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

WA.PHAR.98 Antivirals: HIV– emtricitabine/tenofovir alafenamide (Descovy®)

Effective Date: August 1, 2020

Related medical policies:

- WA.PHAR.97 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. 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.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit:
https://pharmacy.envolvehealth.com/content/dam/centene/envolve-pharmacy-solutions/pdfs/PDL/FORMULARY-CoordinatedCare_Washington.pdf

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®)	**Emtricitabine - tenofovir alafenamide (Descovy®)** may be considered medically necessary for the following indications: • 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. If all criteria are not met, but there are documented medically necessary or situational circumstances based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration. Clients new to Apple Health or new to a MCO, who are requesting regimens for continuation of therapy should be reviewed following the reauthorization criteria listed below.

Clinical policy:

Clinical Criteria	
Emtricitabine/tenofovir alafenamide (Descovy®) ***Preferred Alternative*** *emtricitabine - tenofovir disoproxil fumarate (Truvada®)*	**Emtricitabine - tenofovir alafenamide (Descovy®)** may be authorized when **ALL** of the following are met: 1. When prescribed for PrEP in adults and adolescents at risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex, when patient has**:** a. Negative HIV-1 test prior to initiating treatment; **AND** **b.** Body weight is ≥ 35 kg; **OR** 2. When prescribed for treatment of a confirmed HIV-1 infection in combination with other appropriate antiretroviral agents; AND a. Patient's body weight is ≥ 25 kg; **AND** b. 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; i. Requires renal hemodialysis; **OR** ii. Stabilized creatinine clearance (CrCl) less than 60 mL/min but greater than or equal to 30 mL/min within the prior 3 months; **OR** iii. Stabilized CrCl between 60-89 mL/min **AND** the patient has hypertension plus **ONE** of the following: 1. Diabetes; 2. Hepatitis C 3. African American with family history of kidney disease; **OR** c. Stabilized CrCl greater than 60 mL/min **AND** high risk for bone complications as determined by a history of **ONE** of the following: i. Vertebral compression factor ii. Arm or hip fracture with minimal trauma; iii. T-score ≤ -2.0 (DXA) at the femoral neck or spine iv. Taking glucocorticosteroids for more than 2 months—must include documentation of the following: 1. Diagnosis requiring chronic glucocorticoid regimen; **AND** 2. Current glucocorticoid regimen 3. Expected duration of therapy; **OR** d. Stabilized CrCl between 60-89 mL/min **AND** the patient has chronic kidney disease with proteinuria, low phosphate or is grade 3 or worse; **OR** e. CrCl has decreased ≥ 25% from baseline; **AND** 3. Descovy will not be co-administered with other ART products or any products with a serious contraindication (see Table 1 below) If all of the above criteria are met, the request will be **approved 12 months**
	Criteria (Reauthorization)

	Emtricitabine - Tenofovir alafenamide (Descovy) may be reauthorized if the patient shows previous history of medication use within the last 6 months. The request will be **approved for 12 months** or the pharmacy may submit the claim with Expedited Authorization (EA) • 85000000006: Continuation of pre-exposure prophylaxis (PrEP) therapy. • 85000000007: Continuation of antiviral treatment.

Dosage and quantity limits

Indication	Dose and Quantity Limits
PrEP	• One tablet per day
Treatment of HIV-1	• One tablet per day

Appendix

Table 1: Drugs with Contraindications to Descovy

Drug Name	Contraindicated Drugs
Descovy	No drugs with contraindications

References

1. Descovy® Package Insert. <https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/descovy/descovy_pi.pdf>
2. Micromedex. <https://www.micromedexsolutions.com/>. Accessed 11/22/2019
3. UpToDate. <https://www.uptodate.com/>. Accessed 11/22/2019.
4. 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.
5. 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.
6. 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
7. Krakower D, Daskalakis D, Feinberg J, et al. Tenofovir Alafenamide for HIV Preexposure Prophylaxis: What Can We DISCOVER about its True Value?
8. 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 ransomised trials of PrEP [Editorial]. J Virus Erad. 2018;4:215-24.
9. 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.
10. 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

10/25/2021	Removed statement from note section “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.”
04/01/2021	Policy number updated and related medical policy (HIV Combination) number updated
12/16/2020	Approved by DUR Board
12/02/2020	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