

## Lenacapavir (Sunlenca®)

Place of Service  
Home Infusion Administration  
Infusion Center Administration  
Office Administration  
Outpatient Facility Administration

HCPs: J1961 per 1 mg

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

- [Multi-drug resistant HIV-1 infection](#)

AHFS therapeutic class: Antiretroviral

Mechanism of action: Capsid inhibitor

### **(1) Special Instructions and pertinent Information**

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

### **(2) Prior Authorization/Medical Review is required for the following condition(s)**

All requests for Sunlenca® (lenacapavir) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

#### Multi-drug resistant HIV-1 infection

1. Prescribed by or in consultation with an infectious disease or HIV specialist, **AND**
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, **AND**
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)
<b>Maintenance</b>	
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.*

#### **Coverage Period**

Indefinitely

## ICD-10:

B20

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

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

### **(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

All requests for Sunlenca® (lenacapavir) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

### **(4) This Medication is NOT COVERED for the following condition(s)**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

### **(5) Additional Information**

How supplied:

- 300 mg tablets
  - Tablets packaged as follows:
    - 4-Tablets blister pack (NDC 61958-3001-1)
    - 5-Tablets blister pack (NDC 61958-3001-2)
- Injection dosing kit (NDC 61958-3002-1) contains:
  - 2 single-dose clear glass vials, each containing sufficient volume to allow withdrawal of 463.5 mg/1.5 mL (309 mg/mL) of Sunlenca
  - 2 vial access devices, 2 disposable syringes, and 2 injection safety needles for injection (22-gauge, ½ inch)

### **(6) References**

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Sunlenca® (lenacapavir) [Prescribing information.] Foster City, CA: Gilead Sciences, Inc.; 12/2022.

### **(7) Policy Update**

Date of last review: 1Q2024

Date of next review: 1Q2025

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*