

## **PrEP for HIV National Coverage Determination**

### *Technical Frequently Asked Questions for Pharmacies*

#### **Background**

##### **Q1. Why is CMS posting these FAQs?**

A1. CMS received public feedback asking that more technical information for submitting future Medicare Part B claims for PrEP for HIV be released in advance of the final National Coverage Determination. This FAQ provides more technical detail following the previous posting of the fact sheet. <https://www.cms.gov/files/document/fact-sheet-potential-medicare-part-b-coverage-preexposure-prophylaxis-prep-using-antiretroviral.pdf>

##### **Q2. When will CMS post the final NCD, and what will it cover?**

A2. We expect the final NCD to be posted and effective in late September 2024. The final NCD is expected to be similar to the proposed that was published on July 12, 2023, and pharmacies should prepare now to be ready for this transition. (<https://www.cms.gov/medicare-coverage-database/view/ncaal-decision-memo.aspx?proposed=Y&ncaid=310>).

#### **Enrollment**

##### **Q3. Are pharmacies currently enrolled in Medicare as durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) suppliers required to also enroll as Part B Pharmacy suppliers?**

A3. No. If a pharmacy is already enrolled as a DMEPOS supplier, they can submit future claims for PrEP for HIV drugs and for dispensing/supplying those drugs to their DME Medicare Administrative Contractor (MAC). The DME MAC is where DMEPOS supplier pharmacies currently send claims and, upon Medicare coverage, they will begin processing claims for PrEP for HIV drugs and the dispensing/supplying of those drugs.

##### **Q4. If a pharmacy is not already enrolled as a Medicare provider, which pathway to enrollment should they choose (either a DMEPOS supplier or a Part B Pharmacy supplier)?**

A4. We recommend that pharmacies consider enrolling as a Part B pharmacy supplier because of the lower burden of enrollment. There are additional enrollment requirements for DMEPOS suppliers as they are required to meet supplier standards, accreditation and have a surety bond. Revalidation of Part B Pharmacies is less frequent than revalidation for DMEPOS suppliers. Claims submitted by Part B Pharmacies are submitted to their A/B MAC.

##### **Q5. If I am a pharmacy enrolled only to “roster bill” Medicare for vaccinations, could I also bill for PrEP for HIV drugs and dispensing/supplying using this mechanism when the NCD is effective.**

A5. No. Roster billing would not be an appropriate mechanism to bill for these additional preventive services. Pharmacies will need to be enrolled as either a Part B Pharmacy supplier or a DMEPOS supplier.

#### **Billing Medicare Part B**

\*Note: Throughout this document, we refer to billing “Medicare Part B,” which can apply to billing the DME MAC or the Part A/B MAC depending on the pharmacy’s enrollment type.

##### **Q6. I am a DMEPOS pharmacy accustomed to the Medicare DMEPOS billing and documentation requirements for various DME. Do the same requirements apply to billing Medicare Part B (either**

**billing the DME MAC as an enrolled DMEPOS supplier or billing the A/B MAC as a Part B pharmacy supplier) for HIV PrEP drugs?**

A6. No. The following Durable Medical Equipment (DME) requirements would not be applicable if the NCD is finalized as proposed:

- The regulatory DME order, face-to-face, and refill requirements stated in 42 CFR 410.38;
- Any 30-day limitations for initial supplies and refills;
- Proof of delivery, as stated in 42 CFR 424.57(c)(12).

*We note faxed and electronic prescriptions can be used (ink or wet signatures would not be required).*

**Q7. Will pharmacies need to submit a diagnosis code with a claim to Medicare Part B?**

A7. Pharmacies will need to append a valid diagnosis code (ICD-10 CM) to claims submitted to Medicare Part B. There are multiple diagnosis codes that may be appropriate once the NCD becomes effective. These may include:

- Z11.4: Encounter for screening for human immunodeficiency virus [HIV]
- Z29.81: Encounter for HIV pre-exposure prophylaxis
- Z20.2: Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
- Z11.3: Encounter for screening for infections with a predominantly sexual mode of transmission
- Z11.59: Encounter for screening for other viral diseases
- Z20.5: Contact with and (suspected) exposure to viral hepatitis

**Q8. Once the NCD is effective, what codes would be available to pharmacies to bill PrEP for HIV drugs to Medicare Part B?**

A8. New codes have been established and will be available for use at the time of coverage.

- J0799 - FDA approved prescription drug, only for use as HIV pre-exposure prophylaxis (not for use as treatment of HIV), not otherwise classified, Short Descriptor: HIV prep, FDA approved, noc
- J0750 - Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg, oral, FDA approved prescription, only for use as HIV pre-exposure prophylaxis (not for use as treatment of HIV), Short Descriptor: HIV prep, ftc/tdf 200/300 mg
- J0751 - Emtricitabine 200 mg and tenofovir alafenamide 25 mg, oral, FDA approved prescription, only for use as pre-exposure prophylaxis (not for use as treatment of HIV), Short Descriptor: HIV prep, ftc/taf 200/25 mg
- J0739 - Injection, cabotegravir, 1 mg, FDA approved prescription, only for use as HIV pre-exposure prophylaxis (not for use as treatment for HIV) Short Descriptor: Injection, cabotegravir, 1 mg

**Q9. Once the NCD is effective, what date of service should be used on Medicare claims for dispensing/supplying HIV PrEP drugs?**

A9. The date of service on the claim should be the date the drug is picked up from the pharmacy or, if a mail order pharmacy, the date the drug is mailed. The claim should not include span dates.

**Q10. Assuming that the final NCD will be similar to the proposed decision, could pharmacies bill for oral and injectable PrEP for HIV drugs?**

A10. Yes. Based on the proposed decision, Part B would cover drugs covered as additional preventive services, and the service of supplying the drug regardless of the route of administration. There may also be instances when the injectable PrEP for HIV drug is supplied by the pharmacy to the provider for subsequent administration by a physician or health care practitioner qualified to administer the drug.

**Q11. If the NCD is finalized, will claims submitted to Medicare Part B have to include both the code for the PrEP for HIV drug and the code for supplying the drug?**

A11. A claim for a supplying fee will not necessarily be required. However, a claim for the supplying fee would need to be made on the same claim as the Medicare claim for the covered drug.

**Q12. Can pharmacies supply and bill Medicare Part B for more than a 30-day supply of oral PrEP for HIV drugs? Can pharmacies also bill a supply fee if they fill a prescription for injectable PrEP for HIV?**

A12. Yes. Once the NCD is effective, there will be three codes available to bill the supplying fee for oral PrEP for HIV and two supply codes for the injectable PrEP for HIV drug. Only one of these supplying codes may be on the claim.

**Q13. Must a pharmacy include the National Provider Identifier (NPI) of the ordering practitioner on a Medicare claim?**

A13. Yes. The pharmacy must include the name and NPI of the ordering/referring provider on the claim when billing Medicare Part B.