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HIV/AIDS

"Miraculous" HIV drug to be rolled out after overcoming aid cuts threat

A trial of lenacapavir showed 100% protection against HIV infection. But cuts to foreign aid and criticism over its pricing put the brakes on a worldwide rollout. Elna Schütz asks if we're now seeing the reprieve that advocates were hoping for

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When the drug lenacapavir (Sunlenca for HIV treatment, Yeztugo for HIV prevention) first hit headlines in 2024 it was touted as a "giant leap" forward in the battle against HIV.[1] The early results of a phase 3 trial showed 100% protection against HIV infection among women, and its anticipated rollout would, it was hoped, be a game changer.

Just a few months later, however, cuts to foreign aid—particularly by the US government,[2] but part of a worldwide trend[3]—slashed public health budgets and funding for many projects, including for HIV/AIDS programmes.

After a period of considerable uncertainty a reprieve arrived in September, with news that lenacapavir would be funded by the US President's Emergency Plan for AIDS Relief (PEPFAR), which itself has an uncertain future.[4]

The real test begins now. Can lenacapavir be rolled out efficiently, and at an accessible price point, to the communities that need it most?

How lenacapavir works

Lenacapavir is a long acting, injectable,[5] pre-exposure prophylaxis (PrEP) drug that prevents HIV infection. The drug is an HIV-1 capsid inhibitor, meaning that it disrupts the protein shell that protects the virus's genetic material and enzymes so it cannot replicate.[6] Notably, the drug can inhibit the virus at multiple stages in the life cycle, and has little to no cross resistance with existing antiretroviral agents.

Lenacapavir is currently marketed as Sunlenca for HIV treatment and Yeztugo for PrEP.

The use of the drug for PrEP is preceded by an HIV test to ensure the patient does not have the virus. The first injection is accompanied by oral pills for two days, and then the injection should be repeated every six months.

Challenge

"Lenacapavir has the potential to defeat the HIV crisis," says Asia Russell, executive director of the international advocacy organisation Health GAP.

The drug has been tested in and is targeted at communities that have been underserved by the available HIV prevention technologies, she says. This includes young women in sub-Saharan Africa, transgender people, gender diverse people, men who have sex with men, sex workers, and people who inject drugs. Lenacapavir may be a particularly good fit for these populations because the longlasting injection avoids the stigma and logistical difficulties of accessing and using daily oral PrEP products.

Even in higher income countries the use of existing PrEP options is not ideal. For example, only 36% of people in the US who met the eligibility criteria for PrEP in 2022 were prescribed it, according to data from the US Centers for Disease Control and Prevention (CDC).[7] This was an increase from 23% in 2019.

In the UK in 2023 around 80% of people who would benefit from PrEP did not access it from specialist sexual health services.[8] And in both the UK and US, black populations had the highest unmet need.

Solution?

There is, therefore, an urgent need for alternative, accessible drugs—one that lenacapavir's maker, Gilead Sciences, is well placed to fill, having brought the first PrEP products to market in 2012.

On 18 June the US Food and Drug Administration approved Yeztugo for PrEP.[9] The announcement came with the promise that Gilead was working with insurers and others to make the drug accessible and affordable.

The drug is now available in the US. According to market reports, Gilead is set to have 75% of US insurers on board by the end of the year,[10] with Medicare and Medicaid, the federal programmes that provide health insurance to the most vulnerable, already included.

CVS Health, however, the largest pharmacy benefits manager in the US, is not covering lenacapavir, despite pressure from activists. The decision is partly because of the US list price of more than $28 000 (£21 000; €24 300) a year and also because it has not been adopted by the Department of Health and Human Services' Preventive Services Task Force guidelines, by which CVS is guided.

In the UK, an early access programme for lenacapavir was closed to new patients in April, in part because of pricing. The drug as PrEP is not yet available on the NHS but is currently being considered by the National Institute for Health and Care Excellence, with a marketing authorisation decision due in March 2026.[11]

Sean Hosein, the science and medical editor of Catie, a Canadian HIV information resource, says that the drug is not yet approved in the country. "We hope that it will be by next summer, as it will then become

another option for prevention," he says, adding that price negotiations between the Canadian government and the manufacturer can take up to two years.

Trumped

Following the publication of trial results in July[12] and October 2024, an immediate global rollout, particularly to low and middle income countries, was planned, with agreements with generic manufacturers put in place.

In December 2024 PEPFAR, under then US President Joe Biden, and the Global Fund agreed to roll out the drug to at least two million people in the first three years after approval.[13]

Mitchell Warren, the executive director of AVAC, an international non-profit organisation focused on HIV prevention, says, "It's not as ambitious as we need it to be and as it could be, but it was certainly a more ambitious target than for any other PrEP product in the past 15 years."

The January 2025 inauguration of Donald Trump saw sweeping cuts to US government services, however, including devastating restrictions to PEPFAR funding and cuts to US funding to South Africa in particular.

