UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

FOUNDATION AGAINST INTOLERANCE & RACISM, INC., *Plaintiff*, vs. THE CITY OF NEW YORK, THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, AND DAVE A. CHOKSHI, as Commissioner of the New York City Department of Health and Mental Hygiene, *Defendants*.	Case No.: COMPLAINT JURY TRIAL DEMANDED

"Distinctions between citizens solely because of their ancestry are by their very nature odious to a free people whose institutions are founded upon the doctrine of equality."

- *Hirabayashi v. U.S.*, 320 U.S. 81, 100 (1943)

Plaintiff, by and through its undersigned attorneys, alleges as follows:

PRELIMINARY STATEMENT

1. Plaintiff, Foundation Against Intolerance & Racism, Inc., by counsel, brings this action under the U.S. Constitution, the New York State Constitution, and federal civil rights laws against Defendants City of New York; the New York City Department of Health and Mental Hygiene; and Dave A. Chokshi, the Commissioner of the New York City Department of Health and Mental Hygiene, for violating Plaintiff's members' statutory and constitutional rights through their issuance and enforcement of a municipal policy that illegally classifies individuals on the basis of race, skin color and ethnicity when it comes to the dispensation and administration of lifesaving prophylactics, therapies and treatments for COVID-19.

2. Clinical studies demonstrate that monoclonal antibody and oral antiviral therapies – all of which are experimental treatments under emergency use authorization – are extremely effective at treating patients with mild to moderate COVID-19 who, due to age and underlying medical conditions, are at high risk for progression to severe disease.

3. Plaintiff's members include patients of all races and ethnicities including those who, because they identify or are classified as "non-Hispanic white," are and will be given lower priority in receiving these treatments and therapies than similarly situated patients who identify or are classified as "non-white" or "Hispanic/Latino."

4. Because these therapies and treatments are so effective, Defendants' discriminatory policy substantially increases the risk of hospitalization and death for COVID-19 patients classified as "non-Hispanic white."

5. Further, while monoclonal antibody and oral antiviral therapies are effective in the *short term* at treating patients with mild to moderate COVID-19 who are at high risk for progression to severe disease, their *long term* effects are unknown.

6. Pursuant to the subject municipal policy, young or otherwise healthy persons who identify as or are classified as "non-white" and/or "Hispanic/Latino" have been and are being prioritized for these experimental treatments while vaccinated "non-Hispanic white" patients as old as 64 without other severe risk factors receive no such prioritization.

7. As a result, "non-white" and/or "Hispanic/Latino" patients are disproportionately being made to assume the risk of long term negative side effects from these therapies solely because of the color of their skin and their ethnic heritage.

8. Defendants' illegal policy of race-based medical rationing also promotes a vile and evil canard, rooted in eugenics, that non-white races and ethnicities are more sickly, weak,

and infectious simply because of their skin color and ancestry. Defendants' policy likens darker complexion to a disease or other negative condition. A higher level of melanin, however, is not a comorbidity.

9. Defendants' policy of pathologizing skin color and ancestry has injured and will continue to injure Plaintiff's members by intentionally and unconstitutionally discriminating against them on the basis of their race and ethnicity – classifications that the Supreme Court in *Shaw v. Reno*, 509 U.S. 630, 643 (1993), denounced as "odious to a free people whose institutions are founded upon the doctrine of equality."

10. Since Plaintiff's members have been, or will imminently be, subject to irreparable injury by this unconstitutional and discriminatory municipal policy, and since there is a realistic danger that the aforesaid policy will significantly compromise recognized federal and state statutory and constitutional protections of parties not before the Court, Plaintiff is entitled to nominal damages as well as declaratory and injunctive relief.

11. Plaintiff therefore brings this action for injunctive relief, declaratory judgment, nominal damages, and attorneys' fees pursuant to, *inter alia*, 42 U.S.C. §§ 1983, 1981, 1988, 2000d, and 18116 as well as the New York State Constitution.

JURISDICTION

12. This Court has jurisdiction over Plaintiff's federal law claims under 28 U.S.C §§ 1331, 1343(a), (3), and (4).

VENUE

13. Venue is proper for the United States District Court for the Southern District of New York pursuant to 28 U.S.C. § 1391(b) and (c).

JURY TRIAL DEMANDED

14. Plaintiff demands trial by jury of all issues properly triable thereby.

THE PARTIES

15. Plaintiff Foundation Against Intolerance & Racism, Inc. ("FAIR"), is a not-for profit corporate entity duly organized under the laws of the State of New York, with its principal place of business located at 485 Madison Avenue, 16th Floor, New York, New York 10022.

16. FAIR is a nonpartisan organization dedicated to advancing civil rights and liberties for all Americans. FAIR's purpose and mission are to promote equal protection under the law and to advocate for individuals who suffer discrimination based on their skin color, ancestry, or other immutable characteristics.

17. Among FAIR's members are New York City residents of a number of different races and ethnicities, including white and non-Hispanic/Latino (hereinafter, "white Members").

18. Plaintiff's white Members are at high risk for contracting COVID-19.

19. Said white Members will seek treatment with Anti-SARS-CoV-2 Monoclonal Antibodies ("mAbs") and oral antivirals ("OAVs") (collectively "COVID treatments") if and when they develop symptoms, test positive for SARS-CoV-2, and are within 5-10 days of symptom onset.

