

Fact Sheet: Medicare Part B Coverage of Pre-exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention

CMS covers Preexposure Prophylaxis (PrEP) and other related services to prevent HIV without costsharing (i.e., deductibles or co-pays under Part B).

Visit PrEP for HIV & Related Preventive Services https://www.cms.gov/medicare/coverage/prep

CMS covers PrEP using antiretroviral drugs approved by the U.S. Food and Drug Administration (FDA) to prevent HIV in individuals at increased risk of HIV acquisition.

The determination of whether an individual is at increased risk for HIV is made by a physician or health care practitioner who assessed the individual's history. CMS also covers furnishing HIV PrEP using antiretroviral drugs, including the supplying or dispensing of these drugs and the administration of injectable PrEP.

For individuals being assessed for or using PrEP to prevent HIV, CMS covers all the following as an additional preventive service:

- a) Up to eight individual counseling visits every 12 months, that include HIV risk assessment (initial or continued assessment of risk), HIV risk reduction, and medication adherence. Counseling must be furnished by a physician or other health care practitioner. Individuals must be competent and alert at the time that counseling is provided.
- b) Up to eight HIV screening tests every 12 months.
- c) A single screening for hepatitis B virus (HBV).

These screening tests are covered when the appropriate FDA-approved laboratory tests and point of care tests are used consistent with FDA-approved labeling and in compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations.

The final NCD decision memorandum is available via the **online tracking sheet**.

CMS expanded Medicare Part B coverage using the "additional preventive services" benefit under section 1861(ddd)(1) of the Social Security Act. Coverage under this benefit category means that beneficiaries are not financially responsible for any cost-sharing obligations (i.e., deductibles or co-pays) for any of the above-mentioned covered services. The HIV PrEP NCD is unique because HIV PrEP drugs were 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 suggested that the change may have caused some beneficiaries to miss needed doses of a preventive medication.

CMS provided several resources in advance of issuance of the final NCD, to promote an effective transition and minimize any potential disruption in access for those beneficiaries that were taking HIV PrEP under the Part D benefit.



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.

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If you are not enrolled, we recommend you enroll as a Part B Pharmacy as soon as possible. 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 listen to this webinar or view the transcript.

If you have questions about enrollment please contact your Medicare Administrative Contractor.



Transition of Coverage from Medicare Part D to Part B

HIV PrEP drugs were previously covered under Medicare Part D and were typically subject to a deductible and coinsurance or co-pay. CMS transitioned coverage of PrEP drugs to Medicare Part B, and beneficiaries have no Part B costsharing obligations (i.e., deductibles or co-pays). Antiretroviral drugs used for the treatment of HIV continue to be covered under Medicare Part D, even though these may be the same drugs that are used for HIV PrEP.

CMS communicated with and encouraged Medicare Advantage organizations and Part D sponsors, as prudent course, to inform and educate their enrollees and to reach out to contracted pharmacies regarding the transition of coverage from Medicare Part D to Part B.



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 HIV PrEP drugs and for the pharmacy supplying fee. We expect the following drug and billing and payment codes would be billed by Medicareenrolled pharmacies:

- J0739 Injection, cabotegravir, 1mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv)
- J0750 Emtricitabine 200mg and tenofovir disoproxil fumarate 300mg, oral, FDAapproved 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 oral drug, per 30-days; Short Descriptor: Supply fee HIV prep 30-days
- Q0517 Pharmacy supplying fee for HIV pre-exposure prophylaxis FDA-approved prescription oral drug, per 60-days; Short Descriptor: Supply fee HIV prep 60-days

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- Q0518 Pharmacy supplying fee for HIV pre-exposure prophylaxis FDA-approved prescription oral drug, per 90-days; Short Descriptor: Supply fee HIV prep 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

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 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.

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 include:

- J0739 Injection, cabotegravir, 1mg, FDAapproved 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 preexposure 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 preexposure 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. Please see https://www.cms.gov/medicare/coverage/prep for a current list of diagnosis codes.

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