Reference number(s)
6541-A

Standard Medicare Part B Management HIV PrEP for Medicare Population

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Apretude	cabotegravir
Descovy	emtricitabine and tenofovir alafenamide
Truvada	emtricitabine and tenofovir disoproxil fumarate
Yeztugo	lenacapavir

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met. The criteria outlined in this policy is only applicable to drugs for pre-exposure prophylaxis (PrEP) to prevent human immunodeficiency virus (HIV) infection. Requests for any other indication are not covered under Medicare Part B. Members seeking these agents for uses other than PrEP enrolled in Medicare Part D may seek coverage under their Medicare Part D plan.

Apretude[1]

Apredude is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition. Individuals must have a negative HIV-1 test prior to initiating Apretude (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

Descovy[2]

Descovy is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at

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risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating Descovy for HIV-1 PrEP.

Truvada[3]

Truvada is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test immediately prior to initiating Truvada for HIV-1 PrEP.

Yeztugo[4]

Yeztugo is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition. Individulas must have a negative HIV-1 test prior to initiating Yeztugo.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

HIV Pre-Exposure Prophylaxis (PrEP)

Authorization of 12 months may be granted for pre-exposure prophylaxis (PrEP) to prevent HIV infection.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Apretude, Descovy, Truvada and Yeztugo.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- National Coverage Determination: Preexposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention (NCD 210.15).

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Apretude, Descovy, and Truvada are covered to prevent HIV infection.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

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Using the above referenced drugs under Medicare Part B for PrEP is covered according to the conditions outlined in National Coverage Determination: Preexposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention.

References

1. Apretude [package insert]. Durham, NC: ViiV Healthcare; September 2024.
2. Descovy [package insert]. Foster City, CA: Gilead Sciences, Inc.; June 2025.
3. Truvada [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2024.
4. Yeztugo [package insert]. Foster City, CA: Gilead Sciences, Inc.; June 2025.
5. HIV PrEP NCD (210.15) Version 1. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed January 21, 2026.

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