Drug and Biologic Coverage Policy

Fostemsavir

Table of Contents

Overview .............................................................. 1
Coverage Policy................................................... 1
Reauthorization Criteria ....................................... 2
Authorization Duration ......................................... 2
Conditions Not Covered ....................................... 2
Background .......................................................... 2
References ............................................................ 3

Related Coverage Resources

Quantity Limitations

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 Rukobia™ (fostemsavir extended-release tablet).

Coverage Policy

Fostemsavir extended-release tablet (Rukobia) is considered medically necessary when ALL of the following are met:
1. The individual is 18 years of age or older
2. The individual has a history of multi-drug resistant Human Immunodeficiency Virus (HIV) Infection
3. Used in combination with other antiviral drugs
4. Prescribed by or in consultation with a physician who specializes in the treatment of HIV infection
5. ONE of the following:
   a. Initial Therapy: Attestation that the individual is failing a current antiretroviral regimen due to resistance, intolerance, or safety reasons
   b. For Continuation of treatment: Attestation of positive clinical response

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

**Documentation:** When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts.

**Reauthorization Criteria**

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

**Authorization Duration**

Initial approval and reauthorization duration is 12 months.

**Conditions Not Covered**

Rukobia (fostemsavir extended-release tablet) is considered experimental, investigational or unproven for ANY other use.

**Background**

**Overview**

Rukobia, a human immunodeficiency virus type-1 (HIV-1) gp120-directed attachment inhibitor, in combination with other antiretroviral(s) [ARVs], is indicated 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.¹

**Disease Overview**

Multidrug-resistant HIV-1 infection is usually defined as the presence of phenotypic or genotypic resistance to at least one drug in each of the following three classes: non-nucleoside reverse transcriptase inhibitors (NNRTIs), nucleoside reverse transcriptase inhibitors (NRTIs), and protease inhibitors.⁷ Heavily treatment-experienced adults account for approximately 6% of adults living with HIV who are on ARV treatment.² These patients have few, if any, treatment options left due to resistance, tolerability, and/or safety considerations. Heavily treatment-experienced adults are at greater risk of progression to acquired immunodeficiency syndrome (AIDS) and death than non-heavily treatment-experienced adults.

**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 (BRIGHTE; n = 371).³⁶ 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 (AEs), or unwillingness to use Fuzeon® (enfuviritide injection). There were 15 patients who received Trogarzo® (ibalizumab-uiyk injection) in combination with Rukobia.

**Guidelines**

Treatment with Rukobia is not addressed in guidelines. According to the Department of Health and Human Services Guidelines (December 18, 2019) 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.⁴ 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. Guidelines note that Rukobia as an agent in late-stage clinical studies. The International Antiviral Society-USA recommendations for the treatment and prevention of HIV in adults (2018) note that Trogarzo may be useful as a fully active agent for patients with multiclass-resistant virus.5

References


“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, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., QualCare, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2020 Cigna.