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: 8/7/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when ONE of 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 clinically significant treatment failure, adverse event or contraindication to Cimduo® (Lamivudine-Tenofovir disoproxil) or lamivudine.

II. Pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection due to sexual acquisition and criteria A through G are met:
   A. Adult or adolescent patient weighing at least 35 kilograms.
   B. The patient is at high risk for HIV-1 infection. Any of the following factors identified by the Centers for Disease Control (CDC) may be used to identify high-risk patients:
      1. Patient has a HIV-positive partner(s), especially if partner has unknown or detectable viral load OR
      2. Patient has partner(s) of unknown HIV-1 status AND
         a) There is no or inconsistent condom use OR
         b) There is diagnosis of a STD in the past 6 months OR
      3. Patient has an injection partner with HIV or shares needles, syringes, or other equipment to inject drugs.
   C. The patient has received counseling on safe sex practices and HIV risk reduction.
   D. The patient has no clinical symptoms consistent with acute viral infection.
   E. No HIV exposures are suspected within the past month.
   F. The patient has a confirmed negative HIV-1 test within the week prior to initiation of therapy and every 3 months thereafter while on Truvada®.
   G. Patient has documented clinically significant treatment failure, adverse event or contraindication with combination therapy of individual components emtricitabine (Emtriva®) and generic Tenofovir disoproxil.

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 co-administered 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®.
  - Lamivudine including Cimduo®, Combivir®, Dutrebis™, Epivir® or Epivir-HBV®, Epzicom®, Symfi® or 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

1. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf .
2. Medi-Span®.
3. http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_pi.PDF.
4. https://www.cdc.gov/hiv/risk/prep/index.html.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
8/7/2020	1. **Added** "II.G Patient has documented significant treatment failure, adverse event or contraindication with combination therapy of individual components emtricitabine (Emtriva)® and generic tenofovir disoproxil."
3/18/2020	2. **Changed** I.C **From** "history of intolerance or resistance to" To "clinically significant treatment failure, adverse event or contraindication" under Prior Authorization Criteria. 3. **Changed** IIB **From** "The patient is at high risk of HIV-1 infection" **To** "The patient is at high risk of HIV-1 infection". Any of the following factors identified by the CDC may be used to identify high risk patients: 1. Patient has a HIV-positive partner(s), especially if partner has unknown or detectable viral load OR 2. Patient has partner(s) of unknown HIV-1 status AND a.There is no or inconsistent condom use OR b. There is diagnosis of an STD in the past 6 months OR 3. Patient has an injection partner with HIV or shares needles, syringes, or other equipment to inject drugs" **Under** Prior Authorization Criteria 4. **Added "4.** https://www.cdc.gov/hiv/risk/prep/index.html" **Under** References.
12/19/2019	I. **Changed** item II **under Prior Authorization Criteria** FROM: 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. 6. Minimum age requirement: 18 years old. TO: II. Pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition and criteria A through F are met: A. Adult or adolescent patient weighing at least 35 kilograms. B. The patient is at high risk for HIV-1 infection. C. The patient has received counseling on safe sex practices and HIV risk reduction. D. The patient has no clinical symptoms consistent with acute viral infection. E. No HIV exposures are suspected within the past month. F. The patient has a confirmed negative HIV-1 test within the week prior to initiation of therapy and every 3 months thereafter while on Truvada.
9/6/2019	1. **Updated** item 1 **under References** **From**: http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf. **To:** https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf . 2. **Deleted** item #2 **under References** https://www.azblue.com/~/media/azblue/files/pharmacy-forms-mastery-directory/group/prior-authorization-guidelines/truvada.pdf . 3.
9/20/2018	4. **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. 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. **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. 6. Minimum age requirement: 18 years old. 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. 5. **Added** Biktarvy under Exclusion Criteria section to list of emtricitabine/tenofovir-containing products. 6. **Added** Cimduo® under Exclusion Criteria section to lists of both tenofovir and lamivudine-containing products. 7. **Added** Symfi®, Symfi Lo® under Exclusion Criteria section to lists of both tenofovir and lamivudine-containing products. 8. **Added** Symtuza® under Exclusion Criteria section to lists of emtricitabine/tenofovir-containing products. 9. **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:…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** obsolete URL in **References** item #2.
Click or tap to enter a date.	1.

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**