Amgen Inc.	58406005504	Etanercept 25 MG/0.5ML Solution 0.500 ML UD	2.40%	10.00%	7.40%				$2,984	$2,778				$3,282	7/1/2022
Amgen Inc.	58406042534	Etanercept 25 MG Solution Reconstituted 1.000 EA UD	7.40%	7.40%	339.90%	7.40%	7.40%	6.20%	$3,282	$746	$695	$647	$609	$3,525	1/4/2023
Amgen Inc.	58406042534	Etanercept 25 MG Solution Reconstituted 1.000 EA UD	2.40%	339.90%	7.40%	7.40%	6.20%	9.70%	$746	$695	$647	$609	$555	$3,282	7/1/2022

Manufacturer	NDC	Item Description	% Current Change	% Prior Year 1 Change	% Prior Year 2 Change	% Prior Year 3 Change	% Prior Year 4 Change	% Prior Year 5 Change	Prior Year 1 WAC	Prior Year 2 WAC	Prior Year 3 WAC	Prior Year 4 WAC	Prior Year 5 WAC	WAC After Current Change	WAC Effective Date
Amgen Inc.	58406042541	Etanercept 25 MG Solution Reconstituted 1.000 EA UD	7.40%	7.40%	-72.50%	7.40%	7.40%	6.20%	$820	$2,984	$2,778	$2,587	$2,436	$881	1/4/2023
Amgen Inc.	58406042541	Etanercept 25 MG Solution Reconstituted 1.000 EA UD	2.40%	-72.50%	7.40%	7.40%	6.20%	9.70%	$2,984	$2,778	$2,587	$2,436	$2,221	$820	7/1/2022

Table O-1 shows Minnesota's price transparency for five years of comparative price analysis for all Enbrel NDCs.

The Price Increase - Comparative Price Change Analysis Dashboard[6] provided the following information regarding Enbrel's price increases:

Table O-2

Information from Minnesota

Manufacturer	NDC	Item Description	$ Change 12 Month	% Change 12 Month	$ Change 24 Month	% Change 24 Month
Amgen Inc.	58406001001	Etanercept 25 MG/0.5ML Solution Prefilled Syringe 0.500 ML UD	$209.59	28.1%	$312.39	45.0%
Amgen Inc.	58406001004	Etanercept 25 MG/0.5ML Solution Prefilled Syringe 0.500 ML UD	$838.35	28.1%	$1,249.57	45.0%
Amgen Inc.	58406002101	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	$419.16	28.1%	$624.76	45.0%
Amgen Inc.	58406002104	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	$1,676.66	28.1%	$2,499.10	45.0%

[6] https://www.health.state.mn.us/data/rxtransparency/dashboards/comparative.html

Manufacturer	NDC	Item Description	$ Change 12 Month	% Change 12 Month	$ Change 24 Month	% Change 24 Month
Amgen Inc.	58406003201	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	$419.16	28.1%	$624.76	45.0%
Amgen Inc.	58406003204	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	$1,676.66	28.1%	$2,499.10	45.0%
Amgen Inc.	58406004401	Etanercept 50 MG/ML Solution Cartridge 1.000 ML UD	$419.16	28.1%	$624.76	45.0%
Amgen Inc.	58406004404	Etanercept 50 MG/ML Solution Cartridge 1.000 ML UD	$1,676.66	28.1%	$2,499.10	45.0%
Amgen Inc.	58406005501	Etanercept 25 MG/0.5ML Solution 0.500 ML UD	$209.59	28.1%	$312.39	45.0%
Amgen Inc.	58406005504	Etanercept 25 MG/0.5ML Solution 0.500 ML UD	$838.35	28.1%	$1,249.57	45.0%

Table O-2 shows Minnesota's price transparency comparative price analysis for all Enbrel NDCs.

Maine

The Maine legislature passed two laws related to prescription drug price transparency:

Public Law 2021, Chapter 606 (LD 1636)

This law requires the Maine Health Data Organization (MHDO) to produce an annual report beginning in 2023 that provides information regarding potential savings that could be achieved by subjecting drugs identified as the costliest and most frequently prescribed to a referenced rate as defined in law.[7]

Table O-3
Information from Maine

Potential Savings

[7] https://mhdo.maine.gov/RxReferenceRates.htm.

§8741 2. C. For each drug identified in paragraph A, the organization shall determine the potential savings that could be achieved by subjecting those drugs to the referenced rate as calculated pursuant to paragraph B. The savings must be determined based on the payments reported in the organization's claims database for the most current 12-month period.

Top 100 List	Manufacturer Name	NDC	Item Description	Average WAC Per Unit	Reference Rate	Annual Cost @ Average WAC Per Unit	Annual Cost @ Reference Rate Per Unit	Potential Savings
Brand Most Costly	AMGEN	58406002104	Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD	$1,741.0440	$1,741.0440	$2,493,320	$2,493,320	$0
Brand Most Costly, Brand Most Prescribed	AMGEN	58406003204	Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD	$1,741.0440	$1,741.0440	$14,139,843	$14,139,843	$0

Table O-3 shows the potential savings that could be achieved by subjecting Etanercept 50 MG/ML Solution Prefilled Syringe 1.000 ML UD and Etanercept 50 MG/ML Solution Auto-injector 1.000 ML UD to the referenced rate (determined based on payments reported in MHDO's claims database for the most current 12-month period) is $0.[8]

Public Law 2018, Chapter 406

This law requires MHDO to produce an annual prescription drug report that includes:

- The 25 costliest drugs (determined by total amount spent in the state),
- The 25 most frequently prescribed drugs in the state, and
- The 25 drugs with the highest year-over-year cost increase (determined by total amount spent in the state).[9]

Information is provided for three state fiscal years, which run from July 1 through June 30. The most recent report is outlined below (July 1, 2021 through June 30, 2022):

Top 25 Costliest Drugs

- Overall: Enbrel Sureclick appears #5 on the list.

[8] Pulled from Part III of the International Referenced Rate Pricing for Prescription Drugs 2023 Report accessed via https://mhdo.maine.gov/RxReferenceRates.htm.
[9] https://mhdo.maine.gov/tableau/prescriptionReports.cshtml.

- Commercial: Enbrel Sureclick appears #3 on the list.
- Medicaid: Enbrel Sureclick appears #11 on the list.
- Medicare Advantage: Enbrel Sureclick appears #12 on the list.

Figure O-1
Maine: Enbrel Ranking Among Top 25 Costliest Drugs Overall

Rank	NDC	Drug Name	Drug Class(es)	Number of Prescriptions	Number of Prescription Users	Cost	Cost Per Prescription
Top 25 Overall				535,254	107,680	$757,322,271	
State Total				13,928,196	912,598	$2,762,444,684	
5	58406003204	Enbrel Sureclick	Disease-modifying Antirheumatic Drugs; Immunomodulatory Agents	5,206	820	$35,977,557	$6,911

Figure O-1 shows Enbrel Sureclick is the #5 costliest drug overall in 2021-2022.

Figure O-2
Maine: Enbrel Ranking Among Top 25 Costliest Drugs for Commercial Plans

Rank	NDC	Drug Name	Drug Class(es)	Number of Prescriptions	Number of Prescription Users	Cost	Cost Per Prescription
Top 25 Overall				82,865	20,994	$287,743,460	
State Total				3,769,512	400,330	$777,869,615	
3	58406003204	Enbrel Sureclick	Disease-modifying Antirheumatic Drugs; Immunomodulatory Agents	2,887	454	$18,874,090	$6,538

Figure O-2 shows Enbrel Sureclick is the #3 costliest drug for commercial plans in 2021-2022.

Figure O-3
Maine: Enbrel Ranking Among Top 25 Costliest Drugs for Medicaid

Rank	NDC	Drug Name	Drug Class(es)	Number of Prescriptions	Number of Prescription Users	Cost	Cost Per Prescription
Top 25 Overall				253,227	30,589	$151,049,958	
State Total				2,881,698	204,791	$458,079,261	
11	58406003204	Enbrel Sureclick	Disease-modifying Antirheumatic Drugs; Immunomodulatory Agents	640	114	$4,087,416	$6,387

Figure O-3 shows Enbrel is the #11 costliest drug for Medicaid in 2021-2022.

Figure O-4
Maine: Enbrel Ranking Among Top 25 Costliest Drugs for Medicare Advantage

Rank	NDC	Drug Name	Drug Class(es)	Number of Prescriptions	Number of Prescription Users	Cost	Cost Per Prescription
Top 25 Overall				246,271	64,868	$401,992,957	
State Total				7,276,986	317,518	$1,526,495,808	
12	58406003204	Enbrel Sureclick	Disease-modifying Antirheumatic Drugs; Immunomodulatory Agents	1,679	256	$13,016,052	$7,752

Figure O-4 shows Enbrel is the #12 costliest drug for Medicare Advantage in 2021-2022.

Top 25 Most Frequently Prescribed Drugs: Enbrel does not appear on the list overall, nor specifically for commercial plans, Medicaid, or Medicare Advantage.

Top 25 Drugs with Highest Year-Over-Year Increases: Enbrel does not appear on the list overall, nor specifically for commercial plans, Medicaid, or Medicare Advantage.

Oregon

The Oregon legislature created Oregon's Drug Price Transparency program in 2018 to provide accountability for prescription drug pricing through transparency of specific cost and price information from pharmaceutical manufacturers and health insurers.[10] Drug Price Transparency Program Reports are available from 2019-2022.[11] The 2022 report is outlined below.

The report identifies insurer reporting of the most costly drugs reflects the drugs with the highest total payments made on behalf of covered members, including payments made by carriers and member cost sharing, such as co-pays and co-insurance. Enbrel appears #3 on the list (p. 50):[12]

Figure O-5
Oregon: Top 10 Most Costly Drugs in 2022

Figure 21: Top 10 most costly drugs

Drug	Class	Prescriptions
Adalimumab *Brand name: Humira*	Analgesics - Anti-Inflammatory	$76,966,470
Ustekinumab *Brand name: Stelara*	Dermatologicals	$35,999,195
Etanercept *Brand name: Enbrel*	Analgesics - Anti-Inflammatory	$28,675,010
Bictegravir-Emtricitabine-Tenofovir Alafenamide Fumarate *Brand name: Biktarvy*	Antivirals	$23,245,660
COVID-19 (SARS-CoV-2) mRNA Virus Vaccine *Moderna and Pfizer-BioNTech*	Vaccines	$20,679,117
Elexacaftor-Tezacaftor-Ivacaftor *Brand name: Trikafta*	Respiratory Agents	$17,964,545
Secukinumab *Brand name: Cosentyx*	Dermatologicals	$17,770,873
Pembrolizumab *Brand name: Keytruda*	Antineoplastics and Adjunctive Therapies	$16,463,259
Vedolizumab *Brand name: Entyvio*	Gastrointestinal Agents	$14,872,464
Ocrelizumab *Brand name: Ocrevus*	Psychotherapeutic and Neurological Agents	$11,115,070

Figure O-5 shows Enbrel as #3 on the list of the top 10 most costly drugs in Oregon in 2022.

[10] https://dfr.oregon.gov/drugtransparency/Pages/index.aspx.
[11] https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx.
[12] https://dfr.oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2022.pdf.

Information is also provided in this report regarding drugs with greatest increases in year-over-year health plan spending, as well as the amount of that increase. Enbrel does not appear on the list (p. 51).[13]

California

The California legislature passed two laws related to prescription drug price transparency:

Prescription Drugs Introduced to Market

This dataset provides data for new drugs introduced to market in California with a WAC that exceeds the Medicare Part D specialty drug cost threshold.[14] Prescription drug manufacturers submit information to the California Department of Health Care Access and Information (HCAI), including NDC, a narrative description of marketing and pricing plans, and WAC. For the four years of available data (Q1 2019 - Q4 2022), Amgen Inc. submitted information, but nothing related to Enbrel.

Prescription Drug WAC Increases

This dataset provides data for WAC increases that exceed the statutorily mandated WAC increase threshold of a 16 percent increase for the period including the current quarter and the previous two calendar years for prescription drug products with a WAC greater than $40 for a course of therapy.[15] Amgen Inc. reported NDCs associated with Enbrel in multiple annual reports.

Texas

The Texas legislature passed House Bill 2536 in 2019, requiring pharmaceutical drug manufacturers to report the current WAC of drugs sold in or into Texas to the Texas Health and Human Services Commission (HHSC), as well as separately report specific information related to WAC increases.[16] Amgen Inc. reported WAC information to HHSC in 2020, 2021, 2022, and 2023 and reported price increases in 2023 for prescription drugs other than Enbrel and did not report any qualifying WAC increases in 2021 or 2022.[17]

[13] https://dfr.oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2022.pdf.
[14] https://data.chhs.ca.gov/dataset/prescription-drugs-introduced-to-market.
[15] https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases.
[16] https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/about.
[17] https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/data-overview.

Colorado All Payer Claims Database Transparency Reporting Information

Pursuant to section 10-16-1405(1)(a)(IV), C.R.S., each carrier and PBM must report the 15 prescription drugs that caused the greatest increases in the carrier's premiums in a given year. Please find data gathered from 19 payers pursuant to section 10-16-1405(1)(a)(IV), C.R.S., below.[18]

Figure O-6
Payer Rank of Enbrel Impact on Premiums in 2022

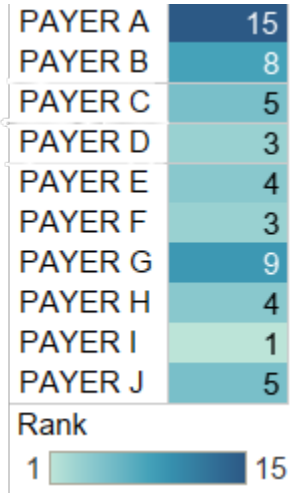


Figure O-6 shows the rank that each payer submitted indicating that Enbrel was a drug in the top 15 prescription drugs that increased premiums. For example, Payer I indicated that Enbrel was the first highest drug responsible for increases to premiums. The box represented shows the rank number and lighter boxes indicate a lower rank, meaning a larger increase in premiums than a lower rank and darker box.

Payers and Pharmacy Benefit Management Firms were required to identify in their submission which 15 drugs caused the highest increases to premiums, however, no additional information was required pursuant to section 10-16-1405(1)(a)(IV), C.R.S. As a result, the specific dollar impact Enbrel had on premiums, or even how its rank compared to other prescription drug premium impacts, is unknown.

While this information can be insightful in understanding Enbrel's impact to a broader portion of the health care system, Board staff do not recommend the Board heavily weigh this information this year. Per section 10-16-1405, C.R.S., only the top drugs are submitted for each reference, and more data and research would be necessary to understand the actual impacts to premiums and relative impact of each drug for each carrier.

[18] Information submitted per section 10-16-1405, C.R.S. is required by all submitters to the APCD. For this submission, 19 submitters provided information.

Manufacturer Pricing Information

The SEC requires all public companies to file a Form 10-K each year, and a Form 10-Q each quarter.[19] These forms provide a financial snapshot of the company's revenues, assets, and liabilities for the previous year. Amgen Inc.'s 2022 10-K details that Enbrel's international Product Revenue decreased from approximately $4.465 billion in 2021 to $4.117 billion in 2022 (p.F-17). Additionally, the 2022 10-K details that Enbrel comprises 17% of total product revenues (p.4). Additional information of estimates of Enbrel's share of Amgen Inc.'s total sales is contained in Appendix K.[20]

[19] United States Securities and Exchange Commission, Form 10-K, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, Transition Report Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934, Amgen Inc., : https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/318154/000031815423000017/amgn-20221231.htm.

[20] Appendix K contains information of Enbrel's estimated net sales for national sales only, whereas this appendix contains information for national and international sales.

Appendix P

Data Sources and Limitations

Data sources and limitations are described in detail here. How these data sources are used and component-specific limitations are outlined in each component's appendix.

All-Payer Claims Database (APCD)

The All Payer Claims Database (APCD) receives claims from Medicaid, Medicare Advantage, and over 40 commercial payers and represents over 4.5 million lives and over 75% of insured Coloradans. The APCD does not have claims data for uninsured Coloradans and some commercial payers and plans. For this affordability review, pharmacy and medical claims from January 2018 through December 2022, which were paid through May 2023, were used for analyses. Drugs are identified on pharmacy claims with their National Drug Code (NDC). APCD claims are categorized by the submitting payer and are categorized as Medicaid, Medicare Advantage, and all other submitters are commercial. Enbrel and identified therapeutic alternatives NDC codes found in the APCD and utilized in these analyses were:

Drug Name	NDC
Enbrel	54868-4782-00*, 54868-5444-00*, 58406-0010-01, 58406-0010-04, 58406-0010-96*[1], 58406-0021-01, 58406-0021-04, 58406-0021-96*, 58406-0032-01, 58406-0032-04, 58406-0032-96*, 58406-0044-01, 58406-0044-04, 58406-0044-96*, 58406-0055-01, 58406-0055-04, 58406-0425-34*, 58406-0425-41*, 58406-0435-01*, 58406-0435-04*, 58406-0445-01*, 58406-0445-04*, 58406-0455-01*, 58406-0455-04*, 58406-0456-01*, 58406-0456-04*.[1]
Cimzia	50474-0700-62, 50474-0710-79, 50474-0710-81
Humira	00074-3799-02, 00074-4339-74, 00074-4339-01, 00074-4339-02, 00074-4339-06, 00074-4339-07, 00074-0243-02, 00074-0616-02, 00074-0817-02, 00074-0067-02, 00074-2540-03, 00074-0124-74, 00074-0124-02, 00074-0554-02, 00074-0554-71, 00074-0124-03, 00074-0124-04, 00074-1539-03
Remicade	57894-0030-01
Simponi	57894-0070-01, 57894-0070-02, 57894-0071-01, 57894-0071-02, 57894-0350-01

[1] (*) inactive NDC. Inactive NDCs were used to gather historical WAC data and any utilization that may have occurred during this time frame if the currently inactive NDCs were active at the time of the claim. Only Enbrel inactive NDCs were included, no inactive NDCs for identified therapeutic alternatives are included.

[2] SSR Health: https://www.ssrhealth.com/

[3] "Best Practices Using SSR Health Net Drug Pricing Data", Health Affairs Forefront, March 10, 2022. DOI: 10.1377/forefront.20220308.712815: https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data

Limitations

- As the APCD does not include claims for all Coloradans, it is a conservative estimate, where utilizers, claims, and associated paid amounts are under-represented.
- Annual estimates of utilization are also likely under-represented as individuals change insurance and move and their entire year of utilization may not be captured in the APCD claims.
- Under federal and state privacy laws, information about drugs with fewer than 12 utilizers in the database must be protected, as it is potentially identifiable at such low numbers. Where utilization is below 12 individuals there will be less information available.
- One commercial payer reported inaccurate units for pharmacy claims. These units were removed, and any calculations using units did not include units from this payer. Dollar amounts and utilization information was reported accurately by this payer and were not removed. The only data element in the affordability review that incorporates units is the course of treatment calculation, which excludes this payer and is therefore an underestimate of the course of treatment.
- Pharmacy claims do not include diagnosis codes. As such, utilization and paid amount analyses were conducted for all Enbrel utilization and separate analyses were not conducted for each FDA-approved indication.

First DataBank AnalySource

AnalySource provides WAC and other pricing benchmarks for all NDCs at current rates and historic levels. Enbrel NDC codes found in AnalySource are listed in table P-1 above.

Limitations

- WAC and other data elements from AnalySource are proprietary and confidential and may only be disclosed through secure channels and may only be discussed by the Board in Executive Session.
- WAC data is updated daily, but other data sources have a greater time lag, meaning that there are NDCs for which there is WAC data, but no utilization data. It is noted when these are included

SSR Health

- Board staff contracted with SSR Health[2] to receive their proprietary U.S. prescription brand drug pricing and analytics net price database, which provides total net revenue and volume estimates for the majority of active brand name prescription drugs in the United States. SSR Health uses net revenues from publicly-available SEC Form 10-K financial reports from drug makers or other public sources to develop a net sales and gross-to-net estimates quarterly for all drugs.[3] The gross-to-net estimates provide a quarterly estimated gross-to-net percent rebate that is inclusive of all concessions and discounts that manufacturers deduct from gross sales. This is inclusive of all rebates, 340B discounts, and point of sale copayment support. SSR Health provides these estimates on a total, statutory Medicaid, and total less statutory Medicaid basis.

Limitations

- Estimates are proprietary and confidential and may only be disclosed through secure channels and may only be discussed by the Board in Executive Session.
- Gross-to-net sales estimates are inclusive of all concessions and discounts that manufacturers deduct from gross sales. This is inclusive of all rebates, 340B discounts, and point of sale copayment support, but cannot provide detailed amounts on these discounts.
- Estimates are for national information and are not specific to Colorado.

UNSUSTAINABLE DRUG PRICES: TESTIMONY FROM THE CEOs (PART II)

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND REFORM HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

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Case 1:25-cv-3452-DDD-STV
Exhibit 33

COMMITTEE ON OVERSIGHT AND REFORM

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Mr. Mark Trudeau, President and Chief Executive Officer, Mallinckrodt Pharmaceuticals
Oral Statement 5

Mr. Thomas Kendris, U.S. Country President, Novartis AG
Oral Statement 7

* Opening statements and the prepared statements for the witnesses are available at: *docs.house.gov*.

