Clinical Policy: Fostemsavir (Rukobia)

Reference Number: CP.PHAR.516
Effective Date: 03.01.20
Last Review Date: 02.22
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Fostemsavir (Rukobia®) is a human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor.

FDA Approved Indication(s)

Rukobia 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Rukobia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. HIV-1 Infection (must meet all)**:**

1. Diagnosis of multidrug-resistant HIV-1 infection;
2. Prescribed by or in consultation with an infectious disease or HIV specialist;
3. Age ≥ 18 years;
4. Documentation of resistance to at least 1 antiretroviral agent from each of 3 classes (NRTI, NNRTI, PI), unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of one of the following at up to maximally indicated dose, unless clinically significant adverse effects are experienced, both are contraindicated, or member is resistant to both: Fuzeon®, Selzentry® if CCR5 tropic;
6. Current (within the past 30 days) HIV ribonucleic acid viral load ≥ 200 copies/mL;
7. Prescribed concurrently with additional antiretroviral agents to which member is susceptible, if available;
8. Dose does not exceed 1,200 mg (2 tablets) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is

NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. HIV-1 Infection (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Rukobia for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1,200 mg (2 tablets) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CYP: cytochrome P450
FDA: Food and Drug Administration
HIV: human immunodeficiency virus

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Fuzeon® (enfuvirtide)	90 mg SC BID	180 mg per day
Selzentry® (maraviroc)	• Concomitant CYP3A inhibitors with or without potent CYP3A inducers: 150 mg PO BID • Concomitant NRTIs, tipranavir/ritonavir, nevirapine, raltegravir, and other drugs that are not	1,200 mg per day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	potent CYP3A inhibitors or CYP3A inducers: 300 mg PO BID • Concomitant CYP3A inducers without a potent CYP3A inhibitor: 600 mg PO BID	

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity, co-administration with strong cytochrome P450 (CYP)3A inducers
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HIV-1 infection	600 mg PO BID with or without food	1,200 mg per day

VI. Product Availability

Extended-release tablet: 600 mg

VII. References

1. Rukobia Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; July 2020. Available at: https://www.rukobia.com. Accessed September 13, 2021.
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. doi: 10.1056/NEJMoa1902493.
3. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. US Department of Health and Human Services. Last updated August 16, 2021. Available at https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0. Accessed September 13, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created, per November SDC including redirection to Fuzeon or Selzentry; references to HIM.PHAR.21 revised to HIM.PA.154.	11.16.20	02.21
1Q 2022 annual review: clarified that HIV-1 infection should be multi-drug resistant per FDA labeling; added requirement for documentation of resistance to at least 1 antiretroviral agent from each of 3 classes (NRTI, NNRTI, PI) as pivotal trial inclusion criteria limited enrollment to those with have ≤ 2 classes of antiretroviral medications remaining at baseline and to align with previously P&T approved approach for Trogarzo; removed requirement for "3 month trial" of Selzentry/Fuzeon and added bypass if member is resistant to both, and revised language for concurrent use with other	09.13.21	02.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
antiretrovirals to align with previously P&T approved approach for Trogarzo; references reviewed and updated.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.