



STARTING THE CONVERSATION WITH YOUR PATIENTS

rewrite

THE STORY OF HIV PREVENTION

with the first and only **long-acting**
injectable PrEP option

 **Apretude**
cabotegravir 200 mg/mL
extended-release injectable suspension
for PrEP pre-exposure prophylaxis

PrEP=pre-exposure prophylaxis.

APRETUDE is administered as an intramuscular injection by a healthcare professional every 2 months after 2 initiation injections administered 1 month apart.

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. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: RISK OF DRUG RESISTANCE WITH USE OF APRETUDE FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED EARLY HIV-1 INFECTION

Individuals must be tested for HIV-1 infection prior to initiating APRETUDE or oral cabotegravir, and with each subsequent injection of APRETUDE, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. Drug-resistant HIV-1 variants have been identified with use of APRETUDE by individuals with undiagnosed HIV-1 infection. Do not initiate APRETUDE for HIV-1 PrEP unless negative infection status is confirmed. Individuals who become infected with HIV-1 while receiving APRETUDE for PrEP must transition to a complete HIV-1 treatment regimen.

Please see additional Important Safety Information throughout. Please click for full [Prescribing Information](#), including Boxed Warning, for APRETUDE.

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Could any of your patients on PrEP benefit from APRETUDE?

Prepare to discuss APRETUDE with your patients



SUPERIOR:

Provided greater protection from HIV than a daily oral PrEP

Significantly lower incidence of HIV-1 infection—**69% (12* vs 39 [P=0.0003])** and **90% (3† vs 36 [P<0.0001])**—vs a daily oral PrEP demonstrated in HPTN 083 and HPTN 084.^{1-3‡§}

- Of the incident and prevalent infections in the APRETUDE arm, INSTI resistance-associated mutations (RAMs) were detected in 4 and 1 participant(s), respectively, in HPTN 083,^{1,4} and no major RAMs were detected in HPTN 084¹
- Of the incident and prevalent infections in the TDF/FTC arm, NRTI RAMs were detected in 4 and 2 participants, respectively, in HPTN 083,⁴ and 1 incident infection with an NRTI RAM was detected in HPTN 084⁵



CONFIDENT:

Every-2-month dosing means no more daily PrEP pills^{||}

Adherence you can confirm with as few as 6 in-office injections per year^{||}

- See additional dosing and HIV-1 testing information at APRETUDEHCP.com

*In HPTN 083, the primary analysis showed a 66% reduction in the risk of acquiring HIV-1 infection (hazard ratio [95% CI]: 0.34 [0.18-0.62]). Further testing revealed 1 of the infections on APRETUDE to be prevalent, yielding a 69% reduction in the risk of incident HIV-1 infection relative to TDF/FTC (hazard ratio [95% CI]: 0.31 [0.16-0.58]); incidence rate was 0.37/100 person-years for APRETUDE vs 1.22/100 person-years for TDF/FTC.¹

†In HPTN 084, the primary analysis showed an 88% reduction in the risk of acquiring HIV-1 infection (hazard ratio [95% CI]: 0.12 [0.05-0.31]). Further testing revealed 1 of the infections on APRETUDE to be prevalent, yielding a 90% reduction in the risk of incident HIV-1 infection relative to TDF/FTC (hazard ratio [95% CI]: 0.10 [0.04-0.27]); incidence rate was 0.15/100 person-years for APRETUDE vs 1.85/100 person-years for TDF/FTC.¹

‡HPTN 083 (N=4566) was a randomized, double-blind, placebo-controlled noninferiority trial of the safety and efficacy of APRETUDE compared with daily oral TDF/FTC for HIV-1 prevention in HIV-1-uninfected men and transgender women who have sex with men and have evidence of high-risk behavior for HIV-1 infection. The primary endpoint was the rate of incident HIV-1 infections among participants randomized to daily oral cabotegravir for up to 5 weeks followed by intramuscular injections of APRETUDE every 2 months compared with daily oral TDF/FTC (corrected for early stopping). The trial included the prespecified ability to test for superiority of APRETUDE over TDF/FTC.^{1,2}

§HPTN 084 (N=3224) was a randomized, double-blind, placebo-controlled superiority trial of the safety and efficacy of APRETUDE compared with daily oral TDF/FTC for HIV-1 prevention in adult, uninfected cisgender women at risk of acquiring HIV-1. The primary endpoint was the rate of incident HIV-1 infections among participants randomized to daily oral cabotegravir for up to 5 weeks followed by injections of APRETUDE compared with oral TDF/FTC (corrected for early stopping).^{1,3}

||While on APRETUDE.

