

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 $\geq 35\text{kg}$
- For members that are cis-gender male or transgender female:
 - i. 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)
- For members that are cis-gender female or transgender male:
 - i. Member must have documentation of contraindication to preferred PrEP medication Truvada (emtricitabine/tenofovir disoproxil fumarate) or intolerance following a 3 month trial of the 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
<i>Change to address requirements for Descovy treatment failure</i>	<i>04/2026</i>
<i>Annual Review</i>	<i>02/2026</i>
<i>Addition of Yeztugo prior authorization criteria Change of Policy name from Apretude to HIV PreP</i>	<i>09/2025</i>
<i>Annual Review</i>	<i>02/2025</i>
<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&T Review</i>	<i>05/2022</i>
<i>New Policy</i>	<i>03/2022</i>