

Antivirals : HIV – emtricitabine / tenofovir alafenamide (Descovy®)

Medical policy no. 12.10.99.02

Effective Date: August 1, 2020

Related medical policies:

- 12.10.00 Antivirals- HIV Combinations

Note: New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least ONE preferred regimen. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.

Background:

Descovy is a two drug combination of tenofovir alafenamide (TAF) 25 mg and emtricitabine (FTC) 200 mg indicated for the treatment of HIV-1 infection and pre-exposure prophylaxis of HIV infection in men who have sex with men (MSM) and transgender women (TGW).

Medical necessity

Drug	Medical Necessity
emtricitabine - tenofovir alafenamide (Descovy®)	<p>Emtricitabine - tenofovir alafenamide (Descovy®) may be considered medically necessary for the following indications:</p> <ul style="list-style-type: none"> • Treatment of HIV-1 in people who have a contraindication to emtricitabine - tenofovir disoproxil fumarate. • Pre-exposure prophylaxis (PrEP) of HIV-1 in studied populations who have a contraindication to emtricitabine - tenofovir disoproxil fumarate.

Clinical policy:

Clinical Criteria	
<p>Pre-Exposure Prophylaxis (PrEP)</p> <p><u>Preferred agents:</u> emtricitabine - tenofovir disoproxil fumarate (Truvada®)</p>	<p>Emtricitabine - tenofovir alafenamide (Descovy®) may be authorized when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Prescribed for PrEP in adults and adolescents at risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex; AND 2. Negative HIV-1 test no more than seven days prior to initiating treatment; AND 3. Body weight is greater than or equal to 35 kg; AND 4. Documentation that client is not a candidate for emtricitabine-tenofovir disoproxil fumarate (Truvada®) due to contraindication or intolerance defined as any ONE of the following; <ol style="list-style-type: none"> a. Requires renal hemodialysis; OR

	<p>b. Stabilized creatinine clearance (CrCl) less than 60 mL/min but greater than or equal to 30 mL/min within the prior 3 months.</p> <p>If all of the above criteria are met, the request will be approved 12 months</p> <p>Criteria (Reauthorization)</p> <p>Tenofovir alafenamide-emtricitabine (Descovy) may be reauthorized when criteria 1 through 4 of the initial authorization criteria are met.</p> <p>If all of the above criteria are met, the request will be approved for 12 months</p>
<p>HIV Infection</p> <p><u>Preferred agents:</u> <i>emtricitabine - tenofovir disoproxil fumarate (Truvada®)</i></p>	<p>Emtricitabine - tenofovir alafenamide (Descovy®) may be authorized when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Emtricitabine - tenofovir alafenamide is used for treatment of HIV-1 in combination with other appropriate antiretroviral agents; AND 2. Body weight is greater than or equal to 35 kg; AND 3. Documentation that client is not a candidate for emtricitabine - tenofovir disoproxil fumarate (Truvada®) due to contraindication or intolerance defined as any ONE of the following; AND <ol style="list-style-type: none"> a. Requires renal hemodialysis; OR b. Stabilized creatinine clearance (CrCl) less than 60 mL/min but greater than or equal to 30 mL/min within the prior 3 months; OR c. Stabilized creatinine clearance (CrCL) between 60 – 89 mL/min AND the patient has hypertension plus one of the following: <ol style="list-style-type: none"> i. Hepatitis C ii. Diabetes iii. African American with family history of kidney disease; OR d. High risk for bone complications as determined by a history of ONE of the following: <ol style="list-style-type: none"> i. Vertebral compression factor ii. Arm or hip fracture with minimal trauma; iii. Patients who have chronic kidney with proteinuria, low phosphate or is grade 3 or worse; iv. T-score ≤ -2.0 (DXA) at the femoral neck or spine v. Taking glucocorticosteroids for more than 2 months. <p>If all of the above criteria are met, the request will be approved 12 months</p> <p>Criteria (Reauthorization)</p> <p>Emtricitabine - Tenofovir alafenamide (Descovy) may be reauthorized if patient shows continued medication adherence defined as:</p> <ol style="list-style-type: none"> a. No break in therapy as shown by consistent prescription claims history OR; b. No more than a 45 day gap between fills <p>If the above criteria are met, the request will be approved 12 months</p>

Dosage and quantity limits

Indication	Dose and Quantity Limits
PrEP	<ul style="list-style-type: none"> One tablet per day
Treatment of HIV-1	<ul style="list-style-type: none"> One tablet per day

References

- Descovy® Package Insert. <https://www.gilead.com/~media/Files/pdfs/medicines/hiv/descovy/descovy_pi.pdf>
- Micromedex. <<https://www.micromedexsolutions.com/>>. Accessed 11/22/2019
- UpToDate. <<https://www.uptodate.com/>>. Accessed 11/22/2019.
- Grant R, Lama J, Anderson P, et al. Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men. N Engl J Med. 2010; 363:2587-2599.
- Thigpen M, Kebaabetswe P, Paxton L, et al. Antiretroviral Preexposure Prophylaxis for Heterosexual HIV Transmission in Botswana. N Engl J Med. 2012; 367:423-434.
- Safety and Efficacy of Emtricitabine and Tenofovir Alafenamide (F/TAF) Fixed-Dose Combination Once Daily for Pre-Exposure Prophylaxis in Men and Transgender Women Who Have Sex with Men and Are At Risk of HIV-1 Infection (DISCOVER). <<https://clinicaltrials.gov/ct2/show/study/NCT02842086>>. Accessed 11/22/2019
- Krakower D, Daskalakis D, Feinberg J, et al. Tenofovir Alafenamide for HIV Preexposure Prophylaxis: What Can We DISCOVER about its True Value?
- Pilkington V, Hill A, Hughes S, et al. How safe is TDF/FTC as PrEP? A systematic review and meta-analysis of the risk of adverse events in 12 randomised trials of PrEP [Editorial]. J Virus Erad. 2018;4:215-24.
- U.S. Food and Drug Administration. FDA briefing document; meeting of the Antimicrobial Drugs Advisory Committee, August 7, 2019. Access at www.fda.gov/media/129607/download on 14 February 2020.
- U.S. Food and Drug Administration. Descovy for HIV pre-exposure prophylaxis:Antimicrobial Drugs Advisory Committee meeting briefing document. 4 July 2019. Access at www.fda.gov/media/129609/download on 14 February 2020.

History

Date	Action and Summary of Changes
09/17/2020	Updated reauthorization criteria for HIV infection
07/15/2020	Updated note section from "TWO preferred agents" to "ONE preferred regimen"
02/04/2020	New policy created