¶After optional oral lead-in and initiation injections.¹

CI=confidence interval; HPTN=HIV Prevention Trials Network; INSTI=integrase strand transfer inhibitor; NRTI=nucleoside reverse transcriptase inhibitor; PrEP=pre-exposure prophylaxis; TDF/FTC=tenofovir disoproxil fumarate/emtricitabine.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

- Do not use APRETUDE in individuals:
 - with unknown or positive HIV-1 status
 - with previous hypersensitivity reaction to cabotegravir
 - receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and rifapentine

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INCLUSIVE:

Evaluated across a diverse population

The most diverse and comprehensive participant population in HIV prevention trials conducted to date^{1-3,§}

- Designed to include key populations at risk for HIV-1: Trials included HIV-1–negative cisgender men and transgender women who have sex with men and cisgender women, with the majority under age 30^{1-3,6}
- In the US, HPTN 083 was inclusive of the Black/African American and Latinx communities, who comprise the greatest percentage of new HIV diagnoses^{1,2,7}



SAFETY PROFILE¹:

Demonstrated in ~4000 participants

- The most common adverse reactions (all grades) observed in at least 1% of subjects receiving APRETUDE were ISRs, diarrhea, headache, pyrexia, fatigue, sleep disorders, nausea, dizziness, flatulence, abdominal pain, vomiting, myalgia, rash, decreased appetite, somnolence, back pain, and upper respiratory tract infection
 - In HPTN 083, 82% of participants who received APRETUDE experienced at least 1 ISR; 97% were Grade 1 or 2, with 3% of participants experiencing Grade 3 and no Grade 4 reactions reported
 - In HPTN 084, 38% of participants who received APRETUDE experienced at least 1 ISR; >99% were Grade 1 or 2, with <1% of participants experiencing Grade 3 and no Grade 4 reactions reported
- 6% of participants receiving APRETUDE and 4% receiving TDF/FTC in HPTN 083, and 1% of participants in both arms of HPTN 084, discontinued due to adverse events (all causality)



Now that you understand what APRETUDE may offer, you and your patients can have productive conversations about whether APRETUDE is right for them

HPTN=HIV Prevention Trials Network; ISR=injection-site reaction; TDF/FTC=tenofovir disoproxil fumarate/emtricitabine.


IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Comprehensive Management to Reduce the Risk of HIV-1 Infection:

- Use APRETUDE as part of a comprehensive prevention strategy, including adherence to the administration schedule and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs). APRETUDE is not always effective in preventing HIV-1 acquisition. Risk for HIV-1 acquisition includes, but is not limited to, condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high prevalence area or network. Inform, counsel, and support individuals on the use of other prevention measures (e.g., consistent and correct condom use; knowledge of partner(s) HIV-1 status, including viral suppression status; regular testing for STIs)

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Clinical overview

This section includes questions that a patient may have regarding how well APRETUDE works and how it differs from and compares with daily oral PrEP options.

Q What is APRETUDE? How is it different from other PrEP options?

A APRETUDE is the first and only long-acting injectable PrEP. Unlike daily oral PrEP, APRETUDE is an injection administered by a healthcare provider. After 2 initiation injections given 1 month apart, APRETUDE is administered every 2 months, which means you no longer need to take a daily pill to help prevent infection with HIV.¹

Q How long has APRETUDE been around?

A APRETUDE was approved by the FDA in December 2021 as the first and only long-acting injectable PrEP option. It offers another option for people who find taking a daily oral PrEP a challenge, or who would simply prefer a long-acting option.^{1,8,9}

Q Can APRETUDE reduce my risk of getting HIV?

A Yes! Studies show that PrEP can help you stay HIV negative. And, while clinical results may vary, in 2 clinical trials, APRETUDE provided superior protection from HIV compared with a daily oral PrEP. Let me give you some more facts¹:

- In Study 1, with 4566 cisgender men and transgender women, HIV transmissions occurred 3 times less often with APRETUDE compared with a daily oral PrEP—better protection with a 69% lower risk of getting HIV (specifically, 12 people became HIV positive on APRETUDE, compared with 39 people on daily oral PrEP)
- In Study 2, with 3224 cisgender women, HIV transmissions occurred 12 times less often with APRETUDE compared with a daily oral PrEP—better protection with a 90% lower risk of getting HIV (specifically, 3 people became HIV positive on APRETUDE, compared with 36 people on daily oral PrEP)

Q Who can take APRETUDE?

