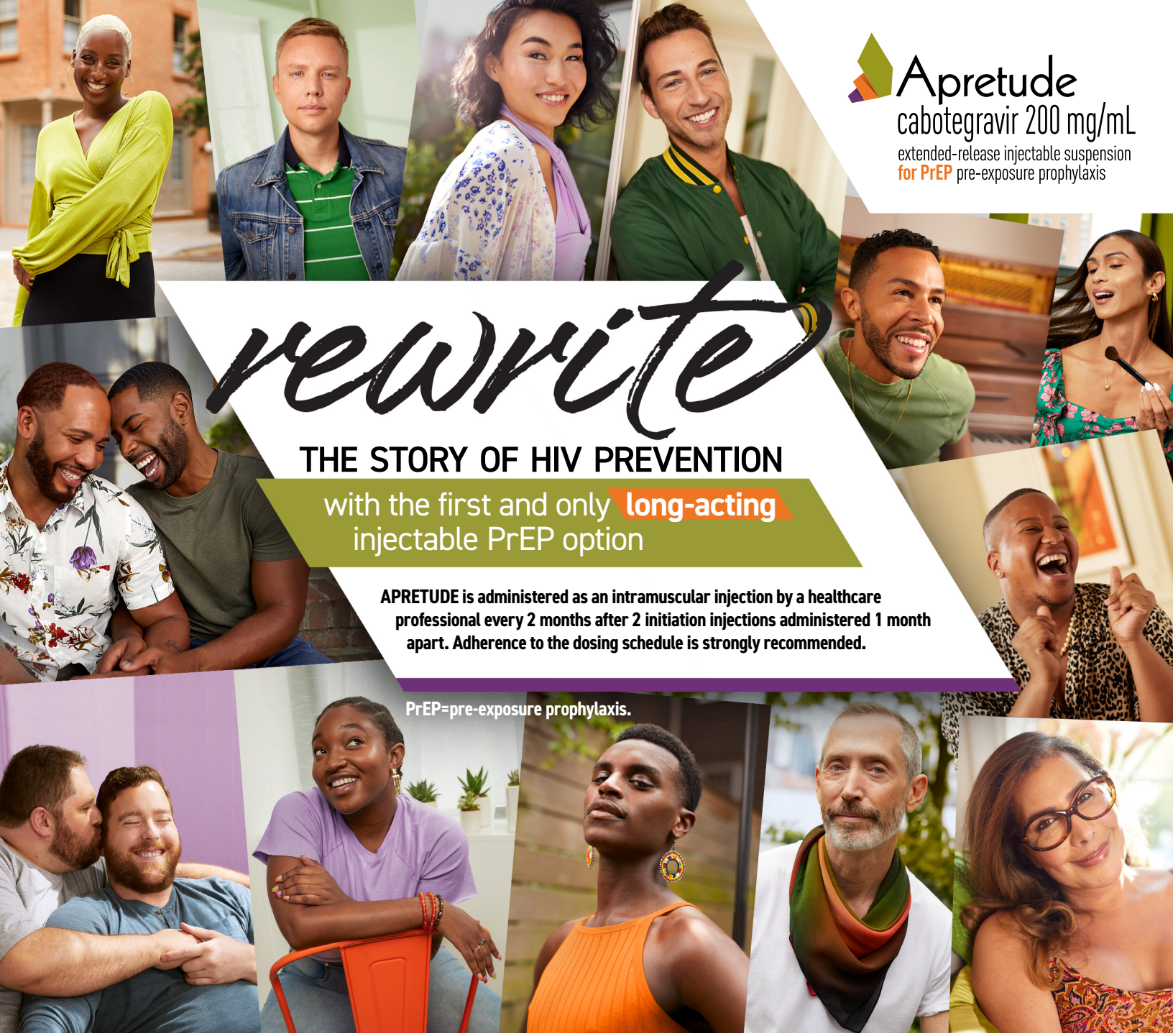

INDICATION

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

10 years ago, PrEP revolutionized the way we approach HIV prevention[1]

Today, there's more work to be done

Despite a decade of use[1]:

- In 2019, there were an estimated 36,398 new HIV infections among adults and adolescents in the US[2]
  - The CDC estimates that 1 in 8 people living with HIV are unaware of their status[3]
- <25% of people who could benefit from PrEP actually receive a prescription[4]

Multiple studies across diverse groups of patients have shown:

- The effectiveness of PrEP is directly tied to the level of patient adherence[5]
- Adherence to a daily medication is an issue for many patients[5]
  - Patients may not communicate with their healthcare providers about the adherence barriers they face[6]
- Many patients would prefer a regimen other than daily dosing[7]

Would you consider a different option for patients like these?

