Clinical Policy: Lenacapavir (Sunlenca, Yeztugo)

Reference Number: CP.PHAR.622
Effective Date: 06.01.23
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Coding Implications
Revision Log

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

Description

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

FDA Approved Indication(s)

Sunlenca is 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.
- For oral loading as a component of the initiation regimen for Bixlenvo™ (bictegravir [BIC]/lenacapavir [LEN]), a complete regimen for the treatment of HIV-1 infection, in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 ribonucleic acid [RNA] less than 50 copies per mL) on a stable antiretroviral regimen with no known or suspected resistance to the individual components of Bixlenvo.

Yeztugo is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition. Individuals must have a negative HIV-1 test prior to initiating Yeztugo.

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 and Yeztugo are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

*For members in **Nevada**, medical management techniques, including quantity management, beyond step therapy is not allowed.

A. Oral Loading for Initiation of Bixlenvo for HIV-1 Infection (must meet all)**:**

1. Request is for Sunlenca for oral loading for initiation of Bixlenvo;
2. Diagnosis of HIV-1 infection;*
   **For multidrug resistant HIV-1 infection, see criteria set I.B below*
3. Prescribed by or in consultation with an infectious disease or HIV specialist;
4. Age ≥ 18 years;
5. Prescribed concurrently with Bixlenvo;
6. Documentation of adherence to a stable oral antiretroviral regimen for HIV-1 for ≥ 3 months;

7. Documentation of sustained virologic suppression as evidenced by HIV-1 RNA viral load < 50 copies/mL for ≥ 3 months;
8. Member has no known or suspected resistance to either bictegravir or lenacapavir;
9. Dose does not exceed both of the following (a and b):
   a. Day 1: 600 mg orally (2 x 300 mg tablets);
   b. Day 2: 600 mg orally (2 x 300 mg tablets).

Approval duration: 7 days

B. Multidrug Resistant HIV-1 Infection (must meet all)**:**

1. Request is for Sunlenca;
2. Diagnosis of multidrug resistant HIV-1 infection;
3. Prescribed by or in consultation with an infectious disease or HIV specialist;
4. Age ≥ 18 years;
5. 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;
6. If CCR5 tropic, failure of maraviroc (Selzentry®), unless contraindicated, clinically significant adverse effects are experienced or member is resistant;*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
7. Current (within the past 30 days) HIV RNA viral load of ≥ 200 copies/mL;
8. Prescribed concurrently with additional antiretroviral agents to which member is susceptible, if available;
9. 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:
Medicaid/HIM/ICHRA– 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Pre-Exposure HIV Prophylaxis (must meet all)**:**

1. Request is for Yeztugo;
2. Member is HIV-negative and has no signs or symptoms of acute HIV infection;
3. Member is considered at high risk for acquiring HIV and meets one of the following (a, b, or c):

a. Engaging in sexual activity with an HIV-1 infected partner;
b. Engaging in sexual activity and one or more of the following (i-vi):
   i. Inconsistent or no condom use;
   ii. Diagnosis of sexually transmitted infections in the past 6 months;
   iii. Exchange of sex for commodities;
   iv. Incarceration;
   v. Not in a monogamous partnership;
   vi. Partner of unknown HIV status with any of the preceding risk factors;
c. Use of illicit injection drugs;

4. Member weighs ≥ 35 kg;
5. Yeztugo is not prescribed concurrently with any other antiretroviral medications, including other agents for PrEP (e.g., Apretude®, Descovy®, emtricitabine/tenofovir disoproxil fumarate);
6. Dose does not exceed the following (a and b):*
   a. Initiation (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. Continuation (i or ii):
      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;
      ii. All of the following (1, 2, and 3):
         1) 300 mg orally (1 x 300 mg tablet) every 7 days for up to 6 months;
         2) Documentation that the scheduled 6-month injection is anticipated to be delayed by more than 2 weeks;
         3) Attestation that tablets will be used only on an interim basis.

**The initiation doses may be repeated if the member misses scheduled a continuation dose by more than 28 weeks and Yeztugo tablets have not been taken.*

Approval duration:
Medicaid/HIM/ICHRA– 12 months (*6 months if tablets are requested for temporary continuation dosing*)
Commercial – 6 months or to the member's renewal date, whichever is longer

D. 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 formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; 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 for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

*For members in **Nevada**, medical management techniques, including quantity management, beyond step therapy is not allowed.

A. Oral Loading for Initiation of Bixlenvo for HIV-1 Infection (must meet all)**:***

**For multidrug resistant HIV-1 infection, see criteria set II.B below*

1. Re-authorization for extension of an initial course of therapy is not permitted. Sunlenca is not to be used for the maintenance of Bixlenvo treatment.

Approval duration: Not applicable

B. Multidrug Resistant 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. Request is for Sunlenca;
3. Member is responding positively to therapy;
4. 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:
Medicaid/HIM/ICHRA– 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Pre-Exposure HIV Prophylaxis (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Yeztugo for a covered indication and has received this medication for at least 30 days;
2. Request is for Yeztugo;
3. Member is responding positively to therapy;

4. Yeztugo is not prescribed concurrently with any other antiretroviral medications, including other agents for PrEP (e.g., Apretude, Descovy, emtricitabine/tenofovir disoproxil fumarate);
5. If request is for a dose increase, new dose does not exceed the following (a and b):*
   a. Initiation (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. Continuation (i or ii):
      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;
      ii. All of the following (1, 2, and 3):
         1) 300 mg orally (1 x 300 mg tablet) every 7 days for up to 6 months;
         2) Documentation that the scheduled 6-month injection is anticipated to be delayed by more than 2 weeks;
         3) Attestation that tablets will be used only on an interim basis.

