

Now What with Injectable LEN for PrEP *How to Translate Ambition into Accelerated Delivery and Impact*

July 2025

The announcements on 9 July 2025 from [Global Fund](#) and [Gilead](#) about their next steps for injectable lenacapavir (LEN) for PrEP are welcome, as [one more part of the process](#). But they raise as many questions as they answer. This brief summary is intended to help outline what is actually known – and not – and what needs to happen next, building on [the timeline here](#).

- **No price or volume commitment have been made public.** The [Global Fund/Gilead](#) announcement focuses on an access agreement with Gilead to procure LEN and re-confirms [their ambition from December with PEPFAR](#) to reach 2 million people over three years with LEN, post-approval and WHO recommendation. It does not include specific volumes or price – and the 2 million people is stated as an ambition over three years, not a commitment to procure the full volume required to meet this target. Fulfilling this ambition will depend on Global Fund replenishment for the next three-year budget.
- **PEPFAR was not part of the announcement.** Current PEPFAR guidance for PrEP and prevention focuses exclusively on pregnant and breastfeeding women only, and it is expected that PEPFAR is still likely to introduce LEN for PrEP, at least for these populations.
- **Regulatory approvals are progressing.** On 19 June 2025, the US FDA approved LEN for PrEP. Gilead also submitted to the European Medicines Agency and their Medicines4All (EU-M4All) program for LMIC as well as with Australia, Brazil, Canada, and South Africa. Approvals are expected later this year. If LEN is approved through the EU-M4All pathway, Gilead will pursue expedited submissions in LMICs. [Gilead has also said](#) that with FDA approval, they will make additional filings in countries that rely on FDA approval for regulatory submission, including Argentina, Mexico and Peru.
- **WHO is expected to release its LEN recommendation and guidelines on 14 July 2025 at IAS 2025** conference in Kigali.
- **Global Fund has notified nine countries that they are eligible to become early adopters for LEN for PrEP** – Eswatini, Kenya, Lesotho, Mozambique, Nigeria, South Africa, Uganda, Zambia, Zimbabwe. They will be able to use current Global Fund support to plan for LEN introduction (based on current PrEP market size). Country grant funds dedicated to LEN will be matched with central funding made available through initial support from the Children's Investment Fund Foundation (CIFF) as part of [their recent replenishment commitment](#). The nine countries are expected to provide demand forecasts for LEN within the next month.
- **AVAC forecasts there could be up to 1.5 million LEN users in 2026 in the top 16 PrEP markets – IF enough product is procured – including 1.2 million in the nine Global Fund-selected countries.** This is more ambitious than the current three-year target – again, assuming funds are available to procure and deliver. [This forecast of the market size](#) uses current overall PrEP market size and assumes, based on implementation science study data, that approximately 60% of PrEP users will choose an injectable option if available.

- **Gilead has confirmed that they can manufacturer enough product to meet this demand over the next three years (in excess of five million LEN users),** if they receive orders. At the same time, at least some, if not all, of the six generic license holders are expected to reach the market by 2027 – [see timeline here](#) (which also includes the time for generic cabotegravir (CAB), expected to reach the market at the same time).
- **Without disclosure of the LMIC “not-for-profit” price by Gilead or Global Fund, it is not clear what volumes will be available to the nine early adopter countries, or to others** – this is especially true for countries in Asia and Latin America that do not fall under current agreements. This makes planning and budgeting extraordinarily hard.
- **It is rumored that for LMICs, a year of LEN will start at \$100 per person per year (PPPY), which is cheaper to procure CAB** – which is currently \$160 PPPY. [See comparative pricing here](#). **NOTE:** these prices are for the product only and **do not include the programmatic costs** to deliver it, create demand for it, train providers, etc.
- **Generic manufacturers are likely to manufacturer LEN at lower costs than Gilead.** Recent models have projected that with large volumes of LEN (5-10 million people per year) made by multiple generics competing for the market, the price could eventually drop to as low as \$40 PPPY (similar to the current cost of oral PrEP) and possibly as low as \$25 PPPY. **But this is not likely to be the price at generic launch in 2027/8 based on the current projections of only 2 million people over three years.** **NOTE:** as of 2024, the total global PrEP market was estimated to be only 3 million total users, which has taken 13 years to build, includes all markets, and is almost entirely oral PrEP, with very limited CAB and dapivirine vaginal ring usage.
- **Getting to 5-10 million LEN users per year will take time and significant investments, in product procurement and in programs delivery.** If “only” 2 million people access LEN over the next three years, getting to 5 million users by 2030 will be very challenging. A more immediate surge of LEN introduction could grow the PrEP market, and the tables below present two scenarios, with many assumptions.

