DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Human Immunodeficiency Virus – Cabenuva Drug Quantity Management Policy – Per Days

- Cabenuva® (cabotegravir extended-release intramuscular injection; rilpivirine extended-release intramuscular injection, co-packaged – ViiV/GlaxoSmithKline)

REVIEW DATE: 02/23/2022

OVERVIEW

Cabenuva is a two-drug co-packaged product of cabotegravir, a human immunodeficiency virus type-1 (HIV-1) integrase strand-transfer inhibitor, and rilpivirine, an HIV-1 non-nucleoside reverse transcriptase inhibitor.[1] It is indicated as a complete regimen for the treatment of **HIV-1 infection** in patients ≥ 12 years of age and ≥ 35 kg to replace their current antiretroviral (ARV) regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable ARV regimen with no of treatment failure and with no known or suspected resistance to cabotegravir or rilpivirine.

Dosing

Cabenuva must be administered by a healthcare professional.[1] Prior to starting Cabenuva, healthcare professionals should carefully select patients who agree to the required monthly 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]

Oral lead-in with Vocabria® (cabotegravir tablets) + Edurant® (rilpivirine tablets) may be used for approximately 1 month (at least 28 days) prior to the initiation of Cabenuva to assess the tolerability of cabotegravir and rilpivirine.[1] Cabenuva may be administered as a once-monthly injection or once every 2 month injection. Table 1 provides the recommended oral lead-in and monthly injection dosing schedule. Table 2 provides the recommended oral lead-in and every 2 month injection dosing schedule.

Table 1. Recommended Oral Lead-In and Monthly Intramuscular Injection Dosing Schedule.[1]

Vocabria + Edurant Lead-In (at Least 28 Days)	Cabenuva Initiation Injections (One-Time Dosing)	Cabenuva Continuation Injections (Once-Monthly Dosing)
Month 1	At Month 2 (On the Last Day of Oral Lead-In Dosing)	Month 3 Onwards
Vocabria (30 mg) QD with a meal	cabotegravir 600 mg (3 mL)	cabotegravir 400 mg (2 mL)
Edurant (25 mg) QD with a meal	rilpivirine 900 mg (3 mL)	rilpivirine 600 mg (2 mL)

QD – Once daily.

Table 2. Recommended Oral Lead-In and Every 2 Month Intramuscular Injection Dosing Schedule.[1]

Vocabria + Edurant Lead-In (at Least 28 Days)	Cabenuva Initiation Dosing	Cabenuva Continuation Injections (Once Every 2 Month Dosing)
Month 1	At Month 2 and Month 3	Month 5 Onwards
Vocabria (30 mg) QD with a meal	cabotegravir 600 mg (3 mL)	cabotegravir 600 mg (3 mL)
Edurant (25 mg) QD with a meal	rilpivirine 900 mg (3 mL)	rilpivirine 900 mg (3 mL)

Availability

Cabenuva is supplied in two dosing kits.[1] The 400 mg/600 mg kit contains one 400 mg/2 mL vial of cabotegravir and one 600 mg/2 mL vial of rilpivirine. The 600 mg/900 mg kit contains one 600 mg/3 mL vial of cabotegravir and one 900 mg/3 mL of rilpivirine.

POLICY STATEMENT

This Drug Quantity Management program has been developed to manage potential dose escalation of Cabenuva. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity
Cabenuva® (cabotegravir extended-release IM injection; rilpivirine extended-release IM injection, co-packaged)	400 mg/600 mg Kit (one 400 mg/2 mL vial of cabotegravir and one 600 mg/2 mL vial of rilpivirine)	1 kit per 30 days
	600 mg/900 mg Kit (one 600 mg/3 mL vial of cabotegravir and one 900 mg/3 mL vial of rilpivirine)	1 kit per 60 days

IM – Intramuscular.

CRITERIA

Cabenuva 400 mg/600 mg Kit
No overrides recommended.

Cabenuva 600 mg/900 mg Kit

1. If the patient has missed greater than two consecutive doses of Cabenuva 400 mg/600 mg, approve a one-time override for one Cabenuva 600 mg/900 mg kit.

2. If the patient is initiating treatment or requires an additional loading-dose for the every other month dosing regimen, approve a one-time override for two Cabenuva 600 mg/900 mg kits.

REFERENCES

1. Cabenuva® injection [prescribing information]. Research Triangle Park, NJ: ViiV Healthcare/GlaxoSmithKline; March 2022.