Unifying Concern Emerges as FDA Approves Twice-Yearly PrEP to Prevent HIV

NMAC, Health GAP, amfAR and other AIDS advocates issue statements about the newly approved Yeztugo (lenacapavir) for HIV PrEP.

June 20, 2025 By Trent Straube

Earlier this week, the Food and Drug Administration (FDA) approved what many HIV advocates herald as a groundbreaking prevention tool with the potential to help end the HIV epidemic: Yeztugo (lenacapavir) is a twice-a-year injection, making it the longest-acting pre-exposure prophylaxis (PrEP) to prevent HIV.

In two large clinical trials, more than 99% of people who used Yeztugo remained HIV negative. What's more, the med, which is manufactured by Gilead Sciences, is highly effective in women, gay men and gender-diverse populations at risk of acquiring HIV through sex. (Studies are underway to test long-acting PrEP for people who inject drugs.)

Yeztugo (lenacapavir) for HIV PrEPGilead Sciences

To learn more about the research and approval of Yeztugo, see "FDA Approves Twice-Yearly Lenacapavir for HIV Prevention."

Since the June 18 approval, leading AIDS organizations and HIV advocates have issued statements about the new prevention option—and a common concern has emerged. Paul Kawata, executive director of NMAC, expresses it succinctly:

"This is a remarkable step forward, but science alone doesn't save lives—access does. Without a strong HIV prevention infrastructure, long-acting PrEP like lenacapavir, won't reach the communities who need it most."

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Yeztugo is expected to cost an estimated $28,000 annually. As the New York Times notes, Apretude (cabotegravir), the only other approved long-acting injection, costs about $24,000 a year; the shots are administered every two months. Lenacapavir sold as Sunlenca for HIV treatment, which must be used in combination with other drugs, costs about $42,000 annually. This is significantly more than oral pills—sold as Truvada and Descovy—that are approved as HIV PrEP. Generic versions of Truvada can cost about $1 per daily pill.

For its part, drugmaker Gilead Sciences has committed to supplying lenacapavir to low-income countries, reports Reuters. Gilead will provide the drug at cost for two to three years. To boost

production, six generic drug manufacturers were issued licenses to produce the med for those countries.

> BREAKING: The US FDA approved #lenacapavir (LEN) for #HIVprevention. “But scientific progress only matters if innovation reaches people.” LEN’s approval is a step forward—but the rollout must be faster and fairer than previous #PrEP options. avac.org/press-releas...
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> — AVAC (@avac.org) June 18, 2025 at 1:41 PM

Of course, Gilead’s committment to low-income countries doesn’t address access and cost in the United States, where about 39,000 people contracted HIV in 2023, the latest federal data available. Of note, new HIV cases remain higher in the South and among certain groups, including Black and Latino men who have sex with men—the very populations that experience more barriers to access health care.

Hence, the unifying concern about the rollout and access of Yeztugo. Below is a brief roundup of select statements released upon the approval of this long-acting PrEP.

Statement by amfAR, the Foundation for AIDS Research chief executive officer Kevin Robert Frost:

> “PrEP is one of the most indispensable tools we have for ending the HIV epidemic. Having the option of a twice-annual shot, rather than relying on a daily pill, will make long-term adherence to PrEP much easier for many. But this remarkable drug will only be as effective as it is accessible and affordable. amfAR calls on Gilead Sciences and the U.S. government to do everything in their power to make sure as many people who want lenacapavir can get it.”

Statement by the Joint United Nations Programme on HIV/AIDS (UNAIDS) executive director and United Nations Undersecretary-General Winnie Byanyima:

> “UNAIDS has seen research that lenacapavir can be produced for just $40 per person per year, falling to $25 within a year of rollout. It is beyond comprehension how Gilead can justify a

price of $28,218. If this game-changing medicine remains unaffordable, it will change nothing. I urge Gilead to do the right thing. Drop the price, expand production and ensure the world has a shot at ending AIDS."

Statement by HIV+Hepatitis Policy Institute executive director Carl Schmid:

"Recent actions by the Trump administration to decimate HIV prevention jeopardize access to preventive measures such as PrEP. In fact, the president's budget zeroes out all CDC [Centers for Disease Control and Prevention] HIV prevention and surveillance funding, hampering our nation's ability to make people aware of and access new HIV prevention measures. Dismantling these programs means that there will be a weakened public health infrastructure and much less HIV testing, which is needed before a person can take PrEP.

