COMMUNITY HEALTH CHOICE

Sunlenca® (lenacapavir)

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

Contents

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 Sunlenca® (lenacapavir) product:

HCPCS Code	Description	Maximum Dosage per Administration
J1961	Injection, lenacapavir, 1 mg	927 mg subQ; 600 mg PO

Diagnosis-Specific Criteria

Sunlenca® (lenacapavir) will be considered medically necessary for members meeting ALL of the following criteria:

Initial authorization: Approve for 6 months

1. Documented diagnosis of HIV-1; AND
2. Documentation of current HIV RNA viral load of greater than 400 copies/mL within the past 30 days (documentation required); AND
3. Prescriber attestation of member adherence to active antiretroviral therapy for at least 6 months; AND
4. Member is failing, or has recently failed therapy within the past 8 weeks; AND
5. Documentation that the member will be taking Sunlenca® (lenavapavir) in combination with an optimized antiretroviral regimen; AND

6. 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
7. Prescriber attests to the member not having any FDA labeled contraindications including concomitant administration of with strong CYP3A inducers

Continuation of Therapy: Approve for 12 months

1. Member has experienced significant clinical response to Sunlenca as evidenced with viral load < 200 copies/mL; AND
2. Prescriber attestation that member has been adherent to prescribed HIV medications; AND
3. Attestation that member will continue an optimized background antiretroviral regimen in combination with Sunlenca (lenacapavir); AND
4. Member has not experienced intolerable side effects or drug toxicity from Sunlenca

Applicable Codes

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

HCPCS Code	Description
J1961	Injection, lenacapavir, 1 mg

Diagnosis Code	Description
B20	Human Immunodeficiency virus (HIV) disease

Policy Revision History

Status	Effective Date	Description
Baseline	TBD	Initial version of Sunlenca (lenacapavir) Diagnosis Specific Criteria