

Medical Drug Clinical Criteria

Subject: Sunlenca (lenacapavir)

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Overview

This document addresses the use of Sunlenca (lenacapavir), a human immunodeficiency virus (HIV) capsid inhibitor approved by the Food and Drug Administration (FDA) for use in combination with other antiretroviral agents for the treatment of HIV infection in heavily treatment-experienced adults with multidrug resistant HIV infection failing their current antiretroviral regimen due to resistance, intolerance or safety considerations. There are two options for treatment initiation with both regimens including oral and subcutaneous administration. Sunlenca maintenance therapy is administered by a healthcare provider every 6 months as a subcutaneous injection.

The safety and effectiveness of Sunlenca was evaluated in a 26-week clinical trial in 72 heavily treatment experienced participants with multidrug resistant HIV infection. Key inclusion criteria included a viral load of ≥ 400 copies per milliliter at screening and resistance to greater than or equal to two agents from at least three of the four main classes of HIV antiretrovirals [nucleoside/nucleotide reverse transcriptase inhibitors (NRTI), non-nucleoside reverse transcriptase inhibitors (NNRTI), protease inhibitors (PI) or integrase strand transfer inhibitors (INSTI)]. At week 26, individuals who received Sunlenca had a greater reduction in viral load than those who received placebo. A viral load of less than 50 copies per milliliter was reported in 81% of the participants in cohort 1 and in 83% in cohort 2.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Sunlenca (lenacapavir)

Requests for Sunlenca (lenacapavir) may be approved if the following criteria are met:

- I. Individual is using to treat human immunodeficiency virus (HIV) infection; **AND**
- II. Individual is using in combination with other antiretroviral agents; **AND**
- III. Individual is heavily antiretroviral treatment experienced with resistance, intolerability or contraindication to antiretrovirals in at least three different classes (NRTI, NNRTI, PI or INSTI); **AND**
- IV. If initiating therapy, individual is failing their current antiretroviral regimen due to resistance, intolerance or safety considerations; **AND**
- V. If initiating therapy, individual has a viral load greater than or equal to 400 copies/mL.

Requests for Sunlenca (lenacapavir) may not be approved for the following:

- I. Use in combination with a strong CYP3A inducer (including but not limited to carbamazepine, phenytoin or rifampin); **OR**
- II. May not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Sunlenca (lenacapavir) Quantity Limit

Drug	Limit
Sunlenca (lenacapavir) 463.5 mg/1.5 mL vial	1 kit (2 vials) per 24 weeks

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HPCPS

J1961 Injection, lenacapavir, 1 mg [Sunlenca]

ICD-10 Diagnosis

B20 Human immunodeficiency virus [HIV] disease

Document History

Reviewed: 8/16/2024

Document History:

- 8/16/2024 – Annual Review: No changes. Coding Reviewed: No changes.
- 8/18/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 1/6/2023 – Select Review: New clinical criteria and quantity limit for Sunlenca. Coding Reviewed: Added HCPCS J3490, C9399. All diagnoses pend. Effective 7/1/2023 Added HCPCS J1961. Added ICD-10-CM B20. Deleted HCPCS J3490, C9399.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 14, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. 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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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