

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1323-6
Program	Prior Authorization/Notification
Medication	Rukobia (fostemsavir)
P&T Approval Date	8/2020, 12/2020, 12/2021, 12/2022, 12/2023, 12/2024
Effective Date	3/1/2025

1. Background:

Rukobia (fostemsavir), 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 multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.¹

Members will be required to meet the coverage criteria below.

2. Coverage Criteria^a:

A. Rukobia

1. **Rukobia** will be approved based on **both** of the following criteria:

a. Patient has been diagnosed with multidrug-resistant HIV-1 infection

-AND-

b. Patient is currently taking or will be prescribed an optimized background antiretroviral regimen

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Rukobia [Package Insert]. Durham, NC: ViiV Healthcare; February 2024.

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Change Control	
8/2020	New program.
12/2020	Revised criteria language related to optimized background regimen.
12/2021	Annual review with no change to clinical criteria.
12/2022	Annual review with no change to clinical criteria. Added state mandate footnote and updated reference.
12/2023	Annual review with no changes to coverage criteria.
12/2024	Annual review with no changes to coverage criteria. Updated reference.