

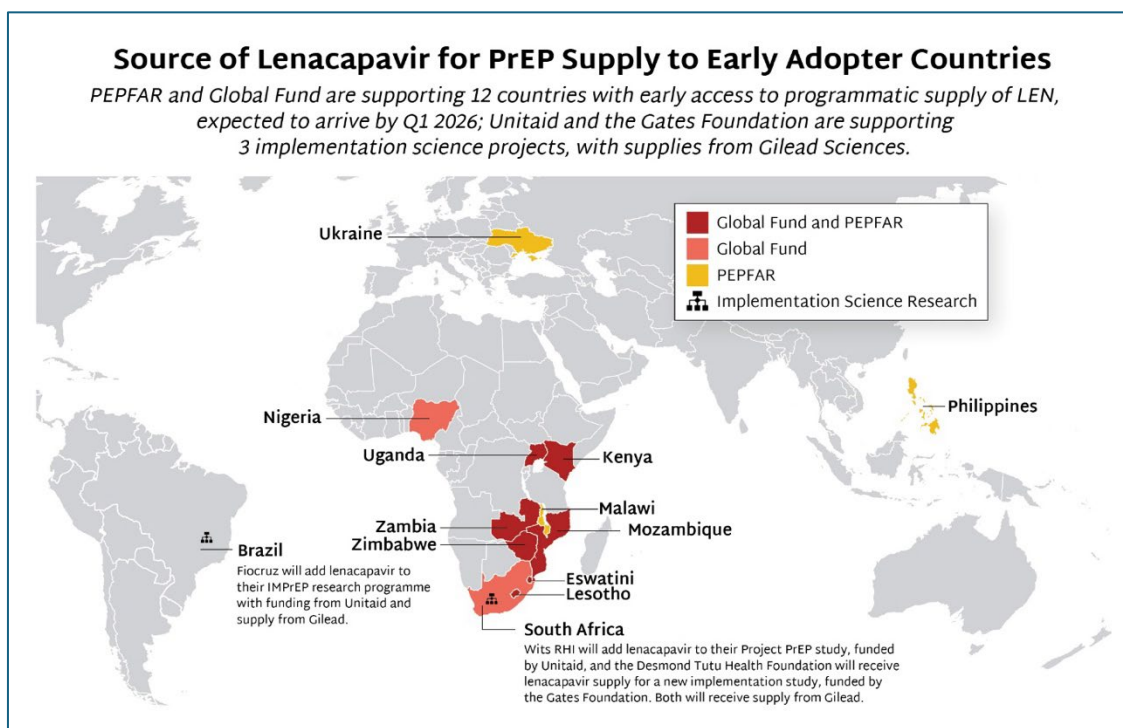


Getting LEN Rollout Right: Resources and Tools

Latest Update: October 2025

[Lenacapavir for PrEP \(LEN\)](#), a six monthly injectable, was found highly effective at preventing HIV in [two large clinical trials](#) in 2024 and has since become the latest PrEP product to enter the market, following [approvals](#) by the US Food and Drug Administration, the European Medicines Agency (EMA), the South African Health Products Regulatory Authority, and [recommendation](#) by WHO. Submissions for approval are currently pending in Brazil, Kenya, Malawi, Zambia, and Zimbabwe, with 11 more submissions across Africa and Asia anticipated imminently, leveraging the EMA's positive opinion. In September 2025, the [Gates Foundation](#) and [Unitaid](#) announced partnerships with generic manufacturers (Hetero Labs and Dr Reddy's Laboratories, respectively) to achieve a price of \$40 USD/person/year for generic injectable LEN, due to become available in 2027 in the countries under Gilead's license territory (including 120 lower and middle income countries).

