

Drug and Biologic Coverage Policy



Effective Date..... 11/1/2023
Next Review Date..... 11/1/2024
Coverage Policy Number IP0083

Fostemsavir

Table of Contents

Overview 1
Medical Necessity Criteria 1
Reauthorization Criteria 2
Authorization Duration 2
Conditions Not Covered..... 2
Background..... 2
References 3

Related Coverage Resources

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

This policy supports medical necessity review for fostemsavir extended-release tablets (**Rukobia™**).

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

Medical Necessity Criteria

Fostemsavir extended-release tablets (**Rukobia**) are considered medically necessary when the following are met:

1. **Human Immunodeficiency Virus (HIV) Infection.** Individual meets **ALL** of the following criteria (A, B, C, and D):
 - A. 18 years of age or older
 - B. History of multi-drug resistant Human Immunodeficiency Virus
 - C. Medication will be taken in combination with other antiviral agents

- D. Medication is prescribed by, or in consultation with, a physician who specializes in the treatment of HIV infection

When coverage is available and medically necessary, 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

Fostemsavir extended-release (Rukobia) tablets are considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial and reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW

Rukobia is a human immunodeficiency virus type-1 (HIV-1) gp120-directed attachment inhibitor.¹ It is indicated in combination with other antiretroviral(s) [ARVs] for the treatment of HIV-1 infection in heavily treatment-experienced adults with **multidrug-resistant HIV-1 infection** failing their current ARV regimen due to resistance, intolerance, or safety considerations.

Clinical Efficacy

The efficacy of Rukobia was established in one ongoing, Phase III, multicenter, 96-week pivotal study in heavily treatment-experienced adults with HIV-1 infection failing their current ARV regimen (BRIGHT; n = 371).^{2,5} Eligible patients were ≥ 18 years of age and had failure of their current ARV regimen (baseline HIV-1 RNA ≥ 400 copies/mL), with no viable ARV combination therapy available because of exhaustion of a least four of six ARV classes (nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, integrase inhibitors, protease inhibitors, CCR5 antagonists, and entry inhibitors). Exhaustion was defined as the elimination of all ARVs within a given class as a fully active option to pair with Rukobia because of resistance, previous adverse events, or unwillingness to use Fuzeon® (enfuvirtide injection). There were 15 patients who received Trogarzo® (ibalizumab-uyk injection) in combination with Rukobia.

Guidelines

According to the Department of Health and Human Services Guidelines (January 20, 2022) for the use of antiviral agents in adults and adolescents with HIV infection, treatment-experienced patients with ongoing detectable viremia who lack sufficient treatment options to construct a fully suppressive regimen may be candidates for Trogarzo and/or Rukobia.³ Patients who continue to have detectable viremia and who lack sufficient treatment options to construct a fully suppressive regimen may also be candidates for research studies or expanded access programs, or they may qualify for single-patient access to an investigational new drug as specified in FDA regulations. The International Antiviral Society-USA recommendations for the treatment and prevention of HIV in adults (2020) note that in the setting of multiclass resistance (three class resistance), the next regimen should be comprised of drugs from new classes if available (evidence rating: BIII); such as Rukobia (evidence rating: Alb) or Trogarzo (evidence rating: BII) with at least one additional active drug in an optimized ARV regimen.⁴

References

1. Rukobia™ extended-release tablets [prescribing information]. Research Triangle Park, NC: ViiV/GlaxoSmithKline; July 2020.
2. Kozal M, Aberg J, Pialoux G, et al. Fostemsavir in adults with multidrug-resistant HIV-1 infection. *N Engl J Med*. 2020;382(13):1232-1243.
3. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. Last Updated: January 20, 2022. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed July 8, 2022.
4. Saag MS, Gandhi RT, Hoy JF, et al. Antiviral drugs for treatment and prevention of HIV infection in adults. 2020 recommendations of the International Antiviral Society-USA Panel. *JAMA*. 2020;324(16):1651-1669.
5. Lataillade M, Lalezari J, Kozal M, et al. Safety and efficacy of the HIV-1 attachment inhibitor prodrug fostemsavir in heavily treatment-experienced individuals: week 96 results of the phase 3 BRIGHTE study. *Lancet HIV*. 2020; 7(11):e740-e751.

“Cigna Companies” refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. © 2023 Cigna.