A APRETUDE was approved for use based on some of the most diverse PrEP studies ever conducted. There were 2 separate clinical studies with nearly 8000 participants, including HIV-negative cisgender men and transgender women who have sex with men, and cisgender women—all who were at risk for getting HIV.^{1,2}

APRETUDE is not for use in people who are HIV positive or whose HIV status is unknown. It also should not be used in people taking certain medications.¹

FDA=US Food and Drug Administration; PrEP=pre-exposure prophylaxis.



IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Comprehensive Management to Reduce the Risk of HIV-1 Infection: (cont'd)

- Use APRETUDE only in individuals confirmed to be HIV-1 negative. HIV-1 resistance substitutions may emerge in individuals with undiagnosed HIV-1 infection who are taking only APRETUDE, because APRETUDE alone does not constitute a complete regimen for HIV-1 treatment. Prior to initiating APRETUDE, ask seronegative individuals about recent (in past month) potential exposure events and evaluate for current or recent signs or symptoms consistent with acute HIV-1 infection (e.g., fever, fatigue, myalgia, skin rash). If recent (<1 month) exposures to HIV-1 are suspected or clinical symptoms consistent with acute HIV-1 infection are present, use a test approved or cleared by the FDA as an aid in the diagnosis of acute HIV-1 infection

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Clinical overview

Q If APRETUDE showed superior efficacy to a daily oral PrEP in 2 clinical trials, does that mean daily oral PrEP does not work well?

A No, in fact, daily oral PrEP has been around for over 10 years, and it has been proven to be an effective option in reducing the risk of acquiring HIV. But protection from HIV with oral PrEP options requires you to take it every day as prescribed, which we know can be a challenge for some people. Adherence is still important with a long-acting PrEP option like APRETUDE, but it does allow for the option of an every-2-month dosing schedule instead of taking a daily pill.^{1,8,10,11}

Q Does PrEP, including APRETUDE, prevent sexually transmitted infections?

A All PrEP options, including APRETUDE, are only proven to help prevent HIV. APRETUDE does not prevent other sexually transmitted infections, such as herpes, syphilis, gonorrhea, or chlamydia. To reduce the risk of getting sexually transmitted infections, you should also practice safer sex, including using a latex or polyurethane condom.¹

Q What are the most common side effects of APRETUDE?

A In clinical trials, which included ~4000 participants on APRETUDE, the most common side effect was injection-site reactions. This included pain, tenderness, hardened mass or lump, swelling, bruising, redness, itching, warmth, loss of sensation at the injection site, abscess, and discoloration.¹

Aside from injection-site reactions, other common side effects reported in $\geq 1\%$ of patients treated with APRETUDE were diarrhea, headache, fever, tiredness, sleep problems, nausea, dizziness, passing gas, stomach pain, vomiting, muscle pain, rash, loss of appetite, drowsiness, back pain, and upper respiratory infection.¹

PrEP=pre-exposure prophylaxis.




IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Comprehensive Management to Reduce the Risk of HIV-1 Infection: (cont'd)

- When using APRETUDE, HIV-1 testing should be repeated prior to each injection and upon diagnosis of any other STIs
- If an HIV-1 test indicates possible HIV-1 infection, or if symptoms consistent with acute HIV-1 infection develop following an exposure event, additional HIV testing to determine HIV status is needed. If HIV-1 infection is confirmed, then transition the individual to a complete HIV-1 treatment
- Counsel HIV-1 uninfected individuals to strictly adhere to the recommended dosing and testing schedule for APRETUDE

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Patient identification

The questions in this section ask whom PrEP is appropriate for and who might benefit from a long-acting option such as APRETUDE.

Q Am I at risk for HIV?

A While not a complete list, some of the risk factors for getting HIV include not using a condom during sex, having had or currently having a sexually transmitted infection, and not knowing the HIV status of your sexual partner(s).¹

In fact, the more people in your sexual network, the more likely you are to be exposed to sexually transmitted infections, including HIV. Certain cities and parts of the country have higher rates of HIV than others, so where you live and travel can also add to your risk.¹²

If you're concerned that you may have been exposed to HIV, we should test for HIV. If you test negative, going on PrEP can help prevent HIV. We can have a discussion to see whether a daily oral, or a long-acting (every-2-month) injectable like APRETUDE, would be the right fit for you and your lifestyle.¹

Q Should I be on PrEP?

