

Long-Acting PrEP: Current Status - October 2025

	LEN	CAB	DVR
Product (pricing, manufacturing, generics)	Gilead licensed 6 generics to produce LEN for 120 countries; Gates & Unitaid have access deals w/ 2 of these; Global Fund & PEPFAR to make LEN available to 2M people over 3 years	LMIC price: \$160 USD/year MPP granted voluntary license to 3 generics - expected in market by 2027	Current price: \$156 USD/year MoU signed with Kiara Health to manufacture in South Africa, but no clear timeline
Regulatory Approval & Normative Guidance	2 regulatory approvals (EMA & FDA) and 5 pending (including South Africa); WHO guidelines published in July 2025; WHO PQ in October 2025	30 regulatory approvals (including EMA); pending in 2 countries; WHO PQ in 2023	10 regulatory approvals ; 2 pending and 1 under review/appeal; WHO PQ in 2021
Planning & Budgeting	By 2026: Gilead has stated capacity to manufacture up to 10M doses - enough for 2.5M users	2023-2026: 2.69M doses available (study & programmatic); USAID budget cuts significantly impact expected volumes being bought	2022-2024: 677k rings available; 2024-2025: CIFF & Global Fund committed up to \$2M for purchase of 150k rings (many are still available to buy); By end of 2026: 323k rings to be manufactured
Delivery & Supply Chain	TBD during 2025/6	~ 15,500 initiations (Q3 2024). No updated figures to date	~ 1,860 initiations (Q3 2024). No updated figures to date
Stakeholder Engagement	Coalition to facilitate recurring meetings with product developers, generic manufacturers, funders, and other stakeholders. Met with all originator and generics developers at AIDS 2024, HIV R4P 2024, and IAS 2025 conferences. Next meetings planned for ICASA 2025.		
Research	PURPOSE 3, 4, & 5 ongoing ; 3 implementation studies ongoing ; develop additional implementation science agenda as needed	38 implementation studies completed, ongoing, or planned in 22 countries ; 2 on hold	13 implementation studies completed, ongoing, or planned in 19 countries ; 2 on hold; positive data on 3-month ring presented at in Oct 2024
Monitoring & Evaluation	Continued monitoring and assessment of initiations via trackers and think tanks. Understand country-specific product introduction issues to inform programmatic rollout		

Long-Acting PrEP: Proposed Priorities H2 2025 to H1 2026

	LEN	CAB	DVR
Product (pricing, manufacturing, generics)	Collaborate with Gilead to encourage continued inclusivity & transparency on pricing & access. Work with 6 generics in parallel to ensure rapid market entry	Collaborate with ViiV and generic manufacturers to understand procurement and accelerate generics progress	Collaborate with PopCouncil on price/volume for 2025/6 & plans for local manufacturing with Kiara; track development of 3-month & dual-purpose rings
Regulatory Approval & Normative Guidance	Engage with Gilead to ensure continued trend of accelerated regulatory submissions. WHO and NRAs to review data ASAP	Continued development of CAB every 4-month formulation (CAB 4M), although trial protocol still includes use of CAB 2M	Advocate for additional submission in high-burden countries
Planning & Budgeting	PEPFAR & Global Fund to work with MoH to expand path to implementation with early adopter MoHs. Countries integrating developing guidelines ASAP. Gates & Unitaid deals with generic manufacturers	Advocate for choice and build CAB demand; advocate for additional option in CAB 4M	Advocate for choice and build DVR demand
Delivery & Supply Chain	MoHs, policy makers, and donors to collaboratively design a country-led intro strategy to accelerate implementation	Track current implementation studies to identify and address evidence gaps	
Stakeholder Engagement	Work with Gilead, Global Fund, PEPFAR, and others to engage in open conversations based on Plan for LEN (Oct 2024) and Gears of LEN (Dec 2024)	Create collective advocacy strategies, continue to integrate civil society perspectives and support implementation of HIV Prevention Choice Manifesto	
Research	Identify implementation science priorities that can be embedded in programmatic rollout and/or run in parallel in anticipation of approval & recs	Ensure further studies are planned to research long-term effects; continue to identify gaps in product intro by country	Advocate for further research on long-term effects and use in conjunction with other prevention methods; identify timelines for 3-month ring intro
Monitoring & Evaluation	Anticipate (LEN) or continue (CAB and DVR) to assess gaps in product intro by country. Push to advance a learning agenda for programmatic rollout		