Antiretroviral Agents
Rukobia (rostemsavir)
Effective 02/01/2023

Plan	☐ MassHealth ☒ MH UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

Overview

Rukobia (fostemsavir) is indicated for the treatment of HIV-1 infection, in combination with other antiretrovirals, in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen.

No PA	Drugs that require PA
Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide) [PD]	Rukobia®(fostemsavir)[PD]
Cabenuva® (cabotegravir/rilpivirine) [PD]	
Descovy® (emtricitabine/tenofovir alafenamide) [PD]	
Delstrigo® (doravirine/lamivudine/tenofovir disoproxil fumarate) [PD]	
Dovato® (dolutegravir/lamivudine) [PD]	
Genvoya® (elvitegravir/cobicistat/emtricitabine/ tenofovir alafenamide) [PD]	
Juluca® (dolutegravir/rilpivirine) [PD]	
Norvir® (ritonavir powder)	
Norvir® (ritonavir solution)	
Norvir ® # (ritonavir tablet) [PD] §	
Odefsey® (emtricitabine/rilpivirine/tenofoviralafenamide) [PD]	
Pifeltro® (doravirine) [PD]	

Prezcobix® (darunavir/cobicistat) [PD]	
Prezista® (darunavir) [PD] §	
Symtuza® (darunavir/cobicistat/emtricitabine/ tenofovir alafenamide) [PD]	
Triumeq® (abacavir/dolutegravir/lamivudine) [PD]	
Triumeq PD® (abacavir/dolutegravir/lamivudine) [PD]	
Truvada® # (emtricitabine/tenofovir disoproxilfumarate)	

#This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

[PD] Preferred Drug. Requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Please note, for antiretroviral agents, a trial with a preferred agent is not required prior to approval of a non-preferred agent.

§ Brand Preferred over generic equivalents. Requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. Member has a diagnosis of HIV-1 infection
2. Member is ≥ 18 years of age
3. Member has ongoing detectable viremia (e.g., >200 copies/mL)
4. Member is antiretroviral experienced with documented historical or baseline resistance, intolerability, and/or contraindication to antiretroviral*
5. Failing current antiretroviral regimen due to resistance, intolerance or safety considerations†
6. Concurrent antiretroviral therapy with at least one other antiretroviral
7. Requested quantity ≤ 2 units/day

*Implies documented history of resistance, adverse reaction, or contraindication to an antiretroviral that is not part of the current regimen.

†Implies documented resistance, adverse reaction, or safety concern with current antiretroviral regimen.

Continuation of Therapy

Resubmission by prescriber will infer a positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be for 12 months.
2. The following quantity limits apply:

Rukobia	60 units per 30 days

References

1. Rukobia (fostemsavir) [prescribing information]. Research Triangle Park, NC: ViiV Healthcare; July 2020.

Review History

05/19/2021 – Created and Reviewed to match MH UPPL for 7/1/2021
07/19/2021 – Removed Cabenuva from criteria to match with MH UPPL. Effective 02/01/2022.
11/16/2022 – Reviewed and updated for Nov P&T. Matched MH by adding "Drug that require PA vs No PA" table. No clinical changes. Effective 2/1/23.

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