UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2176-8
Program	Prior Authorization/Medical Necessity
Medication	Descovy® (emtricitabine/tenofovir alafenamide)*
P&T Approval Date	6/2020, 8/2020, 12/2020, 12/2021, 3/2022, 5/2022, 5/2023
Effective Date	8/1/2023; Oxford only: 8/1/2023

1. Background:

Descovy 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 or 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. [1]

Truvada (emtricitabine / tenofovir disoproxil fumarate) is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg. It is also indicated in at-risk adults and adolescents weighing at least 35 kg for PrEP to reduce the risk of sexually acquired HIV-1 infection.[2]

2. Coverage Criteria[a]:

A. <u>Treatment of HIV Infection:</u>

1. **Descovy** will be approved based on the following criterion:

   a. For the treatment of HIV infection

   Authorization will be issued for 12 months

B. <u>HIV-1 Pre-exposure Prophylaxis (PrEP):</u>

1. **<u>Initial Authorization</u>**

   a. **Descovy 200/25 mg** will be approved based on **<u>all</u>** of the following criteria:

      (1) Request is for 200/25 mg strength

      -AND-

      (2) Used for HIV-1 pre-exposure prophylaxis (PrEP)

-AND-

(3) **One** of the following:

(a) Submission of medical records documenting a history of adverse event or intolerance to prior use of Truvada or generic emtricitabine/tenofovir disoproxil fumarate

-OR-

(b) Submission of medical records documenting an estimated glomerular filtration rate below 90 mL/min

-OR-

(c) Submission of medical records documenting a diagnosis of osteoporosis as defined by a BMD T-score ≤ -2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-score]

-OR-

(d) Submission of medical records documenting a prior low-trauma or non-traumatic fracture

-OR-

(e) Patient is less than 20 years of age

-OR-

(f) Submission of medical records documenting a diagnosis of osteopenia as defined by a BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-scores] with evidence of progressive bone loss on serial DEXA scan

Authorization will be issued for zero copay with deductible bypass for 12 months.

2. **Reauthorization**

a. **Descovy 200/25 mg** will be approved based on **all** of the following criteria:

(1) Request is for 200/25 mg strength

-AND-

(2) Documentation of positive clinical response to Descovy therapy

-AND-

(3) Patient is not a suitable candidate for HIV PrEP with generic emtricitabine/tenofovir disoproxil fumarate

Authorization will be issued for zero copay with deductible bypass for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

* Descovy when prescribed as HIV PrEP is excluded for the majority of our benefits

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Descovy [package insert]. Foster City, CA: Gilead Sciences, Inc.; January 2022.
2. Truvada [package insert]. Foster City, CA: Gilead Sciences, Inc.; June 2020.
3. Mayer KH, Molina JM, Thompson MA, et al. Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial. Lancet 2020; 396: 239–54.
4. Gandhi M, Glidden DV, Mayer KH, et al. Association of age, baseline kidney function, and medication exposure with declines in creatinine clearance on pre-exposure prophylaxis: an observational cohort study. Lancet HIV 2016; 3: e521–28.

Program	Prior Authorization/Medical Necessity – Descovy (emtricitabine/tenofovir alafenamide)
Change Control	
6/2020	New program
8/2020	Revised to include criteria for populations at high-risk of fracture or whom may derive benefit from a more neutral bone mineral density impact. Updated creatinine clearance criterion to 90 mL/min.
8/2020	Administrative change to correct Oxford effective date.
12/2020	Changed creatinine clearance to estimated glomerular filtration rate.
12/2021	Annual review. Added Used for HIV-1 pre-exposure prophylaxis (PreEP) to HIV-1 PREP clinical criteria. Updated references.
3/2022	Changed background to include pediatric patients weighing at least 14 kg. Updated criteria to specify only the 200/25 mg strength is approved for PrEP. Updated references.
5/2022	Formatting changes to clarify PrEP approval.
5/2023	Annual review. Updated background per Truvada package insert.