Scenario 1 assumes the Global Fund/Gilead agreement is “the” primary driver for the next three years, with generics only coming in when volumes are beginning to surpass 1 million users per year – which is too small a market to reduce the price significantly and, more importantly to have impact on the epidemic. This estimate assumes 2 million LEN users over the first three years; \$100 PPPY at launch from Gilead; generic entry in 2027 to transition in 2028; 20% market growth from Years 2-3, and 50% growth rate with reduced price and increased markets from Year 4.

Year	LEN users	Manufacturer	Price Per Person Per Year (PPY)	Total Procurement Cost
2025	196,000	Gilead	\$100	\$19,600,000
2026	820,000	Gilead	\$100	\$82,000,000
2027	984,000	Gilead	\$100	\$98,400,000
2028	1,476,000	2 Generics	\$80	\$118,080,000
2029	2,214,000	4 Generics	\$60	\$132,840,000
2030	3,321,000	6 Generics	\$40	\$132,840,000

Scenario 2 assumes additional donors come in now to meet the market forecast that AVAC projected for 2026; secure the 2 million person years of LEN from Gilead in just two years instead of three; bringing generics in a year earlier; and, more importantly, bringing them into a larger, growing market that will get to larger volumes, lower prices and greater impact faster. This estimate assumes accelerated investment to reach 60% of current PrEP market with LEN from 2026; \$100 PPPY at launch from Gilead but for 18 months; generic entry in early 2027; 20% market growth from Years 2-3, and 50% growth rate with reduced price and more markets from Year 4.

Year	LEN users	Manufacturer	Price Per Person Per Year (PPY)	Total Procurement Cost
2025	250,000	Gilead	\$100	\$25,000,000
2026	1,532,449	Gilead	\$100	\$153,244,900
2027	2,298,674	1 Generic	\$80	\$183,893,880
2028	3,448,010	2 Generics	\$60	\$206,880,615
2029	5,172,015	4 Generics	\$40	\$206,880,615
2030	7,758,023	6 Generics	\$25	\$193,950,577

How to Make Scenario 2 The Reality

Scenario 2 would build the market fast, secure lower PPPY price and achieve greater impact by 2030. How might this be realized:

1. **Advocate with all donors for Global Fund replenishment** – both core funding and additional LEN-specific support.
2. **Advocate for robust PEPFAR funding** to include prevention, PrEP and LEN for all populations.
3. **Gilead and Global Fund** transparently name the price and volumes in the new agreement to facilitate accelerated planning by all stakeholders.
4. **PEPFAR** provide a clear LEN plan, with volumes and countries, to align on with Global Fund country selection and ensuring a more comprehensive joint strategy in more countries.
5. **Unitaid** ensure its [new call for proposals](#) are integrated into the country-level planning to ensure governments are able to see how all three potential funding partners – Global Fund, PEPFAR and Unitaid – are coordinated under a single strategy.
6. **Gates Foundation, Elton John AIDS Foundation, national governments** and other funders join the Global Fund and CIFF in procuring and programming enough LEN (from Gilead and generics) to reach 4 million people by the end of 2027 – double the current ambition.
7. **Gates Foundation, CIFF and Unitaid, and any other donors and technical advisors** to the generic manufacturers, coordinate their work to secure generic launch at no more than \$80 PPPY in 2027 and 3.5 million PY of LEN from at least two generic manufacturers in 2028 at no more than \$60 PPPY by 2028.

Important Funding Opportunity & Selected Resources

- Unitaid's call for proposals: [Cost-effective and high impact rollout of lenacapavir for PrEP](#)
- [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](#)