**MEDICATION POLICY:**
**Truvada®**

**Generic Name:** Emtricitabine/Tenofovir disoproxil

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

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

**GPI Code:** 1210990230

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 7/8/2014

**Date Last Reviewed / Revised:** 9/20/2018

---

**PRIOR AUTHORIZATION CRITERIA**
(May be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of HIV-1 infection and criteria A through C are met:
   A. Truvada® is being used in combination with other antiretroviral agents.
   B. Minimum weight requirement: 17 kg.
   C. Patients weighing 35 kg or more must have documented history of intolerance or resistance to Cimduo® (Lamivudine-Tenofovir disoproxil) or lamivudine.

II. Pre-exposure prophylaxis (PrEP) of HIV-1 and criteria A and B are met:
   A. Documentation of ALL of the following 1 through 6:
      1. The patient is at high risk for HIV-1 infection.
      2. The patient has received counseling on safe sex practices and HIV risk reduction.
      3. The patient has no clinical symptoms consistent with acute viral infection.
      4. No HIV exposures are suspected within the past month.
      5. The patient has a confirmed negative HIV-1 test within the previous week.

III. Post-exposure prophylaxis (PEP) to reduce the risk of HIV infection and criteria A through C are met:
   A. Documentation that the patient experienced a known or suspected possible exposure to the HIV virus.
   B. Truvada® will be initiated within 72 hours of the exposure.
   C. 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®, Biktarvy®, Cimduo®, Complera®, Descovy®, Emtriva®, Genvoya®, Odefsey®, Stribild®, Symfi®, Symfi Lo®, Symtuza®, Vemlidy®, or Viread®.
MEDICATION POLICY: Truvada®

- Lamivudine including Cimduo®, Combivir®, Dutrebis™, Epivir® or Epivir-HBV®, Epzicom®, Symfi® or Symfi Lo®, Symfi Lo®, Triumeq®, or Trizivir®.

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

3. Medi-Span®.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes/Changes</th>
</tr>
</thead>
</table>

CONFIDENTIAL & PROPRIETARY, VENTEGRA, INC.
9/20/2018

1. **Changed** outline structure under Prior Authorization Criteria section and added

   age requirement under first diagnosis, from:

   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.


      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 an 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.

To (addition of section I-C in italics):

I. Documented diagnosis of HIV-1 infection and criteria A through C are met:

   A. Truvada® is being used in combination with other antiretroviral agents.

   B. Minimum weight requirement: 17 kg.
C. Patients weighing 35 kg or more must have documented history of intolerance or resistance to Cimduo® (Lamivudine-Tenofovir disoproxil) or lamivudine.

II. Pre-exposure prophylaxis (PrEP) of HIV-1 and criteria A and B are met:
   A. Documentation of ALL of the following 1 through 6:
      1. The patient is at high risk for HIV-1 infection.
      2. The patient has received counseling on safe sex practices and HIV risk reduction.
      3. The patient has no clinical symptoms consistent with acute viral infection.
      4. No HIV exposures are suspected within the past month.
      5. The patient has a confirmed negative HIV-1 test within the previous week.

III. Post-exposure prophylaxis (PEP) to reduce the risk of HIV infection and criteria A through C are met:
   A. Documentation that the patient experienced a known or suspected possible exposure to the HIV virus.
   B. Truvada® will be initiated within 72 hours of the exposure.
   C. Minimum age requirement: 18 years old.

2. Added Biktarvy under Exclusion Criteria section to list of emtricitabine/tenofovir-containing products.
3. Added Cimduo® under Exclusion Criteria section to lists of both tenofovir and lamivudine-containing products.
4. Added Symfi®, Symfi Lo® under Exclusion Criteria section to lists of both tenofovir and lamivudine-containing products.
5. Added Symtuza® under Exclusion Criteria section to lists of emtricitabine/tenofovir-containing products.
6. Deleted generic drug descriptions of all brand-name drugs listed under lamivudine-containing products in the Drug Exclusions section so that it mirrors the format under the emtricitabine and tenofovir-containing products.

1/10/2018

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:...II. Minimum age requirement: 18 years old” under Prior Authorization Criteria.
## Medication Policy: Truvada®

### 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
Obsolete URL in References Item #2.

---

### 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.**

### DISCUSSION:
Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.