# Drug Coverage Policy

**Effective Date.....08/15/2024**
**Coverage Policy Number.....IP0636**
**Policy Title.....Descovy**

# Human Immunodeficiency Virus – Descovy for Employer Plans

- Descovy® (emtricitabine/tenofovir alafenamide – Gilead)

***INSTRUCTIONS FOR USE***
*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

## Cigna Healthcare Coverage Policy

### 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])**.[1,2] 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).[1,2] 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).[1]

- 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.[2,3]

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.[1] 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.[2,3] 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.[1]

**GUIDELINES FOR PREP**

The International Antiviral Society-USA guidelines provide the most current recommendations for PrEP.[4] Emtricitabine/tenofovir disoproxil fumarate is recommended for all populations at risk of HIV-1 acquisition. Descovy may be used in cisgender men of any sexual orientation and anyone for whom risks do not include receptive vaginal sex or for those when risk is exclusively posed by injection drug use. Descovy is preferred over emtricitabine/tenofovir disoproxil fumarate for individuals with creatinine clearance ≥ 30 to ≤ 60 mL/min or when there is known osteopenia or osteoporosis. The US Public Health Service PrEP for the Prevention of HIV Infection in the US Clinical Practice Guidelines (December 2021) have similar recommendations (Table 1).[5]

**Table 1. US Public Health Service Recommendations for Oral PrEP(December 2021).[5]**

| | Recommendation | Evidence Rating |
|---|---|---|
| **Descovy** | For adult and adolescent (≥ 35 kg) **cis-gender men**[*] and **transgender women**[†]**:**<br>• **Sexually active individuals** who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition.<br><br>Descovy PrEP has **not been studied in cis-gender women**[‡] and is **not recommended** for HIV prevention in individuals at risk through receptive vaginal sex (level of evidence, IA). | IA (cisgender men)<br>IIB (transgender women) |
| **Emtricitabine/tenofovir disoproxil fumarate** | For adult and adolescent (≥ 35 kg) **men and women**:<br>• **Sexually active individuals** who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition; OR | 1A |

| | | |
|---|---|---|
| | • **IDU** and report injection practices that place them at substantial ongoing risk of HIV exposure and acquisition. | |

PrEP – Pre-exposure prophylaxis; * Individuals assigned male sex at birth whose gender identity is male; † Individuals assigned male sex at birth whose gender identity is female; HIV – Human immunodeficiency virus; ‡ Individuals assigned female sex at birth whose gender identity is female; IDU – Injection drug user(s).

## Medical Necessity Criteria

**Descovy is considered medically necessary when ONE of the following are met:**

1. **Treatment of Human Immunodeficiency Virus (HIV)-1 Infection.** Approve for 1 year if the patient meets ONE of the following:
   - **A)** Patient is < 13 years of age; OR
   - **B)** Patient is pregnant; OR
   - **C)** Patient is currently taking Descovy; OR
   - **D)** Patient has tried a regimen containing emtricitabine/tenofovir disoproxil fumarate (Truvada, generic); OR
   - **E)** Patient meets ONE of the following conditions (i, ii, or iii):
     - **i.** Condition 1: Approve if the patient meets ONE of the following (1 or 2):
       1. Patient has tried Biktarvy; OR
       2. Patient is taking rifampin or rifamycin; OR
     - **ii.** Condition 2: Approve is the patient meets ONE of the following (1, 2, or 3):
       1. Patient has tried Triumeq; OR
       2. Patient is taking rifampin or rifamycin: OR
       3. Patient is HLA-B*5701 positive; OR
     - **iii.** Condition 3: Approve if the patient meets ONE of the following (1, 2, 3, 4, or 5):
       1. Request is for Descovy to be used in combination with Evotaz (patient meets a or b):
          - **a.** Patient has tried Epzicom in combination with Evotaz; OR
          - **b.** Patient is HLA-B*5701 positive; OR
       2. Request is for Descovy to be used in combination with Prezcobix (patient meets a or b):
          - **a.** Patient has tried Epzicom in combination with Prezcobix; OR
          - **b.** Patient is HLA-B*5701 positive; OR
       3. Request is for Descovy to be used in combination with ritonavir (Norvir, generic)-boosted darunavir (Prezista, generic) [patient meets a or b):
          - **a.** Patient has tried Epzicom in combination with ritonavir (Norvir, generic)-boosted darunavir (Prezista, generic); OR
          - **b.** Patient is HLA-B*5701 positive; OR
       4. Request is for Descovy to be used in combination with ritonavir (Norvir, generic)-boosted atazanavir (Reyataz, generic) [patient meets a or b]:
          - **a.** Patient has tried ritonavir (Norvir, generic)-boosted atazanavir (Reyataz, generic) in combination with Epzicom; OR
          - **b.** Patient is HLA-B*5701 positive; OR
       5. Request is for Descovy not in combination with Evotaz, Prezcobix, ritonavir (Norvir, generic)-boosted darunavir (Prezista, generic), or ritonavir (Norvir, generic)-boosted atazanavir (Reyataz, generic).

2. **HIV-1 Pre-exposure Prophylaxis (PrEP).** Approve for 1 year if the patient meets one of the following (A or B):
   - **A)** Patient has tried generic emtricitabine/tenofovir disoproxil fumarate tablets; OR

Note: A trial of Truvada (emtricitabine/tenofovir disoproxil fumarate tablets) also satisfies the requirement.

**B)** Patient meets ONE of the following (i, ii, iii, iv, or v):

i. Patient has pre-existing renal disease; OR
ii. Patient has an estimated creatinine clearance < 60 mL/min; OR
iii. Patient has a history of osteoporosis or low bone mineral density at baseline; OR
Note: This refers to baseline prior to pre-exposure prophylaxis therapy.
iv. Patient has a history of pathologic or fragility bone fracture; OR
v. According to the prescriber, the patient has a history of a significant risk factor for osteoporosis or bone loss.

3. **Other Conditions.** Approve Descovy. Note: Examples of other conditions include post-exposure prophylaxis.

## Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

## References


1. Descovy® tablets [prescribing information]. Foster City, CA: Gilead; January 2022.
2. 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.


## Revision Details

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| New | New policy | 08/15/2024 |

The policy effective date is in force until updated or retired.