



Access and Reimbursement Guide

INDICATION

APRETUDE is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition. 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 acquire HIV-1 while receiving APRETUDE for PrEP must transition to a complete HIV-1 treatment regimen.

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.

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CMS=Centers for Medicare & Medicaid Services.

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

ACCESS OVERVIEW

CONDUCTING A BENEFITS VERIFICATION

You can [enroll](#) in ViiVConnect Hub Services to have your patient's benefits verified for you, or your office may perform the verification independently.

OPTION 1

ViiVConnect services

Enrolling in ViiVConnect Hub Services provides support for acquiring and administering APRETUDE for practices, including:

- Performance of benefits verifications
- Assistance in navigating product acquisitions

OPTION 2

Independently managed

For practices that prefer to manage the prescribing and acquisition of APRETUDE on their own:

- This option allows your office to conduct benefits verifications and navigate product acquisitions

Benefits verification results include:

- Predetermination
- Acquisition pathway information
- Prior Authorization (PA) requirement(s)

Factors that can affect access and reimbursement

- 1 Type of payer**
Understanding your patient's insurance status and requirements is essential to helping them access their medication as prescribed.
Your patient may have coverage under one of the following payers:
 - Private or commercial insurance
 - Medicaid and/or Medicare
- 2 Acquisition pathway**
An insurance plan may cover APRETUDE under:
 - The medical and/or pharmacy benefit

This information is confirmed during the benefits verification process, which helps determine how APRETUDE will be acquired and reimbursed for your patient.
- 3 Place of service**
Insurance coverage of medications administered by a provider, such as APRETUDE, may vary depending on where the product is administered. Locations include:
 - Your office
 - A hospital outpatient facility
 - An independent clinic
 - An Alternative Site of Care (ASOC), such as an infusion clinic

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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

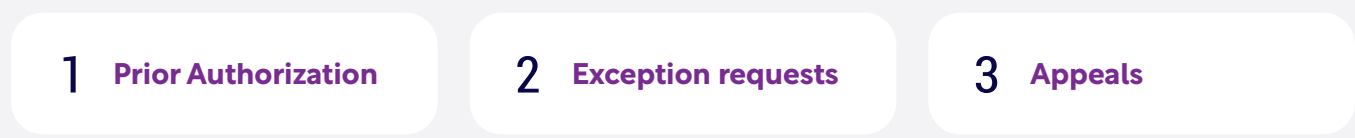
- Use APRETUDE only in individuals confirmed to be HIV-1 negative. HIV-1 resistance substitutions may emerge in individuals with undiagnosed HIV-1 infection who are taking only APRETUDE, because APRETUDE alone does not constitute a complete regimen for HIV-1 treatment. Prior to initiating APRETUDE, ask 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



COVERAGE DECISIONS

PRIOR AUTHORIZATION, EXCEPTION REQUESTS, AND APPEALS

A payer may require more information than a prescription alone to cover APRETUDE. There are 3 primary categories of requests for additional information:



Prior Authorization (PA)

PA is a common payer requirement where providers must submit medical necessity information before coverage is approved for a therapy or service. If the benefits verification shows that your patient's insurance requires a PA for APRETUDE, you will need to prepare the necessary documentation. Since coverage criteria may vary, it is important to review each insurer's specific guidelines.

Tips for submitting a PA

Documentation you may want to include with the required PA form:

- [Letter of medical necessity](#)
- Copy of the medical and/or pharmacy benefit insurance card(s) (front and back)
- Patient's history and current condition
- Date and method of diagnosis, including ICD-10-CM code(s)
- Laboratory results and date
- Confirmation that the patient has been tested and is negative for HIV-1
- Previous therapies/treatments and response to those interventions
- Summary of professional opinion of the patient's likely prognosis without preventive treatment with APRETUDE
- Use the plan's most recent form

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

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 individuals without HIV-1 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.



Exception requests

An exception request is a formal request made by a healthcare provider to a payer asking for coverage of a specific medication, treatment, or service that is not typically included in the insurer's plan.