PrEP ADHERENT:
Takes PrEP as prescribed, but may prefer an alternative mode of administration

PrEP INCONSISTENT:
May routinely miss daily doses despite showing up for appointments

PrEP LAPSED:
Has quietly or overtly discontinued PrEP, but may still be at risk for HIV

CDC=Centers for Disease Control and Prevention.

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

APRETUDE:

the first and only long-acting injectable PrEP option

The most diverse and comprehensive HIV prevention trials conducted to date[8,9]

2 TRIALS

~8000 PARTICIPANTS

CONDUCTED IN COOPERATION WITH THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES THROUGH THE HIV PREVENTION TRIALS NETWORK (HPTN)

HPTN 083 and HPTN 084

2 randomized, double-blind, controlled trials, HPTN 083 and HPTN 084, evaluated the safety and efficacy of APRETUDE compared with daily oral TDF/FTC for HIV-1 prevention in adults at high risk of sexually acquiring HIV-1 infection.[8,9]

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

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

HPTN 083

This noninferiority trial included the prespecified ability to test for superiority of APRETUDE in **cisgender men and transgender women who have sex with men**[1,8]

- 43 sites around the world (N=4566)[8]
- At baseline, the median age of participants was 26 years; 12% of participants were transgender women, 72% were non-white, and 67% were aged <30 years

HPTN 084

This superiority trial evaluated APRETUDE in **cisgender women**

- 20 sites around sub-Saharan Africa (N=3224)[9]
- At baseline, the median age of participants was 25 years; >99% of participants were non-white, >99% were cisgender women, and 49% were aged <25 years

In both studies, the primary endpoint was rate of incident HIV-1 infection.

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)

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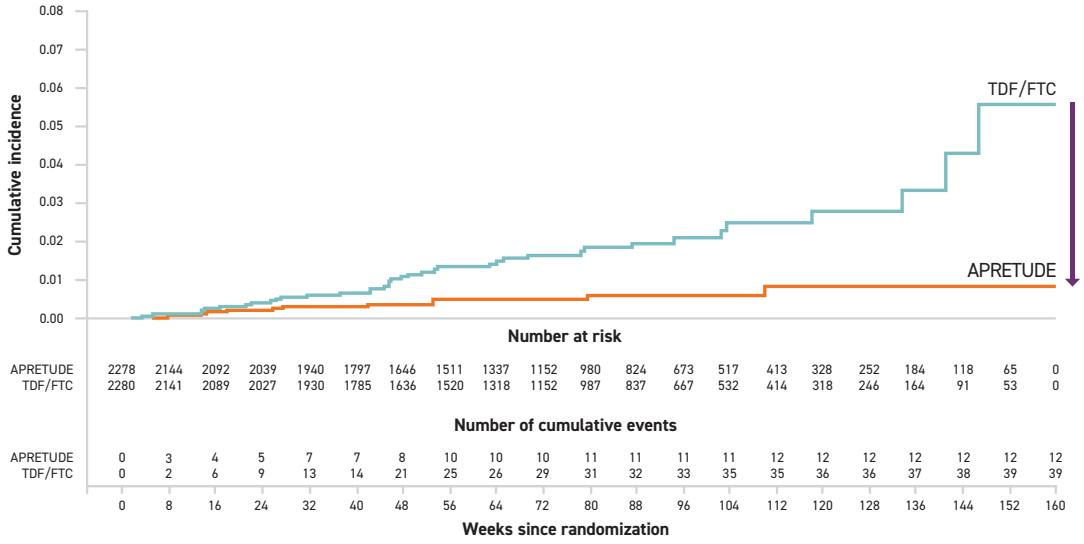
Apretude
cabotegravir 200 mg/mL
extended-release injectable suspension
for PrEP pre-exposure prophylaxis

STUDY 1: **HPTN 083**

APRETUDE delivered superior efficacy with significantly lower incidence of HIV-1 infection vs a daily oral PrEP (TDF/FTC)



Hazard ratio (95% CI): 0.31 (0.16-0.58); *P*=0.0003

69%
LOWER INCIDENCE WITH APRETUDE

HIV-1 INFECTIONS OCCURRED >3x less often WITH APRETUDE

INCIDENT HIV-1 INFECTIONS:

TDF/FTC: 39
in 3193 person-years
(1.22/100 person-years)

APRETUDE: 12‡
in 3211 person-years
(0.37/100 person-years)

