

Sunlenca[®] (lenacapavir) Injection

When requesting Sunlenca[®] (lenacapavir) Injection, the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

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.

Coverage Guidelines

Human Immunodeficiency Virus type 1 (HIV-1) infection

The individual must meet **all** of the following criteria for initial authorization:

- Is 18 years of age or older;
- Is failing a current antiretroviral regimen;
- Has resistance to two or more agents from each of at least THREE of the following antiviral classes:
 - o Nucleoside reverse transcriptase inhibitor (NRTI) [e.g., abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, tenofovir alafenamide, zidovudine]; OR
 - o Non-nucleoside reverse transcriptase inhibitor (NNRTI) [e.g., delaviridine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine]; OR
 - o Protease inhibitor (PI) [e.g., atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir]; OR
 - o Integrase strand transfer inhibitor (INSTI) [e.g., raltegravir, dolutegravir, elvitegravir];
- Sunlenca will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agent(s);
- Sunlenca is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.

The individual must meet **all** of the following criteria for reauthorization:

- Sunlenca will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agent(s);
- Has responded to a Sunlenca-containing regimen (e.g., HIV RNA <50 cells/mm³, HIV-1 RNA ≥ 0.5 log₁₀ reduction from baseline in viral load)

Approval durations

- Initial authorization: 6 months
- Reauthorization: 12 months

Dosing Recommendation

The recommended initial dose is 927 mg via subcutaneous injection one time (Day 1) and maintenance dose of 927 mg every 6 months (26 weeks) from the date of the last injection +/-2 weeks.

References

1. Sunlenca® [prescribing information]. Foster City, CA: Gilead; December 2022.
2. Segal-Maurer S, DeJesus E, Stelbrink 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].