RX.PA.082.MPC Sunlenca® (lenacapavir tablets and subcutaneous injection)

The purpose of this policy is to define the prior authorization process for Sunlenca® (lenacapavir tablets and subcutaneous injection)

Sunlenca, a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor, 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 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

PROCEDURE

A. Initial Authorization Criteria:

1. **Human Immunodeficiency Virus type 1 (HIV-1). All requests must meet the following criteria:**
   - Must be age 18 years or older
   - Must have a documented diagnosis of multidrug resistant HIV-1 infection
   - According to the prescriber, the patient is HIV-1 treatment experienced and is failing a current antiretroviral regimen for HIV; AND
     Note: Failing an antiretroviral regimen for HIV may be due to resistance, intolerance, or safety considerations. Safety considerations may include drug-drug interactions and immune reconstitution syndrome.
   - Must have documentation of current HIV RNA viral load of > 400 copies/mL (within the past 30 days)
   - The patient has a documented resistance to two or more agents from at least THREE of the following antiviral classes (a, b, c, d):
     a) Nucleoside reverse transcriptase inhibitor;
        Note: Examples of nucleoside reverse transcriptase inhibitors include abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, tenofovir alafenamide, zidovudine.
     b) Non-nucleoside reverse transcriptase inhibitor;
        Note: Examples of non-nucleoside reverse transcriptase inhibitor include delaviridine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine.
     c) Protease inhibitor;
        Note: Examples of protease inhibitors include atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir.
     d) Integrase strand transfer inhibitor; AND
        Note: Examples of integrase strand transfer inhibitors include raltegravir, dolutegravir, elvitegravir.
   - The medication will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND
   - Dose does not exceed FDA approved indication

Note: Documentation of initiation dosing option must be provided (option 1 or 2)

a) Initiation Option 1:
   - Day 1: Two SC injections (2 x 1.5mL) and two tabs (2 x 300 mg tab)
   - Day 2: Two tabs (2 x 300 mg tab)

b) Initiation Option 2:
   - Day 1: Two tabs (2 x 300 mg tab)
   - Day 2: Two tabs (2 x 300 mg tab)
   - Day 8: One tab (1 x 300 mg tab)
   - Day 15: Two SC injections (2 x 1.5mL)

- The medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.
- Member must have documentation of creatinine clearance (CrCl) ≥ 15 mL/min

B. Reauthorization Criteria:

1. Human Immunodeficiency Virus type 1 (HIV-1).

MPC Renewal:

- All prior authorization renewals are reviewed on a 1 year interval basis to determine the Medical Necessity for continuation of therapy.
- Documentation of a clinical response, as determined by the prescriber
- Note: Examples of a response are HIV RNA < 50 cells/mm^3 or HIV-1 RNA ≥ 0.5 log_{10} reduction from baseline in viral load.
- The medication will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND
- The medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC) and have been taking Sunleca have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria).Provider has a documented clinical response of the member's condition which has improved based or stabilized upon the prescriber's assessment

C. Sunlenca (lenacapavir) will be considered investigational or experimental for any other use and will not be covered.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year

Codes:

Code	Description
J1961	Injection, lenacapavir, 1 mg

REFERENCES

1. Sunlenca® tablets and subcutaneous injection [prescribing information]. Foster City, CA: Gilead; December 2022.
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.
3. Gupta SK, Sims J, Brinson C, et al. Lenacapavir as part of a combination regimen in treatment-naïve people with HIV: Week 54 results [poster]. Presented at: CROI 2022; Virtual Event; February 12-16, 2022.
4. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. 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 December 26, 2022.
5. Gandhi RT, Bedimo R, Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults 2022 recommendations of the International Antiviral Society–USA Panel. *JAMA.* [Epub ahead of Print Dec 1, 2022].

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/2026*
Annual Review	*02/2025*
Annual policy review. Update to reauthorization criteria for non-MPC renewals	*02/2024*
New Policy	*07/2023*