Cabenuva is a co-packaged product consisting of 2 different injectable drugs: cabotegravir, an integrase strand transfer inhibitor (INSTI), and rilpivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI). Both are once-monthly intramuscular injections given separately at the same time. Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed. Prior to initiating treatment with Cabenuva, oral lead-in dosing (available at no-charge) should be used for approximately 1 month to assess tolerability of cabotegravir and rilpivirine.

Cabenuva (cabotegravir/rilpivirine) will be considered for coverage when the following criteria are met:

**HUMAN IMMUNODEFICIENCY VIRUS TYPE-1 (HIV-1)**

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an HIV specialist; AND
3. Member has a diagnosis of HIV-1; AND
4. Member is currently virologically suppressed (HIV-1 RNA < 50 copies/mL) for at least 3 months; AND
5. Member is stable on a complete oral antiretroviral therapy (ART) regimen and there is a documented clinical reason for switching to Cabenuva; AND
6. Member does NOT have any of the following:
   a) Baseline resistance to either cabotegravir (Vocabria) or rilpivirine (Edurant);
   b) Prior virologic failure with any antiretroviral therapy;
   c) Active hepatitis B virus (HBV) infection.
7. **Dosage allowed/Quantity limit:** prior to initiating treatment with Cabenuva, oral lead-in should be used for at least 28 days to assess tolerability of cabotegravir and rilpivirine. Initiate injections (600 mg of cabotegravir and 900 mg of rilpivirine) on the last day of oral lead-in and continue with injections (400 mg of cabotegravir and 600 mg of rilpivirine) every month thereafter.

*If all the above requirements are met, the medication will be approved for 6 months.*

For **reauthorization**:
1. Chart notes must demonstrate that member remains virologically suppressed (HIV-1 RNA < 50 copies/mL) after initiation of treatment.

*If all the above requirements are met, the medication will be approved for an additional 12 months.*
CareSource considers Cabenuva (cabotegravir/rilpivirine) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>03/17/2021</td>
<td>New policy for Cabenuva (cabotegravir/rilpivirine) created.</td>
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<tr>
<td>10/06/2022</td>
<td>Updated benefit to medical due to OH single PBM.</td>
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References:


Effective date: 10/01/2022
Revised date: 10/06/2022