

Apretude® (cabotegravir intramuscular injection)

When requesting Apretude (cabotegravir intramuscular injection), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

Apretude is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection.

Coverage Guidelines

Pre-exposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)-1 Infection

The individual must meet **all** of the following criteria:

- Is at least 35 kg; AND
- Has negative HIV-1 test result within 1 week prior to the dose of Apretude; AND
- Has no signs and symptoms of acute HIV infection; AND
- Apretude is being prescribed as part of a comprehensive HIV-1 prevention strategy (i.e., adherence to administration schedule and safer sex practices, including condoms); AND
- Apretude is being prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.

Approval duration: 12 months

Dosing Recommendation

If an oral lead-in is used, initiation injections should be administered on the last day of oral lead-in or within 3 days thereafter. The recommended initiation injection doses of Apretude in individuals is a single 600-mg (3-mL) intramuscular injection of Apretude given 1 month apart for 2 consecutive months

After the 2 initiation injection doses given consecutively 1 month apart, the recommended continuation injection dose of Apretude is a single 600-mg (3-mL) intramuscular injection of Apretude every 2 months.

References

1. Apretude® injectable suspension [prescribing information]. Research Triangle Park, NC: ViiV; December 2021.
2. Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. Available at: <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Published December 2021. Accessed on: December 22, 2021.
3. Saag MS, Gandhi RT, Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults. 2020 recommendations of the International Antiviral Society-USA Panel. *JAMA*. 2020;324(16):1651-1669.