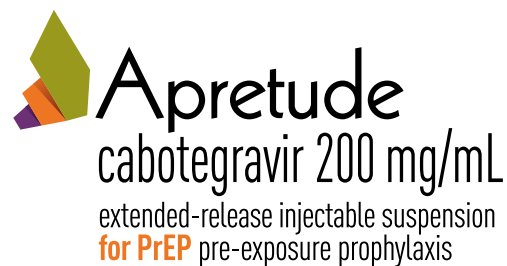


PROFILES IN PrEP

Identify patients who may benefit from switching to **APRETUDE**: the first and only **long-acting** injectable PrEP



APRETUDE is administered as an intramuscular injection by an HCP every 2 months after 2 initiation injections administered 1 month apart. Adherence to the dosing schedule is strongly recommended.



Actor portrayals.
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 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 this piece.
Please click for full [Prescribing Information](#), including Boxed Warning, for APRETUDE.

Are your **PrEP-adherent** patients
facing more challenges with
daily oral dosing than you know?

PrEP-adherent patients
may take PrEP as prescribed, but some may
prefer an alternative mode of administration.

Scroll down for examples

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

Please see additional Important Safety Information throughout this piece.
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Apretude
cabotegravir 200 mg/mL
extended-release injectable suspension
for **PrEP** pre-exposure prophylaxis

ASK YOUR PATIENTS IF THEY WOULD PREFER LESS-FREQUENT DOSING

Adam

33-year-old bisexual man
Dietitian at a nursing home

REASON FOR VISIT/PrEP HISTORY

- In for regular HIV testing as required for PrEP
- On DESCovy* for the last 2.5 years



"I know staying on PrEP is important to reduce my risk of becoming HIV positive, and I am committed to it. My schedule in the nursing home is busy and changes frequently, so I have to do a lot of extra work to remember to take my PrEP pill every day. Is there another option that could work for me?"

Even though Adam is adherent to daily oral PrEP, would you consider offering him another option?

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)

Please see additional Important Safety Information throughout this piece.
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Jared

44-year-old gay man
Occupational therapist

REASON FOR VISIT/PrEP HISTORY

- In for annual physical
- On DESCovy* for 2 years



Actor portrayals.

"My husband is HIV positive. While I understand that undetectable equals untransmittable, my sexual health is important to me—and a part of that for me is taking PrEP to help prevent HIV. But knowing that I'm going to have to keep this up every day is tough. I wish there were another way."

How would you talk to patients like Jared about managing HIV risk?

*APRETUDE has not been compared with DESCovy in clinical trials.

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

Do you have **PrEP-inconsistent** patients who would benefit from an alternative mode of administration?

PrEP-inconsistent patients may routinely **miss daily doses** despite showing up for their appointments.

Scroll down for examples

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

ASK YOUR PATIENTS HOW OFTEN THEY MISS DOSES OF THEIR PRESCRIBED PrEP

Todd

31-year-old gay man
Associate at an accounting firm

REASON FOR VISIT/PrEP HISTORY

- In for symptoms of an STI
- On TRUVADA to prevent HIV, but sometimes does not fill his prescription on time



"I'm lucky enough to take time off and travel whenever I want to. For me, PrEP makes sense, but sometimes I forget to fill my prescription before I leave. I try to limit having sex when I'm off it, but that does present its own set of challenges."

How might you uncover the reason(s) patients like Todd have trouble remembering to fill PrEP prescriptions?

Jasmine

35-year-old cisgender woman
Fashion designer

REASON FOR VISIT/PrEP HISTORY

- In for STI screening
- On TRUVADA, but not fully compliant and realizes she is at risk



Actor portrayals.

"I know that I need to take my PrEP every day, and I try to stay on schedule. But sometimes I forget to take my PrEP daily, and I just have to keep hoping that what I take protects me enough."

What would you suggest to help protect patients like Jasmine from HIV acquisition?

STI=sexually transmitted infection.

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
- Additional HIV testing to determine HIV status is needed if an HIV-1 test indicates possible HIV-1 infection or if symptoms consistent with acute HIV-1 infection develop following an exposure event. If HIV-1 infection is confirmed, then transition the individual to a complete HIV-1 treatment

Please see additional Important Safety Information throughout this piece.
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 **Apretude**
cabotegravir 200 mg/mL
extended-release injectable suspension
for PrEP pre-exposure prophylaxis

Do you have **PrEP-lapsed** patients
who are at risk for HIV?

PrEP-lapsed patients
may have quietly or overtly **discontinued PrEP**
because of personal **challenges with daily dosing**.

