



## MEDICATION POLICY

**Generic Name:** Emtricitabine/Tenofovir disoproxil

**Therapeutic Class or Brand Name:** Truvada®

**Applicable Drugs** (if Therapeutic Class): N/A

**Date of Origin:** 7/8/14

**Date Last Reviewed/Revised:** 1/10/18

**GPI Code:** 1210990230

### Prior Authorization Criteria (may be considered medically necessary when criterion I is met):

- I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:
  - A. HIV-1 infection and criteria 1 and 2 are met:
    1. Truvada® is being used in combination with other antiretroviral agents.
    2. Minimum weight requirement: 17 kg.
  - B. Pre-exposure prophylaxis (PrEP) of HIV-1 and criteria 1 and 2 are met:
    1. Documentation of ALL of the following a through e:
      - a. The patient is at high risk for HIV-1 infection.
      - b. The patient has received counseling on safe sex practices and HIV risk reduction.
      - c. The patient has no clinical symptoms consistent with acute viral infection.
      - d. No HIV exposures are suspected within the past month.
      - e. The patient has a confirmed negative HIV-1 test within the previous week.
    2. Minimum age requirement: 18 years old.
  - C. Post-exposure prophylaxis (PEP) to reduce the risk of HIV infection and criteria 1 through 3 are met:
    1. Documentation that the patient experienced a known or suspected possible exposure to the HIV virus.
    2. Truvada® will be initiated within 72 hours of the exposure.
    3. Minimum age requirement: 18 years old.

### Exclusion Criteria:

- Truvada® should not be coadministered with Hepsera® or products containing:

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- Emtricitabine or tenofovir disoproxil fumarate, or containing tenofovir alafenamide, including Atripla®, Complera®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Stribild®, Vemlidy, or Viread®.
- Lamivudine including Combivir® (lamivudine/zidovudine), Dutrebis™ (lamivudine/raltegravir), Epivir® or Epivir-HBV® (lamivudine), Epzicom® (abacavir sulfate/lamivudine), Triumeq® (abacavir sulfate/dolutegravir/lamivudine), or Trizivir® (abacavir sulfate/lamivudine/zidovudine).

### Other Criteria:

- N/A

### Quantity/Days Supply Restrictions:

- Quantities of up to 30 tablets per 30 days.

### Approval Length:

- **Authorization:**
  - HIV-1 infection: 1 year.
  - Pre-exposure prophylaxis (PrEP): 6 months.
  - Post-exposure prophylaxis (PEP): One time for a total of 28 days.
- **Re-Authorization:**
  - HIV-1 infection: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met.
  - Pre-exposure prophylaxis (PrEP): An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the patient has negative HIV-1 screening tests documented at least every 3 months.
  - Post-exposure prophylaxis (PEP): N/A

### Appendix:

N/A

### References:

1. <http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>.

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2. <https://www.azblue.com/~media/azblue/files/pharmacy-forms-mastery-directory/group/prior-authorization-guidelines/truvada.pdf>.
3. [Medi-Span](#).
4. [http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada\\_pi.PDF](http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada_pi.PDF).

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<b>Historical Tracking Of Changes Made To Policy</b>	
1/10/2018	<ol style="list-style-type: none"> <li>1. <b>Added</b> “Descovy®”, “Vemlidy®”, and “Dutrebis™ (lamivudine/raltegravir)” <b>to lists of excluded products under Exclusion Criteria.</b></li> <li>2. <b>Removed</b> “<a href="https://www.oxhp.com/secure/policy/truvada.pdf">https://www.oxhp.com/secure/policy/truvada.pdf</a>” <b>from References</b> (link no longer valid).</li> </ol>
10/11/2016	<ol style="list-style-type: none"> <li>1. <b>Changed</b> “I. A. HIV-1 infection and criterion 1 is met:...B. Pre-exposure prophylaxis (PrEP) of HIV-1 and criterion 1 is met:...C. Post-exposure prophylaxis (PEP) to reduce the risk of HIV infection and criteria 1 through 2 are met:...II. Minimum age requirement: 12 years old” <b>to</b> “I. A. HIV-1 infection and criteria 1 and 2 are met:...2. Minimum weight requirement: 17 kg...B. Pre-exposure prophylaxis (PrEP) of HIV-1 and criteria 1 and 2 are met:...2. Minimum age requirement: 18 years old...C. Post-exposure prophylaxis (PEP) to reduce the risk of HIV infection and criteria 1 through 3 are met:...3. Minimum age requirement: 18 years old” <b>under Prior Authorization Criteria.</b></li> <li>2. <b>Changed</b> “Truvada® should not be coadministered with products containing emtricitabine or tenofovir disoproxil fumarate including Atripla®, Complera®, Emtriva®, Stribild®, Viread®; with lamivudine-containing products; or with Hepsera®” <b>to</b> “Truvada® should not be coadministered with Hepsera® or products containing: Emtricitabine or tenofovir disoproxil fumarate, or containing tenofovir alafenamide, including Atripla®, Complera®, Emtriva®, Genvoya®, Odefsey®, Stribild®, or Viread®; Lamivudine including Combivir® (lamivudine/zidovudine), Epivir® or Epivir-HBV® (lamivudine), Epzicom® (abacavir sulfate/lamivudine), Triumeq® (abacavir sulfate/dolutegravir/lamivudine), or Trizivir® (abacavir sulfate/lamivudine/zidovudine)” <b>under Exclusion Criteria.</b></li> <li>3. <b>Updated</b>  “<a href="https://www.azblue.com/~media/azblue/files/pharmacy%20forms%20mastery%20directory/group/prior%20authorization%20guidelines/truvada%20rx%20policy.pdf">https://www.azblue.com/~media/azblue/files/pharmacy%20forms%20mastery%20directory/group/prior%20authorization%20guidelines/truvada%20rx%20policy.pdf</a>” <b>to</b>  “<a href="https://www.azblue.com/~media/azblue/files/pharmacy-forms-mastery-directory/group/prior-authorization-guidelines/truvada.pdf">https://www.azblue.com/~media/azblue/files/pharmacy-forms-mastery-directory/group/prior-authorization-guidelines/truvada.pdf</a>” <b>under References.</b></li> </ol>
8/22/2015	<ol style="list-style-type: none"> <li>1. <b>Changed</b> “HIV-1and” <b>to</b> “HIV-1 and” <b>on line B under Criterion I under Prior Authorization Criteria.</b></li> <li>2. <b>Changed</b> “Truvada® should not be coadministered with Atripla®, Complera®, Emtriva®, Stribild®, Viread®, lamivudine-containing products, or Hepsera®” <b>to</b> “Truvada® should not be coadministered with products containing emtricitabine or tenofovir disoproxil fumarate including Atripla®, Complera®, Emtriva®, Stribild®, Viread®; with lamivudine-containing products; or with Hepsera®” <b>under Exclusion Criteria.</b></li> </ol>

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