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The documents listed below are available at: docs.house.gov.

* Letter from the Mayor of Rockford, Illinois, Thomas McNamara; submitted by Rep. Maloney.

* Questions for the Record: to Mr. Bradway at Amgen Inc.; submitted by Rep. Porter.

UNSUSTAINABLE DRUG PRICES: TESTIMONY FROM THE CEOs (PART II)

Thursday, October 1, 2020

HOUSE OF REPRESENTATIVES,
COMMITTEE ON OVERSIGHT AND REFORM,
Washington, D.C.

The committee met, pursuant to notice, at 10:04 a.m., in room 2154, Rayburn House Office Building, Hon. Carolyn Maloney, Chairman of the Committee, presiding.

Present: Representatives Maloney, Norton, Clay, Lynch, Connolly, Raskin, Rouda, Wasserman Schultz, Sarbanes, Welch, Speier, Kelly, DeSaulnier, Plaskett, Gomez, Tlaib, Porter, Comer, Jordan, Gosar, Foxx, Massie, Grothman, Palmer, Cloud, Gibbs, Higgins, Miller, Steube, and Keller.

Chairwoman MALONEY. The committee will come to order.

Without objection, the chair is authorized to declare a recess of the committee at any time.

I now recognize myself for an opening statement.

Good morning, and welcome to Day Two of our landmark series of hearings with drug company CEOs. Yesterday we heard from the CEOs of three drug companies: Celgene, Bristol Meyers Squibb, and Teva. And what we learned was shocking. Drug companies are hiking their prices higher and higher, and placing an even greater burden on the very patients who rely on these drugs to survive. We learned that these skyrocketing prices are simply unsustainable, both for government programs and American families.

We also learned that claims by drug companies that their price increases are necessary for research and development are completely bogus. The internal company documents we obtained show that drug companies hike prices almost entirely for selfish reasons. They do it to meet internal revenue targets, or to increase their own bonuses, in some cases. Drug companies certainly spend some funds on research and development, but nowhere near the windfall profits they are bringing in as a result of their massive price increases.

Finally, in the cases we examined yesterday we learned that drug companies target our country for their biggest price and for their biggest price increases, charging the American people more than the entire rest of the world combined.

They do it simply because they can, because Federal law currently bars our government from negotiating directly with drug companies to lower prices for Medicare. According to the non-par-

tisan CBO, allowing the Federal Government to negotiate directly with drug companies could lower spending on brand name drugs by about $456 billion. So, let that number sink in. It is nearly half a trillion dollars.

Today is Day Two, and we will hear from three more executives. We will hear from the CEO of Amgen, which repeatedly raised the prices of two drugs: Enbrel, which is used to treat rheumatoid arthritis and other painful inflammatory diseases, and Sensipar, which is used to treat the effects of kidney failure and parathyroid cancer.

We will hear from the top U.S. executive from Novartis about the company's massive price increases for Gleevec, a drug that treats chronic myeloid leukemia, a rare form of cancer of the blood and bone marrow.

And we will hear from the CEO of Mallinckrodt about the pricing of its drug called H.P. Acthar Gel, which is used to treat a rare seizure disorder in little babies.

We are going to keep our opening statements short because we want to hear the testimony from our guests. But I would now like to turn to our ranking member for his opening statement.

Mr. COMER. Thank you, Madam Chairwoman, for holding this hearing. I would like to reiterate a few points brought up at yesterday's hearing.

First, Republicans have introduced legislation, H.R. 19, full of bipartisan provisions that the House could pass today and could be signed into law by the end of the week, to decrease the cost of prescription drugs for all Americans.

Second, pharmaceutical innovation is vital to enabling Americans to live longer and healthier lives, but we must ensure those innovative products are accessible and affordable for all Americans.

Third, while brand pharmaceutical manufacturers play a significant role, we must look at the entirety of the pharmaceutical marketplace, including PBMs, health insurers, generic manufacturers, and wholesalers, to truly solve this problem permanently.

At this time, Madam Chair, I would like to yield the balance of my time to Representative Massie.

Mr. MASSIE. Thank you, Ranking Member Comer, and thank you, Madam Chairwoman. I anticipate today's discussion and testimony will involve the U.S. patent system, and so in this opening statement I want to read the patent and copyright clause that is in the Constitution. This clause was so uncontroversial that it was accepted by all of those who were drafting and voting on the Constitution, unanimously and without debate.

It says, "The U.S. Congress shall have power to promote the progress of science and useful arts by securing, for limited times, to authors and inventors the exclusive right to their respective writings and discoveries."

So, some people who haven't studied this issue too much think that perhaps patents are the reason that drug prices are high, but the reality is on a lot of the drugs the patents have expired and there is no restriction from the Patent Office to keep somebody from making the generic versions of the drugs. But there are other impediments not involving patents that stop these generics from coming to market. So, I hope we find out what those are about.

Then I also want to say that our Founding Fathers were really smart here. They knew that if the owner had a limited period to recoup their investment, the inventor and the owner, then they would be able to find the capital and the backers to develop these ideas and discoveries. So, even if you had scientists who would come up with new drugs, for free—let's say they just gave the idea away—these new drugs require millions, hundreds of millions in some cases, of development in order to bring them to market, and without a patent, which is the equivalent of a deed, like a deed to a piece of property—nobody would develop a piece of property if they couldn't get a secure title to the property—patents work the same way. They allow the investors to get secure title to the idea so that they can then invest the money that is required to bring that to market and to test it and make sure it is safe for all human beings.

So, I look forward to a robust discussion on that, and with that I yield back.

Chairwoman MALONEY. I want to thank my colleagues, and with your indulgence, because of my cough, I would like to just lead up to the video that we want to play before we go into it. But I did want to respond to my good friend and colleague, Mr. Comer. I agree we should work on this issue. It is important to the American people. It should be bipartisan. But since you mentioned your bill, I am going to mention mine, H.R. 3, which would merely allow our country to negotiate for lower drug prices for Medicare, as we do with the Veterans Association. It has passed the House. It is now in the Senate.

But what I would really like to do right now is to honor and remember our former chairman, Elijah Cummings, who launched this investigation 18 months ago. His No. 1 priority then, and our No. 1 priority now, is the health and the well-being of the American people, who are being harmed on a daily basis by these astronomical price increases.

So, I would like to conclude my statement by playing a clip of three individuals, patients and doctors, who are being directly and negatively affected by the actions of these three drug companies. And if could now play that video and move quickly forward.

[Video shown.]

Chairwoman MALONEY. Thank you. Thank you very much. I will now introduce our witnesses, and we are grateful for their attendance today and for their testimony.

Our first witness today is Mr. Robert Bradway, who is the Chairman and CEO of Amgen. Amgen sells the anti-inflammatory drug, Enbrel, and the chronic kidney disease drug, Sensipar. Then we will go to Mr. Mark Trudeau, who is the President and CEO of Mallinckrodt Pharmaceuticals. Mallinckrodt sells the autoimmune and inflammatory disease drug, H.P. Acthar Gel. Finally, we will hear from Mr. Thomas Kendris, who is the U.S. Country President of Novartis. Novartis sells the cancer drug, Gleevec.

The witnesses will be unmuted so we can swear them in. Please raise your right hands.

Do you swear or affirm that the testimony you are about to give is the truth, the whole truth, and nothing but the truth, so help you God?

[Response.]

Chairwoman MALONEY. Thank you. Let the record show that the witnesses answered in the affirmative.

Without objection, your written statements will be made part of the record.

With that, Mr. Bradway, you are now recognized for your testimony. If you could unmute your mic.

STATEMENT OF ROBERT BRADWAY, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, AMGEN INC.

Mr. BRADWAY. OK. Thank you. Good morning, Chairwoman Maloney, Ranking Member Comer, and other members of this committee. My name is Bob Bradway and I am the CEO of Amgen, a leading biotechnology company based in Thousand Oaks, California.

Before I begin my formal remarks, I want to acknowledge the work of Elijah Cummings on drug pricing issues as chairman of this committee. I know he is sorely missed by his former colleagues and I wanted to recognize his work dedicated to improving access and affordability for patients.

For 40 years, Amgen's unwavering mission has been to serve patients. We do that through innovative medicines and high-quality biosimilars that treat many of the world's most serious and costly illnesses. We are also engaged in the fight to understand, treat, and prevent COVID–19.

We employ nearly 14,000 people here in the U.S., where we conduct a vast majority of our cutting-edge research and eco-friendly manufacturing.

Amgen is deeply committed to meeting the needs of every patient, every time. Therefore, it is of great concern to us when patients who might benefit from our medicines can't get them.

We are committed to responsible pricing. A few recent examples: In 2018, we launched a new migraine prevention treatment called Aimovig, at a price that was between 20 and 65 percent below market expectations. We also made Repatha, a medicine proven to reduce heart attacks and strokes in patients with stubbornly high cholesterol levels, available at a 60 percent reduced price. This helped lower out-of-pocket costs for patients, especially seniors on Medicare.

Over the last two years we have launched biosimilars to some of the top-selling medicines in the country, and plan to bring more to market over time, providing patients with more affordable treatment options.

Overall, the average net price for Amgen medicines across our entire portfolio in the U.S. declined in 2018 and 2019, and we are on track for further declines this year.

Enbrel is an Amgen medicine that treats patients with autoimmune disorders such as moderate to severe rheumatoid arthritis. Enbrel highlights the tension between ensuring patients have access to critical, innovative medicines and the out-of-pocket costs they are also required to pay. Physicians tell stories of how their waiting rooms were cluttered with canes, crutches, and wheelchairs. Thanks to Enbrel, countless patients have been given a new lease on their lives.

Since Enbrel's approval, we have invested hundreds of millions of dollars in studies for additional uses and to make it more patient friendly. As an example, we recently introduced an easy-to-use self-injection device designed for Enbrel patients whose disease has sapped the strength in their hands.

But innovations like this cost money, and that is partially why we have increased the list price of Enbrel in the past. But what has driven up the list price more than any other factor is the pressure we face to match the price increases of the market leader. I know this sounds strange. Companies in virtually every other industry compete by offering the lowest price. Unfortunately, the current rebate system in the U.S., created with good intent, now often leads to a situation in which not getting kicked off formulary requires matching a competitor's higher price. These higher prices increase the already significant rebates paid to the middlemen, who largely dictate which medicines patients can access, regardless of which medicines their physician prescribes.

Worst still, these rebates, paid on all our medicines, do not translate into lower costs for patients, and that is because they don't get passed on to patients at the pharmacy counter. There is no question that the present rebate system is dysfunctional and does little to serve the very patients it was designed to benefit.

As we wrestle with the worst public health and economic crises of our lifetime the time is now and the place is here to craft the changes that are needed. Innovative biopharmaceuticals are part of the solution to the burden serious diseases impose on patients and society. Amgen can strive for reforms to improve affordability for patients. However, a single manufacturer cannot make that happen alone.

We stand ready to work with members of both parties, the administration, and other stakeholders to develop policy solutions, help improve access and affordability for our patients without stifling innovation. There are so many diseases to confront and patients to help. If we all stay focused on what is best for patients, I am confident we can end up in a better place.

Thank you for the opportunity to speak to you this morning.

Chairwoman MALONEY. Mr. Trudeau, you are now recognized.

STATEMENT OF MARK TRUDEAU, PRESIDENT AND CHIEF EXECUTIVE OFFICER, MALLINCKRODT PHARMACEUTICALS

Mr. TRUDEAU. Chairwoman Maloney, Ranking Member Comer, and members of the committee, thank you for the opportunity to be here today.

I started in the pharmaceutical industry as a research and development engineer nearly 40 years ago. Over the course of my career I have worked on pioneering treatments for several critical diseases, including some of the very first for HIV. The leadership roles that I have had in other regions of the world have allowed me to better understand both the strengths of the U.S. health care system and its challenges. I have devoted myself to this industry because, like the nearly 3,300 employees of Mallinckrodt I know that the therapies that we make improve the lives of patients and their families.

This has been a year of unprecedented challenges. When COVID–19 hit we mobilized to identify therapies to combat the diseases. We consulted with the FDA and NIH regarding potential evaluation of INOmax, our inhaled nitric oxide therapy for the treatment of COVID–19-related respiratory complications, and supported an independent clinical trial being coordinated by Mass General. As of today, nearly 250 hospitals and U.S. health systems have used INOmax as an experimental treatment for COVID–19 patients.

We also secured our supply chain to avoid manufacturing interruption for the critical medications we make and donated 54,000 pieces of PPE, several ventilators, and more than 16,000 gallons of hand sanitizer manufactured in our Missouri plant. We also engaged with Members of Congress and Federal agencies like BARDA to discuss leveraging our extensive experience making high-quality, U.S.-made generics at our plants in Missouri, New York, Illinois, and North Carolina, to bring home the manufacturing of essential medicines and active pharmaceutical ingredients.

Today we are the only American manufacturer of acetaminophen, a key active pharmaceutical ingredient in many medicines, which we proudly make in Illinois and North Carolina.

Our resolve to help patients with critical conditions has never been stronger, and we understand and share the American people's concerns over the availability and affordability of prescription drugs. Mallinckrodt is steadfastly committed to knocking down barriers to patient access. That is particularly true with Acthar Gel.

Acthar is a complex injectable biopharmaceutical product, FDA approved for 19 serious conditions, including infantile spasms, lupus, multiple sclerosis, nephrotic syndrome, and rheumatoid arthritis. Acthar is life-changing therapy for a small group of patients for whom other treatment options have failed, or patients whose conditions, if left untreated, may lead to physical and developmental impacts requiring life-long care, causing great financial strain on families and the American health care system.

Acthar is not patent protected. We do not block generic competitors from entering the market. It is our policy to provide reference samples to generic manufacturers upon request, and we have supported legislation like the CREATES Act to ensure appropriate access to those samples.

Since we acquired Acthar in late 2014, we have invested more than $660 million into modernizing the product, including over $470 million in R&D activities and close to $190 million in manufacturing advancements. We have initiated nine clinical trials with targeted combined enrollment of nearly 1,100 patients, a large number given the rare or complex conditions Acthar typically treats. Results from one study of patients with persistently active rheumatoid arthritis showed that treatment with Acthar resulted in low disease activity for an astounding 62 percent of patients for whom standard treatments did not work.

Since we have owned Acthar, the list price has increased, on average, around five percent annually, not factoring in inflation or significant discounting that we started when we acquired it. In two of the last six years we didn't take any price increase, and last year the net price of Acthar went down, as it will again this year. We

have also improved the ability of patients with a prescription to obtain Acthar through our robust free drug and commercial copay assistance programs, which lead to many patients paying nothing out of pocket.

Like all of Mallinckrodt's employees, I am dedicated to bringing more breakthrough treatments to the market, including Terlipressin, one of two treatments we are developing for patients with advanced liver disease; StrataGraft, our investigative regenerative skin therapy, which may reduce the need for autografting in certain burn patients; and Adrabetadex for Niemann-Pick Type C disease, a high mortality rare disease affecting children and adolescents.

We will not waver in our commitment to serving patients with critical conditions who need better options. Thank you again for the opportunity to be here today.

Chairwoman MALONEY. Thank you. Mr. Kendris, you are now recognized.

STATEMENT OF THOMAS KENDRIS, U.S. COUNTRY PRESIDENT, NOVARTIS AG

Mr. KENDRIS. Thank you, Chairwoman Maloney. Chairwoman Maloney, Ranking Member Comer, members of the committee, thank you for the opportunity to speak with you today.

My name is Tom Kendris and I am the U.S. Country President for Novartis, a leading global medicines company. We use innovative science to develop transformative medicines that improve and extend people's lives. We also develop generics and biosimilars through our Sandoz division, the second-largest generics company in the United States. Our medicines reach close to 800 million people every year. Globally, we are over 100,000 people, with approximately 15,000 employees in the United States. Our global R&D headquarters is in Cambridge, Massachusetts, and we have several manufacturing sites across the U.S.

I have been with Novartis for 25 years, and I still marvel at the passion of our people to tackle the most complex medical challenges. Gleevec was one of the most significant medical advancements in recent history. It revolutionized targeted therapy for cancer. Before Gleevec was introduced in 2001, the five-year survival rate for a patient with chronic myeloid leukemia was only 30 percent. Now the vast majority of CML patients have a normal lifespan. What's more, Novartis continued to study whether the drug could treat other diseases, and today it is approved for six other rare cancers, saving tens of thousands of lives.

A more recent example of our transformative treatments is the development of a gene therapy to treat spinal muscular atrophy, a rare genetic neuromuscular disease that affects primarily babies. The treatment is one of the first gene therapies to be approved in the U.S., with a single injection. Some babies who would otherwise have died by the age of two or three are now going to kindergarten and growing up like other children.

In cell therapies we developed the first CAR-T therapy to treat a rare form of pediatric and young adult leukemia. This therapy can bring a patient from the brink of death to remission. The first patient ever to receive this therapy has been cancer-free for eight

years and is now going to high school and leading a normal life. Spending time with this young patient's family is one of the great privileges of my career.

Beyond rare diseases and cancers, we are reimagining how innovative medicines might improve public health broadly, particularly in sickle cell anemia, malaria, and cardiovascular disease.

I would like to be clear with the committee, however, that at Novartis we recognize that these innovations don't matter if patients cannot afford or get access to them. In the U.S., issues of price and access present systemic challenges that must be addressed together by industry and policymakers, and Novartis is committed to being part of the solution. While CMS predicts national health spending to grow at an average rate of 5.4 percent through 2028, the average net price of our medicines is expected to decrease by 2.5 percent in 2020.

Value-based pricing is a critical tool in addressing affordability and access. When setting prices, we at Novartis consider multiple factors, including the improvements the medicines offer patients, both clinically and in terms of their quality of life, and the benefits that the medicines offer to the health care system and to society.

The industry should adopt a similar approach, and patients should have access to treatments with low cost-sharing, to encourage the use of the most cost-effective options available. We also seek to lower costs by developing low-cost biosimilars and generics through our Sandoz division, which brought the first biosimilar to market in the U.S.

Over the past five years, Novartis has provided medications at no charge to nearly 300,000 U.S. patients experiencing financial hardship or who have limited or no prescription drug coverage. Eligible patients with commercial insurance often pay less than $30 for a 30-day prescription for the vast majority of Novartis' products.

The pharmaceutical industry used to be revered. That trust has eroded, however, and our industry must work to regain it. At Novartis we understand that this trust is earned, not just from bringing breakthrough medicines to patients but by pricing these medicines responsibly and ensuring broad access. While we live in an incredible era of progress in human health, we will only be successful if we can make both of these goals a reality. At Novartis we are passionately committed to doing so.

Thank you for your time this morning and I look forward to answering your questions.

Chairwoman MALONEY. Thank you. I thank all of you.

I now recognize myself for five minutes for questions, and I thank Mr. Comer for allowing me to go over a little of my time. I certainly grant the same to him, and more, to his colleagues on your side of the aisle.

Yesterday we heard the CEOs claim over and over again that they had to raise drug prices to help pay for research and development and promote innovation. But the internal documents we obtained showed that these claims were false. Instead, they showed that these price increases are intended to generate more and more revenues for the drug companies.

Mr. Trudeau, let's start with you. In your written statement today you made the statement, and I quote, "At Mallinckrodt we

believe that pricing for an innovative therapy should reflect the value that the treatment brings to patients, providers, and the health care system as a whole," end quote.

But your company didn't acquire Acthar Gel because you thought it was an innovative therapy. It was a very old drug. You acquired it to meet your financial objectives.

I would like to go through three quick slides with you. First is Exhibit 66, and it is up on the screen.

[Slide.]

Chairwoman MALONEY. This is a slide from a presentation that was prepared when you were considering the acquisition of Questcor, which made Acthar. As a preliminary matter, these talks about Quincy, Quincy was just the code name you used for your real company, Questcor, right?

Mr. TRUDEAU. That is correct, Madam Chairwoman.

Chairwoman MALONEY. Thank you. The title of the slide says, and I quote, "Questcor is a rapidly growing specialty pharmaceutical company with a premium-priced product."

Mr. Trudeau, the premium-priced product was Acthar, and premium-priced just means really expensive. Right?

Mr. TRUDEAU. That is actually not true. What it refers to is that it was priced at a premium to other competitive therapies.

Chairwoman MALONEY. Well let's look at the next slide, Exhibit 67.

[Slide.]

Chairwoman MALONEY. If you look at the fourth bullet, this slide says your acquisition would allow Mallinckrodt to, quote, "achieve aspirational goals with a single transaction," end quote. By "aspirational goals" you are talking about huge revenues, and that is exactly what you got. Acthar sales accounted for a third of your company's net sales from 2017 through 2019. Isn't that right?

Mr. TRUDEAU. The sales are roughly correct, but our aspirational goals were actually to transform the company. Mallinckrodt was originally a generics and imaging company and we were looking to make a transformation to a company that was focused on research, investment, and the opportunity to address patients with severe and critical conditions who are underserved by current therapies.