Common types of exception requests

- **Nonformulary exception:** Requesting approval for a medication or treatment not listed in the plan's formulary
- **Step therapy exception:** If the patient cannot use the preferred medication or treatment due to a medical condition or previous treatment failure, a request is made for a different, nonpreferred option
- **PA exception:** When a treatment or service requires prior approval but the provider requests an exception based on the patient's unique needs

These requests are typically reviewed by the insurance company's medical or pharmacy team, and they may be approved or denied based on the submitted documentation and the insurer's policies.



Appeals

An appeal is a process used to challenge a payer's adverse coverage decision when a beneficiary believes they are entitled to benefits. If an exception request or PA is denied, an appeal can be filed to reconsider the decision. The appeal process, whether it's a written explanation or a verbal request, will vary based on the patient's insurance plan.

Tips for submitting an appeal

- Review the denial notice to understand the reason for denial and to identify the appeal process requirements (documentation, time frame, etc)
- Verify the information submitted on your PA form was complete and accurate. If there were clerical errors, resolve and resubmit
- Include any supporting documentation as required by the payer (the denial letter, letter of medical necessity, patient records, etc)
- Ensure you are submitting to the appropriate location

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



COVERAGE DECISIONS

LETTER OF MEDICAL NECESSITY

Some payers and formulary decision-makers may require a letter of medical necessity before authorizing a specific therapy for your patient. See below for a sample letter of medical necessity. You will want to draft this rationale on official letterhead, keeping your recommendation clear, concise, and compelling.

Consider including the following items in a letter of medical necessity:

- Clearly state the rationale for why APRETUDE is appropriate for the patient
- Support the therapy recommendation by citing Prescribing Information, published study data, and clinical guidelines, as appropriate
- Specify if the patient is already on APRETUDE and is clinically stable
- Explain why the formulary-preferred agents, if applicable, are not appropriate
- Outline possible implications if the patient goes without therapy or if the patient is denied access

Sample letter

SAMPLE LETTER OF MEDICAL NECESSITY
 [Date]
 [Name of health plan]
 [Mailing address]
 Re: [Patient's Name]

 [Plan identification number]
 [Date of birth]
 [Case Identification]
 Dear [Contact Name or Department]:
 I am writing on behalf of my patient, [PATIENT NAME], to document medical necessity for treatment with [PRODUCT] for [INDICATION]. This letter serves to document that [PRODUCT] for [INDICATION] is appropriate, reasonable, and clinically necessary for [PATIENT]. On behalf of the patient, I am requesting approval for use and subsequent coverage/payments.
 [PATIENT NAME]'s laboratory results meet the clinical diagnosis criteria for [INDICATION].
 Summary of Patient's History [Describe the patient's medical condition].
 Information that may be helpful to include:
 • Patient's diagnosis, history, and current clinical status
 • Patient's current or previous antiretroviral therapies attempted
 • Rationale for therapy with [PRODUCT] including clinical evidence
 • Summary of your professional opinion and factors that led to you recommending [PRODUCT] for [INDICATION]
 Based on the above facts, [PRODUCT] is appropriate and reasonable for [PATIENT].
 Please consider coverage of [PRODUCT] on [PATIENT NAME]'s behalf and approve use and subsequent payment for [PRODUCT].
 Please refer to the enclosed Prescribing Information for [PRODUCT]. If you have any further questions regarding this matter, please do not hesitate to call me at [PROVIDER TELEPHONE NUMBER].
 Thank you for your prompt attention to this matter.
 Sincerely,
 [Provider's name], <@EMAILADDRESS>
 [Provider's title]
 [Provider's practice name]
 [Phone number]
 [Fax number]

 Enclosures (attach as appropriate): Prescribing Information (PI), clinic notes, labs, and other supporting documentation.
 CC: [Medical Director, patient, specialty society, insurance Commissioner]

Go to viivconnect.com/sampleletter to customize a sample letter based on your patient's medical history and information below.

