

PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Human Immunodeficiency Virus – Truvada Preferred Specialty Management Policy

- Truvada[®] (emtricitabine and tenofovir disoproxil fumarate – Gilead, generics)

REVIEW DATE: 04/28/2021

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.

Truvada is available as tablets in the following strengths: 100 mg/150mg, 133 mg/200 mg, 167 mg/250 mg, and 200 mg/300 mg.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. The program directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for 1 year in duration.

Documentation: Documentation will be required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, and prescription receipts.

Automation: None.

Preferred Products: generic emtricitabine/tenofovir disoproxil fumarate

Non-Preferred Products: Truvada

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Truvada	1. Approve for 1 year if the patient meets ALL of the following (A <u>and</u> B): A) 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 Preferred Product which, according to the prescriber, would result in a significant allergy or serious adverse reaction [documentation required] .

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Effective 07/01/2021	04/28/2021