Chairwoman MALONEY. Well, let's now look at Exhibit 68.

[Slide.]

Chairwoman MALONEY. Mr. Trudeau, I will just read the headline. It says that your modernization strategy will define the future of Acthar as either a growth asset or a, and I quote, "cash cow," end quote. Isn't it true that this is how you really see this drug, not as an innovative therapy but as a "cash cow"?

Mr. TRUDEAU. No, that is not true, and this document, which I was just recently made aware of, actually was a draft document that was never shown to our board.

But that term is typically applied to products for which no investment is likely to be going forward, and, in fact, that is exactly the opposite with what we have done with Acthar. We have invested nearly $660 million since we acquired the product in 2014.

Chairwoman MALONEY. OK. A cash cow is a profit-making thing. What is a cash cow? That is what you said. I think the document speaks for itself.

Mr. Bradway, may we turn to you? Your company's talking points claim, and I quote, "At Amgen we price our products to reflect the economic value that is delivered to patients, to providers, and payers, the unmet medical need, the size of the patient population, the investment and risk undertaken, and the need to fund continued scientific innovation," end quote.

But your internal documents tell a very different story. So, let's look first at Exhibit 36.

[Slide.]

Chairwoman MALONEY. This is a pricing committee presentation from December 2016. In this document your pricing committee is basing its decision not on innovation or research and development but on what another company, AbbVie, might do with a similar drug. Isn't that right?

Mr. BRADWAY. Yes, Madam Chairwoman. That is correct, and it is important to note what is happening in this discussion. What this reflects is the nature of the—the structure of the biopharmaceutical industry through which we compete for formulary position for our medicines with other molecules in the same therapeutic category. So, what you are seeing here is a snapshot of a discussion about how we position Enbrel versus other molecules that we compete against in this anti-inflammatory category.

Chairwoman MALONEY. Well, this document, it has three scenarios for what AbbVie might do, and it plans out what your company will do in response. Mr. Bradway, these pricing executives are not discussing any of the things that you mentioned in your talking points. They are not discussing research and development, unmet needs, investments, risk undertaken, innovation. Instead of competing with other companies to beat their prices you are all increasing them in lockstep. Isn't that right? That is what the document says, and I think it is scandalous.

Mr. BRADWAY. What you see here is a document that illustrates the competition that exists to keep medicines like Enbrel on formulary. Again, if I may be allowed, Madam Chairwoman, let me say a few words about the structure of the market that requires the kind of rebating that is implied in this document.

As I said, Enbrel competes against 20 different molecules in the anti-inflammatory space. We offer rebates which secure our position on the formulary of the intermediaries who determine which medicines are available for patients to use, and what the effects are of the scenarios that the team is considering in order to make sure that this medicine remains available for those patients who are already on it and those patients whose physicians want to add them to their therapy. So, they are looking at a range of scenarios, and implicit in this is the rebate that would be associated with those scenarios for the product.

Chairwoman MALONEY. Well, let's move on to Mr. Kendris. In your written testimony you say, and I quote, "Given its life-changing attributes we have committed to making Gleevec accessible to patients who need it," end quote. But one of the documents obtained by the committee shows that executives priced Gleevec as high as possible, and they priced it so high, from the documents, to meet revenue targets without triggering negative backlash.

Let's put the slide on the screen, and this is Exhibit 3.

[Slide.]

Chairwoman MALONEY. This is a slide of Gleevec's pricing scenarios, including the risk to Novartis' strategic financial plan, quote, "if action not taken in 2013," end quote. If you look in the top right-hand box, the description of the aggressive pricing model says, quote, "delivers greatest upside while keeping single increases below the 10 percent threshold," end quote. This aggressive model recommends five price increases of 9.9 percent over the course of three years.

Mr. Kendris, my question is, your company chose the most aggressive pricing model, didn't it?

Mr. KENDRIS. Madam Chairwoman, in the next sentence, right after the one you read, the document which I am seeing this morning recommends enhancements to our patient support programs. So, Madam Chairwoman, what I would say is that over the years since Gleevec was introduced onto the market its value increased exponentially, because of the five new indications that we obtained for Gleevec in rare cancers and the tens of thousands of patients whose lives were saved. Over time it became clear that the remissions, not only in CML but in all of those cancers, were robust and long-lasting.

In 2001, we didn't know that. We didn't know how long patients would live and survive after they were given Gleevec. But over time we found out that they did. And we turned cancer, all of these six cancers, from a fatal condition first to a chronic condition and then, with a follow-on product, Tasigna, we turned it into a treatment-free remission condition, basically a cure. They don't have to take a pill any longer.

So, Gleevec was tremendously valuable, and the price increases we took were—we certainly took them over those years, Madam Chairwoman, but we were always the lowest-priced product in the class. The product has been generic now since 2015. We haven't taken a price increase since 2015, and today 55 percent of what we manufacture of Gleevec is given away to patients who can't afford it and given away for free.

Chairwoman MALONEY. Well, the bottom line is that Novartis went with the pricing strategy that would maximize net sales, raising Gleevec's price five times in three years.

The point here is that all the claims by drug companies about why they need to increase prices to pay for research and development and for innovation, they are simply not true. These documents show that they are increasing prices simply to make more money, plain and simple. That is why we need to finally allow the government to negotiate directly for lower prices, like all other countries.

Again, these drug companies make more off the United States than all the other countries in the world combined, buying their products.

There will be further questioning on the rebates and how they are really not working, or not getting to people, but I am over my time as I am, and I want to now recognize Mr. Massie for the same amount of time, for his questions. And thank you very much for allowing me to go through the slides. Thank you.

Mr. MASSIE. Thank you, Madam Chairwoman. Mr. Trudeau, you mentioned that Mallinckrodt was a manufacturer of generic drugs, and that was a big part of your market in the beginning. In general, what percent of prescriptions in the United States are generics?

Mr. TRUDEAU. I believe it is approximately 90 percent at this point.

Mr. MASSIE. So, 90 percent of the prescriptions that are written and filled in the United States, roughly, are for generic drugs. I think that is fantastic. But is the cost of generics in the United States significantly higher than in other countries? How do we compare when you go on a generic label?

Mr. TRUDEAU. Well, typically the United States generic market has been amongst the most efficient, meaning that prices drop most rapidly in the U.S. We have a very efficient market. And generic prices typically, in a relatively short amount of time, many times within a year, drop to about 10 percent of the branded price. So, we have a system that works from a generic perspective, certainly relative to other countries.

Mr. MASSIE. And what are some of the challenges you face when you want to make a generic drug, say after a brand name drug goes off patent? What are some of the hurdles that you have to overcome to get a generic drug to market?

Mr. TRUDEAU. Well, the primary thing that you have to do is generate bioequivalent status. You have to demonstrate that your product is bioequivalent to the branded product. That requires some clinical work. Sometimes it requires other investment, research and development investment. Then, of course, you need to be very efficient, from a manufacturing and distribution standpoint, because you are competing in a very aggressive, competitive marketplace.

Mr. MASSIE. Is there something that we can do in Congress to make it easier to get to a generic label from a brand name label after a drug goes off the patent?

Mr. TRUDEAU. I believe the generic environment today is actually quite good. I think there has been significant improvements on the regulatory side in improving the throughput of generic approvals. I think the statistics show that the FDA has generated significantly more approvals of generic products over the last couple of years. That certainly adds to competition, and that is certainly likely to drive down prices.

Mr. MASSIE. In order to produce a generic without infringing on a patent, the patent has to expire, I suppose, but can you also license the patent or is that not typical in the drug industry?

Mr. TRUDEAU. Certainly, it could be done but that is not typical. Mostly generic products enter the market after the expiration of patents.

Mr. MASSIE. And what is the lifetime of a patent?

Mr. TRUDEAU. Well, a patent can vary, but the lifetime is typically going to be on the order of 20 years. But recognize that is from the actual discovery itself, and much of that timeframe is actually taken up by research and development. Many times, when you launch a branded product you may only have a couple of years

left on the patent, because most of that time has been eroded because it has taken time to develop the product.

So, you know, typically it is 20 years. It can vary a little bit. But that is typically the timeframe.

Mr. MASSIE. That is 20 years from when the invention occurs, and like you said sometimes you are only left with a few years to try and recoup the investment. How many of the drugs that you develop actually result in a profit?

Mr. TRUDEAU. Well, on the generic side, typically you are likely to be reasonably successful because again you are not driving innovation necessary. But what you are doing is you are driving down cost because you are able to bring competitive products to the market.

On the branded side it is a little bit different. On the branded side I think, you know, the likelihood of success while you are actually driving innovation is dramatically lower. We have heard some statistics that 1 in 100 or so drugs ever makes it to market. That is probably in the range. It is a high-failure, high-risk environment when you are developing any kind of new innovation, as we all know.

Mr. MASSIE. Thank you. I have got a few questions for Mr. Bradway. Mr. Bradway, you talked about the sort of, I don't know if you used the word "convoluted" but it seems convoluted to those of us who aren't in the industry and trying to understand the drug pricing schemes and how it involves pharmacy benefit managers and rebates.

Can you tell us roughly what percent of the money that my constituents spend on drugs, or the government spends on drugs for my constituents, goes to pharmacy benefit managers, Mr. Bradway?

Mr. BRADWAY. Yes, I can tell you that the intermediaries, in general, which include the PBMs, have about 46 cents on every dollar in the pharmaceutical industry. So, 46 percent of what you see in the U.S. drug industry reflects revenues that go to the intermediaries, including the PBMs.

Mr. MASSIE. So, that is almost half of the drug price that the consumers pay or the government pays goes to an intermediary instead of the drug company?

Mr. BRADWAY. Or instead of directly to the patient. That is correct.

Mr. MASSIE. And when my constituents pay their copay on a drug, you mentioned that there are rebates that are paid. Do the rebates go to my constituents? Who do they go to?

Mr. BRADWAY. Thank you for raising this question, Congressman. I think this is important for you and your constituents to appreciate.

The copay is a function of list price and the rebates are also a function of list price. So, as list price rises, the rebates to the intermediaries rise as well. However, the other consequence of raising list price is that the patient at the pharmacy counter is having to pay a copay of now a higher list price, and the discounts that have been given to the intermediaries are not provided at the pharmacy counter to the patient.

So, we have wound up with a situation where the intermediaries are getting the rebates and not directly transferring that benefit to the patients. So, the intermediaries are seeing their share of the pie increase while asking the patients to reach into their pocket and pay more in the form of copay.

Again, that copay is not collected by the innovative industry. That copay is collected by the intermediaries in the system.

Mr. MASSIE. So the copay, because of the way the pharmacy benefit managers work and the other intermediaries, the copay that my constituents see, or the check that they have to write out, or sometimes they have to borrow the money for that copay, that copay isn't based on the actual price that goes to the drug company or the final price that the drug company receives for that drug. It is not even based on the real price of the drug once you count the rebates. It is based on a higher effective price. Is that correct?

Mr. BRADWAY. That is correct. You are absolutely right. Your constituents are paying a copay, again, which is a fraction of the list price, and the innovative company is receiving what is known as the net price, which is the list price minus the rebate returned to the intermediaries. And in the United States, the estimate of the rebates is approximately $150 million, but as I said earlier, 46 percent is in the hands of the intermediaries.

Mr. MASSIE. Madam Chairwoman, do I have time for one more question? OK.

So, can you explain to us, Mr. Bradway, what the intent was when we came up the pharmacy benefit manager system, what the intent was and how it was designed to make drugs more accessible or a lower price, and how that mission has possible wandered over the years?

Mr. BRADWAY. Sure, Congressman. I perhaps might point out two things. First, the structure of the rebate system that I am referring to is one that was created by legislation that enables us to interact with the intermediaries in a way that includes paying them rebates in order to secure formulary placement for our medicines.

But, you know, again, I don't want to just point the fingers at the PBMs. I think we heard in Mr. Trudeau's testimony one of the useful functions that the PBMs have played in our system through the years, which is helping convert patients to generic drugs when they are available. It is one of the reasons that we have 90 percent of the prescriptions actually being written for generic drugs.

I think the question, however, is whether they are playing an appropriate role when it comes to innovative, brand-protected innovations and design formularies that separate physician and the patient from one another at the pharmacy counter, where patients can't be sure that they are going to be able to walk away from the pharmacy with the medicine that their doctor intended them to have because of the structure of the rebate system that is in place in our industry.

Mr. MASSIE. It feels like to me, just in closing, we need some kind of truth in pricing here. If people bought cars this way and the actual price of the car wasn't what the consumer paid, and financing was based on a price that wasn't the real price, I think we would be outraged. So, maybe that is something we could look into.

I thank the chairwoman for her indulgence, and I yield back.

Chairwoman MALONEY. Thank you. I now recognize Representative Norton. Representative Norton, you are now recognized.

Ms. NORTON. Thank you very much, Madam Chair. I hope you can hear me.

Chairwoman MALONEY. Yes, we can hear you.

Ms. NORTON. I want to thank you for this very important hearing. In fact, the subject matter, drug pricing, is so important that you have scheduled two days, one after the other, on this subject, so we can clear this matter up.

I want to say to Mr. Bradway, Mr. Trudeau, and Mr. Kendris that we very much appreciate your joining us. Your testimony has been very helpful. We recognize, though, that you produce drugs that are crucial lifelines to patients and to their families. And you heard from the two witnesses who opened these hearings that far too many families lose access with each price increase, and that is before we get to the generic state of a drug.

Mr. Bradway, your company has raised the price of Enbrel 27 times since 2002. Amgen's profits from Enbrel has grown from $1.25 billion in 2003 to more than $5 billion today.

Now to turn to the other Amgen drug under investigation, Sensipar. Since launching the drug in 2004, Amgen has raised the price more than 20 times. Amgen's U.S. sales price for Sensipar also rose from $36 million in 2004 to $1.4 billion in 2018.

Mr. Trudeau, since acquiring Questcor, and, by extension, Acthar, in 2014, Mallinckrodt has raised Acthar's already high price by more than $8,200 per vial. That is a 26 percent increase. From 2014 to 2019, your company generated nearly $6 billion in net sales of Acthar.

Mr. Kendris, since launching Gleevec in 2003, your company has raised the price 22 times. Due to these price increases, your profits have grown from $1 billion in 2009 to more than $2.5 billion today.

Now nearly one in four Americans taking prescription drugs, against this backdrop, report difficulty affording their medicine. We began the hearing today with testimoneys from these two patients, who are on these medications for their lives but are struggling to make ends meet. Like many other families, they have to make heart-wrenching decisions to afford these vital drugs.

Mr. Bradway, yes or no. Will you commit to lowering the list price of Enbrel and Sensipar in the United States?

Mr. BRADWAY. Sensipar is now off patent in the United States and the price of Sensipar has fallen by some 95 percent. And as I said in my opening remarks, we have lowered our net prices across our portfolio in the U.S. over the past two years, and we are on track to repeat that again in 2020.

Ms. NORTON. Mr. Trudeau, yes or no, and I am afraid Mr. Bradway did not give me a yes-or-no answer. Will you commit to lowering the list price—and the reason I asked for a yes or no because my time up—will you commit to lowering the list price of Acthar in the United States? Yes or no.

Mr. TRUDEAU. I will commit to lowering the net price of Acthar in 2020 down to levels that it was in 2015.

Ms. NORTON. Thank you. Mr. Kendris, yes or no. Will you commit to lowering the list price of Gleevec in the United States?

Mr. KENDRIS. Congresswoman Norton, we have—the product went generic five years ago and we have lowered the price by giving discounts on the branded product, huge discounts, 40 or 50 percent discounts.

Ms. NORTON. But I mean the list price. I mean the list price, sir.

Mr. KENDRIS. Yes, we have given discounts on the list price post-generics, and we haven't raised the price. So we have, in effect, lowered the price and we are giving away 55 percent of what we manufacture now for free to patients who cannot afford their medicine. So, we are doing everything we can, Congresswoman, to make sure that every patient who needs Gleevec can get Gleevec.

Ms. NORTON. Thank you. Madam Chair, the problem is that they are not doing everything they can, and that is why this hearing is so important. I yield back.

Chairwoman MALONEY. Thank you.

Mr. Gosar, you are now recognized for questions. Mr. Gosar.

Mr. GOSAR. Thank you, Madam Chairwoman, and I am certainly happy that I follow my good friend, Thomas Massie, because he set the stage for me perfectly.

It seems to me that this hearing and yesterday's hearing are a little tone-deaf. We have countless states that have shut down with businesses crumbling due to the overreactions to COVID–19, yet we are here talking about how certain drugs need to have government-controlled prices. Yet there are millions who are thrust into unemployment because of these harsh restrictions. And this hearing isn't even focused on the drugs or therapeutics that most people have on their mind—a vaccine to COVID–19. But since we are here, I plan to get a little substance out of this hearing.

Today we have CEOs of some of the biggest pharmaceutical companies here with us. The way my colleagues on the other side of the aisle view prescription drugs and price tags are very top line. They see a drug that helps people but since it is not cheap, therefore we need the government to negotiate these prices. In typical fashion, you identify the problem properly but butcher the solution with more government. Ronald Reagan once said, "It isn't the government that is the solution. It is part of the problem."

As a doctor in a past life, the first step when diagnosing an ailment is look to the source and keep it as simple as possible. If there is something preventative that can be done to stop the problem from reoccurring, why not try?

Let's put this theory into practice. Why are drug prices so high? Many point to PBMs, greedy executives, a flawed patent system. Does anyone want to point a finger at the Federal Government? I know I do. In any prescription drug chain you have health insurers, PBMs, drug makers, pharmaceutical wholesalers, pharmacies themselves. What do they all have in common? Government influence and control. Right off the bat, health insurance companies are exempt from antitrust laws. That means they literally do not have to compete.

Many of my colleagues have been mentioning an infusion of competition to help lower prices, but how do you suppose we do this when a link in the chain can legally monopolize? I have been fighting my entire political career and before that to repeal this 75-year-old statute, because you can't even imagine a world where health

insurers have to compete for your businesses instead of leaving most Americans with little to no options.

As for other entities involved in the drug process like PBMs, these companies became a main focus of Obamacare and actually fueled the creation of new rules by CMS under the Obama Administration to come down on PBMs. And how about pharmacies and how they must deal with 340B contracts that set strict price controls on various drugs? No market force there.

And what about the drug makers we have here today? I am sure they could go on all day about how the government is involved in their day-to-day business. Just the FDA regulations alone could keep you guys talking for days, but unfortunately I only have so much time.

My colleagues on the other side of the aisle want to point to our current system and say that this is the free market. Well, if this is the free market and this is competition, it is failing America. What we now have is nowhere near a free market. It is crony capitalism at best, and it is just the excuse my colleague are using to push us closer to socialized medicine, where folks like these testifying today will be decimated and those created therapeutics for those who need it will be lost.

So, I say to you folks here today with us, join the side that is simplifying the prescription drug process. Be for the side of free market competition, because soon you may look like those drug companies in other countries where your profits are kept, your innovation is stifled, and your impact on making this world a better place will be completely evaporated.

Now last—hold your breath—I want to thank the majority for taking the first step in passing Congressman DeFazio's and my bill, the Competitive Health Care Insurance Reform Act, unanimously out of the House last week. This is the first step in which we create a solution where it is market driven. Now let's get the Senate to pass it, and what we see is patients, doctors, and the system all benefiting.

Thank you very much, Madam Chairwoman, and I yield back.

Chairwoman MALONEY. Thank you very much.

Representative Clay, you are now recognized for questions.

Mr. CLAY. Thank you so much, Madam Chair. Let me also thank you for mentioning our late colleague, Elijah Cummings. We knew that this was one of his signature issues and thank you for keeping his memory alive and keeping this effort.

Let me start off by thanking all three witnesses for being here, and let me say hello to a former constituent, Mark Trudeau, who has headed up Mallinckrodt, which has been a part of the St. Louis community for almost 150 years.

And, Mr. Trudeau, let me start with you. You know, part of the concern about Acthar is that it is a pretty old drug with a relatively high price and yet you have said Mallinckrodt is modernizing it. I think you said you have invested more than $600 million in it. Tell us why it is important to modernize this drug, and aren't there other, more modern therapies that can take the place of Acthar?

Mr. TRUDEAU. Thank you for the question, Congressman Clay, and good to see you as well.

So, like many opportunities, there are old drugs that have been repurposed for new indications and new purposes, for example, looking at some of the antivirals that are being developed to treat COVID–19, for example. In the case of Acthar, we believe that it is quite important to create new information, new evidence, things that have led actually to changing our label to provide patients and prescribers, as well as those responsible for reimbursement, the appropriate scientific-based information to make good economic and clinical decisions for their patients.

We are most focused on doing the best that we can for patients that are suffering from severe and critical illnesses who have relatively few options, and Acthar can make a difference in the lives of those patients.

Mr. CLAY. And, you know, I believe in the importance of medical innovation, and you have indicated that R&D is a major focus of your company and imply that Acthar is funding part of that R&D. How much does Mallinckrodt invest in R&D annually, and does your pipeline offer any promising options for patients?

