fostemsavir (Rukobia)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO204

Description

Fostemsavir (Rukobia) is an orally administered gp120 attachment inhibitor.

Length of Authorization

- Initial: Three months
- Renewal: 12 months

Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
fostemsavir (Rukobia)	600 mg extended-release tablets	Human immunodeficiency virus type 1 (HIV-1) infection	60 tablets/30 days

Initial Evaluation

I. Fostemsavir (Rukobia) may be considered medically necessary when the following criteria are met:
   A. Member is 18 years of age or older; **AND**
   B. Medication is prescribed by, or in consultation with, an infectious disease or HIV specialist; **AND**
   C. Provider attestation that fostemsavir (Rukobia) will be used in combination with at least one other antiretroviral medication; **AND**
   D. Member has a diagnosis of **human immunodeficiency virus type 1 (HIV-1) infection** when all of the following are met:
      1. Provider attests the member is heavily treatment-experienced as indicated by treatment failure, contraindication, intolerance, and/or resistance to medications in three or more classes of HIV therapies; **AND**
      2. Provider attests the member has two or less remaining medications that are fully active and available to construct a viable treatment regimen; **AND**
      3. The member is failing their current treatment regimen, as defined by HIV-1 RNA viral load greater than, or equal to, (≥) 200 copies/mL; **AND**
      4. The member does not have concurrent untreated hepatitis B infection.

II. Fostemsavir (Rukobia) is considered investigational when used for all other conditions.

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Documentation of disease response to treatment defined by improvement or stability of disease symptoms [e.g., decreased HIV-1 RNA, increased CD4 cell count from baseline].

Supporting Evidence

I. Fostemsavir (Rukobia) has not been studied in randomized controlled trials in pediatric patients <18 years of age.
II. In the pivotal Phase 3 trial (BRIGHTE), subjects were given fostemsavir (Rukobia) in combination with other antiretroviral(s). Per the National Institute for Health recommendations, HIV-1 infections should never be treated with monotherapy. Fostemsavir (Rukobia) is not approved as monotherapy and must be used in combination with other antiretroviral(s).
III. In the BRIGHTE trial, subjects were included if they had documented resistance, contraindication, or intolerance to three or more antiretroviral classes and had two or less fully active and available antiretroviral agents in two or fewer classes of which a treatment regimen could be constructed. Fostemsavir (Rukobia) is only approved for use in heavily treatment-experienced individuals.
IV. The primary efficacy endpoint in the BRIGHTE trial was the adjusted mean $\log_{10}$ change in HIV-1 RNA from baseline after Day 8 which was -0.17 in the placebo group and -0.79 in the fostemsavir (Rukobia) group (difference: -0.625; 95% CI: -0.810, -0.441; p<0.0001). Increase in CD4 count was found to be clinically significant after 96 weeks. The mean increase was 204.7 c/mm3 and 119.1 for randomized and non-randomized cohorts, respectively. Patients with the lowest CD4 counts at baseline (<20 c/mm3) showed the largest increase by week 96 with a mean of 239.8 c/mm3, a clinically meaningful improvement.
V. In clinical trials HIV-1 RNA suppression was seen after Day 8, thus the initial authorization of three months ensures that there is adequate time to respond to treatment and that the therapy remains safe and effective.
VI. The National Institute for Health defines virologic failure as the inability to maintain suppression of HIV RNA <200 copies/mL and persistent viral loads at this level are often indicative of the viral evolution and drug-resistance mutations.
VII. Subjects with chronic, untreated hepatitis B (HBV) co-infection were excluded from the BRIGHTE trial. Elevations in hepatic transaminases were more commonly observed in subjects with HBV

co-infection and consistent with HBV reactivation, particularly when anti-hepatitis therapy was discontinued.

Investigational or Not Medically Necessary Uses

I. Fostemsavir (Rukobia) has not been sufficiently studied for safety and efficacy for any other condition to date.

References

1. Rukobia [Prescribing Information]. Research Triangle Park, NC: ViiV Healthcare. July 2020.
2. NIH AIDSInfo. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV (2019)
3. Rukobia (fostemsavir) Integrated Review. FDA. 2020
4. Fostemsavir in adults with multi-drug resistant HIV-1 infection (BRIGHTE). *N Engl J Med*. 2020 Mar 26;382(13):1232-1243. (NCT 02362503)

Policy Implementation/Update:

Action and Summary of Changes	Date
Addition of HIV-specialist to criterion 1B, addition of establishing therapy through a different health plan in the renewal criteria, removal of requirement for HIV resistance assessment from renewal criteria as response to treatment is already being assessed via decrease HIV RNA, addition of supporting evidence V.	03/2021
Policy created	11/2020