# WHO recommends injectable lenacapavir for HIV prevention

The World Health Organization (WHO) released today new guidelines recommending the use of injectable lenacapavir (LEN) twice a year as an additional pre-exposure prophylaxis (PrEP) option for HIV prevention, in a landmark policy action that could help reshape the global HIV response. The guidelines are being issued at the 13th International AIDS Society Conference (IAS 2025) on HIV Science, in Kigali, Rwanda.

LEN, the first twice-yearly injectable PrEP product, offers a highly effective, long-acting alternative to daily oral pills and other shorter-acting options. With just two doses per year, LEN is a transformative step forward in protecting people at risk of HIV – particularly those who face challenges with daily adherence, stigma, or access to health care.

"While an HIV vaccine remains elusive, lenacapavir is the next best thing: a long-acting antiretroviral shown in trials to prevent almost all HIV infections among those at risk," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. "The launch of WHO's new guidelines, alongside the FDA's recent approval, marks a critical step forward in expanding access to this powerful tool. WHO is committed to working with countries and partners to ensure this innovation reaches communities as quickly and safely as possible."

The new guidelines come at a critical moment as HIV prevention efforts stagnate with 1.3 million new HIV infections occurring in 2024 – with disproportionate impact among key and priority populations, including sex workers, men who have sex with men, transgender people, people who inject drugs, people in prisons, and children and adolescents. WHO's recommendation on LEN signals a decisive move to expand and diversify HIV prevention, giving people more options to take control over their health with choices that fit their lives.

## Simplified testing: a major barrier removed

As part of these guidelines, WHO has recommended a public health approach to HIV testing using HIV rapid tests to support delivery of long-acting injectable PrEP, including LEN and cabotegravir (CAB-LA). The simplified testing recommendation removes a major access barrier by eliminating complex, costly procedures and enabling community-based delivery of long-acting PrEP through pharmacies, clinics, and tele-health.

## Next steps: call for implementation

LEN joins other WHO-recommended PrEP options, including daily oral PrEP, injectable cabotegravir and the dapivirine vaginal ring, as part of a growing arsenal of tools to end the HIV epidemic. While access to LEN outside clinical trials remains limited at the moment, WHO urges governments, donors and global health partners to begin rolling out LEN immediately within national combination HIV prevention programmes – while collecting essential data on uptake, adherence and real-world impact.

#### Additional WHO recommendations at IAS 2025

For the first time, WHO's treatment guidelines include a clear recommendation for the use of long-acting injectable cabotegravir and rilpivirine (CAB/RPV) as an alternative switching option for antiretroviral therapy (ART) for adults and adolescents who have achieved full viral suppression on oral ART and do not have active hepatitis B infection. This approach is designed to support people living with HIV facing adherence challenges to oral regimens.

Updated guidelines on service delivery integration include recommendations to integrate HIV services with noncommunicable diseases (NCDs) such as hypertension and diabetes, as well as mental health care for depression, anxiety and alcohol use disorders into HIV services, alongside interventions to support ART adherence. Additionally, new guidelines on management of asymptomatic STIs recommend screening of gonorrhoea and/or chlamydia in key and priority populations.

For people living with HIV who have mpox and are either ART naive or have experienced prolonged ART interruption, rapid initiation of ART is strongly recommended. Additionally, early HIV testing is advised for individuals presenting with suspected or confirmed mpox infection. WHO's standard operating procedures further emphasize HIV and syphilis testing for all individuals with suspected or confirmed mpox.

In response to the broader challenges facing HIV programmes, WHO has also issued new operational guidance on sustaining priority HIV services in a changing funding landscape. The guidance aims to provide a stepwise framework to help countries prioritize services, assess risks, monitor disruptions, and adapt systems to protect health outcomes and preserve progress.

"We have the tools and the knowledge to end AIDS as a public health problem," said Dr Meg Doherty, Director of WHO's Department of Global HIV, Hepatitis and STI Programmes and incoming Director of Science, Research, Evidence and Quality for Health. "What we need now is bold implementation of these recommendations, grounded in equity and powered by communities."

HIV remains a major global public health issue. By the end of 2024, an estimated 40.8 million people were living with HIV with an estimated 65% in the WHO African Region. Approximately 630 000 people died from HIV-related causes globally, and an estimated 1.3 million people acquired HIV, including 120 000 children. Access to ART continues to expand, with 31.6 million people receiving treatment in 2024, up from 30.3 million in 2023.

At a time of reduced funding for HIV and health, WHO's new and updated guidelines offer practical, evidence-based strategies to sustain momentum. By expanding prevention and treatment options, simplifying service delivery and promoting integration with broader health services, they support more efficient, equitable, and resilient HIV responses. Now is the moment for bold implementation to ensure these gains translate into real-world impact.

#### Note to the editor

## WHO at the 13th IAS Conference on HIV Science

The IAS 2025, the 13th IAS Conference on HIV Science is being held in Kigali from 13 to 17 July 2025. It is the world's most influential meeting on HIV research and its applications. This biennial conference presents the critical advances in basic, clinical and operational HIV research that move science into policy and practice. Through its programme, the meeting sets the gold standard of HIV science, featuring highly diverse and cutting-edge research.

At IAS 2025, WHO will present new normative guidance through key satellite sessions and engage at the highest level to highlight innovations and promote health equity, while sounding the alarm on the risks posed by declining global health funding. Detailed information on WHO at the conference is here.

### **News Source:**

https://www.who.int/news/item/14-07-2025-who-recommends-injectable-lena capavir-for-hiv-prevention