Clinical Policy: Emtricitabine/Tenofovir (Truvada)

Reference Number: HIM.PA.78
Effective Date: 12.01.14
Last Review Date: 08.19
Line of Business: HIM

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Emtricitabine/tenofovir (Truvada®) is a combination of two nucleoside reverse transcriptase inhibitors (NRTIs).

FDA Approved Indication(s)

Truvada is indicated in combination with:

- Other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection in adults and pediatric patients weighing at least 17 kg
- Safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in at-risk adults and adolescents weighing at least 35 kg

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Truvada is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. HIV-1 Infection (must meet all)**:**

1. Diagnosis of HIV-1 infection;
2. Truvada is prescribed in combination with other antiretroviral agents for the treatment of HIV-1 infection;
3. Dose does not exceed one of the following (a or b):
   a. Adults and pediatric patients weighing ≥ 35 kg: 200/300 mg/day (1 tablet/day);
   b. Pediatric patients (i, ii, or iii):
      i. Weight 17 kg to < 22 kg: 100/150 mg/day (1 tablet/day);
      ii. Weight 22 kg to < 28 kg: 133/200 mg/day (1 tablet/day);
      iii. Weight 28 kg to < 35 kg: 167/250 mg/day (1 tablet/day).

Approval duration: 12 months

B. Pre-exposure HIV Prophylaxis (must meet all)**:**

1. Member is HIV-negative and has no signs or symptoms of acute HIV infection;
2. Member is considered at high risk for acquiring HIV and meets one of the following (a, b, or c):
   a. Engaging in sexual activity with a HIV-1 infected partner;
   b. Engaging in sexual activity and one or more of the following:

i. Inconsistent or no condom use;
ii. Diagnosis of sexually transmitted infections;
iii. Exchange of sex for commodities;
iv. Incarceration;
v. Not in a monogamous partnership;
vi. Partner of unknown HIV status with any of the preceding risk factors;

c. Use of illicit injection drugs;

3. Dose does not exceed 200/300 mg/day (1 tablet/day).

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Truvada for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. HIV-1 infection (i or ii):
      i. Adults and pediatric patients weighing ≥ 35 kg: 200 mg/300 mg/day (1 tablet/day);
      ii. Pediatric patients (a, b, or c):
         a) Weight 17 kg to < 22 kg: 100/150 mg/day (1 tablet/day);
         b) Weight 22 kg to < 28 kg: 133/200 mg/day (1 tablet/day);
         c) Weight 28 kg to < 35 kg: 167/250 mg/day (1 tablet/day);
   b. PrEP: 200 mg/300 mg/day (1 tablet/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HIV: human immunodeficiency virus
PrEP: pre-exposure prophylaxis

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): HIV-1 PrEP in individuals with unknown or positive HIV-1 status
- Boxed warning (s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HIV-1 infection	Adults and pediatric patients weighing ≥ 35 kg: 200/300 mg PO QD Pediatric patients weighing between 17 to < 35 kg: 17 kg to < 22 kg: 100/150 mg PO QD 22 kg to < 28 kg: 133/200 mg PO QD 28 kg to < 35 kg: 167/250 mg PO QD	See regimen
PrEP	200/300 mg PO QD	200/300 mg/day

VI. Product Availability

Tablets: 200 mg/300 mg, 167 mg/250 mg, 133 mg/200 mg, 100 mg/150 mg

VII. References

1. Truvada Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; May 2018. Available at http://www.gilead.com. Accessed May 22, 2019.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. U.S. Department of Health and Human Services. Available at https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0. Updated October 25, 2018. Accessed May 22, 2019.
3. Centers for Disease Control and Prevention, U.S. Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States - 2017 update. 2017. Available at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Accessed May 22, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Reformatted guideline to new format. Adjusted criteria to remove all other HIV drugs. Renamed guideline from HIV medications to Truvada. Added Workflow reference document.	12.15	12.15
Created criteria for treatment of HIV-1 infection per package insert.	08.16	11.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template Added max doses to initial approval criteria The CDC recommends those with a high number of sex partners should receive pre-exposure prophylaxis therefore added Not in a monogamous partnership to criteria Updated references	04.17	08.17
3Q 2018 annual review: no significant changes; clarified indicators of high risk for acquiring HIV; references reviewed and updated.	05.22.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.22.19	08.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.