- Some insurance companies may have specific forms that must be completed in order to document medical necessity
- ViiV Healthcare does not guarantee that use of this letter will result in coverage for its products

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

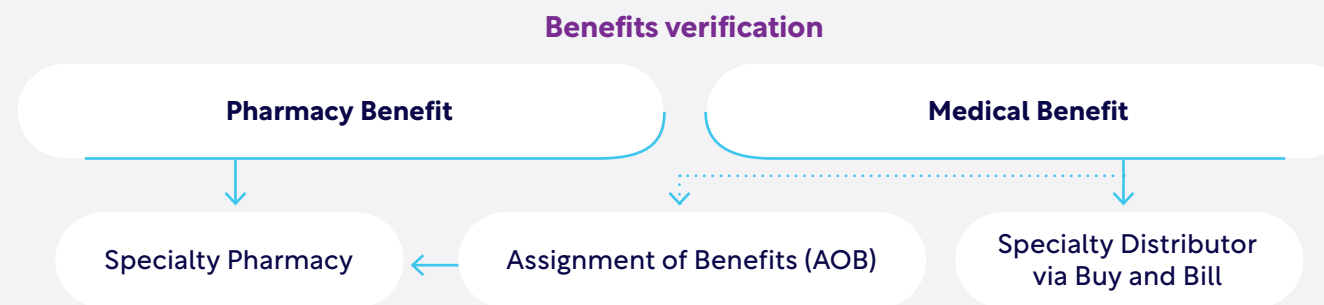
Please see additional Important Safety Information throughout. Please click for full [Prescribing Information](#), including **Boxed Warning**, for APRETUDE.

ACQUISITION PATHWAYS

OVERVIEW

Your patient's insurance plan will determine how APRETUDE is acquired and will be outlined in the summary of benefits.

APRETUDE may be acquired through one of the following pathways:



Pharmacy benefit

If your patient's insurance covers APRETUDE **under the pharmacy benefit**, or if an AOB was performed under the medical benefit, then your office can likely acquire APRETUDE from a **specialty pharmacy**.

See [page 5](#) for more information on acquisition through a specialty pharmacy.



Medical benefit

If your patient's insurance covers APRETUDE **under the medical benefit**, your office can purchase it directly from a **specialty distributor (Buy and Bill)**.

See [page 5](#) for more information on acquisition through a specialty distributor.



Assignment of Benefits (AOB)

In some instances, a specialty pharmacy may be able to bill the patient's medical benefit, also referred to as an AOB. **An AOB is a secondary process used by a payer that will help determine if the ViiV Injectable can be sourced through a specialty pharmacy while covered under a medical benefit.** The process varies widely by payer and, depending on your patient's coverage, is not always an option. Speak with your Field Reimbursement Manager (FRM) if you would like to learn more about an AOB.

An Alternative Site of Care (ASOC) is a medical facility that can manage the medication acquisition process and administer APRETUDE to your patient.

Visit viivconnect.com/asocinfo for additional information on working with an ASOC.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity Reactions:

- Serious or severe hypersensitivity reactions have been reported with APRETUDE, including Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN)



ACQUISITION PATHWAYS

PHARMACY BENEFIT

If your patient’s insurance covers APRETUDE under the pharmacy benefit, you may acquire the product through a specialty pharmacy.

Acquiring APRETUDE through the pharmacy benefit:

- 1 Submit a prescription.** The payer may dictate which specialty pharmacy can fill the prescription. Review the summary of benefits.
- 2 The specialty pharmacy submits the claim to the patient’s payer for APRETUDE and collects the copay.** Remind your patient to answer the call from the specialty pharmacy from a number they may not recognize.
- 3 The specialty pharmacy ships APRETUDE.** The specialty pharmacy and your practice coordinate shipments to arrive in advance of a patient’s scheduled appointment. If you haven’t received any communications from the specialty pharmacy, and your patient’s appointment is fewer than 10 days away, please contact the specialty pharmacy directly.
- 4 Administer the APRETUDE injection.** Schedule subsequent injections.
- 5 Submit claims to your patient’s insurance company for the office visit and the administration of APRETUDE.** Collect the copay from the patient for the office visit (if applicable). If the patient is enrolled in the ViiVConnect Patient Savings Program, submit the Explanation of Benefits (EOB) to ViiVClaims.com for reimbursement of the administration fee.

