

# Exploring Access and Acquisition

**An overview of the pathways to getting patients  
their prescribed YEZTUGO**

## Indication

YEZTUGO is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents ( $\geq 35$  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.

## Contraindications

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

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information for YEZTUGO, including **BOXED WARNING**.

# Understanding Insurance Coverage

**YEZTUGO is a healthcare provider (HCP)–administered medication.** The type of insurance plan a patient has can impact how you start them on YEZTUGO. Understanding each patient’s coverage is essential in determining the acquisition process and helping them start on their prescribed therapy.

## Benefits Coverage

The factors that can determine coverage for YEZTUGO include:

### Type of payer

YEZTUGO is a specialty HCP-administered injectable that can be covered by insurance plans, including:



Commercial



Medicare



Medicaid

### Benefit category

An insurance plan may cover YEZTUGO under:



Medical  
benefit



Pharmacy  
benefit



Both  
pharmacy  
and medical  
benefits

## Reminders

- ✓ Insurance plans may have different requirements for coverage based on the benefit category of coverage (medical vs pharmacy). It is important to understand these details through the benefits investigation
- ✓ An HCP-administered product can be administered at an HCP’s office, a hospital outpatient facility, a clinic, or an alternative site of care

## Important Safety Information (cont’d)

### 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.

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information for YEZTUGO, including **BOXED WARNING**.

# Getting Started

Once you have prescribed YEZTUGO, there are **3 different pathways** you can take to get your patients started, based on your preference and their payer coverage.



## Specialty Pharmacy (SP)

If the payer allows YEZTUGO to be dispensed via specialty pharmacy, a specialty pharmacy can help with the steps to get your patient's prescribed medication shipped to you under either medical or pharmacy benefit.



## In-House Specialty Pharmacy

If you have an in-house specialty pharmacy, they may be able to purchase and dispense YEZTUGO.



## Buy and Bill

If you choose to and the payer covers YEZTUGO under medical benefit, you may be able to acquire YEZTUGO to administer in-office through the buy and bill process.



**Alternative sites of care (ASOCs) can support YEZTUGO access and administration for your patients on your behalf.**

## Important Safety Information (cont'd)

### Warnings and precautions (cont'd)

- 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.

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information for YEZTUGO, including **BOXED WARNING**.



ACQUIRING YEZTUGO THROUGH

# Specialty Pharmacy

**yeztugo**<sup>®</sup>  
(lenacapavir) injection 483.5mg/  
1.5mL

**Specialty pharmacies (SP) can help with the steps to get your patient's prescribed medication shipped to you.** Regardless of how the YEZTUGO components (oral and injectable) are covered, whether under medical or pharmacy benefit, the network SP can support coordination and shipment.

## Reminders

- ✓ YEZTUGO is distributed through a network of specialty distributors and specialty pharmacies. Your patient's insurance may specify from which SPs you can order YEZTUGO
- ✓ Payers will often require clinical documentation or a prior authorization (PA)/ medical exception from the HCP for YEZTUGO approval
- ✓ After product approval, coordinate with SP for drug shipment to align with patient's scheduled injection appointment
- ✓ Make sure patients know to answer calls from the SP



**If you have any questions along the way, you can reach out directly to your Gilead Field Reimbursement Manager and/or the Gilead Advancing Access<sup>®</sup> Program.**

## Important Safety Information (cont'd)

### Warnings and precautions (cont'd)

- **Potential risk of resistance: (cont'd)**
  - 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.

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information for YEZTUGO, including **BOXED WARNING**.



# ACQUIRING YEZTUGO THROUGH Specialty Pharmacy

**yeztugo**<sup>®</sup>  
(lenacapavir) injection 483.5mg/  
1.5mL

**Your office can order YEZTUGO from this network of specialty pharmacies.**

**AcariaHealth**  
[acariahealth.com](http://acariahealth.com)

**Accredo Specialty Pharmacy**  
[accredo.com](http://accredo.com)

**CVS Specialty Pharmacy**  
[cvsspecialty.com](http://cvsspecialty.com)

**Genoa Healthcare/Optum Specialty Pharmacy**  
[genoahealthcare.com](http://genoahealthcare.com),  
part of OptumRx -  
[specialty.optumrx.com](http://specialty.optumrx.com)

**Walgreens Specialty Pharmacy**  
[walgreensspecialtyrx.com](http://walgreensspecialtyrx.com)

**CurantHealth**  
[curanthealth.com](http://curanthealth.com)

**Avita Specialty Pharmacy**  
[avitapharmacy.com](http://avitapharmacy.com)

**Disclaimer:** Not every product acquisition will follow exactly the steps described in the illustrated process on the right side of this page.

