CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Apretude (cabotegravir extended-release)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office
STATUS	Prior Authorization Required

Apretude is an HIV-1 integrase strand transfer inhibitor (INSTI) initially approved by the FDA in December 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 must have documentation of a negative HIV RNA test result within 1 week before initial injection; AND
3. Member must have a trial and failure of a preferred generic oral PrEP therapy; AND
4. Member is NOT taking any of the following concomitantly with Apretude:
   a) Rifampin;
   b) Carbamazepine, oxcarbazepine, phenobarbital or phenytoin;
   c) Any 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.

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

For **reauthorization**:

1. Member must have documentation of a negative HIV RNA test within the last 7 days.

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.

DATE	ACTION/DESCRIPTION
01/12/2022	New policy for Apretude created.

References:

1. Apretude [package insert]. Research Triangle Park, NC; GlaxoSmithKline. December 2021.
2. Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update. Center for Disease Control and Prevention.: Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021. Accessed on January 13, 2022.
3. Landovitz RJ, Li S, Eron Jr JJ, et al. Tail-phase safety, tolerability, and pharmacokinetics of longacting injectable cabotegravir in HIV-uninfected adults: a secondary analysis of the HPTN 077 trial. The Lancet HIV. 2020
4. Landovitz RJ, Donnell D, Clement ME, et al. Cabotegravir for HIV prevention in cisgender men and transgender women. N Engl J Med. 2021;385(7):595-608.
5. Marzinke MA, Grinsztejn B, Fogel JM, et al. Characterization of human immunodeficiency virus (HIV) infection in cisgender men and transgender women who have sex with men receiving injectable cabotegravir for HIV prevention: HPTN 083. Infect Ds. 2021.

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