

Sunlenca® (lenacapavir) Injection

When requesting Sunlenca® (lenacapavir) Injection, the individual requiring treatment must be diagnosed with the following 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 $\geq 0.5 \log_{10}$ reduction from baseline in viral load, improvement or stabilization of CD4 T-cell count).

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; November 2024.
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3. Gupta SK, Berhe M, Crofoot G, et al. Lenacapavir administered every 26 days or daily in combination with oral daily antiretroviral therapy for initial treatment of HIV: a randomized open-label, active-controlled, phase 2 trial. *Lancet HIV*. 2023;10:e15-e23.
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 12, 2024. Available at: <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf>. Accessed on: January 10, 2025.
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*. 2023;329(1):63-84.
6. Smith RA, Raugi DN, Nixon RS, et al; on behalf of the University of Washington-Senegal HIV-2 Study Group. Antiviral activity of lenacapavir against HIV-2 isolates and drug resistant HIV-2 mutants. *J Infect Dis*. 2023 Dec 7. [Epub ahead of print].
7. Gilead Sciences. Pre-exposure prophylaxis study of lenacapavir and emtricitabine/tenofovir alafenamide in adolescent girls and young women at risk of HIV infection (PURPOSE 1). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2023 Dec 19]. Available at: <https://classic.clinicaltrials.gov/ct2/show/NCT04994509>. NLM Identifier: NCT049945091.