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February 1, 2024

Via email (*dora_ins_pdab@state.co.us***)**

Colorado Department of Regulatory Agencies, Division of Insurance
ATTN: Dr. Gail Mizner, MD, FACP, AAHIVS, Chair, Colorado Prescription Drug Affordability Review Board (the "Board")
1560 Broadway, Suite 850
Denver, CO 80202

Re: ***Request for Board Attention to Persistent Process Issues in Advance of Enbrel® Report Review and Votes***

Dear Dr. Mizner:

On behalf of Amgen and its wholly-owned subsidiary, Immunex, we direct the Board's attention to several issues, two of which were previously brought to your attention in Amgen's December 5, 2023 letter. These issues raise serious concerns about the fairness and legality of the Board's review process. We request that these issues be addressed before the Board takes any vote related to Enbrel®:

1. During the October 27, 2023 and December 8, 2023 public meetings, one Board member made on-the-record public comments about conversations with unnamed persons (in which Amgen was not involved) about Enbrel®'s affordability. Such information from a Board member may not be considered by the Board, whether offered in public or closed sessions.

2. The Board has been inconsistent with respect to the standards and procedures it is applying, and the opportunities to assess the information before the Board and meaningfully respond are inadequate and inconsistent with Board policy and stated principles.

Board Member Comments

During the October 27, 2023 meeting, while the Board was still discussing Trikafta, Board member Catherine Harshbarger made comments about unidentified people she stated she had "talked to personally," whom she described as having spent $6,000 out-of-pocket for Enbrel ("Enbrel might be an example, where I've talked to people personally who've spent $6,000 out-of-pocket with their coinsurance."). We raised this issue to you in our December 2, 2023 letter. At the December 8, 2023 meeting, despite our letter identifying the previous comments as a significant process issue, Ms. Harshbarger again cited off-the-record discussions, but the purported figure had grown by 25 percent to $8,000 ("I've talked to people that are spending as much as $8,000 out of their own pocket for Enbrel.").

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Exhibit 49

These remarks, and that they remain unaddressed, contribute to our growing concerns about the lack of standards that are governing the Board's decision-making process and the inconsistent and inadequate processes followed by the Board. In previous public meetings, Ms. Harshbarger has not disclosed any independent engagements with Enbrel® stakeholders, and Amgen is unaware of any that have been otherwise reported. In any event, Amgen believes it is improper for Board members to engage in, or to consider, such "ex parte" conversations. Any information considered by the Board should be submitted publicly and on the record so that Amgen and other interested parties can have a meaningful opportunity to respond, the Board can make informed decisions based on accurate and complete information, and to ensure that there is appropriate accountability for the Board's decisions and actions.

Amgen remains unaware of the source of the information provided by Ms. Harshbarger at either meeting, including whether the conversations were with the same people (and, if not, which price figure she intended to communicate), critical details concerning the type of insurance, whether the patient or patients were eligible for or enrolled in patient assistance programs, and over what period of time the patient(s) paid out-of-pocket expenses. We are therefore unable to comment on and respond meaningfully to the information she introduced. We accordingly request that the Board clarify that the statement made by Ms. Harshbarger will not be considered and state what evidence the Board believes it may consider (in both public and closed sessions), including but not limited to "off-the-record" discussions by members concerning issues before the Board. We also request that Ms. Harshbarger provide in detail the basis for the information she stated on the record and that the Board provide an opportunity for public comment. Failing those steps, and in light of her improper ex parte research and the apparent bias reflected in her statements, we respectfully submit that Ms. Harshbarger should recuse herself from Board deliberations related to Enbrel®, in order to ensure the integrity of the proceedings.

Inadequate Opportunity to Assess and Meaningfully Respond to Information

It is essential that the Board adopt consistent standards and follow consistent procedures. While we recognize that the Board's delay of the Enbrel® affordability report review from December 8, 2023 to February 16, 2024 allowed for a discussion of preliminary information at the December 8 meeting, the time afforded for discussion of Enbrel® remains inadequate and has not been comparable to that afforded to Trikafta. At the October 27 meeting, the Board devoted well over an hour to Trikafta but allotted only 17 minutes of closed session discussion to Enbrel® and Genvoya, combined. At the December 8 meeting, the Board discussed Enbrel® for approximately half an hour in open session. The information before the Board, however, was unclear (e.g., references to Trikafta in the Enbrel slides and no specified time period from which the data were compiled) or incomplete (e.g., data not provided on many of the slides). Moreover, unlike the Trikafta presentation, the presentation from the December 8 meeting has still not been publicly posted, much less updated, on the Board's website as of February 1.

We are also concerned that Enbrel® patients and members of the public may have been prevented from speaking during the "public comment" portion of the October 27 meeting, and no one was permitted to make public comment during the December 15 meeting. First, we learned that, even

before the Board and staff announced they would only be discussing Enbrel® in closed session, the link to sign up for public comment was no longer accepting responses, and no public commenters spoke about Enbrel® specifically. Second, the lack of any opportunity for public comment at the December 15 meeting was contrary to the Board's Policy #2, entitled *Policies and Procedures required by § 24-3.7-102, C.R.S.*, which states, "The Board will provide the opportunity for public comment at each meeting." Amgen, and potentially other stakeholders, had questions and comments regarding the Board's standards and the means by which they were applied to the vote on whether Trikafta was unaffordable to Colorado consumers. Amgen and others have been harmed by not being afforded a reasonable opportunity to raise these issues in the public meeting.

We understand the Board may elect to meet in certain closed sessions, but such meetings obviously do not provide an opportunity for Enbrel® patients, the public, and Amgen to address the Board, making the lack of opportunity at public meetings all the more problematic. Additionally, while the Board and staff have stated on occasion that comments may be submitted in writing, those comments have so far not been acknowledged or responded to. The Board is obliged to respond meaningfully to comments and to ensure that it takes into account the important information that public comment can provide.

We remain concerned that Amgen has been deprived of any meaningful opportunity to address or respond to the information before the Board. Indeed, the deadline for the sole confidential, drug-specific submission requested from manufacturers occurred prior to any clarity being provided on the information that would form the basis of the affordability determination. For instance, the key data populating the *Colorado PDAB 2023 Eligible Drug Dashboard* is identified as 2021 data, yet many of the key figures cited in the Trikafta affordability report are identified as 2022 data. Because we have not been afforded the opportunity to review any 2022 data from the Colorado All-Payer Claims Database (APCD) or the newly reported "top 15" drug lists from payers and pharmacy benefit managers (PBMs), we are unable to provide information that places such data in appropriate context or otherwise clarifies or responds to the information before the Board.

Furthermore, with the Board's reopening of the window for certain stakeholder input through January 21, 2024 and little, if any, information provided on the stakeholders targeted for that additional input, we lack insight into the current state of such information or the impartiality of the process, as we understood was an intent for the public nature of the previous stakeholder listening sessions. These irregularities contribute to our substantial concerns about the introduction of bias from the Board's and staff's selective targeting of stakeholders for input.

We thus believe a public discussion—allotting fair time to Enbrel® and providing clarity and direction on the points set out above and related issues—should take place *before* any determination, draft or final, is made regarding affordability.

* * *

Amgen is driven by its mission to serve patients and committed to improving lives by discovering and developing treatments and cures for serious diseases. Amgen understands that the cost of prescription drugs is a concern for many Coloradans, but also recognizes that these concerns will

only increase if the Board fails to comply with proper procedures and fails to allow for proper public comment. We look forward to the opportunity to hear fair and open Board discussion about affordability of and access to Enbrel®, and we thank you for your attention to these issues.

Regards,

/s/ Kathy Sherman

Kathy Sherman
Associate Vice President, State and International Government Affairs
Global Government Affairs & Policy

COST-BENEFIT ANALYSIS

In performing a cost-benefit analysis, each rulemaking entity must provide the information requested for the cost-benefit analysis to be considered a good faith effort. The cost-benefit analysis must be submitted to the Office of Policy, Research and Regulatory Reform at least ten (10) days before the administrative hearing on the proposed rule and posted on your agency's web site. For all questions, please attach all underlying data that supports the statements or figures stated in this cost-benefit analysis.

DEPARTMENT: Regulatory Agencies (DORA) **AGENCY**: Division of Insurance

CCR: 3 CCR 702-9 Part 4 **DATE:** April 1, 2025

RULE TITLE OR SUBJECT: PART 4.3: CONCERNING AN UPPER PAYMENT LIMIT FOR ENBREL

Per the provisions of 24-4-103(2.5)(a), Colorado Revised Statutes, the cost-benefit analysis must include the following:

1. The reason for the rule or amendment;

By statute, the Prescription Drug Affordability Board (PDAB) may establish upper payment limits (UPLs) for prescription drugs it deems unaffordable, section 10-16-1407(1), C.R.S. The PDAB establishes UPLs through a rulemaking process and a notice has been published in the Colorado register that the Board will begin rulemaking to consider establishing a UPL for the prescription drug Enbrel.

The purpose of the UPL rule is to address high prescription drug costs and the impact these high costs have on patient access to drugs. The high cost of prescription drugs negatively impacts Coloradans' ability to purchase and adhere to the necessary medications they need to thrive. High drug costs also contribute to the unsustainable rise in health care costs and insurance premiums which further impacts the financial health of Coloradans,[1] [2] [3] threatening the health and safety of people in the state and disproportionately harming priority populations and Coloradans with low incomes.[4] *See* S.B. 175, 2021 Leg., 74th Gen. Assemb., 2nd Reg. Sess. (Co. 2021).

2. The anticipated economic benefits of the rule or amendment, which shall include economic growth, the creation of new jobs, and increased economic competitiveness;

UPLs are intended to achieve the following economic benefits:

- Reduce prescription drug costs for consumers. By statute, carriers must use savings from a UPL to reduce consumer costs via reduced out-of-pocket costs and lower premiums.
- Reduce prescription drug costs for consumers through increased competitiveness in the market and lower costs due to the availability of therapeutic alternatives. If the Board considers therapeutic alternatives to establish a specific UPL, this could result in increased use of targeted drugs and lower drug spending by consumers and payers, while maintaining access.[5]
- Increase consumer access to a drug by improving patient adherence and pharmacy fill rates, which can improve the health of consumers and limit increased use of additional medical services for worsening conditions.[6] [7]
- Improve affordability for the health care system by reducing health plan costs for the drug.

[1] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2773825
[2] https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet
[3] https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00469
[4] https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/
[5] https://eadn-wc03-8290287.nxedge.io/wp-content/uploads/2024/04/Upper-Payment-Limit-White-Paper.pdf
[6] https://pubmed.ncbi.nlm.nih.gov/37200029/
[7] https://pubmed.ncbi.nlm.nih.gov/17609491/

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The anticipated economic benefit, including economic growth and the creation of new jobs, is difficult to quantify at this time for two main reasons:

- The Board has not yet specified a UPL amount - The Board is beginning a rulemaking process to review a significant volume of quantitative and qualitative data in determining whether to establish a UPL and what specific dollar amount the UPL should be. Without knowing the specific dollar amount the Board may eventually choose, it is difficult to make more precise estimates of economic benefits.[8]
- Unknown actions of prescription drug supply chain entities - Prescription drug regulations are created and updated at the federal and state levels frequently. The exact impact of such regulations depends on how the various, and often complex and opaquely related, prescription drug supply chain entities respond. The current anticipated economic benefit of the UPL to entities involved in the purchase of and reimbursement for a prescription is best assessed by the entities themselves. As the Board conducts rulemaking to establish a UPL, the Board encourages direct input from prescription drug supply chain entities during the rulemaking process to better understand the economic benefits of a UPL.

3. The anticipated costs of the rule or amendment, which shall include the direct costs to the government to administer the rule or amendment and the direct and indirect costs to business and other entities required to comply with the rule or amendment;

If the Board establishes a UPL, the following direct costs to the government may occur:

- Board staff time - If a UPL is established, staff time will be spent inquiring whether manufacturers intend to make the prescription drug available for sale in the state and rationale, notifying consumers of a decision to establish a UPL, and reporting on UPL and manufacturer responses to the General Assembly. It is anticipated these costs would be minimal.
- Attorney General Office (AGO) staff time - Pursuant to section 10-16-1411(3), C.R.S., the attorney general is authorized to enforce the UPL. The amount of resources needed to enforce a UPL is unknown at this time.

It is anticipated the following businesses and other entities may be impacted: consumers, health care providers, pharmacies, and health insurance carriers. While it is generally difficult to estimate the direct and indirect costs to businesses and other entities because of the two reasons (listed below and in the previous answer), generally it is estimated that the direct and indirect costs will be minimal since the UPL applies to one prescription drug, whereas health care providers, pharmacies, and health insurance carriers typically deal with thousands of prescriptions drugs:

- The Board has not yet specified the UPL amount - The Board is beginning a rulemaking process to review a significant volume of quantitative and qualitative data in determining whether to establish a UPL and what specific dollar amount the UPL should be. Without knowing the specific dollar amount the Board may eventually choose, it is difficult to make more precise estimates of anticipated costs.[9]
- Unknown actions of prescription drug supply chain entities - Prescription drug regulations are created and updated at the federal and state levels frequently. The exact impact of such regulations depends on how the various, and often complex and opaquely related, prescription drug supply chain entities respond. The current anticipated economic benefit of the UPL to entities involved in the purchase of and reimbursement for a prescription is best assessed by the entities themselves. As the Board conducts rulemaking to establish a UPL, the Board encourages direct input from prescription drug supply chain entities during the rulemaking process to better understand the economic benefits of a UPL.

While there may be actual costs to the drug supply chain associated with the implementation of a UPL, those costs are unknown and are unlikely to be substantial

[8] Oregon's PDAB has acknowledged it is difficult to estimate potential savings until a specific UPL is established (see: Prescription Drug Affordability Board (PDAB) Upper Payment Limit (UPL) Report to Legislature).
[9] Oregon's PDAB has acknowledged it is difficult to estimate potential savings until a specific UPL is established (see: Prescription Drug Affordability Board (PDAB) Upper Payment Limit (UPL) Report to Legislature).

4. Any adverse effects on the economy, consumers, private markets, small businesses, job creation, and economic competitiveness; and

It is not anticipated that the UPL will have an adverse effect on consumers, nor that there will be adverse effects on the economy, private markets, small businesses, job creation, and economic competitiveness for two reasons (listed below and in previous answers). Generally it is estimated that the direct and indirect costs will be minimal due to the scope of the rule and its applicability to one prescription drug specifically. While there are currently a total of three prescription drugs the Board has identified for a UPL, the Division anticipates initial effects of the UPL will be incrementally felt among the market in the initial stages of this work. Additionally, it should be noted one potential effect is that a manufacturer may withdraw the drug from the Colorado market, however Colorado Statute provides safeguards for consumers and fines for manufacturers who do not comply with noticing requirements.

- The Board has not yet specified the UPL amount - The Board is beginning a rulemaking process to review a significant volume of quantitative and qualitative data in determining whether to establish a UPL and what specific dollar amount the UPL should be. Without knowing the specific dollar amount the Board may eventually choose, it is difficult to make more precise estimates of adverse effects.[10]
- Unknown actions of prescription drug supply chain entities - Prescription drug regulations are created and updated at the federal and state levels frequently. The exact impact of such regulations depends on how the various, and often complex and opaquely related, prescription drug supply chain entities respond. The current anticipated economic benefit of the UPL to entities involved in the purchase of and reimbursement for a prescription is best assessed by the entities themselves. As the Board conducts rulemaking to establish a UPL, the Board encourages direct input from prescription drug supply chain entities during the rulemaking process to better understand the economic benefits of a UPL.

