VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Human Immunodeficiency Virus – Cabenuva Utilization Management Medical Policy
- Cabenuva® (cabotegravir extended-release intramuscular injection; rilpivirine extended-release intramuscular injection, co-packaged – ViiV/GlaxoSmithKline)

REVIEW DATE: 02/01/2023; selected revision 12/06/2023

OVERVIEW

Cabenuva is a two-drug co-packaged product of cabotegravir, a human immunodeficiency virus type-1 (HIV-1) integrase strand-transfer inhibitor, and rilpivirine, an HIV-1 non-nucleoside reverse transcriptase inhibitor.[1] It is indicated as a complete regimen for the treatment of **HIV-1 infection** in patients ≥ 12 years of age and ≥ 35 kg to replace their current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to cabotegravir or rilpivirine.[1]

Dosing

Cabenuva must be administered by a healthcare professional. Prior to starting Cabenuva, healthcare professionals should carefully select patients who agree to the required monthly injection dosing schedule and counsel patients about the importance of adherence to scheduled dosing visits to help maintain viral suppression and reduce the risk of viral rebound and potential development of resistance with missed doses.[1]

Oral lead-in with Vocabria® (cabotegravir tablets) + Edurant® (rilpivirine tablets) may be used for approximately 1 month (at least 28 days) prior to the initiation of Cabenuva to assess the tolerability of cabotegravir and rilpivirine. Cabenuva may be administered as a once-monthly injection or once every 2-month injection. Table 1 provides the recommended oral lead-in and monthly injection dosing schedule. Table 2 provides the recommended oral lead-in and every 2-month injection dosing schedule.

Table 1. Recommended Oral Lead-In and Monthly Intramuscular Injection Dosing Schedule.[1]

Vocabria + Edurant Lead-In (at Least 28 Days)	Cabenuva Initiation Injections (One-Time Dosing)	Cabenuva Continuation Injections (Once-Monthly Dosing)
Month 1	At Month 2 (On the Last Day of Oral Lead-In Dosing)	Month 3 Onwards
Vocabria (30 mg) QD with a meal	cabotegravir 600 mg (3 mL)	cabotegravir 400 mg (2 mL)
Edurant (25 mg) QD with a meal	rilpivirine 900 mg (3 mL)	rilpivirine 600 mg (2 mL)

QD – Once daily.

Table 2. Recommended Oral Lead-In and Every 2-Month Intramuscular Injection Dosing Schedule.[1]

Vocabria + Edurant Lead-In (at Least 28 Days)	Cabenuva Initiation Dosing	Cabenuva Continuation Injections (Once Every 2-Month Dosing)
Month 1	At Month 2 and Month 3	Month 5 Onwards
Vocabria (30 mg) QD with a meal	cabotegravir 600 mg (3 mL)	cabotegravir 600 mg (3 mL)
Edurant (25 mg) QD with a meal	rilpivirine 900 mg (3 mL)	rilpivirine 900 mg (3 mL)

QD – Once daily.

Guidelines

The Department of Health and Human Services (DHHS) Guidelines for the Use of Antiviral Agents in Adults and Adolescents with HIV (September 21, 2022) recognize Cabenuva as a long-acting antiretroviral regimen that is an optimization option for patients who are engaged with their health care providers, virologically suppressed on oral therapy for 3 to 6 months, and who agree to make the frequent clinic visits needed.[5] Both FDA-approved dosing regimens are appropriate for Cabenuva in virally suppressed patients

(once monthly or every 2-month dosing and with or without oral lead-in). The Guidelines point out that the tablet formulation of cabotegravir (Vocabria®) is only available through the manufacturer, not in community pharmacies. Cabenuva is not recommended as initial therapy for people with HIV because of the lack of data supporting efficacy in this patient population.

International Antiviral Society-USA (IAS-USA) Recommendations on Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults (2022) have similar recommendations to the DHHS guidelines for Cabenuva.[7] In individuals with no history of treatment failure and no known or suspected resistance to either agent, Cabenuva is an option. Cabenuva is noted to give greater patient satisfaction (vs. oral antiretrovirals (ARVs) to those interested in non-oral options for treatment because of privacy, stigma, or convenience reasons. Both approved dosing regimens (with and without oral lead-in) are considered acceptable based on patient preference. If scheduled doses of Cabenuva are missed, resumption of therapy should follow the Prescribing Information. Cabenuva is not recommended for initial therapy in ARV-naïve individuals.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Cabenuva. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Cabenuva as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Cabenuva to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required for use of Cabenuva as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cabenuva is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. **Human Immunodeficiency Virus (HIV)-1, Treatment.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets all of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 12 years of age; AND
     - **ii.** Patient weighs ≥ 35 kg; AND
     - **iii.** Patient has HIV-1 RNA < 50 copies/mL (viral suppression) **[documentation required]**; AND
     - **iv.** Prior to initiating Cabenuva or 1 month lead-in with Vocabria (cabotegravir tablets), the patient was treated with a stable regimen (≥ 4 months) of antiretrovirals for HIV-1 **[documentation required]**; AND
     - **v.** The medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.

