

New HIV treatment shot given only twice a year could be a 'game changer'

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The Food and Drug Administration has approved Sunlenca, an injectable therapy to suppress HIV for patients who suffered drug resistance to other regimens.

Experts say the new injectable, which works with less frequent dosing, can be a game changer for those whose infections don't respond to other treatments.

Developed by Gilead Sciences, the drug is the first of a new class called capsid inhibitors, which work by blocking the protein shell, or capsid, of the virus, disrupting multiple stages of the viral life cycle. In a clinical trial, 83% of patients taking Sunlenca with a combination of other drugs achieved an undetectable viral load after about a year.

What is the HIV treatment Sunlenca?

- Sunlenca, or lenacapavir, is the first of a new class of drugs approved by the FDA for HIV treatment.
- Lenacapavir is an antiretroviral drug, which works by stopping the virus from replicating to keep HIV levels in the body very low.
- Sunlenca is approved for patients with HIV whose infections haven't responded to multiple other treatment regimens.
- The treatment begins with a regimen of tablets by mouth and injections, then maintenance injections every six months.

Who is recommended to take Sunlenca?

The FDA approved Sunlenca for adults with HIV who haven't responded to treatments for managing the virus, such as patients whose infections become resistant to other drugs. It's unclear about how many people suffer from drug-resistant HIV in the U.S., but the federal Centers for Disease Control and Prevention reports about 44% of people in HIV treatment haven't reached viral suppression.

The treatment could be especially helpful for [older patients](#) who were

diagnosed at the height of the epidemic and struggled to adhere to earlier, more complicated treatment regimens, which can contribute to treatment resistance, said Dr. Sabrina Assoumou, a physician and infectious disease specialist at Boston Medical Center.

The twice-yearly drug can also help patients who face barriers to care, such as lack of transportation, by making it easier to adhere to the regimen, said Emory University professor Dr. Wendy Armstrong, a physician and infectious disease specialist. Other barriers include facing stigma at home, living miles from a clinic or homelessness.

The new therapy, she said, gives an opportunity for stakeholders to "bring care that can be effective to people who have real challenges with our traditional medication system."

What are HIV experts' concerns?

The drug would cost \$42,250 to start the therapy, and then \$39,000 a year for maintenance shots.

Many patients get their medications through Medicaid and federal drug assistance programs under the Ryan White CARE Act, but experts such as Dr. William Short, board of directors chair at the American Academy of HIV Medicine, are still concerned.

Medical communities hope the drug will be added swiftly to insurance plan formularies.

"Our hope is that payors will make this agent available to those who need it without significant barriers or challenges," he said.

Why is this new type of drug significant?

Last year, the FDA approved Cabenuva by ViiV Healthcare, the first longest-acting intramuscular injection administered every month to two months. Sunlenca is administered subcutaneously, or just under the skin.

"A subcutaneous injectable is definitely a game changer in terms of quality of life," Assoumou said, explaining that eventually, shots like these could be administered at home.

Meanwhile, research is underway to test whether capsid inhibitors can be used for other patients starting a regimen for the first time or for prevention, experts say. HIV has no cure, but treatments have come a long way, and experts hope expanded access for long-acting drugs could pave the way for easier [treatment regimens](#), Assoumou said.

"It's a really exciting time for people who are in the field," she said, "in terms of improving quality of life and also having more options in our toolbox."

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