5. At least two alternatives to the proposed rule or amendment that can be identified by the submitting agency or a member of the public, including the costs and benefits of pursuing each of the alternatives identified.

One alternative to the proposed regulation would be to not adopt this regulation and not establish an Upper Payment Limit for Enbrel. Without establishing a UPL for this prescription drug, various entities, including Colorado consumers, may not be able to access Enbrel at a lower cost. If this regulation isn't adopted, prescription drug supply chain entities would likely continue operating as usual and the unsustainable high costs of prescription drugs would continue to grow.

Another alternative to the proposed regulation is that the Board could recommend to the General Assembly payment-specific, legislative strategies to address Enbrel's unaffordability for Colorado consumers. While the Board already has the ability to make recommendations to the General Assembly, the Board could provide payer- and payment-focused recommendations specific to the prescription drugs it finds unaffordable. Examples of recommendations could include co-payment caps for unaffordable prescription drugs, limits on utilization management, etc.

[10] Oregon's PDAB has acknowledged it is difficult to estimate potential savings until a specific UPL is established (see: Prescription Drug Affordability Board (PDAB) Upper Payment Limit (UPL) Report to Legislature).

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Regulatory Analysis - Proposed Rule # 3 CCR 702-9 Part 4.3 Upper Payment Limit for Enbrel

(I) A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule; (Colo. Rev. Stat. § 24-4-103(4.5)(a)(I))

The classes of persons affected by the proposed rule to establish an upper payment limit (UPL) for Enbrel may include several actors in the state, including consumers, pharmacies, healthcare providers, and carriers.

Carriers may incur minor administrative and compliance expenses, for example, by implementing new systems or adjusting reporting practices. Furthermore, pharmacies and providers may bear certain administrative burdens if the rule changes documentation, billing, or data-sharing processes; however, the magnitude of these burdens is estimated to be minimal and will vary depending on each entity's current practices.

Colorado consumers may experience increased transparency, more consistent access to prescription benefits, and potentially lower or more predictable costs[1].

Pharmacies and providers may also benefit from clearer regulatory guidelines, potentially fairer reimbursement processes, and improved coordination with carriers and pharmacy benefit managers (PBMs). Carriers may also benefit from standardized regulations, reduced uncertainty in compliance, and possibly a more streamlined claims environment.

- For pharmacies and providers, clearer regulatory guidelines and fairer reimbursement processes may lead to more predictable revenue streams and lower administrative burdens. With standardized rules, they can better plan for operational costs, reduce billing disputes, and streamline processes across different payers. Improved coordination with carriers may also foster more efficient supply chain and claims management, enhancing profitability and supporting growth in a competitive market.[2]

- For carriers, having standardized regulations reduces uncertainty and compliance variability, allowing them to forecast expenses and manage risk more accurately. A streamlined claims environment can decrease administrative costs and improve customer satisfaction by ensuring quicker, more reliable reimbursements. This consistency supports a more robust business model by stabilizing cash flow and reducing the costs associated with regulatory compliance.[3]

It is important to note that while these identified benefits and costs may exist for each class of persons, some economic impacts remain unknown or difficult to quantify until the rule is fully implemented. For example, exact compliance costs depend on the complexity of each carrier's existing systems, pass-through costs to consumers can fluctuate based on broader market conditions, and long-term savings for any group—whether consumers, providers, or carriers—may not be evident until after the rule has operated in practice for a certain period.

[1] https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00469
[2] https://pubmed.ncbi.nlm.nih.gov/37200029/
[3] https://pubmed.ncbi.nlm.nih.gov/17609491/

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(II) To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons; (Colo. Rev. Stat. § 24-4-103(4.5)(a)(II))

As the Board embarks on a rulemaking process—reviewing an extensive volume of quantitative and qualitative data to determine a specific UPL amount—the full range of economic benefits, as well as the short- and long-term impacts of regulatory actions on the prescription drug supply chain, remains to be seen. Without knowing the specific dollar amount the Board may eventually choose, it is difficult to make more precise estimates of the economic benefits.

The proposed rule is designed to reduce prescription drug costs for consumers through reduced out-of-pocket costs and premiums, increased consumer access and adherence, and increased market competition. By statute, carriers must use savings from a UPL to reduce consumer costs via reduced out-of-pocket costs and lower premiums.[4] Consumer access to a drug may be increased by improving patient adherence and pharmacy fill rates, which can improve the health of consumers and limit increased use of additional medical services for worsening conditions.[5,6] Additionally, these efforts also aim to reduce prescription drug costs for consumers through increased competitiveness in the market and lower costs due to the availability of therapeutic alternatives.[7] If the Board considers therapeutic alternatives to establish a specific UPL, this could result in increased use of targeted drugs and lower drug spending by consumers and payers, while maintaining access.

The proposed rule is intended to Improve affordability for the health care system by reducing health plan costs for the drug. Additionally, these efforts seek to decrease overall healthcare system expenses by lowering health plan costs and adjusting pharmacy reimbursements in line with reduced drug prices.

While some cost reductions may appear soon after implementation, other benefits—such as improved adherence or lower premiums—could take longer to materialize as carriers, pharmacies, and other stakeholders adapt to the new UPL. This process may involve updates to reimbursement systems, contract negotiations, and changes in benefit design, all of which can influence the timing and scope of realized savings.

Prescription drug regulations are created and updated at the federal and state levels frequently. The exact impact of such regulations depends on how the various, and often complex and opaquely related prescription drug supply chain entities respond. The Board encourages direct input from prescription drug supply chain entities during the rulemaking process to better understand the economic benefits of a UPL.

(III) The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues; (Colo. Rev. Stat. § 24-4-103(4.5)(a)(III))

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[4] *See* § 10-16-1410(1), C.R.S.
[5] https://pubmed.ncbi.nlm.nih.gov/37200029/
[6] https://pubmed.ncbi.nlm.nih.gov/17609491/
[7] https://eadn-wc03-8290287.nxedge.io/wp-content/uploads/2024/04/Upper-Payment-Limit-White-Paper.pdf

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The direct cost to the government of administering the rule is equivalent to the cost of Board staff time and contractor resources spent preparing data for the Board to review during the UPL rulemaking process.

If the Board establishes a UPL, the following direct costs to the government may occur:

- Board staff time - If a UPL is established, staff time will be spent inquiring whether manufacturers intend to make the prescription drug available for sale in the state and rationale, notifying consumers of a decision to establish a UPL, and reporting on UPL and manufacturer responses to the General Assembly.
- Attorney General Office (AGO) staff time - Pursuant to section 10-16-1411(3), C.R.S., the attorney general is authorized to enforce the UPL. If a UPL is established, the AGO has enforcement authority.

It is difficult to estimate the direct and indirect costs to businesses and other entities because of the reasons listed above. The Board has not yet specified the UPL amount - the Board is beginning a rulemaking process to review a significant volume of quantitative and qualitative data in determining whether to establish a UPL and what specific dollar amount the UPL should be. Without knowing the specific dollar amount the Board may eventually choose, it is difficult to make more precise estimates of anticipated costs.

(IV) A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction;

The probable costs of the rule are direct costs to the government, including implementation by PDAB Staff and enforcement by the AGO as outlined above, and potentially other direct and indirect costs to businesses and other entities, including consumers, health care providers, pharmacies, and health insurance carriers, based on the implementation of a UPL. The benefits of the rule are numerous, including reduced costs for consumers, increased market competitiveness, and increased consumer access.

Inaction could mean that some Colorado consumers may not be able to access Enbrel at a lower cost. If this regulation isn't adopted, prescription drug supply chain entities would likely continue operating as usual.

(V) A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;

The Board is tasked with enacting existing statutes, which include reviewing prescription drug costs, evaluating a drug's impact on Coloradans through affordability reviews, and may set an upper payment limit for certain prescription drugs.

Additionally, the Board has the authority to make recommendations to the General Assembly regarding payment-specific, legislative strategies to address Enbrel's unaffordability for Colorado consumers. While the Board already has the ability to make recommendations to the General Assembly, the Board could provide payer- and payment-focused recommendations specific to the prescription drugs it finds unaffordable. Examples of recommendations could include co-payment caps for unaffordable prescription drugs and limits on utilization management. In addition, the federal government could act to reduce pharmaceutical costs.

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(VI) A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

As previously stated, the Board is tasked with enacting existing statutes, which include reviewing prescription drug costs, evaluating a drug's impact on Coloradans through affordability reviews, and may set an upper payment limit for certain prescription drugs. At this time, the Board is continuing to focus efforts on assessing prescription drug affordability through its established processes of conducting affordability reviews and may begin to set upper payment limits on select drugs, as these are the current tools the Board has the authority to enact.

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July 9, 2025

Via email (*dora_ins_pdab@state.co.us*)

Colorado Department of Regulatory Agencies
Division of Insurance
ATTN: Colorado Prescription Drug Affordability Review Board (PDAB)
1560 Broadway, Suite 850
Denver, CO 80202

Re: Enbrel Upper Payment Limit (UPL) Rulemaking: Process and Substantive Issues

On behalf of Amgen Inc., its wholly-owned subsidiary Immunex Corporation, and its indirect wholly owned subsidiary Amgen Manufacturing, Limited (collectively "Amgen"), we respectfully continue to object to the inconsistent, undisclosed, and otherwise ambiguous processes and procedures employed by the Colorado Prescription Drug Affordability Board (PDAB or Board). This approach extends to the proposed rule itself, which provides nothing of substance to which stakeholders may respond and consequently prevents meaningful participation in the Board's rulemaking process. Reflecting the lack of substance in the proposed rule, the Board's cost-benefit and regulatory analyses do not adequately address the statutorily mandated factors for those analyses. Furthermore, we again raise legal concerns regarding the Board's authority and approach, among other matters.

Amgen is committed to improving the lives of patients by discovering and developing medicines for serious diseases. Amgen understands that the cost of prescription drugs is a concern for many Coloradans, and Amgen has programs in place to ensure affordability while minimizing access hurdles from pharmacy benefit managers (PBMs) and others. 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.

Accurate Assessment of a UPL's Impact Necessitates Clarity on Where and How a UPL Applies

Based on the Board's statements and the State's representations in litigation, we understand that the Board intends a UPL on Enbrel® to apply to all "downstream" transactions (*i.e.*, excluding sales to wholesalers and distributors) involving a drug that is dispensed or administered in Colorado, but excluding transactions involving federal programs and payors. As Amgen has explained, it is clear that such a UPL will harm Amgen and deprive it of the benefits it is entitled to under the federal patent system. But a more detailed assessment of the costs of a UPL, including compliance costs and harms to patient access, is impossible without greater clarity about how the Board intends to apply a UPL.

The Board has not explained how it would determine whether a UPL applies to particular transactions. For example, despite the Board's intent that a UPL not apply to certain transactions—such as those that involve a drug that is ultimately dispensed or distributed outside of Colorado—it will often be difficult or impossible to determine *at the time of a transaction* whether the UPL applies. Moreover, if a drug is acquired outside of Colorado at a cost exceeding the UPL, capping the payments and reimbursements to in-state providers below the acquisition cost will have a detrimental impact on access. Providers' uncertainty over whether they will be properly reimbursed will reduce their willingness to stock these medications. We share the concerns voiced by other stakeholders[1] that this dynamic could result in sites of care across Colorado being unable or unwilling to stock Enbrel®.

Without clarity on which specific transactions are subject to a UPL and how participants in the supply chain will be able to distinguish those transactions and medicines from their UPL-ineligible counterparts, both within the state and beyond its borders, stakeholders cannot accurately assess or provide responsive comments on what exactly a UPL means for their operations and, most importantly, for patient and provider access to medicines.

Beyond Stating the Board's Intent to Adopt a UPL, the Board Has Provided Nothing Meaningful for Amgen and Other Stakeholders to Comment On

Even though the Board is about to hold the second of just three planned rulemaking hearings, the proposed UPL rule remains little more than a blank template. As Amgen has explained in past comments, both the Colorado Administrative Procedure Act and due process require the Board to provide stakeholders with reasonably specific notice of what the agency is proposing to do, including enough factual detail and rationale to permit interested parties to comment meaningfully on the proposal. The Board has not provided such notice regarding the proposed UPL rule.

The proposed Enbrel® UPL rule lacks any meaningful substance for Amgen to respond to. It states only that the Board intends to establish a UPL for Enbrel®. It does not specify the level at which—or even a range within which—the Board is proposing to set the UPL. Nor does it disclose anything about the process, method, or criteria the Board will consider in determining the UPL.

The Board's other rules and guidance do not provide clarity, either. Importantly, the Board was supposed to "determine by rule the methodology for establishing an upper payment limit" in advance; the Board is not allowed to make up the methodology as it goes along.[2] But the Board has not disclosed anything resembling a methodology for setting upper payment limits. The Board's rule purporting to establish a methodology does no such

[1] Healthcare Distribution Alliance (HAD), Letter to the Chair Mizner and Members of the Colorado Prescription Drug Affordability Board, included in May 23, 2025, Board Meeting Materials.

[2] C.R.S. § 10-16-1407(2) (emphasis added).

thing: Instead, it simply (i) restates the statutory factors the Board is required to consider and those it is prohibited from considering, and (ii) lists ten different "price and cost metrics" that the Board "may consider," without specifying how the Board will use that information to establish an upper payment limit.[3] The Board's non-binding guidance adds nothing of substance: Like the rule, it lists ten different price and cost metrics that staff "may compile … for the Board's review" but does not specify what the Board will do with that information.[4]

The Board's first rulemaking hearing and its Data Submission Guide, which was not finalized until after that hearing, have done nothing to fill in these gaps. At the first rulemaking hearing, Board staff presented the Board with a slew of data purporting to reflect the various price and cost metrics listed in the rule that the Board "may consider" when setting a UPL. But the Board did not provide any guidance about how it would utilize that data or what methodology it would follow when establishing a UPL. Similarly, the Data Submission Guide requests a wide range of quantitative and qualitative information from manufacturers and other stakeholders, but it does not shed any light on what the Board is proposing to do with that data or how the data will influence the Board's selection of a UPL.

It appears that the Board is attempting to rush through the rulemaking process without disclosing any of the information that is crucial to allowing Amgen and other stakeholders to comment intelligently on the proposed UPL. This dynamic has put stakeholders in the precarious and unfair position of attempting to provide meaningful input on a proposal that is utterly undefined and open-ended.

A proposed rule should not put stakeholders in the position of both creating and responding to their own hypotheticals at the same time they are expected to help the Board understand the general issue landscape and perspectives on a host of critical issues. This not only violates the Colorado Administrative Procedure Act; it also deprives Amgen and other stakeholders of the meaningful opportunity to be heard that is the core of due process.

Questions of Data Accuracy and Ambiguous or Undisclosed Methodologies Remain as We Approach the Third UPL Rulemaking Hearing for Enbrel®

Amgen has been requesting further information on data irregularities and undisclosed methodologies for more than a year. Despite committing to a response addressing Amgen's questions regarding data aberrations and unknown methodologies at the June 14, 2024, Board meeting[5], neither the Board nor staff has ever provided such a response.

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[3] 3 CCR 702-9, Part 4.1.C.

[4] PDAB Policy 05: Upper Payment Limit Policy and Procedure (Jan. 13, 2023).

