Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:

Descovy and HIV Pre-Exposure Prophylaxis (PrEP) Medications

Effective: October 1, 2023

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☒ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Descovy (emtricitabine/tenofovir alafenamide fumarate), **Truvada (emtricitabine/tenofovir disoproxil fumarate),** and generic **tenofovir disoproxil fumarate 300 mg** are indicated for Human Immunodeficiency Virus (HIV)-1 Treatment and Human Immunodeficiency Virus (HIV)-1 Pre-exposure Prophylaxis (PrEP).

DESCOVY is a two-drug combination of emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV nucleoside analog reverse transcriptase inhibitors (NRTIs). The combination is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg and in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 14 kg and less than 35 kg.

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

The indication does not include use of DESCOVY in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

This program is designed to meet Health Care Reform requirements which require coverage of generic tenofovir disoproxil fumarate 300 mg, Truvada (emtricitabine/tenofovir disoproxil fumarate) 200-300 mg, or Descovy at zero dollar cost share if being used for pre-exposure prophylaxis (PrEP).

The Affordable Care Act (ACA) requires private insurers to cover certain preventive services without any patient cost-sharing (i.e., copayments) when they are delivered by a network provider. The Department of Health and Human Services (HHS) has recognized several recommending bodies (e.g., United States Preventive Services Task Force [USPSTF], Advisory Committee on Immunization Practices [ACIP], Health Resources and Services Administration [HRSA]) who have identified several medication categories that fall within the preventive health mandate.

Clinical Guideline Coverage Criteria

Descovy (emtricitabine/tenofovir alafenamide fumarate)

The plan may cover Descovy for patients when all of the following criteria are met:

1. The patient has a documented diagnosis of HIV-1 infection and is using Descovy as part of an antiretroviral treatment (ART) regimen

OR

2. Both the following:
    a. Descovy 200mg/25mg is being requested for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition

AND

    b. The patient has tried or has a contraindication to or clinical intolerance to emtricitabine/tenofovir disoproxil fumarate 200-300 mg (generic Truvada)

Affordable Care Act (ACA): HIV PrEP Zero Dollar Cost Share

The plan will cover medications for HIV PrEP at zero dollar cost share when the flowing criteria is met:

1. The patient is taking Descovy 200mg/25mg or Truvada 200-300 mg as effective antiretroviral therapy for pre-exposure prophylaxis (PrEP)

Limitations

1. Approval duration is for life of plan.
2. Approvals for PrEP should be authorized at no cost share ($0) per United States Preventive Services Task Force (USPSTF) recommendations

Codes

None

References

1. Centers for Disease Control and Prevention (CDC), US Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2017 Update: A Clinical Practice Guideline. CDC website. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018. Accessed August 19, 2021.
2. Descovy (emtricitabine and tenofovir alafenamide) [prescribing information]. Foster City, CA: Gilead Sciences; January 2022.
3. Truvada (emtricitabine/tenofovir disoproxil fumarate) [prescribing information]. Foster City, CA: Gilead Sciences; June 2020.
4. U.S. Preventive Services Task Force Final Recommendation Statement Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-exposure Prophylaxis. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-ofhuman-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis. Accessed August 19, 2021.
5. Viread (tenofovir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; April 2019.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- July 11, 2023: Effective October 1, 2023, clarified Descovy for PrEP would only be approved at $0 for the 200mg/25mg strength, based on FDA-approved indication, removed criteria that required “trial and failure” with generic Truvada, and updated it to “tried” for Descovy. Removed generic Truvada and generic Viread 300mg from HIV PrEP $0 cost share section. This administrative criteria only applies to Descovy 200mg/25mg and brand Truvada 200-300mg (NF).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed

revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.