B) Patient is Currently Receiving Cabenuva. Approve if the patient has HIV-1 RNA < 50 copies/mL (viral suppression) **[documentation required]**.

Dosing. Approve one of the following dosing regimens (A or B):

A) Once Monthly Dosing Regimen: Approve 600 mg/900 mg intramuscularly for one dose, then approve 400 mg/600 mg intramuscularly once-monthly thereafter (every 4 weeks).

B) Every 2 Months Dosing Regimen: Approve 600 mg/900 mg intramuscularly for two doses, 1 month apart, then approve 600 mg/900 mg intramuscularly once every 2 months thereafter (every 8 weeks).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Cabenuva is not recommended in the following situations:

1. **Pre-Exposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)-1 Infection.** Cabenuva is not indicated for the prevention of HIV.

2. **Co-administration with Antiretrovirals for Human Immunodeficiency Virus (HIV) Treatment.** Because Cabenuva is a complete regimen, co-administration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.[1]

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Cabenuva® injection [prescribing information]. Research Triangle Park, NJ: ViiV/GlaxoSmithKline; April 2022.
2. Orkin C, Arasteh K, Hernandez-Mora G, et al. Long-acting cabotegravir and rilpivirine after oral induction for HIV-1 infection. *N Engl J Med.* 2020;382:1124-1135.
3. Swindells S, Andrade-Villaneuva JF, Richmond GJ, et al. Long-acting cabotegravir and rilpivirine for maintenance of HIV-1 suppression. *N Engl J Med.* 2020; 382;12:1112-1123.
4. Saag MS, Gandhi RT, Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults. 2020 recommendations of the International Antiviral Society-USA Panel. *JAMA*. 2020;324(16):1651-1669.
5. Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new-guidelines. Updated September 21, 2022. Accessed January 23, 2023.
6. Orkin C, Bernal E, Tan DHS, et al. Initiation of long-acting cabotegravir plus rilpivirine as direct-to-injection or with an oral lead-in in adults with HIV-1 infection: Week 124 results of the open-label phase 3 FLAIR study. *Lancet HIV*. 2021;11:e668-e678.
7. Ghandi RT, Bedimo R, and Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults. 2022 recommendations of the International Antiretroviral Society-USA Panel. *JAMA*. 2023;329(1):63-84.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Human Immunodeficiency Virus Type-1 (HIV-1), Treatment:** The indication was modified to as listed to add the qualifier "-1" and "treatment" after HIV. Criteria requiring the patient completed/would complete 1 month of therapy with Vocabria (cabotegravir tablets) + Edurant (rilpivirine tablets), was removed. Cabenuva was added to criteria requiring that prior to initiating therapy with "Cabenuva" or 1 month lead-in with Vocabria the patient was treated with a stable regimen (≥ 4 months) of antiretrovirals for HIV-1. **Conditions Not Recommended for Coverage: Pre-Exposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)-1 Infection** was modified to as listed to add the qualifier "of Human Immunodeficiency Virus (HIV)-1 Infection" after PrEP. **Human Immunodeficiency Virus (HIV), Antiretroviral Treatment-Naïve Patients** was removed because it was not needed. **Co-administration with Antiretrovirals for Human Immunodeficiency Virus (HIV) Treatment** was modified to as listed to add the qualifier "treatment" after HIV.	02/09/2022
Selected Revision	**Human Immunodeficiency Virus Type-1 (HIV-1), Treatment:** The age indication for approval was changed to ≥ 12 years of age and ≥ 35 kg. Previously the age of approval was ≥ 18 years of age.	04/06/2022
Annual Revision	No criteria changes.	02/01/2023
Selected Revision	**Human Immunodeficiency Virus Type-1 (HIV-1), Treatment:** Criteria requiring that, according to the prescriber, the patient either has difficulty maintaining compliance with a daily antiretroviral regimen for HIV-1 OR has severe gastrointestinal issues that may limit absorption or tolerance of oral medications was removed.	12/06/2023