A Sexually active individuals—regardless of sexual orientation, gender identity, or race—can get HIV.

It is important for everyone to be aware of options to help protect themselves from HIV. If you are concerned about your risk for HIV, let's have a conversation about steps you can take to protect yourself, such as using latex or polyurethane condoms, knowing your HIV status and that of your partners, getting tested for other STIs, and learning about PrEP.¹

Women represent about 1 in 5 new HIV diagnoses each year. 55% of women diagnosed with HIV are Black and 18% are Hispanic or Latina.^{7,13}



Q Is APRETUDE just for men who have sex with men?

A No. Anyone, regardless of sexual orientation, gender identity, or race, can get HIV. APRETUDE was studied in men, and transgender women who have sex with men and cisgender women, all groups of people who are greatly affected by HIV. And, the results of 2 separate studies showed that APRETUDE was more effective at preventing people from getting HIV than a daily oral PrEP.¹ (For more information about these clinical trials, go to the "Clinical overview" section on pages 4 and 5.)

Q How do I know if APRETUDE is the right PrEP for me?

A If you find taking a daily pill a challenge, or would prefer a less-frequent dosing option, and you are able to commit to every-2-month injections, then APRETUDE may be a good option for you.^{1,8,9,11}



PrEP=pre-exposure prophylaxis; STI=sexually transmitted infection.


IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Potential Risk of Resistance with APRETUDE:

- There is a potential risk of developing resistance to APRETUDE if an individual acquires HIV-1 either before, while taking, 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. 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

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Patient identification

Before starting any patient on APRETUDE, be sure to counsel them on the following¹:

- APRETUDE should be used for PrEP as part of an overall HIV-1–infection prevention strategy, including:
 - Adherence to the administration schedule. Discuss the importance of maintaining scheduled appointments to help reduce the risk of HIV-1 infections and the development of resistance
 - Safer sex practices, including condoms and other prevention measures such as knowledge of their partner's/partners' HIV-1 status, to reduce the risk of STIs
- APRETUDE should only be used by individuals confirmed to be HIV-1 negative
 - There is a potential risk of developing resistance to APRETUDE if HIV-1 infection is acquired either before or while taking APRETUDE, so testing for HIV-1 will be required before each injection to confirm their HIV-1–negative status
 - If recent (<1 month) exposures to HIV-1 are suspected or clinical symptoms consistent with acute HIV-1 infection are present, use a test approved or cleared by the FDA as an aid in the diagnosis of acute or primary HIV-1 infection
 - If HIV-1 infection is confirmed while on APRETUDE, then the patient must be transitioned to a complete HIV-1 treatment regimen
- As an extended-release injectable PrEP, APRETUDE may remain in their system for 12 months or longer

Please see the Patient Counseling Information for more details, included in the accompanying full Prescribing Information.

FDA=US Food and Drug Administration; PrEP=pre-exposure prophylaxis; STI=sexually transmitted infection.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Long-Acting Properties and Potential Associated Risks with APRETUDE:

- Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). Take the prolonged-release characteristics of cabotegravir into consideration and carefully select individuals who agree to the required every-2-month injection dosing schedule because non-adherence to every-2-month injections or missed doses could lead to HIV-1 acquisition and development of resistance

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Because APRETUDE is the first and only long-acting injectable PrEP available, this section covers questions your patients may have about the dosing and administration.

Q How often will I receive injections?

A APRETUDE requires 2 initiation injections, given 1 month apart. After the initiation injections, you'll come into the office every 2 months to receive an injection of APRETUDE.¹

Q How do I start taking APRETUDE?

A Once we've determined that APRETUDE is right for you, we will need to choose a date for your APRETUDE injection—we call that your Target Appointment Date.* Let's say we select the 18th as your Target Appointment Date. That means you will receive your initiation injections for 2 months in a row on the 18th of each month.

After that, you will need to come to my office for your APRETUDE injection on the 18th of every other month. It's important to adhere to the dosing schedule, but if you can't make it on the 18th, there's a 7-day window on either side of that day that provides some flexibility. However, I strongly recommend you try to stay with your Target Appointment Date.¹

Prior to your first injection—and again before every injection of APRETUDE—we will need to give you an HIV test to confirm that you are HIV negative.¹

Q Does APRETUDE come as a pill?

A One of the benefits of APRETUDE is not to have to remember to take a daily PrEP pill. But there is an oral version we can use for approximately 1 month to see how your body responds to the medication.¹ If there are no problems, we could move you to the injectable form.

