

## RX.PA.058.MPC Apretude® (cabotegravir extended-release injectable)

### PURPOSE:

Apretude® is an HIV-1 integrase strand transfer inhibitor (INSTI) indicated for at-risk adults and adolescents weighing at least 35kg for PrEP to reduce the risk of sexually acquired HIV-1 infection. Maryland Physicians Care requires Prior Authorization for its use.

**Human Immunodeficiency Virus (HIV):** Approve Apretude if the member meets ONE of the following conditions (A or B)

#### A. INITIAL CRITERIA:

- a. Member is prescribed Apretude for pre-exposure prophylaxis (PrEP) of HIV  
**AND**
- b. Member must have a negative HIV-1 test immediately prior to initiating Apretude
  - i. If an antigen/antibody test provides negative results, this must be confirmed using an RNA-specific assay**AND**
- c. Member must weigh  $\geq 35$ kg  
**AND**
- d. Member must have documentation of contraindication to preferred PrEP medications Truvada (emtricitabine/tenofovir disoproxil fumarate) and Descovy (emtricitabine/tenofovir alafenamide) or intolerance to both medications following a 3 month trial of each medication (medication samples will not be accepted for demonstrating intolerance)  
**AND**
- e. For optional oral lead-in treatment: member has documented tolerance to 30-day oral lead-in trial therapy with Vocabria (cabotegravir) tablets (samples will not be accepted for lead-in trial)  
**AND**
- f. Member is not currently taking any of the following medications:
  - i. Carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin or rifapentine**AND**
- g. Prescriber attests to **ALL** of the following:
  - i. Member is considered high-risk for HIV infection
  - ii. Medication adherence counseling was performed

**B. Reauthorization Criteria:**

All prior authorization renewals are reviewed to determine medical necessity for continuation of therapy. Authorizations may be extended based upon:

- MPC Renewal:
  - Chart documentation from the prescriber showing the member has continued to respond to therapy
  - Member must have negative HIV-1 test within 30-days to support continuation of therapy
- Renewal from Previous Insurer:
  - Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria); AND
  - Provider has documented clinical response of the member to treatment

**C. Must be prescribed at a dose within the manufacturer’s dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.**

**D. Apretude will be considered investigational or experimental for any other use and will not be covered.**

**Approval Duration:**

- A. Initial Therapy: Approve for 3 months
- B. Continuation of Therapy: Approve for 6 months

**CPT Code(s):**

CPT Code	Description
J0739	Kit containing one 600mg/3mL single-dose vial of cabotegravir extended-release suspension

**References:**

1. Apretude® injection [prescribing information]. Research Triangle Park, NJ: ViiV Healthcare/GlaxoSmithKline; December 2021.



## REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual Review Change in Non-MPC renewal to renewal from previous insurer</i>	<i>02/2024</i>
<i>Annual Review</i>	<i>02/2023</i>
<i>Update to initial and reauthorization criteria with removal of specialist requirement, failure language with preferred alternatives and resistance testing. Added drug specific CPT code for Apretude</i>	<i>08/2022</i>
<i>P&amp;T Review</i>	<i>05/2022</i>
<i>New Policy</i>	<i>03/2022</i>

