



Cabotegravir (CAB-LA) for PrEP*

Prescribing Information

Dosing/Administration:

1. Direct to Injection Dosing Schedule:

Table 2. Recommended Dosing Schedule (Direct to Injection) for Pre-exposure Prophylaxis in Adults and Adolescents Weighing at Least 35 kg

Intramuscular (Gluteal) Initiation Injection (Month 1 and Month 2)	Intramuscular (Gluteal) Continuation Injection (Month 4 and Every 2 Months Onwards)
APRETUDE ^a 600 mg (3 mL)	APRETUDE ^a 600 mg (3 mL)

^a Individuals may be given APRETUDE up to 7 days before or after the date the individual is scheduled to receive the injections.

2. Dosing with Optional Oral Lead In:

Dosing with OPTIONAL oral lead in

Table 1. Recommended Dosing Schedule (with Oral Lead-in) for Pre-exposure Prophylaxis in Adults and Adolescents Weighing at Least 35 kg

Oral Lead-in (at Least 28 Days)	Intramuscular (Gluteal) Initiation Injection (Month 2 and Month 3)	Intramuscular (Gluteal) Continuation Injection (Month 5 and Every 2 Months Onwards)
Oral cabotegravir 30 mg by mouth once daily for 28 days	APRETUDE ^a 600 mg (3 mL)	APRETUDE ^b 600 mg (3 mL)

^a Should be administered on the last day of oral lead-in or within 3 days thereafter.

^b Individuals may be given APRETUDE up to 7 days before or after the date the individual is scheduled to receive the injections.



3. Dosing after Missed Injections

Table 3. Injection Dosing Recommendations after Missed Injections

Time since Last Injection	Recommendation
If second injection is missed and time since first injection is:	
Less than or equal to 2 months	Administer 600-mg (3-mL) gluteal intramuscular injection of APRETUDE as soon as possible, then continue to follow the every-2-month injection dosing schedule.
Greater than 2 months	Restart with 600-mg (3-mL) gluteal intramuscular injection of APRETUDE, followed by a second 600-mg (3-mL) initiation injection dose 1 month later. Then continue to follow the every-2-month injection dosing schedule thereafter.
If third or subsequent injection is missed and time since prior injection is:	
Less than or equal to 3 months	Administer 600-mg (3-mL) intramuscular injection of APRETUDE as soon as possible, then continue with the every-2-month injection dosing schedule.
Greater than 3 months	Restart with 600-mg (3-mL) gluteal intramuscular injection of APRETUDE, followed by the second 600-mg (3-mL) initiation injection dose 1 month later. Then continue with the every-2-month injection dosing schedule thereafter.

CAB-LA Considerations:

- Potential Risk of Resistance with Apretude

There is a potential risk of developing resistance to Apretude if an individual acquires HIV-1 either before or while taking Apretude or following discontinuation of Apretude. To minimize this risk, it is essential to clinically reassess individuals for risk of HIV-1 acquisition and to **test before each injection** to confirm HIV-1 negative status. Individuals who are confirmed to have HIV-1 infection must transition to a complete HIV-1 treatment regimen.

Alternative forms of PrEP should be considered following discontinuation of Apretude for those individuals at continuing risk of HIV-1 acquisition and initiated within 2 months of the final injection of Apretude.



Patient Assistance Options

Read more [here](#).

1. Apretude Savings Program

<https://www.apretudecopayprogram.com/>

The Apretude Savings Program may help consumers with their out-of-pocket costs for prescribed Apretude.

- The program is for commercially insured consumers prescribed Apretude
- If approved, consumers may pay as little as \$0 copay
- Consumers must be a resident of the United States or US territories
- Up to \$7,850 every calendar year.
- Medicare-eligible consumers and consumers enrolled in government-funded programs are not eligible.

2. Patient Assistance Program (PAP)

<https://www.viivconnect.com/for-providers/patient-enrollment/>

Eligibility for PAP, patients must:

- Live in one of the 50 states, the District of Columbia, or Puerto Rico
 - Have a household income less than or equal to 500% of the Federal Poverty Level based on household size
 - Not be eligible for Medicaid or Puerto Rico's Government Health Plan, Mi Salud
- And either:
- Have no prescription drug coverage, or
 - Have a Medicare Part B, Medicare Part D, or Medicare Advantage Plan, and have spent at least \$600 or more on out-of-pocket prescription expenses during the current calendar year, or
 - Have a private insurance plan limited to generic-only coverage, outpatient use only, or therapeutic class exclusion (non-coverage) of drug

Resources for Healthcare Professionals

1. [Prescribing Information](#)
2. [Readiness Considerations Checklist](#)
3. [Getting Started Overview](#)
 - a. Includes medication acquisition options
 - i. 1. Speciality Pharmacy
 - ii. 2. Buy and Bill
4. [Apretude Ordering Guide](#)

**Most of this information is from the drug company, ViiV Healthcare. We will share more real-world information and context moving forward.*