PHARMACY POLICY STATEMENT
TRICARE

DRUG NAME	Sunlenca (lenacapavir)
BENEFIT TYPE	Medical
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 was 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 must have documented resistance, intolerance or contraindication to at least **ONE** antiretroviral from three different drug classes; AND
4. Member is failing current regimen as evidenced by HIV RNA count > 200 copies/mL; AND
5. Member is **NOT** using Sunlenca as monotherapy. Provider must include documentation of entire anti-retroviral regimen.
6. **Dosage allowed/Quantity limit:** administer initiation and maintenance dosing per one of the options listed in the table below. Quantity limit: 2 vials (1 kit) per 6 months and 1 pack of 4 or 5 tablets with the initial fill.

Initiation Option 1	
Day 1	927 mg by subcutaneous injection (2 x 1.5 mL injections) 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.	

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

For **reauthorization**:
1. Sunlenca is NOT being used as monotherapy; AND
2. Chart notes have been provided that show the member has demonstrated improvement as evidenced by **ONE** of the following:
   a) HIV viral load < 200 copies/mL; OR
   b) Decrease in HIV RNA load from initial authorization

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

TRICARE Prime® Demo by CareSource Military & Veterans™ 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 created.
02/02/2024	Rephrased reauthorization criteria to be more specific and include option for specific viral load decrease as well as continued use of monotherapy; changed viral load requirement from greater than or equal to 400 to greater than equal to 200; simplified that member is failing therapy and removed 8 week trial of current therapy; decreased number of medications that member must be resistance to in each of three classes from two to one; removed that member isn't using CYP3A inducer therapy; removed member has no more than two fully active agents that can be used from the remaining four classes; simplified quantity limit; removed and added references.

References:

1. Sunlenca (lenacapavir) [prescribing information]. Foster City, CA; Gilead Sciences Inc: 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. Margot NA, Naik V, VanderVeen L, et al. Resistance Analyses in Highly Treatment-Experienced People With Human Immunodeficiency Virus (HIV) Treated With the Novel Capsid HIV Inhibitor Lenacapavir. J Infect Dis. 2022;226(11):1985-1991. doi:10.1093/infdis/jiac364

4. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. 2023. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed February 2, 2024.

Effective date: 01/01/2026
Revised date: 02/02/2024