

# PHARMACY POLICY STATEMENT

## Georgia Medicaid

<b>DRUG NAME</b>	<b>Sunlenca (lenacapavir)</b>
BENEFIT TYPE	Medical and Pharmacy
STATUS	Prior Authorization Required

Sunlenca is a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor. Inhibition of HIV-1 replication occurs from interference with multiple steps of the viral lifecycle, including capsid-mediated nuclear uptake of HIV-1 proviral DNA, virus assembly and release, and capsid core formation. Sunlenca was approved in December 2022 and 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 consideration. Sunlenca is the first approved capsid inhibitor-based treatment option for multi-drug resistant HIV-1 infection.

Sunlenca (lenacapavir) will be considered for coverage when the following criteria are met:

### Multidrug-Resistant HIV-1 Infection

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an HIV or infectious disease specialist; AND
3. Member has a diagnosis of multidrug-resistant HIV-1 with documented resistance to at least 2 antiretroviral medications from each of at least 3 classes of antiretroviral medications (NRTI, NNRTI, PI, INSTI) OR member has a documented intolerance or contraindication to antiretroviral medications that would be part of an optimized background regimen; AND
4. Member is failing current therapy after at least 8 weeks due to resistance, intolerability, or contraindication; AND
5. Member has a viral load  $\geq 400$  copies/mL; AND
6. Sunlenca is being prescribed in combination with other antiretroviral agent(s) and not as monotherapy; AND
7. Member has no more than 2 fully active antiretroviral agents remaining from the 4 main classes that can be used; AND
8. Medication is not being used in combination with strong CYP3A inducer therapy (e.g., carbamazepine, phenytoin, or rifampin).
9. **Dosage allowed/Quantity limit:**  
Following initiation dosing options as directed in the prescribing information, commence maintenance dosing as 927 mg subQ (2 injections) every 6 months. QL: 2 vials (1 kit) per 6 months, (plus 1 pack of 4 or 5 tablets with the initial fill).

	Initiation Option 1	Initiation Option 2
Day 1	927 mg by subcutaneous injection (2 × 1.5 mL injections) 600 mg orally (2 × 300 mg tablets)	600 mg orally (2 × 300 mg tablets)
Day 2	600 mg orally (2 × 300 mg tablets)	600 mg orally (2 × 300 mg tablets)
Day 8	–	300 mg orally (1 × 300 mg tablet)
Day 15	–	927 mg by subcutaneous injection (2 × 1.5 mL injections)
<b>Maintenance</b>		
927 mg by subcutaneous injection (2 × 1.5 mL injections) every 6 months (26 weeks) from the date of the last injection +/- 2 weeks.		

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must demonstrate a reduction in viral load from baseline after initiation of treatment.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Sunlenca (lenacapavir) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
01/31/2023	New policy for Sunlenca (lenacapavir) created.

References:

1. Sunlenca (lenacapavir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; December 2022.
2. Segal-Maurer S, DeJesus E, Stellbrink HJ, et al. Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection. *N Engl J Med.* 2022;386(19):1793-1803.
3. Nicolas A Margot, Vidula Naik, Laurie VanderVeen, Olena Anoshchenko, Renu Singh, Hadas Dvory-Sobol, Martin S Rhee, Christian Callebaut, Resistance Analyses in Highly Treatment-Experienced People With Human Privileged & Confidential Immunodeficiency Virus (HIV) Treated With the Novel Capsid HIV Inhibitor Lenacapavir, *The Journal of Infectious Diseases*, Volume 226, Issue 11, 1 December 2022, Pages 1985–1991, <https://doi.org/10.1093/infdis/jiac364>
4. Drugs.com™. Auckland, New Zealand: Drugsite Trust. Updated periodically. \*

\*Utilized exclusively for dosing guidance.

Effective date: 07/01/2023

Revised date: 01/31/2023