Resistance

- Of the incident and prevalent infections in the APRETUDE arm, INSTI resistance-associated mutations (RAMs) were detected in 4 and 1 participant(s), respectively[10]*
- Of the TDF/FTC incident and prevalent infections, NRTI RAMs were detected in 4 and 2 participants, respectively[10]†

*The following INSTI RAMs were detected in 4 participants with incident HIV-1 infection: R263K (n=1), E138A+Q148R (n=1), G140A+Q148R (n=1), and L74I+E138E/K+G140G/S+Q148R+E157Q (n=1). E138K+Q148K were detected for 1 prevalent HIV-1 infection.[10]

†The following NRTI RAMs were detected in 4 participants with incident HIV-1 infection: M184I (n=1), M184V (n=2), and K65R (n=1). M184I (n=1) and M184I/V (n=1) were detected among the prevalent HIV-1 infections.[10]

‡An initial analysis showed 13 incident infections in the APRETUDE arm (hazard ratio [95% CI]: 0.34 [0.18-0.62]). Retrospective testing showed 1 of the 13 to be a prevalent infection, resulting in 12 incident infections.

BASED ON AN ANALYSIS OF PRESPECIFIED SUBGROUPS AND POPULATIONS

An **overall protective effect** was seen **across all subgroups** studied with APRETUDE vs a daily oral PrEP (TDF/FTC)

CI=confidence interval; INSTI=integrase strand transfer inhibitor; NRTI=nucleoside/nucleotide reverse transcriptase inhibitor.

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

Please see additional Important Safety Information throughout.
Please click for full Prescribing Information, including Boxed Warning, for APRETUDE.

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

STUDY 1: **HPTN 083**

Safety profile established in >2200 participants

Adverse drug reactions* of all grades reported in at least 1% of participants receiving APRETUDE

Adverse reactions	APRETUDE every 2 months (n=2281)	TDF/FTC once daily (n=2285)
Injection-site reactions†	82%	35%
Diarrhea	4%	5%
Headache	4%	3%
Pyrexia‡	4%	<1%
Fatigue§	4%	2%
Sleep disorders‖	3%	3%
Nausea	3%	5%
Dizziness	2%	3%
Flatulence	1%	1%
Abdominal pain¶	1%	1%

6% of participants receiving APRETUDE and 4% of participants receiving TDF/FTC discontinued due to adverse events (all causality).

*Adverse reactions defined as "treatment-related" as assessed by the investigator, with the exception of ISRs, where all ISRs were reported regardless of causality.

†Participants who received injection: APRETUDE (n=2117) and TDF/FTC (n=2081).

‡Pyrexia includes pyrexia, feeling hot, chills, and influenza-like illness.

§Fatigue includes fatigue and malaise.

‖Sleep disorders include insomnia and abnormal dreams.

¶Abdominal pain includes abdominal pain and upper abdominal pain.

ISR=injection-site reaction.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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

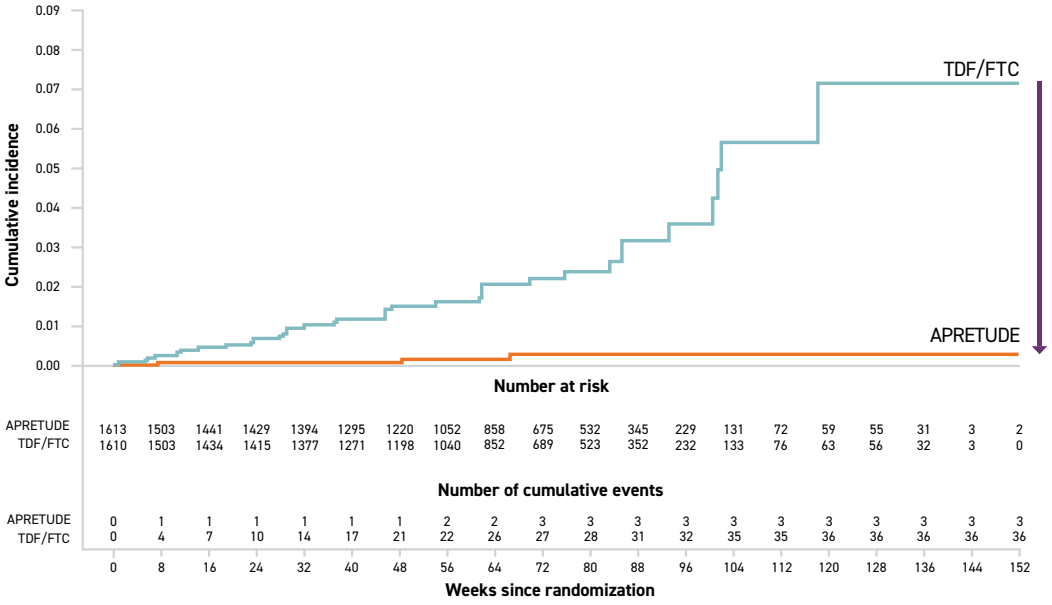
- When using APRETUDE, HIV-1 testing should be repeated prior to each injection and upon diagnosis of any other STIs
- Additional HIV testing to determine HIV status is needed if an HIV-1 test indicates possible HIV-1 infection or if symptoms consistent with acute HIV-1 infection develop following an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