[5] Amgen verbal comments to the Board at the June 14, 2024, Board meeting, requesting clarification on how data for the same year could change substantially, including details on the standards, methodologies, and data used in each phase, and asking for assurances from the Board that any unsupported changes in the data had not unduly influenced Board assessments and deliberations.

The significance of these unanswered data and methodology questions has been underscored by the recently disclosed data miscategorization by a pharmacy benefit manager (PBM). For instance, even basic data categories, such as the number of patients utilizing Enbrel®, have changed in each phase of the Board's assessments. For the 2021 data year, the number of Enbrel® utilizers cited by the Board went from 2,279 utilizers during the eligibility and selection phase, to 3,692 utilizers during the affordability review phase (+62%), and to 2,744 utilizers during the UPL rulemaking phase (- 25.7%).

While we understand this latest round of changes to the reported Enbrel data was due to the purported data miscategorization impacting roughly 7% of pharmacy claims in the database, we have no means to better understand these new figures, assess their accuracy, or evaluate the extent to which they have been "corrected"[6] without access to the data before the Board and without transparent, evidence-based processes and methodologies.

By Emphasizing APCD Data on Patient Out-of-Pocket Costs, the Board Continues to Ignore Amgen's Efforts to Promote Access and Affordability

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—to as little as $0 out-of-pocket for each dose—with no income eligibility requirements. In fact, roughly two-thirds, or 67 percent, of Enbrel® 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.

Although Medicare beneficiaries are not eligible for co-pay cards, approximately three-quarters, or 76 percent, of Enbrel® prescriptions for Medicare beneficiaries 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. 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.

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 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.

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[6] Addendum to the 2023 Affordability Review Summary Report: Enbrel (May 6, 2025).

The above information was provided to the Board in Amgen's submission dated October 2, 2023, but has only been reflected in the Board's affordability report at Appendix K, on page 501 of 534 pages. In subsequent Board meetings, the significant impact for patients of Amgen's co-pay card programs has been largely dismissed by the Board. The Board routinely cites data on patient out-of-pocket costs from the Colorado All Payer Claims Database without acknowledging that these figures do not reflect the beneficial impact of Amgen's patient assistance programs. If the Board sincerely intends to understand and balance the impact of any UPL on out-of-pocket costs to patients against risks to patient access, an appropriately thorough assessment and balanced discussion of manufacturer programs assisting patients must be part of the UPL rulemaking process.

* * *

Amgen is driven by its mission to serve patients and committed to improving lives by discovering and developing treatments and cures for serious diseases. Amgen understands that access to prescription drugs is a concern for many Coloradans, but these concerns will only increase if the Board adopts an ill-considered UPL rule that may limit access to Enbrel® without providing stakeholders sufficient notice of and a meaningful opportunity to comment on the actual substance of the proposed rule. We look forward to the opportunity to hear fair and open Board discussion about the proposed UPL rule, and we thank you for your attention to the aforementioned issues.

Regards,
/s/ Kathy Sherman

Kathy Sherman
Associate Vice President, State and International Government Affairs
Global Government Affairs & Policy

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August 20, 2025

Via email (*dora_ins_pdab@state.co.us*)

Colorado Department of Regulatory Agencies
Division of Insurance
ATTN: Colorado Prescription Drug Affordability Review Board (PDAB or Board)
1560 Broadway, Suite 850
Denver, CO 80202

Re: Enbrel Upper Payment Limit (UPL) Rulemaking: Process and Substantive Issues

Re: **Proposed Upper Payment Limit for Enbrel® (etanercept)** — Request for Specific Notice, Transparent Methodology, Implementation Details, and Correction of Record

Dear Members of the Board:

On behalf of Amgen Inc., its wholly owned subsidiary Immunex Corporation, and its indirect wholly owned subsidiary Amgen Manufacturing, Limited (collectively, "Amgen"), we submit these comments to continue our objection to the Board's inconsistent, undisclosed, and ambiguous processes and procedures regarding the proposed upper payment limit (UPL) for Enbrel®. We also reiterate significant legal concerns with the Board's authority and approach.

Before taking any further action on a UPL for Enbrel®, the Board should:

1. **Clarify aspects of UPL implementation**: provide greater clarity around how covered transactions are identified, which programs and entities are excluded (e.g., federal programs), how self-funded plans may opt into a UPL, enforcement mechanisms, and any safe harbors.
2. **Address UPL information flows and any requisite infrastructure changes**: specify how UPL applicability will be communicated across the supply chain (e.g., identifiers, coding, data fields, and timing) so participants can reliably determine where and when to apply the UPL, including how self-funded plans' UPL opt-in decisions will be communicated.
3. **Correct and document the data record**: adequately reconcile patient counts, utilization, and other data across phases of the review process, as requested by Amgen since early 2024; and provide access to the corrected underlying data, detailed methodologies, and data dictionaries so stakeholders can validate and replicate results.
4. **Recognize and incorporate patient assistance**: adequately reflect the material impact of Amgen's co-pay and patient support programs in any evaluation of out-of-pocket costs.
5. **Hold at least one additional hearing and technical session** to walk stakeholders through the methodology, datasets, calculations, and

implementation mechanics of the UPL prior to any vote to adopt a UPL figure.

The lack of detailed information about UPL implementation has hindered the ability for key stakeholders to provide information sought by the Board in its data submission guide (DSG). Information must flow through the system to indicate where a UPL has been applied, and, given that such a UPL will be a novel administrative challenge to key stakeholders, doing so will require necessary changes in systems, and potentially infrastructure as well, that could take longer than six months to become fully operational.

The following provides greater detail on our continued objections, many of which have been raised in prior letters from Amgen to the Board:

I. The Rule Provides No Meaningful Notice or Methodology

Although the Board is now at its final planned rulemaking hearing, the Enbrel® UPL proposed rule remains essentially a blank template—announcing an intent to set a UPL but omitting both the proposed level or range and any process, method, or criteria for selecting a UPL figure. Restating statutory factors and listing "metrics the Board may consider" does not constitute a methodology and deprives stakeholders of the specificity required by the Colorado Administrative Procedure Act and due process.

II. The Board Must Define Where, How, and by or to Whom a UPL Applies

Based on the Board's statements and the State's representations in litigation, we understand the Board intends a UPL to apply to "downstream" transactions for drugs dispensed or administered to individuals in Colorado by any means, excluding federal programs and payors. As we have previously noted, stakeholders cannot assess compliance costs or access risks without, for instance, clear rules for determining applicability at the time of transaction, including for opt-in/opt-out ERISA plans, which constitute a substantial portion of the commercially insured market, and cross-border transactions. For example, where a medicine is acquired outside Colorado at a cost above the contemplated UPL, capping in-state payments below acquisition cost would predictably reduce provider willingness to stock the product, threatening patient access. We share other stakeholders' concerns that sites of care could become unable or unwilling to stock Enbrel®.

III. A UPL Threatens Significant Harm, and Implementation Details May Exacerbate that Harm

A UPL creates concrete, near-term risks across the drug supply chain and healthcare delivery system, and the details of how a UPL will be implemented may exacerbate those risks:

- **Patients.** Applying a UPL could drive formulary removals, less favorable tiering, or tighter utilization management for UPL drugs, while patients may still be charged cost-sharing based on static co-pays or coinsurance based on unadjusted rates. These are critical considerations given the Board's goal of reducing costs for patients. Key questions include:

  - How exactly drug availability impacts will be evaluated in a timely manner, and how the Board plans to monitor harmful effects caused by a UPL, such as an increase in non-medical switching;
  - The extent to which the Board views a UPL potentially triggering adverse formulary or utilization management (UM) changes; and
  - The extent to which patients may continue paying unadjusted out-of-pocket rates despite a UPL.
- **Providers.** Questions about UPL applicability, such as whether a particular self-funded plan has opted in, create uncertainty in reimbursement and acquisition costs, with potential cash-flow challenges that could discourage stocking UPL-priced drugs, among other considerations. Key questions include:
  - How providers will manage reimbursement and acquisition uncertainty;
  - What safeguards will prevent cash-flow disruptions when UPL applicability is unclear; and
  - How financial risks disincentivizing stocking will be mitigated.
- **Payers.** Colorado payers could reimburse transactions at normal, unadjusted rates for drugs acquired at UPL prices, misaligning payment with acquisition and leaving patient cost-sharing unchanged. Key questions include:
  - How payers may be aware a drug has been UPL-acquired; and
  - How out-of-state or pass-through dynamics will be addressed to avoid inappropriate spillover and cost-sharing distortions.

Any assertions that a UPL will not lead to significant negative consequences are unsupported absent a detailed and adequately vetted blueprint for implementation, eligibility signaling, claims adjudication, monitoring, auditing, enforcement, and subsequent UPL adjustment, among other critical considerations. The immediate risks are significant, and the Board lacks the information necessary to cast an informed vote.

IV. Unresolved Data Irregularities Preclude Informed Comment

Despite the Board's June 14, 2024, commitment to address questions Amgen has raised now for more than a year, there has been no response on key data aberrations and undisclosed methodologies. Recently disclosed PBM data miscategorizations (affecting roughly 7% of pharmacy claims) underscore the problem. Even basic figures have shifted materially across phases for the 2021 data year: 2,279 utilizers at eligibility/selection; 3,692 at affordability review (+62%); and 2,744 at UPL rulemaking (–25.7%). Without access to the Board's data and methods, stakeholders cannot validate these changes or understand the extent to which they have been corrected. The Board should publish a reconciliation memo, release relevant datasets or extracts, and allow technical review before proceeding.

VI. The Record Continues to Understate Manufacturer Assistance and Patient Impact

While Amgen detailed its support programs in an October 2, 2023, submission, this information appears only in Appendix K (p. 501 of 534) of the affordability report and has been largely discounted in subsequent meetings, including during the July 11, 2025, meeting. Reliance on Colorado APCD out-of-pocket data without incorporating key information on manufacturer assistance as it relates to the out-of-pocket data presented mischaracterizes patient costs. Any balanced UPL analysis must fully account for these programs when weighing patient out-of-pocket considerations alongside access risks.

VII. Legal Concerns

Proceeding toward a UPL in the absence of a previously adopted, transparent methodology, and without specific notice of the proposed level or analytical approach, is inconsistent with the Colorado Administrative Procedure Act and principles of due process. At a minimum, after development and adoption of a UPL implementation plan, the Board must re-notice the rule with the elements outlined herein (e.g., a proposed UPL amount and complete methodology, including data sources, weights, adjustments, exclusions, and decision criteria) and allow a meaningful opportunity for comment within the context of a detailed effectuation plan.

Conclusion and Path Forward

Amgen is driven by its mission to serve patients. We recognize concerns about prescription drug affordability, but an ill-defined UPL—adopted without transparent methods, reliable data, or functional information-sharing infrastructure, among other things—would increase access risks for Coloradans, including patients who rely on Enbrel®, particularly vulnerable pediatric populations.

We respectfully request that the Board pause the current rulemaking timeline, correct and document the data record, and shift focus to resolving UPL effectuation. Once UPL implementation can be understood by stakeholders, the Board should then re-notice the rule with the substantive information included necessary for stakeholders to assess the feasibility and risks of any UPL figure.

Regards,
/s/ Kathy Sherman

Kathy Sherman
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October 1, 2025

Via email (*dora_ins_pdab@state.co.us*)

Colorado Department of Regulatory Agencies
Division of Insurance
ATTN: Colorado Prescription Drug Affordability Review Board (PDAB or Board)
1560 Broadway, Suite 850
Denver, CO 80202

Re: Enbrel Upper Payment Limit (UPL) Rulemaking

Re: **Proposed Upper Payment Limit for Enbrel® (etanercept)**

Dear Members of the Board:

On behalf of Amgen Inc., its wholly owned subsidiary Immunex Corporation, and its indirect wholly owned subsidiary Amgen Manufacturing, Limited (collectively, "Amgen"), we submit these comments to object to the Board's proposed upper payment limit (UPL) for Enbrel®.

I. The Proposed UPL Would Not Result in Any Patient Paying Less for Enbrel

Amgen is driven by its mission to serve patients and committed to improving lives by discovering and developing treatments and cures for serious diseases. Amgen understands that the cost of prescription drugs is a concern for many Coloradans, but these concerns will only increase if the Board proceeds to set a UPL for Enbrel and ignores patients' voices.

The Board's rulemaking proceedings have underscored the Board's lack of focus on the many Colorado patients who use Enbrel. As patient advocates have pointed out, the proposed UPL would not provide any direct benefit to patients, because there is no evidence that any patient currently pays more than the proposed UPL out-of-pocket for Enbrel. This is due to a combination of insurance and Amgen's generous patient assistance programs. The Board has largely ignored Amgen's patient assistance programs in its assessment of "affordability," except to insist that Amgen has a "public obligation[]" to continue providing assistance at the same level even as the UPL would dramatically alter the payment and reimbursement landscape in ways not yet acknowledged by the Board. Consequently, any cost savings from a UPL will go not to patients, but to insurance companies.

Board members have not disputed this. Instead, they have emphasized that insurers are required to use any savings from a UPL to "reduce costs to consumers" in general, not to Enbrel patients specifically. The Board,

however, has made no effort to determine whether and to what extent a UPL on Enbrel would reduce insurance premiums or co-pays.

Moreover, this justification for a UPL—that it will reduce costs for insurers, which may or may not translate into marginally lower costs for commercial insurance—is utterly disconnected from the Board's putative reasons for subjecting Enbrel to a UPL. The Board determined that Enbrel was "unaffordable for Colorado consumers" based on claims that "the cost of Enbrel has made it difficult to access the drug" and that patients in Colorado "had trouble affording Enbrel." Yet the Board now acknowledges that a UPL will do nothing to make Enbrel more affordable for patients or improve access.

This is not surprising, because Enbrel is already affordable for patients. As Amgen explained in its October 2, 2023, submission, "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." In concluding that Enbrel was nonetheless "unaffordable" for patients in Colorado, the Board relied on a handful of comments during public meetings and survey responses from 38 Colorado residents—amounting to, at most, roughly 1.5% of the 2,500+ patients who use Enbrel in Colorado each year. The Board never made any effort to determine whether the information it gleaned from this tiny sample was representative of patients' experiences with Enbrel, and it plainly was not.

In sum, the Board's determination to establish a UPL for Enbrel is a solution to a supposed affordability problem that does not exist and would not be helped by a UPL if it did exist. Moreover, Board members have repeatedly acknowledged that they have no clear understanding of whether a UPL will harm patients, with one member insisting that "no one can predict exactly what will happen" if a UPL is established. This uncertainty also reflects the Board's failure to provide any details about how a UPL will be implemented – the absence of which has been raised as a key concern by representatives of critical components of the delivery system, such as the Colorado Pharmacists Society[1] and Healthcare Distribution Alliance[2]. Rather than rush to impose a UPL on Enbrel with no idea what the consequences may be, the Board should listen to stakeholders, such as patients, caregivers, and advocacy groups, who have repeatedly warned the Board of the unintended negative consequences of a UPL.[3]

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[1] *See* Verbal Testimony of Emily Zadvorny, Executive Director of the Colorado Pharmacists Society to the Colorado Prescription Drug Affordability Review Board (Aug. 23, 2025).

[2] *See* Written and Verbal Testimony of Leah Lindahl, Vice President, State Government Affairs, Healthcare Distribution Alliance, to the Colorado Prescription Drug Affordability Review Board (May 23, 2025).

