

Medical Policy:

Sunlenca® (lenacapavir) subcutaneous solution

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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):
- Patient is ≥ 18 years of age; **AND**
 - According to the prescriber, the patient is failing a current antiretroviral regimen for HIV; **AND**
 - 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):
 - Nucleoside reverse transcriptase inhibitor;
Note: Examples of nucleoside reverse transcriptase inhibitors include abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, tenofovir alafenamide, zidovudine.
 - Non-nucleoside reverse transcriptase inhibitor;
Note: Examples of non-nucleoside reverse transcriptase inhibitor include delaviridine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine.
 - Protease inhibitor;
Note: Examples of protease inhibitors include atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir.
 - Integrase strand transfer inhibitor; **AND**
Note: Examples of integrase strand transfer inhibitors include raltegravir, dolutegravir, elvitegravir.
 - The medication will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; **AND**
 - 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):
- The medication will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; **AND**
 - Patient has responded to a Sunlenca-containing regimen, as determined by the prescriber.
Note: Examples of a response are HIV RNA < 50 cells/mm³, HIV-1 RNA ≥ 0.5 log₁₀ 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 (lenacapavir) 309mg/1mL subcutaneous 1.5mL

61958-3004-01	Sunlenca 463.5mg/1.5mL Solution
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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: <i>“improvement or stabilization of CD4 T-cell count”</i>
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.