

<b>Effective Date: 7/1/2023</b>
Reviewed: 3/23
Pharmacy Scope: Medicaid
Medical Scope: Medicaid, Commercial, Medicare-Medicaid Plan

## SUNLENCA (lenacapavir)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

Sunlenca, a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of 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.

All other indications are considered experimental/investigational and not medically necessary.

#### II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with an infectious disease specialist who specializes in the treatment of HIV infection.

#### III. CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted for treatment of HIV-1 when all of the following criteria are met:

- A. Patient has heavily treated multi-drug resistant disease, confirmed by resistance testing, to at least two drugs in at least three classes (see table below); **AND**
- B. Patient has a baseline viral load  $\geq$  400 copies/mL; **AND**
- C. Patient is failing on their current anti-retroviral regimen for at least 2 months; **AND**
- D. Used in combination with highly active antiretroviral therapy (HAART) for which, via resistance testing, the patient's disease is known to be sensitive/susceptible

Class	Examples (not all-inclusive)
Nucleoside reverse transcription inhibitor (NRTI)	Abacavir, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, zidovudine
Non-nucleoside reverse transcription inhibitor (NNRTI)	Delaviridine, efavirenz, rilpivirine, nevirapine, etravirine, doravirine
Protease inhibitor (PI)	Atazanavir, darunavir, fosamprenavir, nelfinavir, ritonavir, tipranavir

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Integrase strand transfer inhibitor (INSTI)	raltegravir, dolutegravir, elvitegravir
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**IV. CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for members continuing with Sunlenca therapy for the treatment of HIV when the following criteria are met:

- A. There is a clinical benefit demonstrated from Sunlenca therapy\* (e.g., reduction in viral load from baseline); **AND**
- B. Sunlenca will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents.\*

*\*Note: increases in viral load from nadir and/ or less than anticipated reduction from baseline should prompt resistance testing for susceptibility and optimization of the background regimen*

**V. QUANTITY LIMIT**

Sunlenca 300 mg tablets have a quantity limit of 1 pack (4 or 5 tablets) per 365 days.

Sunlenca 463.5 mg/1.5 mL (309 mg/mL) single-dose vials for injection have a quantity limit of 3 ml per 6 months (26 weeks).

Indication	Dose
HIV	<u>Initiation Option 1</u> Day 1: 927 mg by subcutaneous injection (2 x 1.5 mL injections) AND 600 mg orally (2 x 300 mg tablets) Day 2: 600 mg orally (2 x 300 mg tablets)
	<u>Initiation Option 2</u> Day 1: 600 mg orally (2 x 300 mg tablets) Day 2: 600 mg orally (2 x 300 mg tablets) Day 8: 300 mg orally (1 x 300 mg tablet) Day 15: 927 mg by subcutaneous injection (2 x 1.5 mL injections)
	<u>Maintenance</u> 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

**VI. BILLING CODE/AVAILABILITY INFORMATION**

- J1961 – injection, lenacapavir, 1mg

*Note:* MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

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**VII. REFERENCES**

Sunlenca [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2022. Accessed March 2023.