[3] *See also* Written Testimony from Kathy Sherman, Associate Vice President, State and International Government Affairs, Amgen, to the Colorado Prescription Drug Affordability Review Board (Aug. 20, 2025),

II. The Proposal to Adopt the Federal MFP as the State UPL for Enbrel Is Improper

The Colorado legislature required the Board, before establishing any UPLs, to "determine by rule the methodology for establishing an upper payment limit." As Amgen has pointed out many times (with no response from the Board), the Board violated that legislative mandate by holding rulemaking hearings to set a UPL for Enbrel without ever establishing a methodology for setting UPLs. The lack of a clear methodology has made it impossible for Amgen and other stakeholders to participate meaningfully in the rulemaking process.

The Board's failure to establish a mandated methodology culminated in the Board's proposal, at the third Enbrel UPL rulemaking hearing on August 22, 2025, to set the UPL for Enbrel at a price that the Board deemed equivalent to the federal "maximum fair price" (MFP). The Board did not perform any independent analysis to determine whether the federal MFP would be appropriate as a UPL in Colorado. Instead, Board members stated that they could avoid the difficulty of determining an appropriate UPL by simply adopting the MFP. As one Board member stated: "I know a lot of people are concerned. How are you going to come up with that price? What is the calculation? Where's the research? Well, in this instance, it was already done at that level." This is improper for several reasons.

First, the Board members' comments show that the Board fundamentally misunderstands the federal MFP. Board members repeatedly suggested that Amgen's participation in the so-called "negotiation" process required by the federal Inflation Reduction Act (IRA) implies that Amgen "agreed to" or was "amenable to" the MFP. That is wrong.

Regarding a drug's federal MFP as a "negotiated" price to which the drug's manufacturer has voluntarily "agreed" is deeply misleading. As Amgen and other drug manufacturers have explained, the IRA does not provide for any meaningful negotiations. Instead, after an exchange of offers bounded by an already drastically low statutory ceiling price, the MFP is unilaterally dictated by the Centers for Medicare and Medicaid Services (CMS). A manufacturer that does not "agree" to the price CMS demands faces a massive, punitive "excise tax" that quickly rises to 19 times the manufacturer's total revenue for the drug. The manufacturer's only alternative is to withdraw all its drugs from Medicare and Medicaid, which together account for nearly half of the national market for prescription drugs. Such withdrawal would cause severe financial harm to the manufacturer and deprive patients nationwide of access to critical medicines.

CMS uses these overwhelming threats to force drug manufacturers to "agree" to the government's price even when it is far below a level that the

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https://doi.colorado.gov/sites/doi/files/documents/August%2022%20Written%20Testimonies.pdf.

manufacturer considers fair and reasonable. Amgen thus had no choice but to adopt the MFP dictated by CMS. To be clear, Amgen strongly disagrees that the MFP is the "maximum fair price" for Enbrel—it is not even *a* fair price. Amgen would never agree to sell Enbrel for this price in a genuine negotiation.[4]

Second, an MFP regulates only the price charged for a drug in sales to individuals and entities participating in Medicare. It is not intended to be, and cannot logically be repurposed as, a price cap for sales made in the private market.

When CMS establishes an MFP, it is well aware that the MFP will not apply to private sales, which account for roughly half of the national market for prescription drugs. CMS is thus able to set the MFP for sales to Medicare at an extremely low level while assuming that sales in private markets will continue to provide a return on the manufacturer's investment and incentivize further innovation.

There is no evidence that CMS concluded the Enbrel MFP would be an appropriate price cap for all transactions for Enbrel across both public Medicare and private markets. Nor is there any basis to assume that CMS would have set the MFP for Enbrel at the same low level if it had been charged with establishing a price cap for private as well as public Medicare transactions.

For its part, the Board has not explained why extending the MFP to private markets is appropriate. Among other things, it has not performed any analysis to show that extending the MFP to private sales would not harm patients and destroy incentives for manufacturers to invest in developing innovative prescription drugs.

In this regard, it is significant that federal law requires Medicare Part D prescription drug plans to cover MFP drugs. This requirement prevents PDPs from dropping an MFP drug from their formularies because the capped price does not allow for the same level of manufacturer rebates.[5] Colorado law does not include any similar requirement, and the Board has not performed any analysis to determine whether the proposed UPL would result in PBMs/insurers dropping Enbrel from their formularies, leading to reduced patient access. Indeed, despite ostensibly being on the cusp of adopting a UPL, the Board has failed to even develop the details on how the UPL would

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[4] For these reasons, Amgen supports the constitutional challenge to the IRA brought by the Pharmaceutical Research and Manufacturers of America (PhRMA), of which Amgen is a member. That challenge is pending in the U.S. Court of Appeals for the Fifth Circuit. *See Nat'l Infusion Ctr. Ass'n v. Kennedy*, No. 25-50661. Regardless of the outcome of that case, the simple fact is that Amgen had no meaningful choice but to accept the MFP dictated by CMS.

[5] *See* 42 U.S.C. § 1395w-104(*l*).

be effectuated across eligible private transactions to individuals within the state of Colorado.

Third, contrary to suggestions made by Board members, there is no evidence that the federal MFP reflects a reasoned analysis of the factors that are relevant to establishing a UPL under Colorado law.

CMS did not provide any meaningful explanation of how it arrived at the MFP. While CMS has published a document purporting to explain how the MFP was determined, that document states only that CMS "considered certain negotiation factors" and "took into account all data in totality." CMS's process for establishing the MFP is a black box: CMS claims to have considered various factors and data (not all of which is public), but it is impossible to know how CMS weighed the factors or how it used the data to calculate the MFP.

For the Board to simply adopt this black-box MFP as the UPL, without conducting any independent analysis of whether the MFP represents a fair and reasonable price for Enbrel, would abdicate the Board's statutory responsibility for setting UPLs. This abdication is made even more problematic by the fact that CMS is not even required to consider the same factors as the Board. For example, the legislature directed the Board to consider "the impact [of a UPL] to older adults and persons with disabilities," but no similar requirement applies to CMS. Adopting the MFP as the UPL is also contrary to the Board's own regulations, which state the MFP is one of numerous factors the Board may consider in setting a UPL, but which do not allow the Board to rely on the MFP to the exclusion of all other factors.

Accordingly, while it might be appropriate to consider the MFP as a *lower bound* on any UPL (since Congress instructed CMS to "achieve the lowest maximum fair price for each selected drug"), it is improper for the Board to set the UPL at the same level as the MFP without independent analysis. The Board cannot refuse to do its job under Colorado law just because that job is difficult.

Conclusion and Path Forward

Amgen is driven by its mission to serve patients. We recognize concerns about prescription drug affordability, but a UPL as currently proposed would discourage pharmaceutical innovation and substantially increase access risks for Coloradans, including patients who rely on Enbrel®, particularly vulnerable pediatric populations. The scope of such risks can only be exacerbated by the absence of appropriate independent analyses and of critical implementation details.

We respectfully request that the Board pause the current rulemaking timeline; address stakeholders' concerns, including those discussed above; and pursue non-UPL efforts and recommendations that will reliably and meaningfully benefit patients.

Regards,
/s/ Kathy Sherman

Kathy Sherman
Associate Vice President, State and International Government Affairs
Global Government Affairs & Policy

COLORADO
Prescription Drug Affordability Board
Division of Insurance

Upper Payment Limit Data Submission Guide

Purpose: This document is meant to provide guidance for stakeholders that are interested in submitting information to the Prescription Drug Affordability Board's (PDAB, the Board) consideration prior to a specific drug's upper payment limit (UPL) rulemaking. The Board will consider the data outlined in the PDAB Staff Data Memo, in addition to any submissions from stakeholders, to determine a UPL for the drugs under review.

This data submission guide (DSG) addresses the:

- Form and manner in which stakeholders can submit data and information,
- Timeline for submission of data before a UPL rulemaking hearing, and
- Types of data requested from different stakeholder groups.

The DSG is meant as a guide; stakeholders are encouraged to submit additional information not outlined in this guide for the Board's consideration.

For more information on PDAB rulemaking, see the linked PDAB Rulemaking Guide folder.

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Exhibit 55

COLORADO
Prescription Drug Affordability Board
Division of Insurance

Data Submission Timeline, Instructions & Requirements

Stakeholders who wish to submit information for the Board's review and consideration should review the PDAB website for the most up-to-date submission deadline. Stakeholders submitting any written testimony, via the DSG or another method, are encouraged to attend the rulemaking hearing they are submitting the information for and also sign up for verbal testimony for the hearing.

Stakeholders are encouraged to provide information on the drug-specific data elements described in this document. Additionally, the Board welcomes any other information that may be helpful when considering a drug's UPL.

Respondents may provide the requested data to the Board by:

- Using the linked forms under each stakeholder type outlined below, or
- Submitting documentation to the staff via email at dora_ins_pdab@state.co.us.

All stakeholders submitting information are asked to provide contact information for the person who will be able to answer questions about the submitted information, particularly if the person submitting is *not* the one to be contacted regarding the submission. Please include:

- Name of Affiliation or Organization
- Contact Name and Title
- Email address
- Telephone number
- City, State, Zip Code

Stakeholders should ensure that the information they are submitting is accurately calculated, thoroughly explained, and includes well-cited sources. It is most helpful to the Board when stakeholders fully illustrate the relevance of their data submission to a specific drug's UPL and how it may help in the Board's decision-making process.

Research and Methods that Employ a Dollars-per-QALY

Per section 10-16-1407(4)(a), C.R.S., the Board shall not consider research or methods that employ a dollars-per-quality adjusted life year (QALY), or similar measure that discounts the value of a life because of an individual's disability or age (see Appendix A for a list of QALY-related terms). Any submissions that include QALYs, as attested by the submitter, will not be provided to the Board for consideration during UPL rulemaking. Staff and contractors may review submissions for QALYs before the submitted information is provided to the Board. Additionally, stakeholders submitting information for the Board's consideration will be asked to attest that either:

- The data or research submitted does not use a QALY or similar measure, or
- Identify that the data or research submitted uses a QALY so that staff may remove it from the Board's consideration.

Submitting Confidential Data

Information containing confidential, proprietary, or trade secret information must be submitted to the Board through a secure File Transfer Protocol (FTP). Stakeholders can request access by emailing staff at dora_ins_pdab@state.co.us. More information on the confidential information submission process document linked here.

COLORADO
Prescription Drug Affordability Board
Division of Insurance

Requested Data Elements

The following section details separate submission requests for:

- **Impact to Older Adults and Persons with Disabilities**
- **Supply Chain Entities** including:
  - Manufacturers
  - Wholesalers
  - Carriers
  - Pharmacy Benefit Managers (PBMs)
  - Pharmacies/Providers

Stakeholders can utilize the linked submission forms at the beginning of each section to submit the requested data elements. Please note that the submission forms are for non-confidential information only. For instructions on how to submit confidential information, please see the confidential information submission process document.

Submissions Regarding Impact to Older Adults and Persons with Disabilities

Stakeholders can submit non-confidential information regarding impact to older adults and persons with disabilities via the submission form linked here.

Stakeholders with lived experience or expertise of the prescription drug's impact on older adults and persons with disabilities are encouraged to submit information to the Board for a drug's UPL rulemaking. The submission can be submitted as written and/or verbal testimony. Though statute specifically addresses the impact to older adults and persons with disabilities, the Board values and welcomes input from all stakeholders impacted by the prescription drug.

Information that may be helpful regarding the prescription drug's impact to older adults and persons with disabilities include:

- Qualitative and quantitative analyses on the impact of the drug on older adults and/or persons with disabilities,
- Clinical effectiveness of the drug compared to its therapeutic alternatives (TAs),
- Any differences in the drug's use or effects for older adults or persons with disabilities (e.g., sensitivity to side effects, adverse effects from taking multiple medicines simultaneously, cognitive impact, impact on daily functioning, comorbidities, etc.),
- Though staff may research certain disability information, they will not make a definitive decision about whether an indication or condition treated by the drug could result in a disability. Stakeholders should describe if an indication or condition treated by the drug could result in a disability and provide their reasoning (e.g., the indication or condition could cause an impairment that could substantially limit one or more major life activities, etc.),
- Information about patient assistance programs:
  - Ease of application process
  - Required paperwork
  - Types of assistance programs, the name of the programs, and their eligibility criteria (e.g. coupon programs vs. assistance programs)
- Any other information you would like the Board to know regarding the drug's impact on older adults and/or persons with disabilities.

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The Board will not accept or consider any research that uses a QALY or similar measure, in accordance with section 10-16-1407(3), C.R.S. Please ensure that all submitted information is well cited and does not contain QALYs or similar measures. See Appendix A for a list of measures that may be similar to QALYs.

Submissions from Supply Chain Entities

The Board requests additional data and information to understand how a potential UPL may impact different supply chain entities, including manufacturers, wholesalers, PBMs, carriers, and providers and pharmacists. Specific data elements that may be helpful to the Board can be divided into the categories below. Note that not all of the categories may be relevant for each supply chain entity.

- **Transactions:** Details on transactions between entities that purchase, sell, reimburse, or otherwise participate in the prescription drug supply chain, including sales information and utilization information.
- **Rebates and Discounts:** Details regarding any rebates or discounts an entity receives or grants another entity that lowers the overall cost of the prescription drug. Provide a range where necessary.
- **Plan Design:** Details regarding decisions on health plan coverage, copayments, coinsurance, deductibles, and cost-sharing.

For each of the requested data elements below, please provide both:

1. Current data for each category, and
2. Projections on how the data may be impacted after a specific dollar amount UPL is set. Provide an explanation for your projection.

Additionally, for the requested data elements below, please provide the following information as relevant:

- Provide multiple years of data and indicate which years you are reporting,
- Describe data sources, including line of business and payer type (e.g., Medicare, Medicaid, commercial) as applicable,
- Show calculations, and
- Outline methodologies and assumptions as needed to better understand data provided.

Finally, please specify if data is presented at the National Drug Code (NDC) level, aggregate level, or another level for the selected drug. If an entity is also submitting information for a selected drug's TAs, please provide the same information (see Appendix B for the list of TAs for Enbrel; see Appendix C for the list of NCD-11s for Enbrel and its TAs).

Information requested of each supply chain entity can be found below.

Manufacturer Submissions

Manufacturers can submit non-confidential information via the submission form linked here.

To help the Board understand the impact of a potential UPL on manufacturers, please respond to the following questions:

- What factors would affect your decision to purchase and/or sell the prescription drug in question?
- How would a UPL impact patients, specifically in the form of lower premiums or out-of-pocket amounts?
- Do you currently participate in the 340B program?

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Manufacturers are encouraged to report both current and projected data at the NDC level for the following requested data elements. Additionally, in a narrative format, provide additional information on the calculation methods, assumptions, interpretations, and caveats related to the data requested in this section.

Transactions

- **Sales, Purchases, and Reimbursements**
  - **Total sales in Colorado:** The total sales of the drug in Colorado, separated by sales to wholesalers and direct purchasers, as applicable.
  - **Average manufacturer price**: The total cost of making the drug, including time for development, rebates, and discounts.
  - **Average price charged:** The average price charged to purchasers, separated by wholesalers and direct purchasers as applicable. Information should include minimum, maximum, median, and mean.
- **Units and Utilization**
  - **Total units sold in Colorado:** The total number of units of the drug sold in Colorado, separated by sales to wholesalers and direct purchasers, if applicable.

