

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 in at-risk adults and adolescents weighing at least 35 kg 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:

- Weighs at least 35 kg;
- Has a negative HIV-1 test result within 1 week prior to the dose of Apretude;
- Has no signs and symptoms of acute HIV infection;
- 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);
- Apretude is being prescribed by or in consultation with a physician who specializes in the management 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; September 2024.
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://stacks.cdc.gov/view/cdc/112360>. Published December 2021. Accessed on: February 3, 2025.
3. Ghandi RT, Bedimo R, and Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults. 2022 recommendations of the International Antiretroviral Society-USA Panel. *JAMA*. 2023;329(1):63-84.
4. Guidelines on long-acting injectable cabotegravir for HIV prevention. Geneva: World Health Organization; 2022. License: CCBY-NC-SA 3.0 IGO. Available at: <https://www.who.int/publications/i/item/9789240054097>. Accessed on February 3, 2025.