HIV+HEP
POLICY INSTITUTE

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Tamara Syrek-Jensen, JD
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
Mailstop S3-02-01
7500 Security Boulevard
Baltimore MD 21244

Subject: Medicare National Coverage Determination for Long-Acting Injectable PrEP

Dear Ms. Syrek-Jensen:

On behalf of the HIV+Hepatitis Policy Institute, an organization dedicated to promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions, we thank you for this opportunity to comment on a National Coverage Determination (NCD) by the Centers for Medicare and Medicaid Services (CMS) on the use of provider-administered pre-exposure prophylaxis (PrEP).

The first provider-administered medication for HIV pre-exposure prophylaxis (Apretude or cabotegravir as PrEP) was approved by the Food and Drug Administration in January 2022. In August 2022, we wrote to you on behalf of 64 organizations to request that CMS quickly and efficiently evaluate provider-administered PrEP for a National Coverage Determination, which is the only pathway to coverage under Medicare Part B. (1)

We commend CMS on moving forward with the NCD process and urge CMS to approve the NCD for provider-administered PrEP.

PrEP is safe and effective, but only 301,000 of the estimated 1.2 million people who could benefit from PrEP are using it. In addition, there are stark and widening racial, ethnic, and gender disparities in uptake, with only 9 percent of eligible African-American individuals and 16 percent of eligible Hispanic/Latino individuals prescribed PrEP, while 66 percent of White individuals eligible for PrEP are prescribed it. (2) The importance of improving PrEP uptake is reflected in the key role PrEP plays both in the National HIV/AIDS Strategy 2022-2025 and in the Prevention pillar of the Ending the HIV Epidemic Initiative. (3) However, Medicare Part B beneficiaries currently cannot access long-acting PrEP. Completion of a NCD will rectify this and

also make provider-administered PrEP available at no cost to the patient. Patient out-of-pocket costs have been a significant barrier to PrEP uptake and the NCD will eliminate this barrier.

FDA approval of cabotegravir as PrEP, the first provider-administered PrEP option, was based on the overwhelming success of two clinical trials showing superiority to daily oral PrEP. In HPTN 083, MSM and transgender participants experienced 69 percent less risk of HIV infection that those in the daily oral PrEP arm; in HPTN 084 cisgender women participants experienced 90 percent risk of HIV infection. Researchers concluded that better adherence was the principal driver of these findings. (4, 5)

Provider-administered PrEP meets all of the requirements for coverage as a preventive service under Medicare Part B.

According to Section 1861 (ddd) of the Social Security Act, CMS may cover "additional preventive services" under Medicare Part B if those services are determined to be:

(A) reasonable and necessary for the prevention or early detection of an illness or disability;
(B) recommended with a grade of A or B by the United States Preventive Services Task Force; and
(C) appropriate for individuals entitled to benefits under part A or enrolled under part B.

We believe Apretude and any future provider-administered medications that may be approved as PrEP by FDA indubitably meet these requirements. The USPSTF A-rating and CDC updated clinical guidelines demonstrate that there is abundant evidence for the necessity of PrEP to stop the spread of HIV. CDC guidelines incorporated clinical recommendations for cabotegravir as PrEP in 2021 even prior to FDA approval. (6) USPSTF circulated a draft update to its 2019 A-rating for PrEP in December 2022. (7)

Medicare covers 10 percent of the population using PrEP, with 65 percent of those beneficiaries being disabled individuals under 65. (8) With the progress of urgently needed efforts to reduce the racial, ethnic, and gender disparities in PrEP uptake, we expect that the proportion of PrEP patients covered by Medicare (including dual eligibles) will rise.

It is important for the NCD to clarify that required ancillary services are covered alongside PrEP medications.

The USPSTF recommendation for PrEP encompasses not only the medication, but also a suite of ancillary services, including HIV testing (HIV-1 RNA assay), STI testing and counseling, and adherence counseling. These services are required at PrEP initiation and for monitoring at follow-up visits. We ask that CMS explicitly cover any ancillary services recommended by USPSTF or future CDC clinical guidance updates as part of the NCD. Medicare does not currently cover PrEP-related ancillary services at the frequencies specified in CDC or USPSTF guidance for individuals using any form of PrEP (daily oral or provider-administered long-

acting). This coverage gap threatens uptake of PrEP and prevention of HIV infection for all Medicare beneficiaries.

We urge CMS to include future provider-administered PrEP medications approved by FDA in the scope of this NCD.

We encourage CMS not to limit the scope of this NCD to cabotegravir as PrEP (Apretude), currently the only FDA-approved provider-administered PrEP medication. There is an active pipeline of PrEP drugs being investigated which is likely to yield other provider-administered PrEP medications in the future. It is important to ensure that adoption of new PrEP medications and modalities are not slowed by a need for separate NCDs for each drug. Disparities in PrEP uptake are only exacerbated when access to new PrEP choices is limited by lack of coverage or cost-sharing barriers. Delaying access to all PrEP options for all Medicare beneficiaries risks diminishing the success of the National HIV AIDS Strategy and the Ending the HIV Epidemic initiative.

If you have any questions or comments, please contact Carl Schmid, HIV+Hepatitis Policy Institute at cschmid@hivhep.org or (202) 462-3042.

Sincerely,

Carl E. Schmid II

References

(1) https://hivhep.org/testimony-comments-letters/64-organizations-request-expedited-medicare-national-coverage-determination-for-long-acting-injectable-prep/.

(2) Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2020. HIV Surveillance Supplemental Report 2022;27- (No. 3). https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2022. Accessed January 17, 2023

(3) Office of National AIDS Policy. National HIV/AIDS Strategy (2022-2025), https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025.

(4) HIV Prevention Trials Network, HPTN 083 Study Summary, available at https://www.hptn.org/research/studies/hptn083.

(5) HIV Prevention Trials Network, HPTN 084 Study Summary, available at https://www.hptn.org/research/studies/hptn084.

(6) US Public Health Service. Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States: 2021 Update, https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf (December 2021).

(7) United States Preventive Services Task Force, draft update: Prevention of HIV Infection: Pre-Exposure Prophylaxis. https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025. December 2022.

(8) Proprietary IQVIA data cited in ViiV NCD request, https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id310.pdf February 2022.