Rebates and Discounts

- **Net prices in Colorado:** The net price of the drug after discounts and rebates. Information should include minimum, maximum, median, and mean.
- **Average rebates and discounts in Colorado:** The average rebates and discounts provided to commercial payers for the drug in Colorado, excluding 340B discounts.
- **Percent of sales of the drug sold in Colorado to 340B providers**
- **Assistance programs offered by the manufacturer:** Documentation explaining manufacturer assistance programs (if any) offered for the drug[1] and how this program helps patients in Colorado with cost-sharing. Please include the following:
  - What is the name of the assistance program?
  - Who is eligible for the assistance program?
  - How is the assistance program designed?
  - How do patients apply, and what is the application process?
  - How is the assistance provided (e.g., co-pay card, reimbursement)?
  - Is the application form available in other languages? If so, which ones and how many?
  - How long does review and approval of each application take?
  - Please submit a copy of an application form for the Board's review.

Wholesaler Submissions

Wholesalers can submit non-confidential information via the submission form linked here.

To help the Board understand the impact of a potential UPL on wholesalers, please respond to the following questions:

- What factors would affect your decision to purchase and/or sell the prescription drug in question?
- How would a UPL impact patients, specifically in the form of lower premiums or out-of-pocket amounts?

[1] Information on manufacturer assistance programs was also requested during each drug's affordability review.

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Wholesalers are encouraged to report both current and projected data at the NDC level for the following requested data elements. In a narrative format, provide additional information on the calculation methods, assumptions, interpretations, and caveats related to the data requested in this section.

Transactions

- **Sales, Purchases, and Reimbursements**
  - **Total sales in Colorado:** The total sales for the drug in Colorado.
  - **Average price per unit charged to purchasers in Colorado:** The average price charged per unit by type of sales (340B vs. WAC). Information should include minimum, maximum, median, and mean.
  - **Percentage of sales in Colorado**: The percentage of sales for the drug in Colorado by type (340B vs. WAC).
- **Units and Utilization**
  - **Total units filled in Colorado:** The total number of units of the drug filled in Colorado by type (340B vs. WAC).
  - **Total units purchased in Colorado:** The total number of units purchased directly from the manufacturer for each payer type. Please indicate the amount of units sold that are expected to be used by Colorado consumers.

Net Price and Chargebacks

- **Net prices in Colorado:** The net price of the drug after any discounts. Information should include minimum, maximum, median, and mean across contracts in Colorado, not including 340B estimates.
- **Average chargebacks received from a manufacturer for business in Colorado:** The average chargebacks received from a manufacturer in Colorado by type of discount.

Carrier Submissions

Carriers can submit non-confidential information via the submission form linked here.

To help the Board understand the impact of a potential UPL on carriers, please respond to the following questions:

- What factors would affect your decision to cover/reimburse the prescription drug in question?
- How would a UPL impact patients, specifically in the form of lower premiums or out-of-pocket amounts?

Carriers are encouraged to report both current and projected data at the NDC level for each type of plan for the following requested data elements. In a narrative format, provide additional information on the calculation methods, assumptions, interpretations, and caveats related to the data requested in this section.

Transactions

- **Sales, Purchases, and Reimbursements**
  - **Total reimbursement amount:** The total reimbursement for the drug.
  - **Patient cost-sharing:** The drug's average out-of-pocket amount, and the change in patient cost-sharing over time.
- **Units and Utilization**
  - **Total units:** The total number of units for which a carrier reimbursed for the drug.
  - **Utilization:** The number of covered patients using the drug.

Rebates and Discounts

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- **Average revenues from rebates for the drug:** The average revenue received from rebates for the drug. Provide an explanation for how you use the revenue (e.g., to reduce premiums, reduce general out-of-pocket costs, reduce out-of-pocket costs for specific drugs, administration, profits, etc)
- **Other retail discounts and fees:** Any additional discounts, concessions, and fees received for the drug.

Plan design

- **Describe any utilization management practices for the drug** (e.g., prior authorization requirements, step therapy, drug tier, drug adherence, etc.) for the drug and TAs.
- **Describe how a UPL might impact:**
  - Formulary placement,
  - Cost-sharing, and/or
  - Benefit design

Pharmacy Benefit Manager (PBM) Submissions

PBMs can submit non-confidential information via the submission form linked here.

To help the Board understand the impact of a potential UPL on PBMs, please respond to the following questions:

- What factors would affect your decision to cover/reimburse the prescription drug in question?

PBMs are encouraged to report both current and projected data at the NDC level for the following requested data elements. In a narrative format, provide additional information on the calculation methods, assumptions, interpretations, and caveats related to the data requested in this section.

Transactions

- **Sales, Purchases, and Reimbursements**
  - **Total reimbursement amount:** The total reimbursement for the drug.
  - **Gross and net revenues for the drug:** The gross and net revenues for the drug in Colorado.
  - **Patient cost-sharing:** The drug's average out-of-pocket amount, and the change in patient cost-sharing over time.
- **Units and Utilization**
  - **Total units:** The total number of units for which a carrier reimbursed for the drug.
  - **Utilization:** The number of covered patients using the drug.

Rebates and Discounts

- **Average revenues from rebates for the drug:** The average revenue received from rebates for the drug. Provide an explanation for how you use the revenue (e.g., to reduce premiums, reduce general out-of-pocket costs, reduce out-of-pocket costs for specific drugs, administration, profits, etc).
- **Total discounts and other fees paid to pharmacies, prescription drug networks, or pharmacy services administrative organizations in Colorado:** The dollar amount or percentage of discounts or fees paid to pharmacies in Colorado.

Plan design

- **Describe any utilization management practices for the drug** (e.g., prior authorization, step therapy, drug tier, drug adherence, etc.)

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- **Describe how a UPL might impact:**
  - Formulary placement,
  - Cost-sharing,
  - Benefit design, and/or
  - Copayment and coinsurance amounts

Pharmacy/Provider Submissions

Pharmacies/providers can submit non-confidential information via the submission form linked here.

To help the Board understand the impact of a potential UPL on pharmacies, please respond to the following questions:

- Are you an independent pharmacy, specialty pharmacy, retail pharmacy, or healthcare provider's office?
- What factors would affect your decision to purchase and/or sell the prescription drug in question?
- How would a UPL impact patients, specifically in the form of lower premiums or out-of-pocket amounts?
- Is this drug purchased directly from the manufacturer or from a drug distributor? If yes, provide a percentage of the drug purchased from the manufacturer and drug distributor.
- What percentage of prescriptions for the drug from your pharmacy, if any, have to be transferred due to being out-of-network?

Pharmacies are encouraged to report both current and projected data at the NDC level for the following requested data elements. In a narrative format, provide additional information on the calculation methods, assumptions, interpretations, and caveats related to the data requested in this section.

Transactions

- **Sales, Purchases, and Reimbursements**
  - **Average purchase price:** The average price the pharmacy purchased the drug by type (340B vs. Medicaid).
  - **Average reimbursement to the pharmacy by insurance type**: The average discount from the average wholesale price as paid by insurance to the pharmacy for the drug.
  - **Total cost**: Drug net cost after discounts and any price adjustment, not including dispensing fees.
  - **Total reimbursement by insurance type**: The total discount negotiated by insurance, including dispensing fees.
  - **Total dispensing fees by type**: The total cost of preparing and dispensing the drugs, including services cost by type (340B vs. Medicaid).
  - **Total sales price of the drug:** The total price and/or reimbursement for the drug (i.e., the average dollars recouped from carrier reimbursement and patient payments). Information should include minimum, maximum, median, and mean.
  - **Percentage of the drug purchased at**: 340B, WAC.
- **Units and Utilization**
  - **Total unit dispensed:** The total number of prescriptions for the drug that were filled.
  - **Utilization:** The total number of patients that filled the prescriptions for the drug.

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- **Cards, coupons, manufacturer discounts, or other discounts:** A description of, and the total dollar amount or any percentage of any cards, coupons, manufacturer discounts, or other discounts patients may receive for the drug, including alternative entities such as Single Care or GoodRx.

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Appendix A

QALY-Related Search Terms[2] [3]

- Utility/utilities
  - Health state utility/utilities
  - Disutility
- Quality-adjusted life-year
- QALYs
- Cost-utility analysis
- Cost effectiveness analysis
- Health years in total (HYT)
- Health-related quality of life (HRQoL)
- EuroQol 5D
- EQ-5D (including EQ-5D-3L and EQ-5D-5L; both of these measures have been developed specifically to estimate QALYs)
- Health utilities index (HUI and HUI-3; also developed to estimate QALYs)
- Short Form 6D (SF-6D)
- Preferences
- Preference elicitation
- Generic preference-based measure
- Disease-specific measure
- Multi-attribute utility theory (MAUT)
- Person trade-off (PTO)
- Time trade-off (TTO)
- Standard gamble (SG)
- Visual analogue scale (VAS)
- Rating scale
- Discrete choice experiment (DCE)

[2] Brazier J, Ratcliffe J, Saloman J, Tsuchiya A. Measuring and Valuing Health Benefits for Economic Evaluation. Vol 1. Oxford University Press; 2016. doi:10.1093/med/9780198725923.001.0001

[3] Drummond MF, Sculpher M, Claxton K, Stoddart GL, Torrance GW. Methods for the Economic Evaluation of Health Care Programmes. Fourth edition. Oxford University Press; 2015.

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Appendix B

Brand and Generic Names for Enbrel and Therapeutic Alternatives (TAs)

Brand Name(s)	Generic Name
Abrilada	Adalimumab-afzb
Abrilada	Adalimumab-atto
Avsola	Infliximab-axxq
Cimzia	Certolizumab pegol
Cyltezo, Adalimumab-abdm, Adalimumab-abdm (Quallent)	Adalimumab-abdm
Enbrel	Etanercept
Hadlima	Adalimumab-bwwd
Hulio, Adalimumab-fkjp	Adalimumab-fkjp
Humira	Adalimumab
Hyrimoz, Hyrimoz (Cordavis), Adalimumab-adaz	Adalimumab-adaz
Idacio, Adalimumab-aacf	Adalimumab-aacf
Inflectra	Infliximab-dyyb
Remicade, Infliximab	Infliximab
Renflexis	Infliximab-abda
Simlandi, Adalimumab-ryvk (Quallent)	Adalimumab-ryvk
Simponi, Simponi Aria	Golimumab
Yuflyma, Adalimumab-aaty	Adalimumab-aaty
Yusimry	Adalimumab-aqvh

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Appendix C

NDC-11s for Enbrel and Therapeutic Alternatives (TAs)

NDC	Brand Name(s)
00025-0328-02	ABRILADA(CF)
00025-0333-02	ABRILADA(CF)
00069-0328-02	ABRILADA(CF)
00069-0333-02	ABRILADA(CF)
00025-0325-01	ABRILADA(CF) PEN
00025-0325-02	ABRILADA(CF) PEN
00069-0325-01	ABRILADA(CF) PEN
00069-0325-02	ABRILADA(CF) PEN
65219-0612-89	ADALIMUMAB-AACF 40MG/0.8ML STARTER PACK CROHN'S, UC, HS
65219-0612-69	ADALIMUMAB-AACF STARTER PLAQUE PSORIASIS
65219-0618-02	ADALIMUMAB-AACF(CF)
65219-0620-20	ADALIMUMAB-AACF(CF)
65219-0612-99	ADALIMUMAB-AACF(CF) PEN
65219-0612-89	ADALIMUMAB-AACF(CF) PEN CROHNS
65219-0610-02	ADALIMUMAB-AACF(CF) PEN PS-UV
65219-0612-69	ADALIMUMAB-AACF(CF) PEN PS-UV
72606-0040-04	ADALIMUMAB-AATY 80MG/0.8ML AUTOINJECTOR
72606-0022-06	ADALIMUMAB-AATY(CF)
72606-0041-01	ADALIMUMAB-AATY(CF)
72606-0022-10	ADALIMUMAB-AATY(CF) AUTOINJ(2)
72606-0022-09	ADALIMUMAB-AATY(CF) AUTOINJECT
72606-0040-04	ADALIMUMAB-AATY(CF) AUTOINJECT
61314-0327-64	ADALIMUMAB-ADAZ(CF)
61314-0327-20	ADALIMUMAB-ADAZ(CF) PEN
00597-0575-60	ADALIMUMAB-ADBM 40MG/0.4ML INJ,PEN,CROHN-UC-H
00597-0575-40	ADALIMUMAB-ADBM 40MG/0.4ML INJ,PEN,PSORIASIS-UVEITIS
00597-0545-44	ADALIMUMAB-ADBM 40MG/0.8ML INJ,PEN,PSORIASIS
00597-0545-66	ADALIMUMAB-ADBM 40MG/0.8ML INJ,PEN,UC-HS STAR
00597-0555-80	ADALIMUMAB-ADBM(CF)
00597-0565-20	ADALIMUMAB-ADBM(CF)
00597-0585-89	ADALIMUMAB-ADBM(CF)

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NDC	Brand Name(s)
00597-0595-20	ADALIMUMAB-ADBM(CF)
82009-0146-22	ADALIMUMAB-ADBM(CF)
82009-0150-22	ADALIMUMAB-ADBM(CF)
00597-0575-50	ADALIMUMAB-ADBM(CF) PEN
82009-0144-22	ADALIMUMAB-ADBM(CF) PEN
00597-0545-66	ADALIMUMAB-ADBM(CF) PEN CROHNS
00597-0575-60	ADALIMUMAB-ADBM(CF) PEN CROHNS
00597-0545-44	ADALIMUMAB-ADBM(CF) PEN PS-UV
00597-0575-40	ADALIMUMAB-ADBM(CF) PEN PS-UV
00597-0545-22	ADALIMUMAB-ADBM(CF)PEN
82009-0148-22	ADALIMUMAB-ADBM(CF)PEN
49502-0416-02	ADALIMUMAB-FKJP
49502-0417-02	ADALIMUMAB-FKJP
49502-0418-02	ADALIMUMAB-FKJP
83257-0020-42	ADALIMUMAB-FKJP(CF)
83257-0021-42	ADALIMUMAB-FKJP(CF)
83257-0022-32	ADALIMUMAB-FKJP(CF) PEN
82009-0158-22	ADALIMUMAB-RYVK(CF)
82009-0156-22	ADALIMUMAB-RYVK(CF) AUTOINJECT
55513-0481-01	AMJEVITA 80MG/0.8ML AUTOINJECTOR
55513-0481-02	AMJEVITA 80MG/0.8ML AUTOINJECTOR
50090-6411-00	AMJEVITA(CF)
55513-0399-01	AMJEVITA(CF)
55513-0410-01	AMJEVITA(CF)
55513-0411-01	AMJEVITA(CF)
55513-0413-01	AMJEVITA(CF)
55513-0479-01	AMJEVITA(CF)
55513-0479-02	AMJEVITA(CF)
50090-6428-00	AMJEVITA(CF) AUTOINJECTOR
55513-0400-01	AMJEVITA(CF) AUTOINJECTOR
55513-0400-02	AMJEVITA(CF) AUTOINJECTOR
55513-0481-01	AMJEVITA(CF) AUTOINJECTOR
55513-0481-02	AMJEVITA(CF) AUTOINJECTOR

