

# Medicare Coverage of HIV Pre-exposure Prophylaxis (PrEP): Information for Patients, Providers, and Pharmacists

### Coverage of PrEP in Medicare: Transition to Coverage in Part B

The federal Centers for Medicare and Medicaid Services (CMS) are considering issuing a final National Coverage Determination (NCD) for PrEP directing Medicare to cover all forms of PrEP (oral and injectable) through Medicare Part B, the portion of Medicare that covers outpatient treatment. If CMS does this, Medicare beneficiaries will be able to get PrEP under Medicare Part B with zero cost-sharing.

This would be a change from the way that Medicare previously covered oral PrEP, which was through Medicare Part D, the Medicare prescription drug program. Medicare Part D is administered by private health insurance plans that Medicare beneficiaries can enroll in. (Some Medicare beneficiaries receive their prescription drug coverage bundled in Medicare Advantage or Part C plans.) Since federal regulations require all antiretroviral drugs, including PrEP, to be included in a Part D plan's formulary without prior authorization or step therapy rules, there could be no prior authorization or step therapy requirements for PrEP under Medicare Part D.¹ However, Medicare Part D plans could require deductible, coinsurance, or copayments for PrEP. The transition to Part B coverage would eliminate these cost sharing requirements for patients.

CMS currently anticipates that the final NCD transitioning PrEP coverage to Part B will be posted and effective in late September 2024. CMS is therefore urging pharmacies to prepare now for this transition. More information is provided below, and further details are available in a <a href="Prep for HIV National Coverage">PrEP for HIV National Coverage</a>
Determination: Technical Frequently Asked Questions for Pharmacies, which CMS released in June 2024.

#### What ancillary services related to PrEP will Medicare cover?

The proposed NCD includes coverage of the following clinical and laboratory services required for PrEP:

- Up to seven individual counseling visits, every 12 months, "that include HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence";
- HIV screening up to seven times annually; and
- A single screening for hepatitis B virus (HBV).<sup>2</sup>

Like the medications for PrEP, these services would be covered under Medicare Part B with no costsharing. In addition to the Technical FAQ for Pharmacies, CMS has published a <u>Fact Sheet</u> on future Part

<sup>&</sup>lt;sup>1</sup> See 42 C.F.R. § 423.120(b)(2)(vi)(C); 84 Fed. Reg. 23,832 (May 23, 2019).

<sup>&</sup>lt;sup>2</sup> Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection, National Coverage Analysis, Proposed Decision Memo (July 12, 2023), <a href="https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=310">https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=310</a> ("Proposed NCD").

B coverage of PrEP that includes suggested billing codes for the above ancillary services, as well as a new diagnosis code (Z29.81: Encounter for HIV pre-exposure prophylaxis) that can be used for PrEP.

Other clinical or laboratory services needed for patients on PrEP, however, would be subject to preexisting Medicare rules regarding coverage. So, for example, Medicare covers screening for chlamydia, gonorrhea, and syphilis for certain groups at increased risk, with no coinsurance or deductible, but the groups eligible for these screenings and the frequency of screenings do not align completely with the CDC recommendations for STI screenings for PrEP.<sup>3</sup> CMS would likely only cover STI screenings as established in these preexisting rules, even for PrEP patients.

In addition, the proposed NCD does not discuss Medicare coverage of hepatitis C screening, so this service would likely also be subject to existing Medicare coverage rules. In general, Medicare covers a single hepatitis C screening for adults born from 1945 through 1965, and annual screening for people at "high risk," with no deductible or coinsurance.<sup>4</sup> "High risk" is defined as those who have used "illicit injection drug[s]" since their last screening test and those who received a blood transfusion before 1992.

CMS's proposed PrEP NCD also does not indicate clearly the extent to which renal function testing will be covered as part of the new Part B PrEP benefit, although it notes that "pregnancy, kidney function, liver function, and lipid testing, may be ordered at the physician or health care practitioner's discretion under existing Medicare coverage." Tests ordered under this coverage may be subject to Medicare Part B's usual deductible and coinsurance requirements.

## What should pharmacies do to ensure that they can fill prescriptions for PrEP under Medicare Part B?

Pharmacies that dispense PrEP should ensure that they are enrolled in Medicare as either: 1) a durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier (CMS-855S), or 2) a Part B Pharmacy supplier (CMS-855B). A pharmacy that is enrolled in Part B solely as a "mass immunization" pharmacy will need to enroll as a Part B Pharmacy supplier. For more information, view CMS's <u>Fact Sheet</u> and <u>Technical FAQ</u> for Pharmacies.

To enroll as a Part B Pharmacy supplier, pharmacies can visit the <u>Medicare Provider Enrollment</u> website, or contact their Medicare Administrative Contractor (MAC) for support. The MAC for Medicare Parts A and B in Massachusetts is National Government Services, Inc., and their contact information is <u>available here</u> (last updated 7/10/2024). Since enrollment in Part B is a multi-step process and takes time, pharmacies seeking to enroll as a Part B Pharmacy supplier in order to continue providing PrEP for Medicare patients are encouraged to begin the process as soon as possible.

<sup>&</sup>lt;sup>3</sup> See Screening for Sexually Transmitted Infections (STIs) and High-Intensity Behavioral Counseling (HIBC) to Prevent STIs (NCD 210.10), <a href="https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=352&ncdver=1">https://www.medicare.gov/medicare.gov/medicare.gov/medicare.gov/medicare.gov/medicare.gov/medicare.gov/medicare.gov/medicare.gov/coverage/sexually-transmitted-infection-screenings-counseling.</a>

<sup>&</sup>lt;sup>4</sup> See Screening for Hepatitis C Virus (HCV) in Adults (NCD 210.13), <a href="https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=361">https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=361</a>; Medicare.gov, Hepatitis C Screenings, <a href="https://www.medicare.gov/coverage/hepatitis-c-screenings">https://www.medicare.gov/coverage/hepatitis-c-screenings</a>.

<sup>&</sup>lt;sup>5</sup> Proposed NCD, supra n.2.

CMS's Fact Sheet also includes anticipated drug and billing and payment codes that pharmacies will use to bill Medicare Part B for PrEP. It will be important for pharmacies to ensure that they are using the correct billing codes in order to avoid patients being charged copayments.

PrEP users with Medicare Advantage plans may need to use an in-network pharmacy to obtain PrEP through Medicare Part B. Medicare Advantage plan members should contact their plan for more information. PrEP users enrolled in fee-for-service Medicare (i.e. traditional Medicare) who need to locate a pharmacy that accepts Part B for PrEP are encouraged to call 1-800-MEDICARE (1-800-633-4227), or to use Medicare's supplier director to locate a pharmacy that accepts Medicare coverage for medical equipment and supplies.

#### Where can I find more information about coverage of PrEP?

A <u>webinar is available</u> with additional details that may be helpful to community health centers and pharmacies as they prepare for the transition from Part D to Part B coverage of PrEP.

For questions regarding PrEP coverage in Massachusetts under private insurance plans or Medicaid (MassHealth), see CHLPI's <u>Frequently Asked Questions</u> guide to PrEP access. For questions about PrEP access beyond Massachusetts, see NASTAD's guide to <u>PrEP/PEP Access</u>.