   **The initiation doses may be repeated if the member misses scheduled a continuation dose by more than 28 weeks and Yeztugo tablets have not been taken*

Approval duration:
Medicaid/HIM/ICHRA– 12 months (*6 months if tablets are requested for temporary continuation dosing*)
Commercial – 6 months or to the member's renewal date, whichever is longer

D. 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 formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; 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 for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid 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
PrEP: pre-exposure prophylaxis
RNA: ribonucleic acid

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, emtricitabine, lamivudine)	Refer to prescribing information	Refer to prescribing information
Non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g., efavirenz, etravirine, Edurant®, Pifeltro®)	Refer to prescribing information	Refer to prescribing information
Protease inhibitors (PIs) (e.g., atazanavir, fosamprenavir, darunavir, 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
maraviroc, MVC (Selzentry®)	Refer to prescribing information	600 mg/day; 1,200 mg/day if taking a potent CYP3A inducer
Fixed-dose combinations (e.g., Biktarvy®, Genvoya®, Stribild®, Triumeq®, Dovato®, 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):
  - Sunlenca: concomitant administration with strong CYP3A inducers
  - Yeztugo: unknown or positive HIV-1 status
- Boxed warning(s):
  - Sunlenca: none reported

- Yeztugo: risk of drug resistance in undiagnosed HIV-1 infection

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose

Lenacapavir (Sunlenca)	Multidrug resistant 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

	Oral loading for initiation of Bixlenvo for HIV-1 infection	Initiation in combination with Bixlenvo: • Day 1: 600 mg PO (2 x 300 mg tablets) • Day 2: 600 mg PO (2 x 300 mg tablets) Sunlenca is only indicated for the oral initiation of Bixlenvo treatment and is not to be used for the maintenance of Bixlenvo treatment	Initiation: See regimen

Lenacapavir (Yeztugo)	HIV-1 PrEP	Initiation:
		• 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)
		
		Continuation:
		• 927 mg SC (2 x 1.5 mL injections) every 6 months (26 weeks) from the date of the last injection ± 2 weeks
			See regimen

Drug Name	Indication	Dosing Regimen	Maximum Dose
		During continuation dosing, if the scheduled 6-month injection is anticipated to be delayed by more than 2 weeks, Yeztugo tablets may be taken on an interim basis (300 mg PO [1 x 300 mg tablet] once every 7 days for up to 6 months if needed), until injections resume. The continuation injection dosage should be resumed within 7 days after the last oral dose. If more than 28 weeks have elapsed since the last injection and Yeztugo tablets have not been taken, reinitiate with initiation dosing schedule from Day 1 and then continue with continuation injection dosing.	

VI. Product Availability

Drug Name	Availability
Lenacapavir (Sunlenca)	• Tablet: 300 mg • Single-dose vial for injection: 463.5 mg/1.5 mL (309 mg/mL)
Lenacapavir (Yeztugo)	• 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.; August 2026. Available at: https://www.sunlenca.com. Accessed September 8, 2026.
2. Yeztugo Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; June 2025. Available at: www.yeztugo.com. Accessed February 6, 2026.
3. 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 25, 2025. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf. Accessed February 6, 2026.
4. Segal-Maurer S, DeJesus E, Stellbrink H-J, et al. Capsid inhibition with lenacapavir in multidrug-resistant HIV-1 infection. *N Engl J Med*. 2022;386(19):1793-1803. doi:10.1056/nejmoa2115542.
5. Centers for Disease Control and Prevention, U.S. Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States - 2021 update. 2021. Available at: https://www.cdc.gov/hivpartners/php/guidelines/index.html. Accessed February 6, 2026.

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
J8499	Prescription drug, oral, non chemotherapeutic, nos
J1961	Injection, lenacapavir, 1 mg
J0738	Injection, lenacapavir, 1 mg, FDA approved prescription, only for use as HIV pre-exposure prophylaxis (not for use as treatment for HIV)
J0752	Oral, lenacapavir, 300 mg, FDA approved prescription, only for use as HIV preexposure prophylaxis (not for use as treatment for HIV)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.11.23	05.23
Added HCPCS code [J1961]	05.24.23	
2Q 2024 annual review: no significant changes; removed HCPCS codes [J3490, C9399]; references reviewed and updated.	01.12.24	05.24
Added disclaimer that medical management techniques, including quantity management, beyond step therapy is not allowed for members in NV per SB 439.	06.04.24	
2Q 2025 annual review: no significant changes, updated therapeutic alternatives in Appendix B; references reviewed and updated.	01.13.25	05.25
RT4: added newly approved brand Yeztugo and corresponding HIV-1 PrEP criteria; for HIV-1 treatment, revised continued approval duration for Commercial from "12 months" to "6 months or to the member's renewal date, whichever is longer" per standard injectable agent approach.	06.24.25	
HCPCS codes added [J0738, J0752].	09.11.25	
Added step therapy bypass for IL HIM per IL HB 5395. Removed failure of Fuzeon per manufacturer discontinuation.	10.14.25	
2Q 2026 annual review: for HIV-1 infection, extended initial approval duration from 7 months to 12 months for this maintenance medication for a chronic condition and extended Commercial approval duration from 6 months to "6 months or to the member's renewal date, whichever is longer"; references reviewed and updated. Added ICHRA line of business.	03.31.26	05.26
RT4: added newly approved indication and corresponding criteria for oral loading as component of the initiation regimen for Bixlenvo for HIV-1 infection.	09.08.26	

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.

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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.

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