PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 8/20/2020
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RUKOBIA (fostemsavir) oral

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

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

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

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis 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

  4. **ALL** of the following:
     a. 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

     d. Able to receive ≥ 1 fully active approved antiretroviral as part of the optimized background therapy (OBT) that contains at least Tivicay (dolutegravir)

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

  6. There are **NO** contraindications
     a. Contraindications include:
        i. Concurrent use with strong CYP3A inducers such as enzalutamide, carbamazepine, phenytoin, rifampin, mitotane, St John's wort (*hypericum perforatum*)

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Rukobia (fostemsavir) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

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

  2. Individual's condition responded while on therapy
     a. Response is defined as:
        i. Achieved and maintains
           1. Decline in HIV-1 RNA of at least 70% from baseline or is now undetectable

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2. 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 level 4 adverse drug effects that may exclude continued use
    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)

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://aidsinfo.nih.gov/understanding-hiv-aids/glossary/1616/optimized-background-therapy

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

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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:
- Tivacay (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)
  - Biktary (bictegravir-emtricitabine-tenofovir alafenamide fumarate)
  - Prezcobix (darunavir-cobicistat)

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

Resources:

Rukobia (fostemsavir) product information, revised by manufacturer 07-2020, accessed 07-23-20 at DailyMed

ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT02362503, Attachment Inhibitor Comparison in Heavily Treatment Experienced Patient; 2020 Feb 17 [Accessed July 24, 2020]. Available from: http://clinicaltrials.gov

Fletcher CV. Overview of antiretroviral agents used to treat HIV. In: UpToDate, Bartlett JG, Sax PE (Eds), UpToDate Inc. http://uptodate.com (Accessed July 24, 2020)

Daar ES. Selecting and antiretroviral regimen for treatment-experienced HIV-infected patients who are failing therapy. In: UpToDate, Bartlett JG, Sax PE (Eds), UpToDate Inc. http://uptodate.com (Accessed July 24, 2020)