"Private insurers and employers must also immediately cover Yeztugo as a required preventive service, which means that PrEP users should not face any cost-sharing or utilization management barriers. Despite a Grade A rating from the USPSTF [United States Preventive Services Task Force] for PrEP, and supporting federal guidance, PrEP users are still being subjected to unlawful co-pays and prior authorization. At a time when there is such an emphasis on prevention to avert chronic diseases, we call on federal and state regulators to step up enforcement of the ACA [Affordable Care Act] preventive services requirement."

Statement by AVAC director of product introduction and access Wawira Nyagah:

"Political will, programmatic implementation and sustainable funding are needed to truly accelerate equitable and impactful introduction of [lenacapavir] worldwide. We have over a decade of hard-won lessons on what it takes to roll out PrEP effectively, and the field cannot afford the delays we have seen with the past launches of daily oral PrEP, the monthly dapivirine vaginal ring (DVR), and every-two-month injectable cabotegravir (CAB). Lives depend on speed, scale and equity."

Statement by PrEP4All's communications and mobilization director, Michael Chancley:

"The stakes couldn't be higher for communities of color that have yet to significantly benefit from PrEP. Lenacapavir shows real innovation for cisgender women and other communities facing unique barriers to adhering to a daily pill, but I fear that we may see the same challenges in access that we saw with Apretude which, despite being the first long-acting PrEP available in the U.S., continues to make up only 2% of PrEP scripts."

Statement by AVAC executive director Mitchell Warren:

"The approval of LEN [lenacapavir] is a much-needed boost for HIV prevention, given the strength of the science and the simultaneous disruption in HIV programs globally. But U.S. FDA approval is just one in a series of steps needed to ensure that injectable LEN can help reduce the 1.3 million new HIV infections that occur each year. Scientific progress only matters if

> innovation actually reaches people. LEN for PrEP is poised to reshape the HIV response, but only if today's approval is accompanied by bold, strategic, effective and equitable rollout that reaches the populations that need access. Otherwise, the world risks squandering this PrEP opportunity, as it has with other PrEP options too often over the past 12 years."

A joint statement by Health Justice Initiative, Health GAP, Just Treatment, ABIA (Brazilian Interdisciplinary AIDS Association) and Sankalp Rehabilitation Trust includes director of Health Justice Initiative Fatima Hassan:

> "Lenacapavir has once-in-a-generation potential to prevent millions of new HIV infections. Accelerating global access to affordable injectable lenacapavir should be Gilead Sciences' CEO Daniel O'Day's top priority. But it will only be rolled out effectively if all LMICs [low- and middle-income countries] are included and there is a single affordable access price, comparable with oral PrEP."

The joint statement also includes the coordinator of the Working Group on Intellectual Property and project assistant at ABIA Susana van der Ploeg:

> "While we wait, vulnerable people remain at risk. We cannot let corporate control and excessive pricing decide who stays HIV-free. Governments in Latin America must act urgently—including rejecting frivolous patents and using compulsory licensing—to ensure equitable access to this breakthrough prevention tool. Brazil in particular needs to be cautious as any voluntary licensing deal Gilead offers to its public manufacturers could in fact have hidden restrictions that could delay and undermine affordable supply."

> The activists' joint statement also calls on governments, funders and global health agencies to:

> Prioritize domestic and international funding for the introduction and equitable rollout of lenacapavir;

> Support countries excluded from Gilead's licensing territory to make use of all available legal tools, such as patent oppositions and compulsory licenses, to overcome patent and other intellectual property barriers;

> Remove unnecessary and restrictive clauses from Gilead's voluntary license, such as the "non-diversion" clause, which would have the effect of preventing excluded countries that issue a compulsory license from purchasing lenacapavir made by one of the licensed generic companies;

> Lower Gilead's "access price" to a price comparable with oral PrEP in all LMICs $25-$40 per

person per year;

Demand full price and supply transparency from Gilead and its procurement partners.

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http://beta.docker.poz.com/article/unifying-concern-emerges-fda-approves-twiceyearly-prep-yeztugo-prevent-hiv