Reference number(s)
4517-A

SPECIALTY GUIDELINE MANAGEMENT

CABENUVA (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension)

POLICY

I. 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 Indication
Cabenuva is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per 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.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: for initial requests, current plasma HIV-1 RNA level (viral load)

III. CRITERIA FOR INITIAL APPROVAL

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

A. Member is currently receiving a stable antiretroviral regimen.
B. Member is virologically suppressed on the current antiretroviral regimen with HIV-1 RNA less than 50 copies per mL.
C. Member has no history of treatment failure.
D. Member has no known or suspected resistance to either cabotegravir or rilpivirine.
E. Member will receive oral lead-in with cabotegravir (Vocabria) and rilpivirine (Edurant) for at least 28 days prior to the initiation of Cabenuva to assess the tolerability of cabotegravir and rilpivirine.

IV. 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 greater than or equal to 200 copies per mL.

V. REFERENCES

1. Cabenuva [package insert]. Research Triangle Park, NC: ViiV Healthcare; January 2021.
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/sites/default/files/inline-files/AdultandAdolescentGL.pdf. Accessed February 15, 2021.