Scroll down for examples

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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

- Counsel HIV-1 uninfected individuals to strictly adhere to the recommended dosing and testing schedule for APRETUDE

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. If individuals at continuing risk of HIV-1 acquisition discontinue APRETUDE, alternative forms of PrEP should be considered and initiated within 2 months of the final injection of APRETUDE

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

ASK YOUR PATIENTS IF A LONG-ACTING INJECTABLE OPTION WOULD BE THE RIGHT PrEP OPTION FOR THEM

Rita

28-year-old transgender woman
Flight attendant

REASON FOR VISIT/PrEP HISTORY

- Started dating multiple men and concerned about acquiring HIV
- Was on DESCovy,* but stopped over a year ago



"I'm not in a monogamous relationship, and I doubt the men I'm dating get tested regularly. I was on PrEP, but I was missing doses here and there. So now I am concerned about my risk for HIV. I feel like I should be back on PrEP, but is there an option that isn't a daily commitment?"

If patients like Rita aren't adherent to the dosing schedule for daily oral PrEP, what measures can you take to help manage their HIV risk?

Seth

27-year-old man
Personal trainer

REASON FOR VISIT/PrEP HISTORY

- In for annual physical and requested an HIV test
- Has taken both TRUVADA and DESCovy* in the past



Actor portrayals.

"When PrEP came out, I was excited to take something that protected me from HIV. I took a break once I got into a serious relationship. It didn't work out, and now I'm dating again, so I need to be back on PrEP. Sticking to a daily schedule was always a challenge for me, though."

Now that Seth is ready to be back on PrEP, what option would you recommend, knowing that he struggles with daily dosing?

*APREUDE has not been compared with DESCovy in clinical trials.

IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS (cont'd)

Long-Acting Properties and Potential Associated Risks with APREUDE:

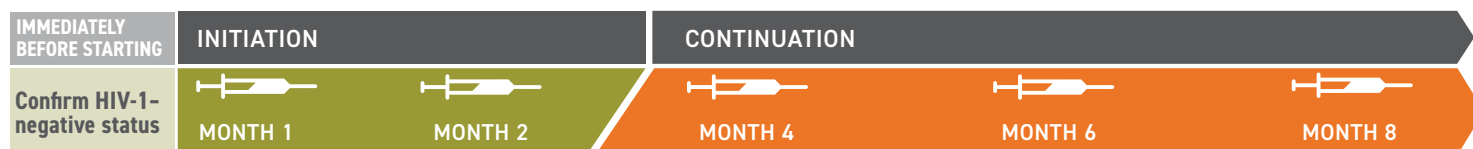
- Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). Take the prolonged-release characteristics of cabotegravir into consideration and carefully select individuals who agree to the required every-2-month injection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

Please see additional Important Safety Information throughout this piece.
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 **Apretude**
cabotegravir 200 mg/mL
extended-release injectable suspension
for PrEP pre-exposure prophylaxis

Confidence with adherence you can confirm in as few as 6 in-office injections per year*

Starting your patients on APRETUDE†



APRETUDE is administered by a healthcare provider as a single 600-mg (3-mL) gluteal intramuscular injection

Healthcare providers should carefully select individuals who agree to the required injection dosing and testing schedule and counsel patients on the importance of adherence to help reduce the risk of HIV-1 infection and development of resistance.

APRETUDE injections can be given up to 7 days before or after the scheduled injection date‡

*After optional oral lead-in and initiation injections.

†For patients concomitantly receiving rifabutin, please see the full Prescribing Information for the adjusted recommended dosing schedule for APRETUDE.

‡After the first injection.

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

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

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

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HIV-1 testing and APRETUDE



PRE-INITIATION VISIT

Screen for HIV-1 infection

- If HIV-1 negative, begin benefit verification before initiating APRETUDE



INITIATION AND CONTINUATION INJECTIONS

Individuals must be tested prior to initiating APRETUDE or oral cabotegravir and with each subsequent injection

- Use a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection
 - If an antigen/antibody test was used and was negative, confirm results with an HIV RNA test
 - Results of confirmatory HIV RNA test can be pending at time of administration

- HIV-1 testing should also occur:
 - When recent exposure to HIV is suspected or clinical symptoms consistent with HIV-1 (eg, fever, fatigue, myalgia, skin rash) are present
 - Upon diagnosis of any other STI
- If positive HIV-1 status is confirmed, transition to a complete HIV-1 treatment

FDA=US Food and Drug Administration.

IMPORTANT SAFETY INFORMATION (cont'd)

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


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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Consider whether patients in your practice could benefit from switching to APRETUDE, the first and only **long-acting** PrEP

 **Apretude**
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extended-release injectable suspension
for **PrEP** pre-exposure prophylaxis

Actor portrayals.

If you're ready to prescribe
APRETUDE, review the
Readiness Considerations Checklist,
which outlines next steps for:

- Office logistics
- Product acquisition and reimbursement
- ViiVConnect access and coverage



[VIEW THE CHECKLIST](#) ►

INDICATION

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