COMMUNITY HEALTH CHOICE

Lenacapavir (Sunlenca®, Yeztugo®)

Effective Date: 5/1/2024
Medical Care Management Committee Approval: 2/15/2024

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Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following lenacapavir products, Sunlenca® and Yeztugo®:

HCPCS Code	Description	Maximum Dosage per Administration
J1961	Injection, lenacapavir, 1 mg (Sunlenca)	927 mg subQ
J0738	Injection, lenacapavir 1 mg (Yeztugo)	927 mg subQ

Diagnosis-Specific Criteria

Lenacapavir will be considered medically necessary for members meeting ALL of the following criteria according to the diagnosis:

Initial authorization: Approve for 6 months

1. For treatment of HIV-1, must meet ALL of the following criteria:
    a. Request is for Sunlenca®; AND
    b. Documented diagnosis of HIV-1; AND
    c. Member is >/= 18 years of age
    d. Documentation of current HIV RNA viral load of greater than 400 copies/mL within the past 30 days (documentation required); AND

e. Prescriber attestation of member adherence to active antiretroviral therapy for at least 6 months; AND
f. Member is failing, or has recently failed therapy within the past 8 weeks; AND
g. Documentation that the member will be taking Sunlenca® (lenavapavir) in combination with an optimized antiretroviral regimen; AND
h. Documented viral resistance to at least 2 drugs from 3 distinct classes of HIV antiretroviral medications (as single agent products or combination products), unless contraindicated or clinically significant adverse effects are experienced); AND
i. Prescriber attests to the member not having any FDA labeled contraindications including concomitant administration of with strong CYP3A inducers

2. For HIV-1 pre-exposure prophylaxis (PrEP)
   a. Request is for Yeztugo®; AND
   b. Documentation showing ALL of the following; AND:
      i. Member is at risk for sexually acquired HIV-1 infection
      ii. Member weight >/= 35 kg
      iii. Negative HIV-1 test
   c. Yeztugo will not be used in combination with any other antiretroviral medications for PrEP or treatment of HIV-1; AND
   d. Member has a history of intolerance, contraindication or adverse event to preferred PrEP treatment options emtricitabine/tenofovir (Truvada and Descovy) and Apretude (cabotegravir)

Continuation of Therapy: Approve for 12 months

1. For treatment of HIV-1, must meet ALL of the following criteria (must be Sunlenca)
   a. Member has experienced significant clinical response to Sunlenca as evidenced with viral load < 200 copies/mL; AND
   b. Prescriber attestation that member has been adherent to prescribed HIV medications; AND
   c. Attestation that member will continue an optimized background antiretroviral regimen in combination with Sunlenca (lenacapavir); AND
   d. Member has not experienced intolerable side effects or drug toxicity from Sunlenca
2. For HIV-1 pre-exposure prophylaxis (PrEP) (must be Yeztugo)
   a. Member is tolerating Yeztugo; AND
   b. Member weight >/= 35 kg; AND
   c. Member continues to be at risk for sexually acquired HIV-1 infection; AND
   d. Attestation that member will be screened for HIV-1 infection prior to each dose; AND
   e. Attestation of intent to administer next dose 26 weeks +/- 2 weeks from prior dose and that member has been counseled on importance of adherence to dosing schedule; AND
   f. Yeztugo will not be used in combination with any other antiretroviral medications for PrEP or treatment of HIV-1; AND
   g. Member has a history of intolerance, contraindication or adverse event to preferred PrEP treatment options emtricitabine/tenofovir (Truvada and Descovy) and Apretude (cabotegravir)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

MEDICAL REVIEW GUIDELINE

Lenacapavir Preferred Product Policy

HCPCS Code	Description
J1961	Injection, lenacapavir, 1 mg (Sunlenca)
J0738	Injection, lenacapavir 1 mg (Yeztugo)

Diagnosis Code	Description
B20	Human Immunodeficiency virus (HIV) disease
Z29.81	HIV pre-exposure prophylaxis

Policy Revision History

Status	Effective Date	Description
Baseline	TBD	Initial version of Sunlenca (lenacapavir) Diagnosis Specific Criteria
Update	11/11/2025	Addition of Yeztugo and PrEP Criteria