Clinical Policy Title:	cabotegravir-rilpivirine
Policy Number:	RxA.689
Drug(s) Applied:	Cabenuva®
Original Policy Date:	09/14/2021
Last Review Date:	01/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Human Immunodeficiency Virus (must meet all)**:**

1. Diagnosis of HIV type-1 infection;
2. Prescribed by or in consultation with an infectious disease or HIV specialist;
3. Member virologically suppressed (HIV-1 RNA <50 copies/mL);
4. Member has no history of treatment failure.

Approval Duration

All lines of business (except Medicare): 12 months

II. Continued Therapy Approval

A. Human Immunodeficiency Virus (must meet all):

1. Member is currently receiving medication, excluding manufacturer samples.

Approval Duration

All lines of business (except Medicare): 12 months

References

1. Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults 2018: Recommendations of the International Antiviral Society–USA Panel. American Medical Association. Available at: https://www.iasusa.org/wp-content/uploads/guidelines/arv/arv_2018.pdf. Accessed November 28, 2023.
2. What's New in the Guidelines? | NIH. clinicalinfo.hiv.gov. Accessed January 17, 2024. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new-guidelines?view=full. Accessed November 28, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/09/2021	09/14/2021
Policy was reviewed: 1. Clinical Policy title was updated to cabotegravir-rilpivirine. 2. Drugs applied section was updated to Cabenuva®. 3. Vocabria was removed from policy.	02/21/2022	04/18/2022

4. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Updated prescriber criteria to HIV specialist. 2. Initial Approval Criteria, I.A.3: Updated age criteria from Age ≥ 18 years to Age ≥ 12 years. 3. Initial Approval Criteria, I.A.4: Updated to include new weight criteria Member weighs ≥ 35 kg. 4. Initial Approval Criteria, I.A.6: Added new criteria "Member has no history of treatment failure." 5. Initial Approval Criteria, I.A.7: Updated to remove prior trial criteria Member has used Vocabria® and Edurant® (25 mg tablet) for at least 4 weeks prior to initiation of Cabenuva® injections. 6. Initial Approval Criteria, I.A.8.b: Updated to include new dosing criteria Every 2-month schedule: 600 mg cabotegravir and 900 mg rilpivirine intramuscularly 1 month apart for 2 consecutive months (initial dose), followed by 600 mg cabotegravir and 900 mg rilpivirine intramuscularly every 2 months thereafter. 7. Continued Therapy Approval, II.A.4.b: Updated to include new dosing criteria 600 mg of cabotegravir and 600 mg of rilpivirine intramuscularly every 2 months. 8. References were reviewed and updated.	06/01/2022	07/18/2022
Policy was reviewed: 1. Removed prior age criteria. 2. Removed prior dosing criteria. 3. Removed prior weight criteria. 4. Updated diagnostic criteria. 5. Removed requirement of known or suspected resistance to cabotegravir or rilpivirine. 6. Updated approval duration. 7. Removed reauthorization requirement for positive response to therapy.	11/28/2023	01/01/2024

8. Removed requirement of HIV-1 RVA <50 copies/mL from continued therapy approval. 9. References were reviewed and updated.		