



# LENACAPAVIR AND LONG-ACTING HIV PREP

## Introduction

This market update consolidates the latest updates on global lenacapavir (LEN) for HIV pre-exposure prophylaxis (PrEP) rollout in low- and middle-income countries (LMICs) and looks ahead to what comes next in biomedical HIV prevention: generic market entry, expanded PrEP coverage, and new long-acting PrEP products in the pipeline.



For more insight into country-level LEN introduction, view an accompanying [country spotlight report](#) from Wits RHI, CHAI, and Unitaid.

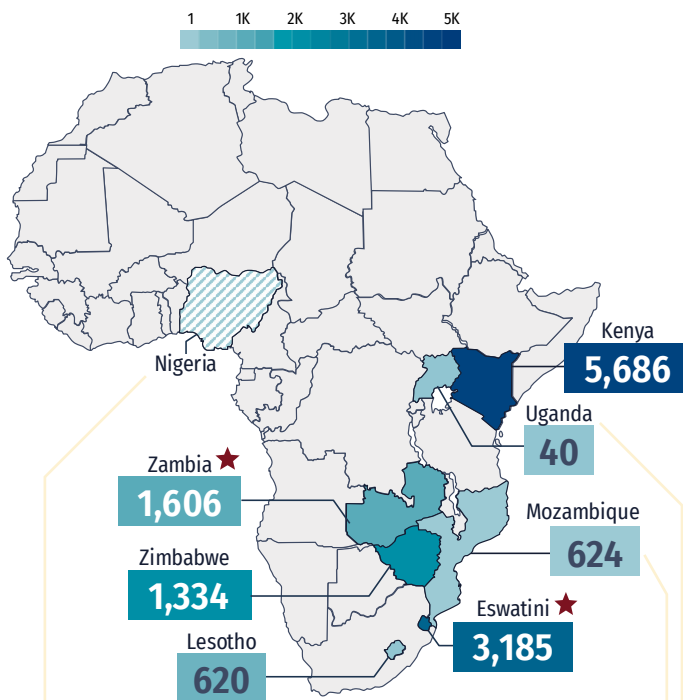
## LENACAPAVIR ROLLOUT STATUS

### Originator (Gilead) market entry in LMICs:

After Global Fund and PEPFAR jointly committed to procuring LEN in a set of early adopter countries, Gilead branded supply began arriving in countries in late 2025, with the first LMIC launches in Zambia and Eswatini.

**Figure 1. LEN Initiations by Country**

Based on latest country data available (March/April 2026)



**1ST LAUNCHED ON DECEMBER 1, 2025**  
World AIDS Day

★ ZAMBIA

★ ESWATINI

**8**

As of the end of April 2026, LEN has now been introduced across a total of eight LMICs, with **Kenya, Zimbabwe, Nigeria, Lesotho, Uganda, and Mozambique** launching after **Zambia and Eswatini**.

CUMULATIVELY, OVER **11K PEOPLE** HAVE INITIATED ON LEN



Nigeria initiated its first client on LEN at the launch ceremony in March; commodities are being distributed to sites, with implementation planned to begin late April/early May.

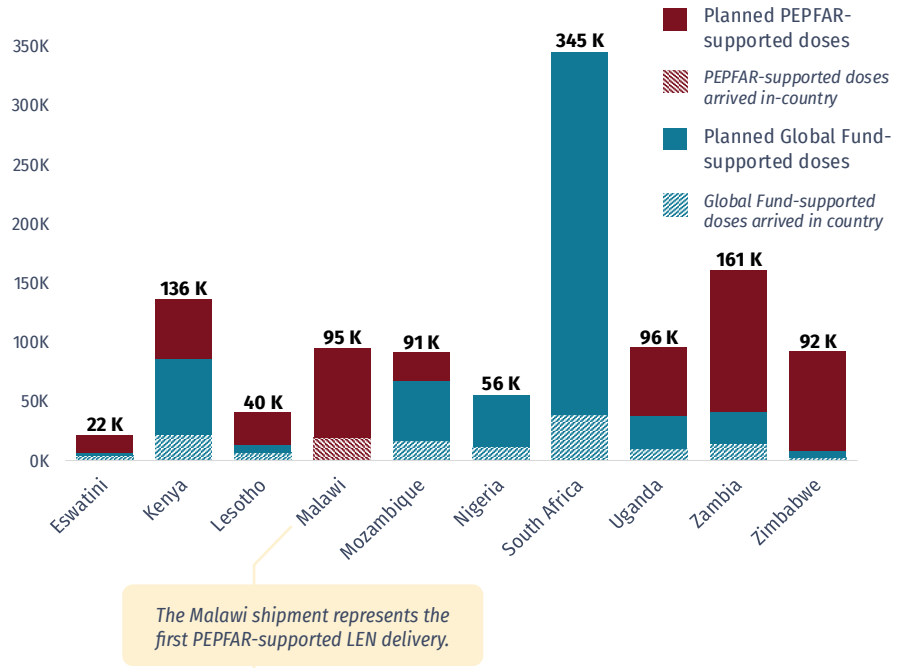
Mozambique and Uganda are the most recent countries to begin implementation – numbers shown here for Uganda are from launch only

