



Commercial/Healthcare Exchange PA Criteria

Effective: February 9, 2023

Prior Authorization: Sunlenca

Products Affected: Sunlenca (lenacapavir) tablet and subcutaneous solution

Medication Description: Sunlenca, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (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.

Covered Uses: treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection

Exclusion Criteria:

1. Concomitant administration of SUNLENCA with strong CYP3A inducers is contraindicated due to decreased lenacapavir plasma concentrations

Required Medical Information:

1. Diagnosis
2. Past therapies tried and failed
3. Current medication list

Prescriber Restriction: The medication is prescribed by, or in consultation with, a physician who specializes in the treatment of HIV infection

Age Restriction: 18 years and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. **Human Immunodeficiency Virus (HIV)-1 Infection, Treatment.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A. **Initial Therapy.** Approve for 6 months if the patient meets ALL of the following conditions (i, ii, iii, iv, and v):
 - i. Patient is \geq 18 years of age; **AND**
 - ii. According to the prescriber, the patient is failing a current antiretroviral regimen for HIV; **AND**
 - iii. According to the prescriber, the patient has resistance to two or more agents from at least THREE of the following antiviral classes (a, b, c, d):
 - a. Nucleoside reverse transcriptase inhibitor;

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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.

- iv. The medication will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; **AND**
- v. The medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.

Renewal Criteria

1. **Patient is Currently Receiving Sunlenca.** Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):

- i. The medication will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; **AND**
- ii. Patient has responded to a Sunlenca-containing regimen, as determined by the prescriber.

Note: Examples of a response are HIV RNA < 50 cells/mm³, HIV-1 RNA ≥ 0.5 log₁₀ reduction from baseline in viral load.

References:

1. Product Information: SUNLENCA(R) oral tablets, subcutaneous injection, lenacapavir oral tablets, subcutaneous injection. Gilead Sciences Inc (per FDA), Foster City, CA, 2022.

Policy Revision history

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|-------|----------------|-------------------|-------------------|------------|
| 1 | New Policy | New Policy | All | 02/09/2023 |

