

Policy Name	Policy Number	Scope								
Cabotegravir extended-release; rilpivirine extended-release (Cabenuva)	MP-RX-FP-16-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth								
<p>Service Category</p> <table border="0"> <tr> <td><input type="checkbox"/> Anesthesia</td> <td><input type="checkbox"/> Medicine Services and Procedures</td> </tr> <tr> <td><input type="checkbox"/> Surgery</td> <td><input type="checkbox"/> Evaluation and Management Services</td> </tr> <tr> <td><input type="checkbox"/> Radiology Procedures</td> <td><input type="checkbox"/> DME/Prosthetics or Supplies</td> </tr> <tr> <td><input type="checkbox"/> Pathology and Laboratory Procedures</td> <td><input checked="" type="checkbox"/> Part B Drugs</td> </tr> </table>			<input type="checkbox"/> Anesthesia	<input type="checkbox"/> Medicine Services and Procedures	<input type="checkbox"/> Surgery	<input type="checkbox"/> Evaluation and Management Services	<input type="checkbox"/> Radiology Procedures	<input type="checkbox"/> DME/Prosthetics or Supplies	<input type="checkbox"/> Pathology and Laboratory Procedures	<input checked="" type="checkbox"/> Part B Drugs
<input type="checkbox"/> Anesthesia	<input type="checkbox"/> Medicine Services and Procedures									
<input type="checkbox"/> Surgery	<input type="checkbox"/> Evaluation and Management Services									
<input type="checkbox"/> Radiology Procedures	<input type="checkbox"/> DME/Prosthetics or Supplies									
<input type="checkbox"/> Pathology and Laboratory Procedures	<input checked="" type="checkbox"/> Part B Drugs									
<p>Service Description</p> <p>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.</p> <p>Background Information</p> <p>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).</p> <p>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.</p> <p>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.</p>										

Policy Name	Policy Number	Scope				
Cabotegravir extended-release; rilpivirine extended-release (Cabenuva)	MP-RX-FP-16-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth				
<p>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.</p>						
<p>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.</p>						
<p>Applicable Codes</p>						
<p>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.</p>						
<table border="1"> <thead> <tr> <th data-bbox="253 1236 323 1264">HCPCS</th> <th data-bbox="878 1236 1000 1264">Description</th> </tr> </thead> <tbody> <tr> <td data-bbox="253 1272 323 1299">J0741</td> <td data-bbox="428 1272 1130 1299">Injection, cabotegravir and rilpivirine 2mg/3mg [Cabenuva]</td> </tr> </tbody> </table>			HCPCS	Description	J0741	Injection, cabotegravir and rilpivirine 2mg/3mg [Cabenuva]
HCPCS	Description					
J0741	Injection, cabotegravir and rilpivirine 2mg/3mg [Cabenuva]					
<table border="1"> <thead> <tr> <th data-bbox="253 1346 323 1373">ICD-10</th> <th data-bbox="878 1346 1000 1373">Description</th> </tr> </thead> <tbody> <tr> <td data-bbox="264 1381 311 1409">B20</td> <td data-bbox="428 1381 967 1409">Human immunodeficiency virus [HIV] disease</td> </tr> </tbody> </table>			ICD-10	Description	B20	Human immunodeficiency virus [HIV] disease
ICD-10	Description					
B20	Human immunodeficiency virus [HIV] disease					

Policy Name	Policy Number	Scope
Cabotegravir extended-release; rilpivirine extended-release (Cabenuva)	MP-RX-FP-16-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
<p>Medical Necessity Guidelines</p> <p>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.</p> <p><i>Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.</i></p> <p><u>Cabenuva (cabotegravir extended-release; rilpivirine extended-release) Injection</u> Requests for Cabenuva (cabotegravir extended-release; rilpivirine extended-release) injection may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> 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. <p>Continuation requests for Cabenuva (cabotegravir extended-release; rilpivirine extended-release) injection may be approved if the following criteria are met:</p> <ul style="list-style-type: none"> 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. <p>Cabenuva (cabotegravir extended-release; rilpivirine extended-release) injection may not be approved for the following:</p> <ul style="list-style-type: none"> 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. 		

Policy Name	Policy Number	Scope
Cabotegravir extended-release; rilpivirine extended-release (Cabenuva)	MP-RX-FP-16-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> 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

- 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.
- DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
- 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.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

© CPT Only – American Medical Association

Medical Policy

Healthcare Services Department

Policy Name Cabotegravir extended-release; rilpivirine extended-release (Cabenuva)	Policy Number MP-RX-FP-16-23	Scope <input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth													
Policy History															
<table border="1"> <thead> <tr> <th>Revision Type</th> <th>Summary of Changes</th> <th>P&T Approval Date</th> <th>UM/CMPC Approval Date</th> </tr> </thead> <tbody> <tr> <td>Annual Review</td> <td>Add continuation request criteria.</td> <td>11/18/2024</td> <td>12/18/2024</td> </tr> <tr> <td>Policy Inception</td> <td>Elevance Health's Medical Policy adoption.</td> <td>N/A</td> <td>11/30/2023</td> </tr> </tbody> </table>	Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date	Annual Review	Add continuation request criteria.	11/18/2024	12/18/2024	Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023			
Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date												
Annual Review	Add continuation request criteria.	11/18/2024	12/18/2024												
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023												
<table border="1"> <tbody> <tr> <td>Annual Review</td> <td>Add continuation request criteria.</td> <td>11/18/2024</td> <td>12/18/2024</td> </tr> <tr> <td>Policy Inception</td> <td>Elevance Health's Medical Policy adoption.</td> <td>N/A</td> <td>11/30/2023</td> </tr> </tbody> </table>				Annual Review	Add continuation request criteria.	11/18/2024	12/18/2024	Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023				
Annual Review	Add continuation request criteria.	11/18/2024	12/18/2024												
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023												
Reviewed: 10/28/2024															