

lenacapavir (Sunlenca)

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administratiton

Infusion Center Administration

Office Administration

Outpatient Facility Administration

Drug Details

USP Category: ANTIVIRALS

Mechanism of Action: Capsid inhibitor

HCPCS:

J1961:Injection, lenacapavir (only for use as hiv treatment), 1 mg

How Supplied:

463.5 mg/1.5 mL (309 mg/mL) in single-dose vials

Condition(s) listed in policy (see coverage criteria for details)

- Multi-Drug Resistant HIV-1 Infection

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

The Sunlenca tablet formulation is managed under the outpatient Pharmacy Benefit. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

The Sunlenca subcutaneous formulation is covered under the Medical Benefit, please submit clinical information for prior authorization review.

This policy only applies to the drug Sunlenca. This policy does NOT apply to the drug Yeztugo. Yeztugo tablets and injections that are used for HIV-1 PrEP (pre-exposure prophylaxis) are covered under the Medical Benefit and do not require a prior authorization.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Multi-Drug Resistant HIV-1 Infection

Meets medical necessity if all the following are met:

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1. Prescribed by or in consultation with an infectious disease or HIV specialist
2. Patient's HIV-1 isolate has documented resistance to at least one (1) antiretroviral medication from three (3) separate drug classes of antiretroviral medications
3. Confirmation that Sunlenca will be taken in combination with an optimized background antiretroviral regimen which contains at least one other partially or fully active antiretroviral medication.

Covered Doses:

Initiation Option 1	
Day 1	927 mg by subcutaneous injection (2 x 1.5 mL injections) <i>600 mg orally (2 x 300 mg tablets)</i>
Day 2	<i>600 mg orally (2 x 300 mg tablets)</i>
Initiation Option 2	
Day 1	<i>600 mg orally (2 x 300 mg tablets)</i>
Day 2	<i>600 mg orally (2 x 300 mg tablets)</i>
Day 8	<i>300 mg orally (1 x 300 mg tablets)</i>
Day 15	927 mg by subcutaneous injection (2 x 1.5 mL injections)
Maintenance	
927 mg by subcutaneous injection (2 x 1.5 mL injections) every 6 months (26 weeks) from the date of the last injection +/- 2 weeks.	

Missed dose: If more than 28 weeks since last injection and clinically appropriate to continue Sunlenca, restart initiation from Day 1, using either Option 1 or Option 2.

Tablets can be requested from the member's Pharmacy Benefit.

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

Coverage Period:

Indefinitely

ICD-10:

B20

References

1. Sunlenca (lenacapavir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; November 2024.

Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- No clinical change to policy following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee