Protocol for Cabenuva® (cabotegravir/rilpivirine) Injectable
Approved July 2021

Background:

Cabenuva*, is a two-drug co-packaged product of cabotegravir, a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI), and rilpivirine, an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI), 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 (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*

Criteria for approval:

1. Patient meets ONE of the following conditions (A or B):
   - **A. Initial therapy – Patient must meet the following:**
     a. Patient is ≥ 18 years of age
     b. Patient has HIV type-1 (HIV-1) infection
     c. Patient has HIV-1 RNA < 50 copies/mL (viral suppression)
     d. According to the prescriber, the patient has completed, or will complete, and is tolerating or will tolerate approximately 1 month of therapy (lead-in) with Vocabria (cabotegravir tablets) + Edurant (rilpivirine tablets"
     e. Patient is currently receiving antiretrovirals for the treatment of HIV-1 with a stable regimen (≥ 4 months)
     f. Patient has no documented history of suspected resistance to cabotegravir or rilpivirine
   - **B. Patient is currently receiving Cabenuva and meets the following:**
     a. Patient has HIV type-1 (HIV-1) infection; **AND**
     b. Patient has HIV-1RNA <50 copies/mL (viral suppression)
2. Medication is prescribed by or in consultation with a physician who is experienced in the treatment of HIV infection"
3. According to the prescriber, the patient meets ONE of the following (a or b):
   a. Patient has difficulty maintaining compliance with a daily antiretroviral regimen for HIV1; **OR**
   b. Patient has severe gastrointestinal issues that may limit absorption or tolerance of oral medications
4. Patient does not have any contraindications to therapy
5. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Initial Approval Duration: 6 months

Continuation of therapy:

1. Medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection or Infectious disease
2. Patient has not experienced a virologic failure while on Cabenuva, defined as two consecutive plasma HIV-1 RNA levels greater than or equal to 200 copies per mL
3. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Renewal Approval Duration: 6 months

References:

1. Cabenuva® injection [prescribing information]. Research Triangle Park, NJ: ViiV Healthcare/GlaxoSmithKline; Research Triangle Park, NC. January 2021

2. 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.

3. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically

4. Swindells S, Andrade-Villaneuva JF, Richmond GJ, et al. Long-acting cabotegravir and rilpivirine for maintenance of HIV1 suppression. N Engl J Med. 2020; 382;12:1112-1123