MEDICAL MUTUAL®

Drug Policy

Policy:	**Truvada Preferred Step Therapy**	**Annual Review Date:** **06/16/2022**
Impacted Drugs:	**Truvada (emtricitabine/tenofovir disoproxil fumarate)**	**Last Revised Date:** **06/16/2022**

OVERVIEW

Truvada is a two-drug combination of emtricitabine and tenofovir disoproxil fumarate, both human immunodeficiency virus type 1 (HIV-1) nucleoside analog reverse transcriptase inhibitors. It is indicated for the following uses:

- **Treatment of HIV-1 infection,** in combination with other antiretrovirals, in adults and pediatric patients weighing ≥ 17 kg.
- **Pre-exposure prophylaxis (PrEP)**, to reduce the risk of sexually acquired HIV-1 infection, in at-risk adults and adolescents weighing ≥ 35 kg

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: None

Preferred Medication

- Generic emtricitabine/tenofovir disoproxil fumarate

Non-Preferred Medication

- Truvada

PREFERRED STEP THERAPY CRITERIA

1. If the patient meets BOTH of the following, authorization for a non-preferred medication may be given.
    a. The patient has tried one preferred product [documentation required]; AND
    b. The non-preferred product is being requested due to a formulation difference in the inactive ingredient(s) [e.g. differences in dyes, fillers, preservatives] between the non-preferred product and the bioequivalent generic preferred product which, according to the prescriber, would result in a significant allergy or serious adverse reaction [documentation required]

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria
Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation

supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Truvada tablets [prescribing information]. Foster City, CA: Gilead Sciences; June 2020.
2. Emtricitabine and tenofovir disoproxil fumarate tablets [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals; November 2020.
3. Emtricitabine/tenofovir disoproxil fumarate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 10 February 2022. Accessed 14 June 2022.