**2** **Two more countries** are expected to launch in Q2: **Malawi** and **South Africa** received their first shipments of LEN in April, from PEPFAR and Global Fund, respectively.

Within these first ten early adopter countries introducing LEN in early 2026, planned procurement from Global Fund and PEPFAR is expected to support more than

**600,000**  
**LEN initiations**  
in 2026 (Figure 2).

**Figure 2. 2026 Planned LEN Procurement and Completed Shipments (Doses)**  
Data as of end of April 2026



In April 2026, the United States government and Global Fund announced they had increased their procurement commitment from 2 million to

**3 million people**  
**over the next 2-3 years.**

However, this is still far below the global need.

**Figure 3. Joint Global Fund and PEPFAR LEN Commitment (2026-2028)**



In addition to these ten countries, **14 more LMICs** are planning to launch LEN by the end of 2026 or early 2027, with support from the Global Fund and/or PEPFAR

**Table 1. Countries currently or planned to receive LEN by 2027**

Support Source	Countries
<b>GLOBAL FUND</b>	Benin, Botswana, Dominican Republic, Eswatini, Fiji, Georgia, Haiti, Honduras, Indonesia, Kenya, Lesotho, Morocco, Mozambique, Nigeria, Papua New Guinea, Rwanda, South Africa, Thailand, Uganda, Zambia, Zimbabwe
<b>PEPFAR</b>	Eswatini, Kenya, Lesotho, Malawi, Mozambique, Philippines, Uganda, Ukraine, Zambia, Zimbabwe
<b>CONFIRMED IMPLEMENTATION SCIENCE STUDIES</b>	Zambia, South Africa, Brazil

Note: Some countries are also including LEN in Memorandums of Understanding and implementation plans with the US government. Country lists will be updated on an ongoing basis.

## SPOTLIGHT: GENERATING EVIDENCE THROUGH IMPLEMENTATION SCIENCE STUDIES TO CATALYZE SCALE



Beyond programmatic rollout, implementation science studies in Brazil, Zambia, and South Africa are supporting evidence generation to rapidly inform broader service delivery in LMICs. Collectively, these studies are implementing a variety of facility-based and decentralized delivery models including pharmacies, mobiles, and community health worker delivery to reach adolescent girls and young women, pregnant and breastfeeding women, men who have sex with men, transgender populations, and people who inject drugs.

### ZAMBIA

#### SCALE-IT

**SCALE-IT**, funded by Unitaid, led by the University Teaching Hospital/Ministry of Health in Zambia is implementing a hub-and-spoke model.

### SOUTH AFRICA

#### LEN4PREP

**LEN4PrEP**, funded by Unitaid and implemented by Wits RHI, is implementing LEN within a package of sexual and reproductive health services through various delivery models.

#### ACCEL

The **ACCEL** study, funded by Unitaid and led by the Africa Health Research Institute, will implement and evaluate the impact and cost-effectiveness of community-based strategies.