20. Said white Members are suffering injury in fact from Defendants' racially and ethnically discriminatory policy because they and other non-Hispanic/Latino white individuals cannot and will not be able to obtain monoclonal antibodies and/or oral antiviral treatments in the City of New York when they contract COVID-19 unless they demonstrate a medical

condition or other factors that increase their risk for severe illness from the virus, while non-white and Hispanic/Latino residents of New York City are not required to make such a showing.

21. And, as more fully set forth below, even if they make such a showing, said white Members will be given the lowest possible priority because of their skin color and ethnicity.

22. Plaintiff's white Members are also suffering injury in fact from Defendants' racially and ethnically discriminatory policy because said policy subjects them to an increased risk of serious illness or death when they acquire COVID-19.

23. Defendants' unlawful policy further injures Plaintiff's white Members because it causes them apprehension due to their increased risk of physical, psychological and financial harm from COVID-19.

24. Further, Plaintiff's members are suffering injury in fact from Defendants' racially and ethnically discriminatory policy because members who are classified as "non-white" and/or "Hispanic/Latino" under the policy (hereinafter "non-white Members") have been and are being prescribed and administered these experimental medicines pursuant to it despite the fact that, but for said members' ethnicity and skin color, such treatments often are not medically indicated.

25. Solely because of their skin color or ancestry, these non-white Members have been and are being made to serve as test subjects and to assume a disproportionate share of the risk of long term negative side effects from these experimental therapies. This has caused and will continue to cause said non-white Members apprehension of long term harm.

26. That at all times relevant herein, defendant City of New York (hereinafter, "defendant City") was and still is a municipal corporation duly organized and existing under and by virtue of the laws of the State of New York.

27. That at all times herein mentioned, defendant City operated, controlled and maintained an agency, subdivision and department known as the City Department of Health and Mental Hygiene ("DOHMH").

28. That at all times relevant herein, defendant Dave A. Chokshi was and is the commissioner of the DOHMH, and as such was and is employed by defendant City.

29. In such capacity, defendant Chokshi is responsible for setting, promulgating and enforcing all directives, orders and policies of the DOHMH.

30. That at all times herein mentioned, defendant Chokshi was acting within the course and scope of his employment with defendant City.

31. That at all times herein mentioned, defendant Chokshi was acting under color of state law.

32. Defendant Chokshi is sued in his official capacity.

FACTUAL BACKGROUND

Efficacy of OAVs and Monoclonal Antibody Treatments

33. The FDA recently approved oral antiviral therapies to treat patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease, regardless of vaccination status.

34. Among these are monoclonal antibody products and oral antivirals that are extremely effective at preventing and treating COVID-19.

35. The oral antiviral Paxlovid demonstrated an 88% reduction in hospitalizations and death in patients at high risk for severe COVID-19 disease.

36. The oral antiviral Molnupiravir demonstrated a 30% reduction in hospitalizations and death in patients at high risk for severe COVID-19 disease.

37. Both of these oral antivirals must be administered very quickly, within five days of symptom onset, otherwise the patients have a substantially higher risk of becoming gravely ill or dying.

38. Both Paxlovid and Molnupiravir have received Emergency Use Authorization from the U.S. Food and Drug Administration ("FDA"). Paxlovid is authorized for patients age 12 and older, and Molnupiravir is authorized for patients age 18 and older.

39. In clinical trials, the monoclonal antibody product Sotrovimab (which is sold under the brand name Xevudy) demonstrated an 85% reduction in hospitalizations and death in patients at high risk for severe COVID-19 disease, and it is the only authorized mAb expected to be effective against the Omicron variant of the SARS-CoV-2 virus.

40. Sotrovimab also must be administered very quickly, within 10 days of symptom onset, otherwise the patients have a substantially higher risk of becoming gravely ill or dying.

Surge in COVID-19 Cases

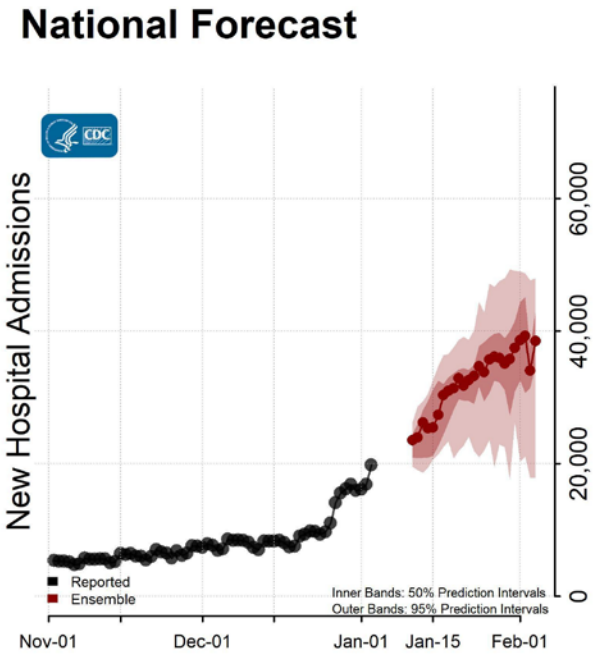
41. The authorization of oral antivirals comes at a time of a significant surge in cases and reduced effectiveness of existing therapeutics due to the Omicron variant, which is now the predominant variant nationally.

