

**Congress of the United States**  
**Washington, DC 20515**

February 4, 2022

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

The Honorable Rochelle P. Walensky  
Director  
Centers for Disease Control and Prevention  
1600 Clifton Road  
Atlanta, GA 30329

Dear Administrator Brooks-LaSure and Director Walensky:

On December 20, 2021, the Food and Drug Administration (FDA) approved a potentially transformative new kind of pre-exposure prophylaxis (PrEP) against the risk of sexually acquired HIV: Apretude.<sup>1</sup>

We commend the FDA for approving this breakthrough treatment: injectable PrEP. By making PrEP easier for patients than ever before, Apretude can play a critical role in preventing new HIV infections — enabling millions of Americans to live free from fear of HIV. To ensure that this life-saving medication is as accessible as possible to the people who need it most, particularly LGBTQ+ people and people of color, we urge you to ensure that public and private insurance plans cover Apretude at no cost to patients — just like the other forms of PrEP.

PrEP has been a critical tool in the decades-long effort to overcome the HIV epidemic. When taken properly, PrEP is 99 percent effective against sexually acquired HIV infections.<sup>2</sup> For that reason, PrEP is recommended for 1.2 million people in the United States.<sup>3</sup> According to the Centers for Disease Control and Prevention (CDC), increased use of PrEP between 2015 and 2019 contributed to an eight percent decrease in new HIV infections.<sup>4</sup> Because PrEP has proven to be such an effective public health tool, the CDC aims to ensure that by 2030, at least 50 percent of the people who could benefit from PrEP are using it.<sup>5</sup>

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<sup>1</sup> *FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention*, U.S. Food and Drug Administration (Dec. 20, 2021), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention>.

<sup>2</sup> *Pre-Exposure Prophylaxis (PrEP)*, Centers for Disease Control and Prevention (Aug. 6, 2021), <https://www.cdc.gov/hiv/risk/prep/index.html>.

<sup>3</sup> *PrEP for HIV Prevention in the U.S.*, Centers for Disease Control and Prevention (Nov. 23, 2021), [https://www.cdc.gov/nchstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html#anchor\\_1637678358](https://www.cdc.gov/nchstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html#anchor_1637678358).

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

Regrettably, using PrEP effectively can be challenging. Until now, the only way to administer PrEP was to take a pill every single day.<sup>6</sup> What's more, oral PrEP requires quarterly blood tests and follow-up appointments to monitor for HIV infection and detect side effects.<sup>7</sup>

These burdens are a major reason why far fewer people take PrEP than could benefit from the treatment, and why many of the people who do use PrEP struggle with it. Multiple medical, social, and socioeconomic factors make it challenging for many people to meet these demands, including poverty, mental health conditions, challenges with substance use, social pressure to conceal the medication, and simple forgetfulness.<sup>8</sup> As a result, in 2020, only 25 percent of the people for whom PrEP was recommended were even prescribed it.<sup>9</sup>

Not only has access to PrEP been inadequate, it has also been inequitable. The disparate impacts of HIV on communities of color and transgender women are mirrored by the disparately low access to PrEP in those same communities. While the rate of HIV infections among Black Americans is eight times as high as among white Americans, just nine percent of the Black Americans for whom PrEP is recommended have been prescribed this vital preventative medication, compared to 66 percent of comparable white Americans. Similarly, while the HIV infection rate among Hispanic Americans is four times as high as among white Americans, only 16 percent of recommended Hispanic Americans have been prescribed PrEP.<sup>10</sup> Moreover, although transgender women face a high risk of HIV infection, only 32 percent of trans women who are eligible take PrEP.<sup>11</sup> Making PrEP accessible to every person who needs it is vital to winning our ongoing fight to eradicate HIV and to affirm LGBTQ+ and racial justice.