Please see additional Important Safety Information throughout.
Please click for full Prescribing Information, including Boxed Warning, for APRETUDE.

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

STUDY 2: **HPTN 084**

APRETUDE delivered superior efficacy with significantly lower incidence of HIV-1 infection vs a daily oral PrEP (TDF/FTC)



Hazard ratio (95% CI): 0.10 (0.04-0.27); *P*<0.0001

90%
LOWER INCIDENCE WITH APRETUDE

HIV-1 INFECTIONS OCCURRED
12x
less often
WITH APRETUDE

INCIDENT HIV-1 INFECTIONS:

TDF/FTC: 36
in 1946 person-years
(1.85/100 person-years)

APRETUDE: 3†
in 1960 person-years
(0.15/100 person-years)

Resistance

- Of the infections in the APRETUDE arm, no major INSTI RAMs were detected
- Of the incident infections in the TDF/FTC arm, NRTI RAMs were detected in 1 of the participants[11]*

*In the TDF/FTC arm, the NRTI RAM M184V was detected in 1 participant with an incident HIV-1 infection. There were no prevalent HIV-1 infections detected.[11]

†An initial analysis showed 4 incident infections in the APRETUDE arm (hazard ratio [95% CI]: 0.12 [0.05-0.31]). Retrospective testing showed 1 of the 4 to be a prevalent infection, resulting in 3 incident infections.

BASED ON AN ANALYSIS OF PRESPECIFIED SUBGROUPS AND POPULATIONS

An **overall protective effect across age and BMI groups**
vs a daily oral PrEP (TDF/FTC)

BMI=body mass index.

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. 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

Please see additional Important Safety Information throughout.
Please click for full Prescribing Information, including Boxed Warning, for APRETUDE.

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

STUDY 2: **HPTN 084**

Safety profile established in >1600 participants

Adverse drug reactions* of all grades reported in at least 1% of participants receiving APRETUDE

Adverse reactions	APRETUDE every 2 months (n=1614)	TDF/FTC once daily (n=1610)
Injection-site reactions†	38%	11%
Headache	12%	13%
Nausea	4%	8%
Dizziness	4%	6%
Diarrhea	4%	4%
Upper respiratory tract infection	4%	4%
Fatigue‡	3%	3%
Vomiting	2%	5%
Decreased appetite	2%	4%
Abdominal pain§	2%	2%
Somnolence	2%	2%
Myalgia	2%	1%
Rash‖	2%	1%
Sleep disorders¶	1%	1%
Back pain	1%	<1%

1% of participants receiving APRETUDE and 1% of participants receiving TDF/FTC discontinued due to adverse events (all causality).

*Adverse reactions defined as "treatment-related" as assessed by the investigator, with the exception of ISRs, where all ISRs were reported regardless of causality.

†Participants who received injection: APRETUDE (n=1519) and TDF/FTC (n=1516).

‡Fatigue includes fatigue and malaise.

§Abdominal pain includes abdominal pain and upper abdominal pain.

‖Rash includes rash, erythema, pruritus, macular, papular, maculopapular.

¶Sleep disorders include insomnia and abnormal dreams.

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 or missed doses could lead to HIV-1 acquisition and development of resistance

Please see additional Important Safety Information throughout.
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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†

IMMEDIATELY BEFORE STARTING	INITIATION		CONTINUATION		
CONFIRM HIV-1–NEGATIVE STATUS	MONTH 1	MONTH 2	MONTH 4	MONTH 6	MONTH 8

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.

An optional oral lead-in may be used prior to the initiation of APRETUDE to assess the tolerability of cabotegravir.

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

"It's been very easy to set up my APRETUDE appointments because not only do you try and set it for 2 months out, but there's a buffer window of a week on either end of that. It fits in my lifestyle well."

