Government of District of Columbia Department of Health Care Finance

Yeztugo® (lenacapavir) Prior Authorization Request

REQUEST DATE: _____

PATIENT INFORMATION

PATIENT LAST NAME: _____

PATIENT FIRST NAME: _____ **MIDDLE INITIAL:** _____

PATIENT MEDICAID ID: _____ **DATE OF BIRTH:** _____

PRESCRIBER INFORMATION

PRESCRIBER LAST NAME: _____

PRESCRIBER FIRST NAME: _____

PRESCRIBER PHONE: _____ **PRESCRIBER FAX:** _____

PRESCRIBER DEA NUMBER: _____ **PRESCRIBER NPI NUMBER:** _____

PERSON COMPLETING FORM: _____

PHARMACY NAME: _____ **PHARMACY PHONE NUMBER:** _____

DRUG REQUESTED: _____

On June 18, 2025, the FDA approved Gilead's Yeztugo® (lenacapavir) for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired human immunodeficiency virus type 1 (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® is the first twice-yearly subcutaneous (SC) FDA-approved PrEP option for HIV prevention. Lenacapavir, a capsid inhibitor.

INITIATION OF YEZTUGO® INCLUDES PROVIDER-ADMINISTERED SC INJECTIONS AND SELF-ADMINISTERED ORAL TABLETS: ON DAY 1, 927 MG (TWO 1.5-ML INJECTIONS) AND 600 MG (TWO 300-MG TABLETS) ARE ADMINISTERED. ON DAY 2, 600 MG IS ADMINISTERED ORALLY. AFTER INITIATION, 927 MG IS ADMINISTERED SC EVERY 6 MONTHS.

INFORMATION REQUIRED FOR PRIOR AUTHORIZATION APPROVAL. PLEASE CHECK ALL THE APPLICABLE CRITERIA

- ○ At risk for acquiring HIV: Per CDC guidelines (Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings) and USPSTF recommendation (Recommendation: Human Immunodeficiency Virus (HIV) Infection: Screening | United States Preventive Services Taskforce) consider patients to be "at risk" based on sexual behaviors as well as IVDU.
- ○ Diagnosis of HIV pre-exposure prophylaxis (PrEP) is in the patient's recent medical records and documented on prescription. **ICD-10 Code (i.e. Z29.81 Encounter for HIV pre-exposure prophylaxis)_____**
- ○ Age ≥16 years and weight ≥35 kg
- ○ **Document rational/ shared clinical decision-making (SCDM) for Yeztugo® and pertinent clinical information Check all applicable below (recommend attachment of clinical notes):**
  - ○ Preference of long-acting injection to other available FDA indicated PrEP medications.
  - ○ Current difficulty with daily pill use.
  - ○ List documented contraindication(s), side effect(s), or adverse effect(s) to prior prescribed PrEP medication(s): _____
  - ○ Renal or kidney disease
  - ○ Other:_____
- ○ When screening for HIV-1 infection prior to initiating YEZTUGO®, if an antigen/antibody-specific test is used and provides negative results, then such negative results should be confirmed using an RNA-specific assay, even if the results of the RNA-assay are available after YEZTUGO® initiation. The medication will be administered only if the individual has a negative HIV-1 FDA approved test result and additionally as clinically appropriate. **CPT code_____ Test Date:**_____

  CONTRAINDICATION: Unknown or positive HIV-1 status. **Testing is required before each treatment dose.**

  WARNING: Potential risk of developing resistance to lenacapavir if an individual acquires HIV-1 either before or when receiving YEZTUGO®.

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- ○ FDA Labeled dosing recommendations for **initiation** therapy with **Strong and Moderate CYP3A Inducers** will be followed.
- ○ Patient was educated on the long "tail" of gradually declining drug levels when discontinuing long-acting lenacapavir (Yeztugo®) injections and the risk of developing a drug-resistant HIV if infection is acquired during that time.

  WARNING: Potential risk of developing resistance to lenacapavir following discontinuation of YEZTUGO®.
- ○ There is a quantity Limit (injection): 2 doses per year (1 per 6 months). If request is for greater than 2 per year. Provide clinical justification for supplemental dose:_____
- ○ ADDITIONAL INFO (Please provide any additional clinical information that you feel is important to this review, i.e. if a patient is currently taking the requested drug, including how they've been receiving it (samples, investigational, paying out of pocket, etc.) Specify date initiated and duration:

  _____

LENGTH OF AUTHORIZATION CRITERIA

Length of authorization: **up to 6 months**

PRIOR AUTHORIZATION RENEWAL

- ○ Patient met and continues to meet the initial review criteria; **AND**
- ○ The patient has not experienced any treatment-restricting adverse effects, treatment failure, or resistance to Yeztugo® (lenacapavir)?

How supplied

- Oral Tablet: 300 MG: Subcutaneous Solution: 309 MG/1 ML
- Both tablet and injectable must be dispensed by specialty pharmacy

ADDITIONAL INFORMATION:

For More Clinical Advice About Long-Acting Injectable PrEP Guidelines:

- ❖ Call the National Clinicians Consultation Center PrEPline at 855-448-7737
- ❖ CDC HIV Hotlines, Warmlines, and Consultation & Referral Services website at https://www.cdc.gov/hiv/resourcelibrary/hotlines.html
- ❖ Go to the CDC HIV website for clinician resources at https://www.cdc.gov/hiv/clinicians/index.html
- ❖ It is recommended that providers receive training on the proper administration of lenacapavir (Yeztugo®) to minimize injection site reactions.

By signature, the prescriber confirms the above information is complete, accurate, and verifiable by member's records.

PRESCRIBER'S SIGNATURE: _____ **DATE**: _____