## Important Safety Information (cont'd)

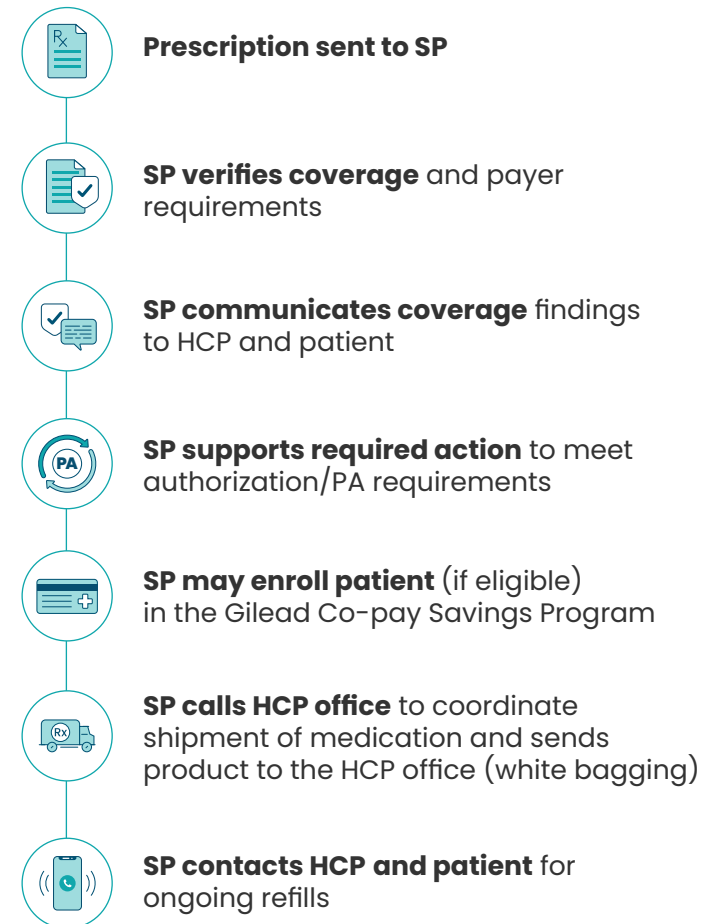
### Warnings and precautions (cont'd)

- 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.

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information for YEZTUGO, including **BOXED WARNING**.

## Specialty Pharmacy Process





ACQUIRING YEZTUGO THROUGH

# In-House Specialty Pharmacy

**yeztugo**<sup>®</sup>  
(lenacapavir) injection 483.5mg/  
1.5mL

**Your office may have an in-house specialty pharmacy that can purchase and dispense the patient's prescribed medication.**

## Reminders

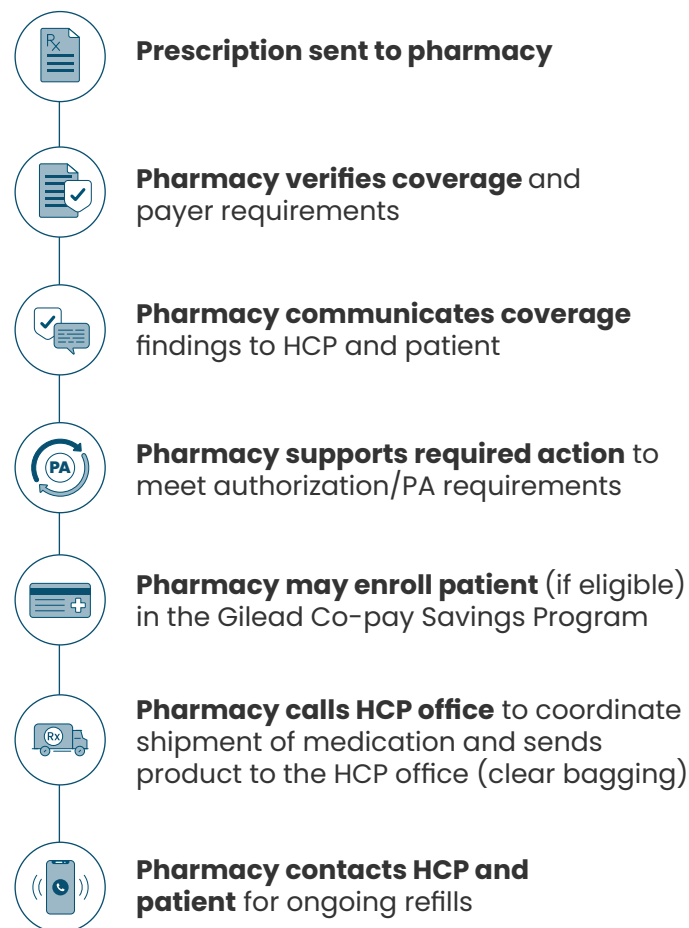
- ✓ There are instances where an in-house specialty pharmacy may not be approved to dispense YEZTUGO by a payer
- ✓ YEZTUGO is distributed through a network of specialty distributors and specialty pharmacies