Mr. TRUDEAU. We invest approximately $350 million a year in research and development, which is a large number for a company of our size. We believe that our pipeline is very promising and we have specifically focused on these underserved patients with severe and critical conditions that have relatively few options. So, we are developing two products for patients with severe liver disease, a product for adolescents and children that have a high mortality rate, called Niemann-Pick Type C. We are also developing a novel biotherapy to treat burns, severe burns, to reduce the need for autografting. So, our pipeline is really focused on driving innovation for these particular underserved patients.

Mr. CLAY. So, in my home state of Missouri COVID–19 has been a major concern. It is my view that during a national public health crisis like we are facing today pharmaceutical and health care companies should be focused on finding solutions.

Perhaps all three witnesses can tell us what your companies are doing in response to this national pandemic. Mr. Bradway, we can start with you.

Mr. BRADWAY. Thank you. We are very active in addressing the pandemic. I share your belief that all of the innovative biopharmaceutical industry needs to be working together, to find ways to develop vaccines, to develop therapies that can help prevent the infection from becoming serious, can help develop therapies to prevent the immune overreaction, which we see for many who are infected with the virus, and to be finding other ways to try to diminish the burden of this disease on our society.

But I am impressed by the speed and scale of the efforts underway, both at our company and across the industry, and I am optimistic that we will have solutions.

Mr. CLAY. Thank you. Madam Chair, can the other witnesses respond, or has my time expired?

Chairwoman MALONEY. Time has expired but the witnesses may respond.

Mr. CLAY. Thank you.

Mr. TRUDEAU. Madam Chairwoman, I am happy to comment on that. We agree with the Congressman that it is very important

that we do everything that we can to combat this challenging health crisis that we have created by COVID–19. We have done at least four things. One is that we have invested and partnered on clinical trials around one of our innovative therapies called INOmax, that can potentially help with patients that are ventilated as a result of COVID–19. It is being used at physician discretion today as an experimental therapy in over 250 hospitals.

We have donated PPE, ventilators, hand sanitizer around the country, and we have also made available some of our health care professionals, at company cost, to be treating patients on the front line. We believe it is that important to do everything that we can to combat this challenge.

Chairwoman MALONEY. Thank you. Mr. Palmer, you are now recognized for questions.

Mr. PALMER. Thank you, Madam Chairman. I would like to start off by saying that obviously we are all interested in lowering drug prices, but at the same time we don't want to overreach and implement policies that stifle research and innovation that has literally brought us lifesaving miracle drugs. In fact, we want to encourage the discovery of new drugs, but at the same time, you know, discovering these new drugs doesn't do a lot of good if people who need the drugs can't afford them.

So, I want to followup on Mr. Massie's points on patents, and I brought this up yesterday. I support extending the length of patents if an extension will lower drug prices. And what I would like to know from each of you, and if you can answer concisely so that I can get in a couple of other things I would appreciate it, would extending the patent protections reduce drug prices? And we will start with Mr. Trudeau.

Mr. TRUDEAU. I believe that anything that we can do to incent innovation, and extending patent life could be one of those things, is likely to give the health care system an opportunity to get drugs to patients more efficiently and more effectively and potentially at lower prices.

Mr. PALMER. And Mr. Kendris and Mr. Bradway, if you agree with that, or do you have anything to add to that? I want to ask a couple of other questions.

Mr. BRADWAY. I think innovative biopharmaceuticals are an important way to control health care costs. We advocate for maintaining the 12 years of data exclusivity, in particular, for biologic drugs. So, we think that is an appropriate standard, and we see innovation as a way to bring down health care costs overall in the United States.

Mr. PALMER. OK.

Mr. KENDRIS. Congressman Palmer, I would agree with what the other two witnesses just said and would say that patents are essential to incentivize innovative companies to invest in high-risk research. And the patent system as it stands right now does that, and we support it.

Mr. PALMER. See, the reason, I think Mr. Massie and I both are asking these questions is because it should be obvious to everyone that a drug company needs to be able to recover their cost. My understanding of the private drug research industry is that it has led the way in the development of some incredible drugs, but there are

also a number of drugs that never made it to market. And you have to deal with that stranded cost that goes into your decisions on pricing of other drugs.

So, my question would be what would happen if the development of drugs—to the development of these life-changing, lifesaving drugs, if companies couldn't recover their cost? That should be a fairly simple question to answer. Mr. Trudeau?

Mr. TRUDEAU. Again, I believe my colleagues have agreed with this as well. Incentives are important if you are undertaking innovation, which inherently has risk. So, any additional incentives that can be provided to, you know, provide the potential to reduce that risk or increase the reward certainly are likely to lead to even more innovation, more inventions, and in the case of drugs, probably more potential cures or treatments down the line.

Mr. PALMER. If you guys have some ideas on incentives, whether it is write-offs for losses or other incentives that the government could provide, I would like for you to provide that to me and to this committee in writing.

But I do want to go back to something else that was discussed earlier, and that is the issue of rebates. Some of the information that I have gathered over the years—and this is not the first time I have looked at this; I started looking at this my first term in Congress—seems that there is some substantial abuse in the rebates and how this is handled. That might be an example of something that the Federal Government thought was a good idea at the time that is not working out quite so well.

That said, I would appreciate getting some feedback from each of you on incentives that you think would help the companies bring these prices down yet not compromise, in any way, the ability of companies to develop these drugs that, like I say, are not only lifesaving but life-improving.

Madam Chairman, I yield back.

Chairwoman MALONEY. Thank you. I now recognize Mr. Rouda. You are now recognized for questions.

Mr. ROUDA. Thank you, Madam Chairwoman. First, I would like to recognize the critical importance of the drugs that all of your companies manufacture——

[Pause.]

Mr. ROUDA. I apologize. The mic was not on.

Thank you, Madam Chairwoman. First, I would like to recognize the critical importance of the drugs that all of your companies manufacture to the health and well-being of many Americans. The essential nature of the prescription drugs and treatments you manufacture make it all the more vital for us to ensure their continued availability and affordability for all.

Mr. Trudeau, Mallinckrodt drug Acthar has proven effective and received FDA approval for numerous conditions that you outlined in your opening testimony. Acthar was first approved by the FDA in 1952, and it was actually priced at below $100 for 50 years. However, over the past two decades we have seen an astronomical price increase at the expense of American patients and taxpayers.

In 2001, Questcor, now a subsidiary of Mallinckrodt, acquired the rights to Acthar for $100,000, when the price per vial was still at or below $100—a vial, just like this, for $100, just 20 years ago.

Almost immediately, the price of the drug started to increase, and then, in August 2007, the price skyrocketed from $1,600 a vial to $23,000 per vial, literally overnight. When Mallinckrodt acquired Questcor in 2014 for $5.6 billion, the price of a vial already exceed $30,000.

So, today that same vial, from 50 years ago, that cost only $100, now costs $39,000, a 40,000 percent increase. Let me repeat, a 40,000 percent increase from this to this, in a matter of two decades. It is clear, American taxpayers are increasingly footing the bill for this drug.

While the number of Medicare Part D beneficiaries receiving Acthar increased by around 25 percent from 2013 to 2018, the cost to the Federal Government nearly tripled over that same time.

Mr. Trudeau, do you know how much your company has collected from Medicare Part D in recent years?

Mr. TRUDEAU. I don't know the exact amount. Certainly, it has been many millions of dollars.

Mr. ROUDA. It has. It has actually been approximately $2.5 billion between 2015 and 2018.

Mr. Trudeau, when Mallinckrodt acquired Acthar, how much of Acthar sales came from Medicare?

Mr. TRUDEAU. At the time of acquisition, the Medicare sales were approximately 25 to 30 percent.

Mr. ROUDA. That is correct, and that number has grown quickly. Do you know what percent is Medicare sales now?

Mr. TRUDEAU. I do. It is approximately 55 percent.

Mr. ROUDA. That is what the committee's information shows as well. We have gone from 25 percent to actually more than 60 percent of Mallinckrodt's net sales are from Acthar.

So, not only is Medicare your largest purchaser but internal data obtained by the committee shows that you also charge Medicare more than any other payer. Medicare's average net price, per vial, right here, is more than $4,300 more than what commercial payers pay. Do you know how much the Federal Government would have saved if Medicare had received the same discount—the same discount—as commercial payers between 2015 and 2018?

Mr. TRUDEAU. I don't know the exact amount, but the number would have been significant. In fact, Acthar is not on Medicare formularies, which actually prevents access to Medicare patients who could actually benefit from the drug. We would be very happy to consider similar discounts in Medicare if we had formulary positions and could get the same access that we get with commercial payers.

Mr. ROUDA. That would be helpful, and I am sure the American taxpayer would like to see it since the committee's estimate is that it would save American taxpayers $150 million a year.

Unfortunately, Mallinckrodt's 2013 tax inversion to Ireland has also burned American taxpayers. Is it safe to say you moved your headquarters over there to dodge corporate taxes here in the United States by having a lower corporate tax rate in Ireland?

Mr. TRUDEAU. No. That is, in fact, completely untrue. We spun out from a parent company that was Irish, and so this spun company, Mallinckrodt, became Irish as well.

Mr. ROUDA. Madam Speaker, I see that my time has expired so I shall yield back.

Chairwoman MALONEY. Thank you very, very much for your questions.

Mr. Cloud, you are now recognized for questions. Mr. Cloud.

Mr. CLOUD. Thank you, Chairwoman. It seems to me that oftentimes in Congress we go about trying to fix a problem before really stopping to ask what is broken about it. And, you know, we are talking about drug pricing, which we all agree we want to fix. It is definitely out of control. But I think it is important we stop to ask what brings costs down in an economy, and that is competition and customer accountability through price transparency.

Yesterday I had a chart up here that showed just how complicated that pricing system is, which makes it extremely hard for a customer to hold the manufacturers accountable or the system accountable when it comes to price transparency. In any other industry that is really how it work. You have a manufacturer that produces a product, the customer is able to look at pricing and market keeps prices low.

Now to foster innovation we have a U.S. patent system, of course, that protects research, incentivizes new cures. It has led to the U.S. being the undisputed leader in innovation, and to that extent the system is working. But what is broken is the customer accountability aspect and the price transparency that keeps prices in check.

Even if you think about the American people, they think that they go to their doctor, the doctor prescribes the best medicine, but that is not really what is happening, Mr. Bradway, is it? You talked about PBMs and what you are having to do to compete. Can you speak to that?

Mr. BRADWAY. Well, yes, so the physician hopefully is prescribing the most appropriate medicine for the patient. The challenge is, at that moment the physician and the patient may not know whether they are actually going to be able to walk away from the pharmacy counter with their medicine in hand or whether their insurance company is going to try to direct them to select something else.

Mr. CLOUD. Right. Manufacturers, basically, you have to pay rebates, or some would call it kickbacks even, to get a higher placing on the formulary, right?

Mr. BRADWAY. Correct. The structure that you have created for our industry involves us paying a rebate to the intermediaries in order to secure, amongst other things, formulary placement.

Mr. CLOUD. So, that is one mechanism in which the market is being manipulated, in a sense, breaking that customer accountability mechanism.

Americans also understand, you know, that companies do need to make a profit to exist and to create new cures. I don't think Americans have a problem with that. We understand that the profits today lead to new cures tomorrow. What they do have a problem with is abuse of the patent system, namely product hopping, adding on patents to extend introduction of generics, patent evergreening, you know, small changes to dosages and such that have little change but you gain an extension to your patent, and

then pay for delay. And these are issues, I think, that manufacturers do have to take seriously.

Now while I wish we had PBMs and pharmacies here—and I would encourage the chair and the committee to consider that if we are going to have a real discussion on pricing—we need to have all the players here, because the system is complex and it is broken in a number of different areas.

But my understanding is that Amgen has—you talked about Sensipar and you mentioned that the patent is—time has expired on that. Are you saying that generics are now available?

Mr. BRADWAY. Yes. That is correct. Generics now supply approximately 95 percent of the market, and the product transacts at about 95 percent less than what was prevailing before patent expiration.

Mr. CLOUD. OK. Now we had Teva here yesterday, and my understanding is that you had an agreement with them, Amgen did, to keep Sensipar—them from producing generics for Sensipar for a couple of years. Is that correct?

Mr. BRADWAY. No, that is incorrect. We sued Teva for infringing on our intellectual property, and they ended up settling with us after having launched at risk, settling with us for having, again, launched against the uncertainty of their patent position.

Mr. CLOUD. OK. But the timing, I guess, is interesting, that that lawsuit was dropped at the same time you all ended up purchasing some of their properties, I guess.

The thing that I think is important to note here is that we have a couple of bills that we are looking at. One is H.R. 19, which actually goes to address these different issues, where the system is broken, versus H.R. 3, which is a takeover of the system. And, you know, as we look at this I think it is important for us to keep in mind, let's not throw out the system that has brought the best innovation and has led to new cures that have helped so many people here and around the world. And I would really caution against a government takeover that H.R. 3 subscribes. Thank you.

Chairwoman MALONEY. Representative Welch, you are now recognized for questions.

Mr. WELCH. Thank you very much. Mr. Palmer said it well, that these drugs are a tremendous health benefit, extending lives and alleviating pain, but if we can't afford it, it does no one any good. And the question here is about the pricing practices of big pharma and how that is putting the cost of health care out of reach for individuals, for taxpayers, and for employers who are trying to provide health care for their employees.

I want to ask Mr. Bradway about the pricing strategy for a few of his drugs. What I understand, Mr. Bradway, Enbrel was originally approved by the FDA in 1998 for rheumatoid arthritis, and Amgen acquired the rights to sell Enbrel in 2002. Is that correct?

Mr. BRADWAY. That is correct.

Mr. WELCH. So, you bought a product—your company bought a product. It didn't create a product. Correct?

Mr. BRADWAY. Correct. We bought a product that was in short supply, a product for which there were tens of thousands of patients on a wait list, seeking therapy, and then——

Mr. WELCH. I get it. Fair and square, you bought the product. You didn't invent it. Correct?

Mr. BRADWAY. That is correct.

Mr. WELCH. And then you marketed it, and you produced it, and you raised the price of it. Correct?

Mr. BRADWAY. Yes, but I was trying to explain one of the important things that we did was invest in process improvements that enabled us to move literally tens of thousands of patients off the waiting list and be able——

Mr. WELCH. Well, I am going to the price, because the question here is not the legitimacy of what you did. It is legal to buy the product. You didn't invent it. One of the arguments that pharma makes is it costs so much to "invent." Well that didn't happen. What you did is you saw a market and you responded to it and you produced it.

But my understanding is that you have raised the price by 450 percent, to $5,500 for a monthly supply. It is about $70,000 a year. Is that correct?

Mr. BRADWAY. Yes, that sounds correct.

Mr. WELCH. All right. And in Canada that is $1,800 as opposed to $5,500. Is that true?

Mr. BRADWAY. That sounds correct.

Mr. WELCH. OK. Here is the question. Why can't people that are Americans get it for $1,800?

Mr. BRADWAY. There are a couple of things to observe. First, many of the medicines that are approved, the innovative medicines like Enbrel that are approved in the United States are not available in markets like Canada.

Mr. WELCH. Let's—let's—you know, we are throwing this word "innovative" around. This product was invented in 1998. I mean, this is not new. This is decades old. So, my question is why can't an American get the Canadian price?

Mr. BRADWAY. Yes. This is a product that we have continued to invest in. The product that patients use today is not the product that it was in 1998.

Mr. WELCH. So, a Canadian can buy this for $1,800, but you won't give the benefit of that price to the United States of America and our citizens.

Mr. BRADWAY. The product that you see today is not the product that it was in 1998.

Mr. WELCH. Let me ask you this. There is a lot of evidence in the record now that when your company, and other pharmaceutical companies, are making the decision on pricing, they have to meet revenue targets. You have got shareholders to take care of and you have got executive compensation to be mindful of. Correct?

Mr. BRADWAY. I don't think of it in that way, no.

Mr. WELCH. You don't think of it but you get the benefit of it.

Mr. BRADWAY. When we look at the pricing of——

Mr. WELCH. I mean, there are payouts of $100 million to executives, and it is really heartbreaking for a lot of folks who can't figure out how in the world they are going to get the medication for a person in their family that they love.

Let me ask you this. What is the problem of a company that is selling a product in bulk to a buyer, having a discussion with that

buyer about a bulk price discount? Do you have some philosophical objection to that?

Mr. BRADWAY. Congressman, that is what happens every day in our interaction——

Mr. WELCH. Except with Medicare. It is illegal. It is illegal.

Mr. BRADWAY. No, it is not——

Mr. WELCH. All right. Would you be agreeable to having a discussion with a bulk buyer, who happens to be Medicare, about a fair price when they make bulk purchases on behalf of U.S. citizens who are on Medicare?

Mr. BRADWAY. Congressman, if I may explain, we interact every day with——

Mr. WELCH. Well, that is a yes or no. No, that is a yes or no. You have got a big buyer, Medicare, and I am asking if you are willing to negotiate with them about a bulk price discount.

Mr. BRADWAY. The Medicare beneficiaries are represented by the insurance plans and the PBMs, with whom we negotiate every day for the inclusion of our products on the——

Mr. WELCH. So, that is a no to negotiating with Medicare directly.

Mr. BRADWAY. Well, Congressman, what I am trying to explain is what is happening already today. We do think there are some areas for improvement in Medicare, in particular, in Medicare Part D, and we have been advocating for a number of those——

Mr. WELCH. I am only asking about negotiating with the Medicare program. That is it. Yes or no?

Mr. BRADWAY. Yes, I am just trying to make sure, Congressman, that you and your constituents appreciate that that is already happening today. It is happening through the negotiations——

Mr. WELCH. So, why don't we change the law and make it legal to do that?

Mr. BRADWAY [continuing]. That we are having with your intermediaries. So, those discussions are already taking place today.

Mr. WELCH. I am asking about a law that makes it legal. Right now there is a law that makes it illegal, right? It is bizarre that a bulk purchase can't have a discussion and negotiate a bulk price discount. That is the law. Do you think that is a fair law?

Mr. BRADWAY. I don't know that I would agree with your construction of the question, Congressman. What I am saying is that we have a highly concentrated set of intermediaries in the United States health care system, the health care insurance companies and the pharmacy benefit manufacturers, and they are negotiating for the benefit of Medicare today, or across the landscape. Are there improvements that could be made? Absolutely. Do we advocate——

Mr. WELCH. Madam Chair, my time has expired, and I yield back.

Chairwoman MALONEY. Thank you. Mr. Gibbs, you are now recognized for questions.

OK, we can hear you.

Mr. GIBBS. Thank you, Madam Chair. First of all, I want to thank you for this hearing. I also want to make clear, I know Mr. Palmer and others talked about, you know, we want to make sure, we want to thank the drug companies for what they do, producing

these therapeutics and everything, curing cancer and making quality of life better, so we should never forget that.

But I do—you know, listening to all the discussion here about the pricing, it is enough to make your head spin. I guess, Mr. Kendris, you said that Gleevec is also used for six new cancers, OK. Now, has that price come down? I think it hasn't come down, has it? What is the status of that, Mr. Kendris?

Mr. KENDRIS. No, Congressman. We did raise the price over the years.

Mr. GIBBS. Yes, OK. Well, what I am trying to understand, in other sectors of our economy, when you have more utilization, and obviously you have more utilization of the product because you say it is now cleared by FDA to use in six types of cancer, so you have more utilization of the product, why does the product go up? Is it because it is the formulary process that we are having so much discussion and all the intermediaries and the complexity of this drug pricing and how it is broken? I mean, the price should come down.

Mr. KENDRIS. I think the answer to your question, Congressman, is that the value of Gleevec went up over those years, for a variety of reasons, including the patients survived longer, lived longer, it became a chronic disease instead of a fatal disease, and more patients were able to benefit because we got more indications from the FDA approved over those years.

Mr. GIBBS. I get that. So, more patients are buying it. You know, it is being utilized more. But that ought to drive the price down, because you can put your fixed costs over more customer base. In any other business, in any other industry that is how that works. If you are selling a product and you can sell more of that product to a bigger customer base, that drives down the cost because your fixed costs are more over the customer base. Do you see what I am trying to say? Does that make sense? But apparently it doesn't work that way with drugs.

Mr. KENDRIS. Congressman, in this case—I understand what you are saying, but in this case, for these rare cancers, the commercial opportunity is actually quite small. The patient populations are very small——

Mr. GIBBS. Let me ask the question——

Mr. KENDRIS [continuing]. But the research and development commitment is high.

Mr. GIBBS. That makes sense. That is the first comment I have heard today that makes some sense. You did say 65 percent of that drug, you give it away. Is that true?

Mr. KENDRIS. Today, 55 percent is given away for free, post generic approval, since 2016.

Mr. GIBBS. And I know Mr. Bradway said the same thing about Repatha, 60 percent discounts. So, there are a lot of things going on there. The drug companies are doing their best to help people that need the drug to get the drugs. So, I am kind of assuming—does anybody go without these drugs that need it, that they are getting it even if they can't afford to pay for it?

