

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 1323-7
Program	Prior Authorization/Notification
Medication	Rukobia (fostemsavir)
P&T Approval Date	8/2020, 12/2020, 12/2021, 12/2022, 12/2023, 12/2024, 12/2025
Effective Date	3/1/2026

**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.

Members will be required to meet the coverage criteria below.

**2. Coverage Criteria<sup>a</sup>:**

**A. Authorization**

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.**

<sup>a</sup> 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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<b>Change Control</b>	
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.
12/2025	Annual review with no changes to coverage criteria.