—Ben, a real patient taking APRETUDE

*After optional oral lead-in and initiation injections.

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

‡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

Please see additional Important Safety Information throughout.
Please click for full Prescribing Information, including Boxed Warning, for APRETUDE.

Apretude
cabotegravir 200 mg/mL
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for PrEP pre-exposure prophylaxis

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 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

When a payer covers PrEP, HIV testing should also be covered.[12] The payer or your lab can help you understand which tests may be covered and available

FDA=US Food and Drug Administration; STI=sexually transmitted infection.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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

Please see additional Important Safety Information throughout.
Please click for full Prescribing Information, including Boxed Warning, for APRETUDE.

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

Profiles in PrEP

Do you have a similar patient who might benefit from switching to APRETUDE?

PrEP ADHERENT

Adam

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

"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?

Actor portrayal.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Risk of Reduced Drug Concentration of APRETUDE Due to Drug Interactions (cont'd):

- 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

Please see additional Important Safety Information throughout.
Please click for full Prescribing Information, including Boxed Warning, for APRETUDE.

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

Profiles in PrEP

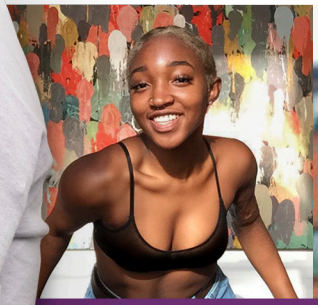
Do you have a similar patient who might benefit from switching to APRETUDE?

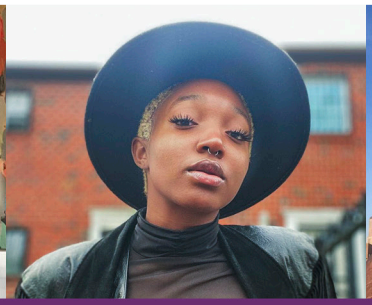
PrEP INCONSISTENT

Jasmine

35-year-old cisgender woman
Fashion designer

"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?

Actor portrayal.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥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

Please see additional Important Safety Information throughout.
Please click for full Prescribing Information, including Boxed Warning, for APRETUDE.

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

Profiles in PrEP

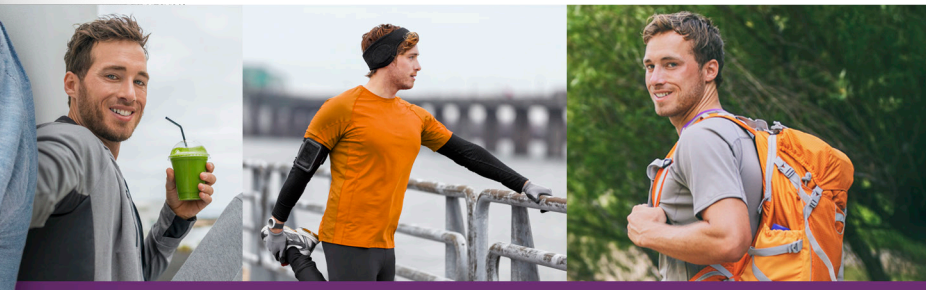
Do you have a similar patient who might benefit from switching to APRETUDE?

PrEP LAPSED

Seth

27-year-old man
Personal trainer

"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?

Actor portrayal.

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

Please see additional Important Safety Information throughout.
Please click for full Prescribing Information, including Boxed Warning, for APRETUDE.

Only with APRETUDE:

SUPERIOR efficacy proven in 2 clinical trials and the CONFIDENCE that comes from adherence you can confirm in office

SUPERIOR

Provided greater protection from HIV than a daily oral PrEP (TDF/FTC)[8,9]

Significantly lower incidence of HIV-1 infection—**69%** (P=0.0003) in MSM and TGW, and **90%** (P<0.0001) in cisgender women—vs a daily oral PrEP demonstrated in HPTN 083 and HPTN 084*†

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§

INCLUSIVE

Evaluated across a diverse patient population[8,9]

A comprehensive trial program that included cisgender men and transgender women who have sex with men, and cisgender women*†

*HPTN 083 (N=4566) was a randomized, double-blind, 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 rate of incident HIV-1 infection. The trial included the prespecified ability to test for superiority of APRETUDE over TDF/FTC.[8]

†HPTN 084 (N=3224) was a randomized, double-blind, 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 rate of incident HIV-1 infection.[9]

‡While on APRETUDE.

§After optional oral lead-in and initiation injections.

MSM=men who have sex with men; TGW=transgender women.

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

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