### BRAZIL

#### IMPREP

**ImPrEP**, funded by Unitaid and led by Fiocruz, is implementing LEN through public health services and mobile clinics.

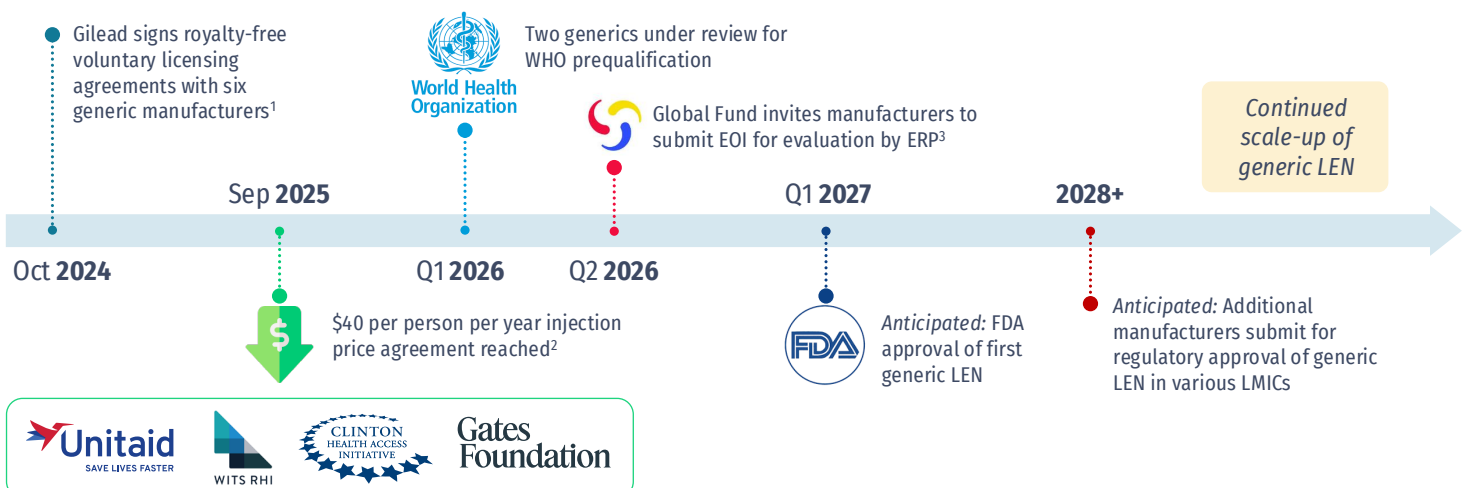


Currently, LEN supply for LMICs produced by Gilead is only being channeled to Global Fund and PEPFAR for programmatic implementation in certain early adopter countries. All orders from Global Fund, PEPFAR, and additional volumes being procured for implementation studies are being procured through the Global Fund platform, Wambo.

## Generic LEN timelines:

In 2024, Gilead signed royalty-free voluntary licensing agreements with six generic manufacturers. In 2025, Unitaid funded Wits RHI and CHAI to negotiate a pricing agreement and support generic development with Dr. Reddy's Lab, in parallel to an agreement negotiated by the Gates Foundation with Hetero. These agreements unlocked a **US\$40 per person per year price for LEN injections** (Figure 4). With these conditions in place, generic development is advancing rapidly. Unitaid is also funding WHO to accelerate the normative and regulatory pathway for generic LEN, including development of WHO guidelines, prequalification (PQ), and the collaborative registration procedure to speed national registration in LMICs. Generic regulatory and WHO PQ submissions have begun for the first two suppliers and the Global Fund Expert Review Panel (ERP) is now open, meaning **initial market entry is anticipated in early 2027**. Unitaid is also supporting the government of South Africa to **identify an additional local manufacturer** to further expand generic suppliers of the injectable.

**Figure 4. Timeline for Generic LEN Introduction and Scale**



1) Press release: [Gilead signs royalty-free voluntary licensing agreements for lenacapavir](#)

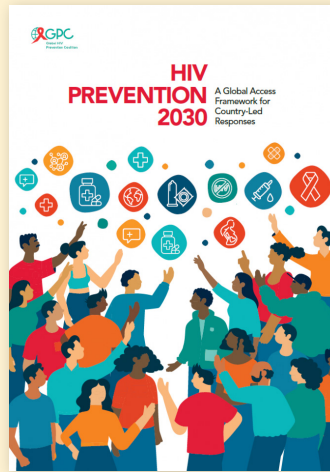
2) Press Release: [Unitaid, CHAI, and Wits RHI enter into landmark agreement with Dr. Reddy's to make HIV prevention tool lenacapavir affordable in LMICs](#)

3) [Global Fund EOI invitation for LEN for ERP](#)

## Market Estimates:

- ▶ With successful early introductions underway, additional launches planned throughout the rest of 2026, and **generic market entry expected by Q1 2027**, we have the potential to dramatically expand the PrEP market in LMICs, if substantial additional funding is secured.
- ▶ However, 2026 LEN volumes are heavily concentrated in Africa and many countries still rely on domestic funding and may not have access to generics.
- ▶ Rapidly expanding access to reach LEN's market potential will require **further market-shaping, concerted political will, effective partner coordination, and community engagement**, among other factors.
- ▶ CHAI developed market estimates (Figure 5) to quantify multiple scenarios, including the possibility of consistency or low-growth in the PrEP market as well as high-growth over the next five years. To reach UNAIDS targets by 2030, PrEP supply and use will need to grow significantly. **Based on 2026 procurement commitments, market estimates are tracking with the "high" scenario, with potential to build to the "UNAIDS target ambition" scenario.**

