UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 3128-7
Program	Step Therapy
Medications	Descovy® (emtricitabine/tenofovir alafenamide)
P&T Approval Date	10/2019, 8/2020, 8/2021, 3/2022, 5/2022, 5/2023
Effective Date	8/1/2023; Oxford only: N/A

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Truvada® (emtricitabine/tenofovir disoproxil fumarate) before providing coverage for Descovy® (emtricitabine/tenofovir alafenamide) when prescribed for HIV pre-exposure prophylaxis (PrEP).

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

   a. Request is for 200/25 mg strength

-AND-

b. Patient has a history of intolerance or contraindication to Truvada or generic emtricitabine/tenofovir disoproxil fumarate

-AND-

c. Using as effective antiretroviral therapy for PrEP (Pre-exposure Prophylaxis)

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

C. Other Indications

1. **Descovy** will be approved

Authorization will be issued 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 and/or Notification 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.

Program	Step Therapy – Descovy (emtricitabine/tenofovir alafenamide)
Change Control	
10/2019	New step therapy program that requires the use of Truvada before benefit coverage of Descovy when prescribed for HIV-1 pre-exposure prophylaxis.
8/2020	Updated authorization language for PreP to include zero dollar cost share.
8/2020	Administrative change to correct Oxford effective date.
8/2021	Annual review with no changes to coverage criteria. Updated references.
3/2022	Changed background to include pediatric patients weighing at least 14 kg and added generic Truvada to coverage criteria. Updated criteria to specify only the 200/25 mg strength is approved for PrEP. Changed authorization duration from 24 months to 12 months. Updated references.

5/2022	Formatting changes to clarify PrEP approval.
5/2023	Annual review. Updated background per Truvada package insert.