CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Rukobia (fostemsavir)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Rukobia is a human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor initially approved by the FDA in 2020. It is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations, in combination with other antiretroviral(s).

Rukobia is a prodrug without significant biochemical or antiviral activity that is hydrolyzed to the active moiety, temsavir, which is an HIV-1 attachment inhibitor. Temsavir binds directly to the gp120 subunit within the HIV-1 envelope glycoprotein gp160 and selectively inhibits the interaction between the virus and cellular CD4 receptors, thereby preventing attachment. The efficacy and safety of Rukobia were evaluated in the Phase 3 BRIGHTE study of 371 HTE adult patients who continued to have high levels of viral RNA despite being on OBT. In this study, 71% of patients had been treated for HIV for more than 15 years, 85% had been exposed to ≥5 HIV treatment regimens before entering the study, and 86% had a history of AIDS.

Rubokia (fostemsavir) will be considered for coverage when the following criteria are met:

Multidrug-Resistant HIV-1 Infection

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a HIV specialist or infectious disease specialist; AND
3. Member must have documented resistance, intolerance or contraindication to at least **ONE** antiretroviral from three different drug classes; AND
4. Member is failing current regimen as evidenced by HIV RNA count > 200 copies/mL; AND
5. Member is **NOT** using Rukobia as monotherapy. Provider must include documentation of entire anti-retroviral regimen.
6. **Dosage allowed/Quantity limit:** administer 600 mg orally twice daily. Quantity limit: 60 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Rukobia is NOT being used as monotherapy; AND
2. Chart notes have been provided that show the member has demonstrated improvement as evidenced by **ONE** of the following:
   a) HIV RNA load < 200 copies/mL; OR
   b) Decrease in HIV RNA load from initial authorization; AND

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Rukobia (fostemsavir) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/30/2020	New policy for Rukobia created.
04/05/2022	Transferred to new template. Updated references. Added quantity limit; Added infectious disease specialist to prescriber requirements
02/01/2024	Removed adherence attestation from reauthorization criteria; Removed requirement of anti-retroviral agent availability; simplified trial wording; updated references

References:

1. Rukobia [package insert]. Research Triangle Park, NC; GlaxoSmithKline: 2022.
2. 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. 2023. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed February 1, 2024.
3. Kozal M, Aberg J, Pialoux G, et al. Fostemsavir in adults with multidrug-resistant infection. N Engl J Med. 2020 Mar 26;382(13):1232-1243. doi: 10.1056/NEJMoa1902493.

Effective date: 07/01/2024
Revised date: 02/01/2024