

You are invited to attend a program...

Say Yes to a New Era in HIV Prevention

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5:20 PM

Cleveland Clinic Administrative Campus
3175 Science Park Drive
Beachwood, Ohio 44122

This program is developed and offered by Gilead. This is not an official program of the Cleveland Clinic.

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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 for YEZTUGO on the following page and the accompanying full Prescribing Information, including BOXED WARNING.

Please be aware that if you are a licensed US physician, nurse practitioner, or physician assistant, the meal associated with this program may be reportable under the federal Open Payments/Sunshine Act and/or state law equivalents, and disclosed as required by law. Gilead does not provide or reimburse for alcohol at Educational Programs.

Gilead policy and the PhRMA Code limit attendance of this program to HCPs. Spouses and guests may not attend unless independently qualified to attend.

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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 (intra-dermal 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.
- Co-administration 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.

Please see the accompanying full Prescribing Information for YEZTUGO, including BOXED WARNING.



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