

## PHARMACY POLICY STATEMENT

### Indiana Medicaid

|                     |                              |
|---------------------|------------------------------|
| <b>DRUG NAME</b>    | <b>Yeztugo (lenacapavir)</b> |
| <b>BENEFIT TYPE</b> | Medical                      |
| <b>STATUS</b>       | 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)<br>and<br>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> +/-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. Yeztugo [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/hiv/nexus/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-Quinones 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

Effective date: 01/01/2026

Revised date: 09/19/2025