42. Indeed, due to the highly contagious Omicron variant, the number of Americans contracting COVID-19 is skyrocketing.

43. As of January 8, 2022, the Centers for Disease Control and Prevention (CDC) estimated that the Omicron variant accounts for over 98% of all cases in the United States, and 99.3% of all cases in New York State. *See* https://covid.cdc.gov/covid-data-tracker/#variant-proportions (accessed Jan. 15, 2022).

44. Moreover, the CDC has stated that it expects "a rapid increase in infections" of the Omicron variant in the United States," that this variant is "driving rapid epidemic growth," and that there likely will be "steep epidemic trajectories." According to the CDC, the number of Omicron infections are "exponentially increasing" as a result of its increased transmissibility and the variant's ability to evade immunity conferred by past infection or vaccination. Further, "given the likely increase in number of infections, the absolute numbers of people with severe outcomes could be substantial." *See* https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/mathematical-modeling-outbreak.html (accessed Jan. 15, 2022).

45. The CDC forecasts a steep increase nationally in new hospital admissions per day over the next few weeks due to COVID-19 infections.



46. Dr. Janet Woodcock, the acting commissioner of the FDA, recently testified before a Senate committee that "most people are going to get COVID."

47. The U.S. is averaging over 700,000 daily new COVID-19 cases, according to the CDC, and hospitalizations are hitting record levels. New York City is averaging approximately 22,000 daily cases. *See* https://covid.cdc.gov/covid-data-tracker/#trends_dailycases.

48. The New York City Department of Health has found that with the Omicron variant, "more people [have been] infected more quickly in NYC than any other point in the pandemic." *See* https://www1.nyc.gov/assets/doh/downloads/pdf/covid/omicron-variant-report-jan-13-22.pdf (accessed Jan. 18, 2022).

NIH Statement about Supply Shortages and Patient Triage

49. On or about December 23, 2021, the National Institute of Health ("NIH") issued a statement expressing that supply shortages require the administration of these therapies to patients to be triaged. The statement read in pertinent part: "With the increase in cases of COVID-19 and the emergence of the Omicron (B.1.1.529) variant of concern, there may be logistical or supply constraints that make it impossible to offer the available therapy to all eligible patients, making patient triage necessary."

New York State Prioritization Memo

50. Thereafter, the New York State Department of Health issued a guidance memo to all New York State medical providers entitled "Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies and Oral Antivirals for the Treatment of COVID-19 During Times of Resource Limitations" (hereinafter "State Prioritization Memo"). A copy of this memo is annexed hereto as Exhibit 1.

51. The State Prioritization Memo provides that "[i]n times of limited supplies of monoclonal antibodies (mAbs) and oral antivirals (OAVs), providers should prioritize patients eligible for treatment based on their level of risk for progressing to severe COVID-19. In

addition, the most efficacious products should be prioritized for patients with the highest risk for hospitalization and death."

52. The State Prioritization Memo then sets out a matrix with five different "risk groups" for what it described as "Tier 1" patients.

53. According to the State Prioritization Memo, Tier 1 patients are those who have "mild to moderate symptoms, test positive for SARS-CoV-2," and are within 5-10 days of symptom onset.

54. Tier 1 is broken into 5 groups, which are labeled 1A, 1B, 1C, 1D, and 1E.

55. The highest priority Tier 1 patients are assigned to group 1A, the next highest are assigned to group 1B, and so on.

56. The State Prioritization Memo directs that medical providers should assign each patient to one of these groups.

57. Group 1A – the highest risk category – is for patients: (1) of any age with moderate to severe immunocompromise, regardless of vaccine status; (2) age 65 and older and not fully vaccinated with at least one risk factor for severe illness; or (3) age 65 or older that is a resident of a long-term care facility environment.

58. Group 1B – the second highest risk category – is for patients: (1) under 65 years of age and not fully vaccinated with two or more risk factors for severe illness; or (2) over 65, not fully vaccinated, and with no risk factors.

59. Group 1C – the third highest risk category – is for patients under 65 years of age and not fully vaccinated with at least one risk factor for severe illness.

60. Group 1D – the fourth highest risk category – is for patients over age 65 and fully vaccinated with at least one risk factor for severe illness.

61. Group 1E – the lowest risk category – is for patients: (1) under 65 years of age and fully vaccinated with at least one risk factor for severe illness; or (2) age 65 and older and fully vaccinated with no other risk factors.

62. The State Prioritization Memo directs medical providers to assign each patient to a group within Tier 1 and then prioritize them within their respective groups according to each patient's number of "risk factors."

63. With respect to "risk factors," the State Prioritization Memo references the NIH COVID-19 Treatment Guidelines, which in turn directs readers to a CDC webpage for a list of risk factors for severe COVID-19.

64. In addition to the risk factors enumerated on the CDC website, the State Prioritization Memo expressly provides that "non-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19."

