

fostemsavir (Rukobia[®])

Policy # 00739

Original Effective Date: 04/12/2021

Current Effective Date: 04/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider fostemsavir (Rukobia[®])[†] for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for fostemsavir (Rukobia) will be considered when the following criteria are met:

- Patient has a diagnosis of HIV-1; AND
- Patient is 18 years of age or older; AND
- Patient has heavily treatment-experienced multidrug resistant HIV-1, defined as trying and failing at least 4 of the following 6 antiretroviral classes: 1. Nucleoside Reverse Transcriptase Inhibitors (NRTIs); 2. Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs); 3. Integrase Strand Transfer Inhibitors (INSTIs); 4. Protease Inhibitors (PIs); 5. C-C motif chemokine receptor (CCR5) antagonists; and 6. Entry Inhibitors; AND
- Patient is failing their current antiretroviral drug regimen due to resistance, intolerance, or safety considerations; AND
- Patient will continue taking an antiretroviral drug regimen along with the requested drug.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of fostemsavir (Rukobia) when patient selection criteria are not met to be **investigational.***

Background/Overview

Rukobia, an HIV-1 gp120-directed attachment inhibitor, in combination with other antiretroviral(s), 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. Rukobia is available as a 600 mg extended release tablet that is taken twice daily with or without food.

Antiviral medications are the mainstay of therapy for HIV. Treatment for HIV often involves the use of multiple drugs (either multiple tablets or a combination drug). Many classes of antiviral medications exist, including:

- Nucleoside Reverse Transcriptase Inhibitors (NRTIs): abacavir, Videx®[†], Emtriva®[†], Epivir®[†], Zerit®[†], Viread®[†], zidovudine, abacavir-lamivudine, abacavir-lamivudine-zidovudine, Truvada®[†], emtricitabine-tenofovir disoproxil fumarate, Descovy®[†], lamivudine-zidovudine, Cinduo™[†], Temixys™[†]
- Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs): Rescriptor®[†], Pifeltro™[†], efavirenz, Intelence®[†], nevirapine/XR, Edurant®[†], Delstrigo™[†], Complera®[†], Odefsey®[†], Atripla®[†], efavirenz-emtricitabine-tenofovir disoproxil fumarate, Symfi®[†], Symfi Lo®[†]
- Integrase Strand Transfer Inhibitors (INSTIs): Isentress®[†], Tivicay®[†], Stribild®[†], Biktarvy®[†], Triumeq®[†], Genvoya®[†], Juluca®[†], Dovato®[†]
- Protease Inhibitors (PIs): Reyataz®[†], Prezista®[†], Lexiva®[†], Crixivan®[†], Viracept®[†], Norvir®[†], ritonavir, Invirase®[†], Aptivus®[†], Kaletra®[†], Prezcoibix®[†], Evotaz®[†], Symtuza™[†]
- C-C motif chemokine receptor (CCR5) antagonists: Selzentry®[†]
- Entry Inhibitors: Fuzeon®[†]

It is estimated that roughly 6% of adults with HIV-1 are deemed to be heavily treatment experienced. Heavily treatment experienced patients are at a significantly higher risk of progressing to AIDS and death compared to those that are not heavily treatment experienced. There is another medication on the market, Trogarzo, that carries the same indication as Rukobia, however it is an infused product that is given every 2 weeks. Although not specifically addressed in the Department of Health and Human Services treatment guidelines at the time of this publication, Rukobia is an option for therapy in patients that are heavily treatment experienced with multi-drug resistant HIV-1. These patients have very limited options for therapy.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Rukobia, in combination with other antiretroviral(s), 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.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Rukobia in heavily treatment-experienced adult subjects with HIV-1 infection is based on 96-week data from a Phase 3, partially-randomized, international, double-blind, placebo-controlled trial (BRIGHT). The BRIGHT trial was conducted in 371 heavily treatment-experienced subjects with multiclass HIV-1 resistance. All subjects were required to have a viral load greater than or equal to 400 copies/mL and less than or equal to 2 classes of antiretroviral medications remaining at baseline due to resistance, intolerability, contraindication, or other safety concerns. Subjects were enrolled in either a randomized or nonrandomized cohort defined as follows:

- Within the randomized cohort (n = 272), subjects had 1, but no more than 2, fully active and available antiretroviral agent(s) at screening which could be combined as part of an efficacious background regimen. Randomized subjects received either blinded Rukobia 600 mg twice daily (n = 203) or placebo (n = 69) in addition to their current failing regimen for 8 days of functional monotherapy. Beyond Day 8, randomized subjects received open label Rukobia 600 mg twice daily plus an investigator-selected optimized background therapy (OBT). This cohort provides primary evidence of efficacy of Rukobia.
- Within the nonrandomized cohort (n = 99), subjects had no fully active and approved antiretroviral agent(s) available at screening. Nonrandomized subjects were treated with open-label Rukobia 600 mg twice daily plus OBT from Day 1 onward. The use of an investigational drug(s) as a component of the OBT was permitted in the nonrandomized cohort.

In the randomized cohort, the mean HIV-1 RNA reduction from baseline was significantly greater with Rukobia vs. placebo at Day 8 (primary endpoint) [-0.79 log₁₀ copies/mL vs. -0.17 log₁₀ copies/mL, respectively; difference -0.63 log₁₀ copies/mL; P less than 0.001]. At Week 48 (all patients on Rukobia + OBT), 54% of patients achieved viral suppression (HIV-1 RNA less than 40 copies/mL) and CD4 T-cell count increased to a mean of 139 cells/mm³ (median baseline 99 cells/mm³). In the non-randomized cohort, at Week 48, 38% of patients achieved viral suppression and the mean CD4 T-cell count increased to 63.5 cells/mm³ (median baseline 41 cells/mm³).

References

1. Rukobia [package insert]. Viiv Healthcare. Research Triangle Park, North Carolina. Updated July 2020.
2. Rukobia Drug Evaluation. Express Scripts. Updated July 2020.

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03/04/2021	Medical Policy Committee review
03/10/2021	Medical Policy Implementation Committee approval. New policy.
03/03/2022	Medical Policy Committee review
03/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/02/2023	Medical Policy Committee review
03/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/07/2024	Medical Policy Committee review
03/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2025	Medical Policy Committee review
03/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2026	Medical Policy Committee review
03/11/2026	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

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****Medically Necessary** (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.