CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Yeztugo (lenacapavir)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Yeztugo is a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor 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. Individuals must have a negative HIV-1 test prior to initiating Yeztugo.

Yeztugo (lenacapavir) will be considered for coverage when the following criteria are met:

Pre-exposure Prophylaxis (PrEP) of HIV Infection

For **initial** authorization:

1. Member is at least 16 years of age and 35 kg or more; AND
2. Provider attests member is at risk for HIV infection; AND
3. Member has had or will have a negative HIV RNA test before initial and subsequent injections; AND
4. Member is not a candidate for oral PrEP therapy (ex. difficulty with adherence, significant renal disease, trouble swallowing pills etc.).
5. **Dosage allowed/Quantity limit:** Maintenance quantity limit: 2 injections per 6 months.

Table 1. Dosing Schedule for YEZTUGO Initiation and Continuation in Adults and Adolescents Weighing at Least 35 kg

Time	
	Dosage of YEZTUGO: Initiation[a]
Day 1	927 mg by subcutaneous injection (2 x 1.5 mL injections) and 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
	Dosage of YEZTUGO: Continuation
Every 6-months (26 weeks)[b] +/-2 weeks	927 mg by subcutaneous injection (2 x 1.5 mL injections)

a. The complete initiation dosing schedule, consisting of subcutaneous injections and oral tablets, is required; the efficacy of YEZTUGO has only been established with this dosing schedule.
b. From the date of the last injection.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Member has had or will have a negative HIV RNA test before injections.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Yeztugo (lenacapavir) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/08/2025	New policy for Yeztugo (lenacapavir) created.
09/19/2025	Added requirement that member is not a candidate for oral PrEP with examples.

References:

1. Yeztguo [prescribing information]. Gilead Sciences, Inc.; 2025.
2. Chou R, Spencer H, Bougatsos C, Blazina I, Ahmed A, Selph S. Preexposure Prophylaxis for the Prevention of HIV: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force [published correction appears in JAMA. 2023 Nov 14;330(18):1805. doi: 10.1001/jama.2023.19501.]. *JAMA*. 2023;330(8):746-763. doi:10.1001/jama.2023.9865
3. Centers for Disease Control and Prevention. Clinical Guidance for PrEP. https://www.cdc.gov/hivnexus/hcp/prep/index.html. Accessed July 8, 2025.
4. Bekker LG, Das M, Abdool Karim Q, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women. *N Engl J Med.* 2024;391(13):1179-1192. doi:10.1056/NEJMoa2407001
5. Kelley CF, Acevedo-Quiñones M, Agwu AL, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons. *N Engl J Med.* 2025;392(13):1261-1276. doi:10.1056/NEJMoa2411858
6. Gandhi RT, Landovitz RJ, Sax PE, et al. Antiretroviral Drugs for Treatment and Prevention of HIV in Adults: 2024 Recommendations of the International Antiviral Society-USA Panel. *JAMA*. 2025;333(7):609-628. doi:10.1001/jama.2024.24543

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