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NDC	Brand Name(s)
55513-0482-01	AMJEVITA(CF) AUTOINJECTOR
55513-0482-02	AMJEVITA(CF) AUTOINJECTOR
72511-0400-01	AMJEVITA(CF) AUTOINJECTOR
72511-0400-02	AMJEVITA(CF) AUTOINJECTOR
55513-0670-01	AVSOLA
83457-0124-02	CDV HUMIRA(CF) PEN 80 MG/0.8 ML
83457-0107-01	CDV HYRIMOZ(CF) PEN 80 MG/0.8 ML
83457-0113-01	CDV HYRIMOZ(CF) PEN CROHNS-ULCER COLITIS START 80 MG/0.8 ML
83457-0112-01	CDV HYRIMOZ(CF) PEN PSORIASIS START 80 MG/0.8 ML-40 MG/0.4ML
50474-0700-62	CIMZIA
50474-0710-79	CIMZIA
50474-0710-81	CIMZIA
50474-0750-10	CIMZIA
50474-0710-81	CIMZIA 2X200 MG/ML START KT
00597-0495-40	CYLTEZO 40MG/0.4ML INJ,PEN,PSORIASIS-UVEITIS
00597-0370-82	CYLTEZO(CF)
00597-0400-89	CYLTEZO(CF)
00597-0405-80	CYLTEZO(CF)
00597-0485-20	CYLTEZO(CF)
00597-0495-60	CYLTEZO(CF) 40MG/0.4ML INJ,PEN,CROHN-UC-H
00597-0375-97	CYLTEZO(CF) PEN
00597-0495-50	CYLTEZO(CF) PEN
00597-0375-16	CYLTEZO(CF) PEN CROHN'S-UC-HS
00597-0495-60	CYLTEZO(CF) PEN CROHN'S-UC-HS
00597-0375-16	CYLTEZO(CF) PEN CROHN'S-UC-HS STARTER 40 MG/0.8 ML
00597-0375-23	CYLTEZO(CF) PEN PSORIASIS-UV
00597-0495-40	CYLTEZO(CF) PEN PSORIASIS-UV
00597-0375-23	CYLTEZO(CF) PEN PSORIASIS-UVEITIS STARTER 40 MG/0.8 ML
58406-0010-01	ENBREL
58406-0010-04	ENBREL
58406-0021-01	ENBREL
58406-0021-04	ENBREL
58406-0055-01	ENBREL

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NDC	Brand Name(s)
58406-0055-04	ENBREL
58406-0044-01	ENBREL MINI
58406-0044-04	ENBREL MINI
58406-0032-01	ENBREL SURECLICK
58406-0032-04	ENBREL SURECLICK
50090-6705-00	HADLIMA
78206-0183-01	HADLIMA
78206-0183-99	HADLIMA
50090-6706-00	HADLIMA PUSHTOUCH
78206-0184-01	HADLIMA PUSHTOUCH
78206-0184-99	HADLIMA PUSHTOUCH
50090-6704-00	HADLIMA(CF)
78206-0186-01	HADLIMA(CF)
78206-0186-99	HADLIMA(CF)
50090-6707-00	HADLIMA(CF) PUSHTOUCH
78206-0187-01	HADLIMA(CF) PUSHTOUCH
78206-0187-99	HADLIMA(CF) PUSHTOUCH
83257-0016-42	HULIO
83257-0017-42	HULIO
83257-0019-32	HULIO PEN
00074-3799-02	HUMIRA
00074-0124-02	HUMIRA 80MG/0.8ML INJ PEN KIT
00074-0124-03	HUMIRA 80MG/0.8ML INJ,PEN,CROHNS STARTER
00074-4339-01	HUMIRA PEN
00074-4339-02	HUMIRA PEN
00074-4339-74	HUMIRA PEN
50090-4487-00	HUMIRA PEN
00074-0243-02	HUMIRA(CF)
00074-0616-02	HUMIRA(CF)
00074-0817-02	HUMIRA(CF)
83457-0243-02	HUMIRA(CF)
83457-0616-02	HUMIRA(CF)
83457-0817-02	HUMIRA(CF)

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NDC	Brand Name(s)
00074-0124-04	HUMIRA(CF) 80MG/0.8ML INJ,PEN,CD-UC-HS STARTER PKG
00074-0124-02	HUMIRA(CF) PEN
00074-0124-74	HUMIRA(CF) PEN
00074-0554-02	HUMIRA(CF) PEN
00074-0554-71	HUMIRA(CF) PEN
83457-0124-02	HUMIRA(CF) PEN
83457-0554-02	HUMIRA(CF) PEN
00074-0124-03	HUMIRA(CF) PEN CROHN'S-UC-HS
00074-0124-04	HUMIRA(CF) PEN PEDIATRIC UC
00074-1539-03	HUMIRA(CF) PEN PSOR-UV-ADOL HS
00074-1539-03	HUMIRA(CF) PEN PS-UV-ADOL HS START 80 MG/0.8 ML-40 MG/0.4 ML
83457-0103-01	HYRIMOZ
83457-0203-56	HYRIMOZ
83457-0102-01	HYRIMOZ PEN
83457-0202-50	HYRIMOZ PEN
61314-0473-64	HYRIMOZ(CF)
61314-0476-64	HYRIMOZ(CF)
61314-0509-64	HYRIMOZ(CF)
83457-0101-01	HYRIMOZ(CF)
83457-0108-01	HYRIMOZ(CF)
83457-0201-46	HYRIMOZ(CF)
61314-0454-20	HYRIMOZ(CF) 80MG/0.8ML INJ,PEN
61314-0454-68	HYRIMOZ(CF) 80MG/0.8ML INJ,PEN
61314-0454-36	HYRIMOZ(CF) 80MG/0.8ML INJ,PEN,CD-UC STARTER
61314-0531-64	HYRIMOZ(CF) 80MGX1,40MGX1 INJ,SYR, PEDIATRIC (1 KIT)
61314-0517-36	HYRIMOZ(CF) 80MGX1,40MGX2,INJ,PEN PSORIASIS (1 KIT)
61314-0454-68	HYRIMOZ(CF) PEDIATRIC CROHN'S
61314-0531-64	HYRIMOZ(CF) PEDIATRIC CROHN'S
61314-0454-20	HYRIMOZ(CF) PEN
61314-0473-20	HYRIMOZ(CF) PEN
61314-0473-77	HYRIMOZ(CF) PEN
61314-0473-92	HYRIMOZ(CF) PEN
83457-0100-01	HYRIMOZ(CF) PEN

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NDC	Brand Name(s)
83457-0107-01	HYRIMOZ(CF) PEN
83457-0200-40	HYRIMOZ(CF) PEN
61314-0454-36	HYRIMOZ(CF) PEN CROHN-UC START
83457-0113-01	HYRIMOZ(CF) PEN CROHN-UC START
61314-0517-36	HYRIMOZ(CF) PEN PSORIASIS
83457-0112-01	HYRIMOZ(CF) PEN PSORIASIS
65219-0556-18	IDACIO(CF)
65219-0554-08	IDACIO(CF) PEN
65219-0574-04	IDACIO(CF) PEN
65219-0554-38	IDACIO(CF) PEN CROHN'S-UC
65219-0554-38	IDACIO(CF) PEN CROHN'S-ULCERATIVE COLITIS START 40 MG/0.8 ML
65219-0554-28	IDACIO(CF) PEN PLAQUE PSORIASIS STARTER 40 MG/0.8 ML
65219-0554-28	IDACIO(CF) PEN PSORIASIS
00069-0809-01	INFLECTRA
57894-0160-01	INFLIXIMAB
57894-0030-01	REMICADE
78206-0162-01	RENFLEXIS
78206-0162-99	RENFLEXIS
00006-4305-02	RENFLEXIS
51759-0402-02	SIMLANDI(CF) AUTOINJECTOR
51759-0402-17	SIMLANDI(CF) AUTOINJECTOR
51759-0513-21	SIMLANDI(CF) AUTOINJECTOR
57894-0070-01	SIMPONI
57894-0070-02	SIMPONI
57894-0071-01	SIMPONI
57894-0071-02	SIMPONI
57894-0071-02	SIMPONI 100 MG/ML PEN INJECTOR
57894-0071-01	SIMPONI 100 MG/ML SYRINGE
57894-0350-01	SIMPONI ARIA
72606-0024-01	YUFLYMA(CF)
72606-0030-06	YUFLYMA(CF)
72606-0023-04	YUFLYMA(CF) 80 MG/0.8 ML AUTOINJECTOR
72606-0023-07	YUFLYMA(CF) AI CROHN'S-UC-HS

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Affordability Board
Division of Insurance

NDC	Brand Name(s)
72606-0030-10	YUFLYMA(CF) AUTOINJECT (2 PCK)
72606-0023-04	YUFLYMA(CF) AUTOINJECTOR
72606-0030-09	YUFLYMA(CF) AUTOINJECTOR
72606-0023-07	YUFLYMA(CF) AUTOINJECTOR CROHN'S-UC-HS STARTER 80 MG/0.8 ML
70114-0220-02	YUSIMRY(CF) PEN

Upper Payment Limit (UPL) Benchmarks - Enbrel Cost and Price Metrics

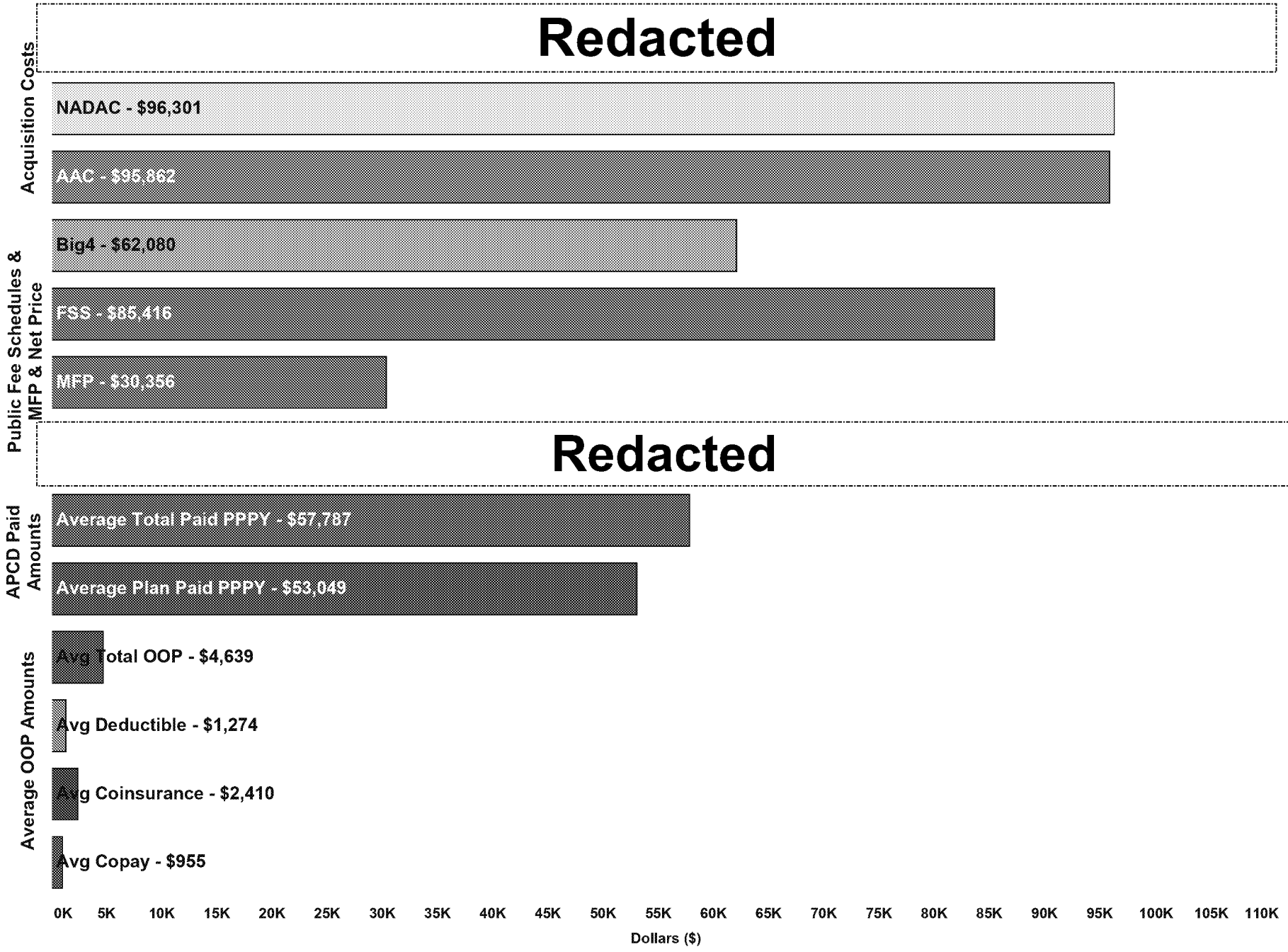
The graphs below are prepared by staff to help the Board visualize the different cost and price metrics for Enbrel and its therapeutic alternatives (TAs). The first graph outlines the price and cost metrics for Enbrel, while the remaining graphs present one price and cost metric specifically, and compare Enbrel with its TAs.

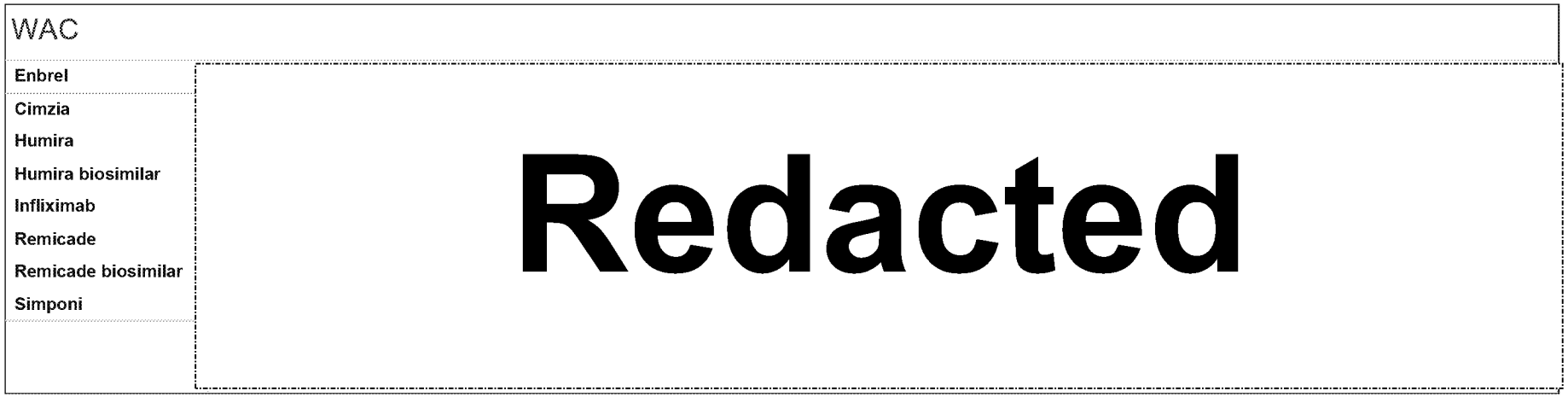
The graphs include data from the Colorado All Payer Claims Database (CO APCD) and the following price benchmarks:

