

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

Medical policy no. 12.10.99.AA-2
2020

Effective Date: August 1,

Related medical policies:

- 12.10.99 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://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx>

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. <p>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.</p> <p>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.</p> |

Clinical policy:

| <i>Clinical Criteria</i> | |
|---|---|
| <p><i>Emtricitabine/tenofovir alafenamide (Descovy®)</i></p> <p><i>Preferred Alternative</i> <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. 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: <ol style="list-style-type: none"> 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 <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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 $\geq 25\%$ 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) <p>If all of the above criteria are met, the request will be approved 12 months</p> |
| Criteria (Reauthorization) | |

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| | <p>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)</p> <ul style="list-style-type: none"> 85000000006: Continuation of pre-exposure prophylaxis (PrEP) therapy. 85000000007: Continuation of antiviral treatment. |
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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 |

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 randomised 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 |
|---------------------------------|----------------------------------|
| Policy:Antivirals: HIV- Descovy | Medical Policy No. 12.10.99.AA-2 |
| | Last Updated 10/25/2021 |

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|-------------------|---|
| 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 |