

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2237-5
Program	Prior Authorization/Medical Necessity - Colorado
Medication	Descovy [®] (emtricitabine/tenofovir alafenamide)*
P&T Approval Date	4/2021, 12/2021, 3/2022, 5/2022, 10/2023
Effective Date	1/1/2024

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

The Colorado State Board of Pharmacy Statewide Protocol for HIV PrEP and post-exposure prophylaxis (PEP) prohibits health plans from requiring prior authorization or step therapy when prescribed by a qualified Colorado-licensed pharmacist.

2. Coverage Criteria^a:

<p>A. <u>Treatment of HIV Infection:</u></p> <p>1. Descovy will be approved based on the following criterion:</p> <p>a. For the treatment of HIV infection</p> <p>Authorization will be issued for 12 months</p> <p>B. <u>HIV-1 Pre-exposure Prophylaxis (PrEP):</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Descovy 200/25 mg will be approved based on <u>all</u> of the following criteria:</p> <p>(1) Request is for 200/25 mg strength</p> <p style="text-align: center;">-AND-</p>

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

-AND-

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

(a) Prescribed by a qualified Colorado-licensed pharmacist

-OR-

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

-OR-

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

-OR-

(d) 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-

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

-OR-

(f) Patient is less than 20 years of age

-OR-

(g) 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 **one** of the following criteria:

(1) Both of the following:

(a) Request is for 200/25 mg strength

-AND-

(b) Prescribed by a qualified Colorado-licensed pharmacist

-OR-

(2) All of the following:

(a) Request is for 200/25 mg strength

-AND-

(b) Documentation of positive clinical response to Descovy therapy

-AND-

(c) 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.

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 – Colorado - Descovy (emtricitabine/tenofovir alafenamide)
Change Control	
4/2021	New program
12/2021	Added diagnosis requirement 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.
10/2023	Annual review. Updated background per Truvada package insert.