Clinical Policy: Emtricitabine/Tenofovir (Truvada®)
Reference Number: HIM.PA.78
Effective Date: 12/14
Last Review Date: 08/17
Line of Business: Health Insurance Marketplace

Coding Implications
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 emtricitabine, a nucleoside reverse transcriptase inhibitor (NRTI), and tenofovir, an acyclic nucleotide analog (i.e., nucleotide reverse transcriptase inhibitor).

FDA approved indication
Truvada is indicated:
- For the treatment of human immunodeficiency virus (HIV)-1 infection in adults and pediatric patients weighing at least 17 kg
- In combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. HIV-1 Infection (must meet all)**:**
1. Diagnosis of HIV infection;
2. Truvada will be 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 or b):
   a. Engaging in sexual activity with a HIV-1 infected partner;
   b. Engaging in sexual activity within a high prevalence area 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. Use of illicit drugs or alcohol dependence;
v. Incarceration;
vi. Not in a monogamous partnership;
vii. Partner of unknown HIV status with any of the preceding risk factors;

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

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized);

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Truvada for HIV-1 and has received this medication for at least 30 days;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. Adults and pediatric patients weighing ≥ 35 kg: 200 mg/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. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Truvada for pre-exposure HIV-1 prophylaxis and has received this medication for at least 30 days;
2. Documentation of a positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 200 mg/300 mg/day (1 tablet/day).

Approval duration: 12 months

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

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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 policy – HIM.PA.21 or evidence of coverage documents

IV. Appendices/General Information

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

V. References

1. Truvada Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; April 2016. Available at http://www.gilead.com. Accessed April 2017. .
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed April 2017.
3. Centers for Disease Control and Prevention, U.S. Public Health Service. Pre-exposure prophylaxis for the prevention of HIV infection in the United States—2014: a clinical practice guideline. 2014. Available at http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf. Accessed April 18, 2017.

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
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

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 Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.