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PHARMACY POLICY – 5.01.588

Pharmacologic Prevention and Treatment of HIV/AIDS

Effective Date:	Oct. 1, 2026	RELATED MEDICAL POLICIES:
Last Revised:	Nov. 1, 2026	5.01.636 Chronic Hepatitis B and D Antiviral Therapy
Replaces:	N/A	

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Introduction

HIV and AIDS remain global problems due to difficulties preventing and treating these diseases. HIV is a lifelong condition that currently has no cure. There are some US Food & Drug Administration (FDA) approved medications available that when taken as prescribed can prevent HIV. This is referred to as pre-exposure prophylaxis (or PrEP), and these medications can significantly reduce the chance of getting HIV. For individuals who have HIV, treatment usually involves taking two or three drugs to control the virus and help prevent it from becoming resistant to treatment. This policy describes when brand name drugs may be considered medically necessary for PrEP and HIV treatment.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
Truvada (emtricitabine and tenofovir disoproxil fumarate)	**Truvada (emtricitabine and tenofovir disoproxil fumarate) may be considered medically necessary when the following criteria are met:** • The individual has tried and had an inadequate response or intolerance to generic emtricitabine and tenofovir disoproxil fumarate

Drug	Investigational
As listed	**The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.** **All other uses of the drugs listed for conditions not outlined in this policy are considered investigational.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Truvada (emtricitabine and tenofovir disoproxil fumarate) may be approved up to 3 years.**
Re-authorization criteria	**Truvada (emtricitabine and tenofovir disoproxil fumarate) may be approved up to 3 years as long as medical necessity criteria are met and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation, and medication history

Related Information

Benefit Application

Pharmacy Benefit

Truvada (emtricitabine and tenofovir disoproxil fumarate) is managed through the pharmacy benefit.

Evidence Review

Description

Medical Condition

HIV is a chronic, progressive infection that remains a major public health concern in the United States. As of 2023, an estimated 1.13 million people living with HIV (PLWH) in the US, corresponding to a prevalence of 395 per 100,000 population. The epidemic is characterized by significant demographic and geographic disparities. Males account for 77% of PLWH, and the highest prevalence is observed in the 55–64 age group (26%). Black/African American individuals represent 39% of PLWH, while Hispanic/Latino and White individuals each account for 27%. Estimated new HIV infections (incidence) declined by 12% from 2018 to 2022, while over 38,800 new HIV diagnoses occurred in 2023, with the highest diagnosis rate among those aged 25–34 years. Men who have sex with men are disproportionately affected, accounting for 66% of new diagnoses, and Black/African American individuals continue to experience the highest rates of new diagnoses among both men and women. Viral suppression rates in 2023 were 68% for men and 66% for women, indicating ongoing challenges in achieving optimal treatment outcomes. HIV-related deaths have decreased from 5.1 per 100,000 in 2000 to 1.6 per 100,000 in 2023, reflecting improvements in care.

The introduction and widespread use of ART have transformed HIV from a fatal disease to a manageable chronic condition, with life expectancy for PLWH now approaching that of the general population. As a result, the HIV population is aging: in 2023, 54% of PLWH in the US were aged 50 years or older. This demographic shift has led to increased multimorbidity and non-AIDS-related comorbidities. In a real-world analysis of 73,078 adults with HIV receiving ART in the US between July 2024 and June 2025, 8,188 (11%) experienced at least one regimen switch over the one-year period; notably, switches among virologically suppressed individuals

(<200 copies/mL) accounted for 83% of all switches, indicating that switching is driven primarily by regimen optimization rather than virologic failure. Among these suppressed switches, 51% were attributed to treatment simplification, defined as lowering pill burden, reducing the number of anchor agents, or transitioning to a complete long-acting injectable regimen such as cabotegravir/rilpivirine. Following switching, 2DR use roughly doubled, from 14% pre-switch to 28–29% post-switch.

