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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 02/12/2026

Cabenuva® (cabotegravir + rilpivirine)

HCPCS: J0741

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list.
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: Align with FDA recommended dosing
 - b. Authorization Period: One year at a time
 - c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Cabenuva is indicated as a complete regimen for the treatment of human immunodeficiency virus type-1 (HIV-1) infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace their current antiretroviral (ARV) regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable ARV regimen with no history of treatment failure and with no known or suspected resistance to cabotegravir or rilpivirine.
- Cabenuva is a two-drug co-packaged product of cabotegravir, a HIV-1 integrase strand-transfer inhibitor (INSTI), and rilpivirine, an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI) given as a once monthly or once every 2 months injection. Cabenuva is an option for patients who would benefit from an extended interval dosing regimen versus a daily oral treatment and may be an advantage for some patients who may be more optimally managed with

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less frequent dosing.

- Vocabria, an oral formulation of cabotegravir, may be taken in combination with Edurant®, an oral formulation of rilpivirine, for one month prior to initiating treatment with Cabenuva to assess tolerance.
- The efficacy of Cabenuva is similar to established oral antiretroviral therapy (ART). The initial approval of Cabenuva for maintenance therapy in adults with HIV-1 was evaluated in two Phase III, randomized, multinational, active-controlled, non-inferiority trials in more than 1,100 patients. The primary efficacy endpoint was the proportion of subjects with plasma HIV-1 RNA $\geq$ 50 copies/mL at week 48.
 - In the first trial, at Week 48, Cabenuva was non-inferior to Triumeq® or a dolutegravir-containing regimen: 2.1% and 2.5% of patients did not maintain viral suppression.
 - In the second trial, at Week 48, Cabenuva was non-inferior to patients' existing oral antiretrovirals: 1.6% and 1.0% of patients did not maintain viral suppression.
- Standard Treatment/Guidelines:
 - The standard of care for patients with HIV includes taking daily pills to adequately manage their condition. Single-tablet regimens (STRs) are the mainstay of HIV therapy today because they offer the convenience of providing multiple ARVs in a single pill and have been successfully used to initiate and maintain viral load suppression. Viral failure can occur for many reasons including development of drug resistance, suboptimal adherence, and drug intolerance/toxicity prompting a new antiretroviral regimen to be designed.
 - The Health and Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV: Management of the Treatment-Experienced Patient – Optimizing Antiretroviral Therapy in the Setting of Viral Suppression (2024) offers the following recommendations related to the use of Cabenuva:
 - A long-acting ARV regimen of injectable cabotegravir (CAB) and rilpivirine (RPV) given every 1 or 2 months is an optimization option for patients virologically suppressed on oral therapy for at least 3 months, no history of treatment failure, and with no known or suspected resistance to either CAB or RPV (Strong Recommendation; Data from RCTs).
 - Pregnant persons who present to care on long-acting CAB and RPV should be switched to a preferred or an alternative three-drug ARV regimen recommended for use in pregnancy per the Perinatal Guidelines (Strong Recommendation; Expert Opinion).
 - The 2024 Recommendations of the International Antiviral Society-USA Panel (IAS-USA) for Antiviral Drugs for Treatment and Prevention of HIV Infection in Adults recommends CAB/RPV in persons who experience stigma or adverse consequences of taking pills daily or in response to strong patient preference (Strong panel support: evidence from 1 or more randomized clinical trials).
 - IAS-USA also notes that long-acting CAB/RPV may be considered in conjunction with intensive care management and adherence support for people who are unable to take oral ART consistently despite extensive efforts and clinical support, those at high risk of HIV disease progression, and virus susceptible to both CAB and RPV (Strong panel support: evidence from nonrandomized clinical trials or case-control studies).

References:

1. Cabenuva [prescribing information]. Research Triangle Park, NJ: ViiV Healthcare/GlaxoSmithKline; November 2025.
2. Vocabria [prescribing information]. Research Triangle Park, NJ: ViiV Healthcare/GlaxoSmithKline; April 2025.
3. 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.
4. 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.
5. ViiV Healthcare. Use of long-acting cabotegravir for pre-exposure prophylaxis to prevent infection with HIV. Data on file. January 25, 2021.
6. Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2018–2022. HIV Surveillance Supplemental Report, 2024; 29 (No.1). <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2024. Accessed December 8, 2025.
7. 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. Available at <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv>. Accessed December 8, 2025.
8. Gandhi RT, Landovitz RJ, Sax PE, et al. Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults: 2024 Recommendations of the International Antiviral Society–USA Panel. *JAMA.* 2024; doi:10.1001/jama.2024.24543.
9. IPD Analytics New Drug Review for Cabenuva. February 2021.

Policy History												
#	Date	Change Description										
1.3	Effective Date: 02/12/2026	Annual review with no changes to criteria.										
1.2	Effective Date: 02/13/2025	Annual review with no changes to criteria										
1.1	Effective Date: 05/01/2024	UM medical management system update for BCBS and BCN <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
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MAPPO	No											
BCNA	No											
1.0	Effective Date: 02/08/2024	New policy <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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BCN	No											
MAPPO	No											
BCNA	No											

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://daily.med.nlm.nih.gov/dailymed/index.cfm>.

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Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form
Cabenuva (rilpivirine) HCPCS CODE: J0741



This form is to be used by participating physicians to obtain coverage for Cabenuva. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Pt weight (in kg) Date recorded: _____	City /State/Zip
Diagnosis	Phone/Fax: P: () - F: () -
Drug Name ☐	NPI
Dose and Quantity	Contact Person
Directions	Contact Person Phone / Ext.
Date of Service(s)	

STEP 1: DISEASE STATE INFORMATION

- Is this request for initiation or renewal of therapy?
☐ Initiation ☐ Continuation **Date patient started therapy:** _____
- How is this medication being administered?
☐ Self-administered ☐ Health Care Professional administered (**Continue to #3**)
- Site of administration?
☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #4) Reason for Hospital Outpatient administration: _____
- Please specify location of administration if hospital outpatient infusion:** _____
- Please provide the NPI number for the place of administration:** _____
- Initiation AND Continuation of therapy:**
a. Please check the patient's diagnosis: ☐ HIV-1 infection ☐ Other: _____
- Continuation request:** Cabenuva start date: _____
a. Have the patient's signs and symptoms improved with Cabenuva?
☐ Yes ☐ No, Comment: _____

Please add any other supporting medical information necessary for our review

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name

Physician Signature

Date

Step 2: Checklist	☐ Form Completely Filled Out ☐ Attached Chart Notes	☐ Weight (specify lb or kg) , BSA
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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