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# Lenacapavir — The Twice-Yearly HIV Injection That Could Change Prevention

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CURATED & WRITTEN BY

**Bharat Choudhary**

UPSC Educator & Content Creator •
linkedin.com/in/epicbharat

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# Lenacapavir — The Twice-Yearly HIV Injection That Could Change Prevention

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**WHY IN NEWS**

Zimbabwe became one of the first countries to launch a nationwide rollout of Lenacapavir (brand name: Yeztugo), developed by Gilead Sciences — the world's first twice-yearly injectable pre-exposure prophylaxis (PrEP) for HIV prevention, approved after landmark PURPOSE 1 and PURPOSE 2 clinical trials showed ~99.9% effectiveness.

## WHAT IS PREP AND WHY IT MATTERS

**PrEP (Pre-Exposure Prophylaxis)** is a prevention strategy where HIV-negative individuals take antiretroviral medicine to significantly reduce the risk of contracting HIV. It is not a vaccine — it does not generate immunity — but it prevents the virus from establishing a permanent infection if exposure occurs.

**Existing oral PrEP (Truvada/Generic):** A daily pill combining tenofovir and emtricitabine. Extremely effective (>99% when taken daily) but requires:

- **Daily adherence** — missing doses reduces protection
- **Regular clinic visits** for HIV testing and prescription renewal
- **Stigma management** — carrying/taking daily pills in high-stigma environments

**The adherence problem** is the central challenge in HIV prevention. Studies consistently show that people most at risk — young women in sub-Saharan Africa, sex workers, people who inject drugs — have the hardest time maintaining daily pill regimens due to stigma, irregular access to healthcare, and life circumstances.

## LENACAPAVIR: THE SCIENCE

**Lenacapavir** (brand: *Yeztugo*) is a **novel capsid inhibitor** developed by **Gilead Sciences** (USA).

### *MECHANISM OF ACTION*

HIV uses a **capsid protein** to protect its genetic material and control replication inside host cells. Lenacapavir targets and disrupts the capsid protein at multiple stages of the viral replication cycle — preventing viral assembly, transport, and integration into the host cell's DNA.

This multi-stage mechanism is why it is:

**Highly potent at low doses** — less drug needed

**Long-acting** — a single subcutaneous injection provides protective drug levels for **6 months**

**Effective against drug-resistant HIV strains** that have developed resistance to other antiretrovirals

### *ADMINISTRATION*

**Subcutaneous injection** (just under the skin, typically in the abdomen)

**Twice yearly** (every 26 weeks)

Administered by a healthcare worker

### *CLINICAL TRIALS: PURPOSE 1 AND PURPOSE 2*

Two landmark Phase 3 trials demonstrated Lenacapavir's efficacy for PrEP:

**PURPOSE 1** (Africa — cisgender women and adolescent girls):

5,338 participants across Uganda and South Africa

Zero HIV infections in the Lenacapavir arm vs. 16 in the daily oral TDF/FTC (tenofovir/emtricitabine) arm

**100% efficacy** in the initial trial data (later revised to ~99.9%)

**PURPOSE 2** (Global — cisgender men, transgender women/men):

Confirmed efficacy across diverse populations

96% reduction in HIV infections compared to daily oral PrEP

## ZIMBABWE: THE CONTEXT

Zimbabwe has one of the world's highest HIV burden:

**HIV prevalence:** ~11.9% of adults aged 15–49

**People living with HIV:** ~1.3 million

**New infections annually:** ~33,000

**Most at-risk group:** Young women aged 15–24 (prevalence 3× higher than young men)

The Lenacapavir rollout specifically targets:

Women and girls aged **16–25** — most biologically vulnerable to HIV (cervical tissue susceptibility + power imbalances in sexual relationships)

**Health workers** in high-burden settings

Others at substantial risk

Zimbabwe's national rollout makes it one of the first countries to implement the injection at scale after WHO prequalification.

## INDIA'S ROLE IN GLOBAL HIV MEDICINE

India's pharmaceutical industry is central to global HIV treatment access:

- **Generic ARVs (antiretrovirals)** manufactured by Indian firms — primarily **CIPLA, Sun Pharma, Aurobindo** — supply approximately **80% of HIV treatment** in low-income countries
- **CIPLA's 2001 decision** to offer a triple ARV combination for $1/day (vs. $10,000+/year from Western firms) transformed global HIV treatment access
- Generic lenacapavir: **Gilead has licensed** generic manufacturing rights to several companies including Indian firms — generic versions are expected to bring the cost from ~$40,000/year (US price) to under $100/year for low-income countries

**PEPFAR (President's Emergency Plan for AIDS Relief)** — the US programme launched in 2003 — funds HIV treatment in Africa and is a major purchaser of Indian-manufactured generics.

