Who Will Access the Newest Long-Acting PrEP to Prevent HIV?

Pending FDA approval, drugmaker Gilead Sciences says it will supply the twice-yearly PrEP injection lenacapavir in low-income countries.

June 4, 2025 By Trent Straube

Amid the brutal onslaught of HIV headlines in recent months—about the Trump budget cuts, massive layoffs and rising death tolls—one topic remains a source of optimism: a groundbreaking long-acting PrEP to prevent HIV. Specifically, the drug lenacapavir, which is administered by injection twice a year as pre-exposure prophylaxis, or PrEP.

After several studies found the twice-yearly PrEP to be highly effective in women, gay men and gender-diverse populations, the Food and Drug Administration (FDA) could approve the drug any day now (a determination is expected by June 19). In preparation, global leaders and advocates have been working to ensure that the world's most vulnerable populations will be able to access the powerful prevention tool, especially as the Trump administration has cratered U.S. funding for HIV programs abroad and within the states.

For its part, drugmaker Gilead Sciences has committed to supplying lenacapavir to low-income countries if it wins FDA approval, 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.

Gilead expects to profit from sales of the drug in the United States, according to Reuters, which reports that the U.S. price tag is likely to be around $25,000 a year, similar to the cost of ViiV Healthcare's Apretude (extended release cabotegravir), a long-acting injectable given every two months that the FDA approved as PrEP in December 2021.

Other sources of financial support for access to lenacapavir in low-income countries may arrive in the near future. For instance, i-Base reports that when philanthropist Bill Gates spoke this week at the 25th anniversary of the Gates Foundation, he mentioned that future plans would include a commitment to rolling out lenacapavir to prevent HIV.

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Lenacapavir is the first HIV capsid inhibitor. In December 2022, the FDA approved the long-acting injectable as treatment for certain people living with HIV; it's sold as Sunlenca.

To date, the FDA has approved three forms of PrEP: Truvada and Descovy are daily pills, and Apretude is a shot given every two months. It should be noted that due to lack of evidence, Descovy is not yet indicated as PrEP for cisgender women and trans men. Generic (and much cheaper) versions of Truvada are available.

Under the rules of the Affordable Care Act (ACA, or Obamacare), preventive health services that receive an A or B grade from the U.S. Preventive Services Task Force (USPSTF) must be covered by health insurance. In August 2023, the USPSTF gave all three forms of PrEP an A grade. However, conservatives have in recent years filed lawsuits challenging the ACA's mandate to cover preventive health services, ranging from PrEP to cancer screenings. Courts have mostly upheld the coverage, but Kennedy v. Braidwood Management, Inc. (formerly Becerra v. Braidwood Management, Inc.), a case currently before the Supreme Court could endanger robust prevention coverage in the future. A ruling is expected by early July.

For more about that lawsuit, see "Supreme Court Heard Arguments on Preventive Health Care Coverage. How'd It Go?" And for more about PrEP, see the POZ Basic on HIV Prevention.

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