HIV+HEP
POLICY INSTITUTE

August 10, 2023

SUBMITTED ONLINE: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=310

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Coverage and Analysis Group
Center for 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 Pre-Exposure Prophylaxis Using Antiretroviral Therapy to Prevent HIV Infection

Dear Ms. Katonak and Dr. Li:

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 issuing the recently released draft decision memorandum for the National Coverage Determination (NCD) by the Centers for Medicare and Medicaid Services (CMS) on pre-exposure prophylaxis (PrEP) using antiretroviral therapy to prevent HIV infection.

Before we offer our specific comments on the draft NCD, we want to thank you for acting so quickly on this proposal and for your genuine interest in expanding Medicare coverage of all forms of PrEP as a no-cost preventive service. This will help improve PrEP access and uptake and bolster efforts to end the HIV epidemic in the United States. 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.[1] In February 2023 we submitted public comments on the NCD during the initial public comment period.[2]

While we commend CMS on the draft NCD memorandum specific to provider-administered PrEP, we urge CMS to amend it in a number of areas, as described below. Additionally, we do have a number of implementation concerns pertaining to oral PrEP that CMS must address. These are also described below.

With deep and widening racial, ethnic, and gender disparities in uptake, access to PrEP through Medicare is of paramount importance to making sure that Medicare beneficiaries are able to benefit from the widening array of PrEP options without cost-sharing. Medicare beneficiaries (including those dually eligible for Medicaid) comprise 10 percent of the population using PrEP,[3] including both individuals over 65 as well as disabled individuals under 65. We thank CMS for making clear that all FDA-approved forms of PrEP would be available without cost-sharing. This means that Medicare beneficiaries will have unfettered access to future novel forms of PrEP immediately after FDA approval.

Please find below our specific comments, suggestions, and areas of concern.

We call for CMS to amend the draft NCD to cover <u>all</u> CDC-recommended ancillary services at the annual frequencies specified in current CDC guidance.

As described in the draft NCD, PrEP encompasses not only medication, but also a suite of ancillary services, including STI testing and counseling, HIV testing (HIV-1 RNA assay), renal function testing, and adherence counseling. These services are required at PrEP initiation and for monitoring at follow-up visits, with a different cadence of testing recommended in the CDC's most recent guidance for oral and injectable PrEP.[4]

We commend CMS' draft NCD memo for covering up to seven visits annually including HIV risk assessment and adherence counseling, as well as HIV screening seven times a year and HBV screening once a year. However, we urge CMS to clarify that the seven covered HIV screenings encompass both HIV-1 RNA testing—qualitative and quantitative—as well as HIV antibody-antigen testing at frequencies specified in current CDC practice guidelines. We also urge CMS to state explicitly that renal function testing (especially important for older PrEP users) is covered semiannually.

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

[2] https://hivhep.org/testimony-comments-letters/comments-on-medicare-national-coverage-determination-for-long-acting-injectable-prep/.

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

[4] 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).

We ask that CMS explicitly cover all ancillary services recommended for people on PrEP within the USPSTF A-rated recommendation for PrEP. Also, since an update to USPSTF's recommendation is pending,[5] we also ask that CMS explicitly incorporate the most recent USPSTF and CDC clinical guidance updates into the NCD. Whenever the standards of care for PrEP change, including ancillary services or frequency of laboratory testing, these new standards should be incorporated without delay into Medicare coverage. Any coverage gaps threaten improved uptake of PrEP and prevention of HIV infection for all Medicare beneficiaries.

We are especially concerned that the draft NCD does not include coverage of required STI tests at the cadence recommended by CDC's PrEP guidelines.

We are disappointed by CMS' failure to align Medicare coverage of STI screenings with CDC guidelines for PrEP. CMS' draft decision memo states that CMS "recognize[s] that the CMS STI screening policy differs from the above CDC recommendations regarding the frequencies of STI screenings and chlamydia and gonorrhea screening in men receiving PrEP," and also cites USPSTF's 2021 STI screening recommendations[6] which conclude that the evidence is "insufficient to assess the balance of benefits and harms of screening for chlamydia and gonorrhea in men." Though CMS states that "in the future, we may consider screening for additional populations if recommended with a Grade A or B by the USPSTF," it is important to recognize that USPSTF already does encompass quarterly chlamydia and gonorrhea screenings for men who have sex with men and transgender women within its A-rating for PrEP. The 2021 STI screening recommendations are superseded for all PrEP patients by the STI screening recommendations in the USPSTF PrEP recommendation (which will be updated later this year).

To state that "diagnostic STI testing may be performed for any sexually active beneficiary with signs or symptoms of infection" is not sufficient. Detection of asymptomatic STI infection—and the resulting decrease of HIV transmission risk—is part of the rationale for quarterly STI testing as recommended in current CDC practice guidelines. We urge CMS to match Medicare coverage with CDC recommendations, as is already done by commercial insurance as well as most state Medicaid programs.

