PRIOR AUTHORIZATION POLICY

POLICY: Human Immunodeficiency Virus – Rukobia Prior Authorization Policy
- Rukobia™ (fostemsavir extended-release tablets – ViiV/GlaxoSmithKline)

REVIEW DATE: 07/12/2023

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.

CIGNA NATIONAL FORMULARY COVERAGE:

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 (BRIGHTE; 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 (i.e., 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® (enfuviritide subcutaneous injection). There were 15 patients who received Trogarzo® (ibalizumab-uiyk intravenous injection) in combination with Rukobia.

Guidelines

According to the Department of Health and Human Services Guidelines (May 26, 2023) 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, Rukobia, or Sunlenca® (lenacapavir tablets/subcutaneous injection).[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 (2022) for the treatment and prevention of HIV in adults recognize Rukobia in the setting of integrase strand-transfer inhibitor (INSTI) resistance. If INSTI resistance is relatively limited and a new antiviral regimen is to include an INSTI, the regimen should also include at least one and preferably two other fully active drugs, optimally from drug classes not previously used which may include among other agents, Rukobia.[4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rukobia. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Rukobia as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Rukobia to be prescribed by or in consultation with a physician who specializes in the condition being treated.

- **Rukobia™ (fostemsavir extended-release tablets – ViiV/GlaxoSmithKline)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Human Immunodeficiency Virus (HIV) Infection.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has HIV type 1 (HIV-1) infection; AND
     - **iii.** According to the prescriber, the patient is failing a current antiretroviral regimen for HIV; AND
     - **iv.** According to the prescriber, the patient has exhausted at least FOUR of the following antiretroviral classes defined as elimination of all antiretrovirals

within a given class due to demonstrated or projected resistance to the agent(s) in that class OR due to significant intolerance (FOUR of a, b, c, d, e, or f):

a) Nucleoside reverse transcriptase inhibitor; OR
Note: Examples of nucleoside reverse transcriptase inhibitors include abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, tenofovir alafenamide, zidovudine.

b) Non-nucleoside reverse transcriptase inhibitor; OR
Note: Examples of non-nucleoside reverse transcriptase inhibitor include delaviridine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine.

c) Protease inhibitor; OR
Note: Examples of protease inhibitors include atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir.

d) Fusion inhibitor; OR
Note: Examples of fusion inhibitors include Fuzeon (enfuviritide subcutaneous injection).

e) Integrase strand transfer inhibitor; OR
Note: Examples of integrase strand transfer inhibitors include raltegravir, dolutegravir, elvitegravir.

f) CCR5 antagonist; AND
Note: Examples of CCR5 antagonists include Selzentry (maraviroc tablets).

v. The medication will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND

vi. The medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.

B) Patient is Currently Receiving Rukobia. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has HIV-1 infection; AND

ii. The medication will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND

iii. Patient has responded to a Rukobia-containing regimen, as determined by the prescriber.
Note: Examples of a response are HIV RNA < 40 cells/mm^3, HIV-1 RNA ≥ 0.5 $\log_{10}$ reduction from baseline in viral load.

CONDITIONS NOT COVERED

- **Rukobia™ (fostemsavir extended-release tablets – ViiV/GlaxoSmithKline)**

is(are) considered experimental, investigational, or unproven for ANY other use(s).

REFERENCES

1. Rukobia™ extended-release tablets [prescribing information]. Research Triangle Park, NC: ViiV/GlaxoSmithKline; January 2022.
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: March 23, 2023.
4. Ghandi RT, Bedimo R, Hoy JF, et al. Antiviral drugs for treatment and prevention of HIV infection in adults. 2022 recommendations of the International Antiviral Society-USA panel. *JAMA.* 2023;329(1):63-84.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/13/2022
Annual Revision	No criteria changes.	07/12/2023