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## DRUG POLICY

# Descovy (emtricitabine/tenofovir alafenamide)

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### DESCRIPTION

The United States Preventive Services Task Force (USPSTF) recommends offering pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy to persons at high risk of human immunodeficiency virus (HIV). The intent of this policy is to provide a way to identify those members who are using Descovy (emtricitabine/tenofovir alafenamide) for PrEP and are unable to use the preferred drug, Truvada (emtricitabine/tenofovir disoproxil fumarate). These identified members are eligible to receive cost share waiver (i.e. no copay, coinsurance, or deductible) when the criteria is met.

#### FDA-Approved Indications

#### **Treatment of Human Immunodeficiency Virus-1 (HIV-1) Infection**

Descovy is indicated, in combination with other antiretroviral agents, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing at least 35 kg.

Descovy is indicated, 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.

#### **HIV-1 Pre-Exposure Prophylaxis (PrEP)**

Descovy is 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.

### Limitations of Use:

The PrEP 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 for Initial Approval

The requested drug will be covered with a zero dollar member cost share when the following criteria are met:

- The requested drug is prescribed as monotherapy for pre-exposure prophylaxis of human immunodeficiency virus (HIV) infection

#### **AND**

- The preferred drug, Truvada (emtricitabine/tenofovir disoproxil fumarate), is not an appropriate alternative because the patient has mild-moderate renal impairment or risk factors for osteoporosis or bone loss.

#### **OR**

- The patient has tried Truvada (emtricitabine/tenofovir disoproxil fumarate) and it was discontinued due to new onset or worsening renal impairment, bone loss, bone pain or pain in extremities.

Cost share waiver will be for **12 months**.

### Continuation of Therapy

Cost share waiver of **12 months** may be granted for members that meet all initial authorization criteria.

## **CLINICAL RATIONALE**

Pre-exposure prophylaxis (PrEP) reduces the risk of HIV infection acquisition through the use of daily oral antiretroviral medications. The only antiretroviral therapies with current evidence to support safety and efficacy for PrEP are tenofovir disoproxil fumarate (TDF) 300 mg in combination with emtricitabine (FTC) 200 mg and tenofovir alafenamide (TAF) 25 mg in combination with emtricitabine (FTC) 200 mg. Truvada, a single tablet containing both tenofovir disoproxil fumarate 300 mg and emtricitabine 200 mg and Descovy, a single containing both tenofovir alafenamide 35 mg and emtricitabine 200 mg are the only FDA-approved agents for the indication of PrEP. Current clinical practice guidelines for the prevention of HIV infection recommend the use of PrEP in individuals at a substantial risk of HIV acquisition.

Individuals identified at high risk of acquiring HIV infection include men who have sex with men (MSM), heterosexual women and men, and persons who inject drugs who have at least one of the following risk factors: HIV-positive sexual partner, recent bacterial sexually-transmitted infection (STI), a high number of sex partners, a history of inconsistent or no condom use, engage in commercial sex work, HIV-positive injecting partner, or share injection equipment.

PrEP should only be initiated in individuals who have tested negative for HIV infection. Individuals receiving PrEP should be re-tested for HIV infection every 3 months, as dual therapy with TDF/FTC is inadequate for treatment of HIV infection.

The safety and efficacy of TDF/FTC for PrEP among men or transgender women who have sex with men was evaluated in iPrEx, a phase 3, randomized, double-blind, placebo-controlled trial. 2,499 participants were randomized to a fixed-dose combination of TDF/FTC or placebo. The primary outcome was incidence

of documented HIV seroconversion and was assessed following 4,237 person years. Treatment with TDF with FTC was associated with a 42% risk reduction.

Partners PrEP was a randomized, double-blind, placebo-controlled trial that evaluated the safety and efficacy of TDF/FTC and TDF alone against placebo. 4,785 heterosexual serodiscordant couples were randomized to one of the three treatment arms. Efficacy was estimated at 67% for TDF and 75% for TDF/FTC compared to placebo. No statistically significant difference in efficacy was observed between the two treatment regimens amongst men, amongst women, amongst both men and women, or between men and women.

The Bangkok Tenofovir Study (BTS) was a phase 3, randomized, double-blind, placebo-controlled study that evaluated the safety and efficacy of daily TDF for HIV prevention in persons who inject drugs. 2,413 injection drug users were included in the study and followed for a mean of 4.6 years. An intention-to-treat analysis included participants with high adherence and detectable tenofovir serum levels and was associated with a 73.5% risk reduction for HIV acquisition compared to placebo.

The safety and efficacy of Descovy (TAF/FTC) for PrEP was evaluated in DISCOVER, a randomized, double-blind, multinational trial that included men and transgender women who have sex with men. The trial included two treatment arms, one receiving TAF/FTC 25 mg/200 mg and the other receiving TDF/FTC 300 mg/200 mg. TAF/FTC was found to be non-inferior to TDF/FTC in reducing the risk of acquiring HIV-1 infection.

Based upon the results of these studies, TDF/FTC and TAF/FTC are the only recommended regimens for MSM as TDF alone has not been studied in this population. TDF alone has been shown to be safe and effective in heterosexually active adults and persons who inject drugs and may be considered as an alternative regimen to TDF/FTC. TAF/FTC should not be used for persons at risk from receptive vaginal sex, as efficacy has not been studied in this population.

The United States Preventive Services Task Force (USPSTF) recommends that the following persons be considered for PrEP:

1. Men who have sex with men, are sexually active, and have 1 of the following characteristics:
  - A serodiscordant sex partner (ie, in a sexual relationship with a partner living with HIV)
  - Inconsistent use of condoms during receptive or insertive anal sex
  - A sexually transmitted infection (STI) with syphilis, gonorrhea, or chlamydia within the past 6 months
2. Heterosexually active women and men who have 1 of the following characteristics:
  - A serodiscordant sex partner (ie, in a sexual relationship with a partner living with HIV)
  - Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (eg, a person who injects drugs or a man who has sex with men and women)
  - An STI with syphilis or gonorrhea within the past 6 months
3. Persons who inject drugs and have 1 of the following characteristics:
  - Shared use of drug injection equipment
  - Risk of sexual acquisition of HIV (see above)

## PROCEDURES AND BILLING CODES

**To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.**

- N/A

## REFERENCES

- Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>. Published March 2018.
- Truvada [package insert]. Foster City, CA: Gilead Sciences, Inc; June 2020.
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- U.S. Preventative Services Task Force (USPSTF). Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis. Available at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis#bootstrap-panel--6>. Updated June 11, 2019. Accessed September 14, 2020.
- 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 randomized, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial. *Lancet*. 2020;396(10246):239-254. Accessed September 14, 2020.
- Baranek B, Wang S, Cheung AM et al. The effect of tenofovir disoproxil fumarate on bone mineral density: a systematic review and meta-analysis. *Antivir Ther*. 2020. doi: 10.3851/IMP3346. Online ahead of print. Accessed September 14, 2020.

## POLICY HISTORY

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