Throughout the year, however, support for a quick rollout of lenacapavir has been strong.

In July, both the World Health Organization and the European Medicines Agency backed the drug, with WHO publishing guidance for its use[14] and the EMA publishing a positive opinion about the drug.[15]

Other notable HIV treatment guidelines published in the past few months have included lenacapavir, including those by the CDC[16] and the International Antiviral Society-USA Panel.[17]

The Global Fund has remained committed to the drug's rollout. In July it signed an access agreement[18] with Gilead that aimed to introduce lenacapavir to low and middle income countries at the same time as higher income countries. All that was needed was funding.

In early September the US government recommitted[19] to the PEPFAR ambitions made under the Biden administration.

Now, countries around the world are seeking local approval for lenacapavir, with a particular focus on those in Africa, which is home to around 65% of people living with HIV.

South Africa became the first country on the continent to register lenacapavir for use,[20] and plans to roll out the drug as early as February 2026. On 18 November 2025, South Africa's department of health approved the inclusion of injectable lenacapavir on the country's essential medicines list.

Kenya intends to start its rollout by January,[21] with Eswatini, Lesotho, Mozambique, Nigeria, Uganda, Zambia, and Zimbabwe set to follow.[22] Eswatini and Zambia have already received 500 doses each of lenacapavir, according to a 19 November communique[23] from the US State Department, which has pledged to provide up to two million doses to countries by 2028.

Leora Pillay, the lead of HIV prevention advocacy at non-governmental organisation Frontline AIDS, is positive about the process so far. "It has moved much faster than other forms of PrEP and other drugs, and that's been really positive," she says. "And it's shown the persistence and commitment of some countries to register the drug quickly, and by funders to support it."

Pricing and equality

Despite the progress, experts remain concerned about whether the rollout of the drug will be fast enough and equitable. Pricing, particularly in low income countries, remains a concern.

The rumoured negotiated not-for-profit price for the Global Fund is around $100 a person for two injections.[24] Warren says this is high, at over double the price for Gilead's oral PrEP and a similar price to long acting cabotegravir, an injectable on the market that is administered every month or two. He explains that cabotegravir had strong regulatory approval, but high prices and limited supplies hindered its rollout.

In a September announcement,[25] manufacturers and partners said that generic versions of lenacapavir would likely be available at around $40 a year in 120 low and middle income countries, beginning in 2027. This does not include the $15 for the compulsory initial pill regimen that has to be taken when starting or restarting a course of the drug (see box).

"We want to drive lenacapavir to price parity with oral PrEP and ideally get it even lower as the market grows," Warren says.

He says that while there is a considerable market for HIV treatment, the same does not exist for PrEP as a preventative. That market would need to be built from around 1.5-2 million people up to about 2-5 million, and it would require increased donor and government participation and funding.

Lise Jamieson, principal researcher at the Health Economics and Epidemiology Research Office in South Africa, says that while high demand is an ambitious target, it would also be incredibly impactful.

"If we have successful demand creation for this product and can get 1.4 million people in South Africa to use lenacapavir annually by 2030, and keep up with those numbers over many years, then we could, over 20 years, avert 19% of new HIV infections," she tells *The BMJ*.

But Pillay worries if affordability will be possible in the long term. She points to the need for governments to cover the costs longer term in a sustainable way, so that lenacapavir coverage is not entirely reliant on donor funding.

The health systems to roll out the drug need to be built up or rebuilt in cases where PEPFAR cuts have hit hard. Clinics have closed and been forced to reduce staff numbers, while programmes focusing on areas such as mother-to-child HIV transmission or HIV testing have also been cut. Sub-Saharan Africa has been particularly affected, with South Africa seeing the dismissal of around 8000 healthcare workers as a result of US aid cuts. Similar consequences have been reported around the world, from the Philippines to Ukraine.

"In some countries we've seen a reduction in community led interventions funded by the likes of the Global Fund, just because they've needed support in making sure that the health system skeleton remains intact," Pillay says. She points to Kenya as a concerning example.

"This idea that we are going to be able automatically to roll out lenacapavir after the infrastructure's been decimated is magical thinking by the US administration," Warren says.

Still, he says there is a "great desire" from communities and countries throughout East and southern Africa "who want to get this right." Warren wants to hold on to the optimism that came with the trial results.

"The idea that two or three countries could get it before the end of this year, in the same year as the US launched the product, is unprecedented," he says. He hopes that the rollout will stand as an example for how other drugs are made available to low and middle income countries.

"That is hugely important, and I hope it sets the standard for innovation of the future."

I have read and understood BMJ policy on declaration of interests and have no relevant interests to declare.

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Use of AI: I disclose that I used AI, namely ChatGPT, to direct me to news articles, academic research, and other sources that I then used in my reporting.

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