PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Sunlenca (lenacapavir)
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. Members is failing current therapy after at least 8 weeks due to resistance, intolerability, or contraindication; AND
5. Member has a viral load ≥ 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)
Maintenance		
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: 08/01/2023
Revised date: 01/31/2023