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

PURPOSE

Cabenuva® is a two-drug co-packaged product of cabetogravir (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 regiment with no history of treatment or suspected resistance to cabotegravir or rilpivirine. Maryland Physicians Care requires Prior Authorization for its use.

Human Immunodeficiency Viris (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 ≥ 35kg
AND
d. 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. For oral Vocabria (cabotegravir) lead-in: Member has documented contraindication or intolerance to preferred INSTI formulary alternative Isentress (raltegravir)
AND
g. Member has documented tolerance to 30-day oral lead-in trial therapy with Vocabria (cabotegravir) tablets and Edurant (rilpivirine) tablets
AND
h. Member has no documented history of suspected resistance to cabotegravir (INSTI) or rilpivirine (NNRTI)
AND
i. For Cabenuva: member has documented contraindication or intolerance to a formulary oral combination product
AND
j. Cabenuva is prescribed by or in consultation with a specialist 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
- Non- MPC Renewal:
  - Members who have previously been taking Cabenuva and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria).
  - Member has not been receiving medication samples for Cabenuva; AND
  - 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
Update to initial criteria: age and weight addition. Update to reauthorization criteria to include MPC vs Non-MPC authorization renewal	*10/2022*
Annual review and J-Code Update	*02/2022*
Addition of dosing requirements	*12/2021*
P&T Review	*05/2021*