Clinical Policy: Lenacapavir (Sunlenca)

Reference Number: NH.PHAR.622
Effective Date: 06.24
Last Review Date: 04.25
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Lenacapavir (Sunlenca®) is a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor.

FDA Approved Indication(s)

Sunlenca is indicated for the treatment of HIV-1 infection, in combination with other antiretroviral(s), in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Sunlenca is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. HIV-1 Infection (must meet all)**:**

1. Diagnosis of multidrug resistant HIV-1 infection;
2. Prescribed by or in consultation with an infectious disease or HIV specialist;
3. Age ≥ 18 years;
4. Documentation of resistance to at least 2 antiretroviral medications from at least 3 of the 4 main classes (NRTI, NNRTI, PI, INSTI), unless clinically significant adverse effects are experienced or all are contraindicated;
5. Current (within the past 30 days) HIV ribonucleic acid viral load of ≥ 200 copies/mL;
6. Prescribed concurrently with additional antiretroviral agents to which member is susceptible, if available;
7. Dose does not exceed one of the following (a, b, or c):*
   a. Initiation Option 1 (i and ii):
      i. Day 1: 927 mg by subcutaneous injection (2 x 1.5 mL injections) and 600 mg orally (2 x 300 mg tablets);
      ii. Day 2: 600 mg orally (2 x 300 mg tablets);
   b. Initiation Option 2 (i-iv):
      i. Day 1: 600 mg orally (2 x 300 mg tablets);
      ii. Day 2: 600 mg orally (2 x 300 mg tablets);
      iii. Day 8: 300 mg orally (1 x 300 mg tablet);
      iv. Day 15: 927 mg by subcutaneous injection (2 x 1.5 mL injections);

c. Maintenance:
   i. 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.

**The initiation doses may be repeated if the member misses scheduled a maintenance dose by more than 28 weeks, and it is clinically appropriate to continue Sunlenca.*

Approval duration: 7 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL, the no coverage criteria policy: CP.PMN.255; or
   b. For drugs NOT on the PDL, the non-formulary policy: CP.PMN.16; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy: CP.PMN.53.

II. Continued Therapy

A. HIV-1 Infection (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Sunlenca for multidrug resistant HIV-1 infection and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):*
   a. Initiation Option 1 (i and ii):
      i. Day 1: 927 mg by subcutaneous injection (2 x 1.5 mL injections) and 600 mg orally (2 x 300 mg tablets);
      ii. Day 2: 600 mg orally (2 x 300 mg tablets);
   b. Initiation Option 2 (i-iv):
      i. Day 1: 600 mg orally (2 x 300 mg tablets);
      ii. Day 2: 600 mg orally (2 x 300 mg tablets);
      iii. Day 8: 300 mg orally (1 x 300 mg tablet);
      iv. Day 15: 927 mg by subcutaneous injection (2 x 1.5 mL injections);
   c. Maintenance:
      i. 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 .

**The initiation doses may be repeated if the member misses scheduled a maintenance dose by more than 28 weeks, and it is clinically appropriate to continue Sunlenca.*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL, the no coverage criteria policy: CP.PMN.255; or
   b. For drugs NOT on the PDL, the non-formulary policy: CP.PMN.16; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy: CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
HIV-1: human immunodeficiency virus type 1
INSTI: integrase strand transfer inhibitors
NNRTI: non-nucleoside reverse transcriptase inhibitor
NRTI: nucleos(t)ide reverse transcriptase inhibitor
PI: protease inhibitor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Nucleos(t)ide reverse transcriptase inhibitors (NRTIs) (e.g., abacavir, tenofovir disoproxil fumarate, Emtriva®)	Refer to prescribing information	Refer to prescribing information
Non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g., efavirenz, nevirapine, Edurant®)	Refer to prescribing information	Refer to prescribing information
Protease inhibitors (PIs) (e.g., atazanavir, fosamprenavir, Invirase®, Viracept®)	Refer to prescribing information	Refer to prescribing information
Integrase strand transfer inhibitors (INSTIs) (e.g., bictegravir, dolutegravir, elvitegravir, raltegravir)	Refer to prescribing information	Refer to prescribing information
Fuzeon® (enfurvirtide, T-20)	Refer to prescribing information	Adults: 180 mg/day Children 6 years and older: 4 mg/kg/day
maraviroc, MVC (Selzentry®)	Refer to prescribing information	600 mg/day; 1,200 mg/day if taking a potent CYP3A inducer

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Fixed-dose combinations (e.g., Genvoya®, Stribild®, Odefsey®, Descovy®, Truvada®)	Refer to prescribing information	Refer to prescribing information

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): concomitant administration with strong CYP3A inducers
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose

HIV-1 infection	Initiation Option 1:
	• Day 1:
	  ○ 927 mg SC (2 x 1.5 mL injections)
	  ○ 600 mg PO (2 x 300 mg tablets)
	• Day 2: 600 mg PO (2 x 300 mg tablets)
	
	Initiation Option 2:
	• Day 1: 600 mg PO (2 x 300 mg tablets)
	• Day 2: 600 mg PO (2 x 300 mg tablets)
	• Day 8: 300 mg PO (1 x 300 mg tablet)
	• Day 15: 927 mg SC (2 x 1.5 mL injections)
	
	Maintenance:
	• 927 mg SC (2 x 1.5 mL injections) every 6 months (26 weeks) from the date of the last injection ± 2 weeks
	
	During the maintenance period, if more than 28 weeks have passed since the last injection and it is clinically appropriate to continue Sunlenca, restart from Day 1, using either Initiation Option 1 or Option 2.
		Initiation: See regimen
		
		Maintenance: 927 mg/6 months

VI. Product Availability

- Tablet: 300 mg
- Single-dose vial for injection: 463.5 mg/1.5 mL (309 mg/mL)

VII. References

1. Sunlenca Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; December 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215973s000lbl.pdf. Accessed January 11, 2023.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. US Department of Health

and Human Services. Last updated September 21, 2022. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf. Accessed January 11, 2023.
3. Segal-Maurer S, DeJesus E, Stellbrink H-J, et al. Capsid inhibition with lenacapavir in multidrug-resistant HIV-1 infection. New England Journal of Medicine. 2022;386(19):1793-1803. doi:10.1056/nejmoa2115542. Accessed January 20, 2023

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3490	Unclassified drugs
C9399	Unclassified drugs or biologicals
J8499	Prescription drug, oral, non chemotherapeutic, nos
J1961	Injection, lenacapavir, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.24	06.24
Annual review, no significant changes	04.25	04.25

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.