

Injectable PrEP

A Factsheet for MSM Advocates and Community Members in the Asia-Pacific Region

Injectable pre-exposure prophylaxis (PrEP) is an exciting new HIV prevention option. Injectable cabotegravir for PrEP (CAB PrEP) is highly effective and only requires one injection every two months. Some people may find this easier to use than other forms of pre-exposure prophylaxis (PrEP), such as pills.

CAB PrEP is not yet available in most countries. However, it is important to start learning about the method now. This



factsheet provides basic information to raise awareness of CAB PrEP among gay, bisexual, and other men who have sex with men (MSM). It also describes actions MSM can take to advocate for the approval and availability of CAB PrEP in their country.

What is CAB PrEP?

CAB PrEP is an injection of the antiretroviral (ARV) drug cabotegravir for HIV prevention. CAB PrEP is one type of long-acting injectable PrEP (LAI-PrEP). CAB PrEP is also called long-acting injectable cabotegravir (CAB-LA) in World Health Organization (WHO) guidance. It is only for people who test negative for HIV. CAB PrEP is administered by intramuscular injection (medicine injected into a muscle). The first two injections are given one month apart. After the second injection, CAB PrEP is given every two months.

Like other forms of PrEP, CAB PrEP does not protect against other sexually transmitted infections (STIs). To protect against STIs and pregnancy, correct and consistent condom use is important.

How effective is CAB PrEP?

All PrEP methods work only when used correctly. When taken as prescribed, oral PrEP reduces the risk of HIV infection through sexual exposure by about 99 percent. A meta-analysis of the two efficacy studies on CAB PrEP found that the risk of becoming infected with HIV was 79 percent lower among study participants receiving CAB PrEP than those receiving TDF/FTC as oral PrEP, likely due to higher rates of correct use. This means that CAB PrEP could reduce HIV transmission even more than oral PrEP. For CAB PrEP, "correct use" means receiving the injection every other month. This may be easier for some people than correct use of oral PrEP, because many people find it difficult to take the oral pill consistently as prescribed.

Photo caption: Khanh, a young MSM, receives counseling on HIV services – including PrEP – from a staff at a social enterprise supported by the EpiC project in Hanoi, Vietnam. *Photo Credit: Vu Ngoc Dung for FHI 360*











How does CAB PrEP work?

ARVs in general, including CAB, circulate throughout the body. CAB PrEP works by preventing HIV from entering human cells and multiplying. If the virus cannot multiply, it dies inside the body.

We know CAB PrEP reduces the chance of getting HIV through sexual exposure. We do not know if CAB PrEP works as HIV prevention when people are exposed to HIV through needles and syringes since the studies were not designed to test this transmission route. People who inject drugs can still benefit from CAB PrEP to prevent HIV through sex.

How long does CAB PrEP take to start working?

For most people, CAB PrEP begins preventing HIV about one week after their first injection.

Who can use CAB PrEP?

CAB PrEP is intended for people who do not already have HIV and are at risk of getting HIV through sexual exposure. Clinical trials found CAB PrEP to be safe and highly effective among cisgender men, transgender women who have sex with men, and cisgender women.

CAB PrEP is one of several options for HIV prevention among MSM, including daily oral PrEP, event-driven (ED) oral PrEP, post-exposure prophylaxis (PEP), and condoms. It is important for people at risk of HIV to be able to choose a method that works for them based on how it is used, its effectiveness, how the person could be exposed to HIV, and other factors important to them. For those who find it difficult to take the oral PrEP pill as prescribed, CAB PrEP may be easier to use correctly; however, some individuals may find it challenging to get the intramuscular injections at a clinic, or potentially other locations, every two months. CAB PrEP is easier to use without the knowledge of sexual partners, which may be helpful for some people.

What is the status of CAB PrEP in the Asia-Pacific Region?

In 2022, WHO added CAB PrEP to its list of recommended PrEP options for people at risk of HIV and released its guidelines for CAB PrEP. As of June 2023, CAB PrEP only has regulatory approval in a few countries, only one of which (Australia) is in the Asia-Pacific Region. However, the drug's license holder, ViiV Healthcare, is working to expand regulatory approval globally. It has submitted applications for national regulatory approval of CAB PrEP in China, Malaysia, Myanmar, Philippines, Thailand, and Vietnam. In addition, ViiV Healthcare has signed a licensing agreement with Medicines Patent Pool—an organization supported by the United Nations to increase access to medicines in lowand middle-income countries. This agreement will allow local manufacturers in 90 low- and middle-income countries to develop, manufacture, and supply a generic version of injectable CAB.

"Our region needs to scale up PrEP for men who are having sex with men and transgender women. The community looks forward to having both longacting injectable PrEP and oral PrEP widely available in the countries in Asia-Pacific as part of the HIV prevention options."

 Midnight Poonkasetwattana, Executive Director, APCOM



Despite these efforts, CAB PrEP may not be widely available in some countries in the Asia-Pacific Region for several years. In addition, it is likely to be more expensive than oral PrEP, which may cause countries to delay offering it as part of universal health care or as a first-choice option.

Are any other drugs being studied as injectable PrEP?

Injectable lenacapavir is currently being studied as HIV PrEP. This form of injectable PrEP may be even easier to use than CAB PrEP: The dosing schedule will require injections only twice a year, and the injections are subcutaneous (just under the skin) instead of intramuscular (in the muscle), offering the future potential for individuals to self-inject lenacapavir PrEP. However, if lenacapavir PrEP is found effective, approvals and availability are likely to happen much later than for CAB PrEP. In addition, lenacapavir PrEP is currently more expensive than CAB PrEP.

