

Where We Are Now with LEN for PrEP



Global Fund & PEPFAR announce coordination to reach 2 million people with LEN for PrEP



World Health Organization

WHO guidelines development group to review evidence and formulate clinical guidance



FDA grants Gilead Priority Review status of LEN for PrEP



FDA grants approval of LEN for PrEP



World Health Organization

WHO guidelines and recommendations announced at IAS in Kigali



EMA grants approval of LEN for PrEP

Gates Foundation



Gates Foundation and Unitaid announce

investments in generic LEN to provide the injectable at \$40 per person per year in LMICs starting in 2027 plus \$15-17 for oral loading dose



PEPFAR, Global Fund and governments begin to procure initial LEN supplies; advocacy and additional investments needed to accelerate speed, scale, equity and impact

Dec 17 2024

Dec 19 2024

Jan 28-30 2025

Feb 3 2025

Feb 18 2025

Feb 24 2025

Jun 18 2025

July 9 2025

July 14 2025

July 25 2025

Aug 26 2025

Sept 4 2025

Sept 24 2025

Oct 6 2025



Gilead submits new drug application to U.S. Food and Drug Administration for twice-yearly lenacapavir for HIV prevention



EUROPEAN MEDICINES AGENCY
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Gilead submits marketing authorization application to the European Medicines Agency



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European Medicines Agency agrees to accelerated review of LEN for PrEP



Gilead and Global Fund announce access agreement and finalize initial supply for nine priority countries



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EMA announces recommendation of market authorization of LEN for PrEP, two months ahead of schedule



PEPFAR recommits to partnership with Gilead in coordination with the Global Fund to deliver LEN for PrEP to at least 2 million people over 3 years



World Health Organization

LEN injection and loading dose tablets are pre-qualified by WHO, the first products pre-qualified under WHO's new abridged PQ procedure