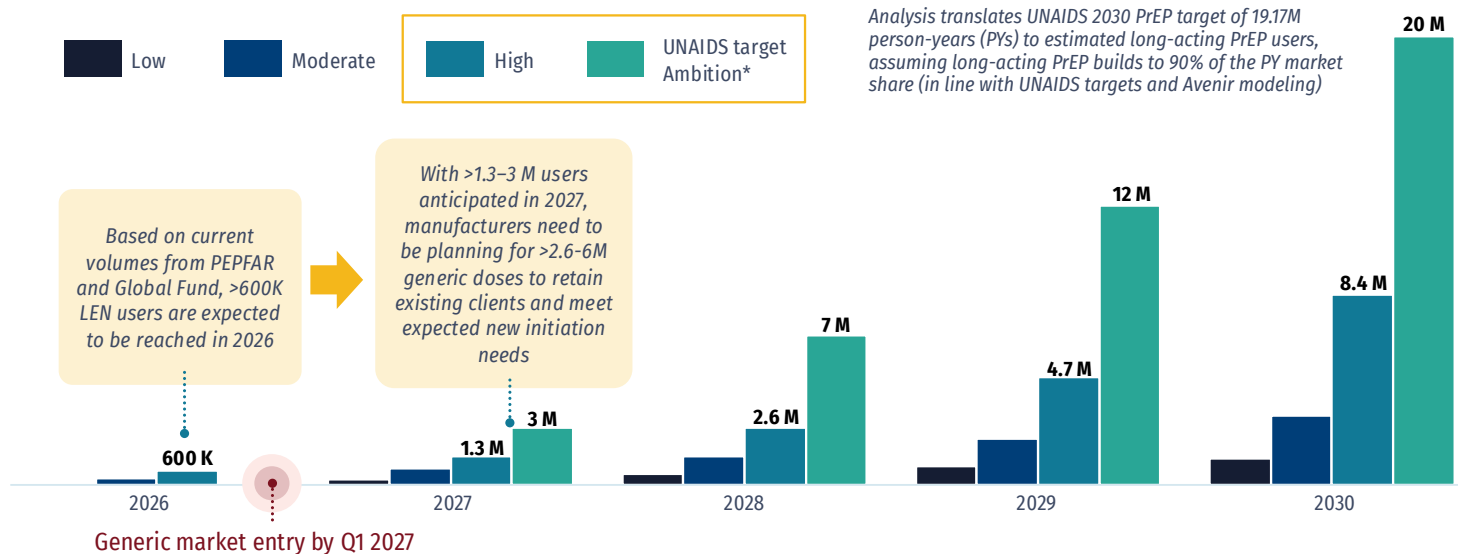
### HIV PREVENTION 2030: GLOBAL ACCESS FRAMEWORK



In March 2026, UNAIDS published the [HIV Prevention 2030 Global Access Framework](#) re-emphasizing the goal of

**90% of people**  
in need using prevention options,  
highlighting the target of  
**20 million**  
**person-years**  
on PrEP (including long-acting PrEP)  
by 2030.

