Medical Policy

Cabenuva (cabotegravir and rilpivirine)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-112
CURRENT VERSION EFFECTIVE DATE	3/1/2023
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Cabenuva (cabotegravir and rilpivirine) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Cabenuva will be provided for 6 months and may be renewed. Renewals will be provided for 12 months.

- Max Units (per dose and over time):
  - Cabenuva 600 mg/900 mg kit: 1 kit x 1 fill
  - Cabenuva 400 mg/600 mg kit: 1 kit every 28 days

Initial

A. Patient is 18 years of age or older; **AND**
B. Patient has a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection; **AND**
C. Patient is virologically suppressed with HIV-RNA < 50 copies/mL and is on a stable antiretroviral regimen; **AND**
D. Patient has no history of treatment failure or known or suspected resistance to cabotegravir or rilpivirine; **AND**
E. Patient has not had a previous hypersensitivity reaction to cabotegravir or rilpivirine; **AND**
F. Patient will NOT receive concomitant therapy with ANY of the following medications that can result in significant decreases of cabotegravir and/or rilpivirine; **AND**
    a. Carbamazepine
    b. Oxcarbazepine
    c. Phenobarbital
    d. Phenytoin
    e. Rifabutin
    f. Rifampin
    g. Rifapentine
    h. Dexamethasone (more than a single-dose treatment)
    i. St. John's wort
G. Patient will complete oral cabotegravir and rilpivirine ≥ 28 days prior to starting therapy; **AND**
H. Patient has been counseled to contact their healthcare provider if they plan to miss a scheduled monthly injection visit to coordinate treatment with oral therapy to replace up to 2 consecutive monthly injections.

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity reactions, hepatotoxicity, serious post-injection reactions, and unremitting depression, etc.; **AND**
C. Patient has not experienced virologic failure and has documented adherence to therapy, clinical improvement and/or stabilization.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. CABENUVA (cabotegravir extended-release injectable suspension; rilpivirine extendedrelease injectable suspension), co-packaged for intramuscular use. Initial U.S. Approval: 2021

CODING

Applicable NDC Codes	
49702-253-15	CABENUVA 400-mg/600-mg Kit - single-dose vial of 400 mg/2 mL (200 mg/mL) cabotegravir, single-dose vial of 600 mg/2 mL (300 mg/mL) rilpivirine
49702-240-15	CABENUVA 600-mg/900-mg Kit - single-dose vial of 600 mg/3 mL (200 mg/mL) cabotegravir, single-dose vial of 900 mg/3 mL (300 mg/mL) rilpivirine

Applicable Procedure Code	
J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg

Applicable ICD-10 Codes	
B20	Human immunodeficiency virus (HIV) disease
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status

EVIDENCE BASED REFERENCES

1. Product Information: CABENUVA intramuscular extended-release suspension, cabotegravir intramuscular extended-release suspension, rilpivirine intramuscular extended-release suspension. Viiv Healthcare (per FDA), Research Triangle Park, NC, 2022.

POLICY HISTORY

Original Effective Date	5/24/2022
Revised Date	03/01/2023 – Adopted by MA UMC
P&T Committee Endorsement	5/24/2022
Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan	01/01/2024