Specialty pharmacy network for APRETUDE

Accredo Specialty Pharmacy
Phone: (877) 856-4670
Fax: (888) 302-1028

Coordinated Care Network
Phone: (877) 349-6330
Fax: (412) 825-3525

Optum Specialty Pharmacy
Phone: (855) 427-4682
Fax: (877) 342-4596

AHF Pharmacy
Phone: (877) 429-0708
Fax: (833) 814-1322

Curant Health
Phone: (866) 460-8040
Fax: (866) 437-8411

Walgreens Specialty Pharmacy
Phone: (888) 347-3416
Fax: (877) 231-8302

Avita Pharmacy
Phone: (866) 437-6717
Fax: (803) 358-3034

CVS Specialty Pharmacy
Phone: (855) 801-8262
Fax: (866) 279-1993

BioPlus Specialty Pharmacy
Phone: (866) 514-8082
Fax: (800) 269-5493

Mail-Meds Clinical Pharmacy
Phone: (800) 939-2022
Fax: (855) 523-0910

CenterWell Specialty Pharmacy
Phone: (800) 486-2668
Fax: (877) 405-7940

MediLink RxCare Specialty Pharmacy
Phone: (609) 956-1900
Fax: (609) 521-4001

MEDICAL BENEFIT

If your patient’s insurance covers APRETUDE under the medical benefit, you may purchase the product directly from a specialty distributor (Buy and Bill).

Acquiring APRETUDE through the medical benefit:

- 1 Order APRETUDE from a specialty distributor.** Your practice buys APRETUDE from the specialty distributor, and the specialty distributor sends directly to your office for inventory.
- 2 Schedule and administer APRETUDE.** Coordinate with the patient to schedule their appointment. Pull the product from inventory and administer to the patient. Your practice will need to schedule and confirm your patient’s follow-up appointment to ensure their subsequent injection is available and ready to administer in time for their next appointment.
- 3 Bill for reimbursement.** Once administered, your practice will bill the patient’s insurance for APRETUDE reimbursement and administration services. Your practice is also responsible for collecting any copays or coinsurance for APRETUDE. If applicable, submit payer claim forms for reimbursement of APRETUDE, its administration, and the office visit. After receiving payer reimbursement, if the patient is enrolled in the ViiVConnect Patient Savings Program, submit the EOB to ViiVClaims.com for reimbursement of the administration fee.

Buy and Bill considerations for your practice

Ensure your practice has a contract with the patient’s payer, and you are aware of the terms for reimbursement.

Specialty distributor network for APRETUDE

ASD Specialty Healthcare
(800) 746-6273

CuraScript Specialty Distribution
(800) 942-5999

McKesson Specialty
(800) 482-6700

Besse Medical
(800) 543-2111

McKesson Medical-Surgical
(800) 446-3008

Morris & Dickson Specialty Distribution, LLC
(800) 388-3833

Cardinal Health Specialty
Acute: (855) 855-0708
Provider: (877) 453-3972

McKesson Plasma and Biologics
(877) 625-2566

Oncology Supply
(800) 633-7555

IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS AND PRECAUTIONS (cont’d)

Hypersensitivity Reactions: (cont’d)

- Discontinue APRETUDE immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated

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

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



BILLING AND CODING

REFERENCE SHEET FOR COMMONLY USED CODES

These codes are only intended to support APRETUDE for pre-exposure prophylaxis (PrEP). The codes in this guide are not all inclusive and are for informational purposes only; appropriate codes can vary by patient, setting of care, and payer. The use of the following codes does not guarantee reimbursement.

