Now What with Injectable LEN for PrEP

How to Translate Ambition into Accelerated Delivery and Impact

Version 2.0, Updated November 2026

Since results of the PURPOSE efficacy trials were announced in 2024, injectable lenacapavir for PrEP (LEN) has generated enormous excitement and opportunity – and frustration. By the end of 2024, Gilead Sciences provided six voluntary licenses to generic manufacturers and submitted multiple regulatory filings, and the Global Fund and PEPFAR committed to an ambition to reach two million people over three years, pending regulatory approvals and WHO guidelines. It seemed like bold ambition – and it was, compared to the previous launches of oral PrEP, vaginal ring and CAB.

But this ambition was always defined as a floor, not a ceiling. In April 2026, the collaboration increased the goal to reach three million people over three years with LEN for PrEP. **Now, though, AVAC is calling for a new minimum floor: reach three million in two years (2026-2027). No less and no slower, with a push for more and faster.**

In July 2025, AVAC published *Now What with Injectable LEN for PrEP*, outlining priorities to ensure introduction moved swiftly. Without speed, scale and equity, LEN is simply exciting science; but, with them, LEN can be a transformational moment in the HIV/AIDS response.

AVAC has continued to document in this comparative timeline that injectable LEN is hitting key milestones for initial product introduction faster than any previous PrEP product. LEN's accelerated timeline reflects a field-wide effort to learn lessons from previous PrEP introduction. As of November 2026, LEN is recommended by WHO; has 19 regulatory approvals, and counting; is being introduced in a number of implementation science projects; and is being introduced as part of public health programs in a number of countries, with support from the Global Fund and PEPFAR/GHSD; and the US FDA approved the first generic version.

This progress must not be confused with success, and the initial introduction, while faster and more ambitious, is not even close to delivering the volumes that will drive prices lower and, more importantly, impact at scale. As AVAC documented in April 2026, the commitment of three million in three years does not meet the true demand for PrEP or to deliver impact. This updated summary outlines what is actually known – and not – and what needs to happen next.

The bottom-line: **at a minimum, reach three million people in two years (2026-2027).**

Increasing ambition now will save money and accelerate the time to impact.

To do that:

1. **Countries need to provide ambitious forecasts** based on actual demand and need and programmatic opportunity, not based on budget.
2. **Global Fund and PEPFAR/GHSD need to place orders now** for enough doses for at ***least 2.4 million people in 2027*** (given that 600,000 person years of LEN was ordered for 2026). In addition, advocacy needs to mobilize domestic resources and other new donors to increase volumes further.
3. **National regulators need to ensure rapid approval and/or regulatory waivers of generic LEN** so that there are no delays in transitioning from Gilead to lower-priced generics, which should begin happening early next year, and that there is adequate and consistent access to product in-country.
4. **Gilead and the approved generic manufacturers need to commit the supplies** to make this delivery schedule in 2027 and ensure commodity security.
5. **Countries and communities need to develop the programmatic infrastructure and robust demand creation to deliver that quantity** as part of comprehensive prevention choice programs, so that product reaches people who need and want it and that no product is wasted.

With initial generics expected to launch by the end of 2026, prices will be lower, and there will be at least three suppliers of LEN to help ensure commodity security. By committing to reach three million people with LEN in two years, the market growth will accelerate even further from 2028, providing incentives to the other generic manufacturers to get to the market and increase competition to drive the price even lower. This market development will also help build the programmatic infrastructure to expand choice and prepare for the possible introduction in 2028 of monthly oral alimatravir, if it is also shown to be safe and effective, along with other new options.

Here what is actually known – and not – as of November 2026, what needs to happen next, and where advocates can demand action.

- **Global Fund and GHSD supported orders for initial supplies for 2026 for 12 early adopter countries for LEN for PrEP** – Eswatini, Kenya, Lesotho, Malawi, Mozambique, Nigeria, Philippines, South Africa, Uganda, Ukraine, Zambia, and Zimbabwe. Early adopters are using financing from Global Fund Grant Cycle 7 (GC7) funds and/or GHSD central funding to introduce LEN. For Global Fund, country grant funds dedicated to LEN are being complemented with central funding made available through support from the Children's Investment Fund Foundation (CIFF) as part of their GC8 replenishment commitment.

- **LEN introduction programs began in December 2025, and ten African countries have now received initial LEN supplies.** There are early reports of high demand, limited supplies and logistical challenges – issues that have been raised repeatedly by advocates and ministries, and need to be addressed urgently. Global Fund and GHSD are expanding to 17 additional countries, beginning later this year and in the first half of 2027.

