POLICY TITLE: *Cabenuva® (cabotegravir/rilpivirine) Injectable Policy*

DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**

ORIGINAL DATE: ***April 2021***

Last P&T Committee Approval Date: May 2021

Product Applicability: *mark all applicable products below*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All *States*: [ ] GA [x] MD [ ] OH [ ] TX [ ] NM [x] IN
GOVERNMENT PROGRAMS	[ ] MA HMO [ ] MA C-SNP [ ] MA D-SNP [ ] MSSP [ ] Next Gen ACO [ ] MA All
	[X] Medicaid *States*: [ ] KY [X] MD
OTHER	[x] Self-funded/ASO

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 B)

A. **Initial Therapy** - Member must meet **ALL** of the following:
   a. Member has HIV type-1 (HIV-1) infection
      AND
   b. Member is ≥ 18 years of age
      AND

c. Member has HIV-1 RNA < 50 copies/mL (virologically suppressed)
AND
d. Member has no documented history of treatment failure with other medications used for managing HIV-1 infection
AND
e. For oral Vocabria (cabotegravir) lead-in: Member has documented contraindication or intolerance to preferred INSTI formulary alternative Isentress (raltegravir)
AND
f. Member has documented tolerance to 30-day oral lead-in trial therapy with Vocabria (cabotegravir) tablets and Edurant (rilpivirine) tablets
AND
g. Member has no documented history of suspected resistance to cabotegravir (INSTI) or rilpivirine (NNRTI)
AND
h. For Cabenuva: member has documented contraindication or intolerance to a formulary oral combination product
AND
i. Cabenuva is prescribed by or in consultation with a specialist in the treatment of HIV infection

B. Member Currently Treated with Cabenuva:

a. Member has HIV type-1 (HIV-1) infection
AND
b. Member is ≥ 18 years of age
AND
c. Member has HIV-1 RNA < 50 copies/mL (virologically suppressed)
AND
d. Member has documented claims supporting prior treatment initiation with 30-day oral lead-in trial therapy with Vocabria (cabotegravir) tablets and Edurant (rilpivirine) tablets (samples will not be accepted for lead-in trial)
AND
e. Member has documented claims supporting continuation of therapy with Cabenuva (samples will not be accepted as a continuation of therapy)

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

Approval Duration:

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

CPT Code	Description
J3490	Unclassifed drugs Single-dose vial of 400mg/2mL Cabotegravir Single-dose vial of 600mg/2mL Rilpivirine

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	
P&T Review	*05/21*

References:

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