Medical Policy:

Sunlenca® (lenacapavir) subcutaneous solution

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.374	February 13, 2025	February 9, 2023

Definitions

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

Length of Authorization

Initial: 6 months
Continuation: 12 months

Dosing Limits [Medical Benefit]

Initiate using one of two dosage regimens (2-day or 15-day regimen);

- Initial (2-day regimen option), **927 mg (two 1.5-mL injections) subQ** PLUS 600 mg (two 300-mg tablets) orally on day 1, then 600 mg (two 300-mg tablets) orally on day 2

- Initial (15-day regimen option), 600 mg (two 300-mg tablets) orally on day 1, 600 mg (two 300-mg tablets) orally on day 2, 300 mg (one 300-mg tablet) orally on day 8, then **927 mg (two 1.5-mL injections) subQ** on day 15

Maintenance: **927 mg (two 1.5-mL injections) subQ every 6 months** from the date of the last injections +/- 2 weeks

Guideline

I. Initial Approval Criteria

1. Human Immunodeficiency Virus (HIV)-1 Infection, Treatment.

A. Initial Therapy. Approve for 6 months if the patient meets ALL of the following conditions (i, ii, iii, iv, and v):

i. Patient is ≥ 18 years of age; **AND**

ii. According to the prescriber, the patient is failing a current antiretroviral regimen for HIV; **AND**

iii. According to the prescriber, the patient has resistance to **TWO** or more agents from at least **THREE** of the following antiviral classes (a, b, c, d):

a. Nucleoside reverse transcriptase inhibitor;
Note: Examples of nucleoside reverse transcriptase inhibitors include abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, tenofovir alafenamide, zidovudine.

b. Non-nucleoside reverse transcriptase inhibitor;
Note: Examples of non-nucleoside reverse transcriptase inhibitor include delaviridine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine.

c. Protease inhibitor;
Note: Examples of protease inhibitors include atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir.

d. Integrase strand transfer inhibitor; **AND**
Note: Examples of integrase strand transfer inhibitors include raltegravir, dolutegravir, elvitegravir.

iv. The medication will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; **AND**

v. The medication is prescribed by, or in consultation with, a physician who specializes in the treatment of HIV infection.

II. Renewal Criteria

B. **Patient is Currently Receiving Sunlenca**. Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):

i. The medication will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; **AND**

ii. Patient has responded to a Sunlenca-containing regimen, as determined by the prescriber.
Note: Examples of a response are HIV RNA < 50 cells/mm^3, HIV-1 RNA ≥ 0.5 log$_{10}$ reduction from baseline in viral load, improvement or stabilization of CD4 T-cell count

Applicable Procedure Codes

Code	Description
J1961	Injection, lenacapavir, 1 mg

Applicable NDCs

Code	Description
61958-3002-01	Sunlenca (lencapavir) 309mg/1mL subcutaneous 1.5mL

61958-3004-01	Sunlenca 463.5mg/1.5mL Solution

ICD-10 Diagnoses

Code	Description
B20	HIV

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/13/2025	Annual Review: Renewal criteria added to Note: "*improvement or stabilization of CD4 T-cell count*"
EmblemHealth & ConnectiCare	1/3/2024	Annual Review: Removed code J3490, added J1961, updated NDCs
EmblemHealth & ConnectiCare	02/09/2023	New Policy

References

1. Product Information: SUNLENCA® oral tablets, subcutaneous injection, lenacapavir oral tablets, subcutaneous injection. Gilead Sciences Inc (per FDA), Foster City, CA, 2022.