Medical Policy

Sunlenca® (lenacapavir)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-138
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

*Policy applies to all markets where IFP, SG, or MA plans are offered

Brand New Day/Central Health Medicare Plan Health develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third-party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Health Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Health Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. *Brand New Day/Central Health Medicare Plan Health policies and practices are compliant with federal and state requirements, including mental health parity laws.*

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Sunlenca, lenacapavir therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Sunlenca will be provided for 6 months and may be renewed unless otherwise specified.

- Max Units (per dose and over time):
  - 927 mg every 24 weeks

Medical Policy

Initial

A. Patient is 18 years of age or older; **AND**
B. Patient has a viral load of ≥400 copies/mL; **AND**
C. Patient has documented failure or resistance to ≥2 medications from each class of ≥3 of these four classes of antiretrovirals: **AND**
    a. Nucleoside reverse-transcriptase inhibitors
    b. Non-nucleoside reverse-transcriptase inhibitors
    c. Protease inhibitors
    d. Integrase strand transfer inhibitors
D. Patient will take in combination with an optimized antiviral background regimen including one or more other antiretroviral agent.

Renewal

Coverage can be renewed based upon the following criteria:

A. The medication will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; **AND**
B. Disease response with treatment as defined by decreasing trend in viral load or continued viral load suppression.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value.

DEFINITIONS

A. Sunlenca (lenacapavir) injection, for subcutaneous use. Initial U.S. Approval: 2022
    a. SUNLENCA (lenacapavir) for injection is a sterile preservative-free, clear, and yellow with no visible particles solution for subcutaneous injection. It is supplied as 2 single-dose vials that contain 463.5 mg/ 1.5 mL of lenacapavir. The kit also contains 2 disposable syringes, and 2 injection safety needles for subcutaneous injection (22-gauge, ½ inch).

CODING

Applicable NDC Codes	
61958-3002-01	Sunlenca (lencapavir) 309mg/1 mL- 1.5ml

Applicable Procedure Code	
J3490	Unclassified drug

Applicable ICD-10 Codes	
B20	HIV

EVIDENCE BASED REFERENCES

1. Sunlenca [package insert]. Foster City, CA; Gilead Sciences, Inc; December 2022. Accessed February 2023.
2. Segal-Maurer S, DeJesus E, Stelbrinka HJ; for the CAPELLA Study Investigators. Capsid inhibition with lenacapavir in multidrug-resistant HIV-1 infection. *N Engl J Med.* 2022; 1793-1803.

POLICY HISTORY

Original Effective Date	2/28/2023
Revised Date	
P&T Committee Endorsement	02/28/2023
Updated to Brand New Day/Central Health Medicare Plan	01/01/2024