Coalition to Accelerate Access to Long-Acting PrEP Coalition Co-Convenors: Coalition Secretariat:

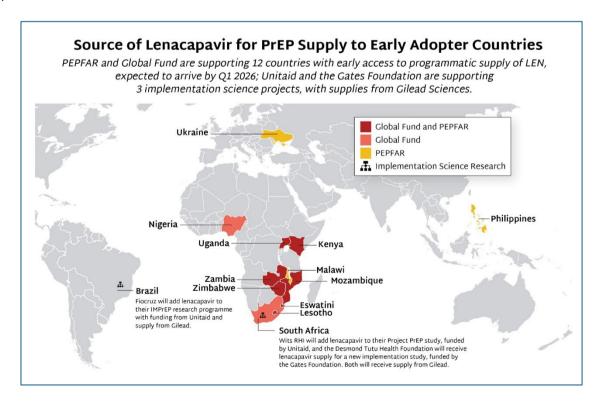




Getting LEN Rollout Right: Resources and Tools Latest Update: 12 November 2025

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 initial approval by the US Food and Drug Administration in June 2025 and recommendation by WHO. (See here for a full list of current approvals and submissions.) 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 <u>announced</u> support to nine countries for early LEN adoption. In September PEPFAR <u>confirmed support</u> 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 <u>call for proposals</u> launched in July 2025. Overall, these countries anticipate receiving LEN in early 2026, or even earlier in some cases- a <u>much faster timeline</u> than has been seen with previous PrEP products.



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

Tool

How can this support LEN rollout?

Category

	Category	1001	How can this support LEN rollout?
	Normative	WHO guidelines on LEN for	WHO guidelines provide a basis for
	Guidance	PrEP	development of national guidelines.
	Normative	Standard Operating Procedure	This adaptable SOP supports the
	Guidance	(SOP) for LEN for PrEP	development and adoption of national
	9 5.1.4.5.1.100	(00) / 101 == 111111111111111111111111111111	SOPs that align with WHO LEN
			guidelines.
	Normative	Template for technical working	This template can aid in setting up a
	Guidance	group (TWG) terms of	TWG to develop national LEN
	Guidance	reference	guidelines.
	Normative	Evidence from the PURPOSE	Evidence around use of LEN by
	Guidance	trials shared at IAS 2025	adolescents and pregnant and lactating
	Guidance	thats shared at IAO 2025	populations, as well as around certain
			drug interactions, can be incorporated
	Diagning/	PrEP-it	into local clinical guidelines.
	Planning/	PIEP-IL	This web-based tool can help set PrEP
	Monitoring and		(including LEN) targets, estimate costs
	Evaluation		and impact associated with targets,
			identify priority areas for PrEP for
			adolescent girls and young women,
	D ::	W// 10 1 11 : D :1	and forecast needed commodities.
	Provider	WHO and Jhpiego Provider	This toolkit can be used to train
	Training	Training Toolkit on Use of Oral	clinicians to provide multiple PrEP
		and Long-Acting HIV PrEP	methods, including LEN.
	Provider	Lenacapavir Provider Tools	These editable tools can be used to
	Training	and Job Aids	support providers to deliver LEN for
			PrEP, and include client fact sheets,
			counselling job aids, and charts to
			support initiation, injection, and
			switching.
	Site	PrEP Site Implementation and	This assessment tool can be used to
	Assessment	New Product Readiness	evaluate and improve existing PrEP
		Assessment Tool	services at a facility and to prepare for
			the optimal delivery of new PrEP
			products, such as LEN for PrEP.
	Site	Site readiness assessment	This adaptable template can be used
	Assessment	template	to determine which sites are ready to
			begin delivering LEN for PrEP.
	Site	Facility-level checklist and	These tools can help ensure optimal
	Assessment	SOP template- coming soon!	PrEP delivery at facility level.
	Community-led	Training package for	
	Support	community and other non-	
		clinical cadres- coming soon!	
	Community-led	Adaptable templates and	
	Support	tools- coming soon!	

Monitoring and	WHO Consolidated Guidelines	These guidelines present a standard
Evaluation	on Person-centred HIV	minimum dataset, priority indicators,
	Strategic Information	and recommendations to strengthen
		data use across HIV prevention, and
		can be used to develop LEN indicators.
Monitoring and	HIV Drug Resistance (HIVDR)	This toolkit can assist ministries of
Evaluation	Monitoring Toolkit	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

- <u>Tracking Lenacapavir Rollout</u>: 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