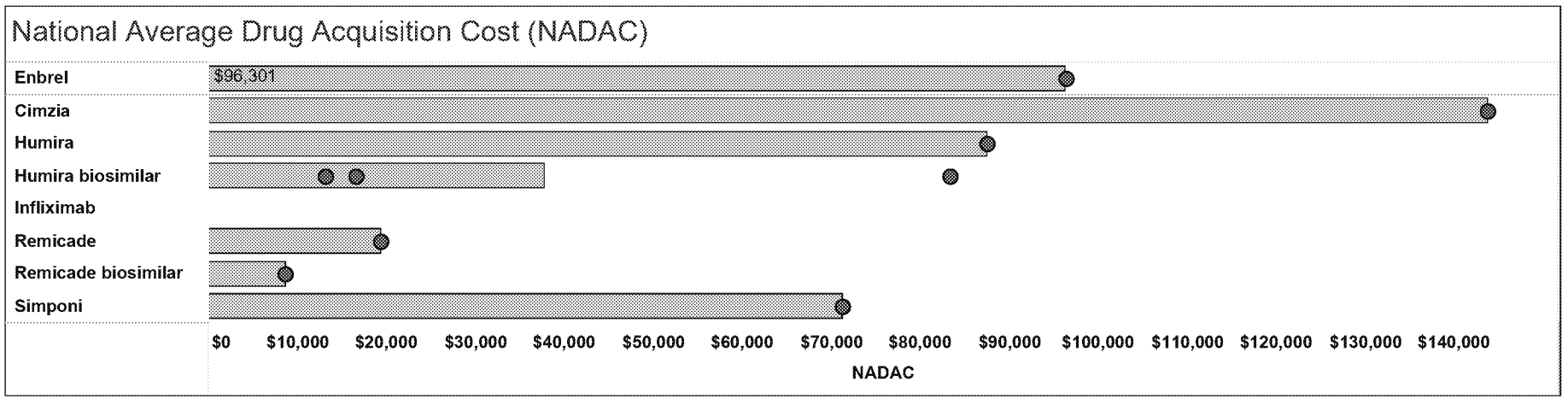
- Acquisition Costs
- Public Fee Schedules, Maximum Fair Price (MFP), and Net Price (*confidential*)
- Average out-of-pocket amounts
- Age Distribution of Enbrel Utilizers by Payer Type (*newly added on August 19*)

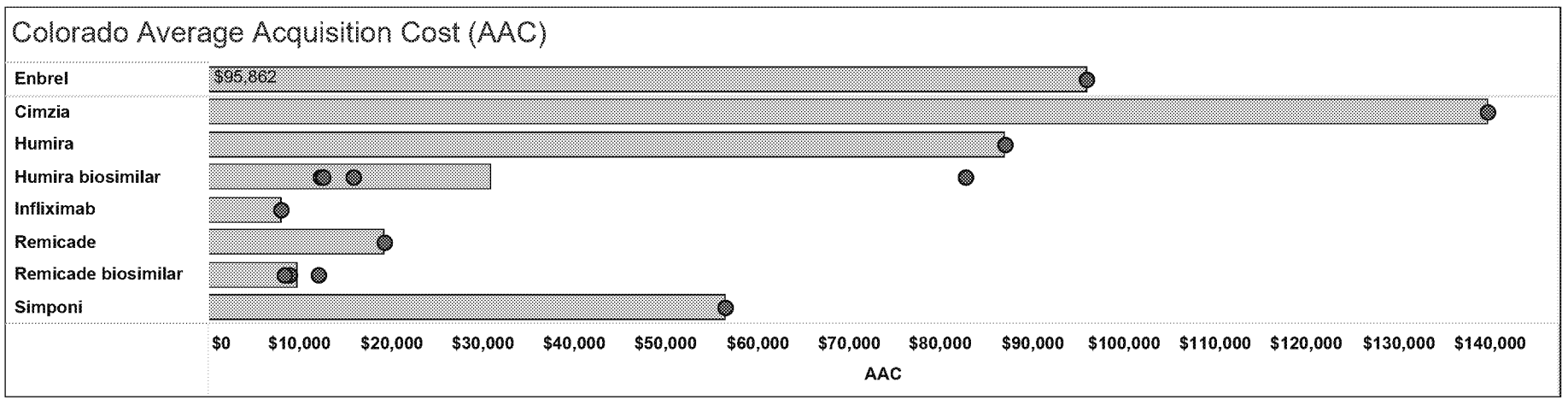
The graphs align with the data in the "Summary" tab of the Excel workbook. Biosimilars have been grouped together, but each is still shown on the graphs to demonstrate the price and cost variability.

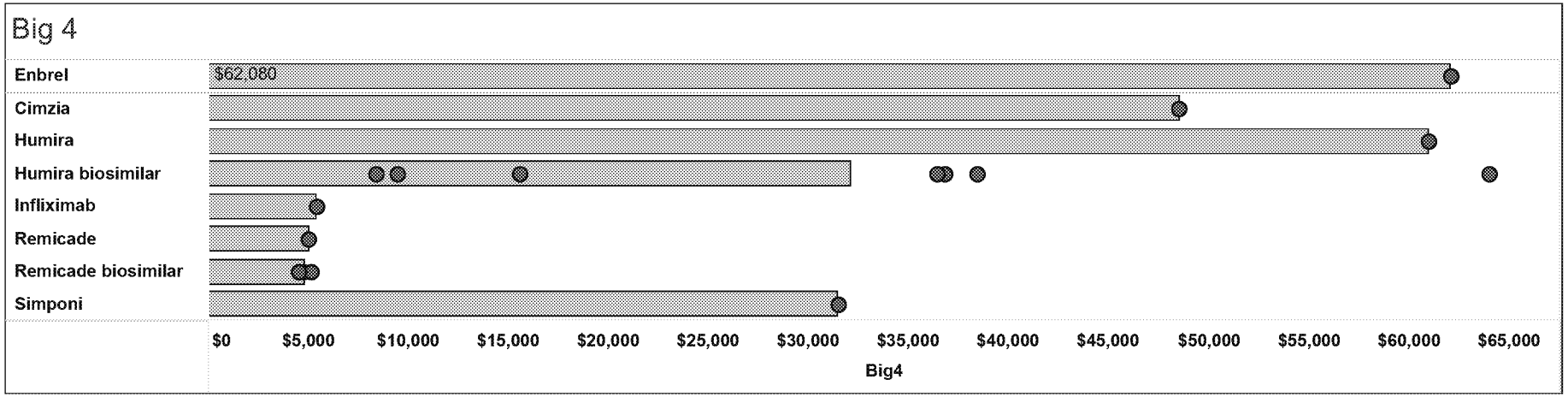
Enbrel Cost and Price Metrics

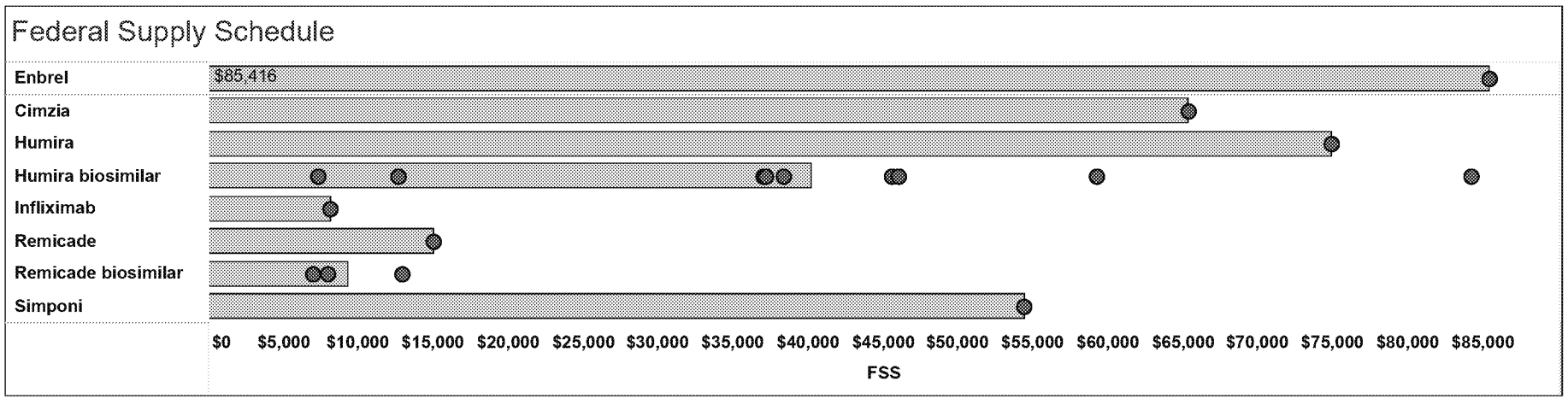


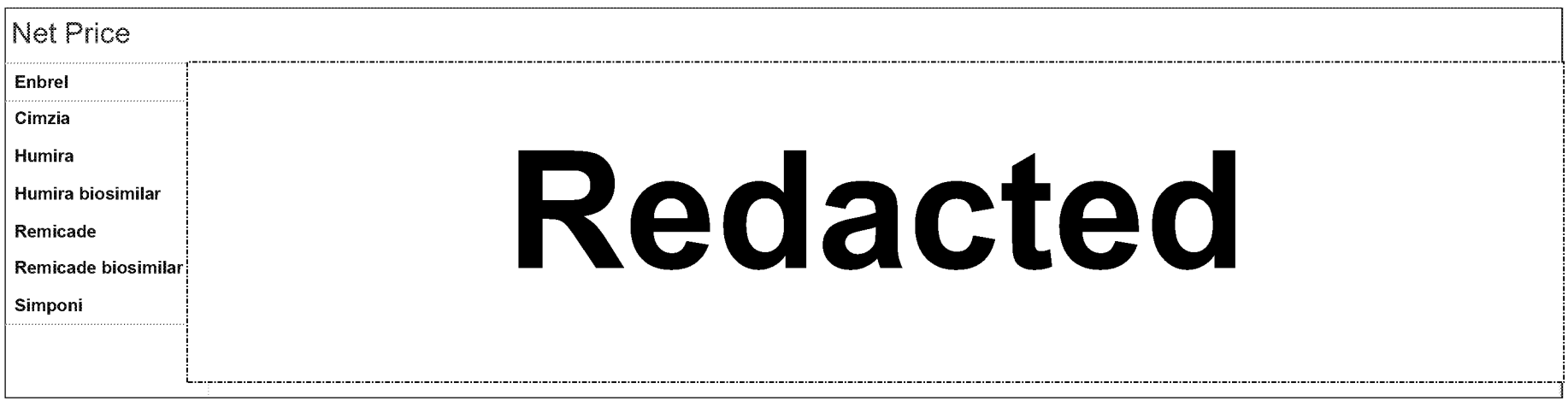

WAC
Enbrel
Cimzia
Humira
Humira biosimilar
Infliximab
Remicade
Remicade biosimilar
Simponi
Redacted

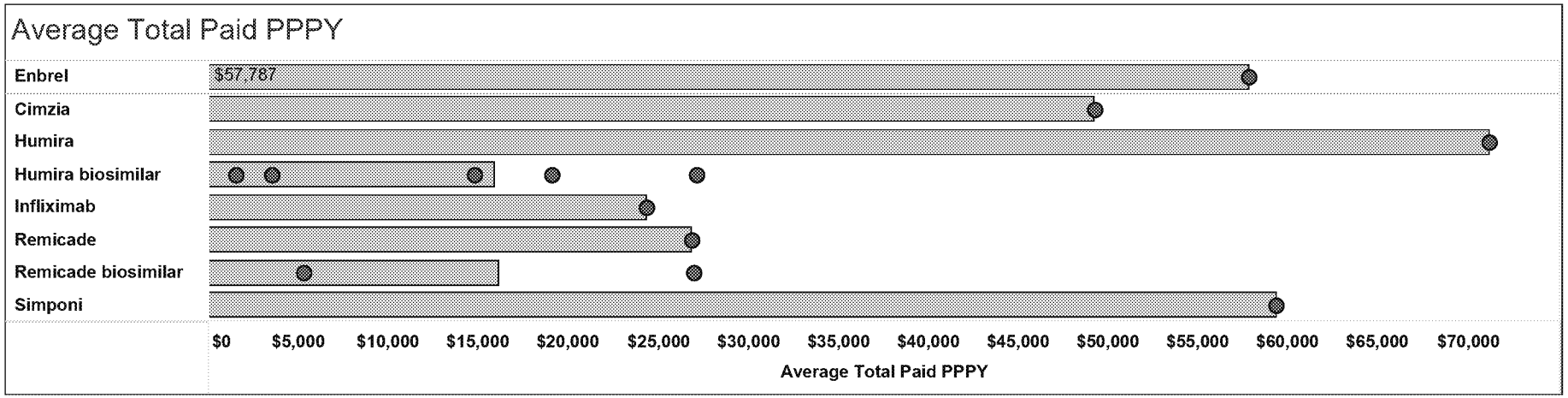

National Average Drug Acquisition Cost (NADAC)
Enbrel
Cimzia
Humira
Humira biosimilar
Infliximab
Remicade
Remicade biosimilar
Simponi
$96.301
$0
$10,000
$20,000
$30,000
$40,000
$50,000
$60,000
$70,000
$80,000
$90,000
$100,000
$110,000
$120,000
$130,000
$140,000
NADAC

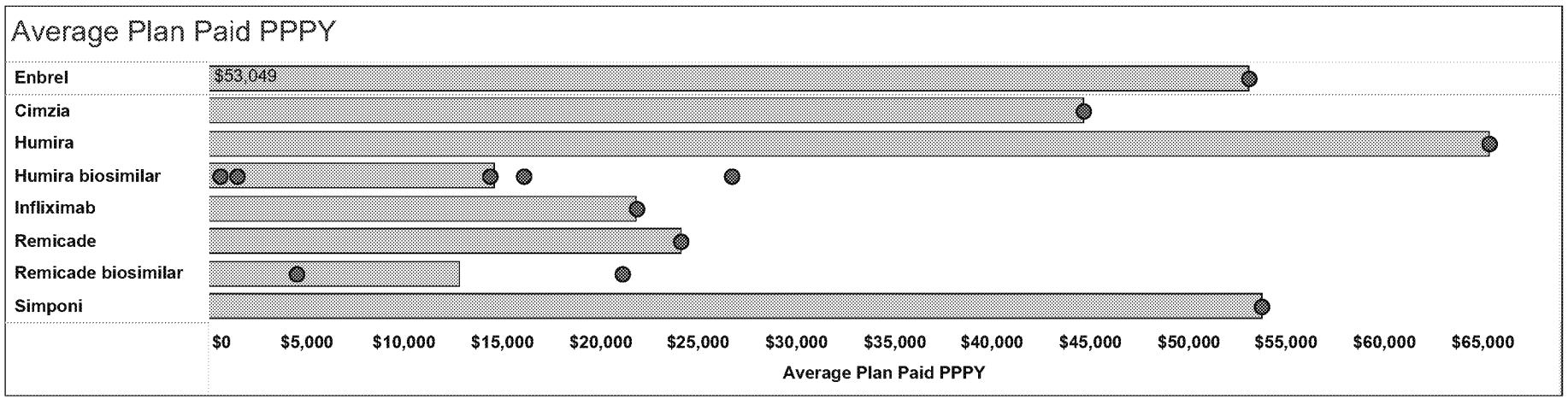

Colorado Average Acquisition Cost (AAC)
Enbrel
Cimzia
Humira
Humira biosimilar
Infliximab
Remicade
Remicade biosimilar
Simponi
$95.862
$0
$10,000
$20,000
$30,000
$40,000
$50,000
$60,000
$70,000
$80,000
$90,000
$100,000
$110,000
$120,000
$130,000
$140,000
AAC