The oral version may also be used in the event you have to miss an injection visit.¹ (If your patient has any questions about missed injection appointments, see *What if I can't keep up with my appointments or I'm traveling and miss my Target Appointment Date?*)

Q How often will I get tested for HIV while taking APRETUDE?

A You will be tested to confirm you are HIV negative before starting APRETUDE, and again before each injection of APRETUDE to ensure you have remained HIV negative. Testing also ensures that anyone who becomes HIV positive can be immediately transitioned to a complete HIV treatment regimen.¹

Potential exposure to HIV may require another HIV test to confirm your negative status.

*Target Appointment Date=the date you will receive your APRETUDE injection.
PrEP=pre-exposure prophylaxis.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity Reactions:

- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with APRETUDE
- Discontinue APRETUDE immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated

Hepatotoxicity:

- Hepatotoxicity has been reported in a limited number of individuals receiving cabotegravir with or without known pre-existing hepatic disease or identifiable risk factors
- Clinical and laboratory monitoring should be considered and APRETUDE should be discontinued if hepatotoxicity is suspected and individuals managed as clinically indicated

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Q Where on my body will I receive the injection?

A APRETUDE is injected into the buttocks. Only a healthcare provider can administer the injection.¹

Q Do the injections hurt?

A In both of the clinical studies, the most common side effects for APRETUDE were injection-site reactions. Injection-site reactions in the clinical studies included pain, tenderness, hardened mass or lump, swelling, bruising, redness, itching, warmth, loss of sensation at the injection site, abscess, and discoloration.¹

- In Study 1, with cisgender men and transgender women, 82% of participants reported an injection-site reaction. Of those, 41% reported a mild reaction, 56% reported a moderate reaction, and 3% said the reaction was severe
- In Study 2, with cisgender women, 38% of participants had an injection-site reaction. Here, 66% had a mild reaction and 34% a moderate reaction. Less than 1% said it was a severe reaction

Q Can I return to regular activities right after my injection appointment?

A After the injection, you may be fine to return to your daily activities. If there are any concerns, we will discuss them.

Q Does someone need to drive me to and from my appointment?

A You can drive yourself to and from your appointment.

Q What if I can't keep up with my appointments or I'm traveling and miss my Target Appointment Date?

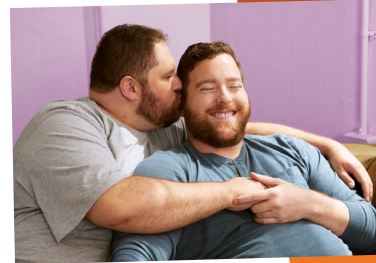
A As with any other form of PrEP, it's very important that you adhere to the recommended dosing schedule in order for it to be effective.¹

The good news is, once you start APRETUDE, there is some flexibility around when you need to receive your injection. We have from 7 days before to 7 days after your Target Appointment Date.¹

If we know in advance you need to miss an injection by more than that 7-day window, we can shift you to oral cabotegravir for up to 2 months to replace the missed injection. But, if you need to go longer than 2 months, we would have to shift you to a different daily oral PrEP to maintain protection and then shift back to APRETUDE injections when you are again able to adhere to the recommended dosing schedule.¹

If something comes up and you miss your injection by more than the 7-day window without planning in advance, we will need to reconfirm that you are still HIV negative and that APRETUDE is still the right fit for you and your life before we resume.¹

PrEP=pre-exposure prophylaxis.



IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Depressive Disorders:

- Depressive disorders (including depression, depressed mood, major depression, persistent depressive disorder, suicidal ideation or attempt) have been reported with APRETUDE
- Promptly evaluate patients with depressive symptoms

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Cost and coverage

This section provides answers to questions about the programs available to help cover the costs of APRETUDE.

Q How much does APRETUDE cost? Will my insurance pay for it?

A The amount you'll pay for APRETUDE depends largely on your insurance.

There is a website, ViiVConnect, which can help us determine exactly what your co-pay will be and whether you are eligible for any of the company's patient support programs.

Q What if my insurance company wants me to go on generic PrEP?

A Your insurance may require that you get prescribed daily oral PrEP first. However, if we determine that a long-acting PrEP option may be the best fit for you, we might be able to work with them so you can start APRETUDE.¹ If needed, we'll contact your insurance company and work toward getting your prescription.

Q What if I don't have insurance? Is there a patient assistance program?

