Generic Name: : Emtricitabine

Therapeutic Class or Brand Name: Emtriva®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 12106030

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/7/2020

Date Last Reviewed / Revised: N/A

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 is met:

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

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. Emtriva® is part of a daily combination therapy with generic tenofovir disoproxil.

   G. The patient has a confirmed negative HIV-1 test within the week prior to initiation of therapy and every 3 months thereafter while on combination.

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. Emtriva® is used in combination with generic tenofovir disoproxil fumarate and initiated within 72 hours of the exposure.

C. Minimum age requirement: 18 years old.

Exclusion Criteria

- Emtriva® should not be co-administered with 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 capsules 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/clinicians/guidelines/index.html
2. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf .

3. Medi-Span®.
4. https://www.gilead.com/-/media/files/pdfs/medicines/hiv/emtriva/emtriva_pi.pdf
5. https://www.cdc.gov/hiv/risk/prep/index.html.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
8/7/2020	1. New Policy.