

## PHARMACY POLICY STATEMENT North Carolina Marketplace

<b>DRUG NAME</b>	<b>Rukobia (fostemsavir)</b>
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
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  $\geq 5$  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 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 to at least one antiretroviral from three drug classes or have failed at least 3 drug classes for HIV treatment due to intolerance or contraindication; AND
4. Member has 2 or fewer fully active anti-retroviral agents available to add to Rukobia (fostemsavir); AND
5. Member is failing current regimen as evidenced by HIV RNA count > 200 copies/mL; AND
6. Member is NOT using Rukobia (fostemsavir) as monotherapy. Provider must include documentation of entire anti-retroviral regimen.
7. **Dosage allowed/Quantity limit:** 600mg 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 (fostemsavir) 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
3. Member is adherent to antiretroviral regimen as prescribed proven through claim history, chart notes, or prescriber/member attestation.

***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

References:

1. Rukobia [package insert]. Research Triangle Park, NC; GlaxoSmithKline. Jan 2022.
2. Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Available at: <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed October 10, 2020.
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: 01/01/2023

Revised date: 04/05/2022