



HIV Injectables

Drug(s) Applied:	Apretude (cabotegravir extended-release injectable suspension) Cabenuva (cabotegravir/rilpivirine extended-release injectable suspension)
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Curative considers all [Grade A USPSTF](#) recommendation PrEP agents to be preferred with evidence of medical necessity. All other agents that are currently not Grade A recommended PrEP are considered non-preferred including Yeztugo.

Criteria:

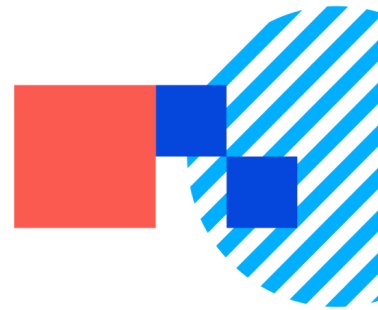
Drug(s) Applied are considered medically necessary when the requested drug meets ALL the criteria below:

Coverage is recommended for all evidence-based [DHHS guideline-recommended](#) regimens (Category AI, All, AIII), preferring covered formulary options. When multiple combination regimens or formulations are DHHS-recommended, approval should prioritize those covered on formulary either individually or as a combination. Curative considers Cabenuva as a drug used for convenience. Curative considers all other injectable agents for HIV treatment to be non-preferred including Sunlenca.

I. Initial Therapy Criteria

A. HIV PrEP as indicated by chart notes within past 180 days

1. Request is for Apretude **and**
2. Patient is a sexually active adult or adolescent weighing at least 35 kg (77 lb) who has engaged in anal or vaginal sex in the past 6 months and has at least ONE of the following:
 - a) A sexual partner who has HIV (especially if the partner has an unknown or detectable viral load)
 - b) A bacterial sexually transmitted infection (syphilis, gonorrhea, or chlamydia for men who have sex with men and transgender women; gonorrhea and syphilis for heterosexual women and men) in the past 6 months
 - c) A history of inconsistent or no condom use with sex partner(s) whose HIV status is not known; assessing risk in conversation with the patient and considering factors such as number of partners, the specific sexual activities a person engages in, and whether their sex partner or partners are in a group with a higher prevalence of HIV (eg, men who have sex with men or with men and women, transgender women, persons who inject drugs, and persons who engage in transactional sex) **and**
3. Confirmed negative infection status for HIV-1 infection using an HIV-1 test in the



past 30 days

Approval Duration: 12 months

B. HIV treatment as indicated by chart notes within past 180 days

1. HIV injectable drugs for convenience are NOT restricted from coverage under the patient's benefit **and**
2. Request is for Cabenuva **and**
3. Patient is 12 years of age or older and weighs at least 35 kg (77 lb) **and**
4. Has been stable on a complete oral regimen for at least 3 months **and**
5. Labs confirm patient is virologically suppressed with HIV-1 RNA <50 copies/mL in the past 30 days **and**
6. Chart notes and/or prescriber do not indicate a history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

Approval Duration: 12 weeks

*If oral lead-in therapy is requested, ensure oral option is approved for up to 6 weeks as well.

II. Continued Therapy Criteria

A. HIV PrEP as indicated by chart notes within past 12 months

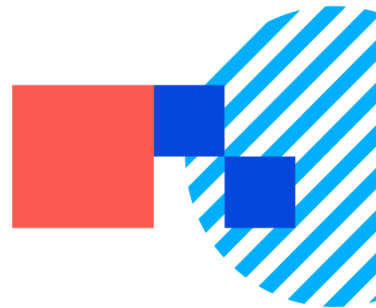
1. Request is for Apretude **and**
2. Patient meets the initial therapy criteria above **and**
3. Confirmed negative infection status for HIV-1 infection using an HIV-1 test in the past 30 days

Approval Duration: 12 months

B. HIV treatment as indicated by chart notes within past 12 months

1. HIV injectable drugs for convenience are NOT restricted from coverage under the patient's benefit **and**
2. Request is for Cabenuva **and**
3. Patient meets the initial therapy criteria above **and**
4. Chart notes, claims and/or prescriber do not indicate there was a missed injection of Cabenuva by more than 7 days and oral dosing was not being taken in the interim **and**
5. Labs within the past 4 months confirm patient has maintained viral suppression with HIV-1 RNA < 200 copies/mL while on requested therapy

Approval Duration: 12 months



If submitting for medical billing:

J0739, cabotegravir extended-release injectable suspension (Apretude), 1 unit = 1 mg

J0741, cabotegravir and rilpivirine (Cabenuva), 1 unit = 2mg/3mg