

RX.PA.006.MPC Cabenuva® (cabotegravir/rilpivirine) Injectable Policy

PURPOSE

Cabenuva® is a two-drug co-packaged product of cabotegravir (INSTI – integrase strand-transfer inhibitor) and rilpivirine (NNRTI – non-nucleoside reverse transcriptase inhibitor) indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace current antiretroviral regimen in virologically suppressed (HIV-1 RNA < 50 copies per mL) on stable antiretroviral regimen with no history of treatment or suspected resistance to cabotegravir or rilpivirine. Maryland Physicians Care requires Prior Authorization for its use.

Human Immunodeficiency Virus (HIV): Approve Cabenuva if the member meets **ONE** of the following conditions (A or D)

A. Initial Therapy - Member must meet **ALL** of the following:

- a. Member has HIV type-1 (HIV-1) infection
AND
- b. Member is ≥ 12 years of age
AND
- c. Member weighs ≥ 35 kg
AND
- d. Must provide documentation (within 90 days of request) that member has HIV-1 RNA < 50 copies/mL (virologically suppressed)
AND
- e. Member has no documented history of treatment failure with other medications used for managing HIV-1 infection
AND
- f. Member has no documented history of suspected resistance to cabotegravir (INSTI) or rilpivirine (NNRTI)
AND
- g. Must provide documentation that Cabenuva is prescribed by a specialist with significant experience in the treatment of HIV infection

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling.

C. Cabenuva will be considered investigational or experimental for any other use and will not be covered.

D. Reauthorization Criteria

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 12 month intervals based upon the indication of use and all of the following:

MPC Renewal:

- Documentation from the provider that the member remains a candidate for treatment with Cabenuva based upon the prescriber's assessment while on therapy
- Documentation that the member's remained adherent to injectable cycle during entire course of treatment
- Recent lab work (within last 2 months) confirming virologic suppression
 - HIV-1 RNA < 50 copies/mL
- Renewal from Previous Insurer:
 - Members who have received prior approval (from insurer other than MPC) and have been taking Cabenuva, or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).
 - Provider has documented positive clinical response to therapy for the member from baseline

Approval Duration:

- A. Initial Therapy: Approve for 6 months
- B. Continuation of Therapy: Approve for 1 year

CPT Code	Description
J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg

References:

1. Cabenuva® injection [prescribing information]. Research Triangle Park, NJ: ViiV Healthcare/GlaxoSmithKline; January 2021.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Updated initial criteria to include lab requirement within 90 days of medication request</i>	06/2025
<i>Annual Review</i>	02/2025
<i>Removal of monthly dosing and site of service requirements</i>	03/2024

<i>Annual review</i>	<i>02/2024</i>
<i>Selected Revision</i> Update to require site of service restrictions. Removal of INSTI and optional oral lead-in requirements. Requirements on monthly administration vs every other month administration	<i>1/2024</i>
<i>Selected Revision</i> Minor grammatical edit; Addition of Tivicay as preferred INSTI requirement	<i>12/2023</i>
<i>Selected Revision</i> Clarification of treatment failure due to non-compliance; Addition of oral pill contraindication or intolerance	<i>11/2023</i>
<i>Selected Revision</i> Oral lead in therapy with Vocabria (cabotegravir) tablets and Edurant (rilpivirine) tablets updated as optional	<i>05/2023</i>
<i>Annual review</i>	<i>02/2023</i>
<i>Update to initial criteria: age and weight addition. Update to reauthorization criteria to include MPC vs Non-MPC authorization renewal</i>	<i>10/2022</i>
<i>Annual review and J-Code Update</i>	<i>02/2022</i>
<i>Addition of dosing requirements</i>	<i>12/2021</i>
<i>P&T Review</i>	<i>05/2021</i>