Truvada® (emtricitabine-tenofovir disoproxil fumarate) Viread® (tenofovir disoproxil fumarate) Emtriva® (emtricitabine)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Truvada® (emtricitabine-tenofovir disoproxil fumarate), Viread® (tenofovir disoproxil fumarate), and Emtriva® (emtricitabine) drug policy is to ensure the appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. Truvada® is a combination agent that combines Emtriva® (emtricitabine) and Viread® (tenofovir disoproxil fumarate), nucleoside reverse transcriptase inhibitors.

Truvada® is approved by the Food and Drug Administration (FDA) for the treatment of HIV-1 infection in combination with other antiretroviral agents in adults and pediatric patients weighting at least 17 kg and for HIV-1 pre-exposure prophylaxis (PrEP) in combination with safer sex practices in adults at high risk. Viread® is FDA-approved for the treatment of HIV-1 infection in combination with other antiretroviral agents and for the treatment of chronic hepatitis B in adults and patients 2 years of age and older weighing at least 10 kg. Emtriva® is FDA-approved for the treatment of HIV-1 infection in combination with other antiretroviral agents.

The use of Viread® in combination with Emtriva® for pre-exposure prophylaxis (PrEP) is a guideline-recommended use supported by compendia. Viread®, alone, may also be used for PrEP for heterosexual men and women and persons who inject drugs. The use of Viread® without Emtriva® for PrEP has not been adequately studied to support use in other high-risk populations.

POLICY

Initial Criteria

I. Viread® and generics (tenofovir disoproxil fumarate) and Emtriva® (emtricitabine) are considered medically necessary for pre-exposure prophylaxis when the following criteria are met:

A. Member is at high risk for HIV acquisition (see Appendix A)
AND

B. Member has a documented negative HIV test result prior to initiating therapy
AND
C. Member will be tested for HIV infection every 3 months while receiving therapy

Initial approval will be for **6 months**.

II. Truvada® is considered medically necessary for pre-exposure prophylaxis when the following criteria are met:

A. Member is at high risk for HIV acquisition (see Appendix A)
AND
B. Member has documented negative HIV test result prior to initiating therapy
AND
C. Member will be tested for HIV infection every 3 months while receiving therapy
AND
D. Member has an allergy, intolerance, or contraindication to an excipient in the individual brand or generic agents, emtricitabine and tenofovir disoproxil fumarate. An unwillingness to take the two ingredients separately does not preclude this requirement.

Initial approval will be for **6 months**.

Continuation Criteria

I. Re-authorization of **6 months** may be granted when the following criteria are met:
A. Member meets all initial criteria
B. Member has not tested HIV-positive

The use of Truvada® and individual agents are not subject to the criteria within this policy when used for the treatment of HIV-1 or hepatitis B infection.

APPENDIX

Appendix A: Risk factors for HIV acquisition

1. HIV-positive sexual partner
2. Recent sexually-transmitted infection (STI) with syphilis, gonorrhea, or chlamydia
3. High number of sex partners
4. History of inconsistent or no condom use
5. Performs commercial sex work
6. Injects drugs and shares drug injection equipment

CLINICAL RATIONALE

Pre-exposure prophlyaxis (PrEP) reduces the risk of HIV infection acquisition through the use of daily oral antiretroviral medications. The only antiretroviral therapies with current evidence to support safety and efficacy for PrEP are tenofovir disoproxil fumarate (TDF) 300 mg and emtricitabine (FTC) 200 mg. Truvada, a single tablet containing both tenofivir disoproxil fumarate 300 mg and emtricitabine 200 mg, is the only FDA-approved agent for the indication of PrEP. Current clinical practice guidelines for the prevention of HIV infection recommend the use of PrEP in individuals at a substantial risk of HIV acquisition.

Individuals identified at high risk of acquiring HIV infection include men who have sex with men (MSM), heterosexual women and men, and persons who inject drugs who have at least one of the following risk

factors: HIV-positive sexual partner, recent bacterial sexually-transmitted infection (STI), a high number of sex partners, a history of inconsistent or no condom use, engage in commercial sex work, HIV-positive injecting partner, or share injection equipment.

PrEP should only be initiated in individuals who have tested negative for HIV infection. Individuals receiving PrEP should be re-tested for HIV infection every 3 months, as dual therapy with TDF/FTC is inadequate for treatment of HIV infection.

The safety and efficacy of TDF/FTC for PrEP among men or transgender women who have sex with men was evaluated in iPrEx, a phase 3, randomized, double-blind, placebo-controlled trial. 2,499 participants were randomized to a fixed-dose combination of TDF/FTC or placebo. The primary outcome was incidence of documented HIV seroconversion and was assessed following 4,237 person years. Treatment with TDF with FTC was associated with a 42% risk reduction.

Partners PrEP was a randomized, double-blind, placebo-controlled trial that evaluated the safety and efficacy of TDF/FTC and TDF alone against placebo. 4,785 heterosexual serodiscordant couples were randomized to one of the three treatment arms. Efficacy was estimated at 67% for TDF and 75% for TDF/FTC compared to placebo. No statistically significant difference in efficacy was observed between the two treatment regimens amongst men, amongst women, amongst both men and women, or between men and women.

The Bangkok Tenofovir Study (BTS) was a phase 3, randomized, double-blind, placebo-controlled study that evaluated the safety and efficacy of daily TDF for HIV prevention in persons who inject drugs. 2,413 injection drug users were included in the study and followed for a mean of 4.6 years. An intention-to-treat analysis included participants with high adherence and detectable tenofovir serum levels and was associated with a 73.5% risk reduction for HIV acquisition compared to placebo.

Based upon the results of these studies, TDF/FTC is the only recommended regimen for MSM as TDF alone has not been studied in this population. TDF alone has been shown to be safe and effective in heterosexually active adults and persons who inject drugs and may be considered as an alternative regimen to TDF/FTC.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable.

REFERENCES

- Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018.
- Truvada [package insert]. Foster City, CA: Gilead Sciences, Inc; 2016.
- Viread [package insert]. Foster City, CA: Gilead Sciences, Inc; 2018.
- Emtriva [package insert]. Foster City, CA: Gilead Sciences, Inc; 2018.

POLICY HISTORY

Policy #: 05.02.65
Policy Creation: June 2019
Reviewed:
Revised:
Current Effective Date: July 15, 2019