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FDA Approves First Injectable Drug for HIV Treatment

By [Caroline Tien](#)Fact checked by [Ashley Hall](#)February 04, 2021 | **NEW**

Key Takeaways

- The FDA has approved an injectable drug, Cabenuva, for the treatment of HIV in adults.
- Cabenuva is administered once a month in the form of a shot. It represents an alternative to current standard-of-care oral medication regimens requiring a pill be taken every day.
- Doctors and researchers expect Cabenuva to have broad appeal.

People who require treatment for HIV can now opt for monthly shots rather than daily pills. On January 21, the Food and Drug Administration (FDA) approved Cabenuva, an injectable drug manufactured by the pharmaceutical company ViiV Healthcare, for the management of the virus in adults.

The news follows the publication of research that suggests that Cabenuva is equally as effective as currently available oral medications at keeping viral load low and symptoms in check.

“Having this treatment available for some patients provides an alternative for managing this chronic condition,” [John Farley, MD, MPH](#), director of the Office of Infectious Diseases in the FDA's Center for Drug Evaluation and Research, said in a press release.

What This Means For You

If you are HIV-positive, you now have a wider array of treatment options that have the potential to simplify your medication regimen and safeguard your privacy. Reach out to your doctor to learn more about your treatment options.

Cabenuva Could Potentially Help Prevent HIV

Cabenuva consists of cabotegravir and rilpivirine. The former, according to [Paul Volberding, MD](#), professor of epidemiology and biostatistics at the University of California San Francisco School of Medicine, is an integrase inhibitor; the latter is a non-nucleoside reverse-transcriptase inhibitor (NNRTI).

Both integrase inhibitors and NNRTIs are classes of drugs that prevent HIV from replicating in the cells, foiling its attempted takeover of the immune system.

Cabotegravir, like Cabenuva itself, is owned by ViiV Healthcare; rilpivirine, on the other hand, is owned by Janssen Pharmaceuticals.

“HIV treatment requires at least two drugs from different classes to be effective and avoid drug resistance,” hence the combination, Volberding tells Verywell.

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Two phase 3 2019 studies, the ATLAS and FLAIR clinical trials, found that Cabenuva was safe as well as effective in adults who were already virologically suppressed, meaning they had fewer than 50 HIV copies per milliliter of blood. More recent studies show that cabotegravir alone increased protection from HIV infection in at-risk women.

Related: [An Overview of HIV Treatment](#)

Cabotegravir has yet to be approved for HIV prevention because the “data is pretty new, whereas the data on the effects of [cabotegravir] on [HIV] treatment has been around for a little while,” [Jonathan Appelbaum, MD](#), a professor of internal medicine and director of the clinical sciences department at the Florida State University College of Medicine, tells Verywell. However, he expects that ViiV Healthcare will file for approval of this treatment relatively soon.

A Welcome Innovation in HIV Treatment

When Cabenuva was submitted to the FDA for review for the first time in 2019 (it was rejected then due to concerns about chemistry, manufacturing, and controls), it received Fast Track and Priority Review status, designations that bump it to the front of the line. It was likely expedited because HIV and AIDS still cause hundreds of thousands of deaths a year worldwide.

"The FDA has tried to be very responsive to HIV," Volberding says. "Partly, this is due to activist pressure. The HIV epidemic is, of course, still a terrible problem, so it makes sense to approve new drugs quickly."

The federal agency approved Vocabria, an oral (tablet) formulation of cabotegravir, along with Cabenuva. Vocabria is meant to be taken in combination with Edurant, an oral formulation of rilpivirine that received approval in 2011, for one month prior to starting Cabenuva in order to "ensure the medications are well-tolerated," according to the press release.

Some of the 1,182 HIV-positive adults who participated in the ATLAS and FLAIR trials reported mild adverse side effects, including:

- Fever
- Nausea
- Headache
- Fatigue
- Dizziness
- Sleep disturbances
- Musculoskeletal pain
- Skin reactions at the injection site

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Cabenuva Is Projected to Be Popular

If the results of the ATLAS and FLAIR trials are any indication, Cabenuva will have broad appeal. There are plenty of reasons why twelve shots a year might be preferable to 365 pills a year, Appelbaum tells Verywell. The most obvious, perhaps, is the ease of adherence.

"If you have to take something every day for the rest of your life, you're going to forget at times, and so we also know that these drugs don't work if they're not taken," he says. "So if you just go once a month for your shot, then we know that you're going to be here, you're going to be fine, your blood levels will be okay, and your virus will be under control."

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There can also be psychological comfort in medicating less rather than more. As Appelbaum points out, there is still a social stigma associated with being HIV-positive.

"If you're taking a daily pill or a pill more than once a day, every time you take it, you're kind of reminded of the disease that you have," he says. "And so I think patients feel that, 'Hey, I go in once a month, get my injection, and I don't have to think about HIV for the next month.'"

In addition, it can be stressful or even dangerous for people with HIV to take their medication around others. "They may be living with a roommate, or they may be in a relationship where they don't feel comfortable disclosing their status, so they don't have to worry about keeping pills around [if they are eligible for Cabenuva]—they could just go to the pharmacy or to the provider and get their injection," Appelbaum says.

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Since receiving FDA approval, ViiV Healthcare will apply for a change to Cabenuva's label. The change would mean patients only have to receive six shots a year, compared to 12. ViiV Healthcare, according to Appelbaum, has data that suggests injecting Cabenuva every eight weeks, or bimonthly, is equally as effective as injecting it every four weeks, or monthly.