Original Effective Date: 05/31/2023
Current Effective Date: 03/08/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C25206-A

Sunlenca (lenacapavir)

PRODUCTS AFFECTED

Sunlenca (lenacapavir)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Multi-drug resistant HIV-1 Infection

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing.
Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by- case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. MULTI-DRUG RESISTANT HIV-1 INFECTION:
   1. Documented diagnosis of HIV-1
      AND
   2. Documentation of current HIV RNA viral load of greater than or equal to 200 copies/mL (within the past 30 days) [DOCUMENTATION REQUIRED]
      AND
   3. Prescriber attestation of member adherence to highly active antiretroviral therapy for at least 6

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months AND member is failing, or has recently failed therapy within the past 8 weeks [MOLINA REVIEWER NOTE: Please verify historical claims unless benefit is not managed by Molina]
AND

4. Documented viral resistance to at least TWO drugs from each of at least THREE classes of HIV antiretroviral medication (as single agent products or combination products), unless contraindicated or clinically significant adverse effects are experienced. Documented resistance as measured by resistance testing, completed while member is current to therapy or within 4 weeks if possible. [DOCUMENTATION REQUIRED]
    a. Protease inhibitor (PI)
    b. Nucleoside reverse transcriptase inhibitor (NRTI)
    c. Non-nucleoside reverse transcriptase inhibitor (NNRTI)
    d. Integrase Strand Transfer Inhibitor (INSTI)

AND

5. Documentation that Sunlenca (lenacapavir) will be used as part of a complete regimen, which consists of at least 2, and preferably 3 fully active agents (to which the member is susceptible), with resistance testing which supports that a medically appropriate regimen cannot be constructed without the use of Sunlenca (lenacapavir)
AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Sunlenca (lenacapavir) include: Concomitant administration with strong CYP3A inducers.]

CONTINUATION OF THERAPY:

A. MULTI-DRUG RESISTANT HIV-1 INFECTION:

1. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance)
AND
2. Documentation of decreased viral load <200 copies/mL indicating clinically significant disease response and improvement as a result of treatment [DOCUMENTATION REQUIRED]
AND
3. Documentation member continues to take an optimized background regimen (OBR) of antiretroviral therapy in combination with Sunlenca (lenacapavir) (review Rx history for compliance)
AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified infectious disease or HIV specialist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Initiation:
Tablets: One blister pack containing Four or Five 300 mg tablets
Injection: Two 1.5 mL vials

Maintenance: Injection: Two 1.5 mL vials every 6 months

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PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral, Subcutaneous

DRUG CLASS:
Antiretrovirals - Capsid Inhibitors

FDA-APPROVED USES:
Indicated, in combination with other antiretroviral(s), for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 whose current antiretroviral regimen is failing due to resistance, intolerance, or safety considerations.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Sunlenca (lenacapavir) can be initiated using one of two dosage regimens.

Option 1:

Initiation:
Day 1: 600 mg orally (2 x 300 mg tablets) AND 927 mg by subcutaneous injection (2 x 1.5 mL injections)
Day 2: 600 mg orally (2 x 300 mg tablets)
Maintenance:
Every 6 months (26 weeks)*; 927 mg by subcutaneous injection (2 x 1.5 mL injections)

Option 2:

Initiation:
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 tablets)
Day 15: 927 mg by subcutaneous injection (2 x 1.5 mL injections)
Maintenance:
Every 6 months (26 weeks)*; 927 mg by subcutaneous injection (2 x 1.5 mL injections)

*During the maintenance period, if more than 28 weeks have elapsed since the last injection and if clinically appropriate to continue treatment, restart the initiation dosage regimen from Day 1, using either Option 1 or Option 2.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

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Lenacapavir is a multistage, selective inhibitor of HIV-1 capsid function. It directly binds to the capsid protein (p24) subunits. Lenacapavir interferes with capsid-mediated nuclear uptake of HIV-1 proviral DNA, virus assembly and release, and capsid core formation, inhibiting HIV-1 replication. This mechanism allows lenacapavir to inhibit HIV-1 replication in the early and late stages of the life cycle.

The safety and efficacy of lenacapavir were assessed in the CAPELLA trial (ClinicalTrials.gov number, NCT04150068), which was a 52-week randomized, placebo-controlled, double blind study in HIV-1 infected (n=72) and heavily treatment-experienced subjects with multidrug resistance. Inclusion criteria included that member had to be receiving and failing (HIV-1 RNA level of ≥400 copies per milliliter) for at least 8 weeks, with a documented resistance to at least 2 antiviral medications from 3 of the 4 main classes of antiretrovirals. The patients also had to have 2 or less fully active antiretrovirals remaining from the 4 main classes, which could be effectively combined to form a viable regimen.