**If you have any questions along the way, you can reach out directly to your Gilead Field Reimbursement Manager and/or the Gilead Advancing Access<sup>®</sup> Program.**

**Disclaimer:** The process illustration on the right side of this page is an example of the in-house specialty pharmacy product acquisition pathway. However, every pharmacy follows their own process.

## In-House Specialty Pharmacy Process



## Important Safety Information (cont'd)

### Warnings and precautions (cont'd)

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

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information for YEZTUGO, including **BOXED WARNING**.



## ACQUIRING YEZTUGO THROUGH Buy and Bill

**yeztugo**<sup>®</sup>  
(lenacapavir) injection 483.5mg/  
1.5mL

**If you choose and your patient's insurance covers YEZTUGO under the medical benefit, you may be able to acquire it to administer in-office through the buy and bill process.** If the oral component is not covered under the medical benefit, you may receive it separately through a network SP or your in-house SP.

### Reminder

- ✓ Coordinate with specialty distributors to deliver YEZTUGO in time for injection appointments

**If you have questions, reach out to your Gilead Field Reimbursement Manager and/or the Gilead Advancing Access<sup>®</sup> Program.**

### Specialty Distributors

**YEZTUGO can be ordered from one of the network specialty distributors below:**

McKesson Specialty/  
McKesson Plasma and Biologics

Cardinal Specialty

Besse Medical,  
a Cencora Company

ASD Healthcare,  
a Cencora Company

Morris & Dickson Specialty

CuraScript Specialty Distribution

### Buy and Bill Process



**HCP office verifies coverage** for patient's insurance plan



**HCP office purchases product** through network specialty distributor



**HCP office will store, manage, and track** their inventory of YEZTUGO



**HCP office may submit medical claims** for product and its administration to patient's insurance for processing



**Patient or HCP office may pay** any co-pays or coinsurance owed by the patient



**HCP office may submit claim** for Gilead Co-pay Savings Program

The list of authorized distributors is updated periodically and subject to change.

Please visit [gilead.com/medicines/authorized-distributors](https://gilead.com/medicines/authorized-distributors) for updates.

**Disclaimer:** Not every product acquisition will follow exactly the steps described in the illustrated process on the right side of this page.

### Important Safety Information (cont'd)

#### Adverse reactions

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

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information for YEZTUGO, including **BOXED WARNING**.

# Co-pay Savings Program



**The Gilead Co-pay Savings Program** assists eligible, commercially insured patients with their co-pays.<sup>a</sup>

- **Up to \$8,000** in cost-sharing assistance per calendar year, including **up to \$100** per visit for injection administration per treatment with no monthly limit
- If eligible, Gilead Co-pay Savings Program may be able to help your patients lower their co-pay to **as low as \$0**



## Reimbursement Considerations

- **If product is being acquired through a specialty pharmacy or in-house specialty pharmacy**, the pharmacy will process the co-pay card information and apply it to the patient's out-of-pocket costs
- **If product is being acquired through buy and bill**, your office will submit an Explanation of Benefits through [PrEP.AdvancingAccess.com/hcp](https://PrEP.AdvancingAccess.com/hcp)

## Enrollment Process

**You can enroll your patient in the Gilead Co-pay Savings Program by visiting [GileadAdvancingAccess.com/copay-coupon-card](https://GileadAdvancingAccess.com/copay-coupon-card).**

<sup>a</sup>Co-pay coupon support is available for commercially insured eligible patients only. Additional restrictions may apply. Subject to change; for full terms and conditions, visit [www.gileadadvancingaccess.com/copay-coupon-card](https://www.gileadadvancingaccess.com/copay-coupon-card). This is not health insurance.

