

Long-Acting PrEP— Current Status as of October 2024

	CAB	DVR	LEN
Product (pricing, manufacturing, generics)	Current LIC price from ViiV made public: £23.50/vial (approx. \$180/year). Voluntary license granted from MPP to 3 generics – expected in market by 2027	Current price from PopCouncil is approx. \$156/years. MOU signed with Kiara Health to manufacture in South Africa but no clear timeline for local manufacturing	Gilead announced early review of PURPOSE 1 and 2 trial data in June and September. LEN was safe and effective in both trials, with no infections shown (PURPOSE 1) and a 96% lower HIV rate (PURPOSE 2). Gilead licensed six generic manufacturers to produce LEN for 120 countries
Regulatory Approval & Normative Guidance	25 regulatory approvals (including EMA); pending in 8 countries; WHO pre-qualification in 2023	Approved in 11 countries; 2 pending review/appeal; WHO pre-qualification in 2021	Possible regulatory submissions by end of 2024; WHO initiating PQ process and guidelines development
Planning & Budgeting	Total 2023-2026 volume: updated to 2.64M doses available (study and programmatic supply)	677k rings available 2022-2024, 323k to be manufactured by end of 2026. CIFF and Global Fund committed up to USD\$2 million over 2024-2025, for purchase of approx. 150k DVRs.	Gilead has stated capacity to manufacture up to ten million doses of lenacapavir by 2026 - enough for 2.5 million potential lenacapavir users.
Delivery & Supply Chain	Approx. 15,500 initiations as of Q3 2024	Approx 1,860 initiations as of Q3 2024	TBD during 2024/5, pending regulatory approvals and Gilead supplies
Stakeholder Engagement	Establishment of the Coalition’s Civil Society (CS) Caucus; facilitating reoccurring meetings with product developers; generic manufacturers; funders; and other stakeholders – meetings with all three developers at AIDS 2024 and R4P conferences		
Research	39 implementation studies completed, ongoing or planned in 22 countries; findings from two US real-world evidence studies showed more than 99% effectiveness of CAB	14 implementation studies completed, ongoing or planned in 9 countries. Positive data on 3-monthly ring presented at R4P	PURPOSE 3, 4 & 5 ongoing; develop additional implementation science agenda, as needed
Monitoring & Evaluation	Continued monitoring and assessment of initiations via trackers and think tanks. Understand country-specific product introduction issues to inform programmatic rollout		TBD during 2024/5