



Apretude PrEP Is Effective and Feasible in Real-World Studies

The long-acting injectable was more than 99% effective, and users experienced less stigma and more confidence about protection against HIV.

October 25, 2024 By [Liz Highleyman](#)

Apretude (injectable cabotegravir), currently the longest-acting approved [pre-exposure prophylaxis \(PrEP\)](#) method, has proved to be highly effective in real-world use, matching its good results in clinical trials, according to study results presented at [IDWeek 2024](#).

Three real-world studies showed that Apretude, which is administered by a health care provider every other month, was at least 99% effective for preventing HIV acquisition when used consistently. What's more, an implementation study found that people who used the long-acting injectable reported decreased stigma and anxiety.

"The findings presented at IDWeek 2024 continue to support the strong and sustained effectiveness of Apretude for people in real life, outside the controlled environment of a clinical trial," ViiV Healthcare chief medical officer Harmony Garges, MD, MPH, said in a [news release](#). "We believe long-acting options have the potential to be transformative in increasing uptake among a broad range of people that could benefit from PrEP and are critical to ending the HIV epidemic."

Oral PrEP was first approved in 2012, but [it has still not reached its full potential](#). Once-daily Truvada (tenofovir disoproxil fumarate/emtricitabine) is around 99% effective when taken as directed, but some people have trouble remembering to take a pill every day, may feel stigma around using antiretrovirals that are also used to treat HIV or may be hesitant to have pill bottles that could be lost or stolen.

The Food and Drug Administration [approved Apretude for HIV prevention](#) in 2021, but uptake has been slow. ViiV is working on [longer-acting cabotegravir formulations](#) that could be administered every four or six months.

Gilead Sciences recently reported that its twice-yearly long-acting injectable PrEP candidate, lenacapavir, [was highly effective](#) in clinical trials for cisgender women in Africa and for gay and bisexual men and gender-diverse individuals. However, lenacapavir for PrEP has not yet been submitted for FDA approval, so it likely will not be available until late 2025. [Update: Gilead [completed a New Drug Application](#) for lenacapavir PrEP in December 2024.]

Apretude Studies

The approval of Apretude was supported by the results from two large randomized clinical trials showing that the long-acting injectable works even better than daily PrEP pills [for cisgender men and transgender women who have sex with men](#) (HTPN 083) and [for cisgender women in Africa](#) (HPTN 084). These results have since been borne out in real-world studies.

At IDWeek, Moti Ramgopal, MD, and colleagues presented an analysis from the Trio Health HIV Research Database. It included 526 HIV-negative adults and adolescents seen at 12 clinics across all regions of the United States who received at least one Apretude injection between December 2021 and January 2024. Over three quarters were men, 14% were cisgender women and 9% were transgender; the median age was 32 years. About half were white and a third were Black. A majority (70%) had previously used oral PrEP.

Although Centers for Disease Control and Prevention PrEP guidelines state that both HIV antigen/antibody and HIV RNA tests should be repeated before each injection, this was done for only 34% of participants. But 63% had at least one type of test prior to all injections, and more than 90% were screened for HIV at least half the time. No new HIV seroconversions were reported over two years of follow-up. Apretude was generally safe and well tolerated, with only 0.5% having injection site reactions noted in their medical records.

The researchers also looked at PrEP persistence in a subset of 474 people with at least two injections, finding that 83% were still on Apretude at the end of follow-up. A majority received their shots on time, 33% had delayed injections and just 3% had a missed injection. Among the 85 people who stopped Apretude, 15% reinitiated it, 56% switched to oral PrEP, 44% used no PrEP and the rest were lost to follow-up. No seroconversions were reported within a year after Apretude discontinuation.

Ricky Hsu, MD, of the AIDS Healthcare Foundation, and colleagues presented real-world findings from the OPERA study, the largest cohort of Apretude users in routine clinical care. The analysis included 764 Apretude users and 18,507 oral PrEP users. The median age was similar in both groups (median 31 and 32 years), but women, Black people and those with Medicaid or commercial insurance were more likely to use Apretude. PrEP use also differed regionally, with a higher proportion of people in the Northeast using Apretude and higher proportions in the South and West using oral PrEP.

Apretude was at least 99.7% effective, the researchers reported. There were two new HIV seroconversions, one of whom discontinued Apretude and was diagnosed while on oral PrEP and one with inconsistent testing. As in the Trio Health study, HIV testing before and during Apretude use often did not conform to guidelines.

Most people (85%) who started Apretude were considered to have “complete initiation,” meaning they received their first two initiation injections 60 days or less apart. Of these 646 people, 69% received all their continuation shots on time. However, 11% received their second injection late (median seven days) and 24% had delayed continuation injections (median three days).

Megan Heise, PhD, of the University of California San Francisco, and colleagues, analyzed Apretude use at eight “safety net” clinics run by the San Francisco Department of Public Health that serve people covered by public insurance; the [Ward 86 clinic](#) at San Francisco General Hospital was the largest site.

The analysis included 111 people who started Apretude between March 2022 and May 2024. About two thirds were cisgender men, 19% were cisgender women, 10% were nonbinary and 5% were trans women; the median age was approximately 37 years. Unlike the two previous studies, this population had high rates of mental health problems (57%), substance use (51%) and unstable housing or homelessness (36%). Nearly 40% switched from oral PrEP, a third had used oral PrEP in the past and 28% had never tried PrEP.

Again, no seroconversions were reported. After six months of follow-up, 83% were still using Apretude, and most injections (85%) were on time. Of the 19 people who stopped Apretude, four switched to oral PrEP and the rest used no subsequent PrEP. The most common reasons for discontinuation were self-perceived low HIV risk, side effects and loss to follow-up. Substance use and mental health diagnosis were associated with greater likelihood of Apretude discontinuation, but unstable housing was not.

The researchers concluded that long-acting injectable PrEP is a feasible option for this population, and retention rates were higher than those seen with oral PrEP. They suggested that an “integrated wraparound mental health and substance use treatment model” is a key to successful implementation.

Finally, the PILLAR study looked at the experiences of more than 200 cisgender gay and bisexual men and transgender men who started Apretude after previously using daily oral PrEP. Nearly a quarter were Black and 39% were Latino.

The men generally found long-acting injectable PrEP to be acceptable, feasible and convenient, [ViiV announced](#). Although 45% of participants reported injection site reactions, nearly 90% said they were able to resume their normal activities the same day, and just 8% said they were bothered by injection pain, which decreased over time.

Recalling barriers to oral PrEP use, 15% worried about privacy while taking their pills, 24% felt they had to hide their PrEP from others and 29% were concerned about PrEP-related stigma. In a survey taken six months after starting Apretude, only 1% or less reported concerns about privacy or stigma.

Men who completed interviews reported reduced stress and fear about missing PrEP doses and increased confidence about protection against HIV. They noted that flexible clinic scheduling, transportation assistance and virtual appointments could help facilitate good adherence to injectable PrEP.

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