COMMON GROUND
HEALTHCARE COOPERATIVE

PHARMACY POLICY STATEMENT
Common Ground Healthcare Cooperative (CGHC)

DRUG NAME	**Cabenuva (cabotegravir/rilpivirine)**
BILLING CODE	J0741
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office
STATUS	Prior Authorization Required

Cabenuva is a co-packaged product consisting of 2 different injectable drugs: cabotegravir, an integrase strand transfer inhibitor (INSTI), and rilpivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI). Both are once-monthly intramuscular injections given separately at the same time. Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed. Prior to initiating treatment with Cabenuva, oral lead-in dosing (available at no-charge) should be used for approximately 1 month to assess tolerability of cabotegravir and rilpivirine.

Cabenuva (cabotegravir/rilpivirine) will be considered for coverage when the following criteria are met:

HUMAN IMMUNODEFICIENCY VIRUS TYPE-1 (HIV-1)

For **initial** authorization:

1. Member is at least 12 years of age and weigh at least 35 kg; AND
2. Medication must be prescribed by or in consultation with an HIV specialist; AND
3. Member has a diagnosis of HIV-1; AND
4. Member is currently virologically suppressed (HIV-1 RNA < 50 copies/mL) for at least 3 months; AND
5. Member is stable on a complete oral antiretroviral therapy (ART) regimen and there is a documented clinical reason for switching to Cabenuva; AND
6. Member does NOT have any of the following:
   a) Baseline resistance to either cabotegravir (Vocabria) or rilpivirine (Edurant);
   b) Prior virologic failure with any antiretroviral therapy;
   c) Active hepatitis B virus (HBV) infection.
7. **Dosage allowed/Quantity limit:** prior to initiating treatment with Cabenuva, oral lead-in may be used for at least 28 days to assess tolerability of cabotegravir and rilpivirine.
   One month dosing schedule: Initiate injections (600 mg of cabotegravir and 900 mg of rilpivirine) on the last day of oral lead-in and continue with injections (400 mg of cabotegravir and 600 mg of rilpivirine) every month thereafter.
   Two-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 every 2 months thereafter.

If all the above requirements are met, the medication will be approved for 6 months.

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For **reauthorization**:
1. Chart notes must demonstrate that member remains virologically suppressed (HIV-1 RNA < 50 copies/mL) after initiation of treatment.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Common Ground Healthcare Cooperative (CGHC) considers Cabenuva (cabotegravir/rilpivirine) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
03/17/2021	New policy for Cabenuva (cabotegravir/rilpivirine) created.
11/16/2021	Added J code. Changed to medical benefit only.
05/13/2022	Updated age and weight requirements; Added every 2 month dosing; Updated lead-in therapy to optional; Updated references.

References:

1. Cabenuva [package insert]. Research Triangle Park, NC; GlaxoSmithKline. April 2022.
2. Vocabria [package insert]. Research Triangle Park, NC; GlaxoSmithKline. January 2021.
3. 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 March 17, 2021.
4. Swindells S, Andrade-Villanueva JF, Richmond GJ, et al. Long-Acting Cabotegravir and Rilpivirine for Maintenance of HIV-1 Suppression. *N Engl J Med*. 2020;382:1112-1123.
5. Orkin C, Arasteh K, Hernández-Mora MG, et al. Long-Acting Cabotegravir and Rilpivirine after Oral Induction for HIV-1 Infection. *N Engl J Med*. 2020;382:1124-1135.
6. Rizzardini G, Overton ET, Orkin C, et al. Long-Acting Injectable Cabotegravir + Rilpivirine for HIV Maintenance Therapy: Week 48 Pooled Analysis of Phase 3 ATLAS and FLAIR Trials. *J Acquir Immune Defic Syndr*. 2020;85(4):498-506.
7. Overton ET, Richmond GJ, Rizzardini G, et al. Long-acting cabotegravir and rilpivirine dosed every 2 months in adults with HIV-1 infection (ATLAS-2M), 48-week results: a randomised, multicentre, open-label, phase 3b, non-inferiority study. *Lancet*. 2020;396(10267):1994-2005.

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