

Yeztugo® (lenacapavir) Injection

When requesting Yeztugo® (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

Yeztugo is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35 kg who are at risk for HIV-1 acquisition.

Coverage Guidelines

Pre-exposure Prophylaxis (PrEP) of Human Immunodeficiency Virus-1 (HIV-1) Infection.

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

- Weighs ≥ 35 kg;
- Has a negative HIV-1 test result ≤ 7 days prior to the dose of Yeztugo;
- Yeztugo is prescribed as part of a comprehensive HIV-1 prevention strategy (i.e., adherence to administration schedule and safer sex practices, including condoms);
- Yeztugo is prescribed by or in consultation with a physician who specializes in the management of HIV infection.

Approval duration: 7 months

Dosing Recommendations

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 injections +/- 2 weeks.

References

1. Yeztugo® tablets and subcutaneous injection [prescribing information]. Foster City, CA: Gilead; June 2025.
2. Guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable pre-exposure prophylaxis (PrEP). Geneva: World Health Organization; 2025. License: CC-BY-NC-SA 3.0 IGO.
3. WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection: provider module for oral and long-acting PrEP. Geneva: World Health Organization; 2024. License: CC BY-NC-SA 3.0 IGO.
4. Landovitz RJ, Molina JM, and Buchinder SP for the International Antiviral Society-USA (IAS-USA) Panel. Preexposure prophylaxis for HIV: Updated recommendations from the 2024 International Antiviral Society-USA Panel. *JAMA*. 2025 June 27. [Online ahead of Print].
5. US Preventative Services Task Force. Preexposure prophylaxis to prevent acquisition of HIV. US Preventative Task Force Recommendation Statement. *JAMA*. 2023;330(8):736-745.