Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Cabotegravir extended-release; rilpivirine extended-release (Cabenuva)	MP-RX-FP-16-23	☒ MMM MA ☒ MMM Multihealth

Service Category

- ☐ Anesthesia
- ☐ Surgery
- ☐ Radiology Procedures
- ☐ Pathology and Laboratory Procedures
- ☐ Medicine Services and Procedures
- ☐ Evaluation and Management Services
- ☐ DME/Prosthetics or Supplies
- ☒ Part B Drugs

Service Description

This document addresses the use of Cabotegravir extended-release; rilpivirine extended-release (Cabenuva) , a drug approved by the Food and Drug Administration (FDA) for the treatment of 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.

Background Information

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.

Policy Name	Policy Number	Scope
Cabotegravir extended-release; rilpivirine extended-release (Cabenuva)	MP-RX-FP-16-23	☒ MMM MA ☒ MMM Multihealth

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.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

ICD-10	Description
B20	Human immunodeficiency virus [HIV] disease

Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Cabotegravir extended-release; rilpivirine extended-release (Cabenuva)	MP-RX-FP-16-23	☒ MMM MA ☒ MMM Multihealth

Medical Necessity Guidelines

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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

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.

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.

Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Cabotegravir extended-release; rilpivirine extended-release (Cabenuva)	MP-RX-FP-16-23	☒ MMM MA ☒ MMM Multihealth

Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

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
Exceptions	
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.	

Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 10, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; 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: September 21, 2022. Available at https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new-guidelines. Accessed: October 13, 2022.

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.

Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Cabotegravir extended-release; rilpivirine extended-release (Cabenuva)	MP-RX-FP-16-23	☒ MMM MA ☒ MMM Multihealth

Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption	N/A	11/30/2023

Reviewed: 08/18/2023