Clinical Policy Title:	cabotegravir-rilpivirine
Policy Number:	RxA.689
Drug(s) Applied:	Cabenuva®
Original Policy Date:	08/09/2021
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Cabotegravir-rilpivirine (Cabenuva®) is a two-drug co-packaged product of cabotegravir, a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI), and rilpivirine, an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI), is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
cabotegravir-rilpivirine (Cabenuva®)	HIV type-1 infection	*Recommended monthly dosing schedule*: Initiate injections of Cabenuva® (600 mg of cabotegravir and 900 mg of rilpivirine) on the last day of oral lead-in and continue with injections of Cabenuva® (400 mg of cabotegravir and 600 mg of rilpivirine) every month thereafter. *Recommended every 2-month dosing schedule:* : Initiate injections of Cabenuva® (600 mg of cabotegravir and 900 mg of rilpivirine) on the last day of oral lead-in. Cabenuva® injection should be administered at Month 2, Month 3, and every 2 months thereafter	600 mg per dose intramuscularly for cabotegravir; 900 mg per dose intramuscularly for rilpivirine

Dosage Forms

cabotegravir-rilpivirine (Cabenuva®):

- Cabenuva® 400-mg/600-mg Kit:
  - single-dose vial of 400 mg/2 mL (200 mg/mL) cabotegravir
  - single-dose vial of 600 mg/2 mL (300 mg/mL) rilpivirine
- Cabenuva® 600-mg/900-mg Kit:
  - single-dose vial of 600 mg/3 mL (200 mg/mL) cabotegravir
  - single-dose vial of 900 mg/3 mL (300 mg/mL) rilpivirine

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 specialist;
3. Age ≥ 18 years;
4. Member has viral HIV-1 RNA < 50 copies/ mL
5. Member does not have known or suspected resistance to cabotegravir or rilpivirine;

a. Member has used Vocabria® and Edurant® (25 mg tablet) for at least 4 weeks prior to initiation of Cabenuva® injections;

b. Dose does not exceed :600 mg of cabotegravir and 900 mg of rilpivirine intramuscularly for one dose, then 400 mg of cabotegravir and 600 mg of rilpivirine intramuscularly once-monthly thereafter (every 4 weeks).

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Human Immunodeficiency Virus (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Member has HIV-1 RVA <50 copies/mL
4. If request is for a dose increase, it should not exceed :400 mg of cabotegravir and 600 mg of rilpivirine intramuscularly once-monthly.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
INSTI: integrase strand transfer inhibitor
NNRTI: non-nucleoside reverse transcriptase inhibitor
RNA: ribonucleic acid
HIV: human immunodeficiency virus

PrEP: Pre-Exposure Prophylaxis

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Cabenuva®:
    - Previous hypersensitivity reaction to cabotegravir or rilpivirine;
    - Coadministration with drugs where significant decreases in cabotegravir and/or rilpivirine plasma concentrations may occur, which may result in loss of virologic response.
  - Vocabria®:
    - Previous hypersensitivity reaction to cabotegravir;
    - Coadministration with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and rifapentine;
    - Positive HIV-1 status for HIV-1 PrEP.

  *Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Cabenuva®: Residual concentrations of cabotegravir and rilpivirine may remain in the systemic circulation of patients up to 12 months or longer. It is essential to initiate an alternative, fully suppressive antiretroviral regimen no later than 1 month after the final injection doses of Cabenuva®. If virologic failure is suspected, prescribe an alternative regimen as soon as possible.
- Vocabria®: Because Vocabria® in combination with Edurant® (rilpivirine) is a complete regimen, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.
- Prior to initiating treatment with Cabenuva®, oral lead-in dosing should be used for approximately 1 month to assess the tolerability of cabotegravir and rilpivirine.
- HIV-1 Screening: Screen all individuals for HIV-1 infection prior to initiating Vocabria® and Apretude™ for HIV-1 PrEP and at least once every 3 months while taking Apretude™.
- The use of Vocabria® as an oral lead-in and in participants who miss planned injections with Apretude™ to reduce the risk of acquiring HIV-1 infection.

References

1. Cabenuva® (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension) [prescribing information]. Triangle Park, NC: ViiV Healthcare; January 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212888s000lbl.pdf. Accessed February 21, 2022.
2. Vocabria® (cabotegravir) tablet [prescribing information]. Triangle Park, NC: ViiV Healthcare; February 2022. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Vocabria/pdf/VOCABRIA-PI-PIL.PDF. Accessed February 21, 2022.
3. IPD Analytics Rx Insights_New Drug Review_Cabenuva_02 2021.pdf. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=cabenuva. Accessed February 21, 2022.
4. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2022. Accessed with

subscription at: http://www.clinicalkey.com. Accessed February 21, 2022.

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. 4. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 5. References were reviewed and updated.	02/21/2022	04/18/2022