Mr. KENDRIS. We are doing everything we can. When we receive a patient complaint, we investigate each and every one, and we have a variety of ways of trying to ensure that that patient will get access to the product that they need.

Mr. GIBBS. And then, you know, the other area I think I see where the structure is broken is when you talk about 46 percent of a cost is going to the intermediaries, PBMs, and that seems like a problem. And I think it was you who made the comment, or one of the witnesses talked about the generics, and you go to the drugstore, the patient, to make sure they get the right generic, and the intermediary is doing that with the health insurer and everything. I always thought that is where the pharmacist fits in. The pharmacist, what role do they have now? Are they getting kind of pushed out by the intermediaries, or how does that function?

Mr. KENDRIS. Well, certainly the pharmacist at the drugstore is not responsible for the fact that the discounts that the manufacturers are giving to middlemen and intermediaries are not being passed on to the patient. That is not the responsibility of the pharmacist.

Mr. GIBBS. No, I understand that. But the pharmacist, if they say you can get another drug, a generic alternative, you know, and you are negotiating with the intermediaries, the PBMs, where does the pharmacist fit into that discussion, that the patient does get to make sure that the patient does get the right drug if there is a generic equivalent?

Mr. KENDRIS. I think the negotiation that you are referring to does not include the pharmacist in that case. Negotiating with the intermediary, with the middlemen, a contract, and that is how we sell it to the middlemen.

Mr. GIBBS. I am out of time, but I just want to followup on that. Do you think we should be looking into the role of the intermediaries and how it affects the patient and the doctor and the pharmacist, making sure they get the right drug, the right generic drug, a generic alternative, and——

Chairwoman MALONEY. The gentleman's time has expired, but the witness may answer the question.

Mr. KENDRIS. I do, Congressman. I think that we should do everything we can to make sure that the discounts are passed along to the patient.

Mr. GIBBS. Thank you. Thank you, Madam Chair.

Chairwoman MALONEY. Mr. Sarbanes, you are now recognized.

Mr. SARBANES. Thank you, Madam Chair. Can you hear me OK?

Chairwoman MALONEY. Yes, we can.

Mr. SARBANES. I appreciate the hearing, as a continuation of yesterday, and I want to thank the witnesses for being here.

I have heard a lot of you say that, you know, things are off patent now, the pricing over the last two years has gone down, et cetera. That doesn't excuse the price gouging that happens when things are still under patent, you have the exclusivity, and so forth. And I just don't buy that these price declines were part of your business plan. I think it is a response to the scrutiny that you are under, so it is nice to talk about that and kind of dance around the essence of the price gouging that has been going on for years and years.

But I don't trust the industry to do the right thing when we are not looking at you with these klieg lights, and so we need to put more guardrails in place, and this hearing is about that. This is why Elijah Cummings started this inquiry originally, and we are

going to keep following through. And there is going to have to be major restricting of how the industry operates going forward. I know you are trying to duck and cover here, but you better anticipate that that is coming, because the American public is fit to be tied about the high prices of prescription drugs.

Mr. Bradway, I want to talk about Medicare Part D. That is 45 million seniors that are served by that program, and we are all contributing as taxpayers to the strength of the Medicare program. Your company has collected more than $7 billion in gross sales from selling Enbrel to Medicare Part D between 2013 and 2018. Is that correct?

Mr. BRADWAY. Those numbers sound right.

Mr. SARBANES. OK. And in the same timeframe you collected, or Amgen collected about $4 billion from selling Sensipar to Medicare Part D beneficiaries. So, it is an understatement that Amgen gets a lot of business from the Medicare program.

Does Amgen offer Medicare Part D comparable discounts to other—to the discounts that you give to other government purchasers?

Mr. BRADWAY. For example, the Medicaid prices that we offer are lower than Medicare, as you know, because it is statutorily designed to be lower than the Medicare Part D program. So, it is not the case that all of our government——

Mr. SARBANES. What about the veterans? What about Veterans Health Administration?

Mr. BRADWAY. The veterans' health program is also different from the Medicare Part D program. It includes both statutory price allowances as well as formulary restrictions, which are not part of Medicare Part D, as you are aware.

Mr. SARBANES. Well, I think Amgen's discounts to the Veterans Health Administration are about twice what Medicare is currently receiving. But let's face it, that is because the VA is allowed to negotiate drug prices with the industry and Medicare Part D doesn't get those same opportunities, because we don't have that ability to negotiate. We proposed a bill last December, House Democrats did. This is common-sense legislation that would allow Medicare to negotiate directly with drug manufacturers for lower prices, just like the VA and the Department of Defense are able to do.

I am not going to ask you for your position on whether we should be negotiating. I think I can guess what it is. But it seems to me that if your industry—again, to get back to the broader sort of macro picture here—your industry has figured out a way to do business with governments overseas that negotiate and are much more aggressive on behalf of their consumers and their taxpayers in dealing with the industry, and your industry has found a way to be able to manage a relationship and conduct your affairs even though you are giving a better pricing to the VA and DoD because you are having to negotiate there.

So, you will figure out a way, I am confident, to survive as an industry, to make reasonable profits, even if we move forward and put negotiation in place with respect to the Medicare program, which is all we are trying to do. And Mitch McConnell and the Senate Republicans have stood in the way of this. They have blocked the door to better opportunity for consumers and patients for years

now, but we are not giving up. We are going to keep the heat on, we are going to keep pushing, and we are going to do it because every day we have constituents coming up to us, scratching their head, looking at us in disbelief, and saying, "Why is it, in a free market economy, in the United States of America, you can't negotiate on behalf of 45 million Medicare beneficiaries for better drug prices?" We are going to keep pushing on that because it is the only thing that makes sense.

And with that I will yield back, Madam Chair.

Chairwoman MALONEY. Thank you. The gentleman's time has expired.

Mr. Higgins, you are now recognized.

Mr. HIGGINS. Thank you, Madam Chair, and I appreciate the continuation of this hearing from yesterday. This is incredibly important subject matter. And I am finding that the arguments from both sides of the aisle are quite similar.

Mr. Bradway, I am going to address my questions to you, sir. Respectfully, I understand businesses across the United States have costs associated with opening their doors to the public, and in order to stay in business you have be able to cover those costs. We know that high costs associated with developing new drugs and

[Inaudible.] Please clarify for us...

[Inaudible.] ...Recoup development costs, and what would be the result of...

[Inaudible.]

[Pause.]

Chairwoman MALONEY. We have a technical problem here right now. We are going to try to fix it.

[Pause.]

Mr. HIGGINS [continuing]. This time.

Chairwoman MALONEY. There. He is back. Mr. Higgins. We lost you for a while. OK.

Mr. HIGGINS. Yes, ma'am. I have no receiving signal at this time. If we are back on, I don't know if my question was received by Mr. Bradway.

Mr. BRADWAY. I am afraid I didn't hear the full question, so if you wouldn't mind repeating it then I will do my best to answer it for you.

Mr. HIGGINS. Yes. Basically, sir, let me just quantify quickly, in the interest of time. I have a couple of hard questions for you, so I am going to begin with a soft one. We recognize it costs a lot of money to develop a new drug. We get that. We understand the basic business principles are recouping initial investment cost. What is the importance of maintaining that formula, and what would happen to the development of new drugs if there were legislative action out of Congress that would restrict research and development of new pharmaceuticals and restrict companies investing in that research from recouping their initial costs? What would happen to the development of new pharmaceuticals?

Mr. BRADWAY. I don't think we would see innovative new drugs being developed for diseases like Alzheimer's or the many forms of cancers that remain not cured today, or autoimmune disorders.

Mr. HIGGINS. OK.

Mr. BRADWAY. And if I may, Congressman——

Mr. HIGGINS. I want you to know, we all get that. We understand. We understand that there are legitimate expenses for the development of new 21st century, high-tech, very effective pharmaceuticals. We understand that there are investments in many formulas that never make it to market, and that becomes part of the expense that needs to be recouped. We get that. On both sides of the aisle I am hearing the same argument.

But I must say that I concur with many of my colleagues across the aisle here. I do not understand, my constituents do not get it, why the same formula drugs, from the same manufacturer, across the border in Canada, can be two, three times less than it is here in the United States.

My wife has M.S. The pharmaceuticals are a constant challenge. She receives a therapy that is equivalent to like chemotherapy for M.S. every six months, and every six months we have the same battle with the insurance companies due to restrictions from the pharmaceutical companies.

My constituents don't understand. I don't understand. We expect to fix it, and we are going to fix it out of Congress. There is a bill in the Senate right now, Madam Chair, that if it would be introduced in the House, if it passed in the Senate, it would pass in the Senate, it would be introduced in the House, it could be law in a couple of weeks. We could really move forward to fix this thing.

But I would like the gentleman to answer, just one more time, why are pharmaceuticals so much less in Canada than they are in the United States? Because I don't get it, and my constituents don't get it either. I give you the floor, good sir. You have a minute and five seconds. Explain the variance of prices between Canada and the United States.

Mr. BRADWAY. I share your frustration and empathize with those who are struggling to understand the difference between the two systems.

As I said previously, in the United States 46 cents of every dollar are in the hands of intermediaries in the pharmaceutical supply chain, not in the hands of the innovative companies. In Canada that is not the case. Canada does not have 46 cents of every dollar——

Mr. HIGGINS. But does your company not get to spend the Canadian earnings?

Mr. BRADWAY. I am trying to——

Mr. HIGGINS. You don't get to keep that money?

Mr. BRADWAY. No, of course we do. I am just trying to——

Mr. HIGGINS. OK. So, let's stop talking about the difference of expenses in the United States versus Canada, because you have a worldwide market. Do you have a board of directors for the United States and then one for Canada, two different companies?

Mr. BRADWAY. No. Certainly not.

Mr. HIGGINS. Thank you. So, your profits are your profits. Your expenses are your expenses. Why do the drugs cost so much less in Canada than here?

Madam Chair, my time has expired but I would like the gentleman to answer the question.

Mr. BRADWAY. Again, I would point out——

Chairwoman MALONEY. The gentleman may answer the question.

Mr. BRADWAY. Thank you, Madam Chairwoman. I would point out that in the United States many innovative drugs are available which are not available in Canada. If you look at drugs approved in the United States over the last decade——

Chairwoman MALONEY. Excuse me. That was not the question. The question from the gentleman was why does it cost two or three times, or upwards, four or five or six times more in the United States, where we produce the drug, why does it cost so much less in Canada, and I would say in Europe too? As I said earlier, we pay more for drugs in America than the entire world, combined.

So, that is his question. What is the answer?

Mr. BRADWAY. Thank you, Madam Chairwoman. The answer is that countries like Canada are prepared to ration and restrict the access to innovative new medicines in exchange for offering lower prices to the ones that they choose to grant access to.

Chairwoman MALONEY. Well, I respectfully disagree. The answer to that question is to allow Medicare to negotiate directly for drug prices with the drug companies, as they do in Canada and in Europe, and they are not allowed to do it in the United States. And that is one of the things many of us would like to do, to lower the price for the people that we work for.

I would like now to go to Wasserman Schultz. Congresswoman Schultz, you are now recognized.

Ms. WASSERMAN SCHULTZ. Thank you, Madam Chair. I want to pick up where I left off yesterday and ask about another nefarious tactic that drug companies use to maintain market exclusivity and sky-high prices.

This committee's investigation shines a spotlight on the ways that drug companies use litigation as a key part of their strategic plans to delay generic entry. Like yesterday, I again want to focus on how prices were inflated for lifesaving medication used to treat cancer.

Mr. Kendris, yes or no. Novartis engaged in patent litigation with the first manufacturer to apply to make a generic version of Gleevec. Correct?

Mr. KENDRIS. Yes, we did.

Ms. WASSERMAN SCHULTZ. OK. Some pharmaceuticals challenge the legitimacy of Novartis' patents, but rather than litigate, Novartis struck a deal with Sun, known as "pay for delay." Under the settlement, Sun agreed to delay generic entry into the U.S. for six months. Novartis made $1.3 billion in U.S. net revenue from Gleevec sales during that six-month delay.

As the first generic manufacturer, Sun Pharma was entitled to 180 days of exclusivity, meaning no other generics could enter the market during that period. Although Sun Pharma initially announced it would price its generic 30 percent below the price of Gleevec, it ultimately entered the market just 6.4 percent lower than the cost of Gleevec. In an internal email, Novartis executives hailed this high price as, quote, "good news."

Mr. Kendris, do you think delaying generic entry was indeed good news for patients?

Mr. KENDRIS. Congresswoman, when we settled that case we actually accelerated the introduction of a generic Sun product into the U.S. If we had litigated and further litigated, that litigation

could have gone through the length of the patent, which would have been another three years. So, our settlement actually meant that the Sun product was on the market faster, actually two and a half years, I believe, faster than it would have been had we done what you are saying other companies do, and I understand that happens. But in our case, we did not get paid for delay and there was no litigation that went on for years to delay the generic onto the market. It was actually accelerated.

Ms. WASSERMAN SCHULTZ. You are right. There was no litigation because you paid for delay. Published estimates suggest that this pay-for-delay settlement with Sun Pharmaceuticals created $700 million in excess costs for consumers. This is unacceptable.

Sun Pharma originally said they would price their generic, were they allowed to move forward through the normal process without being challenged by Novartis to do so, that they were going to price their generic 30 percent below Gleevec's price. After you paid for delay and after you negotiated the so-called better deal sooner for consumers, they only priced it 6.4 percent below, and delayed their entry into the market by six months.

It is patients that are left holding the bag when companies like Novartis exploit the patent system to keep their market share. Research shows that 42 percent of cancer patients deplete their entire net worth in the first two years after their diagnosis. And I will tell you, I am a cancer survivor. I know what it is like to go through the 15 months of hell that I went through, and the countless stories I have heard from constituents who battle cancer every day.

In total, Novartis sued at least five companies in order to prevent generic competition for Gleevec, leading to a class action lawsuit that alleged that Novartis was engaging in sham litigation.

And now you know that protection of intellectual property rights is important for any company. But when you have proactive prices that become anti-competitive, used to delay generic entry and drive sales, both patients and the U.S. health care system suffer.

So, if companies don't behave responsibly, Congress must act to rein in this unconscionable behavior. No one should be unable to afford the medication they need to survive, and brand-name companies, every single day try to delay as long as possible competition in the market, which drives up costs for patients who need this vital access to drugs.

The annual cost of your drug went as high as $123,000 a year for cancer patients. That is insanity. It is robbery, and it kills people, as a result of them not being able to afford your drug. I don't know how you sleep at night.

Thank you. I yield back the balance of my time.

Chairwoman MALONEY. Thank you. Thank you for your statement.

Mr. KENDRIS. Chairwoman?

Chairwoman MALONEY. Mrs. Miller, you are now recognized.

Mrs. MILLER. Thank you, Chairwoman Maloney and Ranking Member Comer, and thank you to all the witnesses for being here today. I am pleased that we are able to continue with this conversation, because as we all know, the United States is the leading global innovator for groundbreaking medicine.

However, now more than ever, during the COVID–19 pandemic, it is extremely important that research and innovation is at the forefront of pharmaceutical development. While we look toward our future we need to ensure that the public and private innovators are utilized to address situations such as a pandemic and improve access to everyday lifesaving medications.

Mr. Kendris, how has the COVID–19 pandemic—there you are, good—how has the COVID–19 pandemic highlighted the need for innovation as we are all racing to develop better therapeutics and vaccines?

Mr. KENDRIS. In so many ways, Congresswoman. Thank you for the question. Many companies, including Novartis, are working on therapeutics. We have two of our products in clinical trials now to see if they will work for the cytokine storm that COVID–19 patients suffer. We do not have a vaccines business, but we are helping other companies who do. Our company, AveXis, formerly AveXis, has agreed to manufacture a vaccine for one particular vaccine maker, and we are also making available our Sandoz products that would be used to treat—our generics products, that would be used to treat COVID–19 patients. We are making them available at cost, no profit, or for free. We are making them available. We announced that a while ago, toward the beginning of COVID–19 pandemic.

So, we are doing all we can to find therapeutics. We have research candidates in the lab, I think about 20 research candidates in the lab, so not yet in clinical development, that are being investigated for possible use against COVID–19.

Mrs. MILLER. OK.

Mr. KENDRIS. We have also—yes, please.

Mrs. MILLER. OK. Well, I was just going to say, I also want to know, since Gleevec is classified as a specialty medication could you please discuss how this impacts the price and the market?

Mr. KENDRIS. Gleevec is a very specific medication. It is the first targeted drug, the first smart drug, as people call it, the very first one, in 2001. As a specialty medication, as I mentioned in some earlier questions, the cancers that it treats are actually rare diseases with small patient populations. CML may be the largest patient population but GIST, stomach cancer, that came second, and then five other rare cancers that came after that, very rare, small patient populations. But Gleevec, because it is a targeted cancer therapy, works very, very well, very efficaciously, for those cancers. So, it is a specialty product in that it targets these specific cancers and helps turn these cancers from fatal to chronic, or even, with our follow-on product, to a disease where treatment can be—or remission can be obtained treatment-free. The patient can stop taking Tasigna.

Mrs. MILLER. But that——

Mr. KENDRIS. They can't stop taking Gleevec.

Mrs. MILLER. OK.

Mr. KENDRIS. So, yes, please. I am sorry.

Mrs. MILLER. Well, I was going to, but you didn't answer how it impacted the price, being specialty.

Mr. KENDRIS. That is something——

Mrs. MILLER. I will move on, because I do have other questions.

Mr. KENDRIS. Thank you.

Mrs. MILLER. Many of my colleagues across the aisle continue to advocate for single-payer health care that would discourage and stifle innovation. If it were to become a reality, what would the innovation space then look like for a drug like H.P. Acthar Gel and multiple sclerosis?

Mr. Bradway, could you discuss the importance of preserving the Bayh-Dole?

Mr. BRADWAY. Well, I think you were asking a question about a Mallinckrodt drug, so I don't know whether you wanted to direct it to Mr. Trudeau or whether you had a more general question that you wanted me to address.

Mrs. MILLER. Well, more generally, because I do want to get into moving from this into how would the march-in rights affect innovation. So, that is just an example.

Chairwoman MALONEY. The gentlelady's time has expired. The gentleman——

Mr. BRADWAY. Sorry, Madam Chairwoman. I didn't hear your statement.

Chairwoman MALONEY. Her time has expired but you may answer her question.

Mr. BRADWAY. Thank you. Thank you, Congresswoman. I think the effect would be chilling on innovation. I think the size of the so-called march-in rights for intellectual property would have a very deleterious effect on those who commit resources to risky research and development.

Chairwoman MALONEY.—yields back. Mr. Khanna, you are now recognized for questions.

Mr. Khanna? Representative Khanna? Is he there?

Mr. KHANNA. Yes, I think I was muted.

Chairwoman MALONEY. OK.

Mr. KHANNA. Thank you, Madam Chair.

Chairwoman MALONEY. We hear you now.

Mr. KHANNA. Can you hear me?

Chairwoman MALONEY. Yes, we can.

Mr. KHANNA. Great. I want to focus my line of questioning concerning the Amgen Enbrel drug, and if you could first explain, sir, the Enbrel drug—and this is for Mr. Bradway—it is an anti-inflammatory drug? Am I understanding that it was introduced in 1998?

Mr. BRADWAY. That is correct.

Mr. KHANNA. And it is one of the best-selling drugs in the world. Is that correct? It is largely for arthritis?

Mr. BRADWAY. Yes. It is for a form of arthritis known as rheumatoid arthritis and other autoimmune disorders.

Mr. KHANNA. And the primary patent on this expired in 2010. Correct?

Mr. BRADWAY. No. When you say the primary patent what are you referring to? Are you referring to the patent on the molecule itself that is Enbrel?

Mr. KHANNA. Yes.

Mr. BRADWAY. No, the patent on the molecule that is Enbrel has not expired. It was granted in——

Mr. KHANNA. What expired in 2010?

Mr. BRADWAY. A different patent but not a patent on the molecule.

Mr. KHANNA. What was that patent on?

Mr. BRADWAY. That was a use patent.

Mr. KHANNA. So, that expired. Correct?

Mr. BRADWAY. Correct.

Mr. KHANNA. How many patent applications have you filed since then to try to extend the monopoly on Enbrel?

Mr. BRADWAY. I don't know how many patent applications we have filed but I would guess several——

Mr. KHANNA. You don't know how many patent applications you have filed on one of your most important drugs?

Mr. BRADWAY. I wouldn't know that off the top of my head.

Mr. KHANNA. A thousand?

Mr. BRADWAY. No. I would guess it's——

Mr. KHANNA. Is it five?

Mr. BRADWAY. Excuse me, Congressman. I would guess that it is several dozen patents.

Mr. KHANNA. Sixty-eight patents. Doesn't that strike you—I mean if you were just talking to your neighbor or some person you were growing up with, you know, go back to when you were in high school, and they say, OK, you come up with a new drug. Let's say, OK, you file a patent. Do you think any person would say, yes, we should file 68 patents on a certain drug and extend that patent protection until 2037? I mean, just step back from your role as CEO. Do you think most Americans would think that makes common sense?

