CVS Health Will Not Cover Twice-Yearly HIV PrEP Yeztugo for Now

CVS won't add Gilead's Yeztugo (lenacapavir), which the FDA OK'd in June, to its coverage list. Plus, regular PrEP denials remain common.

September 4, 2025 By Laura Schmidt

CVS Health announced it will not add Gilead Sciences' latest HIV prevention drug Yeztugo (lenacapavir), which is given as a shot every six months, to its commercial plans despite its proven effectiveness, at least for now, Reuters reports.

The decision is based on clinical, financial and regulatory factors, CVS spokesperson David Whitrap told Reuters. What's more, CVH Health will not cover Yeztugo under its Affordable Care Act (ACA) formularies. ACA rules require that health insurers must cover other forms of pre-exposure prophylaxis (PrEP). However, the Food and Drug Administration approved Yeztugo as PrEP in June, and so far it does not meet the requirements for ACA prevention coverage (more on this below).

Yeztugo is priced at $28,000 yearly (or $14,000 per shot), and HIV drugmaker Gilead is still negotiating with CVS Health, Reuters reports.

Mitchell Warren, executive director of the AIDS nonprofit AVAC, called CVH Health's decision "a grave disappointment and frankly a missed opportunity." He also told Reuters that "it does reflect a price that is too high and a U.S. pharmaceutical pricing structure that is frankly not sustainable."

PrEP efers to medication used by an HIV-negative person to reduce the risk of contracting HIV.

To date, the Food and Drug Administration (FDA) has approved four forms of PrEP: Truvada and Descovy are daily pills; Apretude is a shot given every two months; and Yeztugo is a twice-yearly injectable that is highly effective in women, gay men and gender-diverse populations. Due to insufficient evidence, Descovy is not yet indicated as PrEP for cisgender women and trans men. Generic (and much cheaper) versions of Truvada are available. To learn more about PrEP, see the POZ Basics on HIV Prevention: Pre-Exposure Prophylaxis (PrEP).

Under the rules of the Affordable Care Act (ACA, or Obamacare), health insurers must cover preventive health services that receive an A or B grade from the U.S. Preventive Services Task Force (USPSTF). In August 2023, USPSTF gave an A grad to all three PrEP forms of HIV prevention that had been approved at that time: Truvada, Descovy and Apretude. However, conservatives in recent years have filed lawsuits challenging the ACA's mandate to cover preventive health services. These include not just PrEP but also cholesterol-lowering statins, vaccines and many screenings for cancer, diabetes and hepatitis.

In June 2025, the Supreme Court upheld the ACA mandate to cover these preventive services but stressed that the task force falls under the leadership of the nation's health secretary. Currently, that person is Roberts F. Kennedy Jr., who is already dismantling federal health programs and services. He recently removed members of the Advisory Committee on Immunization Practices (ACIP), a panel of experts that sets U.S. vaccine policy.

For Yeztugo to be covered under ACA requirements, the USPSTF would have to give the twice-yearly injection an A or B grade.

Lenacapavir was approved under the brand name Sunlenca in 2022 to treat certain people with highly resistant HIV. It is the first HIV capsid inhibitor. As such, it is not a vaccine that trains the immune system to fight the virus, but since all traditional HIV vaccine candidates have failed in large trials to date, long-acting PrEP is a powerful tool in the prevention toolbox.

Under the brand name Yeztugo, it was approved as HIV PrEP based on impressive data from the Phase III PURPOSE 1 and PURPOSE 2 studies. Yeztugo can be a good option for teens and young adults, a group that often struggles with consistent adherence to daily prevention pills.

What's more, results from PURPOSE 1 showed that lenacapavir was 100% effective for young cisgender women in South Africa and Uganda. The injections significantly reduced HIV incidence compared with the background incidence rate and were superior to daily Truvada pills.

Several U.S. government health care programs, including the Veterans Administration and the Medicare program for people aged 65 and over, have already added lenacapavir to coverage lists. Some state-run Medicaid plans, including California and New York, already cover the prevention drug, according to Reuters.

HIV+Hepatitis Policy Institute executive director Carl Schmid issued the following statement about CVS Health not covering Yeztugo:

“The entire world is excited by this drug and its potential contribution to preventing and eventually ending HIV. However, a drug will only work if people can access it and right now CVS Health, which owns the largest pharmacy benefit manager in the country, is shamefully blocking people from taking it, unlike other payers.”

More than a decade after the FDA’s approval of Truvada for HIV prevention, PrEP has yet to reach its full potential. In fact, less than a third of the 1.2 million people in the United States who could benefit from PrEP were using it in 2021, according to the Centers for Disease Control and Prevention.

For those who do choose to take HIV PrEP, insurance denials occur often in the United States, despite a coverage mandate under the ACA. In fact, a recent study involving 11,410 individuals found that 23.7% reported at least one prescription denial for PrEP.

“We urge CVS, which has been committed to ending HIV in the past, to reconsider their decision immediately,” Schmid said. “Additionally, we call on federal and state regulators to ensure that plans are in compliance with the federal government’s PrEP coverage guidance and the many state laws that require coverage of all PrEP drugs.”

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