Optum Rx®

Sunlenca® (lenacapavir) – New drug approval

- On December 22, 2022, the FDA announced the approval of Gilead Sciences' Sunlenca (lenacapavir), in combination with other antiretroviral(s), for the treatment of human immunodeficiency virus (HIV)-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

- Sunlenca is the first of a new class of drugs called capsid inhibitors to be FDA-approved for treating HIV-1. Sunlenca works by blocking the HIV-1 virus' protein shell (the capsid), thereby interfering with multiple essential steps of the viral lifecycle.

- The efficacy of Sunlenca was established in a 52-week, randomized, double-blind, placebo-controlled study (CAPELLA) of 72 heavily treatment-experienced subjects with multiclass resistant HIV-1. Patients were enrolled into one of two study groups. One group was randomized to receive either Sunlenca or placebo in a double-blind fashion, and the other group received open-label Sunlenca. The primary measure of efficacy was the proportion of patients in the randomized study group achieving ≥ 0.5 $\log_{10}$ copies/mL reduction from baseline in HIV-1 RNA during the initial 14 days vs. baseline.

    - The proportion of subjects achieving a ≥ 0.5 $\log_{10}$ decrease in viral load was 87.5% in the Sunlenca group vs. 16.7% in the placebo group (treatment difference 70.8%; 95% CI: 34.9, 90.0; $p < 0.0001$).

- Sunlenca is contraindicated in patients taking strong CYP3A inducers due to decreased lenacapavir plasma concentrations, which may result in the loss of therapeutic effect and development of resistance to Sunlenca.

- Warnings and precautions for Sunleca include immune reconstitution syndrome, long-acting properties and potential associated risks with Sunlenca, and injection site reactions.

- The most common adverse reactions (≥ 3%) with Sunlenca use were nausea and injection site reactions.

- The recommended dose of Sunlenca can be initiated using one of two recommended dosage regimens, see Table 1 and Table 2 below. Healthcare providers should determine the appropriate initiation regimen for the patient.

    - Sunlenca injection is for administration into the abdomen by a healthcare provider.

Table 1: Recommended Treatment Regimen for Sunlenca Initiation and Maintenance, Option 1

Treatment Time	
	Dosage of Sunlenca: Initiation
Day 1	927 mg by subcutaneous injection (2 x 1.5 mL injections) 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
	Dosage of Sunlenca: Maintenance
Every 6 months (26 weeks)[a] +/-2 weeks	927 mg by subcutaneous injection (2 x 1.5 mL injections)

Continued . . .

[a] From the date of the last injection.

Table 2: Recommended Treatment Regimen for Sunlenca Initiation and Maintenance, Option 2

Treatment Time	
	Dosage of Sunlenca: Initiation
Day 1	600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Day 8	600 mg orally (2 x 300 mg tablets)
Day 15	927 mg by subcutaneous injection (2 x 1.5 mL injections)
	Dosage of Sunlenca: Maintenance
Every 6 months (26 weeks)[a] +/-2 weeks	927 mg by subcutaneous injection (2 x 1.5 mL injections)

[a] From the date of the last injection.

- Gilead Sciences launch plans for Sunlenca are pending. Sunlenca will be available as a 300 mg tablet and a 463.5 mg/1.5 mL (309 mg/mL) sterile, preservative-free injectable solution.