

# PrEP for HIV National Coverage Determination (NCD) Technical Frequently Asked Questions for Pharmacies

## Background

### Why is CMS posting these FAQs?

CMS received public feedback asking that more technical information for submitting Medicare Part B claims for PrEP for HIV be released. Also see the fact sheet at <https://www.cms.gov/files/document/fact-sheet-potential-medicare-part-b-coverage-preexposure-prophylaxis-prep-using-antiretroviral.pdf>.

### What does the final NCD cover?

CMS, under Medicare Part B, covers Pre-exposure Prophylaxis (PrEP) and other related services to prevent HIV without cost-sharing (i.e., deductibles or co-pays under Part B). Visit PrEP for HIV & Related Preventive Services <https://www.cms.gov/medicare/coverage/prep>. The final NCD was published on September 30, 2024, and is available at <https://www.cms.gov/medicare-coverage-database/view/ncacal-tracking-sheet.aspx?NCAId=310>.

## Enrollment

### 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?

No. If a pharmacy is already enrolled as a DMEPOS supplier, the pharmacy can submit 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 they process claims for PrEP for HIV drugs and the dispensing/supplying of those drugs.

### 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)?

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. For more information on pharmacy enrollment, listen to [this webinar](#) or [view the transcript](#) and visit <https://www.cms.gov/medicare/coverage/prep> and see the “How Do I Enroll” section.

### 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?

No. Roster billing is not an appropriate mechanism to bill for these additional preventive services. Pharmacies 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.

**I am a DMEPOS pharmacy accustomed to the Medicare DMEPOS billing and documentation requirements for various DME. Do the same payment 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?**

The following DMEPOS) payment requirements are not applicable when billing PrEP for HIV drugs under the NCD:

- The DMEPOS order, face-to-face, and refill requirements stated in 42 CFR 410.38;
- Any 30-day limitations for initial supplies and refills.

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

### **Do pharmacies need to submit a diagnosis code with a claim to Medicare Part B?**

Pharmacies need to append at least one valid diagnosis code (ICD-10 CM) to claims submitted to Medicare Part B. There are multiple diagnosis codes that may be appropriate under this NCD. These may include:

- Z29.81: Encounter for HIV pre-exposure prophylaxis
- Z11.4: Encounter for screening for human immunodeficiency virus [HIV]
- Increased risk factors reported: Z11.4, Z29.81, Z20.6, Z20.2, Z11.3, Z11.59, Z20.5, Z79.899, Z86.59, Z87.898, Z72.89, F11.10, F11.20, F11.21, F11.90, Z72.51, Z72.52, Z72.53, Z72.89, Z32.00, Z32.01, Z32.02, Z20.828, Z20.89, Z20.9

### **What are the expectations of the pharmacy when it comes to PrEP drugs?**

The dispensing pharmacy is expected to have and maintain the order from the ordering physician or non-physician practitioner and proof of delivery (i.e., a signed receipt or some other indication the item was dispensed to the beneficiary). The diagnosis code should be obtained from the ordering practitioner. At this time CMS has determined it is appropriate to deprioritize the review of these claims so that all involved parties can transition to the new environment.

### **What codes are available to pharmacies to bill PrEP for HIV drugs to Medicare Part B?**

New codes have been established and are available for use:

- 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
- Q0516 - Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 30-days

- Q0517 - Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 60-days
- Q0518 - Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription oral drug, per 90-days
- Q0519 - Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 30-days
- Q0520 - Pharmacy supplying fee for hiv pre-exposure prophylaxis fda approved prescription injectable drug, per 60-days

### **What date of service should be used on Medicare claims for dispensing/supplying HIV PrEP drugs?**

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.

### **Can pharmacies bill for oral and injectable PrEP for HIV drugs?**

Yes. Medicare Part B covers these drugs as additional preventive services and Medicare covers the service of supplying the drug. 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.

### **Do 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?**

To bill Medicare Part B for the supplying fee, it must be on the same claim as the Medicare claim for the covered drug.

### **Can pharmacies supply and bill Medicare Part B for more than a 30-day supply of oral PrEP for HIV drugs?**

Yes. There are three codes available to bill the supplying fee for oral PrEP for HIV with 30, 60 and 90-day options. Only one of these supplying codes may be on the claim.