The trial design included 2 cohorts. The first cohort (N=36) included patients with stable viremia and HIV- 1 RNA greater than 400 copies per milliliter. Those patients received either oral lenacapavir or placebo, in addition to their failing therapy for the first 14 days. At Day 15, the group treated with oral lenacapavir then continued subcutaneous lenacapavir every 6 months in addition to an optimized background treatment regimen (OBR). The patients that received placebo, then transitioned to an oral lenacapavir lead in with optimized background regimen, then continued subcutaneous lenacapavir every 6 months in addition to an optimized background treatment regimen. The second cohort (n=36) was non-randomized. The patients were patients with HIV-1 RNA of less than 400 copies or had not been found eligible to participate in cohort 1. These patients received oral lenacapavir lead in with optimized background regimen, then continued subcutaneous lenacapavir every 6 months in addition to an optimized background treatment regimen.

The primary efficacy end point was the percentage of patients who had a reduction from baseline of at least 0.5 log10 copies per milliliter in plasma HIV-1 RNA viral load by day 15. The secondary endpoint was the “percentage of patients with a viral load of less than 50 copies per milliliter and the percentage with a viral load of less than 200 copies per milliliter at week 26 after the initiation of subcutaneous lenacapavir.” Cohort 1 reported 87.5% of patients achieving a greater than 0.5 log10 decrease in viral load, with a treatment difference (95% Confidence Interval) of 70.8% (34.9 to 90.0 %), compared to placebo. In the maintenance period, evaluations were performed at 26 and 52 weeks. At week 26, 81% of patients had HIV-1 RNA <50 copies per milliliter. At week 52, 83% of patients had HIV-1 RNA <50 copies per milliliter.

Lenacapavir-associated capsid substitution developed in eight patients. Although this resistance was detected, four of the eight patients had resuppression while receiving lenacapavir, with HIV-1 RNA levels less than 50 copies per milliliter. Per the manufacturer, “In the clinical trial, patients who had treatment-emergent resistance to Sunlenca either had inadequate OBR drug levels or lack of active agents in the OBR.”

The most commonly reported adverse reactions were injection site reactions (65%) and nausea (4%). The median time to resolution of injection site reactions, excluding nodules or indurations, was 5 days.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Sunlenca (lenacapavir) are considered experimental/investigational and therefore, will follow Molina’s Off- Label policy. Contraindications to Sunlenca (lenacapavir) include: Concomitant administration with strong CYP3A inducers.

OTHER SPECIAL CONSIDERATIONS:

Sunlenca (lenacapavir) injection is for administration into the abdomen by a healthcare provider using an aseptic technique. Vial should be stored in the original carton until just prior to preparation in order to protect from light. Sunlenca (lenacapavir) tablets are available in blister packs containing 4 or 5 tablets. Tablets are to be dispensed and stored only in the original blister pack.

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There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to SUNLENCA during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258- 4263.

Lenacapavir is a substrate of P-gp, UGT1A1 and CYP3A. Strong and moderate CYP3A inducers can decrease the plasma concentrations of lenacapavir, which may lead to loss in effect and development of resistance. Coadministration with strong CYP3A inducers in contraindicated. Combined P-gp, UGT1A1, and strong CYP3A inhibitors may increase the plasma concentration of lenacapavir. Coadministration is not recommended.

Drug Resistance testing for persons taking a non-long acting antiretroviral regimen should be performed while the member is still taking the regimen or within 4 weeks after discontinuing the failing regimen, if possible.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J1961	Injection, lenacapavir, 1 mg

AVAILABLE DOSAGE FORMS:
Sunlenca SOLN 463.5MG/1.5ML
Sunlenca TBPK 4 x 300MG
Sunlenca TBPK 5 x 300MG

REFERENCES

1. Sunlenca (lenacapavir) tablets, for oral use; injection, for subcutaneous use [prescribing information]; Foster City, CA: Gilead Sciences, Inc., November 2024.
2. Segal-Maurer, S., DeJesus, E., Stellbrink, H. J., Castagna, A., Richmond, G. J., Sinclair, G. I., Siripassorn, K., Ruane, P. J., Berhe, M., Wang, H., Margot, N. A., Dvory-Sobol, H., Hyland, R. H., Brainard, D. M., Rhee, M. S., Baeten, J. M., Molina, J. M., & CAPELLA Study Investigators (2022). Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection. The New England journal of medicine, 386(19), 1793–1803. https://doi.org/10.1056/NEJMoa2115542
3. Protocol for: Segal-Maurer S, DeJesus E, Stellbrink H-J, et al. Capsid inhibition with lenacapavir in multidrugresistant HIV-1 infection. N Engl J Med 2022;386:1793-803. DOI: 10.1056/NEJMoa2115542
4. Virologic failure: NIH. (2022, September 22). Retrieved March 6, 2023, from https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/virologic-failure?view=full
5. 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. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed 4 December 2023.

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6. 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. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed 26 December 2024.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Quantity FDA-Approved Uses References	Q1 2025
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Coding/Billing Information References	Q1 2024
New Criteria	Q2 2023

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