



YEZTUGO initiation requires 2 separate prescriptions:

 Tablets	 Injectable
300 mg (quantity: 4)	463.5 mg/1.5-mL injection (quantity: 2)
NDC: 61958-3401-1	NDC: 61958-3402-1
HCPCS Level II code: J0752	HCPCS Level II code: J0738

 **Confirm whether patient's plan requires or prefers a specific specialty pharmacy (SP)**

- Contact your FRM or Gilead Advancing Access® to request support

 **Send both Rx's (tablets & injectable) to a Gilead-contracted SP**

- Indicate # of refills for injectable Rx continuation dose
 - » Consider including documentation with Rx's proactively to expedite the process
- If benefit coverage is split,* Rx's may need to be sent to separate SPs

 **Specialty pharmacy conducts benefits investigation for each Rx (tablets & injectable)**


- Confirms proof of insurance
- Confirms coverage status
- SP outlines required payer documentation for HCP submission (eg, HIV test results, chart notes)

 **Ensure all required information/documentation has been submitted to payer**

- Be prepared to respond to SP requests for additional action/documentation required for approval
 - » SPs will make a minimum of 3 attempts before placing Rx on hold or cancelling
- If benefit is split,* the coverage approval processes may follow separate paths and timing. For example, separate documentation may be required with each Rx

 **Remind patients to expect to be contacted by their SP for shipment authorization**

- Provide your patient with their SP's name and contact information
 - » Consider encouraging patients to proactively reach out to the SP to provide required consent

 ***Split benefit=** when tablets & injectable are covered under different benefit types, eg, tablets are covered by pharmacy benefit, injectable covered under medical benefit

FRM=Field Reimbursement Manager; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

 **Reminder: Plan approval timing may vary depending on individual coverage**

- Approval times will vary from several weeks to several days. Patient and provider response for documentation from SP or payer will directly impact the time to payer approval
- If benefits are split,* approval process may follow different timelines



Questions?

Contact your FRM or Gilead Advancing Access at 1-800-226-2056 or [GileadAdvancingAccess.com/hcp](https://www.gileadadvancingaccess.com/hcp)

Information provided in this resource is for informational purposes only and is only intended to support YEZTUGO. Providers should consult with payers for all relevant coverage, coding, and reimbursement requirements. This resource is not intended to be legal advice or substitute for a provider's independent judgment.

Indication

YEZTUGO is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents (≥35 kg) who are at risk for HIV-1 acquisition. Individuals must have a negative HIV-1 test prior to initiating YEZTUGO.

Important Safety Information

BOXED WARNING: RISK OF DRUG RESISTANCE WITH USE OF YEZTUGO IN UNDIAGNOSED HIV-1 INFECTION

- **Individuals must be tested for HIV-1 infection prior to initiating YEZTUGO, and with each subsequent injection of YEZTUGO, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. Drug-resistant HIV-1 variants have been identified with use of YEZTUGO by individuals with undiagnosed HIV-1 infection. Do not initiate YEZTUGO unless negative infection status is confirmed. Individuals who acquire HIV-1 while receiving YEZTUGO must transition to a complete HIV-1 treatment regimen.**

Please see additional Important Safety Information on the following page, and [click here](#) for full Prescribing Information for YEZTUGO, including BOXED WARNING.

Important Safety Information (cont'd)

Contraindications

- YEZTUGO is contraindicated in individuals with unknown or positive HIV-1 status.

Warnings and precautions

• Comprehensive risk management:

- Use YEZTUGO to reduce the risk of HIV-1 acquisition as part of a comprehensive prevention strategy including adherence to the administration schedule and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs).
- HIV-1 acquisition risk includes behavioral, biological, or epidemiologic factors including, but not limited to, condomless sex, past or present STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high-prevalence area or network. Counsel individuals on the use of other prevention methods to help reduce their risk.
- Use YEZTUGO only in individuals confirmed to be HIV-1 negative. Evaluate for current or recent signs or symptoms consistent with HIV-1 infection. Confirm HIV-1 negative status prior to initiating, prior to each subsequent injection, and as clinically appropriate.

• Potential risk of resistance:

- There is a potential risk of developing resistance to YEZTUGO if an individual acquires HIV-1 before or when receiving YEZTUGO, or following discontinuation. HIV-1 resistance substitutions may emerge in individuals with undiagnosed HIV-1 infection taking only YEZTUGO, because YEZTUGO alone is not a complete regimen for HIV-1 treatment.
- To minimize this risk, it is essential to test before each injection and additionally as clinically appropriate. Individuals confirmed to have HIV-1 must immediately begin a complete HIV-1 treatment regimen.
- Alternative forms of PrEP should be considered after discontinuation of YEZTUGO for those who are at continuing risk of HIV-1 acquisition and should be initiated within 28 weeks of the last YEZTUGO injection.

• Long-acting properties and potential associated risks:

- Residual concentrations of YEZTUGO may remain in systemic circulation for up to 12 months or longer after the last injection.
- Select individuals who agree to the required injection dosing schedule because nonadherence or missed doses could lead to HIV-1 acquisition and development of resistance.

- **Serious injection site reactions:** Improper administration (intradermal injection) has been associated with serious injection site reactions, including necrosis and ulcer. Only administer YEZTUGO subcutaneously.

Adverse reactions

- **Most common adverse reactions** ($\geq 5\%$) in YEZTUGO clinical trials were injection site reactions, headache, and nausea.

Drug interactions

- Strong or moderate CYP3A inducers may significantly decrease YEZTUGO concentrations. Dosage modifications are recommended when initiating these inducers.
- It is not recommended to use YEZTUGO with combined P-gp, UGT1A1, and strong CYP3A inhibitors.
- Coadministration of YEZTUGO with sensitive substrates of CYP3A or P-gp may increase their concentrations and result in the increased risk of their adverse events. YEZTUGO may increase the exposure of drugs primarily metabolized by CYP3A initiated within 9 months after the last injection of YEZTUGO.

Dosage and administration

- **HIV screening:** Test for HIV-1 infection prior to initiating, prior to each subsequent injection, and as clinically appropriate using an approved or cleared test for the diagnosis of acute or primary HIV-1 infection.
- **Dosage:** Initiation dosing (injections and tablets) followed by once-every-6-months continuation injection dosing. Tablets may be taken with or without food.
 - **Initiation:** 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.
 - **Continuation:** 927 mg by subcutaneous injection every 6 months (26 weeks) from date of last injection ± 2 weeks.
- **Anticipated delayed injections:** If scheduled 6-month injection is anticipated to be delayed by more than 2 weeks, YEZTUGO tablets may be taken on an interim basis (for up to 6 months) until injections resume. Dosage is 300 mg orally (1 x 300-mg tablet) once every 7 days. Resume continuation injections within 7 days of the last oral dose.
- **Missed injections:** If more than 28 weeks have elapsed since the last injection and YEZTUGO tablets have not been taken, restart with initiation dosing if clinically appropriate.
- Dosage modifications of YEZTUGO are recommended when initiating with strong or moderate CYP3A inducers. Consult the full Prescribing Information for recommendations.

[Click here for full Prescribing Information for YEZTUGO, including BOXED WARNING.](#)

For more information about YEZTUGO acquisition pathways and resources for your practice, visit [YEZTUGOhcp.com](https://www.yeztugohcp.com)