## Cabenuva (cabotegravir/rilpivirine) – New indication

- On March 29, 2022, ViiV Healthcare announced the FDA approval of Cabenuva (cabotegravir/rilpivirine), as a complete regimen for the treatment of human immunodeficiency virus (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 < 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.
    - Cabenuva was previously approved for this indication in adults only.
- The drug label for Vocabria®, a single-ingredient oral tablet formulation of cabotegravir, was also updated to include a similar expanded indication for short-term treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg.
- The approval of Cabenuva for the expanded indication was based on studies in adults and the MOCHA study in adolescents. MOCHA was an open-label, non-comparative study in 23 adolescents that evaluated the safety, tolerability, and pharmacokinetics of oral and injectable cabotegravir and oral and injectable rilpivirine.
- Prior to initiating treatment with Cabenuva, oral lead-in dosing may be considered to assess the tolerability of cabotegravir and rilpivirine with the recommended dosage used for approximately 1 month or the healthcare provider and patient may proceed directly to injection of Cabenuva without the use of an oral lead-in.
- Cabenuva intramuscular injections are administered either once monthly or once every 2 months.
    - Recommended monthly dosing schedule: Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine) is initiated on the last day of current antiretroviral therapy or oral lead-in and Cabenuva (400 mg of cabotegravir and 600 mg of rilpivirine) is continued every month thereafter.
    - Recommended every-2-month dosing schedule: Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine) is initiated on the last day of current antiretroviral therapy or oral lead-in for 2 consecutive months and Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine) is continued every 2 months thereafter.
- Refer to the Cabenuva drug label for complete dosing and administration recommendations.