65. Thus, while non-Hispanic white individuals who test positive for COVID-19 are ineligible for mAb or OAV treatments unless they also demonstrate "a medical condition or other factors that increase their risk for severe illness," similarly situated "non-white" or "Hispanic/Latino" individuals are *automatically* eligible for these life-saving antiviral treatments without having to make such a showing and regardless of the individual's medical situation. The State Prioritization Memo's risk group matrix is as follows:

Tier 1: Prioritization Groups for the Treatment of COVID-19 For treatment, patients must have mild to moderate symptoms, test positive for SARS-CoV-2, and be within 10 days of symptom onset for mAbs or within 5 days for oral antivirals		
Risk Groups	**Recommended Therapy/Approach**	**Notes on Prioritization**
1A. Any age with moderate to severe immunocompromise regardless of vaccine status **or** Age 65 and older and not fully vaccinated with at least one risk factor for severe illness **or** Age 65 or older that is a resident of a long-term care facility environment	**Refer for monoclonal antibody therapy** (mAb) or prescribe Paxlovid, ideally within 24 hours of positive test Consider molnupiravir if the options above are not available	If needed, prioritize patients based on • Age • Number of risk factors
1B. Under 65 years of age and not fully vaccinated with **two or more** risk factors for severe illness or over 65 and not fully vaccinated (no risk factors)	Consider mAbs or OAVs if supplies allow	If needed, prioritize patients based on • Age • Number of risk factors
1C. Under 65 years of age and not fully vaccinated with at least one risk factor for severe illness	Consider mAbs or OAVs if supplies allow	If needed, prioritize patients based on • Age
1D. Over age 65 and fully vaccinated with at least one risk factor for severe illness	Consider mAbs or OAVs if supplies allow	If needed, prioritize patients based on • Age • Number of risk factors • Receipt of booster • Time since last vaccination
1E. Under 65 years of age and fully vaccinated with at least one risk factor for severe illness **or** Age 65 and older and fully vaccinated with no other risk factors	Consider mAbs or OAVs if supplies allow	If needed, prioritize patients based on • Age • Number of risk factors • Receipt of booster • Time since last vaccination

NYC DOHMH's Health Advisory #39

66. On or about December 27, 2021, defendant City, through its DOHMH, which was and is led by defendant Chokshi, issued a directive entitled "2021 Health Advisory #39" (hereinafter, the "NYC Order") to all medical providers in the City of New York. It was immediately implemented and is still in effect.

67. The NYC Order commands all medical providers in the City of New York to "adhere to New York State Department of Health guidance on prioritization of high risk patients for anti-SARS-CoV-2 therapies during this time of severe resource limitations." A copy of the NYC Order is annexed hereto as Exhibit 2.

68. The NYC Order thus directs in mandatory terms that all New York City medical providers must triage and prioritize COVID-19 patients according to risk grouping matrix set forth in the State Prioritization Memo.

69. Further, in a section of the NYC Order entitled "Eligibility," the NYC Order directs that New York City medical providers must "[c]onsider race and ethnicity when assessing an individual's risk" for severe COVID-19 illness.

70. According to the NYC Order, which expressly incorporates and adopts the State Prioritization Memo's five risk groups, recommended therapies, and risk factors, being "non-white" or "Hispanic/Latino" serves to elevate a patient's risk status, place them in a higher risk category, and give them preference over similarly situated "white" patients – such as the Plaintiff's white Members – for access to the limited supply of lifesaving COVID-19 treatments and therapies. This creates a racial hierarchy in which non-Hispanic white persons are always at the bottom.

71. By way of illustration, imagine that two patients, one white and one black, present to the same health care provider with mild to moderate symptoms of COVID-19. Both test positive for SARS-CoV-2, and both are within 5 days of symptom onset. Both patients are also under 65 years of age and are fully vaccinated. According to the NYC Order, the white patient would not be placed in any prioritized risk group in Tier 1, while the black patient would be placed in Tier 1 risk group 1E, solely because he or she is a "non-white race." As a member of the higher risk group, the black patient would be given priority over the white patient for mAbs or OAV treatment. This treatment advantage is not based on any objective medical need or scientific study, but solely on racial and ethnic discrimination.

72. Similarly, consider a situation where two 70-year-old patients, one white and one of Hispanic ethnicity, present in a doctor's office with mild to moderate symptoms of COVID-19. Both are fully vaccinated, both test positive for SARS-CoV-2, and both are within 5 days of symptom onset. Neither has any underlying medical conditions. The white patient would be

placed in category 1E, the lowest risk group, while the Hispanic patient – solely because of her ethnicity – would be placed in category 1D, a higher risk group than the white patient. The Hispanic patient, like the black patient in the previous example, would be given priority over the white patient for mAbs and oral antiviral treatment simply because of her ethnic heritage.

73. Under Defendants' policy, even if two patients each had moderate to severe immunocompromise, and therefore were both placed in risk group 1A, the non-white or Hispanic/Latino patient would be prioritized over a non-Hispanic white patient for no reason other than their skin color and/or ancestry.

74. The same holds true for each of the risk groups, since the NYC Order directs providers to adhere to the State Prioritization Memo, which in turn directs that providers prioritize each patient within each risk group according to the patient's number of "risk factors."

75. Solely because of their skin color and/or ethnicity, a non-white or Hispanic/Latino patient will always be assigned one more risk factor than identically situated white patients – such as Plaintiff's white Members herein – and therefore, under the NYC Order, the non-white or Hispanic/Latino patient will always be prioritized ahead of Plaintiff's white Members when it comes to receiving life-saving therapies and prophylaxis against COVID-19.

76. Patients younger than 65 with no risk factors but who happen to have been born non-Hispanic white are always guaranteed to be at the end of the line.

77. This is not because any race or ethnicity has a medical susceptibility or genetic predisposition to severe COVID-19 disease, but because, according to the NYC Order, the City of New York believes that such discrimination is warranted because of "longstanding systemic

health and social inequities" that have been visited on those who are "non-white" or "Hispanic/Latino."