Mr. BRADWAY. Congressman, I think what is appropriate is the question of whether we are investing in innovation that deserves to be protected by patents, and fortunately——

Mr. KHANNA. No, I get all that. I get the debate, innovation. I understand we need patents. But just from a common-sense perspective, there is a drug, people take that drug. If you were talking to an ordinary person and you said, "We are going to file 68 different patents on this drug to protect our rights on it until 2037," do you think they would think that that was logical?

Mr. BRADWAY. Well again, Congressman, I think it would require a discussion about what those patents are being issued for, what innovation we are claiming in the patents, and we are fortunate to have the patent rights in this country protected by——

Mr. KHANNA. How much does the drug cost in Europe compared to in the United States?

Mr. BRADWAY. I don't have the answer to that question, Congressman.

Mr. KHANNA. You don't know how much the drug is priced in Europe? Would it surprise you if you know that the drug was 50 percent cheaper for Europeans than Americans?

Mr. BRADWAY. No, it wouldn't surprise me, but I remind you, Congressman, that we don't and have never sold or marketed the drug in Europe.

Mr. KHANNA. But you are selling the drug in Europe where you face actually competition. Isn't that correct?

Mr. BRADWAY. No, sorry, Congressman. We don't sell the drug in Europe. We don't own the product in Europe.

Mr. KHANNA. But my understanding is in Europe the price is 50 percent—it has similar bio, similar competition, and that has caused the price to drop by nearly 50 percent since 2018. Is that not accurate?

Mr. BRADWAY. Congressman, I wouldn't know the answer to that. We don't own the rights to Enbrel in Europe, so you would need——

Mr. KHANNA. No, I understand you don't, but Enbrel is being sold in Europe for 50 percent less, and you have competition there. Correct?

Mr. BRADWAY. Again, Congressman, I don't have the facts about Enbrel pricing in Europe. We have——

Mr. KHANNA. Can you make a commitment to the American people today that no American should pay more than people in Europe are paying for Enbrel? I mean, it is a simple thing. Are you an American, sir?

Mr. BRADWAY. Yes, I am. Proudly.

Mr. KHANNA. OK. So, can you tell your fellow citizens that no American should pay more for Enbrel than someone in Europe?

Mr. BRADWAY. Well, Congressman, the patent in Europe has expired, so the European situation is different from what we have in the United States.

Mr. KHANNA. So, the European patent has expired, so you think the Europeans don't want innovation for their drugs? I mean, so the Europeans don't think they need innovation, yet you think you need patents until 2037. I am asking you a very simple question. Make a commitment today, to the American people, that no one will pay a dime more for Enbrel than people pay in Europe. If you love this country, if you love America, you should be willing to tell Americans that they shouldn't be paying more than the French and the Germans and Europeans. Are you willing to make that commitment today, to the American people?

Mr. BRADWAY. Congressman, I would just repeat that in Europe the intellectual property for that product has expired.

Mr. KHANNA. I am just asking you a simple question. You can say no. If it were me and someone said will you make a commitment——

Chairwoman MALONEY. The gentleman's time has expired——

Mr. KHANNA [continuing]. Paying more than Europeans, I would say absolutely. Are you willing to make that commitment?

Mr. BRADWAY. We don't sell Enbrel in Europe, Congressman.

Chairwoman MALONEY. I take that as a no.

Moving along, Mr. Steube, you are now recognized for questions.

Mr. STEUBE. Thank you, Madam Chair.

Over 3.5 million Floridians are enrolled in some form of Medicare prescription drug coverage. With so many of my fellow Floridians and constituents dependent on lifesaving prescriptions, I understand the need for affordable drug prices.

Despite the efforts of Republicans to make bipartisan progress to reform the prescription drug standards, our Democratic colleagues refuse to collaborate. They will try to suggest that H.R. 3, which is a key example of partisan government overreach, would solve some of the problems that we are discussing today. This is not the case, and the Trump administration decisively acted to approve a

record number of generic drugs and bring down overall prescription prices down 13 percent. Obviously, there is still a lot of work left to do and I am glad we are taking steps to discuss this situation and hope we can move toward establishing solutions.

Mr. Bradway, my first question is to you. What is Amgen currently doing to assist in this mutual goal of providing Americans with lower drug prices?

Mr. BRADWAY. Congressman, thank you for the question. As I mentioned in my opening statement, our net prices in the United States have decreased in 2018 and 2019, and we are on track to have further decreases in 2020.

In addition, Congressman, we have made a significant investment in biosimilars and we are making available to patients and prescribers biosimilar medicines for some of the biggest-selling drugs in the United States, at more affordable prices than the innovator products that they are designed to replicate.

In addition, Congressman, we are working with a variety of different patient assistance programs through which we give away free drugs to those who are uninsured and can't afford their drugs or underinsured. We try to provide copay assistance for those who are struggling, who have insurance plans but are struggling with making payments for their deductibles and seeking to make contributions to other charitable foundations that can assist patients with their medicines as well.

So, across the board, sir, we are trying to do quite a lot to help make sure that patients who need medicines can afford them.

Mr. STEUBE. I was interested that in your testimony you stated that Amgen voluntarily lowered the list price of one of your medicines by 60 percent. However, you described a situation where even after lowering the list price some patients did not see a meaningful difference in what they had to pay out of pocket at the pharmacy. Some of my colleagues believe that forcing you to lower your prices will solve all of our problems, but it doesn't seem like that happened in that instance. Can you explain why?

Mr. BRADWAY. Thank you, Congressman. Yes. You are referring to a drug called Repatha, which is our product designed to lower cholesterol and prevent heart attacks and strokes. It is one of our most important innovative new medicines. We lowered the list price for that medicine by 60 percent in order to try to make it more affordable at the pharmacy counter. Remember, that patients pay a copay as a function of list price, so by lowering the list price we were lowering their out-of-pocket expenses.

However, we found that it took more than a year for the insurance plans to move patients, to direct patients from the high list price product to the low list price product. So, we ran the experiment and found that it didn't work in the way that we thought it would. We see this as an example of how the system is not working today for patients, and that is one of the reasons why we think we need to reform the rebate system that exists in the United States today.

Mr. STEUBE. Thank you. I understand there are certain payment programs in place which can help patients afford drugs like Enbrel and Sensipar. Would you be able to discuss their effectiveness in any other similar initiatives that you are discussing?

Mr. BRADWAY. Thank you. Yes, we have a number of programs designed to help patients pay for expensive medicines. So, for example, in the case of Enbrel we have copay assistance in place so that more than three-quarters of the patients who use Enbrel today have a copay of less than $50 a month for their medicine.

When it comes to Medicaid, 93 percent of patients are able to receive their medicine at less than $10 a month in copay. And when it comes to Medicare, we have 77 percent of the patients being able to receive their medicine at less than $50 a month.

So, there are examples across our portfolio of the ways that patients are benefiting from the support provided to them in order to be able to access these innovative, life-changing medicines.

Mr. STEUBE. Does Amgen utilize rebates for PBMs and how does that impact patient price?

Mr. BRADWAY. Yes, we do use rebates. Again, rebates are a function of list price, so if we increase the list price we increase the rebate. You might ask why are we increasing the rebates? Why do we feel pressured to increase the rebate, and the answer is to secure competitive formulary position for our molecules. So, we increase the list price to be able to increase the rebate to the intermediaries. The unfortunate effect of that is it also increases the out-of-pocket cost for patients at the pharmacy counter. And again, that is why we advocate for changes that would include passing through the rebate at the pharmacy counter.

Mr. STEUBE. Thank you. My time has expired. Thank you for being here.

Mr. BRADWAY. Thank you.

Chairwoman MALONEY. Thank you.

Congresswoman Speier, you are now recognized for questions.

Ms. SPEIER. Thank you, Madam Chair, and thank you all for participating today. I appreciate it. I think all of us appreciate it. Many others declined the invitation.

I want to start with Mr. Kendris and Gleevec. Gleevec is a miracle drug. My former chief of staff's wife died of CML. Had she lived another couple of years Gleevec would have been discovered as this miracle drug and her condition would have been chronic and she would be alive today. So, we truly appreciate the miracle that Gleevec has become for leukemia patients.

I would like to educate the public on what LOE is. It is called loss of exclusivity. And I would like for the staff, if they would, to put a slide that the committee got that was part of a presentation that was, I guess, provided to some of the staff of the company, and shows a dramatic increase in the price of Gleevec toward the end of its exclusivity.

[Slide.]

Ms. SPEIER. In fact, between 2013 and 2015, Novartis' price increase accelerated. It raised the price of Gleevec five times in two years. It turned out to be a 20 percent increase in that drug.

Now company executives knew that Gleevec sales would decrease once it lost its exclusivity so they tried to get as much profit out of the drug for as long as they could. This plan was explicitly stated in internal documents by Novartis executives who wanted to, quote, "maximize value of brand prior to loss of exclusivity." Is that not the case, Mr. Kendris?

Mr. KENDRIS. Congresswoman, can you identify the document that you have in front of you? I don't have it in front of me right now.

Ms. SPEIER. Well, the staff would be able to provide you that, but they are evidently documents you provided to the committee.

Mr. KENDRIS. Yes.

Ms. SPEIER. So, it is a fact. In the last two years of exclusivity you raised the price almost 20 percent. There is a chart we can put up that shows your net revenues going from $1.9 billion to $2.53 billion, and I don't know if the committee staff can put that on.

Mr. KENDRIS. Congresswoman—I am sorry. Please.

Ms. SPEIER. So, I mean, the question is, did you not increase the price of Gleevec some 20 percent in the last two years because you saw that there was going to be loss of exclusivity?

Mr. KENDRIS. Congresswoman, I don't know specifically why the increases in that period were taken. I was not there in the oncology——

Ms. SPEIER. All right. We will move on.

Mr. KENDRIS. But I can tell you that, as I was saying earlier, it is indisputable that Gleevec, that its value increased over the time it was on the market, and it was always the lowest product in its class, the lowest-priced product in his class.

Ms. SPEIER. OK. Mr. Kendris, I am reclaiming my time——

Mr. KENDRIS. Yes, please.

Ms. SPEIER [continuing]. Because I want to go to another line of questioning. I just want to point out that Medicare—this is the Federal Government—paid $5.6 billion to your company between 2011 and 2018, and that one-third of all the money you made in the United States came from the taxpayers through Medicare. And Medicare right now is two years from basically falling off a cliff.

I want to go to each of you now and ask you this question. How much money do you spend on marketing? Mr. Kendris?

Mr. KENDRIS. Our marketing spend, Congresswoman, is approximately 400 million U.S. dollars in direct-to-consumer advertising.

Ms. SPEIER. OK. $400 million. How much do you spend in Europe?

Mr. KENDRIS. I am not sure I know the answer to that off the top right now but I can get you that.

Ms. SPEIER. All right. Thank you. If you would get that to the committee.

Mr. KENDRIS. Thank you. I will.

Ms. SPEIER. Mr. Bradway, how much do you spend in direct-to-consumer marketing?

Mr. BRADWAY. Direct-to-consumer TV advertisement in the U.S., less than $200 million.

Ms. SPEIER. $200 million. How much do you spend in Europe?

Mr. BRADWAY. A fraction of that. Not on TV but in other forms of——

Ms. SPEIER. In fact, there is no TV allowed in Europe. Is that correct?

Mr. BRADWAY. I believe that is correct. Maybe

[Inaudible.]

Ms. SPEIER. And then, Mr. Mallinckrodt, how much do you spend?

Mr. TRUDEAU. We don't spend any money on direct-to-consumer advertising, Congresswoman.

Ms. SPEIER. All right. Mr. Trudeau?

Mr. TRUDEAU. Yes, that was me, Mr. Trudeau. We don't spend any money on direct-to-consumer advertising.

Ms. SPEIER. All right. My final question is this. Do you all commit—and I just need a yes-or-no answer—do each of you commit to not increase the cost of your drug, moving forward, beyond the inflation each year?

Mr. Bradway?

Mr. BRADWAY. I would point out that we have decreased our prices——

Ms. SPEIER. So, yes or no, sir.

Mr. BRADWAY [continuing]. We have decreased our prices over the last three years and increase of list prices have been below inflation. So, you know——

Ms. SPEIER. Your answer is yes, you would commit to doing that.

Mr. BRADWAY. My answer is that is how we have been operating the business the last couple of years.

Ms. SPEIER. OK. Mr. Trudeau?

Mr. TRUDEAU. As I said earlier, we are committing to reducing the net price of Acthar to 2015 levels by the end of 2020, which is the first year—2015 was the first year, actually full year, we acquired Acthar.

Ms. SPEIER. And Mr. Kendris?

Mr. KENDRIS. As to net prices, Congresswoman, yes.

Ms. SPEIER. All right. Thank you. I yield back.

Chairwoman MALONEY. Mr. Keller, you are now recognized. Mr. Keller.

Mr. KELLER. Thank you, Madam Chair. We all need to ensure patients access to affordable drugs, particularly those in rural areas that rely on essential safety net programs. Contract pharmacies are essential to the rural areas of Pennsylvania that I have the privilege to represent. About 80 percent of rural hospitals are 340B. They use pharmacies to provide access to outpatient drugs for those who need them, many of whom are seniors and/or have chronic conditions.

Mr. Kendris, thank you for being here. I wanted to ask you about your new, quote, "integrity initiative to address duplicate discounts requiring covered entities to register and upload 340B claims data originating from contract pharmacies onto a new web-based platform."

Your announcement from August expresses support for a sustainable 340B program. I do have concerns about this threatening hospitals in Pennsylvania, and their ability to offer home infusion services, telemedicine, and expand their outpatient facilities, stretching scarce resources to patients in need.

So, Mr. Kendris, what kind of collaboration have you had with 340B hospitals about his integrity initiative?

Mr. KENDRIS. Thank you, Congressman Keller, for the question. I appreciate it.

So, Congressman Keller, we support the intent and the design of the 340B program to help lower outpatient drug prices for the uninsured and the net profit safety net providers that you were just

describing to your constituencies. They serve underserved populations in those communities and the 340B program helps them. We support the 340B program.

However, we also believe that over many years there have been some abuses that have grown into the system, and we are trying to resolve those abuses. We have raised the problem over the years—many companies have—with HRSA, and we are committed to ensure that our medicines are accessible to as many patients as possible, and through 340B as well. But we believe that the current state of the program is somewhat distorted from its original intent——

Mr. KELLER. I understand that. If I could just jump in.

Mr. KENDRIS. Thank you.

Mr. KELLER. I have a letter dated August 17, explaining your integrity initiative. My question was, prior to the letter have you talked to hospitals about this program and how it might be implemented?

Mr. KENDRIS. I believe that our staff is in contact with hospitals. We are collecting responses to that letter, and we are going to continue to work with them.

Mr. KELLER. So, if I can just jump in, I have got a limited amount of time. So, if you are in consultation with the hospitals, when were you planning on making this in effect and stopping some of the discounts to the 340B hospitals? It is my understanding that were to begin at the beginning of this month.

Mr. KENDRIS. We had asked for the data by October 1st. We are still evaluating the responses. We have not heard from all the hospitals, and we are evaluating the data that we have received, and we are going to continue to evaluate that data. And as we move forward, it is going to be based on what we see in the data we receive.

Mr. KELLER. So, if a hospital hasn't registered that data by October 1st, are they still going to be able to participate in the discounts?

Mr. KENDRIS. Yes. We still intend to honor valid, legitimate 340B discounts, and what we will do is we will see the responses, we will look at the data, and then we will talk to the hospitals and move on from there.

Mr. KELLER. OK. And a question on the web-based portal. Is this a secure platform or should we be concerned about data security?

Mr. KENDRIS. I believe it is a secure platform. I can check with our team on that, but I believe it is.

Mr. KELLER. OK. Do you expect there to be any administrative burden on hospitals, or what would that be?

Mr. KENDRIS. No. Actually, we believe that it is easy to pull this data. It is not burdensome. It is actually the same claims data that they have been sharing with the intermediaries that we talked about earlier in the hearing. So, the data should be available—I think it takes about five minutes every two weeks to pull this data.

Mr. KELLER. So, you know that the intermediaries have this data already. So, have you asked them for the data, rather than make the hospitals do it if it is already available? Have you looked at another way to get it?

Mr. KENDRIS. I think that relationship is between the hospitals and the intermediary, and I think we have to ask the hospitals for it. I can check into that, Congressman, but I believe that is what we have.

Mr. KELLER. OK. I just would like to end by saying that 340B discounts are crucial for my constituents, and we should be thoughtful about how any changes to the program would affect this going forward. We need to ensure that the changes to the program are manageable and in the best interest of health providers and the patients they serve.

Thank you, and I yield back.

Mr. KENDRIS. We agree, Congressman. Thank you.

Chairwoman MALONEY. Thank you.

Mr. Connolly, you are now recognized.

Mr. CONNOLLY. Thank you, Madam Chairwoman.

Mr. Trudeau, when you acquired Questcor, one of the very lucrative drugs in their command was Acthar. Is that correct?

Mr. TRUDEAU. That was virtually the only product that they had.

Mr. CONNOLLY. And it is my understanding that when Acthar first came on the market a vial, one vial, cost $40. By the time you acquired Questcor that price had gone up to almost $31,000. Is that correct?

Mr. TRUDEAU. That is correct.

Mr. CONNOLLY. Forty dollars to $31,000 for the same vial. And my understanding is the only difference wasn't the composition of the drug. It was the status, the legal status of the drug, that Questcor was able to get Acthar granted orphan drug status before you purchased it. Is that correct?

Mr. TRUDEAU. That is not necessarily the only thing but certainly that was something that did occur, that Acthar was granted orphan drug status.

Mr. CONNOLLY. Well, should we not correlate the two events, with respect to the value put on a vial of the drug? I mean, how do we explain going from $40 to $31,000 for the same vial, with the same efficacy and impact on a patient, other than it got reclassified as an orphan drug, which gave it a seven-year market monopoly for that designated use. Isn't that correct?

Mr. TRUDEAU. It did get an orphan drug designation. That is correct. In addition, the label was actually updated in 2010 to reflect the current set of 19 indications.

Mr. CONNOLLY. Right. So, the skyrocketing inflation in this particular drug had nothing to do with PBMs, for example. It had to do with the positioning of the drug as an orphan drug and the protection that provided, which allowed it to have highly enhanced value, which made it an attractive acquisition for your company. Is that not correct?

Mr. TRUDEAU. Based on FCC filings that Questcor filed at the time, the company was actually in an existential situation. They had a very essential drug for infantile spasms, and they were potentially looking at going out of business and not being able to provide that drug anymore to the marketplace.

Mr. CONNOLLY. So, you kind of came in and saved the day.

Mr. TRUDEAU. When we acquired Questcor and we acquired Acthar we did three things: one, we invested in clinical trials and

manufacturing; two, we started engaging with our customers to provide discounts and rebates; and three, we provided extensive patient assistance programs to minimize patient out-of-pocket expense and ensure that patients that could benefit from Acthar had good access to the drug.

Mr. CONNOLLY. And when you provide this drug through Medicare, for example, what is the discount?

Mr. TRUDEAU. We provide all allowable discounts under statute, and as I discussed earlier, Acthar is not on any Medicare formularies, and certainly if there were an opportunity for Acthar to get a formulary position in Medicare there might be the opportunity to provide additional discount, similar to what we do in the commercial sector.

Mr. CONNOLLY. Would the discount in this case, with respect to, say, Medicare, be about one percent?

Mr. TRUDEAU. I believe most recent data is on the order of one to two percent. That is correct.

Mr. CONNOLLY. Yes. So, a $31,000 drug that once cost $40, you are giving rebates to Medicare of less than one percent between 2015 and 2018.

Is it also true that your company is looking to use this drug for other treatments, other than the original infant seizure treatment it was developed for?

Mr. TRUDEAU. The company has been developing evidence to support the 19 FDA-approved indications that are currently on the label.

Mr. CONNOLLY. And if you do that, do you do that under the auspices of your protective status as an orphan drug or do you have to redefine that, because it is no longer being used exclusively for that original purpose?

Mr. TRUDEAU. The orphan drug exclusivity actually expired a number of years ago. Acthar is not affected. It does not have any exclusivity under any of the traditional patents or other exclusivities such as orphan drug. It is a drug that is designed primarily for underserved patients that have very few alternatives, a relatively very small population that is very sick.

Mr. CONNOLLY. I appreciate that, although I would add when you charge $31,000, or now $33,000 a vial, in today's price, I think that is not much of an alternative for a lot of patients either.

I yield back, Madam Chairwoman.

Chairwoman MALONEY. Thank you.

Ms. Foxx, you are now recognized for questions.

Ms. FOXX. Thank you very much, Madam Chairman. I want to thank our witnesses for being here today, for being where you are today.

My first question is for Mr. Kendris. Mr. Kendris, it has been said that Gleevec is a magic bullet for people fighting chronic myeloid leukemia. Can you discuss why this drug was such a game-changer?

