Drug and Biologic Coverage Policy

Effective Date.....**5/1/2024**
Next Review Date… **5/1/2025**
Coverage Policy Number **IP0090**

HIV Products for Individual and Family Plans

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Related Coverage Resources

Multi-Source Brand Name Drugs (IP0011)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

The Patient Protection and Affordable Care Act (PPACA) requires plans to cover certain preventive medications at no cost-share ($0). HIV products may be covered as preventive when used for HIV-1 pre-exposure prophylaxis. Refer to applicable benefit plan language for Individual and Family Plans.

This policy supports medical necessity review of the following HIV products for either preventive or treatment uses.

- **darunavir propylene glycolate** 600 mg, 800 mg tablet
- **Descovy**® (emtricitabine/tenofovir alafenamide)
- **Truvada**® (emtricitabine/tenofovir disoproxil fumarate)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Individual and Family Plans:

Product	Criteria
darunavir propylene glycolate 600 mg, 800 mg tablet	**Darunavir propylene glycolate** is considered medically necessary when there is documented trial of **darunavir ethanolate** (generic for Prezista) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.
Descovy (emtricitabine/tenofovir alafenamide)	**Descovy** is considered medically necessary when the individual meets **ONE** of the following (1 or 2): 1. **Treatment of human immunodeficiency virus type 1 (HIV-1).** 2. **HIV-1 Pre-exposure Prophylaxis (PrEP).** Documentation of **ANY** of the following (A, B, or C): A. Documentation of an estimated glomerular filtration rate (eGFR) ≤ 60 mL/min/1.73m^2 B. **ONE** of the following (i, ii, iii, or iv): i. Diagnosis of osteoporosis as defined by a BMD T-score </= -2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); individual **specific** BMD T-score must be submitted ii. Diagnosis of osteopenia as defined by a BMD T-score between -1 and -2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) with evidence of progressive bone loss on serial DEXA scan; individual specific BMD T-score must be submitted iii. Documentation of a prior low-trauma or non-traumatic fracture iv. Documented history of clinical risk factor(s) for osteoporosis (for example, early menopause, hyperparathyroidism, adynamic bone disease C. Documentation of a History of adverse event or intolerance to emtricitabine/tenofovir disoproxil fumarate (Truvada), or is otherwise medically inappropriate.
Truvada (emtricitabine/tenofovir disoproxil fumarate)	**Truvada** is considered medically necessary when the individual meets **BOTH** of the following (1 and 2): 1. Documentation of **ONE** of the following (A, B, C, or D): A. Treatment of HIV B. HIV Preexposure Prophylaxis (PrEP) C. HIV Postexposure Prophylaxis (PEP) D. Treatment of Hepatitis B 2. Documented trial of **emtricitabine/tenofovir disoproxil fumarate** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.

When coverage is available, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of HIV products are considered medically necessary for continued use when the above medical necessity criteria are met.

Authorization Duration

Initial approval duration is 12 months unless otherwise stated.
Reauthorization approval duration is 12 months unless otherwise stated.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

The Centers for Disease Prevention and Control (CDC) estimates that there are 1.2 million individuals ≥ 13 years of age in the US living with HIV infection, including 14% of individuals who are unaware of their infection. Antiretrovirals (ARVs) are used for the treatment of human immunodeficiency virus (HIV) infection in adults and children. The ARVs have also been used for the prevention of HIV acquisition following occupational or non-occupational exposure in the post-exposure prophylaxis setting (PEP and nPEP, respectively) and for the prevention of HIV acquisition among high-risk uninfected individuals (pre-exposure prophylaxis [PrEP]). Because HIV is a rapidly evolving area of research and guidelines are updated frequently, the most current and up-to-date information can be accessed through the National Institutes of Health.[2]

References

1. Descovy® tablets [prescribing information]. Foster City, CA: Gilead; January 2022.
2. Guidelines portal. Available at: http://aidsinfo.nih.gov/guidelines. Accessed on May 18, 2022.
3. Truvada® tablets [prescribing information]. Foster City, CA: Gilead; June 2020.