Regimens including InSTIs remain the standard of care for both first-line and maintenance ART owing to their high efficacy and high barrier to resistance. However, InSTI-based regimen, particularly BIC and dolutegravir (DTG), have been associated with weight gain and metabolic dysregulation, including increased risks of insulin resistance and new-onset diabetes. Real-world data have further shown that switching from NNRTI- or PI-based ART to InSTI-based ART is associated with an 81% higher risk of incident hypertension (adjusted hazard ratio 1.81; 95% CI, 1.42-2.31).

HIV primarily targets and depletes CD4+ T-cell lymphocytes, which are essential for immune function. The virus binds to and enters CD4+ T-cells, where it replicates and integrates into the host genome. This leads to direct viral-mediated destruction of CD4+ T-cells and chronic immune activation, resulting in progressive immunodeficiency. The loss of CD4+ T-cells impairs the body's ability to mount effective immune responses, increasing susceptibility to opportunistic infections and certain malignancies. HIV infection progresses through several stages: acute infection (often presenting as flu-like symptoms or asymptomatic), chronic asymptomatic infection (which can last 8–10 years without treatment), and AIDS, defined by a CD4+ T-cell count below 200 cells/mm^3 or the presence of AIDS-defining illnesses. Without ART, survival after an AIDS diagnosis is typically 1–3 years. Effective ART suppresses viral replication to undetectable levels, allowing immune recovery, reducing morbidity and mortality, and preventing sexual transmission of HIV (the U=U principle: undetectable equals untransmittable). However, chronic immune activation and inflammation persist even with viral suppression, contributing to accelerated aging and increased risk of non-AIDS comorbidities.

2019 Update

Reviewed Trogarzo (ibalizumab) prescribing information and conducted a literature search from July 1, 2018, through July 31, 2019. No new evidence found that would change this policy.

2020 Update

Reviewed Trogarzo (ibalizumab) prescribing information and conducted a literature search on the management of HIV individuals who are failing therapy. No new evidence found that would change this policy. Added an "Investigational" table and a "Documentation Requirements" table to policy.

2021 Update

Reviewed Trogarzo (ibalizumab) and Rukobia (fostemsavir) prescribing information and conducted a literature search on the management of HIV individuals who are failing therapy. Included a new Trogarzo warning regarding the risk of embryo-fetal toxicity and updated the HIV statistics referenced within policy. No new evidence found that would change this policy.

2022 Update

Reviewed prescribing information for all drugs in policy and conducted a literature search on PrEP. Added coverage criteria for Apretude (cabotegravir extended-release injectable suspension) for use 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.

2023 Update

Reviewed prescribing information for all drugs in policy. Added coverage for Sunlenca (lenacapavir) for the treatment of multidrug resistant HIV-1 in adult individuals.

2024 Update

Reviewed prescribing information for all drugs in policy. No changes to policy statements.

2025 Update

Reviewed prescribing information for all drugs in policy. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Removed step therapy requirement from Apretude (cabotegravir extended-release injectable suspension) coverage criteria. Removed step therapy requirement from Descovy (emtricitabine and tenofovir alafenamide) HIV pre-exposure prophylaxis (PrEP) coverage criteria. Clarified that Apretude (cabotegravir extended-release injectable suspension) is managed through both the medical and pharmacy benefit. Added coverage criteria for Yeztugo (lenacapavir).

2026 Update

Reviewed prescribing information for all drugs in policy. Removed coverage criteria for Apretude (cabotegravir extended-release injectable suspension), Descovy (emtricitabine and tenofovir alafenamide), Rukobia (fostemsavir), Sunlenca (lenacapavir), Trogarzo (ibalizumab), and Yeztugo (lenacapavir). Removed reference to non-formulary exception reviews.

