Apretude is an HIV-1 integrase strand transfer inhibitor (INSTI) initially approved by the FDA in 2021. It is indicated for the pre-exposure prophylaxis (PrEP) of HIV infection in at-risk adults and adolescents weighing at least 35 kg. Apretude is the first injectable medication for the prevention of HIV, taken every two months. The use of oral cabotegravir (Vocabria) as a lead-in prior to initiating therapy with Apretude is optional. Individuals must have a negative HIV test prior to initiating Apretude to prevent drug resistance.

Apretude (cabotegravir extended-release) will be considered for coverage when the following criteria are met:

**Pre-exposure Prophylaxis of HIV infection**

For initial authorization:
1. Member must be at least 12 years of age and weigh at least 35 kg; AND
2. Member is not a candidate for oral PrEP (ex. difficulty with adherence, significant renal disease, trouble swallowing pills etc.); AND
3. Member has had or will have completed an HIV RNA test before initial and subsequent injections; AND
4. Member is NOT taking any of the following concomitantly with Apretude:
   a) Rifampin;
   b) Carbamazepine, oxcarbazepine, phenobarbital or phenytoin;
   c) Other antiretroviral therapy.
5. **Dosage allowed/Quantity limit**: Initiate Apretude with a single 600-mg (3-mL) injection given 1 month apart for 2 consecutive months on the last day of an oral lead-in if used or within 3 days and continue with the injections every 2 months thereafter. Quantity Limit: 3 mL per 56 days.

*If all the above requirements are met, the medication will be approved for 2 months.*

For reauthorization:
1. Member has had or will have completed an HIV RNA test before injections.

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

CareSource considers Apretude (cabotegravir extended-release) 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>Event</th>
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</thead>
<tbody>
<tr>
<td>01/12/2022</td>
<td>New policy for Apretude created.</td>
</tr>
<tr>
<td>05/11/2023</td>
<td>Simplified HIV RNA testing requirement and removed 7-day window; added quantity limit.</td>
</tr>
<tr>
<td>08/16/2023</td>
<td>Rephrased trial of oral PrEP to patient is not a candidate for oral PrEP and added examples.</td>
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References:


Effective date: 01/01/2024
Revised date: 08/16/2023

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