### **Can pharmacies bill a supply fee if they fill a prescription for injectable PrEP for HIV and provide the drug to the beneficiary?**

Yes, there are two supply codes for the injectable PrEP for HIV drug. Only one of these supplying codes may be on the claim.

### **Can the pharmacy also bill a supply fee if they provide the injectable drug directly to the practitioner?**

The supply fee must be billed on the same claim as the PrEP for HIV drug. If the practitioner bills Medicare Part B for the PrEP for HIV drug, the pharmacy is not able to bill for the drug and therefore, not able to bill the supply fee. We understand in such arrangements that the pharmacy may invoice the practitioner.

### **Must a pharmacy include the National Provider Identifier (NPI) of the ordering physician or non-physician practitioner on a Medicare claim?**

Medicare Part B claims submitted to a DME MAC must include the name and NPI of the enrolled ordering/referring physician or non-physician practitioner in order for the claim to process. This information should also appear on claims submitted to A/B MACs. The name and NPI must appear in the Order and Referring dataset. This dataset provides information on all physician and non-physician

practitioners, by their NPI, who are of a type/specialty that is legally eligible to order and refer in the Medicare program and who have current enrollment records in Medicare. Pharmacists do not appear in the dataset and cannot order PrEP drugs for payment under Medicare Part B. For more information, please visit <https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/order-and-referring> and for information about who can order and certify please see <https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos/ordering-certifying>.

### **Can pharmacists furnish PrEP related services?**

Currently, under Medicare Part B, pharmacists are not eligible for direct payment for services furnished to Medicare patients. That is, if a pharmacist, under state scope of practice laws, furnishes counseling, injects a PrEP drug or orders PrEP, those services cannot be paid directly to the pharmacist and the drugs cannot be paid by Medicare Part B. Pharmacists may provide, when all conditions are met, services as auxiliary personnel “incident to” a physician’s or other practitioner’s service in certain settings. The incident to regulations require supervision by a physician or other practitioner, and such services would be billed by the supervising physician or practitioner. For further details regarding “incident to” services, we recommend that interested parties consult 42 CFR §§ 410.26 and 410.27 and <https://www.cms.gov/medicare/payment/fee-schedules/physician-fee-schedule/advanced-practice-providers/incident-services-supplies>.

### **How are the PrEP for HIV drugs and supply fees priced?**

In accordance with this National Coverage Determination (NCD), Medicare Administrative Contractors (MACs) will publicly post the payment allowances for the HCPCS codes for the PrEP for HIV drugs and supply fees. Please check the website of your MAC and contact them directly with questions. <https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/who-are-macs>.

We note that the CY 2025 Medicare Physician Fee Schedule (PFS) (89 FR 61930 through 61934) and CY 2025 Outpatient Prospective Payment System (OPPS) (89 FR 59399 through 59402) proposed rules included proposals that specified pricing for drugs covered as additional preventive services (DCAPS), such as PrEP for HIV drugs, proposed to be effective beginning on January 1, 2025. CMS will issue the final CY 2025 PFS and final CY 2025 OPPS rules in late fall 2024, which will further address these payment policy proposals.

### **Is CMS requiring reporting of modifiers on the HIV PrEP drugs and services claims?**

No. CMS is not requiring any modifiers on claims related to this NCD. Claims will be processed by the DME MAC or A/B MAC without any modifier; however, the presence of a modifier should not, in itself, result in a claims rejection.

### **How should a pharmacy bill if the beneficiary has a Medicare Advantage plan?**

Medicare Advantage plans must follow this National Coverage Determination (NCD), including providing PrEP drugs for HIV with no cost sharing at in-network providers beginning on September 30, 2024, the date this NCD was issued. Payment for PrEP drugs and services under this NCD for a Medicare enrollee should be billed to the enrollee’s Medicare Advantage plan, not Original Medicare. Please see the August 1, 2024, [HPMS memo](#) for additional information about billing and contact the Medicare Advantage plan for further information.

**If a pharmacy is not enrolled in Part B and the person with Medicare has to go elsewhere, what can I do to help them find an alternative pharmacy?**

Some smaller pharmacies aren't set up to process drugs covered by Part B (Medical Insurance). If you go to a pharmacy and they can't bill Medicare for PrEP, call 1-800-MEDICARE (1-800-633-4227). TTY users can call 1-877-486-2048. We'll help you find another pharmacy where you can get your PrEP. A mail order pharmacy may be available.