

Fact Sheet: Potential for Medicare Part B Coverage of Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy (oral or injectable) to Prevent Human Immunodeficiency Virus (HIV)

Summary

The Centers for Medicare & Medicaid Services (CMS) is sharing information to encourage pharmacies and other interested parties to prepare for a potential National Coverage Determination (NCD) for Preexposure Prophylaxis (PrEP) Using Antiretroviral Drugs to Prevent HIV. CMS is not announcing any coverage changes at this time; however, 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. We want to share as much information as possible before issuing a NCD to avoid any possible disruptions for beneficiaries.

Fact Sheet

CMS is releasing new details on how people with Medicare would be able to get medications to prevent HIV without cost-sharing (i.e., deductibles or co-pays under Part B) if the proposed decision would be finalized.

On July 12, 2023, 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 in individuals at high risk of HIV acquisition. The determination of whether an individual is at high risk for HIV would be made by a physician or health care practitioner who assessed the individual's history. In addition, CMS proposed to cover the administration of injectable PrEP using antiretroviral drugs to prevent HIV.

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. Counseling would be furnished by a physician or other health care practitioner, and individuals must be competent and alert at the time that counseling is provided.

Additionally, CMS proposed to cover HIV screenings up to seven times annually and a single screening for hepatitis B virus for beneficiaries under Part B. These screening tests were proposed to be covered using the appropriate FDA-approved laboratory tests and point-of-care tests, if used consistent with FDA-approved labeling, and in compliance with the Clinical Laboratory Improvement Amendments regulations.

The proposed NCD decision memorandum is available via [the online tracking sheet](#). There could be changes to the final decision based on the public comments received on the proposed decision.

CMS' proposed NCD, if finalized, would expand Medicare Part B coverage using the "additional preventive services" benefit under section 1861(ddd)(1) of the Social Security Act. Coverage

under that benefit category would mean that beneficiaries would not be financially responsible for any cost-sharing obligations (i.e., deductibles or co-pays) for any of the above-mentioned covered services. The proposed HIV PrEP NCD is unique because HIV PrEP drugs are currently covered under Medicare Part D. Several public commenters on the proposed NCD expressed concern over the potentially complex transition of these preventive drugs from Medicare Part D to Part B. Some commenters have suggested that the change may cause some beneficiaries to miss needed doses of a preventive medication. We have not finalized the proposed decision, but on October 10, 2023, announced that a final decision was forthcoming. The NCD will be effective when the final decision is issued. There is no delay in the effective date for an NCD.

By providing the following information in advance of any issuance of a final NCD, CMS intends to promote an effective transition and minimize any potential disruption in access for those beneficiaries currently taking HIV PrEP under the Part D benefit, if the proposed approach is finalized.

Pharmacies

To bill for oral HIV PrEP drugs under Part B, a pharmacy must be 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).

To verify if your pharmacy is already enrolled, please visit [the Medicare Fee-For-Service Public Provider Enrollment dataset](#) and enter the pharmacy's NPI in the search bar.

If you are not enrolled, we recommend you enroll as a Part B Pharmacy as soon as possible in preparation for the potential final NCD, as coverage under Medicare Part B would be effective at the time the final NCD is posted. Pharmacies enrolled in part B with the provider type "mass immunization" will need to enroll as provider type "pharmacy".

To enroll as a Part B pharmacy, please see the [Medicare Provider Enrollment instructions on CMS.gov](#).

If you have questions about enrollment please [contact your Medicare Administrative Contractor](#).

Potential Transition of Coverage from Medicare Part D to Part B

Currently, HIV PrEP drugs may be covered under Medicare Part D and are typically subject to a deductible and coinsurance or co-pay. CMS' proposed NCD, if finalized, would transition coverage of PrEP drugs to Medicare Part B, and beneficiaries would not have Part B cost-sharing obligations (i.e., deductibles or co-pays). Antiretroviral drugs used for the treatment of HIV would continue to be covered under Medicare Part D, even though these may be the same drugs that are used for HIV PrEP.

