

PHARMACY POLICY STATEMENT

Marketplace

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 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

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.

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 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 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: 07/01/2024

Revised date: 02/02/2024