We ask CMS to modify language in the NCD referring to "persons at high risk for HIV acquisition."

Referring to persons at "high risk" for HIV translates into a variety of harms to people who would benefit from HIV prevention. Many individuals who should be on PrEP to prevent HIV do not perceive themselves as being at "high risk"; additionally, some providers may themselves stigmatize people seen as "high risk." In addition, many patients do not disclose their sexual or

[5] 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.
[6] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/chlamydia-and-gonorrhea-screening.

substance use behaviors to their providers. For this reason, the CDC's most recent PrEP guidelines recommend that PrEP be discussed with all sexually active adults and adolescents, and that PrEP be prescribed to all who request it. Without an explicit endorsement of these principles in the finalized NCD, providers may unnecessarily limit access to PrEP to the many patients who are not comfortable detailing their reason for wanting to be on PrEP. We suggest the NCD use the term "at an increased risk for HIV acquisition" instead.

We urge CMS to incorporate language in the final NCD affirming that prior authorization or other utilization management should not be used for PrEP medications.

Utilization management is not generally employed for HIV drugs in Part D, as specified in the Medicare Prescription Drug Benefit Manual.[7] We believe this should also apply to HIV drugs through Part B, including PrEP. We urge CMS to state that utilization management should not be used for PrEP accessed through Part B, whether fee-for-service Part B, or through a Medicare Advantage plan. We also urge CMS not to allow prior authorization for the purpose of assessing HIV risk: this should be the clinician's determination, not the payor's.

We urge CMS to resolve implementation issues prior to requiring coverage of oral PrEP medications through Medicare Part B rather than Part D.

While we commend CMS on its bold and innovative move to provide coverage of all forms of PrEP to Medicare beneficiaries without copay by moving all PrEP drugs to Part B,[8] we believe there are a number of implementation issues that must be addressed. A transition to coverage of oral PrEP from coverage in Part D to coverage in Part B will require careful implementation and guidance from CMS to ensure that patients, pharmacies, plans, and providers have clarity in the course of a potentially confusing transition. We note that though all pharmacies in the United States may bill Part D, only 76 percent of pharmacies have enrolled to bill Medicare Part B,[9] only a few of which will have experience dispensing the few oral self-administered drugs currently available through Part B. Some unenrolled pharmacies are providing PrEP to thousands of PrEP patients who would need to switch if these pharmacies do not enroll to bill Part B, which is more complex and requires more documentation than billing through Part D.

Dispensing oral PrEP through Part B may expose PrEP patients to new obstacles. For instance, Part B medications must be picked up within a day after prescriptions are billed. Pharmacies are only allowed to dispense a 30-day supply, rather than a 90-day supply that PrEP users are accustomed to and prefer. We urge CMS to ensure that 90-day fills of PrEP are available through Part B.

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[7] https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/partdmanuals, chapter 6, section 30.2.5.

[8] https://www.hiv.gov/blog/cms-proposes-medicare-coverage-for-prep-invites-public-comment-by-august-11.

[9] https://oig.hhs.gov/oei/reports/oei-02-15-00440.pdf, page 3.

Shipment of PrEP medications by mail and telehealth are of critical importance to PrEP access. CMS must guarantee that mail order shipments of oral PrEP medications through Part B are feasible, including for patients seen by telehealth, to ensure smooth access to oral PrEP through Part B. **We encourage CMS to meet with members of the HIV community, pharmacists, providers, plans, and manufacturers to fully understand and prepare for these important implementation issues.**

Ultimately, CMS must provide clear guidance for PrEP patients who may be confused by the need to switch pharmacies, as well as to providers, pharmacies, and plans. We urge CMS to eliminate any barriers and disincentives for pharmacies to enroll in Part B billing. **While we know that CMS' goal is to increase access to all forms of PrEP without cost-sharing, we do not want to create any new barriers to accessing oral PrEP.**

We would also note that oral HIV treatment and post-exposure prophylaxis (PEP) medications would continue to be available through Part D. Two oral PrEP medications (Truvada, or emtricitabine/tenofovir disoproxil fumarate, and Descovy, or emtricitabine/tenofovir alafenamide fumarate), may also be prescribed as a component of HIV treatment or PEP. We must be certain that Medicare enrollees living with HIV, and those trying to access emergency post-exposure prophylaxis, do not encounter confusion at the pharmacy counter when trying to access their medications. Clear communication and guidance are required so that plans, pharmacy staff, and providers can continue to provide smooth and timely access to each of these important interventions in both Part B and Part D.

If you have any questions or comments, please contact Carl Schmid, HIV+Hepatitis Policy Institute at cschmid@hivhep.org or (202) 462-3042, or Kevin Herwig, HIV+Hepatitis Policy Institute at kherwig@hivhep.org or (617) 666-6634.

Sincerely,

Carl E. Schmid II
Executive Director