Reference number(s)
4517-A

Specialty Guideline Management Cabenuva

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Cabenuva	cabotegravir extended-release injectable suspension and rilpivirine extended-release injectable suspension

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Cabenuva is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per milliliter [mL]) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

All other indications are considered experimental/investigational and not medically necessary.

Compendial Uses

HIV-1 infection with viremia[2,3]

Documentation

Submission of the following information is necessary to initiate the prior authorization review for initial requests:

- Plasma HIV-1 RNA level (viral load) within the last 6 months
- For HIV-1 infection with viremia only: laboratory results, chart notes, or medical record documentation supporting high risk of disease progression.

Coverage Criteria

Human Immunodeficiency Virus Type 1 (HIV-1) Infection[1-3]

Authorization of 12 months may be granted for treatment of human immunodeficiency virus type 1 (HIV-1) infection when either of the following criteria is met:

- Member meets all of the following criteria:
  - Member is currently receiving a stable antiretroviral regimen.
  - Member is virologically suppressed on the current antiretroviral regimen with HIV-1 RNA level (viral load) less than 50 copies per mL.
  - Member has no history of treatment failure.
  - Member has no known or suspected resistance to either cabotegravir or rilpivirine.
- Member meets all of the following criteria:
  - Member has viremia (i.e., elevated HIV-1 RNA level [viral load]).
  - Member has high risk of disease progression (e.g., cluster of differentiation 4 [CD4] count less than 200 cells per microliter, history of acquired immunodeficiency syndrome [AIDS]-defining complications).
  - Member is unable to achieve or maintain virologic suppression while on oral antiretroviral therapy (ART) despite intensive medication adherence support.
  - The prescriber attests that they have discussed the significant risk of resistance to certain drug classes (e.g., non-nucleoside reverse transcriptase inhibitors [NNRTIs], integrase strand transfer inhibitors [INSTIs]) if virologic failure is experienced while receiving treatment with the requested medication.
  - Member has no known or suspected resistance to either cabotegravir or rilpivirine.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for treatment of human immunodeficiency virus type 1 (HIV-1) infection when the member

has not experienced a virologic failure while on the requested drug, defined as two consecutive plasma HIV-1 RNA levels (viral loads) greater than or equal to 200 copies per mL.[1-3]

References

1. Cabenuva [package insert]. Durham, NC: ViiV Healthcare; September 2024.
2. 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 https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed January 6, 2025.
3. Gandhi RT, Landovitz RJ, Sax PE, et al. Antiretroviral drugs for treatment and prevention of HIV in adults: 2024 Recommendations of the International Antiviral Society–USA Panel. JAMA. Published online December 1, 2024. doi: 10.1001/jama.2024.24543