- **Over the first nine months (December 2025 to August 2026), there have been over 120,000 LEN initiations in 10 African countries**. Of this total, almost half occurred in South Africa – which only launched LEN in June. Country reports are consistently showing:

    - Strong initial demand is outpacing the initial supplies that are in-country.
    - LEN is proving to be the preferred PrEP option, when users are given a choice.
    - In those countries with greater than six months of experience, the majority of users are returning on schedule for their second dose – but not necessarily at the >90% seen in the PURPOSE 1 and 2 phase 3 trials.
    - The initial supply of LEN was based on available resources from the Global Fund and PEPFAR/GHSD, with a total procurement of 1.2 million doses, or enough for around 600,000 person years of protection in 2026, depending on user patterns after six months. Countries reported at AIDS 2026 in July and in subsequent meetings that they are slowing demand generation activities and limiting the number of facilities that are offering LEN until increased supplies are ordered and delivery dates are confirmed.

- **The Global Fund and PEPFAR/GHSD are currently reviewing demand forecasts for 2027.** Country programs need to plan for the continuation doses for those who initiated LEN in 2026 as well as, hopefully, significant increases in initiations in 2027 – both in the early adopter countries as well as in new countries that may launch LEN.

- **Generic manufacturing is moving according to schedule.** As forecasted by AVAC last year, initial generic submissions to national regulators, US FDA and WHO have already been submitted, and the US FDA just approved the injectable form of LEN from Dr. Reddy's at the end of October. Initial generic deliveries will now begin before the end of the year, pending national approvals, initial orders to the generics, and the lead-time between orders and deliveries, which is currently unknown. In April 2026, the Global Fund launched the Expert Review Panel (ERP) process for generic LEN, to enable quality assured and time-bound procurement of generic LEN pending full regulatory approval. As of November 2026, ERP recommendation to procure LEN vials has been obtained for Hetero and Dr. Reddy's vials and for the generic tablets for the oral loading dose from

Hetero. Gilead will need to continue to supply the oral tablets in the short-term, even as generic injectables are ordered, delivered and used.

- **2027 will, therefore, be a blended year with LEN supplies anticipated to come from both Gilead and the generic manufacturers, with the latter taking over the supply from 2028.** The lead-times that generic manufacturers will need to satisfy orders is not yet known, but it may be less than Gilead's 6-9-month lead-time. Both Gilead and the generics need forecasts and actual orders within the next few months of 2026 to ensure supply reaches countries in 2027 and that there is uninterrupted commodity security.

- **Orders for 2026 amounted to enough LEN for approximately 600,000 person years of protection, out of the three million person-years (in three years) of the Global Fund/PEPFAR commitment.** This leaves approximately 2.4 million person years of LEN to be procured in 2027 and 2028, under the current Global Fund/PEPFAR commitment. But given demand and the entry of generic product, this should be the ambition for 2027 alone.

- **AVAC forecasted there could have been up to 1.5 million LEN users in 2026 in the top 16 LMIC PrEP markets – IF enough product had been financed and procured – including 1.3 million in the 12 Global Fund and PEPFAR early adopter countries.** This is more ambitious than the current target – 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. With the PrEP market traditionally growing 20% each year and with additional countries being added, ***the three-year, 2026-2028 volume should be in excess of 6.5 million users***, more than double the current commitment but within the volumes that Gilead said they could make, even before generics reached the market.

- **Gilead had confirmed that they can manufacture enough product to meet demand in excess of seven million LEN users over the next three year),** if they receive orders. The generic manufacturers have not yet confirmed their capacity and lead-times. Orders for 2027 for both Gilead and for generics need to happen now to ensure deliveries are made, guaranteeing uninterrupted supply, for both continued effective use for those who want to remain on LEN, as well as anticipated (and necessary) market growth to deliver impact.

- **At least two of the six generic license holders are expected to reach the market in 2027** – see timeline here. In September 2025, the Gates Foundation and Unitaid announced partnerships with two of the six license holders (Hetero and Dr. Reddy's) to make LEN available at a price of $40 per person per year for injections, plus $15-17 for the oral loading dose. Both generics are in the process of filing for regulatory approval and WHO prequalification and approvals could happen by the end of 2026. Timing and pricing from the other four generic manufacturers are less clear.

