MEDICAL MUTUAL®

Drug Policy

Policy:	**HIV Pre-Exposure Prophylaxis Step Therapy**	**Annual Review Date:** **06/20/2024**
Impacted Drugs:	**Descovy (emtricitabine/tenofovir alafenamide)**	**Last Revised Date:** **06/20/2024**

OVERVIEW

Descovy and emtricitabine/tenofovir disoproxil fumarate are indicated for the **treatment of human immunodeficiency virus (HIV)-1 and the prevention of HIV-1 (pre-exposure prophylaxis [PrEP])**. Non-PrEP indications are not the target of this policy. These agents are two-drug combinations of emtricitabine and tenofovir, both nucleoside reverse transcriptase inhibitors (NRTIs). Descovy and emtricitabine/tenofovir disoproxil fumarate contain different forms of tenofovir; tenofovir alafenamide and tenofovir disoproxil fumarate, respectively.

For PrEP, the indications differ between the two products. Descovy is not indicated in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness has not been evaluated in this population (Limitation of Use).

- Descovy for PrEP: Indicated in at-risk adults and adolescents weighing ≥ 35 kg to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex.
- Emtricitabine/tenofovir disoproxil fumarate for PrEP: Indicated in at-risk adults and adolescents weighing ≥ 35 kg to reduce the risk of sexually acquired HIV-1 infection.

The DISCOVER trial demonstrated the non-inferiority of Descovy and emtricitabine/tenofovir disoproxil fumarate for HIV-1 prevention (PrEP) in HIV-seronegative men or transgender women who have sex with men and are at risk of HIV-1 infection. However, changes in renal biomarkers and bone mineral density significantly favored Descovy over emtricitabine/tenofovir disoproxil fumarate.

For PrEP, emtricitabine/tenofovir disoproxil fumarate is not recommended in individuals with estimated creatinine clearance < 60 mL/min. Descovy can be used in patients with creatinine clearance ≥ 30 mL/min and in those with creatinine clearance < 15 mL/min who are on chronic hemodialysis.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: None

Preferred Medications

- Generic emtricitabine/tenofovir disoproxil fumarate

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Non-Preferred Medications

- Descovy

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried the preferred product [documentation required], approve the non-preferred product.
   Note: a trial of brand Truvada also satisfies this requirement [documentation required]

2. If the patient has an indication other than Pre-Exposure Prophylaxis (PrEP) of HIV1 infection, such as treatment of HIV and post-exposure prophylaxis, approve the non-preferred product.

3. If the patient meets ONE of the following, approve the non-preferred product.
   a. The patient has pre-existing renal disease
   b. The patient has an estimated creatinine clearance < 60 mL/min
   c. The patient has a history of osteoporosis or low bone mineral density at baseline
      Note: This refers to baseline prior to pre-exposure prophylaxis therapy.
   d. The patient has a history of pathologic or fragility bone fracture
   e. According to the prescriber, the patient has a history of a significant risk factor for osteoporosis or bone loss

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria
Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
   1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR

2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Descovy® tablets [prescribing information]. Foster City, CA: Gilead; January 2022.
2. Emtricitabine and tenofovir disoproxil fumarate tablets. East Windsor, NJ: Aurobindo; July 2023.
3. Truvada® tablets [prescribing information]. Foster City, CA: Gilead; October 2023.
4. Gandhi RT, Bedimo R, Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults. 2022 recommendations of the International Antiviral Society-USA Panel. *JAMA.* 2023;329(1):63-84.
5. US Public Health Service. Pre-exposure prophylaxis for the prevention of HIV infection in the United States – 2021 update. A clinical practice guideline. Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Accessed on April 29, 2024