Mr. KENDRIS. Thank you, Congresswoman, for the question. Yes, it was a game-changer. It was the first targeted therapy. So, you may have heard the term "smart drug." It was the first smart drug. It turned off a particular gene and it was able to be extremely efficacious, first in chronic myeloid leukemia and then in gastro-

intestinal stomal tumors, and then in five rare cancers, and that is because it was a smart drug. It worked very specifically on these very specific cancers, and by its mechanism of action the efficacy was so high that, as I said earlier, diseases, these six cancers, or seven cancers, were turned from fatal conditions for a patient who had died before Gleevec, into conditions where they lived and they were able to lead normal lives. And now we have developed a follow-in product, Tasigna, which allows patients to go treatment-free. If they get remission for a long enough time they no longer have to take any drug.

Ms. FOXX. OK. So, what is the current list price of Gleevec?

Mr. KENDRIS. The current list price of Gleevec is $120,000, and the net price is $85,000.

Ms. FOXX. OK.

Mr. KENDRIS. The price of a generic is $4,200.

Ms. FOXX. OK. So, how much does the average patient pay for it?

Mr. KENDRIS. Well, the average out-of-pocket cost for a Part D patient, Congresswoman, is $856 a year.

Ms. FOXX. OK. So, how does the patient get such a discount price?

Mr. KENDRIS. I think it depends on who the patient is and what their insurance coverage is.

Ms. FOXX. OK.

Mr. KENDRIS. The price I just gave you was for a Medicare Part D patient, for out-of-pocket cost, $856 average annual out-of-pocket cost.

Ms. FOXX. OK. So, a drug considered a magic bullet, and basically it is not quite a cure but it puts people in remission, has gone down from $120,000 to $856 for Part D. Thank you very much for that.

So, I would like to ask Mr. Trudeau, how does your company decide the right price to set for a new drug that may truly save someone's life?

Mr. TRUDEAU. Thank you, Congresswoman. What we try to do is we try to match the value that we believe that our products are going to bring to patients and kind of compare those two. And the value is in two ways. One is the benefit that it provides to patients themselves and their families, and again, we are typically developing drugs for some very devastating diseases where there are relatively few alternatives. And then we are also looking and creating data, actually, to see what value it may bring to the overall health care system.

So, for example, using the drug might increase the drug cost but it might have the impact of reducing overall health care costs for a particular disease.

Ms. FOXX. So, Mr. Bradway, the Congressional Budget Office estimates that Democrats' H.R. 3 would result in 38 fewer cures being developed over the next decade. What would be the impact on patients and innovation if there were 38 fewer cures created over the next decade?

Mr. BRADWAY. Well, I think that is potentially devastating. So, not only devastating to the patients and their families but I think also to the economy. I think our economy benefits from innovation

that enables us to treat serious illnesses. We are seeing the benefit of that every day now. So, anything that diminishes that opportunity I think would be tragic.

Ms. FOXX. OK. Very quick question for all three of you. On average, how often does your company, or even the whole pharmaceutical industry, bring to market a novel or game-changing treatment or cure? Each one of you answer fairly quickly, please.

Chairwoman MALONEY. The gentlelady's time has expired. The gentlemen may answer her question.

Ms. FOXX. Please answer. Mr. Bradway?

Mr. BRADWAY. Thank you for the question. We have 22 different novel, game-changing medicines that have been approved throughout our history. We have three, for example, this year. We are waiting for registration-worthy data. So, from one year to the next is different but 22 through our history, three more that we are waiting for this year.

Mr. KENDRIS. Congresswoman, it is Tom Kendris. For Novartis, I believe it could be more, but I believe last year we had at least four. This year I believe we have already had two, and we may have more to come this year. So, it is three to five almost every year, as an average, I would say.

Ms. FOXX. Mr. Trudeau?

Mr. TRUDEAU. Congresswoman, I think from an industry perspective we are trying to get as many novel, lifesaving medicines to the market as we can. For our company specifically, we are hoping to have two or three in the next two to three years.

Ms. FOXX. Thank you. I am sorry for going over, Madam Chairman.

Chairwoman MALONEY. Mrs. Plaskett, you are now recognized for questions.

Ms. PLASKETT. Thank you so much, Madam Chair, and thank you to the witnesses for being with us this day to answer these questions and to provide more information about drug pricing.

Mr. Bradway, when we talk about high drug prices, many times we talk about the list price. And large discounts are provided off the list price and then, as part of the insurance design patients are charged a percentage as a co-insurance. But my understanding is that this is always a percentage of the list price and not the discounted price. Is that correct? Do I have that correct?

Mr. BRADWAY. Yes, you have that generally correct.

Ms. PLASKETT. OK. I know my answer is probably simplistic. So, what are some of the ways in which to bring down what a patient pays? Your thoughts on that.

Mr. BRADWAY. Well, we have advocated for changes to the system that would include, for example, passing the rebates that have been negotiated between the intermediaries and the innovatives comes through to the patients at the pharmacy counter. That would have the immediate effect of reducing the out-of-pocket costs for the patient in the picking up the innovative medicine.

Second, we have advocated for placing an out-of-pocket cap on patients so that after they have paid a certain amount for their medicines during the course of the year they reach a cap and no longer have to have a copay.

So, those are two examples of things that we are advocating for. And as you may be aware, we have also taken the unusual step of even lowering list prices for our medicines by 60 percent in the case of our game-changing medicine known as Repatha, which lower the risk of heart attack and stroke.

Ms. PLASKETT. Great. Thank you. But in some instances the list price, they may go up, and there are reasons for that. But my understanding, as well, and I hope this is not too simplistic, but has the net price, what is actually made off the drug, gone down in recent years for any of the products that you make?

Mr. BRADWAY. Yes, Congresswoman. In 2018 and 2019, and again we expect in 2020, that the net prices for our portfolio in the United States will have decreased. So, across our portfolio net prices have fallen.

Ms. PLASKETT. And then can you explain to us how the net prices go down but yet the list price may go up, in many instances?

Mr. BRADWAY. Yes, Congresswoman. That occurs when the rebates that we are giving to the intermediaries exceed the increases in list price.

Ms. PLASKETT. Mm-hmm. OK. And can you explain how can biosimilars play a role in reducing health care costs and costs for patients?

Mr. BRADWAY. Yes, Congresswoman. Again, Amgen is a heavy investor in biosimilars. We have committed more than $2 billion to develop a portfolio of biosimilars. We make three of those available today in the U.S., with a plan to add more, to patients and prescribers. We provide them at a price that is a discount to what the innovative products are charging, and commit to having a reliable, safe supply of that lower-cost alternative available to patients.

Ms. PLASKETT. Thank you. Thanks so much for that.

I want to ask any of the witnesses, how have your companies, if you are, in fact, involved in the fight against COVID–19, what are the steps any of your companies are taking to improve diversity in clinical trials?

Mr. KENDRIS. Congresswoman, it is Tom Kendris from Novartis.

Ms. PLASKETT. Thank you.

Mr. KENDRIS. Thank you for the question. So, before COVID–19 hit our global drug development group was focused on this issue for our own clinical trials. It is a crucial step that must be taken, because I think the basis of your question, I am sure you realize, if a product is studied in a limited patient population, after it is approved doctors are comfortable prescribing it only in that limited patient population. So, if it is not studied in a minority population, whatever minority population that is, doctors will be more hesitant to prescribe it there because they don't have data.

So, we recognized before COVID broke that we needed to change that in our own clinical trials. Since the COVID–19 pandemic began, what we have done through our Novartis U.S. Foundation is to begin the process of convening other companies, and some groups like the NAACP and other groups focused on racial equity, to have a conversation about this very issue across the industry, so that we can improve diversity in clinical trials, in all clinical trials of all types, and to address the underlying problems, which have to do with many things, but trust for patients who are in clin-

ical trials would be one of those things. And that is going to take a broader conversation that we are going to try and convene.

Ms. PLASKETT. Yes. Thank you.

Chairwoman MALONEY. The gentlelady's time has expired.

Ms. PLASKETT. Thank you, Madam Chair. I would love to be part of that conversation, and I know the congressional Black Caucus is very concerned about this, and we would love to offer any thoughts and discussions on this.

And thank you, Madam Chair, for holding this hearing. I wanted to, at some point, ask these gentlemen, in another form, about how do we move manufacturing back to U.S. flags and what we can do to support bringing that infrastructure and those jobs back to our country.

But thank you for the hearing.

Chairwoman MALONEY. Mr. Grothman, you are now recognized for questions.

Mr. GROTHMAN. First I have a question for Mr. Kendris, and this is kind of a followup on a previous question. I also am concerned about the 340B program. Right now there are companies out there like Eli Lilly—I am aware they are not here today. They have refused to continue to offer the 340B prescription drug discounts to contract pharmacies that our kind of safety net hospitals, critical access hospitals, and community health centers rely upon.

To my knowledge, Novartis, at this point, has not refused to provide new discounts. However, you have been requesting claims data in order to prevent potential duplicative discounts.

Are you willing to give us assurances today that Novartis will be a good steward of the 340B program moving forward and will not do what Eli Lilly has done?

Mr. KENDRIS. Our intent, Congressman, is to be a good steward of the program. As you said, we have asked for data from the hospitals that will help us to avoid paying multiple duplicate discounts. So, we support the program, and allowing hospitals to use our discounts to provide the patient care that was originally intended by 340B. But what we don't support is allowing intermediaries, middlemen, to profit from the program.

Mr. GROTHMAN. OK. The next question, I guess, is really for any one of you. I guess maybe I should pick somebody else. Maybe we will pick Mr. Trudeau.

Specialty biologics are some of the major drivers of prescription drug costs because they often treat very particular diseases with limited patient populations. Evidence has shown that introduction of biosimilars in the market reduces that cost for patients. Since all your companies do have biologics on the market, how has the introduction of biosimilars impacted the price of your medications, and have any of you tried to prevent biosimilars from coming to market in an effort to stifle competition? And a followup question, how can Congress incentivize companies to break more biosimilars to market?

Mr. TRUDEAU. Congressman, thank you for the question. We are focused on what is in the best interest of patients, meaning that patients have access to the best possible medications they have for their condition at the lowest possible cost. We also support competition. Biosimilars, in some markets, have been shown to enhance

competition. Our company does not produce biosimilars, so that might be a question better directed to one of the other individuals.

Mr. GROTHMAN. OK.

Mr. BRADWAY. Congressman, this is Bob Bradway from Amgen. We are active in the biosimilar market. We have invested a couple billion dollars to develop our capabilities here in the U.S. We think this will provide an appropriate alternative choice for patients and providers.

So, far we have launched three medicines, the first two in the cancer field, where we have had very strong receptivity to our product offerings. So, we are providing those at a discount to the originator products and see a significant market already, after a short time being on the market. So, we think that the industry as created by the legislation known as BPCIA is working effectively, and the U.S. is nearly——

Mr. GROTHMAN. OK.

Mr. BRADWAY [continuing]. Biosimilars, and expect us, again, to be an important opportunity for patients and providers.

Mr. GROTHMAN. Let me just give you a quick yes-or-no question on this. President Trump's FDA released a biosimilar action plan which streamlined the process to approve biosimilars. We believe this is resulting in significantly more approvals of biosimilars than under the Obama Administration, which was not as aggressive in this area.

Would you agree the President's plan is saving patients money?

[No response.]

Mr. GROTHMAN. OK. I will give you a different question. Do you agree, you know, in trying to get more biosimilars to market under the President's plan, is that saving patients money?

Mr. KENDRIS. Congressman, it is Tom Kendris from Novartis. I am not sure that I am familiar with the President's plan, but we have Sandoz, as I mentioned earlier, a generics company and a biosimilars company. We brought the first biosimilar to market, Zarxio, in 2015. So, we certainly support biosimilars, and Zarxio itself——

Mr. GROTHMAN. Let me give you a quick followup question because I am on my final minute here.

Mr. KENDRIS. Sorry.

Mr. GROTHMAN. I am going to be introducing a bill, or have introduced, H.R. 8190, a Biosimilar Insulin Access Act, which will expand on what President Trump has done. Will you guys pledge not to get in the way of any expansion of biosimilars? Is that something you are going to fight, or do you—will you agree that we should be getting more biosimilars to market?

Mr. KENDRIS. Congressman, it is Tom Kendris. I think generally speaking we support more biosimilars coming to the market. Sandoz has biosimilars in its pipeline and is actively trying to get them onto the U.S. market, and that will help patients and reduce health care costs in the U.S.

Mr. GROTHMAN. Thank you.

Chairwoman MALONEY. The gentleman's time has expired. Representative Raskin, you are now recognized.

Mr. RASKIN. Thank you, Madam Chair.

Mr. Kendris, our investigation found that drug companies use anticompetitive tactics to prevent generic competition in order to prop up profits. Novartis engaged in pay for delay, where companies pay off generic competitors to delay their entry into the market. Novartis struck a deal with the first generic competitor to postpone its entry by six months. This is on Gleevec. The generic originally announced it would price its product 30 percent below Gleevec, but then they ultimately set the price at only six percent below Gleevec.

Experts say that these various maneuvers employing a six-month delay and then a six-month duopoly, resulted in $700 million in excess costs to payers alone, in a single year, in 1915-'16. And you collected your highest net revenue from Gleevec during that two-year period when more than 100 Novartis employees collected more than $1 million a year, and the CEO, I understand, earned a total of $72 million that year.

One strategy of anticompetitive exclusion is to engage in restrictive contracts with health plans and pharmacies to ensure that those health plans and pharmacies only cover or dispense the branded, or non-generic, form of the drug. These contracts are called National Drug Code locks on generics, or NDC blocks, for National Drug Code.

Internal records showed that Novartis developed and implemented an NDC block strategy. Novartis offered higher Gleevec rebates or discounts to health plans in exchange for their plans blocking generics from the covered drug list. This meant that Gleevec would automatically be substituted instead of a generic version.

Mr. Kendris, do you agree that NDC blocks are fundamentally anticompetitive?

Mr. KENDRIS. Congressman Raskin, no, I don't agree with that. I think payer contracting actually saves the health plans and the brand is cheaper than the generics in that case. What we did was we lowered the price of the branded product with steep discounting, and we competed with generics on price with our brand.

Mr. RASKIN. Well, but why did you need to institute a formal block to keep the generics from being in competition at that point?

Mr. KENDRIS. It wasn't to prevent generics to be in competition. There were physicians and patients who wanted branded Gleevec, and in order not to be automatically substituted at the pharmacy counter those patients wanted Gleevec, and these payers, who we contracted, wanted to get Gleevec brand to them.

Mr. RASKIN. Well, you actually promoted to consumers the idea that they should only order Gleevec. Tell us about your dispense-as-written campaign for doctors to write "dispense as written" or "DAW" on prescriptions.

Mr. KENDRIS. That is a campaign to make sure that doctors and patients know that if they want Gleevec, the branded product, and many patients who are stable, in remission from cancer, want to stay on the branded product and not go to a generic, if they want that they need to write—they need the doctor to write the prescription for Gleevec, the brand, or they will be automatically substituted at the pharmacy. So, that is what "dispense as written" means, and it is for the patients and the doctors who would like

to keep the patient on Gleevec as opposed to being switched to a generic automatically at the pharmacy.

Mr. RASKIN. But don't you actually try to influence consumers or patients in that choice? You say, "It is your right to ask your pharmacist for branded Gleevec. Tell them to dispense as written. The power is in your hands. Demand the brand. Multiple generics can lead to patient confusion. If you get generic your medication may change shape, color, size, from month to month." Aren't you actually out there campaigning against generics and making the patient believe that they need to get the branded pill?

Mr. KENDRIS. Look, Congressman, we have our own generic company that sells thousands and thousands of generics every year. In fact, they are the second-largest seller of generics in the United States. So, we don't do what you just described. What we are doing is we are reaching out to patients and doctors who already want to stay on the brand, and we are educating them how they have to do it. They will not be able to stay on the brand if they want to unless they write a prescription for Gleevec.

Mr. RASKIN. Did you pursue the NDC blocks in order to try to keep Novartis' market share up, even with generics in the market? Is that why you went for the NDC block strategy?

Mr. KENDRIS. No. That is part of the negotiation with the payer in the contracting process.

Mr. RASKIN. OK. Well, Madam Chair, I just think that these NDC blocks were tremendously profitable for Novartis, as they have been for other companies, and the cost is not paid by the company. It is paid by the patients, it is paid by Medicare, and all of us through increased prices.

But thank you for your testimony. I yield back to you, Madam Chair.

Chairwoman MALONEY. Thank you.

Mr. Comer, you are now recognized.

Mr. COMER. Thank you, Madam Chair. My first few questions will be addressed to Mr. Bradway with Amgen.

Sir, you explained in your opener that net prices are not the same as list prices. You said that part of the list price calculation includes benefits to patients. Can you quickly explain how you are able to calculate that?

Mr. BRADWAY. Yes. The list price is the price that we establish. The rebates are the price that we pay to the intermediaries, creating a net price. It is the net price that we receive. And the patient then pays a copay as a function of the stated list price.

Mr. COMER. While patients no doubt benefit from these lifesaving drugs, I think you can understand that patients have a hard time understanding that cost benefit calculation. How can patients be sure they are getting the best price available for their medicine?

Mr. BRADWAY. Thank you, Congressman. I think that is an important issue, the issue of transparency, and it is very difficult in the system that is in place today. It is difficult, for example, because patients don't get the benefit of the rebate at the pharmacy counter. In fact, it is very hard for a patient to have any idea what rebate has been negotiated between their plan sponsor, their PBM, and the innovative drug company. So, it is a challenging problem,

even for the initiated patient who wants to try to get the answer to your question.

But we and others publish our list prices, for example, on the website, for our individual medicines. We provide an indication of the range of rebates and, therefore, give a sense for what the net price is. But our net price is different for individual payers, based on the contracts that we have negotiated with each of them individually.

Mr. COMER. I spent a lot of time in the hearing yesterday talking about my dissatisfaction with the PBMs and that process, so I am going to shift gears and mention that for a second.

Mr. Kendris with Novartis, this is an incredibly complicated process. It seems to me that the savings are not always being passed on to the consumer. President Trump, in one of his recent Executive orders, mandated that PBMs pass these rebates onto Medicare Part D patients, but this covers only a small percentage of the patient population.

Mr. Kendris, what can we, in Congress, do to ensure patients are benefiting from these discounts rather than middlemen like PBMs?

Mr. KENDRIS. Ranking Member Comer, thank you for the question. I think one answer to your question, quickly, would be transparency, and I think that we need to encourage patient access and affordability. And I think there are three ways.

We can give access to value-based products, value-priced products with low cost-sharing so we encourage their use and we don't restrict their access to formularies. We can cap what patients have to pay in out-of-pocket costs for drugs in Medicare Part D. And we can require plans to share some of the discounts they negotiate for drugs with patients. Those savings should be passed along to patients at the pharmacy counter. Those three things would encourage patient access and affordability.

Mr. COMER. And I agree 100 percent with your statement about transparency. Who is the agency or bureaucracy in charge with overseeing the PBMs and their transparency? Who holds the PBMs accountable? Educate me on that.

Mr. KENDRIS. That is a very good question, Ranking Member Comer, and I think perhaps HHS is the answer. Perhaps HHS should be overseeing the PBMs, and to some extent they probably do. But I think the oversight and the changes in terms of passing on discounts at the pharmacy counter is something that needs to happen. Maybe it is HHS. Maybe it is a different approach. I am not sure.

Mr. COMER. And I think that is something, Madam Chair, I mentioned to you after the hearing yesterday, that is something that we should certainly look into more when we are going to continue our efforts to investigate the out-of-control costs of drugs for Americans.

One other thing, and my time is running out, but just to touch on what Representative Keller mentioned with the price difference between Europe and the United States, I don't think any of like that but I am curious, how much do you spend on litigation in Europe versus the United States? Is there a big difference in your litigation costs?

Mr. KENDRIS. I believe there probably is. I would have to get back to you with specifics, Ranking Member Comer, but there is a probably a difference.

Mr. COMER. If both of you all could get that back to me I would just love to know, out of curiosity.

Madam Chair, I yield back.

Chairwoman MALONEY. Mr. Gomez, you are now recognized, and Mr. Gomez is the vice chair of this committee.

Mr. GOMEZ. Thank you so much. Mr. Trudeau, I want to followup on something you said to Chairwoman Maloney when she asked you about the cash cow slide. Can we put up Exhibit 68 again, please?

[Slide.]

Mr. GOMEZ. So, now let's just review this slide. It refers to Acthar as, and I am quoting from the title here, "a cash cow." Now Mr. Trudeau when Chairwoman Maloney asked you about this you downplayed it. You said, "Oh, it is just a draft and it was never sent to the board." You were pretty much implying that your companies doesn't view this drug as a cash cow. Do you still stick with the assertion that your company does not view Acthar as a cash cow? Yes or no.

Mr. TRUDEAU. Yes, I do.

Mr. GOMEZ. OK. Thank you. Are you familiar with the term "synonym." Synonym?

Mr. TRUDEAU. Cinnamon?

Mr. GOMEZ. Syn-o-nym. Yes, the term that basically refers to one word means the same thing as another word, right, or nearly the same thing. Are you familiar with that concept?

Mr. TRUDEAU. I am, sir, yes.

Mr. GOMEZ. OK. So, we obtained some emails that I want you to take a look at, and it is from your company's execs.

