

Cabenuva® (cabotegravir and 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 the 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 either cabotegravir or rilpivirine.

Coverage Guidelines

Human Immunodeficiency Virus Type-1 (HIV-1) Infection

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

- Is 12 years of age or older;
- Weighs at least 35 kg;
- Has HIV-1 RNA < 50 copies/mL (viral suppression);
- Was treated with a stable regimen ($\geq$ 3 months) of antiretrovirals prior to initiating Cabenuva or one month lead-in with Vocabria (cabotegravir tablets);
- Cabenuva is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection

The individual must meet the following criteria for re-authorization:

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

Approval duration (initial and renewal): 12 months

Dosing Recommendations

Recommended Monthly Dosing Schedule:

Initiate injections of Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine) on the last day of current antiretroviral therapy or oral lead-in and continue with injections of Cabenuva (400 mg of cabotegravir and 600 mg of rilpivirine) every month thereafter.

Recommended Every-2-Month Dosing Schedule:

Initiate injections of Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine) on the last day of current antiretroviral therapy or oral lead-in for 2 consecutive months and continue with injections of Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine) every 2 months thereafter.

References

1. Cabenuva® injection [prescribing information]. Research Triangle Park, NJ: ViiV/GlaxoSmithKline; September 2024.
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/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new-guidelines>. Updated September 12, 2024. Accessed February 3, 2025.
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.
7. Ghandi RT, Bedimo R, and Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults. 2022 recommendations of the International Antiretroviral Society-USA Panel. *JAMA*. 2023;329(1):63-84.