**Figure 5. Long-Acting PrEP Market Estimates (annual users)**



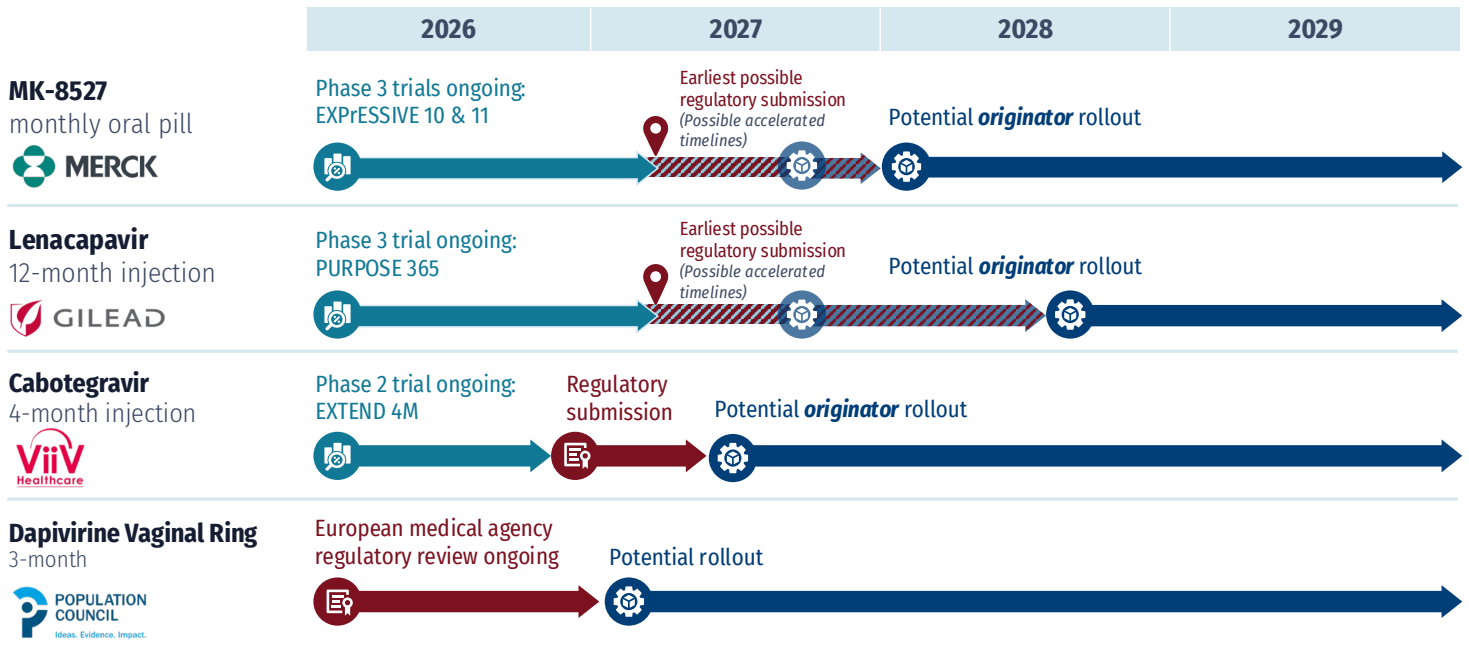
Note: Market estimates also include Unitaid procurement – Unitaid is procuring LEN for 165,000 person-years over 3 years for implementation research

- ▶ Figure 5 is based on preliminary estimates that will be refined. National governments are utilizing data on current PrEP use and demand for long-acting products to develop forecasts for 2027 and beyond, indicating their full ambition without fiscal constraint. CHAI is also working on a global LEN forecast, leveraging these inputs.

# LONG-ACTING PREP PRODUCT PIPELINE

Through effective market-shaping interventions, LEN is now leading the way as the first long-acting prevention product with a clear, near-term pathway to an affordable generic version. A pipeline of biomedical prevention products is also advancing, including 4- and 12-monthly injectables, a monthly oral pill, and a 3-monthly vaginal ring. However, none of these products have generic licensing agreements in place yet, leaving timelines for affordable LMIC access uncertain (Figure 6). Beyond the products highlighted here, there are other products in early phases of clinical development, including broadly neutralizing antibodies, implants, inserts, vaccines, and more. CHAI and Wits RHI are also closely monitoring convergence of the prevention and treatment pipelines, with the same molecules being investigated for use in both prevention and treatment. Monitoring and assessing risks associated with drug resistance and supply chain complexities will be critical for ensuring optimal care among end users and sustaining healthy markets.

**Figure 6. Estimated Timelines for Originator Product Availability**  
(generic availability unknown, dependent on licensing)



Timelines are subject to change. More information related to ongoing studies available at [clinicaltrials.gov](https://clinicaltrials.gov)



Generic development of **long-acting cabotegravir (CAB-LA)** is also continuing. Access to affordable generic CAB-LA will be crucial for long-acting injectable treatment regimens, which require at least two effective antiretrovirals.

## About Project PrEP

Project PrEP is one project within Unitaid’s portfolio of investments to accelerate access to LEN. Through Project PrEP, Wits RHI and CHAI are advancing supply- and demand-side work in partnership with generic suppliers, governments, and communities to drive rapid, equitable access to LEN in LMICs and expand the PrEP market, including through generating real-world evidence on LEN delivery to inform successful rollout and expansion. This investment aims to achieve price reductions, prepare health systems, and establish enabling demand-side conditions that address barriers to access and catalyze accelerated LEN scale-up. For more information, please see the Project PrEP Brief [here](#).