JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS127
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	Subject **Rukobia**	*Revision Date*	12/08/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Rukobia

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I. POLICY

A. **Rukobia** (fostemsavir) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Rukobia may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing all the following:
      1. Patient has a diagnosis of HIV-1 infection
      2. Significant antiretroviral treatment experience with documented historical or baseline resistance, intolerability, and/or contraindications to antiretrovirals in at least three classes
      3. Inadequate response to current antiretroviral regimens evidenced by HIV RNA viral load greater than or equal to 400 copies/mL
      4. Patient has at least one responsive antiretroviral (but no more than two antiretrovirals) that can be used concurrently with Rukobia to create an effective treatment regimen
   3. Prescriber is, or has consulted with, an infectious disease specialist, or a certified HIV provider

III. AUTHORIZATION PERIOD/LIMITATIONS

1. Initial approval will be for 12 months of therapy
2. Approval for continuation of therapy may be extended in 12-month intervals with documentation showing beneficial response to treatment

IV. EXCLUSIONS

A. Rukobia will not be approved for the following:
   1. Pediatric patients

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2. Patients using strong cytochrome P450 3A inducers (carbamazepine, phenytoin, rifampin, enzalutamide, mitotane, St. John's wort, etc.)
3. Patients with a history of hypersensitivity reactions to fostemsavir or any other component of Rukobia
4. Patients that are breast-feeding
5. Any indications or usage that is not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Rukobia[Prescribing Information]. Research Triangle Park, NC: ViiV Healthcare; 2020 July

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
10/21/2020	Policy Creation
12/08/2021	Updated Exclusions section regarding physician samples

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