Clinical Policy: Emtricitabine/Tenofovir Alafenamide (Descovy)

Reference Number: IL.ERX.PMN.235
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Emtricitabine/tenofovir alafendamide (Descovy®) is a combination of two nucleoside reverse transcriptase inhibitors (NRTIs).

FDA Approved Indication(s)
Descovy is indicated:

- In combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection in adults and pediatric patients weighing at least 35 kg
- 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 25 kg and less than 35 kg
- 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.

Limitations of use: 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions that Descovy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. HIV-1 Infection (must meet all)**:**

1. Diagnosis of HIV-1 infection;
2. Descovy is prescribed in combination with other antiretroviral agents for the treatment of HIV-1 infection;
3. Member weighs ≥ 25 kg;
4. Not recommended in patients with CrCl <30 mL/min
5. Dose does not exceed 200/25 mg/day (1 tablet/day).

Approval duration: 12 months

B. Pre-exposure HIV Prophylaxis (must meet all)**:**

1. Member is HIV-negative and has no signs or symptoms of acute HIV infection;
2. Member is considered at high risk for acquiring HIV and meets one of the following (a, b, or c):
   a. Engaging in sexual activity with a HIV-1 infected partner;
   b. Engaging in sexual activity and one or more of the following:
      i. Inconsistent or no condom use;
      ii. Diagnosis of sexually transmitted infections;
      iii. Exchange of sex for commodities;
      iv. Incarceration;
      v. Not in a monogamous partnership;
      vi. Partner of unknown HIV status with any of the preceding risk factors;
   c. Use of illicit injection drugs;

3. Member weighs ≥ 35 kg;
4. Dose does not exceed 200/25 mg/day (1 tablet/day).

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Descovy for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 200/25 mg/day (1 tablet/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is **sufficient** documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food andDrug Administration
HIV: human immunodeficiency virus
PrEP: pre-exposure prophylaxis

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): HIV-1 PrEP in individuals with unknown or positive HIV-1 status
- Boxed warning (s): post-treatment acute exacerbation of hepatitis b and risk of drug resistance with use of Descovy for HIV-1 PrEP in undiagnosed early hiv-1 infection

Appendix D: General Information

- Tenofovir is available in two forms: tenofovir alafenamide (TAF; found in Descovy) and tenofovir disoproxil fumarate (TDF; found in Truvada). TAF is associated with fewer bone and renal toxicities than TDF, while TDF is associated with lower lipid levels. According to the Department of Health and Human Services guidelines for the use of antiretroviral agents in adults and adolescents with HIV (last updated December 2019), safety, cost, and accessibility are among the factors to consider when choosing between these drugs. One form is not preferred over the other.
- Examples of bone/renal co-morbidities and risk factors include but are not limited to:
  - Bone disease: osteoporosis, osteopenia, receiving chronic corticosteroids or other therapies known to decrease bone density (e.g., aromatase inhibitors, androgen deprivation therapy, doxorubicin, cyclophosphamide), frail/underweight
  - Renal disease: chronic kidney disease, estimated creatinine clearance < 60 mL/min, albuminuria, family history of kidney disease, diabetes, receiving nephrotoxic medications

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HIV-1 infection, PrEP	200/25 mg PO QD	200/25 mg/day

VI. Product Availability

Tablets: 200 mg emtricitabine/25 mg tenofovir alafenamide

VII. References

1. Descovy Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; December 2019. Available at www.descovy.com. Accessed April 27, 2020.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. U.S. Department of Health and Human Services. Available at https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Updated December 18, 2019. Accessed April 27, 2020.
3. Centers for Disease Control and Prevention, U.S. Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States - 2017 update. 2017. Available at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Accessed April 27, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.15.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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