ON THE COVER

New use of HIV medication could help transform PrEP care

Elizabeth Briand

This past June, a drug called lenacapavir received FDA approval as a twice-yearly injection to protect against HIV infection. This approval marks what could be a significant advance in preventing new cases in an epidemic that has cost more than 44 million lives worldwide since the early 1980s. Clinical trials have shown that lenacapavir may offer a nearly impenetrable shield against HIV infection for individuals at high risk of contracting the virus.

Marketed as Yeztugo, lenacapavir is the latest addition to the PrEP medication toolbox. Over the last decade, PrEP has helped combat the spread of HIV both nationally and globally. As an antiretroviral drug, it has reduced the risk of acquiring HIV through sexual intercourse by up to 99%.

Although the success rates for PrEP are high, the challenge has been in educating and getting people to take the medications. Lenacapavir is unique in that individuals would only need one injection twice a year, something experts say could help increase utilization of the drug and, at the same time, increase prevention effectiveness.

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"In general, many people that should be on PrEP are not on PrEP, and we need to increase that number significantly," said Steven K. Barnett, MD, senior vice president, medical services and chief medical officer for CAN Community Health in Tampa, FL.

"Lenacapavir could reduce barriers for many, improving HIV prevention across the nation and the world."

Manufactured by Gilead, lenacapavir already is being used to treat adults with an HIV-1 infection that is resistant to other drugs. The repurposing of the medication—and the promise of its simple twice-yearly dosing—made its approval one of the most highly anticipated for clinicians and administrators on the front lines of the decades-long HIV epidemic.

That anticipation was heightened when results from a 2024 randomized controlled trial of lenacapavir in Uganda and South Africa were shared. Known as the PURPOSE 1 trial, it was unique in that it focused solely on women, including those who were pregnant and breastfeeding, in parts of the world where women are at higher risk of developing HIV than men.

Of the 2,134 women who were given lenacapavir in the trial, none of them contracted HIV. Among the women who were given Truvada, which is a daily prophylactic pill, 1.5% of women contracted HIV. Those that received Descovy, another daily medication, saw a 1.8% rate of infection.

The zero percent contraction rate led the trial's independent review committee members to stop the study early with the recommendation that all trial participants should be given the medication because of the protection it could provide.

Affordability and access

Although its approval is being heralded as a game changer, some have voiced concerns about the cost and availability of the medication, which could be more than $28,000 a dose. The manufacturer notes that few people will pay full price for the medication, just as the vast majority of users pay far less than retail price for Apretude, another injectable PrEP medication that requires a dose every 2 months. Generic versions of daily oral PrEP medications can cost as little as a dollar a dose.

"Affordability of PrEP varies," said E. Michael Murphy, PharmD, APhA's senior advisor for state government affairs. "For oral PrEP, generic options are available, and many patients use manufacturer copay cards, patient assistance programs, or coverage through Medicaid, Medicare, or private insurance."

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For cabotegravir and lenacapavir, cost may be a more significant barrier. "These long-acting injectables are expensive, and insurance coverage varies," Murphy said. "Access may hinge on public programs, 340B pricing, and patient assistance offerings, all of which could be at risk with funding cuts."

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Barnett, though, expects that lenacapavir will be covered for individuals who have insurance. "Lenacapravir was just approved, so it will take a few weeks to a few months for this coverage to be fully implemented by insurance companies, but we expect this to happen in the very near future," he said. "For uninsured, these companies offer patient assistance programs that can provide the medications at little to no charge if the patient qualifies based on their income."

One other potential roadblock to the use of injectable PrEP is the fact that it must be administered by a health care professional. This may be a challenge for individuals who live in rural communities, who may not have access to providers who can give them the injections, or who may have difficulty managing ongoing health care needs.

A long road to successful prevention

Anyone who was alive in the 1980s and 1990s remembers the catastrophic early days of the HIV/AIDS epidemic in the United States, a time marked by discrimination, fear, and a frustrating lack of progress in treatment and prevention. Cases grew at a devastating rate, starting in 1981 when there were 270 reported cases of AIDS, the most advanced stage of HIV infection. By the mid-1980s, more than 130,000 Americans were contracting HIV every year. In 1992, AIDS became the leading cause of death for U.S. men between the ages of 25 years to 44 years. Two years later, it was the leading cause of death for all Americans in that age group.

Globally, the epidemic proved just as calamitous. According to UNAIDS, more than 88 million people have acquired HIV since the start of the epidemic, and more than 42 million have died from AIDS-related illnesses. As of 2024, approximately 40.8 million people around the world are living with HIV, including more than 1.2 million people in the U.S. over the age of 13 years.

