

Cabenuva® (cabotegravir extended-release injectable suspension/rilpivirine extended-release injectable suspension)



When requesting Cabenuva® (cabotegravir and rilpivirine extended-release injectable suspensions), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace their current antiretroviral (ARV) regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable ARV regimen with no history of treatment failure and with no known or suspected resistance to cabotegravir or rilpivirine.

Coverage Guidelines

Human Immunodeficiency Virus Type-1 (HIV-1), Treatment

The individual must meet **all** of the following criteria for initial approval:

- Patient is greater than or equal to 12 years of age and weighs greater than or equal to 35 kg; AND
- Patient has HIV-1 RNA < 50 copies/mL (viral suppression); AND
- Patient was treated with a stable regimen (≥ 4 months) of antiretrovirals prior to initiating Cabenuva or one month lead-in with Vocabria (cabotegravir tablets); AND
- Patient has difficulty maintaining compliance with daily antiretroviral regimen OR has severe gastrointestinal issues that may limit absorption or tolerance of oral medications; AND
- The medication is prescribed by or in consultation with a physician who specializes in treatment of HIV infection

The individual must meet the following criteria for renewal:

- Patient has HIV-1 RNA < 50 copies/mL (viral suppression)

Approval duration (initial and renewal): 12 months

Dosing Recommendation

Once Monthly Dosing:

After an oral lead-in is used, initiation injections should be administered on the last day of oral lead-in. The recommended initiation injection doses of Cabenuva in individuals is a single 600-mg (3-mL) intramuscular injection of cabotegravir and a single 900-mg (3-mL) intramuscular injection of rilpivirine.

After the initiation injection doses are given, the recommended continuation injection dose of Cabenuva is a single 400-mg (2-mL) intramuscular injection of cabotegravir and a single 600-mg (2-mL) intramuscular injection of rilpivirine every month.

Once Every 2 Month Dosing:

After an oral lead-in is used, initiation injections should be administered on the last day of oral lead-in. The recommended initiation injection doses of Cabenuva in individuals is a single 600-mg (3-mL) intramuscular injection of cabotegravir and a single 900-mg (3-mL) intramuscular injection of rilpivirine given 1 month apart for 2 consecutive months.

After the initiation injection doses are given, the recommended continuation injection dose of Cabenuva is a single 600-mg (3-mL) intramuscular injection of cabotegravir and a single 900-mg (3-mL) intramuscular injection of rilpivirine every 2 months.

References

1. Cabenuva® injection [prescribing information]. Research Triangle Park, NJ: ViiV Healthcare/GlaxoSmithKline; March 2022.
2. Orkin C, Arasteh K, Hernandez-Mora G, et al. Long-acting cabotegravir and rilpivirine after oral induction for HIV-1 infection. *N Engl J Med*. 2020;382:1124-1135.
3. Swindells S, Andrade-Villaneuva JF, Richmond GJ, et al. Long-acting cabotegravir and rilpivirine for maintenance of HIV-1 suppression. *N Engl J Med*. 2020; 382;12:1112-1123.
4. Saag MS, Gandhi RT, Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults. 2020 recommendations of the International Antiviral Society-USA Panel. *JAMA*. 2020;324(16):1651-1669.
5. Adolescents with HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Updated January 20, 2022. Accessed January 31, 2022.
6. Orkin C, Bernal E, Tan DHS, et al. Initiation of long-acting cabotegravir plus rilpivirine as direct-to-injection or with an oral lead-in in adults with HIV-1 infection: Week 124 results of the open-label phase 3 FLAIR study. *Lancet HIV*. 2021;11:e668-e678.