Clinical Policy: Emtricitabine/Tenofovir (Truvada)

Reference Number: AZ.CP.PHAR.37
Effective Date: 11.16.16
Last Review Date: 05.22.2019
Line of Business: Medicaid – AZ

Revision Log

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

Description

Truvada is the combination of emtricitabine (Emtriva®) and tenofovir disoproxil fumarate (Viread®), both of which are nucleoside analog HIV-1 reverse transcriptase inhibitors.

FDA approved indication

Truvada is indicated:

- In combination with other antiretroviral agents for the treatment of human immunodeficiency virus, type one (HIV-1) infection in adults and pediatric patients weighing at least 17 kilograms
- 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
- In combination with a third antiretroviral agent for HIV post-exposure prophylaxis (PEP) after occupational or non-occupational exposure to HIV, including sexual assault.

Policy/Criteria

Provider shall submit documentation (which may include office chart notes and lab results) 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 current HIV-1 infection;
2. Dose does not exceed one tablet daily of the weight-appropriate dose.

Approval duration: One year

B. HIV Post-Exposure Prophylaxis (must meet all)

1. Use for HIV post-exposure prophylaxis (PEP) including any of the following diagnosis:
    a. Contact with and (suspected) exposure to HIV
    b. Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
    c. Contact with and (suspected) exposure to potentially hazardous body fluids

2. Truvada is being given as a part of a CDC recommended PEP Regimen with at least 1 additional antiretroviral agent such as Isentress, Tivicay, Prezista+Ritonavir/Norvir.
3. Truvada is dosed 200mg-300mg once daily.
4. Member has not received Truvada within the prior 60 days.

Approval duration: 30 days

C. Other diagnoses/indications

1. Refer to CP.PMN.53 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 a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed one tablet daily of the weight-appropriate dose.

Approval duration: One year

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 CP.PMN.53 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 – CP.PMN.53 or evidence of coverage documents;

B. AHCCCS covers treatment only for illness or disease. Preventative treatment (PrEP) with Truvada for high-risk individuals is not covered.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

PrEP: pre-exposure prophylaxis

Appendix B: General Information

- **Black Box Warning:** TRUVADA is not approved for the treatment of chronic hepatitis B virus (HBV) infection. Severe acute exacerbations of hepatitis B have been reported in patients coinfected with HIV-1 and HBV who have discontinued TRUVADA. Therefore,

hepatic function should be monitored closely in HBV-infected patients who discontinue TRUVADA. If appropriate, initiation of anti-hepatitis B therapy may be warranted. (5.1)

- **Black Box Warning:** TRUVADA used for a PrEP indication must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initial use and periodically during use. Drug-resistant HIV-1variants have been identified with the use of TRUVADA for a PrEP indication following undetected acute HIV-1 infection. Do not initiate TRUVADA for a PrEP indication if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed.

Appendix C: Therapeutic Alternatives
N/A

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Treatment of HIV-1 infection	1 tab PO QD of the weight-appropriate dose If CrCl 30-49 ml/min: 1 tab PO q 48 hrs Do not use if CrCl < 30 ml/min, or if the patient is on hemodialysis	200 mg/300 mg QD

VI. Product Availability

Oral tablets emtricitabine / tenofovir: 100 mg /150 mg, 133 mg/200 mg, 167 mg/250 mg, 200 mg/300 mg

VII. References

1. Truvada® Prescribing Information. Foster City, CA: Gilead Sciences; April 2017.
2. Micromedex Healthcare Series [Internet Database]. Greenwood Village, CO: Thomson Healthcare. Updated periodically. Accessed May 26, 2017.
3. Clinical Pharmacology Website. Available at http://clinicalpharmacology-ip.com/. Tampa, FL: Gold Standard Inc.; Accessed May 26, 2017.
4. American Hospital Formulary Services Drug Information. Truvada. Available at http://www.medicinescomplete.com/mc/ahfs/current/. Accessed May 26, 2017.
5. Centers for Disease Control and Prevention (CDC) HIV/AIDs. Available at: https://www.cdc.gov/hiv/risk/pep/index.html Accessed May 22, 2019.

Reviews, Revisions, and Approvals	Date
Converted to new template; minor changes to verbiage and grammar. References updated.	05.26.17
Annual review and rebranded	08.20.18
Added approval information for Post Exposure Prophylaxis (PEP)	05.22.19

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.

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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.

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