In July 2025, the Global Fund [announced](#) support to nine countries for early LEN adoption. In September PEPFAR [confirmed support](#) for seven of those countries and an additional three countries, bringing the total number of early adopter countries supported to 12. Both funders have jointly committed to reaching up to two million users with LEN over three years, starting in these countries. Unitaid, in coordination with CIFF, WHO, and implementing partners, is also actively supporting LEN introduction, including through implementation science programmes in Brazil and South Africa and through a Unitaid [call for proposals](#) launched in July 2025. Overall, these countries anticipate receiving LEN in early 2026, or even earlier in some cases- a [much faster timeline](#) than has been seen with previous PrEP products.



The resources below, alongside insights drawn from the report [Getting PrEP Rollout Right This Time](#), can support countries in the early stages of LEN planning. These tools, and many others, are all publicly available on [PrEP Watch's Fundamentals of PrEP Planning pages](#) and are being disseminated as part of a coordinated effort between AVAC, CHAI, the Global Fund, PEPFAR, Unitaids, Wits RHI, and WHO under the [Coalition to Accelerate Access to Long-Acting PrEP](#) to streamline efforts on tool development. Further tools will be posted as they become available. Newly-added tools are indicated with a red star. ★

Category	Tool	How can this support LEN rollout?
Normative Guidance	WHO guidelines on LEN for PrEP	WHO guidelines provide a basis for development of national guidelines.
★ Normative Guidance	Standard Operating Procedure (SOP) for LEN for PrEP	This adaptable SOP supports the development and adoption of national SOPs that align with WHO LEN guidelines.
Normative Guidance	Template for technical working group (TWG) terms of reference	This template can aid in setting up a TWG to develop national LEN guidelines.
Normative Guidance	Evidence from the PURPOSE trials shared at IAS 2025	Evidence around use of LEN by adolescents and pregnant and lactating populations, as well as around certain drug interactions, can be incorporated into local clinical guidelines.
Planning/ Monitoring and Evaluation	PrEP-it	This web-based tool can help set PrEP (including LEN) targets, estimate costs and impact associated with targets, identify priority areas for PrEP for adolescent girls and young women, and forecast needed commodities.
★ Provider Training	WHO and Jhpiego Provider Training Toolkit on Use of Oral and Long-Acting HIV PrEP	This toolkit can be used to train clinicians to provide multiple PrEP methods, including LEN.
★ Provider Training	Lenacapavir Provider Tools and Job Aids	These editable tools can be used to support providers to deliver LEN for PrEP, and include client fact sheets, counselling job aids, and charts to support initiation, injection, and switching.
Site Assessment	PrEP Site Implementation and New Product Readiness Assessment Tool	This assessment tool can be used to evaluate and improve existing PrEP services at a facility and to prepare for the optimal delivery of new PrEP products, such as LEN for PrEP.
Site Assessment	Site readiness assessment template- coming soon!	This adaptable template can be used to determine which sites are ready to begin delivering LEN for PrEP.
Site Assessment	Facility-level checklist and SOP template- coming soon!	These tools can help ensure optimal PrEP delivery at facility level.
Community-led Support	Training package for community and other non-clinical cadres- coming soon!	
Community-led Support	Adaptable templates and tools- coming soon!	

Monitoring and Evaluation	<u>WHO Consolidated Guidelines on Person-centred HIV Strategic Information</u>	These guidelines present a standard minimum dataset, priority indicators, and recommendations to strengthen data use across HIV prevention, and can be used to develop LEN indicators.
Monitoring and Evaluation	<u>HIV Drug Resistance (HIVDR) Monitoring Toolkit</u>	This toolkit can assist ministries of health, project implementers and policy makers develop HIVDR monitoring strategies and support the collection and testing of blood samples for HIVDR testing amongst LEN for PrEP users.

If there are other resources that you are already using that might be helpful to others, or if there is a resource that is not being addressed by the list above, please do let us know at prepwatch@avac.org.

[Click here](#) for more information and resources on LEN for PrEP.

Additional Selected Resources

- [Tracking Lenacapavir Rollout](#): online tracking tool of all the moving parts.
- [Getting PrEP Rollout Right This Time](#)
- [Gears of Lenacapavir for PrEP Rollout](#)
- [Plan for Accelerating Access to Injectable Lenacapavir for PrEP](#)