78. Moreover, Defendants' illegal policy of race-based rationing promotes a vile and evil canard, rooted in eugenics, that non-white races and ethnicities are more sickly, weak, and infectious simply because of their skin color and ancestry. Defendants' policy pathologizes darker skin colors by likening them to a disease or other negative condition. A higher level of melanin, however, is not a comorbidity.

79. Further, while clinical studies demonstrate that mAbs and OAVs – all of which are experimental therapies without FDA approval – are extremely effective at treating patients with mild to moderate COVID-19 who, due to age and underlying medical conditions, are at high risk for progression to severe disease, they often are unnecessary for younger patients without underlying medical comorbidities.

80. Nevertheless, young or otherwise healthy "non-white" and Hispanic persons are being prescribed and administered these experimental medicines pursuant to the NYC Order – solely because of the color of their skin and their ethnic appearance – even though they likely do not need them and stand to gain no benefit from them. In contrast, similarly situated young and otherwise healthy "white" patients are not offered these experimental therapies, and therefore are not being put at risk for any of their as yet unknown harmful effects.

81. Thus, under the NYC Order, persons of color and ethnic minorities, such as Plaintiff's non-white Members, are being used as test subjects and are disproportionately bearing the risk of future adverse consequences from these experimental therapeutics.

82. Simply put, through their NYC Order, Defendants are purposefully engaging in an overtly discriminatory, unlawful and unconstitutional racial- and ethnic-preference medical treatment policy that quite literally has life-or-death stakes.

83. Plaintiff's white and non-white Members' injuries are traceable to the NYC Order, which is enforced by defendants Chokshi and the DOHMH.

FIRST CLAIM

VIOLATION OF 42 U.S.C. § 1983 – EQUAL PROTECTION UNDER THE FOURTEENTH AMENDMENT

84. Plaintiff repeats and realleges each and every allegation set forth above as though fully set forth at length herein.

85. Defendants, acting under color of New York law, have adopted a policy pursuant to which Plaintiff's Members are being discriminated against because of their race and ethnicity.

86. Plaintiff's Members are being irreparably harmed by Defendants' denial of their right to equal protection, and they will continue to be irreparably harmed unless Defendants' unlawful conduct is enjoined.

87. Plaintiff's Members have no adequate remedy at law.

SECOND CLAIM

DISCRIMINATION UNDER 42 U.S.C. § 1981

88. Plaintiff repeats and realleges each and every allegation set forth above as though fully set forth at length herein.

89. Defendants' acts, practices, and policies described herein constitute intentional discrimination against Plaintiff's Members on the basis of their race, in violation of the Civil Rights Act of 1866, 42 U.S.C. § 1981.

90. Plaintiff's Members are being irreparably harmed by Defendants' flagrant discrimination, and they will continue to be irreparably harmed unless Defendants' unlawful conduct is enjoined.

91. Plaintiff's Members have no adequate remedy at law.

THIRD CLAIM

VIOLATION OF TITLE VI OF THE CIVIL RIGHTS ACT OF 1964

92. Plaintiff repeats and realleges each and every allegation set forth above as though fully set forth at length herein.

93. 42 U.S.C. § 2000d provides that "[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance."

94. Defendants City of New York and its DOHMH receive federal financial assistance to provide therapies, including mAb products and OAVs, for the treatment of COVID-19.

95. Defendants' acts, practices, and policies described herein violate Title VI and they also mandate that all medical providers within the City of New York, including those who receive federal financial assistance to provide therapies for the treatment of COVID-19, violate Title VI by discriminating on the basis of race, color and national origin and by denying patients lifesaving medical treatments because they are white.

96. Plaintiff's Members are being irreparably harmed by Defendants' flagrant discrimination, and they will continue to be irreparably harmed unless Defendants' unlawful conduct is enjoined.

97. Plaintiff's Members have no adequate remedy at law.

FOURTH CLAIM

VIOLATION OF SECTION 1557 OF THE AFFORDABLE CARE ACT

98. Plaintiff repeats and realleges each and every allegation set forth above as though fully set forth at length herein.

99. Section 1557 of the Patent Protection and Affordable Care Act, codified at 42 U.S.C. § 18116, provides, among other things, that no individual shall be subjected to discrimination on the grounds of race, color or national origin under any health program or activity, any part of which is receiving federal financial assistance.

100. Defendants City of New York and its DOHMH receive federal financial assistance to provide therapies, including mAb products and OAVs, for the treatment of COVID-19.

101. Defendants' acts, practices, and policies described herein violate Section 1557 and they also mandate that all medical providers within the City of New York, including those who receive federal financial assistance to provide therapies for the treatment of COVID-19, violate Section 1557 by discriminating on the basis of race, color and national origin and by denying patients lifesaving medical treatments because they are white.

102. Plaintiff's Members are being irreparably harmed by Defendants' flagrant discrimination, and they will continue to be irreparably harmed unless Defendants' unlawful conduct is enjoined.

103. Plaintiff's Members have no adequate remedy at law.

FIFTH CLAIM

VIOLATION OF ARTICLE I, § 11 OF THE NEW YORK STATE CONSTITUTION

104. Plaintiff repeats and realleges each and every allegation set forth above as though fully set forth at length herein.