References

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7. Bourgi K, Jenkins CA, Rebeiro PF, et al. Weight gain among treatment-naïve persons with HIV starting integrase inhibitors compared to non-nucleoside reverse transcriptase inhibitors or protease inhibitors in a large observational cohort in the United States and Canada. J Int AIDS Soc. 2020;23(4):e25484.

8. Truvada (emtricitabine and tenofovir disoproxil fumarate). Prescribing Information. Gilead Sciences, Inc.; Foster City, CA. Revised April 2024.

History

Date	Comments
11/01/18	New policy, approved October 9, 2018, effective February 1, 2019. Add to Prescription Drug section. Trogarzo (ibalizumab) may be considered medically necessary when criteria are met. Added HCPCS codes J3490, J3590.
01/01/19	Coding update, added new HCPCS code J1746 (new code effective 1/1/19).
09/01/19	Annual Review, approved August 22, 2019. Policy updated with literature review; no changes to policy statements. Removed HCPCS codes J3490 and J3590.
10/01/20	Annual Review, approved September 1, 2020. No changes to policy statements.
12/01/20	Interim Review, approved November 10, 2020. Changed policy name from Trogarzo (ibalizumab) to Pharmacologic Treatment of HIV/AIDS. Added Rukobia (fostemsavir) to policy for the treatment of multidrug resistant HIV-1.
11/01/21	Annual Review, approved October 21, 2021. No changes to policy statements.
01/01/22	Interim Review, approved December 14, 2021. Added criteria for both Descovy (emtricitabine and tenofovir alafenamide) and Truvada (emtricitabine and tenofovir disoproxil fumarate) for the treatment of HIV-1 infection and PrEP when the patient has tried generic emtricitabine and tenofovir disoproxil fumarate first.
07/01/22	Annual Review, approved June 14, 2022. Changed title from Pharmacologic Treatment of HIV/AIDS to Pharmacologic Prevention and Treatment of HIV/AIDS. Added criteria for Apretude (cabotegravir extended-release injectable suspension) for PrEP to reduce the risk of HIV-1 infection. Added HCPCS code J0739.
02/01/23	Annual Review, approved January 10, 2023. Added coverage for Sunlenca (lenacapavir) for the treatment of multidrug resistant HIV-1 in adult individuals. Changed the wording from "patient" to "individual" throughout the policy for standardization. Added HCPC code J3490 for Sunlenca.
07/01/23	Coding update. Added new HCPCS code J1961
01/01/24	Coding update. Added new HCPCS codes J0750, J0751 & J0799.
08/01/24	Annual Review, approved July 8, 2024. No changes to policy statements.
03/01/25	Annual Review, approved February 11, 2025. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12

Date	Comments
	months. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Removed step therapy requirement from Apretude (cabotegravir extended-release injectable suspension) coverage criteria. Removed step therapy requirement from Descovy (emtricitabine and tenofovir alafenamide) HIV pre-exposure prophylaxis (PrEP) coverage criteria. Removed HCPCS code J3490, since HCPC J1961 now represents Sunleca.
11/01/25	Interim Review, approved October 14, 2025. Clarified that Apretude (cabotegravir extended-release injectable suspension) is managed through both the medical and pharmacy benefit. Added coverage criteria for Yeztugo (lenacapavir). Added new HCPCS codes J0752 and J0759, effective 10/01/25.
10/01/26	Annual Review, approved September 8, 2026. Removed coverage criteria for Apretude (cabotegravir extended-release injectable suspension), Descovy (emtricitabine and tenofovir alafenamide), Rukobia (fostemsavir), Sunlenca (lenacapavir), Trogarzo (ibalizumab), and Yeztugo (lenacapavir). Removed reference to non-formulary exception reviews. Removed HCPCS codes J0738, J0739, J0750, J0751, J0752, J0799, J1746, J1961.
11/01/26	Minor update. Related medical policy title changed from 5.01.636 Chronic Hepatitis B Antiviral Therapy to 5.01.636 Chronic Hepatitis B and D Antiviral Therapy.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.