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 Apreptude
    i. If an antigen/antibody test provides negative results, this must be confirmed using an RNA-specific assay
AND
c. Member must weigh ≥ 35kg
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
- Non-MPC Renewal:
  - Members who have previously been taking Apretude and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria); AND
  - Member has not been receiving medication samples for Apretude; 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
Annual Review	*02/2023*
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	*08/2022*
P&T Review	*05/2022*
New Policy	*03/2022*