curative

# HIV Injectables

| | |
|---|---|
| **Drug(s) Applied:** | **Apretude** (cabotegravir extended-release injectable suspension)<br>**Cabenuva** (cabotegravir/rilpivirine extended-release injectable suspension) |

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, AII, 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

curative

**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