MEDICAL MUTUAL®

Drug Policy

Policy:	**20210302**	**Initial Effective Date:**
Code(s):	**HCPCS J3490**	**Annual Review Date: 02/20/2025**
SUBJECT:	**Cabenuva® (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension)**	**Last Revised Date: 02/20/2025**

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

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]

POLICY STATEMENT

This policy involves the use of Cabenuva. Prior authorization is recommended for pharmacy and medical benefit coverage of Cabenuva. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing (medical benefit requests only), Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis. 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.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

RECOMMENDED AUTHORIZATION CRITERIA

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

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FDA-Approved Indications

1. **Human Immunodeficiency Virus (HIV)-1, Treatment.** Approve for the duration below if the patient meets ONE of the following conditions (A or B):
   - **A)** Initial Therapy: Approve if the patient meets all the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 12 years of age; AND
     - **ii.** Patient weighs ≥ 35kg; AND
     - **iii.** Patient has HIV-1 RNA < 50 copies/mL (viral suppression) *****; AND
     - **iv.** Prior to initiating Cabenuva or 1 month lead-in with Vocabria, the patient was treated with a stable regimen (≥ 3 months) of antiretrovirals for HIV-1 *; 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 meets all the following (i):
     - **i.** Patient has HIV-1 RNA < 50 copies/mL (viral suppression) *****.

Dosing in Cabenuva. *Dosing must meet the following* [medical benefit only]:
Recommended Monthly Dosing Schedule: Initiate injections of Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine) on the last day of current antiretroviral therapy or 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 current antiretroviral therapy or oral lead-in for 2 consecutive months and continue with injections of CABENUVA every 2 months thereafter

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year (365 days)
B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Cabenuva has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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.** Because Cabenuva is a complete regimen, co-administration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.[1]

3. **Human Immunodeficiency Virus (HIV)-2 Infection.** Cabenuva is not indicated in patients with HIV-2 infection.[1] The Department of Health and Human Services guidelines further note that HIV-2 is intrinsically resistant to non-nucleoside reverse transcriptase inhibitors, therefore, Cabenuva is not recommended for people with HIV-2.[5]

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

*** Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Cabenuva® injection [prescribing information]. Research Triangle Park, NJ: ViiV Healthcare/GlaxoSmithKline; December 2023.
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. Rajesh RT, Landovitz RJ, and Sax P, et al. Antiretroviral drugs for treatment and prevention of HIV in adults: 2024 recommendations of the International Antiviral Society USA-Panel. *JAMA.* 2024 Dec 1 [Epub ahead of Print]..
5. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Last Updated: September 12, 2024. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf. Accessed on: February 4, 2025.
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.

Prior approval is required for HCPCS Codes J3490

†When *unclassified drugs* (J3490) is determined to be Cabenuva