ICD-10-CM Diagnosis Codes ¹	
Z29.81	Encounter for human immunodeficiency virus (HIV) pre-exposure prophylaxis
Z01.812	Encounter for preprocedural laboratory examination
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
Z11.4	Encounter for screening for HIV
Z11.59	Encounter for screening for other viral diseases
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Z20.5	Contact with and (suspected) exposure to viral hepatitis
Z20.6	Contact with and (suspected) exposure to HIV
Z51.81	Encounter for therapeutic drug-level monitoring
Z72.51	High-risk heterosexual behavior
Z72.52	High-risk homosexual behavior
Z72.53	High-risk bisexual behavior
Z79.899	Other long-term (current) drug therapy

Place of Service Codes ¹	
11	Office
17	Walk-in Retail Health Clinic
19	Off Campus—Outpatient Hospital
22	On Campus—Outpatient Hospital
49	Independent Clinic
71	Public Health Clinic
72	Rural Health Clinic

CPT Code for reporting the injection ^{1,2}	
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

ViiV Healthcare does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

References: 1. National Alliance of State and Territorial AIDS Directors. *Pre-Exposure Prophylaxis (PrEP), Post-Exposure Prophylaxis (PEP), and Other HIV Prevention Strategies: Billing and Coding Guide*. October 2023. Accessed May 16, 2025. <https://nastad.org/sites/default/files/2023-10/PDF-HIV-Prevention-BillingAndCoding-101223.pdf> 2. American Medical Association. CPT® code 96372: injection of drug/substance under skin or into muscle. Accessed May 16, 2025. <https://www.ama-assn.org/practice-management/cpt/cpt-code-96372-injection-drugsubstance-under-skin-or-muscle>

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

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

CPT Modifier ¹	
33	For delivery of an evidence-based service in accordance with a USPSTF A or B rating in effect and other preventive services mandated by legal or regulatory bodies; add 33 to the procedure only for commercial payers

HCPCS Codes HCPCS Billing Unit: 600 billing units ²⁻⁷	
J0739	Injection, cabotegravir, 1 mg; effective July 1, 2022
G0011	Individual counseling for pre-exposure prophylaxis by physician or qualified healthcare professional to prevent HIV. Includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15-30 minutes
G0012	Injection of pre-exposure prophylaxis drug for HIV prevention, under skin or into muscle
G0013	Individual counseling for pre-exposure prophylaxis by clinical staff to prevent human immunodeficiency virus (HIV). Includes: HIV risk assessment initial or continued assessment of risk, HIV risk reduction, and medication adherence
Q0519	Pharmacy supplying fee for HIV pre-exposure prophylaxis FDA approved prescription injectable drug, per 30-days
Q0520	Pharmacy supplying fee for HIV pre-exposure prophylaxis FDA approved prescription injectable drug, per 60-days
Q0521	Pharmacy supplying fee for HIV pre-exposure prophylaxis FDA approved prescription

HCPCS Modifiers ⁵	
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient

National Drug Codes ^{8,9}	
10-digit NDC	APRETUDE 600-mg/3-mL kit 49702-264-23
11-digit NDC	APRETUDE 600-mg/3-mL kit 49702-0264-23
Billing Units	NDC = ML 3

ViiV Healthcare does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

CPT=Current Procedural Terminology; FDA=United States Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code; USPSTF=United States Preventive Services Task Force.

