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5.01.058

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Anti-Infective Agents	**Original Policy Date:**	March 12, 2021
Subject:	Cabenuva	**Page:**	1 of 5

Last Review Date: March 7, 2025

Cabenuva

Description

Cabenuva (cabotegravir/rilpivirine)

Background
Cabenuva is a 2-drug co-packaged product containing cabotegravir, a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI), and rilpivirine, an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI). Cabotegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral DNA integration which is essential for the HIV replication cycle. Rilpivirine is a diarylpyrimidine NNRTI of HIV-1 and inhibits HIV-1 replication by non-competitive inhibition of HIV-1 reverse transcriptase (1).

Regulatory Status
FDA-approved indication: 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 the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine (1).

Cabenuva may be initiated with oral cabotegravir and oral rilpivirine prior to the intramuscular injections or the patient may proceed directly to injection of Cabenuva without an oral lead-in. Cabenuva must be administered by a healthcare professional (1).

Hypersensitivity reactions have been reported during postmarketing experience with rilpivirine-containing regimens. Reactions include cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Cabenuva should be discontinued immediately if signs or symptoms of hypersensitivity reactions develop (1).

Hepatotoxicity has been reported in patients receiving cabotegravir or rilpivirine with or without known pre-existing hepatic disease or identifiable risk factors. Patients should have their liver chemistries monitored and treatment with Cabenuva should be discontinued if hepatotoxicity is suspected (1).

Healthcare professionals should carefully select patients who agree to the required monthly or every-2-month injection dosing schedule and counsel patients about the importance of adherence to scheduled dosing visits to help maintain viral suppression and reduce the risk of viral rebound and potential development of resistance with missed doses (1).

The safety and efficacy of Cabenuva in pediatric patients less than 12 years of age or weighing less than 35 kg have not been established (1).

Related policies
Apretude, Trogarzo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cabenuva may be considered **medically necessary** if the conditions indicated below are met.

Cabenuva may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. HIV-1 infection
    a. Age 12-17 **only**: weight ≥ 35 kg
    b. Patient is virologically suppressed (HIV-1 RNA less than 50 copies/mL)
    c. Cabenuva will replace the current antiretroviral regimen
    d. **NO** history of treatment failure
    e. **NO** known or suspected resistance to either cabotegravir or rilpivirine
    f. Cabenuva will be administered by a healthcare professional
    g. Prescriber has counseled the patient regarding the required injection dosing schedule and the importance of adherence to scheduled dosing visits
    h. Prescriber agrees to monitor for hypersensitivity reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
    i. Prescriber agrees to monitor LFTs for hepatotoxicity

Prior – Approval *Renewal* Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. HIV-1 infection
    a. Age 12-17 **only**: weight ≥ 35 kg
    b. HIV-1 RNA remains at less than 50 copies/mL
    c. Cabenuva will be administered by a healthcare professional
    d. Prescriber agrees to monitor for hypersensitivity reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
    e. Prescriber agrees to monitor LFTs for hepatotoxicity

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Cabenuva is a 2-drug co-packaged product containing cabotegravir, a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI), and rilpivirine, an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI). Cabenuva is used in the treatment of HIV-1 infection to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL). The safety and efficacy of Cabenuva in pediatric patients less than 12 years of age or weighing less than 35 kg have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Cabenuva while maintaining optimal therapeutic outcomes.

References

1. Cabenuva [package insert]. Research Triangle Park, NC: ViiV Healthcare; September 2024.

Policy History

Date	Action
March 2021	Addition to PA
June 2021	Annual review
March 2022	Annual review
April 2022	Removed oral lead in dosing requirement and removed the word “monthly” from the requirement for scheduled dosing per PI update. Reduced age requirement to 12 years and older and added requirement for patients age 12-17 to weight at least 35 kg per PI update
June 2022	Annual review
March 2023	Annual review and reference update. Changed policy number to 5.01.058
June 2023	Annual review and reference update
March 2024	Annual review and reference update
June 2024	Annual review
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.