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**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Necessity</th>
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</table>
| 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. |

**Clinical policy:**

| Clinical Criteria | Emtricitabine - tenofovir alafenamide (Descovy®) may be authorized when ALL of the following are met:  
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;  
   a. Requires renal hemodialysis; **OR** |
|-------------------|-------------------------------------------------|
| Pre-Exposure Prophylaxis (PrEP) | Preferred agents:  
Emtricitabine - tenofovir disoproxil fumarate (Truvada®) |
### HIV Infection

**Preferred agents:**
- **emtricitabine - tenofovir disoproxil fumarate (Truvada®)**

**Emtricitabine - tenofovir alafenamide (Descovy®)** may be authorized when **ALL** of the following are met:

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**
   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:
      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:
      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.

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 patient shows continued medication adherence defined as:

a. No break in therapy as shown by consistent prescription claims history **OR**;

b. No more than a 45 day gap between fills

If the above criteria are met, the request will be **approved 12 months**

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b. Stabilized creatinine clearance (CrCl) less than 60 mL/min but greater than or equal to 30 mL/min within the prior 3 months.

If all of the above criteria are met, the request will be **approved 12 months**

### Criteria (Reauthorization)

Tenofovir alafenamide-emtricitabine (Descovy) may be reauthorized when **criteria 1 through 4** of the initial authorization criteria are met.

If all of the above criteria are met, the request will be **approved for 12 months**
Dosage and quantity limits

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose and Quantity Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>PrEP</td>
<td>One tablet per day</td>
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<tr>
<td>Treatment of HIV-1</td>
<td>One tablet per day</td>
</tr>
</tbody>
</table>

References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action and Summary of Changes</th>
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<tbody>
<tr>
<td>09/17/2020</td>
<td>Updated reauthorization criteria for HIV infection</td>
</tr>
<tr>
<td>07/15/2020</td>
<td>Updated note section from &quot;TWO preferred agents&quot; to &quot;ONE preferred regimen&quot;</td>
</tr>
<tr>
<td>02/04/2020</td>
<td>New policy created</td>
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