

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

<b>DRUG NAME</b>	<b>Yeztugo (lenacapavir)</b>
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	
<b>Dosage of YEZTUGO: Initiation<sup>a</sup></b>	
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)
<b>Dosage of YEZTUGO: Continuation</b>	
Every 6-months (26 weeks) <sup>b</sup> +/- 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:**

- 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
<b>07/08/2025</b>	New policy for Yeztugo (lenacapavir) created.
<b>09/19/2025</b>	Added requirement that member is not a candidate for oral PrEP with examples. ODM approved on 10/27/25.

**References:**

- Yeztguo [prescribing information]. Gilead Sciences, Inc.; 2025.
- 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
- Centers for Disease Control and Prevention. Clinical Guidance for PrEP. <https://www.cdc.gov/hivnexus/hcp/prep/index.html>. Accessed July 8, 2025.
- Bekker LG, Das M, Abdoor 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
- 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
- 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
- Ohio Administrative Code. (2022, February 23). 5160-1-01 (C) Medicaid medical necessity: definitions and principles. Retrieved February 22 2023 from [codes.ohio.gov](https://codes.ohio.gov).
- Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from [codes.ohio.gov](https://codes.ohio.gov).
- Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from [codes.ohio.gov](https://codes.ohio.gov).

Effective date: 01/01/2026

Revised date: 09/19/2025