

Clinical Policy Title:	cabotegravir, cabotegravir-rilpivirine
Policy Number:	RxA.689
Drug(s) Applied:	Vocabria®, Cabenuva®
Original Policy Date:	08/09/2021
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Cabotegravir (Vocabria®) is a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in combination with Edurant® (rilpivirine) for short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine, for use as:

- Oral lead-in to assess the tolerability of cabotegravir prior to administration of Cabenuva® (cabotegravir- rilpivirine) extended-release injectable suspensions.
- Oral therapy for patients who will miss planned injection dosing with Cabenuva®.

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 (Vocabria®)	HIV type-1 infection	One tablet of Vocabria® 30 mg taken orally once daily for approximately 1 month in combination with one tablet of Edurant® (rilpivirine) 25 mg taken orally once daily with a meal	30 mg orally per day
cabotegravir-rilpivirine (Cabenuva®)	HIV type-1 infection	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.	600 mg per dose intramuscularly for cabotegravir; 900 mg per dose intramuscularly for rilpivirine

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Dosage Forms

- cabotegravir (Vocabria®): Tablets: 30 mg
- 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 infectious disease specialist;
3. Age ≥ 18 years;
4. Member has viral HIV-1 RNA < 50 copies/ mL on current ORT regimen;
5. Member does not have known or suspected resistance to cabotegravir or rilpivirine;
6. For Vocabria®: Member was treated with a stable regimen of antiretrovirals for HIV-1 prior to initiating Vocabria®;
7. For Cabenuva®: Member has used Vocabria® and Edurant® (25 mg tablet) for at least 4 weeks prior to initiation of Cabenuva® injections;
8. Dose does not exceed one of the following (a or b):
 - a. Vocabria®: 30 mg orally per day;
 - b. Cabenuva®: 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, request meets one of the following (a or b):
 - a. Vocabria®: 30 mg orally per day;
 - b. Cabenuva®: 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

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.
- 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.

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 August 09, 2021.
2. Vocabria® (cabotegravir) tablet [prescribing information]. Triangle Park, NC: ViiV Healthcare; January 2021. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Vocabria/pdf/VOCABRIA-PI-PIL.PDF. Accessed August 09, 2021.
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 August 09, 2021.
4. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2021. Accessed with

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Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/09/2021	09/14/2021