105. Article I, § 11 of the New York State Constitution provides that "No person shall be denied the equal protection of the laws of this state or any subdivision thereof. No person shall, because of race, color, creed or religion, be subjected to any discrimination in his or her civil rights by any other person or by any firm, corporation, or institution, or by the state or any agency or subdivision of the state."

106. That by virtue of the aforementioned acts, Defendants have violated the rights of Plaintiff's Members under the New York State Constitution to equal protection of the laws and to be free of racial and ethnic discrimination.

107. Plaintiff's Members are being irreparably harmed by Defendants' flagrant discrimination, and they will continue to be irreparably harmed unless Defendants' unlawful conduct is enjoined.

108. Plaintiff's Members have no adequate remedy at law.

* * *

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court provide the following relief:

a. Declare that Defendants' conduct violates Plaintiff's Members' rights to equal protection under the U.S. Constitution;

b. Declare that Defendants' conduct violates Plaintiff's Members' rights under 42 U.S.C. § 1981 to the full and equal benefit of all laws;

c. Declare that Defendants' conduct violates Plaintiff's Members' rights under Title VI to be free of discrimination based on their race, color or national origin;

d. Declare that Defendants' conduct violates Plaintiff's Members' rights under § 1557 of the Affordable Care Act to be free of discrimination based on their race, color or national origin;

e. Declare that Defendants' conduct violates Plaintiff's Members' rights to equal protection under the Constitution of the State of New York;

f. Enjoin Defendants from continuing to deprive Plaintiff's Members of their constitutional and statutory rights and from requiring that medical providers consider race and ethnicity as risk factors in setting patients' priority level for receiving COVID treatments;

g. Award Plaintiff nominal damages;

h. Award Plaintiff attorneys' fees and other litigation costs reasonably incurred in this action pursuant to 42 U.S.C. § 1988;

i. Grant Plaintiff such other relief as this Court deems just and proper.

Dated this 20th day of January, 2022

Ameer Benno, Esq.

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EXHIBIT "1"

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Acting Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies and Oral Antivirals for the Treatment of COVID-19 During Times of Resource Limitations

Introduction

In times of limited supplies of monoclonal antibodies (mAbs) and oral antivirals (OAVs), providers should prioritize patients eligible for treatment based on their level of risk for progressing to severe COVID-19. In addition, the most efficacious products should be prioritized for patients with the highest risk for hospitalization and death.[1]

According to the NIH COVID-19 Treatment Guidelines, triage and prioritization should only be implemented when logistical or supply constraints make it impossible to offer the therapy to all eligible patients. During periods of limited resources, the Panel suggests:

- Prioritizing the **treatment** of COVID-19 **and**
- Prioritizing anti-SARS-CoV-2 mAbs and OAVs for **unvaccinated or incompletely vaccinated** individuals and **vaccinated individuals who are not expected to mount an adequate immune response** (e.g., individuals with moderate to severe immunocompromise or individuals aged ≥65 years).

As reminder, Monoclonal antibodies and oral **therapeutics are not a substitute for vaccination** in individuals for whom vaccination is recommended. Providers should continue recommending COVID-19 vaccination as the best strategy to prevent COVID-19 severe disease, hospitalizations, and deaths.

Patients who have moderate to severe immune compromise (due to a medical condition or receipt of immunosuppressive medications or treatments) or are unable to receive COVID-19 vaccines due to a history of a severe adverse reaction to a COVID-19 vaccine should be considered for pre-exposure prophylaxis with a long-acting monoclonal antibody (Evusheld).

How to use this framework

Each patient should be assigned to a group within Tier 1 and then prioritized within the respective group. Patients assigned to 1A should be considered the highest priority, with 1B being the next highest priority and so on. The recommended therapy section notes which groups should receive therapy without exception and which groups may need to be put on a wait list if supplies of a given therapeutic are limited.

[1] In clinical trials, Paxlovid demonstrated an 88% reduction in hospitalizations and death in high-risk unvaccinated adults vs. 85% for Sotrovimab vs. 30% for Molnupiravir

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
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Acting Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

Tier 1: Prioritization Groups for the Treatment of COVID-19
For treatment, patients must have mild to moderate symptoms, test positive for SARS-CoV-2, and be within 10 days of symptom onset for mAbs or within 5 days for oral antivirals

Risk Groups	Recommended Therapy/Approach	Notes on Prioritization
1A. Any age with moderate to severe immunocompromise regardless of vaccine status **or** Age 65 and older and not fully vaccinated with at least one risk factor for severe illness **or** Age 65 or older that is a resident of a long-term care facility environment	**Refer for monoclonal antibody therapy** (mAb) or prescribe Paxlovid, ideally within 24 hours of positive test Consider molnupiravir if the options above are not available	If needed, prioritize patients based on • Age • Number of risk factors
1B. Under 65 years of age and not fully vaccinated with **two or more** risk factors for severe illness or over 65 and not fully vaccinated (no risk factors)	Consider mAbs or OAVs if supplies allow	If needed, prioritize patients based on • Age • Number of risk factors
1C. Under 65 years of age and not fully vaccinated with at least one risk factor for severe illness	Consider mAbs or OAVs if supplies allow	If needed, prioritize patients based on • Age
1D. Over age 65 and fully vaccinated with at least one risk factor for severe illness	Consider mAbs or OAVs if supplies allow	If needed, prioritize patients based on • Age • Number of risk factors • Receipt of booster • Time since last vaccination
1E. Under 65 years of age and fully vaccinated with at least one risk factor for severe illness **or** Age 65 and older and fully vaccinated with no other risk factors	Consider mAbs or OAVs if supplies allow	If needed, prioritize patients based on • Age • Number of risk factors • Receipt of booster • Time since last vaccination