Because Apretude is much easier to take properly than oral PrEP, it promises to make PrEP more accessible, on more equitable terms, than ever before. This injectable drug is effective after only an initial round of two doses, one month apart, followed by an additional dose every two months thereafter.<sup>12</sup> As a result, in the randomized, double-blind trials the FDA cited in approving

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<sup>6</sup> *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States — 2021 Update: A Clinical Practice Guideline*, U.S. Public Health Service (2021), <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>.

<sup>7</sup> *Id.*

<sup>8</sup> *FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention*, U.S. Food and Drug Administration (Dec. 20, 2021), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention>.

<sup>9</sup> *Id.*

<sup>10</sup> *PrEP for HIV Prevention in the U.S.*, Centers for Disease Control and Prevention (Nov. 23, 2021), [https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html#anchor\\_1637678358](https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html#anchor_1637678358).

<sup>11</sup> *Id.*

<sup>12</sup> *FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention*, U.S. Food and Drug Administration (Dec. 20, 2021), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention>.

Apretude, cisgender men and transgender women who have sex with men were 69 percent less likely to become infected with HIV while taking Apretude than while taking oral PrEP.<sup>13</sup> Cisgender women were 90 percent less likely to become infected.<sup>14</sup>

To fully realize the promise of this new preventative medication, we urge you to require public and private insurance to make Apretude available for free to all people for whom PrEP is recommended — just like oral PrEP is today. As it stands, the list price of the drug alone is \$3,700 per dose.<sup>15</sup> And that price does not include the cost of clinic visits and lab tests. Unless you act, Apretude will be financially inaccessible for the very people who need it most.

Last July, you acted to ensure that insurance plans covered oral PrEP for the people who need it, at no cost to patients. The Departments of Labor, Health and Human Services, and Treasury, in collaboration with the CDC and the Centers for Medicare and Medicaid Services (CMS), announced that most public and commercial health care plans had to cover all costs associated with PrEP, including the medication itself, clinic visits, and laboratory tests.<sup>16</sup>

Our health care system must not financially discriminate against what may be the most effective way of preventing this harrowing epidemic. Insurance plans should provide Apretude on those same terms: cost-free. We also urge you to use every tool at your disposal to make all forms of PrEP, including Apretude, free to everyone who needs them, regardless of insurance status.

Only by making Apretude free can we fulfill its promise to liberate millions of people, particularly LGBTQ+ people and people of color, from the risk of HIV infection. Thank you for your life-saving work to end the HIV epidemic. We look forward to working with you.

Sincerely,



Mondaire Jones  
Member of Congress



Ritchie Torres  
Member of Congress

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<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> Brooke Sopelsa, Matt Lavietes, and Benjamin Ryan, *FDA Approves First Injectable HIV Prevention Drug*, NBC News (Dec. 20, 2021), <https://www.nbcnews.com/nbc-out/out-health-and-wellness/fda-approves-first-injectable-hiv-prevention-drug-rcna9426>.

<sup>16</sup> *FAQs About Affordable Care Act Implementation Part 47*, Centers for Medicare and Medicaid Services (July 19, 2021), <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-47.pdf>.

/s/  
Alexandria Ocasio Cortez  
Member of Congress

/s/  
Jan Schakowsky  
Member of Congress

/s/  
Karen Bass  
Member of Congress

/s/  
Jerrold Nadler  
Member of Congress

/s/  
Mark Pocan  
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Troy A. Carter, Sr.  
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Sean Patrick Maloney  
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Bobby L. Rush  
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Judy Chu  
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Adam B. Schiff  
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Henry C. "Hank" Johnson Jr.  
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Eleanor Holmes Norton  
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Jahana Hayes  
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Thomas R. Suozzi  
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Mark Takano  
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Danny K. Davis  
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Rashida Tlaib  
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Debbie Wasserman Schultz  
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Colin Allred  
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Dina Titus  
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Sean Casten  
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Ilhan Omar  
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G. K. Butterfield  
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Sheila Cherfilus-McCormick  
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Jesús G. "Chuy" García  
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