Effective Date: 7/1/2023
Reviewed: 3/23, 12/23, 01/24 Pharmacy Scope: Medicaid Medical Scope: Medicaid, Commercial, Medicare-Medicaid Plan(MMP)

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. SUMMARY OF EVIDENCE

Sunlenca (lenacapavir), a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor used in combination with other antiretrovirals, is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection that has failed their current antiretroviral regimen due to resistance, intolerance, or safety considerations. Sunlenca carries warnings of immune reconstitution syndrome, increased exposure and risk of adverse reactions to drugs primarily metabolized by CYP3A, and injection site reactions. If discontinued, residual concentrations may remain in systemic circulation for up to 12 months and an alternative fully suppressive antiretroviral should be initiated no later than 28 weeks after the final injection of Sunlenca. The most common adverse reactions reported with Sunlenca use include nausea and injection site reactions. The efficacy and safety of Sunlenca was based on a randomized, placebo-controlled, double-blind, multicenter trial, in which 72 heavily treatment-experienced subjects with multiclass resistant HIV-1 were enrolled in the randomized cohort (N=36) or non-randomized cohort (N=36) based on their 0.5 log10 HIV-1 RNA decline compared to the screening visit or time of enrollment. At the end of the 14-day functional monotherapy period, in which patients in Cohort 1 continued their failing ARV regimen and were randomized to receive either Sunlenca or placebo, 88% (n = 21/24) of patients who were administered Sunlenca achieved the study's primary endpoint of a ≥0.5 log10 decrease in viral load compared with 17% (n = 2/12) of patients in the placebo group. In the maintenance period, in which Sunlenca was administered to all patients in Cohort 1 in combination with an optimized background regimen (OBR), 83% (n = 30/36) of participants achieved an undetectable viral load (<50 copies/mL) at Week 52.

IV. 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 ≥ 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

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

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
Integrase strand transfer inhibitor (INSTI)	raltegravir, dolutegravir, elvitegravir

V. 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*

VI. 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	Initiation Option 1

	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) Initiation Option 2 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) 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

VII. BILLING CODE/AVAILABILITY INFORMATION

- J1961 – injection, lenacapavir, 1mg

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Sunlenca was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Sunlenca according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

VIII. REFERENCES

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