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Acting Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

Notes

- We recommend using BMI ≥30 as a cutoff for weight-based risk factor
- The risk of severe disease increases with the number of comorbidities, even among fully vaccinated individuals[2]
- Non-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19
- See CDC guidance for further information on specific medical conditions and associated risk
- Fully vaccinated is currently defined as having received two doses of an mRNA vaccine, or a single dose of the Johnson & Johnson vaccine

[2] Bierle *et al*, mAb Treatment of Breakthrough COVID-19 in Fully Vaccinated Individuals with High-Risk Comorbidities. *JID* 2021

EXHIBIT "2"

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Dave A. Chokshi, MD, MSc
Commissioner

2021 HEALTH ADVISORY #39

COVID-19 ORAL ANTIVIRAL TREATMENTS AUTHORIZED AND SEVERE SHORTAGE OF ORAL ANTIVIRAL AND MONOCLONAL ANTIBODY TREATMENT PRODUCTS

- **Two COVID-19 oral antiviral therapies have received Emergency Use Authorization from the U.S. Food and drug Administration (FDA), Paxlovid (Pfizer) and molnupiravir (Merck).**
  - **Paxlovid and molnupiravir reduce the risk of hospitalization and death by 88% and 30% respectively, in patients at high-risk for severe COVID-19 disease when started early after symptom onset.**
  - **Prescriptions in New York City (NYC) will be filled by Alto Pharmacy to provide free, same day home delivery regardless of insurance or immigration status.**
  - **Paxlovid is the preferred product and is available for patients age 12 years and older.**
  - **Molnupiravir should be considered for patients age 18 years and older for whom alternative FDA- authorized COVID-19 treatment options are not accessible or clinically appropriate.**
- **At this time, Sotrovimab (Xevudy) is the only authorized monoclonal antibody product expected to be effective against the omicron variant of SARS-CoV-2.**
  - **There is a pause on allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV until further notice. These products do not retain activity against omicron and should not be used.**
- **Adhere to New York State Department of Health (NYS DOH) guidance on prioritization of high-risk patients for anti-SARS-CoV-2 therapies during this time of severe resource limitations.**
- **While therapeutic shortages continue, off-label use of remdesivir on an outpatient basis may be an option.**
- **Check nyc.gov/health/covidprovidertreatments regularly for updates.**

December 27, 2021

Dear Colleagues,

This HAN includes information about available COVID-19 outpatient therapeutics, including newly authorized oral antiviral treatment.

While the availability of oral antivirals for treatment of COVID-19 is an important milestone, it comes at a time of a significant surge in cases and reduced effectiveness of existing

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therapeutics due to the omicron variant, which is now the predominant variant nationally and estimated by the Centers of Disease Control and Prevention (CDC) to account for over 90% of cases in New York. Supplies of oral antivirals will initially be extremely limited, and there is now only one monoclonal antibody product that is effective for treatment of infection caused by the omicron variant. While supplies remain low, adhere to the NYS DOH guidance on prioritization of anti-SARS-CoV-2 therapies for treatment and prevention of severe COVID-19 and prioritize therapies for people of any eligible age with moderate to severe immunocompromise regardless of vaccination status or who are age 65 and older and not fully vaccinated with at least one risk factor for severe illness.

COVID-19 Oral Antiviral Treatment

The FDA authorized the first oral antiviral therapies, Paxlovid from Pfizer and molnupiravir from Merck, to treat patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease, regardless of vaccination status. The oral antivirals work by interfering with several steps in the reproductive process of SARS-CoV-2 to prevent efficient replication of the virus in host cells. The U.S. Department of Health and Human Services (HHS) provides oral antivirals at no cost to patients.

Paxlovid is the preferred product, and molnupiravir can be considered for patients age 18 years and older for whom alternative FDA-authorized COVID-19 treatment options are not accessible or clinically appropriate. Limited supply will require providers to prioritize treatment for patients at highest risk for severe COVID-19 until more product becomes available.

Paxlovid clinical trials among 2,246 high-risk patients showed an 88% reduction in the risk for hospitalization and death among people taking Paxlovid compared to those taking placebo. Paxlovid is a combination treatment with PF-07321332 (or nirmatrelvir) and ritonavir. PF-07321332 inhibits the main protease of SARS-CoV-2 virus, the 3CL-like protease, that impedes synthesis of other non-structural proteins and ultimately inhibits viral replication. Ritonavir is a protease inhibitor (also used in HIV treatment) that acts as a pharmacokinetic enhancer of protease inhibitors.

Molnupiravir clinical trials among 1,433 high-risk patients showed a 30% reduction in the risk for hospitalization and death among people taking molnupiravir compared to those taking placebo. Molnupiravir is the pro-drug of a nucleoside analog that competes with the viral RNA polymerase and induces RNA mutations that ultimately have an antiviral effect.