- **The current early adopter countries supported by Global Fund and PEPFAR are primarily low- and middle-income countries and in Eastern and Southern Africa. The Gilead voluntary license agreements cover 120 countries, but excludes a number of high-HIV burden, middle-income countries,** especially in Asia and Latin America, including countries that participated in the PURPOSE 2 LEN for PrEP trial**.** Successfully building a sustainable global market and deliver epidemiologic impact requires truly global access.

- **Getting to 5-10 million LEN users per year, as per the UN global target and as outlined in AVAC's *Gears of Lenacapavir for PrEP Rollout*, will take time and significant investments, in product procurement and in programs delivery – traditional PrEP platforms, new delivery innovations and differentiated service delivery.** If "only" 3 million people access LEN over the next three years, getting to 10 million users by 2030 will be very challenging. A more immediate surge of LEN introduction is needed now to grow the overall PrEP market, increase LEN volumes and drive the procurement price even lower. The tables below present two updated scenarios, with various assumptions.

- **Building the LEN market now is a strategic investment in comprehensive HIV programs.** LEN is not for everyone, and providing an expanded range of prevention options can facilitate people finding an option that might work best for them. But the current novelty and excitement about LEN is an opportunity to engage people in prevention programs. In addition, other prevention options are in development, most notably alimatravir (or MK-8527), a once-monthly oral PrEP option that is currently in two efficacy trials with results expected in late 2027. In addition, Gilead recently expanded their generic licenses to include once-yearly LEN, which is also in late-stage trials. It is essential to build and strengthen prevention platforms now that can more quickly and efficiently integrate new products beginning in late 2027 and 2028 and avoid an innovation pile-up with the pipeline.

Two Potential Scenarios for LEN Market Development

Scenario 1 assumes the Global Fund/PEPFAR commitment is "the" primary driver for the next three years. This estimate assumes 3 million LEN users over the first three years; $100 PPPY at launch from Gilead; generic entry in 2027 with blended deliveries and prices declining in Year 2 with full transition to generics in Year 3; limited market growth in Years 2-3 given limited procurement commitments, and 50% growth rate with reduced price and increased markets from Year 4. But volumes remain relatively low and are split between multiple generics, making it difficult to drive the price lower.

Scenario 1: Baseline from 2025 with Modest Ambition				
Year	**LEN users**	**Manufacturer**	**Avg Price Per Person Per Year (PPPY)**	**Total Procurement**
2026	600,000	Gilead	$100	$60,000,000
2027	900,000	Gilead & 2 generics	$80	$72,000,000
2028*	1,500,000	3 Generics	$50	$75,000,000
2029*	2,250,000	4 Generics	$50	$112,500,000
2030*	3,375,000	5 Generics	$45	$151,875,000
Over 5 years	8,625,000			$471,375,000

Scenario 2 assumes additional donors, procurers and countries come in now to meet the market forecast that AVAC projected for 2026; secure the initial 3 million person years of LEN in two years instead of three; bringing additional generics in 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 the 3 million LEN target in two years, instead of three; $100 PPPY at launch from Gilead but for only 18 months with increased supply at lower prices from generics beginning in early 2027; 50% market growth from Year 3, with reduced price due to higher annual volumes, additional generics and more markets from Year 3.

Scenario 2: Accelerated Market Development and Time to Impact				
Year	**LEN users**	**Manufacturer**	**Avg Price Per Person Per Year (PPPY)**	**Total Procurement**
2026	600,000	Gilead	$100	$60,000,000
2027	2,400,000	Gilead & 2 generics	$60	$144,000,000
2028*	3,600,000	3 Generics	$45	$162,000,000
2029*	5,400,000	4 Generics	$40	$216,000,000
2030*	8,100,000	5 Generics	$25	$202,500,000
Over 5 years	20,100,000			$784,500,000

While Scenario 2 is projected to cost 66% more than Scenario 1, it would deliver 2.5 times as much LEN; drive the unit costs lower; build a sustainable PrEP market for multiple PrEP options; and accelerate the time to reduced HIV incidence and public health impact.

