BlueCross BlueShield
Federal Employee Program

CABENUVA
(cabotegravir/rilpivirine)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Cabenuva is a 2-drug co-packaged product containing 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). Cabotegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral DNA integration which is essential for the HIV replication cycle. Rilpivirine is a diarylpyrimidine NNRTI of HIV-1 and inhibits HIV-1 replication by non-competitive inhibition of HIV-1 reverse transcriptase (1).

Regulatory Status

FDA-approved indication: 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 mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine (1).

Cabenuva may be initiated with oral cabotegravir and oral rilpivirine prior to the intramuscular injections or the patient may proceed directly to injection of Cabenuva without an oral lead-in. Cabenuva must be administered by a healthcare professional (1).

Hypersensitivity reactions have been reported during postmarketing experience with rilpivirine-containing regimens. Reactions include cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Cabenuva should be discontinued immediately if signs or symptoms of hypersensitivity reactions develop (1).

Hepatotoxicity has been reported in patients receiving cabotegravir or rilpivirine with or without known pre-existing hepatic disease or identifiable risk factors. Patients should have their liver chemistries monitored and treatment with Cabenuva should be discontinued if hepatotoxicity is suspected (1).

Healthcare professionals should carefully select patients who agree to the required monthly or

every-2-month injection dosing schedule and counsel patients about the importance of adherence to scheduled dosing visits to help maintain viral suppression and reduce the risk of viral rebound and potential development of resistance with missed doses (1).

The safety and efficacy of Cabenuva in pediatric patients less than 12 years of age or weighing less than 35 kg have not been established (1).

Summary

Cabenuva is a 2-drug co-packaged product containing 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). Cabenuva is used in the treatment of HIV-1 infection to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL). The safety and efficacy of Cabenuva in pediatric patients less than 12 years of age or weighing less than 35 kg have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Cabenuva while maintaining optimal therapeutic outcomes.

References

1. Cabenuva [package insert]. Research Triangle Park, NC: ViiV Healthcare; September 2024.