Eligibility

Oral antiviral treatment is authorized for patients who meet all the following criteria:

- Age 12 years and older for Paxlovid, or 18 years and older for Molnupiravir
- Weigh at least 40 kg (88 pounds)

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- Test positive for SARS-CoV-2 on a nucleic acid amplification test or antigen test; results from an FDA-authorized home-test kit should be validated through video or photo but, if not possible, patient attestation is adequate
- Have mild to moderate COVID-19 symptoms
    - Patient cannot be hospitalized or receiving oxygen therapy due to COVID-19
- Are able to start treatment within 5 days of symptom onset
- Have a medical condition or other factors that increase their risk for severe COVID-19 illness.
    - Consider race and ethnicity when assessing an individual's risk. Impacts of longstanding systemic health and social inequities put Black, Indigenous, and People of Color at increased risk of severe COVID-19 outcomes and death.

For Paxlovid only:

- Therapy is contraindicated for patients with history of clinically significant hypersensitivity reactions to its active ingredients or any other components of the product; are on drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions; or are on drugs that are potent CYP3A inducers where significantly reduced Paxlovid plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. See list of medications in the Paxlovid Fact Sheet for Providers, Section 7.
- Therapy is not recommended for patients with severe kidney (eGFR <30 mL/min) or liver (Child-Pugh Class C) impairment. Dosage adjustments are needed for patients with moderate renal impairment. Providers should discuss with their patients with kidney or liver problems whether Paxlovid is right for them.
- Paxlovid may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in patients with uncontrolled or undiagnosed HIV-1 infection. Patients on ritonavir- or cobicistat-containing HIV or HCV regimens should continue their treatment as indicated.

For molnupiravir only:

- Molnupiravir should be prescribed for patients age 18 years and older for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.
- Molnupiravir is not recommended during pregnancy. Prescribing providers should assess whether a female of childbearing potential is pregnant or not. Advise individuals of childbearing potential to use effective contraception correctly and consistently for the duration of treatment and for 4 days after the last dose of molnupiravir.
- Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and pumping and discarding breast milk during this time.

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- Males of reproductive potential who are sexually active with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.
- For more details, please refer to molnupiravir Fact Sheet for Providers.

Clinical Considerations

Treatment is most effective when given as soon as possible and no more than 5 days after symptom onset. High-risk patients who present within 6 to 10 days of symptoms onset should be referred for monoclonal antibody therapy.

The most common side effects reported during treatment and within 14 days after the last dose of molnupiravir were mild or moderate diarrhea, nausea, dizziness, and headache. For Paxlovid, mild or moderate dysgeusia, diarrhea, hypertension, and myalgia were reported.

Oral antivirals are not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19 and should not be used for longer than 5 consecutive days.

Referring Patients for Oral Antivirals

To ensure equitable access to oral antivirals, the NYC Department of Health and Mental Hygiene (Health Department) has partnered with Alto Pharmacy, a pharmacy delivery service. At this time, this is the only way NYC patients can receive oral antivirals. As supplies increase, additional pharmacies will be added.

Prescriptions placed with Alto Pharmacy will be delivered to the patient's preferred address at no cost. Once the prescription is placed, patients can schedule their delivery on the Alto mobile app, by text, or by phone with Alto pharmacists. Alto Pharmacy can offer direct support in English and Spanish and support in numerous other languages through language line. Prescriptions confirmed by 5 p.m. on weekdays or 1 p.m. on weekends will be delivered the same night. For instructions on how to prescribe oral antivirals in NYC, visit nyc.gov/health/covidprovidertreatments and look for "Referring or Offering Oral Antiviral Therapy" in the "Oral Antiviral Treatment" section.

Providers who would like to automatically have molnupiravir substituted when Paxlovid is unavailable must submit two prescriptions, one for each medication, and state in the notes section of the molnupiravir prescription, "to be used in case Paxlovid prescription cannot be filled because of supply limitation." Substituting with molnupiravir can only be done for patients meeting eligibility criteria and with no contraindications for either product.

Changes to Monoclonal Antibody Use

At this time, Sotrovimab (Xevudy) is the only authorized monoclonal antibody therapeutic that is expected to be effective against the omicron variant of SARS-CoV-2. Supplies of Sotrovimab

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are extremely limited and providers should adhere to NYS DOH prioritization guidance, and refer to the NYC Health Department's Letter to Providers: Omicron and Monoclonal Antibodies.

As of December 23, 2021, there is a pause on further allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV until further notice. Bamlanivimab with etesevimab and REGEN-COV do not retain activity against omicron and should not be used. Monoclonal antibody treatment can no longer be used as post-exposure prophylaxis.

Outpatient Use of Remdesivir

The National Institute of Health (NIH) has issued treatment recommendations given therapeutics shortages and inactivity of some therapeutics against the omicron variant. This includes the use of remdesivir via IV infusion on an outpatient basis. Remdesivir is FDA-approved for hospitalized patients only; use of the drug for outpatient treatment would be an off-label indication. It is currently unknown if this treatment option will be available for patients in NYC. Do not send patients to the hospital to request treatment unless first identifying a facility and making arrangements in advance. See NIH COVID-19 Treatment Guidelines for more information.

Providers not offering treatment can refer patients to NYC Health + Hospitals. Patients can be connected to a health care provider by calling 212-COVID19 (212-268-4319). Treatment is available regardless of immigration status or ability to pay.

Thank you for all you are doing to help support the safety of your patients and our city. Please check nyc.gov/health/covidprovidertreatments regularly for updated guidance, including on treatment supply and prioritization.

Sincerely,

Celia Quinn MD, MPH
Deputy Commissioner
Division of Disease Control