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:** 10/11/16

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:

- 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).

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.
2. https://www.oxhp.com/secure/policy/truvada.pdf.

3. https://www.azblue.com/~/media/azblue/files/pharmacy-forms-mastery-directory/group/prior-authorization-guidelines/truvada.pdf.
4. Medi-Span.
5. http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_pi.PDF.

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Historical Tracking Of Changes Made To Policy	
10/11/2016	1. **Changed** "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" **to** "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" **under Prior Authorization Criteria**. 2. **Changed** "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®" **to** "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)" **under Exclusion Criteria**. 3. **Updated** "https://www.azblue.com/~/media/azblue/files/pharmacy%20forms%20mastery%20directory/group/prior%20authorization%20guidelines/truvada%20rx%20policy.pdf" **to** "https://www.azblue.com/~/media/azblue/files/pharmacy-forms-mastery-directory/group/prior-authorization-guidelines/truvada.pdf" **under References**.
8/22/2015	1. **Changed** "HIV-1and" **to** "HIV-1 and" **on line B under Criterion I under Prior Authorization Criteria**. 2. **Changed** "Truvada® should not be coadministered with Atripla®, Complera®, Emtriva®, Stribild®, Viread®, lamivudine-containing products, or Hepsera®" **to** "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®" **under Exclusion Criteria**.