

PHARMACY POLICY STATEMENT

Georgia Medicaid

DRUG NAME	Rukobia (fostemsavir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT --- 60 tablets/30 days
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Rukobia (Fostemsavir) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with the following disease states and meet their individual criteria as stated.

MULTIDRUG-RESISTANT HIV-1 INFECTION

For **initial** authorization:

1. Member must be at least 18 years of age or older; AND
2. The medication must be prescribed by or in consultation with an HIV 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:** 600mg twice daily.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Rukobia (fostemsavir) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
10/30/2020	New policy for Rukobia (fostemsavir) created.

References:

1. 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.
2. Rukobia [package insert]. Research Triangle Park, NC; GlaxoSmithKline. July 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: 04/01/2021

Revised date: 10/30/2020