** It is important to note that beginning in 2028, there could be additional PrEP options reaching the market that would provide further diversification of the overall PrEP market:*

- *Once-yearly injectable LEN is currently being studied in PURPOSE 365, with a potential regulatory submission in late 2027. The annual dose includes a large volume of LEN as well as the oral loading dose, and the price for the product is currently unknown. While it will likely cost more per year than the six-monthly does due to the large volume of drug, it would cut the clinic service visits in half and reduce overall service delivery costs.*
- *Once-monthly oral alimatravir (AMI) is currently being studied in EXPrESSIVE-10 and EXPrESSIVE-11 efficacy trials, with results anticipated in the latter half of 2027. Merck/MSD has already licensed AMI to seven manufactures, even ahead of knowing if the product works. While the launch price from Merck/MSD is unknown, Merck/MSD did confirm at AIDS 2026 that it would be competitive with generic daily oral PrEP and generic LEN, and their generic license-holders would, presumably reach even lower prices. Moreover, service delivery costs for a monthly oral tablet should be much lower than for injectables.*
- *With the possible introduction of these two options – as well as the Dual Prevention Pill, four-monthly injectable CAB, a three-monthly DVR and weekly oral LEN – the PrEP market from 2028 could be far more complex and competitive.*

How to Make Scenario 2 The Reality: Advocacy Priorities

Scenario 2 would build the market fast, secure lower Per Person Per Year (PPPY) price and achieve greater impact by 2030 for less than $800 million in procurement over five years. The faster the market grows, the more transmission can be averted. Also, if alimatravir reaches the market in 2028 at prices below $40 PPPY from the originator as expected, there is even greater ability to further and more quickly expand the PrEP market and potential impact.

How might this be realized:

1. **Global Fund and PEPFAR need to raise the floor of their commitment** from "2x3 to 3x2" – from two million people over three years to reach at **least three million people in two years, (and 6.5 million in three years and over 20 million in five years)**.
2. **Global Fund needs to increase orders and shipments based on demand-based orders from early adopter countries** as quickly as possible, so countries and programs can build demand more comprehensively and not ration the supplies they have for fear of running out.
3. **Advocates and donors ensure Global Fund has the resources to procure** these volumes to meet demand – orders should be based on what is possible programmatically and not on the available funding. This will require resource mobilization beyond the GC8 replenishment, from existing donors, mobilizing new investors and increasing domestic resources.
4. **PEPFAR/GHSD must obligate all Congressionally appropriated funds**, including surge procurement and programming of LEN.
5. **Ministries of Health need to collaborate with implementation partners and civil society to address supply and demand issues** as they emerge and develop more robust, ambitious forecasts for 2027 – both for continued use by those initiating this year and for new users. They also need to develop the programmatic infrastructure to deliver that quantity so no product is wasted and ensure supplies of other PrEP options so choice can be operationalized; this requires forecasts, demand generation and domestic plans for future procurement.
6. **All procurers place orders for 2027 by October 2026** with both Gilead and generics to ensure uninterrupted supply and expanded global access, whether through the Global Fund or directly with manufacturers.

7. **Global Fund and PEPFAR need to provide clear, transparent LEN plans**, ensuring a more comprehensive joint strategy in more countries, as well as prices and volumes from Gilead and generics.
8. **National regulators need to ensure rapid approval of generic supplies so** that there are no delays in transitioning from Gilead to the generics.
9. **Generic manufacturers must specify their capacity for 2027 and lead-times** from order to delivery to coordinate timely procurement.
10. **Gilead urgently finalizes license and supply agreements** for middle-income countries, especially in Latin America and Asia.
11. **All stakeholders – ministries of health, donors, communities, and Merck/MSD – need to take advantage of the early license agreements for the investigational monthly PrEP pill alimatravir and plan now for broad access and an even more ambitious launch plan.** This option lends itself to innovative delivery models – from pharmacies to community-based distribution approaches. While trials are still enrolling, the field has the time to collectively ensure models are well-conceived and planned, adequately funded, and set up for success.