CMS encourages proactive preparation by parties involved in administering prescription drug benefits and dispensing, as it may take some time to adjust systems to reflect Medicare Part B

payment for these drugs when used as prevention. This may include preparation by parties such as Medicare Part D sponsors, pharmacies, claims clearinghouses, Part D pharmacy claims processors, and pharmacy benefit managers. If the NCD is finalized, affected parties are encouraged to be capable of transitioning coverage immediately on the date that the final NCD is posted. It is critical that beneficiaries have uninterrupted access to HIV PrEP drugs and to their HIV treatments.

Medicare Advantage and cost plan (Part C) organizations and parties involved in processing Part C claims should also work with their contracted pharmacies to prepare for this potential transition to ensure their enrollees have access to HIV PrEP drugs without cost-sharing (i.e., deductibles or co-pays under Part B) if the proposed decision is finalized.

CMS will communicate with and encourage Medicare Advantage organizations and Part D sponsors, as prudent course, to inform and educate their enrollees and to reach out to contracted pharmacies regarding any finalized changes.

Claims Processing and Coding for Fee-for-Service Medicare

Pharmacies:

Original Medicare (fee-for-service) claims submitted by pharmacies must be processed by the DME MAC or the A/B MAC, depending on whether the pharmacy is enrolled as a DMEPOS supplier or a Part B pharmacy. This would include claims for the oral HIV PrEP drugs and for the pharmacy supplying fee. We expect the following drug and billing and payment codes would be billed by Medicare-enrolled pharmacies:

- J0750 – Emtricitabine 200mg and tenofovir disoproxil fumarate 300mg, 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 200/300mg
- J0751 – Emtricitabine 200mg and tenofovir alafenamide 25mg, oral, FDA-approved prescription, only for use as pre-exposure prophylaxis (not for use as treatment of HIV); Short Descriptor: HIV prep, ftc/taf 200/25mg
- Q0516 – Pharmacy supplying fee for HIV pre-exposure prophylaxis FDA-approved prescription drug, per 30-days; Short Descriptor: Supply fee HIV prep 30-days
- Q0517 – Pharmacy supplying fee for HIV pre-exposure prophylaxis FDA-approved prescription drug, per 60-days; Short Descriptor: Supply fee HIV prep 60-days
- Q0518 – Pharmacy supplying fee for HIV pre-exposure prophylaxis FDA-approved prescription drug, per 90-days; Short Descriptor: Supply fee HIV prep 90-days

Physicians or health care practitioners:

Claims would need to be submitted to the A/B MACs for the other covered services related to PrEP for HIV, such as the potential counseling services, laboratory and point of care screening tests, administration of an injectable HIV PrEP drug, and for the injectable HIV PrEP drug if the physician or health care practitioner purchases it.

We anticipate the following billing and payment codes for the other covered services related to HIV PrEP for claims that would be submitted by the physician or health care practitioner may include:

- J0739 – Injection, cabotegravir, 1mg, FDA-approved prescription, only for use as HIV pre-exposure prophylaxis (not for use as treatment for HIV); Short Descriptor: HIV prep, inj, cabotegravir
- G0011: Individual counseling for pre-exposure prophylaxis (PrEP) by physician or QHP [qualified health professional] to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15-30 minutes; Short Descriptor: HIV prep counsel, md 15-30m
- G0013: Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence; Short Descriptor: HIV prep counsel, clin staff
- G0012: Injection of pre-exposure prophylaxis (PrEP) drug for HIV prevention, under skin or into muscle; Short Descriptor: Inj, Prep drug for HIV prev

Diagnosis codes:

Diagnosis codes are required for claims submitted to Medicare. A new diagnosis code recently became available (Z29.81: Encounter for HIV pre-exposure prophylaxis). It is one example of an appropriate code to append to claims for the above services.

As noted above, the NCD is not yet final. There may be changes from the proposed decision based on other public comments.