Additional information about how Gilead may use the patient's information can be found in Gilead's Privacy Statement and Consumer Health Data Privacy Policy available at [www.gilead.com](https://www.gilead.com). If you have any questions about the Gilead Co-pay Savings Program, please call our help desk at 1-855-593-2916, Monday through Friday, 8 AM to 8 PM ET.

## Important Safety Information (cont'd)

### Drug interactions

- Strong or moderate CYP3A inducers may significantly decrease YEZTUGO concentrations. Dosage modifications are recommended when initiating these inducers.

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information for YEZTUGO, including **BOXED WARNING**.



# Field Reimbursement Managers



## Field Reimbursement Manager (FRM) Support

FRMs are here—with their expertise—to provide information about the acquisition process so you can get your patients the medication they need.



## Your Field Reimbursement Managers Can Provide Information About:

- A Gilead Advancing Access<sup>®</sup> Program overview
- General questions involving access, reimbursement, and acquisition
- Navigating the acquisition pathway, so your patients can start their medication without delays
- Providing your office with answers about patient-specific questions and follow-ups

### Important Safety Information (cont'd)

#### Drug interactions (cont'd)

- It is not recommended to use YEZTUGO with combined P-gp, UGT1A1, and strong CYP3A inhibitors.

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information for YEZTUGO, including **BOXED WARNING**.

# Patient Support Program

## Helping your patients access their prescribed Gilead medication

Gilead Advancing Access offers support for your patients through a combination of self-serve options and the ability to connect with a real person. Give them a call and they can help provide information to get your patient started on their prescribed medication.

## Program Offerings



### Dedicated Program Specialists

When you contact Gilead Advancing Access, a program specialist can provide your practice with information on the different acquisition pathways and coverage options.



### Benefits Investigations

Gilead Advancing Access can conduct a benefits investigation. This includes researching and verifying each patient's specific insurance benefits and coverage for YEZTUGO.



### Prior Authorization/Appeals Information

Gilead Advancing Access can provide information to determine prior authorization and appeals requirements and processes.

## Important Safety Information (cont'd)

### Drug interactions (cont'd)

- 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.

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information for YEZTUGO, including **BOXED WARNING**.

# Patient Support Program (cont'd)

## Program Offerings



### Gilead Co-pay Savings Program<sup>a</sup>

Gilead can provide assistance with medication and administration fee out-of-pocket costs for eligible, commercially insured individuals.



### Medication Assistance Program (MAP)

Eligible, uninsured individuals may receive their Gilead medication free through the MAP. Help determine if your patient is eligible for free product assistance online at [GileadAdvancingAccess.com](https://www.gileadadvancingaccess.com).



### Additional Coverage Support

Gilead Advancing Access can research additional coverage options to identify whether your patient may be eligible for additional financial assistance by a state pre-exposure prophylaxis drug assistance program, independent copay foundation, the Medicare Low-Income Subsidy, a state Medicaid program, or a federal or state health insurance exchange.



**Call anytime**  
**Monday through Friday,**  
**9 AM – 8 PM EST**  
**at 1-800-226-2056**

or leave a detailed message  
 after-hours, and a dedicated  
 program specialist will call  
 you back.

<sup>a</sup>Co-pay coupon support is available for commercially insured eligible patients only. Additional restrictions may apply. Subject to change; for full terms and conditions, visit [www.gileadadvancingaccess.com/copay-coupon-card](https://www.gileadadvancingaccess.com/copay-coupon-card). This is not health insurance.

## Important Safety Information (cont'd)

### 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  $\pm$  2 weeks.

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

To explore resources and learn more,  
visit [PrEP.AdvancingAccess.com/hcp](https://PrEP.AdvancingAccess.com/hcp).



[Click here](#) to watch a video  
about Specialty Pharmacy  
acquisition process



[Click here](#) to watch a  
video about Buy and Bill  
acquisition process

## Important Safety Information (cont'd)

### Dosage and administration (cont'd)

- **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 additional Important Safety Information throughout and [click here](#) for full Prescribing Information for YEZTUGO, including **BOXED WARNING**.