**Medicines Patent Pool (MPP):** A UN-backed body that negotiates voluntary licences with innovator companies (like Gilead) to allow generic manufacturers to produce affordable versions for low-income countries. Gilead has signed an MPP licence for Lenacapavir — covering 120+ countries including most of Africa.

## GLOBAL HIV STATISTICS

| Indicator | Data |
|---|---|
| People living with HIV globally | ~39 million |
| New HIV infections per year | ~1.3 million |
| AIDS-related deaths per year | ~630,000 |
| People on antiretroviral treatment | ~30 million |
| Progress toward 95-95-95 targets | 86-89-93% globally (2023) |

**UNAIDS 95-95-95 targets (by 2025):**

- 95% of HIV+ people know their status
- 95% of diagnosed people on treatment
- 95% of treated people virally suppressed (undetectable = untransmittable)

## UPSC RELEVANCE

*Lenacapavir, Yeztugo, Gilead Sciences, capsid inhibitor, PrEP, PURPOSE 1 and 2, PEPFAR, MPP, UNAIDS, 95-95-95 targets, CIPLA, Zimbabwe.* **Mains GS-2:** *India's role in global health; access to medicines and TRIPS flexibilities; PEPFAR and global health financing.* **GS-3:** *Pharmaceutical industry; generic drugs; IPR and public health.* **Interview:** *"Should India's generic drug manufacturing be considered a form of soft power or health diplomacy?"*

## 📌 FACTS CORNER — KNOWLEDGEPEDIA

### LENACAPAVIR — CORE DATA:

Brand name: **Yeztugo** | Developer: **Gilead Sciences** (USA)

Drug class: **Capsid inhibitor** (novel mechanism; first in class)

Route: **Subcutaneous injection**, twice yearly (every 26 weeks)

Indication: **PrEP** (HIV prevention in HIV-negative people)

Efficacy: **~99.9%** HIV prevention (PURPOSE 1 trial: 100% initially)

Approval: WHO prequalified; FDA approved 2024 for PrEP

### PURPOSE TRIALS:

**PURPOSE 1:** Africa (Uganda + South Africa); cisgender women + adolescent girls; 5,338 participants

**PURPOSE 2:** Global; cisgender men, transgender women/men

Comparator: Daily oral **TDF/FTC** (tenofovir/emtricitabine)

### ZIMBABWE HIV DATA:

Prevalence: **~11.9%** adults (15–49)

PLHIV: **~1.3 million**

New infections/year: **~33,000**

Most at risk: Young women aged **15–24**

### GLOBAL HIV DATA:

PLHIV globally: **~39 million**

New infections/year: **~1.3 million**

AIDS deaths/year: **~630,000**

On ART: **~30 million**

UNAIDS target: **95-95-95 by 2025**

### INDIA'S ROLE:

CIPLA: First affordable ARV ($1/day, 2001); manufactured generics for Africa

Indian generic ARV share: **~80% of low-income country HIV treatment**

MPP licence: Gilead licensed generic lenacapavir to Indian firms

### KEY INSTITUTIONS:

**PEPFAR (2003):** US bilateral HIV programme; world's largest; funds African treatment

**UNAIDS:** UN programme coordinating global AIDS response

**MPP:** Medicines Patent Pool; UN-backed; negotiates generic licences

**Gilead Sciences:** US biotech; makes Truvada (oral PrEP), Biktarvy, Lenacapavir

### OTHER RELEVANT FACTS:

Oral PrEP (Truvada): Tenofovir + Emtricitabine; >99% effective with daily adherence; available as generic in India

ART (Antiretroviral Therapy): Suppresses HIV viral load to undetectable; U=U (Undetectable = Untransmittable)

HIV in India: ~2.5 million PLHIV (third largest globally after South Africa and Nigeria)

> National AIDS Control Organisation (NACO): India's nodal body; under Ministry of Health

Sources: Gilead Sciences, UNAIDS, The Hindu

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