**RX.PA.058.MPC HIV Pre-Exposure Prophylaxis (PrEP)**

**Apretude® (cabotegravir extended-release injectable)**
**Yeztugo® (lenacapavir tablets & lenacapavir injection)**

**The purpose of this policy is to define the prior authorization process:**
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.

Yeztugo® is a HIV-1 capsid inhibitor, is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition.

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

**A. INITIAL CRITERIA:**
- Member is prescribed either Apretude or Yeztugo for pre-exposure prophylaxis (PrEP) of HIV
- Member must have a negative HIV-1 test immediately prior to initiating Apreptude or Yeztugo
    i. If an antigen/antibody test provides negative results, this must be confirmed using an RNA-specific assay
- Member must weigh ≥ 35kg
- 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)
- Prescriber attests to **ALL** of the following:
    i. Member is considered high-risk for HIV infection
    ii. Medication adherence counseling was performed

**For Apretude Only:**
- 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)
- Member is not currently taking any of the following medications:
    i. Carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin or rifapentine

**For Yeztugo Only:**

- Must have a trial and failure, contraindication, or intolerance to Apretude for at least 3 months
  - (medication samples will not be accepted for demonstrating intolerance)

**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 and Yeztugo 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 |
| J0799 | Fda approved prescription drug, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv) |

## References:

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

2. Yeztugo® [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; June 2025.

## REVIEW HISTORY

| DESCRIPTION OF REVIEW / REVISION | DATE APPROVED |
|---|---|
| *Annual Review* | *02/2026* |
| *Addition of Yeztugo prior authorization criteria*<br>*Change of Policy name from Apretude to HIV PreP* | *09/2025* |
| *Annual Review* | *02/2025* |
| *Annual Review*<br>*Change in Non-MPC renewal to renewal from previous insurer* | *02/2024* |
| *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* |