

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



When requesting Cabenuva® (cabotegravir and rilpivirine extended-release injectable suspension), 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 indications.

FDA-approved indication

- Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults 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 (HIV)

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

- Patient is greater than or equal to 18 years of age; AND
- Patient has HIV type-1 (HIV-1) infection; AND
- Patient has HIV-1 RNA < 50 copies/mL (viral suppression); AND
- Patient has completed, or will complete, and tolerated 1 month of therapy with Vocabria (cabotegravir tablets) + Edurant (rilpivirine tablets); AND
- The medication is prescribed by or in consultation with a physician who specializes in treatment of HIV infection

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

- Patient has HIV type-1 (HIV-1) infection; AND
- Patient has HIV-1 RNA < 50 copies/mL (viral suppression)

Approval duration (initial and renewal): 12 months

Dosing Recommendation

- Approve 600 mg/900 mg intramuscularly for one dose, then approve 400 mg/600 mg intramuscularly once monthly thereafter (every 4 weeks); OR
- Approve 400 mg/600 mg intramuscularly once monthly (every 4 weeks)

References

1. Cabenuva® injection [prescribing information]. Research Triangle Park, NJ: ViiV Healthcare/GlaxoSmithKline; January 2021.
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. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Updated December 18, 2019. Accessed January 27, 2021.