Medical Drug Clinical Criteria

Subject:	Cabenuva (cabotegravir extended-release; rilpivirine extended-release) Injection		
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Table of Contents

Overview
Coding
References
Clinical criteria
Document history

Overview

This document addresses the use of Cabenuva (cabotegravir extended-release; rilpivirine extended-release), approved by the Food and Drug Administration (FDA) as a complete regimen for the treatment of HIV 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. Cabenuva is a two-drug co-packaged product containing cabotegravir extended-release, an integrase strand transfer inhibitor (INSTI), and rilpivirine extended-release, a non-nucleoside reverse transcriptase inhibitor (NNRTI).

Cabenuva is administered via intramuscular (IM) gluteal injection monthly or every two months by a healthcare professional. Prior to starting therapy, healthcare professionals should carefully select individuals who agree to the injection dosing schedule and counsel individuals about the importance of adherence to help maintain viral suppression and reduce the risk of viral rebound and potential development of resistance with missed doses.

Oral lead-in therapy can be considered prior to the initiation of Cabenuva to assess the tolerability of cabotegravir and rilpivirine. The recommended oral lead-in regimen is Vocabria (cabotegravir) 30 mg in combination with Edurant (rilpivirine) 25 mg daily for one month. Cabenuva injections should be initiated on the last day of oral lead-in. The monthly dosing schedule initiates therapy at a dose of 600 mg/900 mg followed by 400 mg/600 mg every month thereafter. The every 2 months dosing schedule initiates therapy at a dose of 600 mg/900 mg monthly for two months and then every 2 months thereafter.

The Department of Health and Human Services (DHHS) has provided recommendations for the use of Cabenuva. DHHS recommends Cabenuva as an optimization strategy for individuals with HIV currently on oral antiretroviral therapy with documented viral suppression for 3 months to 6 months. Cabenuva candidates should be engaged with their health care provider and agree to make frequent visits to clinic for injections.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Cabenuva (cabotegravir extended-release; rilpivirine extended-release) Injection

Initial requests for Cabenuva (cabotegravir extended-release; rilpivirine extended-release) injection may be approved if the following criteria are met:

I. Individual is using to treat human immunodeficiency virus (HIV) infection; **AND**
II. Individual is antiretroviral treatment-experienced and has been virologically suppressed (HIV RNA less than 50 copies/mL) for at least three months (DHHS); **AND**
III. Individual has no history of treatment failure.

Continuation requests for Cabenuva (cabotegravir extended-release; rilpivirine extended-release) injection may be approved if the following criteria are met:

I. Individual is using to treat human immunodeficiency virus (HIV) infection; **AND**
II. Individual has maintained viral suppression (HIV RNA less than 50 copies/mL) while on Cabenuva therapy.

Cabenuva (cabotegravir extended-release; rilpivirine extended-release) injection may not be approved for the following:

I. Individual is using for pre-exposure prophylaxis (PrEP) of HIV infection; **OR**
II. May not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Cabenuva (cabotegravir extended-release; rilpivirine extended-release) Injection Quantity Limits

Drug	Limit
Cabenuva (cabotegravir extended-release; rilpivirine extended-release) 600 mg/900 mg kit	1 kit per 2 months
Cabenuva (cabotegravir extended-release; rilpivirine extended-release) 400 mg/600 mg kit	1 kit per month
Override Criteria	
Initiation or re-initiation of therapy using the every 2 months dosing schedule: May allow one additional Cabenuva (cabotegravir extended-release; rilpivirine extended-release) 600 mg/900 mg kit in the first two months of initiation or re-initiation of injection therapy.	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J0741	Injection, cabotegravir and rilpivirine 2mg/3mg [Cabenuva]

ICD-10 Diagnosis

B20	Human immunodeficiency virus [HIV] disease

Document History

Revised: 8/16/2024
Document History:

- 8/16/2024 – Annual Review: Add continuation criteria. Coding Reviewed: No changes.
- 8/18/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/18/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 5/20/2022 – Select Review: Remove requirement for oral lead in therapy. Wording and formatting changes. Coding reviewed: No changes.
- 3/14/2022 – Annual Review: Update Cabenuva quantity limit for new every 2 months dosing regimen. Coding reviewed: No changes.
- 11/19/2021 – Annual Review: No changes. Coding reviewed: No changes.
- 06/14/2021 – Select Review: Wording update to lead-in therapy criteria. Coding reviewed: No changes. Effective 10/1/2021 Added HCPCS J0741. Delete HCPCS J3490, C9077.
- 03/15/2021 – Select Review: Add new clinical criteria and quantity limit for Cabenuva. Coding Reviewed: Added HCPCS J3490. All diagnosis pend. Effective 7/1/2021 Added HCPCS C9077. Added ICD-10-CM B20.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 8, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services (DHHS). Last Updated: March 23, 2023. Available at clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new-guidelines. Accessed: July 14, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.