Medical Drug Clinical Criteria

Subject:	Apretude (cabotegravir extended-release injectable suspension)		
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Table of Contents

Overview

This document addresses the use of Apretude (cabotegravir extended-release injectable suspension), an integrase strand-transfer inhibitor (INSTI) approved by the Food and Drug Administration (FDA) in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired human immunodeficiency virus (HIV) infection. Apretude is administered by a healthcare provider once every 2 months as a gluteal intramuscular injection. Individuals must have a negative HIV test prior to initiating Apretude. Cabotegravir is also available for treatment of HIV as an extended-release injectable in combination with rilpivirine under the brand name Cabenuva and in an oral formulation under the brand name Vocabria. Cabenuva is addressed in clinical criteria in ING-CC-0194.

Apretude has a black box warning for risk of drug resistance when used in individuals with undiagnosed HIV infection. Individuals must be tested for HIV infection prior to initiating Apretude and with each subsequent injection of Apretude. Drug-resistant HIV variants have been identified with use of Apretude in individuals with undiagnosed HIV infection. Individuals who become infected with HIV while receiving Apretude for PrEP must transition to a complete HIV treatment regimen.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Apretude (cabotegravir extended-release injectable suspension)

Initial requests for Apretude (cabotegravir extended-release injectable suspension) may be approved if the following criteria are met:

I. Individual weighs at least 35 kg; **AND**
II. Individual is using for pre-exposure prophylaxis (PrEP) of human immunodeficiency (HIV) infection; **AND**
III. Individual will undergo HIV testing immediately (within one week) prior to initiating therapy to verify HIV negative status.

Continuation requests for Apretude (cabotegravir extended-release injectable suspension) may be approved if the following criteria are met:

I. Individual is using for pre-exposure prophylaxis (PrEP) of human immunodeficiency (HIV) infection; **AND**
II. Individual is undergoing HIV testing immediately (within one week) prior to each Apretude injection to verify HIV negative status.

Apretude (cabotegravir extended-release injectable suspension) may not be approved for the following:

I. Individual who is HIV positive or whose HIV status is unknown; **OR**
II. When the above criteria are not met and for all other indications.

Quantity Limits

Apretude (cabotegravir extended-release injectable suspension) Quantity Limit

Drug	Limit
Apretude (cabotegravir extended-release injectable suspension) 600 mg/3 mL vial	1 vial per 2 months
Override Criteria	
Initiation of therapy: May approve one additional vial in the first two months of initiating therapy OR re-initiating therapy after missed doses.	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J0739	Injection, cabotegravir, 1 mg, FDA approved prescription, only for use as HIV pre-exposure prophylaxis (not for use as treatment for HIV) [Apretude]

ICD-10 Diagnosis

Z11.4	Encounter for screening for human immunodeficiency virus [HIV]
Z29.81	Encounter for HIV pre-exposure prophylaxis

Document History

New: 8/15/2025
Document History:

- 8/15/2025 – Annual Review: Add new clinical criteria and quantity limit for Apretude. Coding Reviewed: Added HCPCS J0739 and ICD-10-CM Z11.4, Z29.81.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 19, 2025.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.