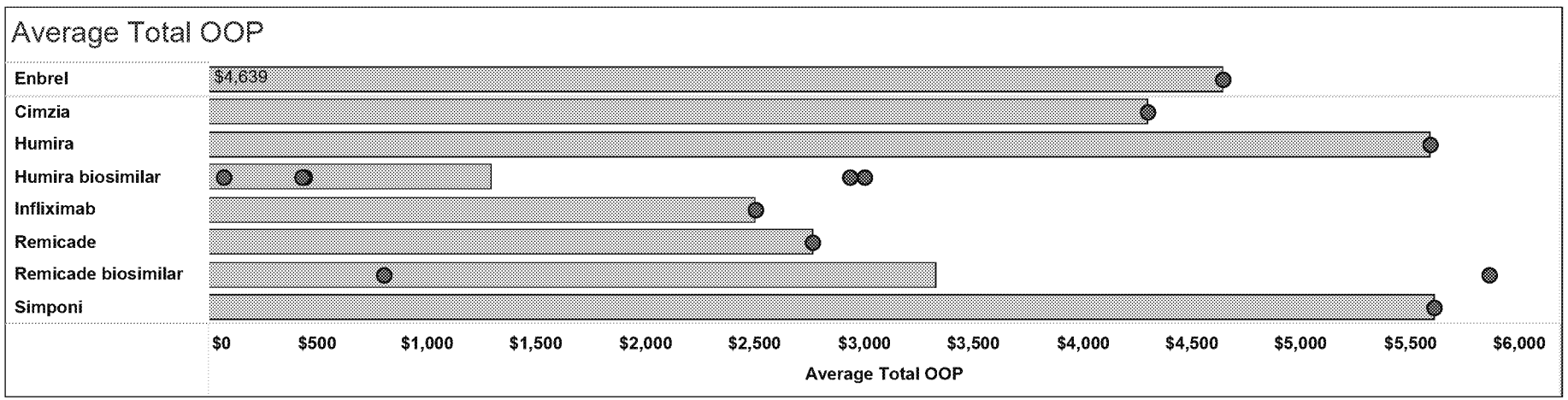

Big 4
Enbrel
Cimzia
Humira
Humira biosimilar
Infliximab
Remicade
Remicade biosimilar
Simponi
$62,080
$0 $5,000 $10,000 $15,000 $20,000 $25,000 $30,000 $35,000 $40,000 $45,000 $50,000 $55,000 $60,000 $65,000
Big4

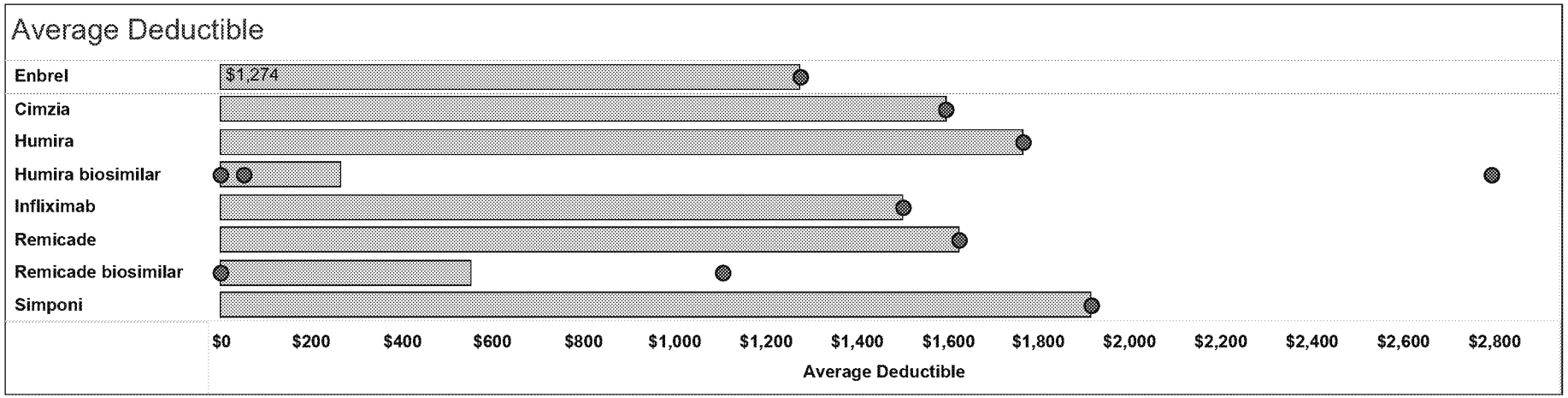

Federal Supply Schedule
Enbrel
Cimzia
Humira
Humira biosimilar
Infliximab
Remicade
Remicade biosimilar
Simponi
$85,416
$0 $5,000 $10,000 $15,000 $20,000 $25,000 $30,000 $35,000 $40,000 $45,000 $50,000 $55,000 $60,000 $65,000 $70,000 $75,000 $80,000 $85,000
FSS

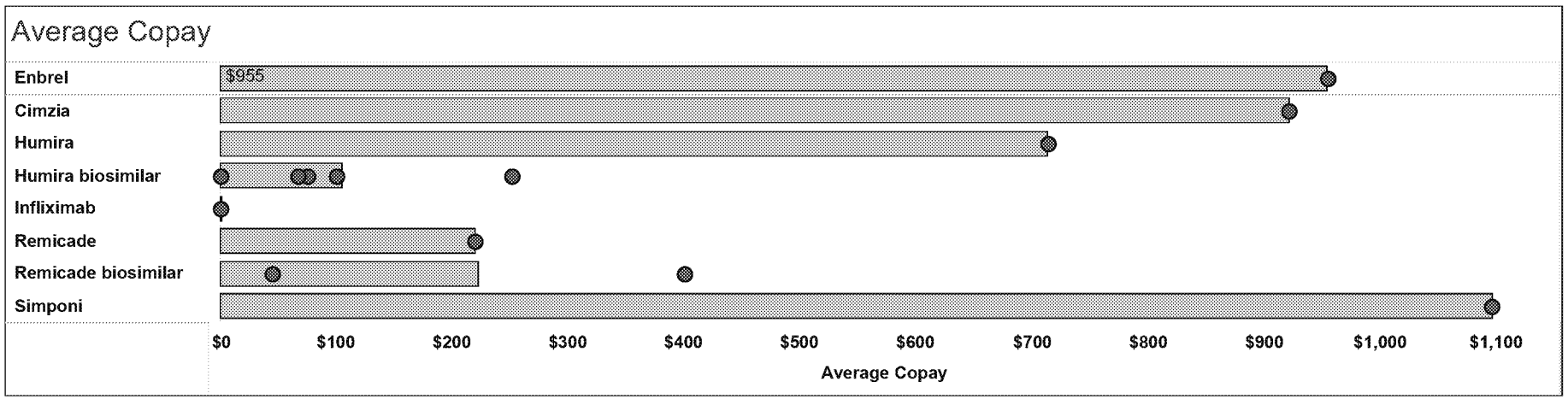

Net Price
Enbrel
Cimzia
Humira
Humira biosimilar
Remicade
Remicade biosimilar
Simponi
Redacted

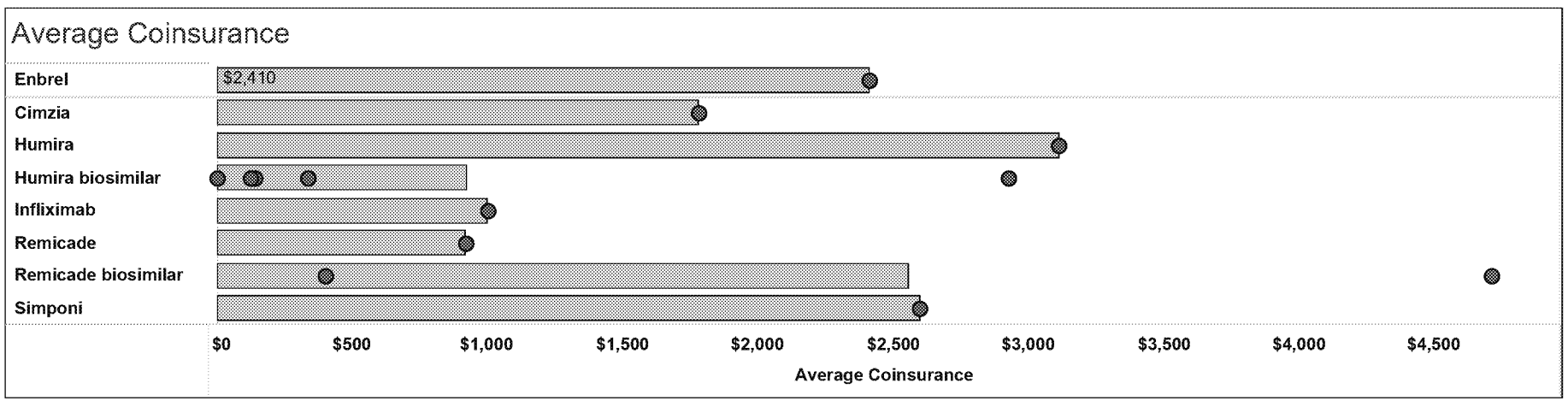

Average Total Paid PPPY
Enbrel
Cimzia
Humira
Humira biosimilar
Infliximab
Remicade
Remicade biosimilar
Simponi
$57,787
$0 $5,000 $10,000 $15,000 $20,000 $25,000 $30,000 $35,000 $40,000 $45,000 $50,000 $55,000 $60,000 $65,000 $70,000
Average Total Paid PPPY

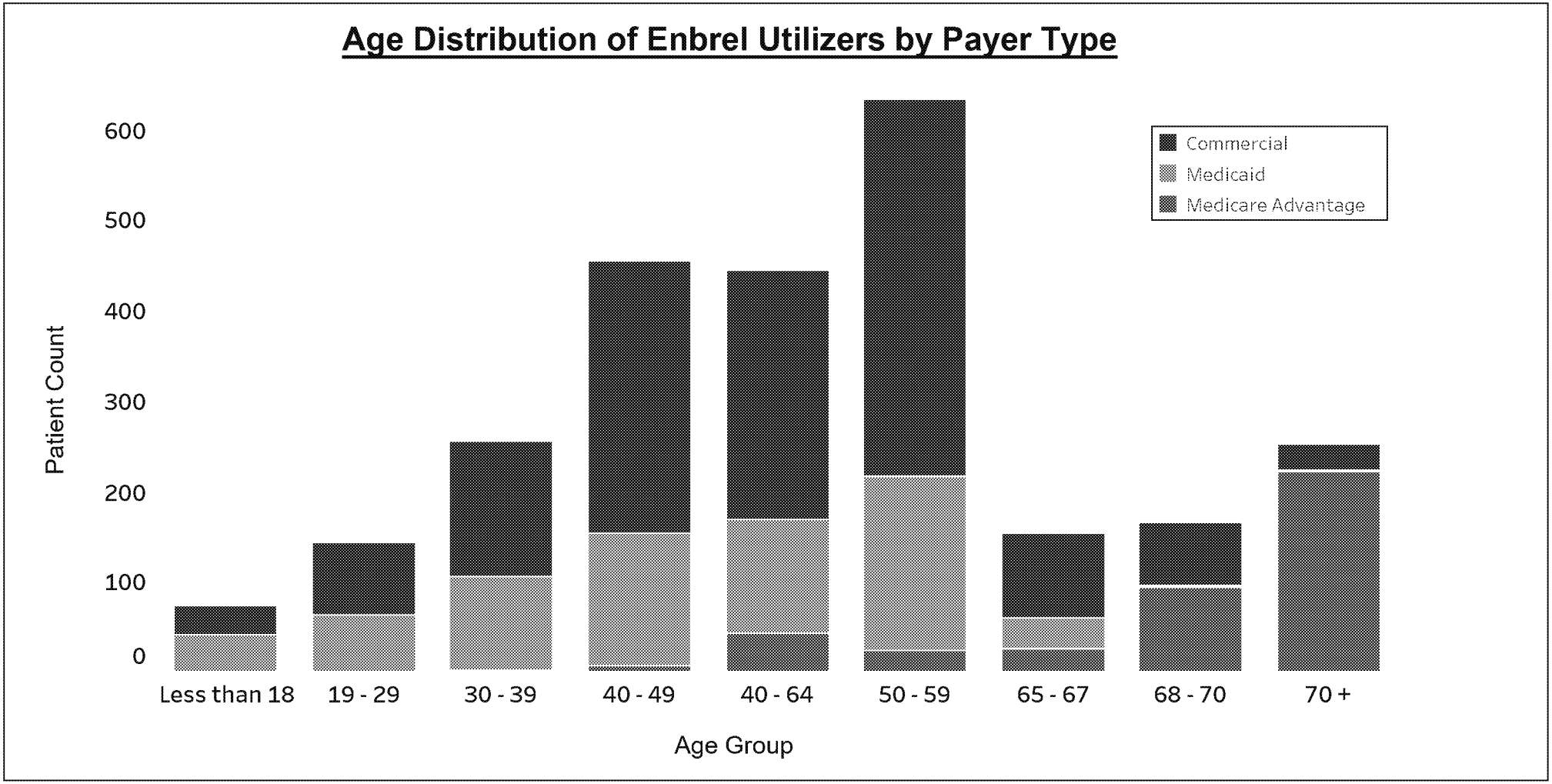

Average Plan Paid PPPY
Enbrel
Cimzia
Humira
Humira biosimilar
Infliximab
Remicade
Remicade biosimilar
Simponi
$53,049
$0 $5,000 $10,000 $15,000 $20,000 $25,000 $30,000 $35,000 $40,000 $45,000 $50,000 $55,000 $60,000 $65,000
Average Plan Paid PPPY


Average Total OOP
Enbrel
Cimzia
Humira
Humira biosimilar
Infliximab
Remicade
Remicade biosimilar
Simponi
$4,639
$0 $500 $1,000 $1,500 $2,000 $2,500 $3,000 $3,500 $4,000 $4,500 $5,000 $5,500 $6,000
Average Total OOP


Average Deductible
Enbrel
$1,274
Cimzia
Humira
Humira biosimilar
Infliximab
Remicade
Remicade biosimilar
Simponi
$0 $200 $400 $600 $800 $1,000 $1,200 $1,400 $1,600 $1,800 $2,000 $2,200 $2,400 $2,600 $2,800
Average Deductible


Average Copay
Enbrel
$955
Cimzia
Humira
Humira biosimilar
Infliximab
Remicade
Remicade biosimilar
Simponi
$0 $100 $200 $300 $400 $500 $600 $700 $800 $900 $1,000 $1,100
Average Copay


Average Coinsurance
Enbrel
$2,410
Cimzia
Humira
Humira biosimilar
Infliximab
Remicade
Remicade biosimilar
Simponi
$0 $500 $1,000 $1,500 $2,000 $2,500 $3,000 $3,500 $4,000 $4,500
Average Coinsurance



It is important to note that the upper payment limit (UPL) methodology must consider the impact of the UPL methodology to older adults and shall not place a lower value on their lives, per section 10-16-1407-(3) and PDAB Rule, 3 CCR 702-9, Part 4.1.C. Older adults are defined in the PDAB Policy 05 as individuals aged 65 and older.