References: 1. Wilcox A. Modifier 33 for preventive care. Find-A-Code website. Accessed May 16, 2025. <https://www.findacode.com/articles/modifier-33-for-preventive-care.html> 2. National Alliance of State and Territorial AIDS Directors. *Pre-Exposure Prophylaxis (PrEP), Post-Exposure Prophylaxis (PEP), and Other HIV Prevention Strategies: Billing and Coding Guide*. October 2023. Accessed May 16, 2025. <https://nastad.org/sites/default/files/2023-10/PDF-HIV-Prevention-BillingAndCoding-101223.pdf> 3. National Alliance of State and Territorial AIDS Directors. Introducing NASTAD's updated PrEP, PEP, and other HIV prevention strategies. Billing and coding guide webinar. October 18, 2023. Accessed May 16, 2025. https://nastad.org/sites/default/files/2023-10/PDF-Webinar-Slides-PrEP-Billing-Coding_0.pdf 4. Centers for Medicare & Medicaid Services. PrEP for HIV & related preventive services. Updated April 14, 2025. Accessed May 16, 2025. <https://www.cms.gov/medicare/coverage/prep> 5. Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated March 26, 2025. Accessed May 16, 2025. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update> 6. Centers for Medicare & Medicaid Services. Fact sheet: Medicare Part B coverage of pre-exposure prophylaxis (PrEP) for human immunodeficiency virus (HIV) prevention. Updated September 30, 2024. Accessed May 16, 2025. <https://www.cms.gov/files/document/fact-sheet-potential-medicare-part-b-coverage-preexposure-prophylaxis-prep-using-antiretroviral.pdf> 7. MLN Connects. Weekly edition. Centers for Medicare & Medicaid Services website. November 14, 2024. Accessed May 16, 2025. <https://www.cms.gov/training-education/medicare-learning-network/newsletter/2024-11-14-mln> 8. National drug code (NDC) conversion table. Maryland.gov website. Accessed May 16, 2025. <https://health.maryland.gov/phpa/OIDEOR/IMMUN/Shared%20Documents/Handout%203%20-%20NDC%20conversion%20to%2011%20digits.pdf> 9. Nevada Medicaid. National drug code (NDC) billing reference. Medicaid.gov website. Updated October 10, 2022. Accessed May 16, 2025. https://www.medicaid.nv.gov/downloads/provider/nv_billing_ndc_reference.pdf

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Depressive Disorders: (cont'd)

- Promptly evaluate patients with depressive symptoms

Apretude
cabotegravir 200 mg/mL
extended-release injectable suspension

ViiVInjectables

BILLING AND CODING: PROVIDER'S OFFICE COMPLETE THE CMS 1500 CLAIM FORM

This form can be used for most payers, including Medicaid and commercial. When filling out the form, be sure to use the correct date of service and codes. Submit the form within the plan's designated claim-filing time frame.

Key fields and codes to be used for APRETUDE have been highlighted.

- 21** Enter the appropriate ICD-10-CM diagnosis code(s) (see [page 6](#) for a list of codes).
- 23** If a Prior Authorization number is obtained by the payer, enter it here.
- 24B** Enter the appropriate place of service code,¹ for example:
 - Office (**code 11**)
 - Walk-in Retail Health Clinic (**code 17**)
 - Off Campus—Outpatient Hospital (**code 19**)
 - On Campus—Outpatient Hospital (**code 22**)
 - Independent Clinic (**code 49**)
 - Public Health Clinic (**code 71**)
 - Rural Health Clinic (**code 72**)
- 24D** Enter appropriate CPT/HCPCS code:
 - CPT 96372 or HCPCS J0739 in the left column
 - In the right column, add HCPCS JZ Modifier to indicate zero drug amount was discarded²

NOTE: For 340B customers, the TB Modifier must be used to replace the JG Modifier³
- 24G** Enter billing units:
One 600-mg kit = 600 billing units^{1,4}

References: **1.** National Alliance of State and Territorial AIDS Directors. *Pre-Exposure Prophylaxis (PrEP), Post-Exposure Prophylaxis (PEP), and Other HIV Prevention Strategies: Billing and Coding Guide*. October 2023. Accessed May 16, 2025. <https://nastad.org/sites/default/files/2023-10/PDF-HIV-Prevention-BillingAndCoding-101223.pdf> **2.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated March 26, 2025. Accessed May 16, 2025. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update> **3.** Centers for Medicare & Medicaid Services. Revised Part B inflation rebate guidance: use of the 340B modifier. December 14, 2023. Accessed May 16, 2025. <https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf> **4.** National Alliance of State and Territorial AIDS Directors. Introducing NASTAD's updated PrEP, PEP, and other HIV prevention strategies. Billing and coding guide webinar. October 18, 2023. Accessed May 16, 2025. https://nastad.org/sites/default/files/2023-10/PDF-Webinar-Slides-PrEP-Billing-Coding_0.pdf

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

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

BILLING AND CODING: HOSPITAL, NURSING FACILITY, OR OTHER INPATIENT FACILITY COMPLETE THE CMS 1450/UB-04 CLAIM FORM

This form can be used for most payers, including Medicaid. When completing claim forms, make sure the date of service, billing codes, and billing units are accurate. Submit the form within the plan's designated claim-filing time frame.

