April 2026

Getting PrEP Rollout Right This Time: Considerations for LEN for PrEP Introduction

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 receive regulatory approval. As countries prepare for LEN introduction, it is essential to apply lessons from over a decade of PrEP implementation, drawing guidance from Getting PrEP Rollout Right This Time and recommendations outlined in the country planning section of the Gears of Lenacapavir for PrEP Rollout.

Regulatory Approval and Normative Guidance

- In June 2025, LEN was approved by the US Food and Drug Administration, and in July 2025, received a positive opinion from the European Medicines Agency. These rulings can support and expedite the regulatory review process in other countries.
- In October 2026, WHO granted LEN prequalification status, which supports procurement in countries where LEN has not yet received regulatory approval.
- WHO guidelines on LEN for PrEP were released in July 2025- PrEP technical working groups (TWGs) in country can now begin reviewing and adapting these into national guidelines.
- In countries where the PURPOSE trials were conducted, local evidence from the trials can support guidelines development, including on recommendations for LEN for PrEP use by all populations.
- Evidence from the PURPOSE trials shared at IAS 2025 showed LEN was safe and efficacious when used by adolescents and by pregnant and lactating populations. This can further support inclusion of these populations in LEN for PrEP national guidelines. Evidence on interactions between LEN and medications for tuberculosis, erectile disfunction, and high cholesterol shared at the same session can also be incorporated into local clinical guidelines.

Planning and Budgeting

- Gilead has not yet released their LMIC pricing, but have committed to "access pricing" for low income, high incidence countries. CSOs should continue to advocate for pricing transparency to allow MoH to plan accordingly and to accelerate LEN's addition to national essential medicines lists. Generic versions of LEN, currently under development by six manufacturers, are expected to become available in 2027 and are likely to be less expensive than the originator product.
- A meeting convened by the Gates Foundation in June 2025 examined the cost-effectiveness of LEN in a range of scenarios, with cost-effectiveness thresholds varying by incidence rate. The results of these modelling exercises can support MoH with planning and budgeting.
- MoH need to consider what choice means in their local context, and whether that includes offering multiple injectable PrEP products or just one alongside other PrEP modalities such as oral PrEP and the dapivirine vaginal ring (DVR). If countries or implementers currently offering cabotegravir (CAB) are planning to exclusively transition to LEN, guidance must be drafted and issued to support providers in managing existing CAB users to switch to another product.
- The latest evidence on preference for CAB vs oral PrEP, data on product switching from PrEPared to Choose, and evidence from PURPOSE 2 on preference for LEN vs

oral PrEP can help with demand forecasting and support decision making on procurement for injectables vs oral PrEP. It is important to note that users who choose to enrol in a study on PrEP injectables may be predisposed to choose an injectable, and real world preferences for injectables may be lower.
- Global Black Gay Men Connect's recent reports, The Global Need for Long-Acting PrEP among Key Populations: Forecasts of Global Demand 2025-2030 and Long-Acting PrEP Market Assessment for Key Populations: Global Access and Readiness Report (2025) can support LEN target setting for key population (KP) groups, particularly men who have sex with men, transgender women, female sex workers, and people who inject drugs.
- Budgets for LEN introduction need to include costs for awareness campaigns, demand generation, updates to M&E systems, and provider training and quality assurance.
- In order to ensure LEN's availability over the long term, MoH should now be planning how to fund procurement once donor funding ends or reduces. This can include taxpayer levies, adding PrEP to national health insurance schemes, and exploring private sector (including pharmacy) models that include user cost-sharing.
- Tools to support budgeting and planning can be found on PrEPWatch.org.

Stakeholder Engagement

- MOH should engage stakeholders (civil society, implementers, normative agencies and regulatory authorities) to ensure readiness for rapid and equitable LEN introduction.
- Engage communities on LEN for PrEP, including young people and KPs. This can take the form of briefings on product introduction, ensuring communities understand the process and know what to expect.
- CSOs should advocate for LEN introduction by providing community insights.
- Engage the private sector, including pharmacies, to explain and promote the value proposition of LEN for PrEP, and ensure providers are ready and motivated to offer it once it becomes available.
- Include stakeholder engagement cost in LEN introduction budgets.
- The Coalition to Accelerate Access to Long-Acting PrEP is fostering coordination amongst a wide range of stakeholders including through a community of practice with early LEN adopter countries.

Demand Generation

- MoH should begin developing status-neutral LEN messaging and campaigns now, alongside information, education, and communication (IEC) materials – ensuring to co-create content with communities.
- Consider using innovative approaches, such as digital platforms, peer-led models, and integrating messaging into popular media.
- Campaign examples and templates can be found on PrEPWatch.org.

Supply Chain Management

- Leverage existing ARV procurement and distribution mechanisms.

- Prioritise equitable access, including rural and underserved areas via community distribution.
- Begin infrastructure assessments of sites selected to offer LEN for PrEP now to ensure facilities meet requirements.
- Tools to support supply chain management can be found on PrEPWatch.org.

Health Service Delivery

- When deciding where to pilot LEN, MoH should consider diverse geographic and social settings, explore differentiated and de-medicalised delivery models (e.g. pharmacies, mobile sites, and within the community), and review existing policies to identify and initiate necessary policy changes to enable LEN delivery by a range of settings and providers (including lower-level cadres). CSOs can support by advocating for these changes.
- Now is the time for MoH and implementers to begin sensitising and training providers on LEN delivery; training of trainer (ToT) and virtual models can support an expedited training process. Consider a phased training approach starting with providers already experienced in PrEP, and if available, CAB for PrEP, delivery. WHO and Jhpiego have released a Provider Training Toolkit to support this process.
- Develop and adapt tools for choice counselling to include LEN as an additional PrEP option.
- Leverage lessons learnt from CAB for PrEP delivery to design effective service delivery models.
- For swifter implementation of LEN for PrEP, target facilities already delivering oral PrEP and/or CAB.
- WHO guidelines released in July 2025 recommend use of rapid diagnostic testing (RDT) for initiation and continuation of both LEN and CAB for PrEP as a more acceptable, convenient, and cost-effective alternative to laboratory-based testing. WHO is continuing to evaluate evidence on use of HIV self-testing (HIVST) for LEN and CAB initiation and continuation and will provide an update once a determination has been made. MoH and implementers should take these recommendations into account when designing LEN delivery models.
- Provider training and counselling materials can be found on PrEPWatch.org.

Research, Monitoring, and Evaluation

- MoH should begin updating monitoring and evaluation (M&E) systems to include LEN, and consider including the following indicators:
    - PrEP uptake by product, age, and population
    - Amount of PrEP dispensed disaggregated by method
    - Reasons for switching and/or discontinuation
    - Number of people with an HIV positive test result while on PrEP, by method
- LEN should be included as part of any “minimum prevention package” being defined by MoH.
- M&E tools for PrEP can be found on PrEPWatch.org.