

# HIV Prevention Snapshot: Long-Acting Cabotegravir (CAB LA)

Cabotegravir (CAB) belongs to a class of antiretroviral (ARV) medicines known as integrase inhibitors. The long-acting injectable formulation of cabotegravir (CAB LA) is approved in multiple countries for use as pre-exposure prophylaxis (PrEP) for the prevention of HIV in adults and adolescents. In 2022, the World Health Organization recommended its use as a PrEP option for people at substantial risk of HIV infection.<sup>1</sup> CAB LA is particularly suitable for individuals who value discretion, are comfortable with injections, or face difficulties storing or consistently taking daily oral medication for PrEP.

However, access to the drug remains severely limited in the Asia-Pacific region due to a lack of uptake by national programs, limited regulatory approvals, and the absence of generic low-cost formulations.

## ADMINISTRATION AND DOSING

CAB LA is given as an intramuscular injection in the gluteal muscle. An optional, one-month lead-in period with oral CAB may be offered to assess tolerance, although some individuals may choose to start directly with injections in consultation with their healthcare provider. Over the initial 12-month period, a total of seven injections are administered. HIV testing is required before initiation and prior to each injection.

## Long-acting cabotegravir dosing with and without an oral lead-in period\*

With lead-in period using oral cabotegravir	Without lead-in period
Oral lead-in using 30 mg once daily for at least 28 days	First and second injections of 600 mg (3 mL) given one month apart <sup>2</sup> ; subsequent injections every two months
	First and second injections of 600 mg (3 mL) given one month apart <sup>3</sup> ; subsequent injections every two months

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

## CLINICAL TRIALS SUPPORTING THE USE OF CAB LA

The safety and efficacy of CAB LA in reducing HIV acquisition compared to the oral combination of tenofovir-emtricitabine was demonstrated in two clinical trials. However, these trials did not include people who inject drugs or sex workers.

<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> The first dose of CAB LA should be given on the last day or within three days of the oral lead-in period.

<sup>3</sup> Individuals may be given the injections up to seven days before or after the scheduled date.

## REGULATORY APPROVALS

CAB LA was approved for use by the U.S. Food and Drug Administration in December 2021 and by the European Commission in September 2023. In the Asia-Pacific region, six countries have approved the product (China, Malaysia, Myanmar, the Philippines, Taiwan, Thailand), one has the registration dossier under review (Vietnam), and one has initiated utilization under their national HIV program with support from the Global Fund (Cambodia).

## VOLUNTARY LICENSES<sup>4</sup> TO GENERIC MANUFACTURERS

The originator company that developed CAB LA (ViiV Healthcare) and the Medicines Patent Pool (MPP) signed a voluntary license in July 2022 to facilitate generic drug production. Three Indian companies have obtained sub-licenses from MPP to produce and market CAB LA in 90 low-income, sub-Saharan African, and least-developed countries. Generic CAB LA is expected to be commercially available through these companies in 2027.

## PRICING AND ACCESS OPPORTUNITIES

ViiV Healthcare's not-for-profit price for CAB LA has declined from £24.70 per injection in 2023 to £20.30 in 2025. This pricing applies only to multi-vial packs (25 doses) procured for public or donor-funded programs in low-income, sub-Saharan African, and least-developed countries.

In the Asia-Pacific region, CAB LA is available through limited government programs and the private market. Cambodia, with Global Fund support, is implementing a CAB LA PrEP project for men who have sex with men and transgender persons in Phnom Penh. In Vietnam, a planned PEPFAR-supported CAB LA program for 2,000 participants was disrupted by U.S. government stop-work orders. In Thailand's private market, oral CAB costs 10,200 Thai Baht ( $\approx$  \$316)<sup>5</sup> for a one-month supply of 30 tablets, while a single injection costs 14,900 Thai baht ( $\approx$  \$463).

Malaysia and Thailand currently are excluded from the voluntary license and would consequently not be eligible to access generic CAB LA when it becomes available. However, to date, Thailand has granted no patent on CAB LA for PrEP, which may provide a mechanism for the country to procure generic CAB LA, as was the case for how they accessed dolutegravir.

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Expanding access to CAB LA will require additional regulatory filings across the region, faster national regulatory approval pathways, and updated national HIV prevention guidelines that include CAB LA. Investments to strengthen PrEP delivery infrastructure will help ensure it reaches communities to optimize prevention gains.

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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> USD=32.20 THB, Bank of Thailand <https://www.bot.or.th/en/statistics/exchange-rate.html> [October 15, 2025]