Key fields and codes to be used for APRETUDE have been highlighted.

- 42** Enter revenue code 0636 (drugs that require detailed coding).¹
- 43** Include the NDC qualifier N4, followed by the 11-digit NDC, unit of measure, and quantity delivered to the patient:
 - While the NDC number issued by the FDA is a 10-digit number, most payers require an 11-digit number. To convert to an 11-digit number, place a "0" before the second set of numbers (after the first dash). For example, the 11-digit NDC for APRETUDE would be 49702-0264-23. *Confirm all requirements, as they may vary by payer*
 - One APRETUDE 600-mg kit
N4 49702-0264-23 ML 3
- 44** Enter appropriate CPT/HCPCS codes:
 - CPT 96372 or
 - HCPCS J0739 along with HCPCS JZ Modifier to indicate zero drug amount was discarded²

NOTE: For 340B customers, the TB Modifier must be used to replace the JG Modifier³
- 66** Enter the appropriate ICD-10-CM diagnosis code (see [page 6](#) for a list of codes).

Important J-code information when filing claims for APRETUDE:

- Payers require the use of a J-code on a claim form
- CMS has issued a permanent J-code for APRETUDE: J0739 (injection, cabotegravir, 1 mg), effective as of July 1, 2022⁴

References: **1.** Centers for Medicare & Medicaid Services. Medicare coverage database. Accessed May 16, 2025. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55913> **2.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated March 26, 2025. Accessed May 16, 2025. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update> **3.** Centers for Medicare & Medicaid Services. Revised Part B inflation rebate guidance: use of the 340B modifier. December 14, 2023. Accessed May 16, 2025. <https://www.cms.gov/files/document/revised-part-b-inflation-rebate-340b-modifier-guidance.pdf> **4.** National Alliance of State and Territorial AIDS Directors. *Pre-Exposure Prophylaxis (PrEP), Post-Exposure Prophylaxis (PEP), and Other HIV Prevention Strategies: Billing and Coding Guide*. October 2023. Accessed May 16, 2025. <https://nastad.org/sites/default/files/2023-10/PDF-HIV-Prevention-BillingAndCoding-101223.pdf>

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



ORDERING INFORMATION

PRODUCT INFORMATION



Product and Strength	600 mg/3 mL cabotegravir
Count	1 vial of 600-mg/3-mL cabotegravir extended-release injectable suspension
G0012¹	Injection of pre-exposure prophylaxis drug for HIV prevention, under skin or into muscle
Storage and Handling²	<ul style="list-style-type: none"> Store at 2 °C to 25 °C (36 °F to 77 °F) in the original carton until ready to use Exposure up to 30 °C (86 °F) is permitted APRETUDE does not require refrigeration. If the pack has been stored in the refrigerator, the vial should be brought to room temperature prior to administration. Do not use any heating methods other than using the warmth of your hands Once APRETUDE has been drawn into the syringe, it can remain for up to 2 hours before injection. The filled syringe should not be placed in the refrigerator. If 2 hours are exceeded, the filled syringe and needle must be discarded Do not freeze or mix with other products or diluents
Administration	APRETUDE is administered as an intramuscular injection by a healthcare professional every 2 months after 2 initiation injections administered 1 month apart. Prior to initiating APRETUDE, cabotegravir tablets may be used as an oral lead-in for approximately 1 month (at least 28 days) to assess tolerability. Adherence to the dosing schedule is strongly recommended. ¹

