PRIOR AUTHORIZATION POLICY

POLICY: Human Immunodeficiency Virus – Rukobia Prior Authorization Policy
- Rukobia™ (fostemsavir extended-release tablets – ViiV)

REVIEW DATE: 07/21/2021

OVERVIEW

Rukobia is a human immunodeficiency virus type-1 (HIV-1) gp120-directed attachment inhibitor.[1] It is indicated in combination with other antiretroviral(s) [ARVs] for the treatment of HIV-1 infection in heavily treatment-experienced adults with **multidrug-resistant HIV-1 infection** failing their current ARV regimen due to resistance, intolerance, or safety considerations.

Clinical Efficacy

The efficacy of Rukobia was established in one ongoing, Phase III, multicenter, 96-week pivotal study in heavily treatment-experienced adults with HIV-1 infection failing their current ARV regimen (BRIGHTE; n = 371).[3,6] Eligible patients were ≥ 18 years of age and had failure of their current ARV regimen (baseline HIV-1 RNA ≥ 400 copies/mL), with no viable ARV combination therapy available because of exhaustion of a least four of six ARV classes (nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, integrase inhibitors, protease inhibitors, CCR5 antagonists, and entry inhibitors). Exhaustion was defined as the elimination of all ARVs within a given class as a fully active option to pair with Rukobia because of resistance, previous adverse events, or unwillingness to use Fuzeon® (enfuviritide injection). There were 15 patients who received Trogarzo® (ibalizumab-uiyk injection) in combination with Rukobia.

Guidelines

According to the Department of Health and Human Services Guidelines (June 3, 2021) for the use of antiviral agents in adults and adolescents with HIV infection, treatment-experienced patients with ongoing detectable viremia who lack sufficient treatment options to construct a fully suppressive regimen may be candidates for Trogarzo and/or Rukobia.[4] Patients who continue to have detectable viremia and who lack sufficient treatment options to construct a fully suppressive regimen may also be candidates for research studies or expanded access programs, or they may qualify for single-patient access to an investigational new drug as specified in FDA regulations. The International Antiviral Society-USA recommendations for the treatment and prevention of HIV in adults (2020) note that in the setting of multiclass resistance (three class resistance), the next regimen should be comprised of drugs from new classes if available (evidence rating: BIII); such as Rukobia (evidence rating: AIb) or Trogarzo (evidence rating: BII) with at least one additional active drug in an optimized ARV regimen.[5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rukobia. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Rukobia as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Rukobia to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rukobia is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Human Immunodeficiency Virus (HIV) Infection.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following conditions (i, ii, iii, iv, v, and vi):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has HIV type 1 (HIV-1) infection; AND
     - **iii.** According to the prescriber, the patient is failing a current antiretroviral regimen for HIV; AND
     - **iv.** According to the prescriber, the patient has exhausted at least FOUR of the following antiretroviral classes defined as elimination of all antiretrovirals within a given class due to demonstrated or projected resistance to the agent(s) in that class OR due to significant intolerance (FOUR of a, b, c, d, e, or f):
       - **a)** Nucleoside reverse transcriptase inhibitor; OR
         Note: Examples of nucleoside reverse transcriptase inhibitors include abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, tenofovir alafenamide, zidovudine.
       - **b)** Non-nucleoside reverse transcriptase inhibitor; OR
         Note: Examples of non-nucleoside reverse transcriptase inhibitor include delaviridine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine.
       - **c)** Protease inhibitor; OR
         Note: Examples of protease inhibitors include atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir.
       - **d)** Fusion inhibitor; OR
         Note: Examples of fusion inhibitors include Fuzeon (enfuviritide for injection).
       - **e)** Integrase strand transfer inhibitor; OR
         Note: Examples of integrase strand transfer inhibitors include raltegravir, dolutegravir, elvitegravir.
       - **f)** CCR5 antagonist; AND
         Note: Examples of CCR5 antagonists include Selzentry (maraviroc tablets).
     - **v.** The medication will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND
     - **vi.** The medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.
   - **B)** Patient is Currently Receiving Rukobia. Approve for 1 year if the patient meets ALL of the following conditions (i, ii, and iii):
     - **i.** Patient has HIV-1 infection; AND
     - **ii.** The medication will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND
     - **iii.** Patient has responded to a Rukobia-containing regimen, as determined by the prescriber.
       Note: Examples of a response are HIV RNA < 40 cells/mm^3, HIV-1 RNA ≥ 0.5 $\log_{10}$ reduction from baseline in viral load.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rukobia is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Rukobia™ extended-release tablets [prescribing information]. Research Triangle Park, NC: ViiV/GlaxoSmithKline; July 2020.
2. Hsu R, Fusco J, Henegar C, et al. Clinical outcomes of heavily treatment experienced individuals in the OPERA cohort [abstract PEB0234]. Presented at: 23rd International AIDS Conference; Virtual; July 6-10, 2020.
3. 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.
4. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. Last Updated: June 3, 2021. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf. Accessed July 1, 2021.
5. Saag MS, Gandhi RT, Hoy JF, et al. Antiviral drugs for treatment and prevention of HIV infection in adults. 2020 recommendations of the International Antiviral Society-USA Panel. *JAMA*. 2020;324(16):1651-1669.
6. Lataillade M, Lalezari J, Kozal M, et al. Safety and efficacy of the HIV-1 attachment inhibitor prodrug fostemsavir in heavily treatment-experienced individuals: week 96 results of the phase 3 BRIGHTE study. *Lancet HIV*. 2020; 7(11):e740-e751.

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