A There is a website, ViiVConnect, which can help us determine whether you are eligible for any of the company's patient support programs. Let's enter your information and find out.

I can also reach out to someone at ViiV to see what other options there are to help you get started on APRETUDE.

PrEP=pre-exposure prophylaxis.



IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Risk of Reduced Drug Concentration of APRETUDE Due to Drug Interactions:

- The concomitant use of APRETUDE and other drugs may result in reduced drug concentration of APRETUDE
- Refer to the full Prescribing Information for steps to prevent or manage these possible and known significant drug interactions, including dosing recommendations. Consider the potential for drug interactions prior to and during use of, and after discontinuation of APRETUDE; review concomitant medications during use of APRETUDE


ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 1\%$, all grades) with APRETUDE were injection site reactions, diarrhea, headache, pyrexia, fatigue, sleep disorders, nausea, dizziness, flatulence, abdominal pain, vomiting, myalgia, rash, decreased appetite, somnolence, back pain, and upper respiratory tract infection.

DRUG INTERACTIONS

- Refer to the full Prescribing Information for important drug interactions with APRETUDE
- Drugs that induce UGT1A1 may significantly decrease the plasma concentrations of cabotegravir

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Why choose APRETUDE?

- APRETUDE is the first and only long-acting* injectable PrEP¹
- Designed to continuously help prevent getting HIV when taken every other month as prescribed¹
- No daily PrEP pills to remember or keep track of while your clients are receiving their regular APRETUDE injections^{1†}
- After 2 initial injections given 1 month apart, APRETUDE is given as few as 6 times a year¹

*APRETUDE is given every other month by a healthcare provider after initiation injections have been given 1 month apart for 2 consecutive months.¹

†Your client may be prescribed about a month of once-daily starter pills to see how well their body tolerates the medicine.¹

Getting started on APRETUDE

TEST

- Confirm patient is HIV-1 negative immediately prior to each injection of APRETUDE¹

VERIFY

- Out-of-pocket costs for patient based on their insurance coverage
 - ViiVConnect can help determine costs for your patient
- Eligibility for any ViiV-sponsored patient support programs

SCHEDULE

- Determine the most appropriate Target Appointment Date and begin scheduling their injections
 - If using the optional oral lead-in, factor this into scheduling



QUESTIONS?

Speak with your APRETUDE Territory Account Manager to make sure you're ready to prescribe APRETUDE and to schedule an introduction with your Field Reimbursement Manager, who will help with questions on access and acquisition after APRETUDE has been prescribed

PrEP=pre-exposure prophylaxis.

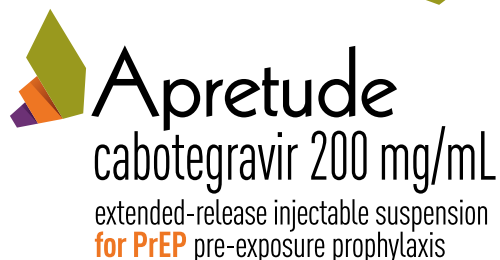
IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS

- **Lactation:** Assess the benefit-risk of using APRETUDE to the infant while breastfeeding due to the potential for adverse reactions and residual concentrations in the systemic circulation for up to 12 months or longer after discontinuation
- **Pediatrics:** Not recommended in individuals weighing less than 35 kg

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The first and only long-acting PrEP option¹

For additional information, visit
[APRETUDEHCP.com](https://www.apretudehcp.com)



Your local ViiV representative can help you with any questions that aren't covered in this guide.

APRETUDE is administered as an intramuscular injection by a healthcare professional every 2 months after 2 initiation injections administered 1 month apart.

PrEP=pre-exposure prophylaxis.

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. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: RISK OF DRUG RESISTANCE WITH USE OF APRETUDE FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED EARLY HIV-1 INFECTION

Individuals must be tested for HIV-1 infection prior to initiating APRETUDE or oral cabotegravir, and with each subsequent injection of APRETUDE, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. Drug-resistant HIV-1 variants have been identified with use of APRETUDE by individuals with undiagnosed HIV-1 infection. Do not initiate APRETUDE for HIV-1 PrEP unless negative infection status is confirmed. Individuals who become infected with HIV-1 while receiving APRETUDE for PrEP must transition to a complete HIV-1 treatment regimen.

Please see additional Important Safety Information throughout.

Please click for full Prescribing Information, including Boxed Warning, for APRETUDE.

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CBTOGM220052 June 2022

Produced in USA.