

# HIV Prevention Snapshot: Lenacapavir

Lenacapavir (LEN) belongs to a class of antiretroviral (ARV) medicines known as capsid inhibitors. It was approved for use as pre-exposure prophylaxis (PrEP) for the prevention of HIV in adults and adolescents weighing at least 35 kg. In 2025, the World Health Organization (WHO) recommended the use of LEN as an option for people at substantial risk of HIV infection.<sup>1</sup> LEN is suitable for individuals who are comfortable with injections or face difficulties storing or consistently taking daily oral medication for PrEP.

## ADMINISTRATION AND DOSING

HIV testing is required before starting LEN and before every injection thereafter. LEN is administered as a subcutaneous injection in the abdomen or the thigh. The dose is split into two injections in different locations. At initiation, over the first two days, oral LEN tablets are administered along with the injections. During the continuation period, injections are given twice a year.

## REGULATORY APPROVALS

In 2025, LEN was approved to use for PrEP by the U.S. Food and Drug Administration (FDA) and the European Commission. The originator company (Gilead Sciences) has had its LEN product approved or has filed for registration and marketing in different countries. However, it has not filed for registration yet in low- and middle-income countries of the Asia-Pacific region.

## Lenacapavir dosing\*

Timing	Dose
<b>Initiation</b>	
Day 1	2 x 1.5 mL injections 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
<b>Continuation</b>	
Every six months or 26 weeks from last injection	2 x 1.5 mL injections

\*According to the U.S Food and Drug Administration and the European Medicines Agency

## CLINICAL TRIALS SUPPORTING THE USE OF LEN

The safety and efficacy of LEN in reducing HIV acquisition compared to the oral combination of tenofovir-emtricitabine was demonstrated in two clinical trials.<sup>2,3</sup> These trials were conducted in cisgender women, cisgender men, transgender women, transgender men, and gender nonbinary individuals. LEN demonstrated 89% to 100% superiority in reducing HIV acquisition compared to the oral regimen.

<sup>1</sup> WHO defines people at substantial risk as key populations, including men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers, and trans and gender-diverse people.

<sup>2</sup> LG Bekker, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women. *N Engl J Med*. 2024.

<sup>3</sup> CF Kelley, et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons. *N Engl J Med*. 2024.

## VOLUNTARY LICENSES TO GENERIC MANUFACTURERS

The originator company signed a voluntary license<sup>4</sup> with six companies in 2024 to produce and market LEN in 120 countries. The generic formulation was submitted for regulatory approval in India and reviewed by the Subject Expert Committee of the Central Drugs Standard Control Organization in October 2025. The committee recommended that the generic companies conduct a Phase III clinical trial in India to demonstrate safety and efficacy and submit bioequivalence data. As a result, market entry for generic LEN and commercial availability will be delayed.

## PRICING AND ACCESS OPPORTUNITIES

The Global Fund to Fight AIDS, TB and Malaria and PEPFAR (U.S. President's Emergency Plan for AIDS Relief) have entered into agreements with the originator company to supply and expand the availability of LEN. However, these efforts have excluded low- and middle-income countries in the Asia-Pacific region except for the Philippines, to which PEPFAR will provide support. Of the countries the originator company has prioritized for securing LEN registration, only three are in the Asia-Pacific region (the Philippines, Thailand, Vietnam).

Collaborations between generic licensees and funding agencies such as the Gates Foundation and Unitaid have led to price reductions to \$40 per person per year for LEN, which is comparable to pricing of oral PrEP.<sup>5,6</sup> Most of the low- and middle-income countries in the Asia-Pacific region will be able to procure LEN

at this price. However, upper-middle-income countries are currently excluded from the voluntary license. This means countries like Malaysia would not be able to access generic LEN under these agreements and would have to opt for other strategies, which could include direct negotiations with the originator company or the issuing of a compulsory license.<sup>7</sup>

Enabling and expanding access to LEN will require additional regulatory filings across the region. To facilitate faster regulatory pathways, national regulatory agencies could participate in existing global mechanisms, such as the WHO Collaborative Registration Procedure.<sup>8</sup>

National policies and HIV prevention guidelines also should be more rapidly updated to include long-acting medicines like LEN as they become available.

Investments to strengthen PrEP delivery infrastructure in both community- and healthcare facility-based programs will help ensure LEN reaches those who would benefit most from HIV prevention programs.

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<sup>4</sup> A voluntary license is an agreement that an originator company or a patent holder may make with other parties that provides the legal right to manufacture, import, and/or distribute the originator company's pharmaceutical product.

<sup>5</sup> Gates Foundation, *Gates Foundation Partners With Indian Manufacturer to Drive Down Cost of, Accelerate Access to Groundbreaking HIV Prevention Tool*, <https://www.gatesfoundation.org/ideas/media-center/press-releases/2025/09/hiv-prevention-lenacapavir>

<sup>6</sup> Unitaid, *Unitaid, CHAI, and Wits RHI enter into a landmark agreement with Dr. Reddy's to make HIV prevention tool lenacapavir affordable in LMICs*, <https://unitaid.org/news-blog/lenacapavir-for-hiv-prevention/>

<sup>7</sup> A compulsory license allows a government to authorize the production or use of a patented product or process without the consent of the patent owner. This flexibility is provided under the World Trade Organization's agreement on intellectual property—the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.

<sup>8</sup> The WHO's Collaborative Registration Procedure is a system whereby national regulators in participating countries can leverage WHO's assessments and prequalification approvals of medicines, vaccines, or medical devices to speed up their own local registration, reducing costs and delays.