In fact, one of these email chains, your corporate executives have a discussion about this exact term, and I quote, "Do we really want to say 'cash cow' to the board?" He obviously recognized how bad this sounds. So, then your company's chief commercial officer responds. In his own email he wrote, and I quote, "Instead of 'cash cow' I will replace it with 'profit maximizer'." So, replacing one term with another term, "cash cow" with "profit maximizer," doesn't change the intent of your company, which is to make as much money as possible, right?

So, Mr. Trudeau, you were under oath when you answered Chairwoman Maloney's question. You swore to tell the truth and the whole truth. Were you trying to mislead the committee?

Mr. TRUDEAU. Not at all. We don't think about Acthar in any——

Mr. GOMEZ. OK. So, let me reclaim my time. Can we put up the next slide?

[Slide.]

Mr. GOMEZ. This is the actual slide that was sent and was included in the final presentation that was prepared for the board, and it includes the term "profit maximizer." Do you deny that, Mr. Trudeau?

Mr. TRUDEAU. No, I don't.

Mr. GOMEZ. OK. So, that was the whole point that Ms. Maloney was trying to make, that your company is trying to maximize prof-

its. Then you denied it, and then you downplayed this document. You said you removed the word "cash cow," but there was no question that you were trying to maximize profits, right? "Cash cow" and "profit maximizer," you just replaced one term with another, but the intent was the same, to make the most money.

I think you owe the chairwoman and this committee an apology. How do you respond?

Mr. TRUDEAU. Very clearly, sir, these were options that were being considered, but I think the actions are what you need to focus on——

Mr. GOMEZ. No. I am going to reclaim my time.

Mr. TRUDEAU [continuing]. And that is that we——

Mr. GOMEZ. Do you—what—do you agree that the main purpose—your team replaced one term with another, right, one term with another, and it was the same intent, to maximize profit, right?

I would like to put up—and your team, your company, has brought in nearly $6 billion in net sales from Acthar. I would like to put up Exhibit 76 on the screen, please.

[Slide.]

Mr. GOMEZ. The presentation emphasizes that the merge was a, quote, "unique opportunity that should be pursued urgently" because this deal would, quote, "provide rapid revenue and earnings growth." In fact, soon after the acquisition your executives boasted about how well this strategy worked, highlighting to shareholders that Acthar had already contributed $123 million toward net sales in only six weeks. In an investor briefing in October 2014, Mr. Trudeau, you personally explained that your company's primary goal was to deliver, quote, "top-level shareholder returns by focusing on highly profitable specialty drugs like Acthar." Do you recall saying that?

Mr. TRUDEAU. I don't recall that specifically but it wouldn't surprise me that I did say that.

Ms. SCANLON. Yes. And the reason why is that, you know, just changing the term from "cash cow" to "profit maximizer" doesn't change your intent. The intent of your company is not to help the bottom line of the health outcomes for the American people or for the public in general. It is to maximize your profits.

Your company then proceeded—you already had this drug and it was already highly profitable, and then you proceeded to increase the drug by more than $82,000 per vial, an additional 26 percent increase. So, I believe that you misled this committee, I believe that you owe the chairwoman an apology, and I believe that you owe the American people an apology as well.

With that, Madam Chair, I yield back.

Chairwoman MALONEY. The gentleman yields back.

Mrs. Tlaib, you are now recognized for questions.

Ms. TLAIB. Thank you so much, Chairwoman. Let's talk about the sham patient assistance programs, which we hear a lot from companies like yours. I know because, you know, many of the big pharma companies use many of these programs in some ways to hike up prices so that they are completely unaffordable, and then they offer these charitable programs so that patients can afford the very drug you have made unreasonably expensive.

So, these so-called fake assistance programs do not get into the underlying problem, and as many constituents tell us, which is that these drugs simply do not have to be expensive, that it is a choice, a choice that every CEO testifying today makes. And it is really a choice that is killing people, in my district and across the Nation.

So, I know you all there are a lot of documents this committee has obtained. These are not things that are coming and falling out and these are not theories. They are all documentation that proves what we are trying to explain to all of you, is that these schemes, again, are hurting people. So, the internal documents obtained by this committee through the investigation show that these so-called sham—you know, they are sham charitable programs—are really just money-making schemes.

So, let's start with Novartis' copay assistance program. In one of your response letters to the committee you stated that Novartis used its copay programs to, quote, "ensure that every patient who needs Gleevec has access to it." Mr. Kendris, would you consider Novartis' copay and other patients assistance programs a financial investment or charity?

Mr. KENDRIS. Congresswoman Tlaib, we are trying to make sure that patients can get access to Gleevec, so when they can't afford it, for whatever reason, we try and make it available——

Ms. TLAIB. Sure. Sure.

Mr. KENDRIS [continuing]. In a variety of different ways, and that is one of them.

Ms. TLAIB. Yes. Well, let me—so the documents don't kind of match up what you are trying to say here. So, documents again obtained by the committee also show that Novartis viewed its copay programs as investment, and strategically—this is a scheme here—you all used it, the copay program, to drive demand for Gleevec, particularly after it began competing with generic versions of the drug.

I would like to put up Exhibit 15 upon on the screen.

[Slide.]

Ms. TLAIB. So, it appears to be an analysis of when to launch the so-called enhanced copay program in anticipation of the generic competition. Can you see that, Mr. Kendris? I want to direct your attention to the table.

Mr. KENDRIS. Yes. Hold on one second, Congresswoman. I am getting a paper copy of it because I don't see it very well on the screen. But I have it now. So, it says, I think on the top, I don't see it on the screen but is the one that you are referring to, does it say "the optimal scenario is a six-month pre-LOE start"?

Ms. TLAIB. That is right.

Mr. KENDRIS. OK.

Ms. TLAIB. So, Novartis expected that every dollar it put into the enhanced copay program—you know, the scheme—that it would get back a return or investment of between 5.1 and 8.9 dollars. That means for every $1,000 put into this copay program, you would expect upwards of nearly $9,000 in profit. Am I reading that correct?

Mr. KENDRIS. I am not sure, Congresswoman.

Ms. TLAIB. Mr. Kendris, you are under—listen, you took an oath——

Mr. KENDRIS. I am sorry.

Ms. TLAIB [continuing]. To be very specific, you are seeing this as investment. In your own charts, from your own company, to this committee you are literally making $9,000 in profit when you insert $1,000 into these sham charitable programs.

Mr. KENDRIS. Congresswoman, I am not sure I understand this chart the way you are describing it.

Ms. TLAIB. OK. So, according to the slide——

Mr. KENDRIS. Sorry.

Ms. TLAIB [continuing]. According to the slide——

Mr. KENDRIS. Yes.

Ms. TLAIB [continuing]. The optimal scenario was to launch the copay programs six months before your company lost exclusive rights to the drug, and then a generic version would become available. That is because launching six months prior would result in the greatest return on investment by keeping patients on Gleevec before lower-cost generics entered the market. Does that sound right to you?

Mr. KENDRIS. Congresswoman, I am looking at the chart, and I see what you are saying——

Ms. TLAIB. OK.

Mr. KENDRIS [continuing]. And I would like the opportunity to take this back and talk to——

Ms. TLAIB. OK. Well, let's look at another document.

Mr. KENDRIS [continuing]. At my oncology business unit. Yes. Sure. Thank you.

Ms. TLAIB. In 2013, Novartis executives appeared to have conducted a literature review to consider enhancing its patient assistance programs, the scam. Let me put this document on the screen. It is Exhibit 14.

[Slide.]

Ms. TLAIB. I hope you can see that. As you can see, executives noted—it is highlighted there—that for patients that have higher copays there is a risk that they may not adhere to the drugs. But then the review reached this conclusion, quote, "Because cancer drugs are a necessity for patients, there is less sensitivity to price increases." What this document is saying, basically, is that cancer patients will keep taking drugs, no matter the price, because they simply have no choice. Am I reading that correct, Mr. Kendris?

Mr. KENDRIS. Congresswoman, the next sentence says something that I also think is a fact——

Ms. TLAIB. Mm-hmm.

Mr. KENDRIS [continuing]. That research shows that there is an upper limit of OOP costs at which patient adherence begins to decline. So——

Ms. TLAIB. Well, you can try to mislead the public, but when it comes down to——

Mr. KENDRIS. I am not trying to mislead. It is——

Ms. TLAIB. Mr. Kendris, your own documents are basically saying, which is really sickening, that it doesn't matter because these are lifesaving drugs. Let's go ahead and increase the prices, even though you don't have to. You have increased the prices to make more of a profit off of people that are suffering from cancer. And all these scams and these, you know, so-called patient assistance programs that you mislead everybody into trying to look like good

citizens, they are not. They are money-making schemes. And it is, again, verified over and over again in documentation provided to this committee.

I yield.

Chairwoman MALONEY. The gentlelady yields. Thank you.

Mrs. Porter, you are now recognized for questions.

Ms. PORTER. Thank you for being here. I want to hear today about innovation. As you know, this is our second day of hearings with the CEOs of big pharma companies, and we have heard so much important information about the very real costs of research and development, R&D.

Mr. Bradway, what was Amgen's total revenue in 2017?

Mr. BRADWAY. Oh gosh. Approximately $22 billion.

Ms. PORTER. OK. So, it was $23.7 billion. How about 2018?

Mr. BRADWAY. I don't have that at hand but it again it would be 24——

Ms. PORTER. That is OK. I have it handy. $22.8 billion. 2019, $23.4 billion. This totals up, because I know it is hard to do math on the fly, to $69.9 billion.

Mr. BRADWAY. Thank you.

Ms. PORTER. Mr. Bradway, over those three years that we are talking about, 2017 to 2018, how much of its own revenue did Amgen invest in that really important research and development work?

Mr. BRADWAY. Approximately $10 billion.

Ms. PORTER. OK. So R&D, taking you at your word here, was about $10 billion. Great. That is a big number. Investing in R&D dwarfs some of your other expenses. Is that right? It is one of your largest expenses.

Mr. BRADWAY. That is correct.

Ms. PORTER. How much did Amgen spend on lobbying over that same three-year period?

Mr. BRADWAY. I don't have the exact number but it is approximately $10 million a year.

Ms. PORTER. That is correct, $32.52 million on lobbying. How much did Amgen pay for the salaries of the top five, the top five executives over this two-year period?

Mr. BRADWAY. Oh goodness. It is about, I would guess, $6.5 million per year, so $13 million would be my guess.

Ms. PORTER. Thirteen million? Would you like to revise? Take a look right here, sir.

Mr. BRADWAY. Sorry. You asked salary. I gave you an answer to the question about salary.

Ms. PORTER. Oh, I am sorry. Let me rephrase. How much did Amgen spend on compensation for the top five executives?

Mr. BRADWAY. That is the number you have written on the board. Thank you.

Ms. PORTER. Could you say that number please, for the committee?

Mr. BRADWAY. Yes. I will assume that your number is correct. It is $124 million.

Ms. PORTER. OK. Wonderful. And then my final question is how much did Amgen spend on stock buybacks in that same two-year period?

Mr. BRADWAY. Sorry. Two-year or three-year period?

Ms. PORTER. Right here. Three-year period. Sorry.

Mr. BRADWAY. Three-year period. I don't know the number off the top of my head, but that includes the period where tax reform was implemented, so I would guess it on the order of $30 billion.

Ms. PORTER. Right around this number. Can you say it for the committee? I am not a witness, sir, so I can't testify as to your profits. I need you to state the number.

Mr. BRADWAY. The number that you have written is $28.6 billion.

Ms. PORTER. Thank you. So, you spent double, more than double, almost triple on stock buybacks over the three-years as you did on R&D. Is my math correct? $10 billion is roughly one-third of $28.6 billion.

Mr. BRADWAY. Yes, but what you haven't included there is the capital that we allocated to acquire research and development externally, which would be about $19 billion in that period.

Ms. PORTER. OK. You make an anti-inflammatory drug called Enbrel, which is used to treat conditions like arthritis. Mr. Bradway, did Amgen do the research that led to the creation of Enbrel?

Mr. BRADWAY. No, not the originally discovery, but we have done millions of dollars of work on——

Ms. PORTER. It is just a yes or no. Did you do the research that led to the creation of Enbrel?

Mr. BRADWAY. Congressman, I stand by my answer. The Enbrel that you use, that patients use today, did we do the research and development work associated with it? Absolutely. Quite a bit of it.

Ms. PORTER. Did you yourself oversee the trials of the drug? Did any executive at Amgen help invent this breakthrough drug?

Mr. BRADWAY. No, I did not. I was not involved in breakthrough development of the drug or the discovery of the drug.

Ms. PORTER. In fact, Enbrel was invented in an academic medical center, and its discovery was funded largely by taxpayers. Amgen later acquired the biotech company who manufactured Enbrel. Amgen did not directly pay for the discovery of Enbrel. Correct?

Mr. BRADWAY. No, that is incorrect. Your statement is wrong. Enbrel was discovered by scientists at a biotechnology company called Genentech.

Ms. PORTER. OK. What I would like to do now, Mr. Bradway, is I would like for you to please explain to the American public why you and four other executives deserve to pay yourselves tens of millions of dollars each year. I have got an empty whiteboard ready to take down your justifications.

Mr. BRADWAY. I recognize that that is a considerable sum of money. I would, of course, point out that I don't have any direct input to my compensation. That is derived by the board and it is forwarded to a vote of the shareholders, who overwhelmingly supported the compensation package for me and the other main executive officers.

Ms. PORTER. Reclaiming my time, sir. Do you not know why you are getting hundreds of millions of dollars, tens of millions of dollars a year? What is the justification? I would like to show the American people.

Mr. BRADWAY. Our compensation is consistent with competitive positions at other companies like ours.

Ms. PORTER. Mr. Bradway, reclaiming my time. The other guy gets paid too much too isn't a justification. I would like to hear what you do to deserve $124 million in salary, you and your top five executives, over a three-year period.

Mr. BRADWAY. Well, more than——

Chairwoman MALONEY. The gentlelady's time has expired. The gentleman may respond to her question.

Mr. BRADWAY. OK. More than 90 percent of my compensation is based on performance measures that include how our shares perform relative to the market, and our compensation program is aligned with that of our owners, our share owners. So, a large part of my compensation reflects the fact that we have been creating value for our share owners by advancing innovative medicines like those that we have in the marketplace today.

Ms. PORTER. I wish you would focus on creating value for sick patients, Mr. Bradway, not just your shareholders. I yield back.

Chairwoman MALONEY. The gentlelady yields back.

Mrs. Kelly, you are now recognized for questions. Mrs. Kelly?

Ms. KELLY. Thank you, Madam Chair. I want to take a moment to address an argument we have heard a lot about today, that pharmacy benefit managers are responsible for rising drug prices. Mr. Trudeau, I would like to start with you first.

The average net price per unit of Acthar, which is the price of the drug after subtracting all rebates and discounts has increased every single year since—I am not going to pronounce this right, but Mallinckrodt purchased Acthar. I would like to put on the screen a graph of the average net price per vial of Acthar between 2015 and 2018.

[Slide.]

Ms. KELLY. This graph was created using data your company provided to the committee. You can see on the chart that in 2015, the average price was around $30,000, and in 2018 it was around $33,000, basically increasing by nearly $3,000 in three years, and that is after factoring in rebates and cost.

Is it fair to say that Acthar's price increased at a faster rate than any discounts or rebates provided to PBMs or others in the supply chain?

Mr. TRUDEAU. I don't believe that is true. We have actually increased discounting significantly to our customers well beyond the rate of increase that is shown there.

Ms. KELLY. OK. In addition, data your company provided to the committee revealed that the rebates that paid Medicare for Acthar are practically nonexistent, in stark contrast to Mallinckrodt's documented efforts to perpetuate this misleading narrative. Excuse me. Between 2015 and 2018, the rebates that you paid to Medicare averaged less than one percent. By comparison, rebates paid to TRICARE for Acthar averaged more than 26 percent.

So, turning to you, Mr. Bradway, U.S. net price of Enbrel, again, the price of the drug after subtracting all rebates and discounts, has also increased since 2014. The same is true for Amgen's drug,

Sensipar. Even though rebates were stable, Amgen increased the price of Sensipar by 34 percent between 2015 and 2018.

And finally to you, Mr. Kendris, data provided to the committee reveals that between 2011 and 2015, the net price of your cancer drug, Gleevec, increased by double digits annually. At the same time, your data suggests that the rebates Novartis paid for Gleevec remained lower than big pharma would lead the public to believe. Between 2009 and 2015, before Gleevec lost exclusivity, the average of all discounts and rebates provided by Novartis related to Gleevec sale was just 15 percent of total gross sales.

Let's be clear. PBMs certainly play a role in our current pricing system. We won't deny that. But based on the data we have received it is equally clear that pointing the finger at PBMs is a convenient way for drug companies to deflect blame for their own actions. So, it simply cannot be that it is just PBMs are responsible for all of these price increases.

I don't know if anyone wants to comment on that.

[No response.]

Ms. KELLY. If not I will yield back my time.

Chairwoman MALONEY. The gentlelady yields back, and the chair now recognizes Mr. Comer for his closing comments.

Mr. COMER. Thank you, Madam Chair, and I will be very brief. We have had two long days of hearings. Hopefully in the future we can come together, instead of identifying all the problems we can try to work toward some solutions to those problems.

I want to mention that many of the problems that my friends on the other side of the aisle mentioned today can be solved in H.R. 19, our bill, the Republican bill. For example, Representative Wasserman Schultz mentioned several times the pay-for-delay settlement. You know, we don't like that. I don't think anybody likes that. That is bipartisan, and that is in our bill, H.R. 19. So, I think that there is an opportunity to work together on this issue moving forward, and I certainly hope that we can do that.

With that, again, I appreciate the hearings that we had. I appreciate all the witnesses that came before us over the last two days, and hopefully we can work together moving forward, because this is an issue the American people are demanding Congress address. And I think that we can do that and I hope that moving forward we work in a bipartisan way to have solutions to the problems.

I yield back.

Chairwoman MALONEY. The gentleman yields back, and I thank the gentleman, and I can assure you that my colleagues and I are open to working with you for solutions and solving this problem.

But before I close I would like to enter into the record a letter to the committee received from the mayor of Rockford, Illinois, Thomas McNamara. The mayor's letter explains the various essential services that the city would have funded with the $500,000 that it spent on Acthar. He mentions installing 350 streetlights, planting 2,000 trees, or replacing two miles of sidewalk.

I ask unanimous consent to place this letter into the record. Without objection, so ordered.

Chairwoman MALONEY. With that let me close by thanking the six, all six of the CEOs who agreed to participate in these two days

of landmark hearings. And I would like to thank the staff for all the work that they did in preparing these hearings.

To me, the single most remarkable revelation coming out of these hearings is the claim by drug companies that they need to raise their prices for research and development or to promote innovation. This is completely and utterly false, it is baseless, and I think Ms. Porter underscored this is in her comments.

The internal documents that we obtained show that the pricing discussions going on inside these companies have nothing to do with research and development or promoting new innovation. They show a meticulous, even ruthless focus on squeezing every possible dollar out of the pockets of the American people and the American taxpayers. Whether you call it a "cash cow" or a "profit maximizer," it shows that these companies view these drugs as a profit basis, in profit-based terms, and that was clear in the documents we saw.

I want to make clear also that these drugs are lifesaving and life-changing in many, many ways, and we are grateful for that. But we cannot let these drug companies continue to target our country, the United States of America, for the biggest and deepest price increases anywhere in the world.

Not everyone knows this but we have a law on the books in this country that bars our country from negotiating directly with drug companies to lower prices for Medicare, one of the biggest drug purchasers in the world. Of course, the companies know this and they exploit it to the tune of hundreds of billions of dollars, and that is what these new documents showed.

These companies make profits in Europe where they negotiate, in Canada, where they negotiate, and in all sorts of other countries that negotiate. But we, in America, we have our arms tied behind our back and we are not allowed to negotiate, to help our people, and that is not a free market. A free market is when two people or two parties come to a table and agree to a price one is willing to pay and the other is willing to accept. Our system is the opposite of a free market. It lets the drug companies increase their prices over and over and over again, dozens of times, by thousands and thousands of dollars, as we heard today and saw in the documents.

This is absolutely unsustainable. We need to pass the legislation that Elijah Cummings championed and that President Trump used to support before he broke his campaign pledges. We finally need to let our government negotiate, just remove this block that does not allow us to be treated fairly. We are exploited in this system.

Now I want to let members know that these two days of hearings will not be our last. We have heard testimony from six CEOs, but we have been investigating several other companies as well. So, I will keep members appraised of the additional hearings, potentially when we return in November and in December.

And finally, I want to thank the members of our committee on both sides of the aisle. This is a critical issue for all of our constituents, and I believe all members demonstrated your command of the material and your desire and drive to help your constituents and to help the American people.

I sincerely hope we can take these findings and move forward on real legislative changes to help American families together. And

with these two days of hearings I again thank the staff that has worked incredibly hard on this, and this hearing is adjourned.

[Whereupon, at 1:36 p.m., the committee was adjourned.]

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