

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 00-00-00
Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE

DATE: August 1, 2024

TO: All Medicare Advantage (MA) Organizations and Part D Plan Sponsors

FROM: Vanessa S. Duran, Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Proposed National Coverage Determination (NCD) on Preexposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention

On July 12, 2023, CMS issued a proposed decision memorandum.¹ In this memorandum, CMS proposed to cover PrEP using antiretroviral drugs (whether oral or injectable) approved by the U.S. Food and Drug Administration (FDA) to prevent HIV infection in individuals at high risk of HIV acquisition. CMS also proposed to cover 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. Additionally, for individuals being assessed for or who are taking PrEP, CMS proposed to cover HIV screening up to seven times annually and a single screening for hepatitis B virus (HBV). The final NCD is expected to be posted and effective in late September 2024 and is expected to be similar to the proposed NCD that was published on July 12, 2023.

In preparation for the expected release of the final NCD, we are providing some additional information for MA organizations and Part D plan sponsors to encourage pharmacies and other interested parties to prepare for the expected transition in coverage for PrEP from Part D to Part B. The final NCD will have important consequences for Medicare beneficiaries, MA organizations, and Part D plan sponsors. The NCD will be effective on the day the final decision is issued, with no delay in the effective date. Because the NCD has not yet been issued, PrEP for HIV prevention is currently still covered by Part D.

If the final NCD is posted as expected, MA organizations will be required to comply with the NCD and cover PrEP, the additional screening tests, and counseling services as a zero-dollar cost-sharing preventive service when provided by an in-network provider.² MA plans may apply utilization management policies so long as they provide coverage consistent with the applicable

¹ <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=310>

² See 42 CFR § 422.100(k), which provides that MA organizations may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services (as defined in § 410.152(l)). Section 410.152(l)(11) includes “Additional preventive services identified for coverage through the national coverage determination (NCD) process.”

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NCD. MA organizations and parties involved in processing Part C claims should work with their contracted pharmacies to prepare for this expected transition to ensure their enrollees have access to the PrEP drugs.

In accordance with the requirements of § 423.120(b)(2)(vi)(C), CMS will not permit Part D plan sponsors to reject claims or implement prior authorization (PA) requirements on all PrEP drugs. Specifically, we will not permit Part D plan sponsors to require PA to determine if a drug is being used for PrEP when it has indications for both HIV prevention and HIV treatment. Denying such claims, or requiring PA to make the determination, may cause those individuals who are taking the medications for HIV treatment to experience unnecessary disruptions in care. However, we will permit Part D plan sponsors to implement edits to reject claims and require PA to prevent Part D payment for drugs that only have an indication for PrEP for HIV prevention. Part D plan sponsors may also consider implementing point-of-sale messaging to inform pharmacies that PrEP drugs are now coverable under Part B.

CMS does not expect or require that a diagnosis code be included on a prescription for any HIV prevention or HIV treatment drugs. However, if a diagnosis code is included, Part D plan sponsors may use that information to determine whether the drug should be covered under Part B, if it is being used for HIV PrEP, or Part D, if it is being used for HIV treatment or HIV post-exposure prophylaxis (PEP). We note that for pharmacies to submit a Part B claim to Medicare, a diagnosis code is required on the claim (please see the Technical Frequently Asked Questions for Pharmacies link referenced below for more information).

MA organizations that offer coordinated care MA-PD plans must establish and maintain a process (including communications and arrangements with network providers) to ensure timely and accurate point-of-sale transactions for drugs that may be covered under Part B or Part D.³ In addition, MA-PDs must issue an organization determination or coverage determination and authorize or provide the drug under Part B or as a benefit under Part D as expeditiously as the enrollee's health condition requires, in accordance with the requirements of 42 CFR Part 422, Subpart M and 42 CFR Part 423, Subpart M, as appropriate.⁴ Therefore, MA-PDs should work with their network pharmacies and prescribers to achieve a high degree of coordination and continuity and assure that point-of-sale transactions are accurate.

CMS expects MA organizations and Part D plan sponsors to communicate the expected change in PrEP for HIV prevention coverage to beneficiaries who may be affected if the final NCD is issued as expected. This will ensure these beneficiaries are aware that PrEP for HIV prevention is expected to no longer be covered under Part D and will instead be covered under Part B without cost sharing as an additional preventive service. Beneficiaries should also be made aware that drugs for HIV treatment and HIV PEP will remain coverable under Part D if the NCD is posted as expected.

In order to prepare for the expected transition in PrEP for HIV prevention coverage from Part D to Part B, we encourage Part D plan sponsors to communicate this expected change to their

³ 42 CFR § 422.112(b)(7).

⁴ *Id.*

contracted pharmacies and inform them that, if they have not already, they will need to enroll in Medicare as either: 1) a durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier (using the CMS-855S enrollment application), or 2) a Part B pharmacy supplier (using the CMS-855B enrollment application) to bill Part B for PrEP for HIV prevention. We encourage sponsors to share the linked [fact sheet](#) and [Technical Frequently Asked Questions for Pharmacies](#) document with PBMs, intermediaries and pharmacies, as these resources provide additional details on how to enroll as a DMEPOS supplier or Part B pharmacy and how to bill Part B for PrEP.

Many interested parties commented on the proposed NCD last year. Some commenters were concerned that a change to Part B coverage might be disruptive for patients who had been receiving coverage under Part D. CMS encourages plans to proactively prepare for the expected transition in coverage of PrEP for HIV prevention from Part D to Part B. With advance preparation, Part D plan sponsors can ensure affected beneficiaries are able to immediately benefit from this change in coverage and not experience any disruptions in care.

If you have any questions concerning this memorandum, please e-mail PartDPolicy@cms.hhs.gov.