Pharmacy Medical Necessity Guidelines:
Yeztugo (lenacapavir sodium)

Effective: November 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RxUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0988	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

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. Individuals must have a negative HIV-1 test prior to initiating YEZTUGO.

COVERAGE GUIDELINES

The plan may authorize coverage of **Yeztugo** for Members when **ALL** of the following criteria are met:

Yeztugo (lenacapavir sodium)

1. The patient has tried or has a contraindication to or clinical intolerance to emtricitabine/tenofovir disoproxil fumarate 200-300 mg (generic Truvada)

LIMITATIONS

- None

CODES

None

REFERENCES

1. Centers for Disease Control and Prevention (CDC), US Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2017 Update: A Clinical Practice Guideline. CDC website. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018. Accessed August 19, 2021.
2. Truvada (emtricitabine/tenofovir disoproxil fumarate) [prescribing information]. Foster City, CA: Gilead Sciences; June 2020.
3. U.S. Preventive Services Task Force Final Recommendation Statement Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-exposure Prophylaxis. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-ofhuman-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis. Accessed August 19, 2021.
4. Yeztugo (lenacapavir sodium) [prescribing information]. Gilead Sciences, Inc. Foster City, CA; June 2025.

APPROVAL HISTORY

November 4, 2025: Reviewed by Pharmacy & Therapeutics Committee.

1. November 10, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical

Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services