References: 1. Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated March 26, 2025. Accessed May 16, 2025. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update> 2. National Alliance of State and Territorial AIDS Directors. Long-acting injectable PrEP is here: frequently asked questions for implementation. May 2022. Accessed May 16, 2025. https://nastad.org/sites/default/files/2022-06/PDF_LAI-FAQ-Formatted-Updated6.13.22.pdf

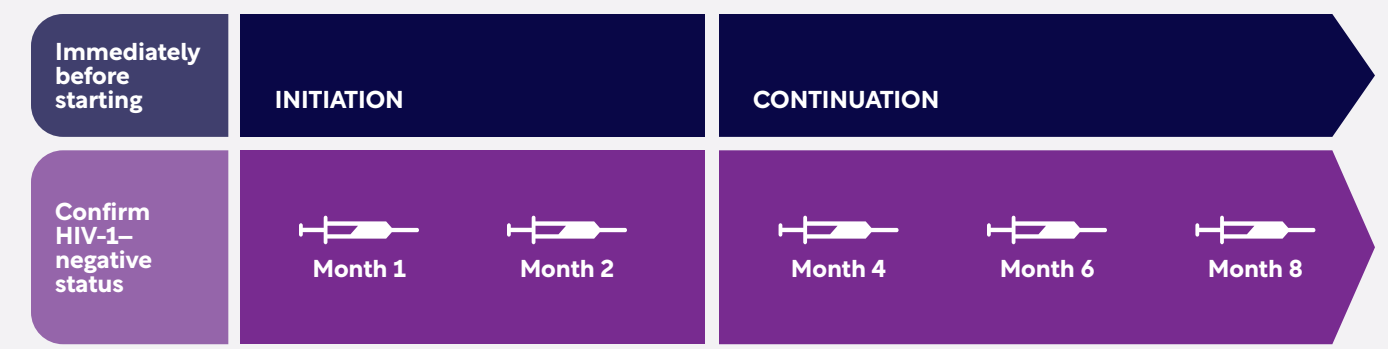
IMPORTANT SAFETY INFORMATION (cont'd)

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.

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

RECOMMENDED DOSING SCHEDULE*



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

HCPs 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.

Prior to initiation injections, an optional oral lead-in may be used to assess tolerability of APRETUDE.[†]

Initiation and continuation injections

- Patients should receive 2 gluteal intramuscular initiation injections administered 1 month apart
- Patients should receive 1 gluteal intramuscular injection every 2 months thereafter for as long as they remain on APRETUDE

HCP=healthcare professional.

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

†The recommended oral lead-in dose is one 30-mg tablet of cabotegravir daily for approximately 1 month (at least 28 days). Initiation injections should be administered on the last day of oral lead-in, if used, or within 3 days thereafter. For more information, please see the full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

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



SERVICES

ViiVCONNECT HUB SERVICES



ViiVConnect Hub services offers support resources to facilitate patient access to APRETUDE. Your office has the flexibility to choose the level of service needed.



USING ViiVCONNECT HUB SERVICES

Through ViiVConnect, you can:

- Conduct a benefits verification
- Navigate acquisition pathways (medical benefit, pharmacy benefit, or both)
- Receive patient-specific case management with a single point of contact
- Confirm eligibility and enroll patients in savings support programs
- Identify formulary exceptions, PA requirements, and predeterminations
- Get information on reimbursement claims, denials, and appeals
- Coordinate with specialty pharmacies to facilitate communication with your patients
- Receive patient enrollment status updates and identify missing information

Enroll your patients in ViiVConnect via one of the following options:



Complete a **APRETUDE Enrollment Form** and fax it to 1-844-208-7676



Visit the **ViiVConnect HCP Portal** to enroll your patients electronically and to take advantage of the portal's additional offerings

PATIENT eSIGNATURE

Get your patient's eSignature authorization by scanning the QR code below.



Call a ViiVConnect Access Coordinator

1-844-588-3288

Toll free. Monday–Friday, 8 AM–8 PM (ET). Language options are available.

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.



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