BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

**PHARMACY COVERAGE GUIDELINE**

# RUKOBIA (fostemsavir) oral

**This Pharmacy Coverage Guideline (PCG):**
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

**Scope**
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

**Instructions & Guidance**
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

## Criteria:

- **Criteria for initial therapy:** Rukobia (fostemsavir) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Infectious Disease specialist.

  2. Individual is 18 years of age or older.

  3. Individual has a confirmed diagnosis of HIV-1 infection in heavily treatment-experienced adult with multi-drug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

4. **ALL** of the following:
    a. Individual is antiretroviral-experienced with documented historical or baseline resistance, intolerance, or safety considerations in **at least three classes**

    b. Failing current antiretroviral regimen with a confirmed plasma HIV-1 RNA ≥ 400 c/mL

    c. Must have ≤ 2 classes with 1 but no more than 2 fully-active antiretrovirals remaining which can be effectively combined to form a viable new regimen, based on current and/or documented historical resistance testing and tolerability and safety

5. Will be used as add-on treatment in combination with other antiretroviral(s) in an OBT regimen.

6. There are **NO** FDA-label contraindications, such as concurrent use with strong CYP3A inducers such as enzalutamide, carbamazepine, phenytoin, rifampin, mitotane, St John's wort (*hypericum perforatum*) which may result in loss of virologic response.

**Initial approval duration**: 6 months

- **Criteria for continuation of coverage (renewal request):** Rukobia (fostemsavir) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Infectious Disease specialist.

2. Individual's condition has responded while on therapy with response defined as achieved and maintains **BOTH** of the following:
    a. Decline in HIV-1 RNA of at least 70% from baseline or is now undetectable
    b. Increase in CD4+ cell count over baseline

3. Individual has been adherent with the medication.

4. Will be used as add-on treatment in combination with other antiretroviral(s) in an OBT regimen.

5. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use as follow:
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. QTc prolongation
        ii. Hepatic injury

**Renewal duration**: 12 months

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- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

  1. **Off-Label Use of Non-Cancer Medications**

  2. **Off-Label Use of Cancer Medications**

## Description:

Rukobia (fostemsavir) is a human immunodeficiency virus type 1 (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 multi-drug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

Fostemsavir 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. Additionally, temsavir can inhibit gp120-dependent post-attachment steps required for viral entry into host cells.

## Definitions:

**Optimized Background Therapy (OBT):**
https://clinicalinfo.hiv.gov/en/glossary/optimized-background-therapy-obt

When a new drug is added to a failing HIV regimen, the other drugs in the regimen (the "background therapy") may also be changed. Any changes are based on a person's resistance test results and treatment history. Optimized background therapy gives a new HIV regimen (or an experimental HIV drug being studied in a clinical trial) the best chance of succeeding.

**Failure of antiretroviral therapy:**
A confirmed HIV ribonucleic acid (RNA) level of > 50 copies/mL while on therapy or intolerance due to drug toxicity

**NNRTI (non-nucleoside reverse transcriptase inhibitors):**
Rescriptor (delavidine, DLV)
Sustiva (efavirenz, EFV)
Intelence (etravirine, ETR)
Edurant (rilpivirine, RPV)
Viramune, Viramune XR® (nevirapine, NVP)

**NRTI (nucleoside reverse transcriptase inhibitors):**
Ziagen (abacavir, ABC)
Epzicom (abacavir + lamivudine)
Trizivir (abacavir + lamivudine + zidovudine)

Videx (didanosine [ddI])
Emtriva (emtricitabine, FTC)
Epivir (lamivudine, 3TC)
Combivir (lamivudine+zidovudine)
Zerit (stavudine, d4T)
Hivid (zalcitabine, ddC)
Retrovir (zidovudine, AZT or ZDV)

**Protease inhibitors:**
Reyataz (atazanavir, ATV)
Prezista (darunavir, DRV)
Lexiva (fosamprenavir, f-APV)
Crixivan (indinavir)
Viracept (nelfinavir, NFV)
Norvir (ritonavir, RTV)
Invirase (saquinavir, SQV)
Aptivus (tipranavir, TPV)

**Integrase inhibitors:**
Tivicay (dolutegravir, DTG)
Vitekta (elvitegravir, EVG)
Isentress, Isentress HD (raltegravir, RAL)

**Cellular chemokine receptor (CCR5) antagonist:**
Selzentry (maraviroc, MVC)

**Boosting agent:**
Tybost (cobicistat, COBI)

**HIV combination products:**
Miscellaneous:
Triumeq (abacavir-dolutegravir-lamivudine) [NRTI+II+NRTI]?
Evotaz (atazanavir-cobicistat)
Biktarvy (bictegravir-emtricitabine-tenofovir alafenamide fumarate)
Prezcobix (darunavir-cobicistat)
Juluca (dolutegravir-rilpivirine)
Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir alafenamide fumarate)
Stribild (elvitegravir-cobicistat-emtricitabine-tenofovir disoproxil fumarate)
Kaletra (lopinavir + ritonavir, LPV/r)

**Reverse transcriptase Inhibitor combinations:**
Epzicom (abacavir-lamivudine)
Trizivir (abacavir-lamivudine-zidovudine)
Atripla (efavirenz-emtricitabine-tenofovir disoproxil fumarate)
Symfi Lo (efavirenz-lamivudine-tenofovir disoproxil fumarate)
Odefsey (emtricitabine-rilpivrine-tenofovir alafenamide fumarate)
Complera (emtricitabine-rilpivrine-tenofovir disoproxil fumarate)
Descovy (emtricitabine-tenofovir alafenamide fumarate)

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Truvada (emtricitabine-tenofovir disoproxil fumarate)
Combivir (lamivudine-zidovudine)

## Resources:

Rukobia (fostemsavir) extended release tablet product information, revised by ViiV Healthcare Company 01-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed July 28, 2022.

Fletcher CV. Overview of antiretroviral agents used to treat HIV. In: UpToDate, Sax PE, Mitty J (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Topic last updated on April 06, 2022. Accessed July 28, 2022.

Daar ES. Selecting an antiretroviral regimen for treatment-experienced patients with HIV who are failing therapy. In: UpToDate, Sax PE, Mitty J (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Topic last updated on October 15, 2020. Accessed July 28, 2022.

ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US). Identifier NCT02362503, Attachment Inhibitor Comparison in Heavily Treatment Experienced Patient; Last Updated February 17, 2020Available from: http://clinicaltrials.gov. Accessed July 24, 2020. Re-reviewed on July 28, 2022.

Kozal M, Aberg J, Pialoux G, et al. Fostemsavir in adults with multidrug-resistant HIV-1 infection. N Engl J Med 2020;382:1232-43. DOI: 10.1056/NEJMoa1902493. Accessed August 03, 2021. Re-reviewed on July 28, 2022.