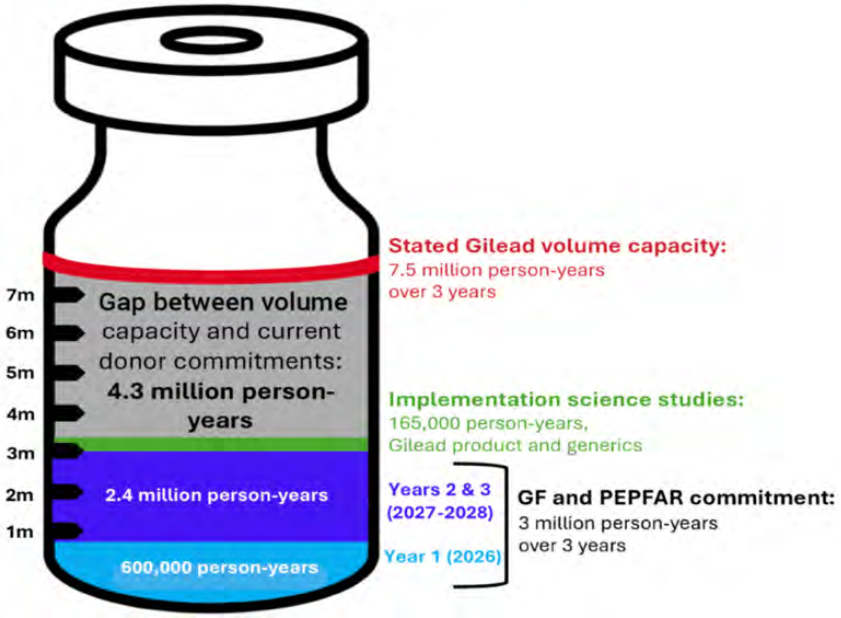
Potential Lenacapavir Supply: 2026-28

Potential market scenario assumptions:

- Current oral PrEP market: 3m people/ year
- 20% growth each year, plus new markets
- 60% of users choose LEN
- 2026 LEN market: 1.5m users; ±$153m procurement
- 2027 LEN market: 2.3m; ±$184m
- 2028 LEN market: 3.4m; ±$172m
- **Three-year market: 7.3m; ±$510m**

- Initial volume capacity from Gilead: 7.5m over 3 years
- Generic entry into market: by mid-2027
- Global Fund reported "price" for Gilead supply: ±$100 PPPY
- Global Fund price for country budgeting: $60 PPPY
- Generic price to initiate: $55 PPPY
- Generic price for continuation: $40 PPPY

***NOTE:** These prices are for the product only and **do not include the programmatic costs** to deliver it, create demand, train providers, monitor, etc.*



Dose (excluding the 4-pill loading dose at initiation)	Every six months
Number of vials per dose	2
Number of injectable doses for a year of protection	2
Number of injectable vials for a year of protection	4
Gilead's statement of annual LMIC production IF ordered	10 million vials
Gilead's statement of annual LMIC production IF ordered	2.5 million person years per year (PPPY)
Global Fund/PEPFAR commitment (Dec 2024) for 2026-2028	3 million person years over 3 years
Possible LEN market in early adopter countries in 2026	1,500,000 person years
Global Fund/PEPFAR orders for 2026 (from Gilead)	600,000 person years
Global Fund/PEPFAR to order for 2027/28 (Gilead & generics)	2,400,000 person years
Gilead's stated lead-time for manufacturing	6-9 months
Generic lead-time for manufacturing	Unclear – possibly less than Gilead
Initial generic approvals (from at least two manufacturers)	Expected by early 2027
Initial deliveries of generic LEN in countries	Injections by Q1 2027, with oral loading doses later in 2027
Price from Gilead to Global Fund	Confidential; rumored ± $100 PPPY
Amount Global Fund asked countries to budget for supply	$60 PPPY
Price from initial generics	$55-57 PPPY to initiate; $40 PPPY ongoing

- Orders for 2027 for both Gilead and for generics needs to happen now to ensure deliveries are made to ensure uninterrupted supply for both continued effective use for those who want to remain on LEN, as well as anticipated (and necessary) market growth to deliver impact.

Selected Resources

- *Tracking Lenacapavir Rollout*: online tracking tool of all the moving parts
- *The Global Fund Technical Briefing Note: Accelerating the introduction and scale-up of lenacapavir for HIV pre-exposure prophylaxis*
- *Funding for Prevention Rollout, Not Close-Out: US Government's Opportunity to Reach At Least Three Million with LEN by 2027*
- *An Advocates' Checklist for Lenacapavir for PrEP Introduction*
- *Getting PrEP Rollout Right This Time*
- *Gears of Lenacapavir for PrEP Rollout*
- *Plan for Accelerating Access to Injectable Lenacapavir for PrEP*
- *The Future of PrEP: Lencapavir & the Fight for Access*: podcast
- *Let's Talk About PrEP: The Future of HIV Prevention*: podcast
- Original version of *Now What with LEN for PrEP* from July 2025

More on LEN: *avac.org/lenacapavir/* & *prepwatch.org/products/lenacapavir-for-prep/*.

More on AMI at *avac.org/alimatravir/*.