What research will inform the introduction of CAB PrEP in the Asia-Pacific Region?

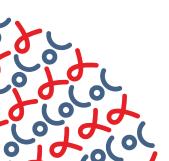
Several studies are ongoing or planned to help countries in the Asia-Pacific Region prepare to implement CAB PrEP as an additional PrEP option. The <u>Integrated Study Tracker</u> on the <u>PrEPWatch website</u> provides information on activities related to all forms of PrEP worldwide and is frequently updated with the latest information.

What PrEP methods are currently available in your country?

Oral PrEP is available in your country now. The dosing schedules for oral PrEP are explained in the box below.

Method	Who?	Why can only some people use this method?
Daily oral PrEP	Everyone	Oral PrEP can be used by anyone without HIV who may be exposed to HIV through sex or injection drug use.
ED PrEP	Only people assigned male at birth	ED PrEP only prevents HIV during sex in people assigned male at birth who are not using gender-affirming hormones.

Biomedical interventions like oral PrEP and CAB PrEP, as well as treatment as prevention, are highly effective. They are also just one part of a combination approach to HIV prevention. Practicing behaviors that are protective against HIV infection, such as using condoms correctly and consistently and limiting the number of sexual partners, is also part of a combination approach to HIV prevention. Efforts or programs that make it easier to lower HIV risk, such as increased access to HIV testing, provider training, violence reduction programs, and law reform, are also critical.



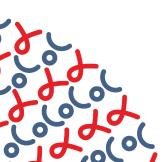
What can advocates and community members do now to expedite the availability of CAB PrEP?

There are several things you can do to help CAB PrEP become available in your area, including:⁴

- Talk to your community. Let your community know about CAB PrEP. Discuss what it would mean to have an injectable PrEP option available for use. Identify your community's questions and concerns around CAB PrEP and include these in advocacy efforts.
- Demand funding to support HIV prevention programs and implementation research, especially for the MSM, transgender, and gender-nonbinary communities.
- Hold decision-makers accountable to support the rollout and implementation of CAB PrEP.

All voices are needed to ensure that CAB PrEP is offered as a true option to all clients based on their preference and not only limited to people unable to tolerate oral PrEP.

- Actively participate as stakeholders—along with ViiV Healthcare, your country's drug administration, the health service payer in your country, HIV service implementers, and potential CAB PrEP users, as well as decision-makers—in efforts to make CAB PrEP available and to demand choice. All voices are needed to ensure that CAB PrEP is offered as a true option to all clients based on their preference and not only limited to people unable to tolerate oral PrEP.
- Be prepared to address the issue of cost as a barrier to availability of CAB
 PrEP during your advocacy efforts. Not only will advocacy and demand generation
 likely play significant roles in driving down the cost of CAB PrEP, but donors are also
 considering assisting with procurement to help remove initial cost-related barriers
 to access.
- Demand equitable access to other HIV prevention methods that currently exist. Although CAB PrEP is not yet available in your country, it is still very important to promote other options that are approved and ready for use, such as daily oral PrEP, event-driven PrEP, PEP, and condoms/lubricants.
- Work with local research sites to ensure that your needs and priorities are being represented.



Additional Resources

- APCOM info-sheet on long-acting injectable PrEP
- Long-acting injectable cabotegravir: implementation science needed to advance this additional HIV prevention choice
- PrEPWatch website
 - Advocates' primer on injectable cabotegravir for prep: trials, approvals, rollout and more
 - Injectable CAB for PrEP
 - Integrated study tracker
 - Translating scientific advance into public health impact: a plan for accelerating access and introduction of injectable CAB for PrEP
- World Health Organization guidelines on long-acting injectable cabotegravir for HIV prevention

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¹ cdc.gov [Internet]. Effectiveness of prevention strategies to reduce the risk of acquiring or transmitting HIV. U.S. Centers for Disease Control and Prevention (CDC); c2022 [cited 2023 May 31]. Available at: https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html#print.

² Fonner V, Ridgeway K, van der Straten A, Lorenzetti L, Dinh N, Rodolph M, et al. Web Annex B. Systematic review, metaanalysis and grade evidence profile on safety, efficacy, and effectiveness of long-acting injectable cabotegravir (CAB-LA) as pre-exposure prophylaxis (PrEP) to reduce the risk of HIV acquisition. In World Health Organization (WHO). Guidelines on long-acting injectable cabotegravir for HIV prevention. Geneva: WHO; 2022. Available at: https://www.who.int/publications/i/item/9789240054097.

³ Marzinke MA, Grinsztejn B, Fogel JM, Piwowar-Manning E, Li M, Weng L, et al. Characterization of human immunodeficiency virus (HIV) infection in cisgender men and transgender women who have sex with men receiving injectable cabotegravir for HIV prevention: HPTN 083. J Infect Dis. 2021 Nov 16;224(9):1581–1592.

⁴ Adapted from box "What can advocates do now?" in: AVAC. Advocates' primer on injectable cabotegravir for PrEP: trials, approvals, rollout and more. 2022; AVAC. Available at: Advocates' Primer on Injectable Cabotegravir for PrEP: Trials, Approvals, Rollout and More | AVAC.