Since the introduction of the first antiretroviral medication zidovudine to treat HIV in 1987, more than 40 drugs have been approved to treat the virus, including lenacapravir. Yeztugo is the brand name of lenacapavir that is for PrEP, and Sunlenca is the brand name of lenacapavir that is for treatment of HIV. Today, around the world, more than 77% of people living with HIV are accessing antiretroviral therapy.

Still, while the rate of new cases has slowed in recent years, it is still alarmingly high, with 1.3 million becoming infected last year worldwide and nearly 38,000 Americans contracting the virus in 2022, the most recent year data were available.

PrEP plays a major role in helping reduce new cases of HIV. Researchers and care providers began making inroads pharmaceutically in the reduction of HIV cases with the introduction of Truvada in 2012. The concept of using antiretrovirals to prevent HIV was researched for years prior, but the introduction of Truvada marked the first time it became widely available through an FDA-approved medication.

"PrEP works by preventing HIV from establishing a permanent infection in the body," said Murphy. "Oral PrEP involves taking antiretroviral medications that stop the virus from replicating if exposure occurs. Injectable PrEP delivers a long-acting medication that maintains protective drug levels in the bloodstream for weeks or months."

Prior to the introduction of PrEP, "prevention strategies focused primarily on behavior-based interventions, condom use, regular HIV testing, risk reduction counseling, and access to clean syringes for people that use injectable drugs," said Murphy. "Post-exposure prophylaxis was available for emergency situations after potential exposure. PrEP filled a major gap by offering proactive, ongoing protection for individuals at high risk."

The issue with PrEP has long been centered on getting medications to the people who need it most and ensuring that they continue to take it and have access to it. Roadblocks have come in the form of stigma, cost, and awareness, as well as reaching people in regions globally where resources and access to health care may be limited.

UNAIDS notes that risk factors for HIV are compounded by "marginalization, discrimination, and—in some cases—criminalization, resulting in higher median HIV prevalence among certain groups of people," including gay men and other men who have sex with men, sex workers, people who inject drugs, transgender people, and incarcerated individuals.

Beyond access, the long-term success of PrEP for individuals is dependent on adherence, said Murphy. "Consistent use drastically reduces the risk of HIV transmission."

Being able to offer PrEP in an injectable form and as an alternative to daily pills may make a significant difference in people's ability to stick to their regimen of care.

"Oral PrEP must be taken every day, and if a dose is missed, it may lead to lack of protection," said Barnett. "We recommend injectable PrEP if appropriate since it has been shown to be slightly more effective since there is no chance of missing a dose."

Preventing the disease before it starts is not only the right thing to do clinically and morally, but it also helps keep health care costs down for individuals

and for nations. Gilead, the producer of lenacapavir, estimates that a person diagnosed with HIV will end up spending more than $1.1 million on care over the course of their lifetime. For people without health care or safety nets, that cost could be a death sentence.

That is one reason recent cuts to international aid spending have caused deep concern over what happens next in the prevention battle. While U.S. aid continues for the treatment of HIV and AIDS in low-income countries, a number of cuts have gone through for preventative care.

Medicaid cuts in the United States could cause similarly significant disruptions to prevention efforts. A study published in the June 2025 issue of *The Lancet HIV* noted that "PrEP medications are highly efficacious for preventing new HIV infections, but the population impact of PrEP depends on whether prescribed PrEP reaches the people at greatest risk and whether there is adherence and persistence over time." Their study showed that between 2012 to 2022, mean PrEP coverage in the United States skyrocketed from 6% to 26.3%, while HIV diagnosis rates decreased from 13% to 10.6% per 100,000 people.

The study went on to note that decreases in HIV diagnoses were greater in states with higher PrEP coverage. A great many of the people who are accessing PrEP are doing so through the support of Medicaid, not necessarily private insurers.

"Federal cuts have been devastating for PrEP access," Murphy said. "Medicaid is a primary payer for PrEP, especially for underserved communities in the U.S. Cuts will reduce coverage, shrink provider networks, and restrict access to newer formulations like long-acting injectables."

He added, "Internationally, USAID and [the President's Emergency Plan for AIDS Relief] have been essential in scaling PrEP access globally. Reductions in funding could stall or reverse progress, particularly in low-income countries where HIV remains a major public health crisis."

Barnett noted that abroad "each pharmaceutical company has traditionally provided their medications at significantly reduced pricing or free to areas where insurance and income levels are very low."

Gilead last year made a deal to allow six companies around the world to make and sell generic versions of lenacapavir at affordable prices to 120 high-incidence, low-income countries. Until those companies are able to ramp up their production, the company said it would distribute the medication at "no-profit" to 2 million people in those countries, according to *The New York Times*. In the United States, copay assistance programs and patient assistance programs are also available for individuals who are under- or uninsured.

Pharmacist support for PrEP

Pharmacists can play a significant role in helping to inform people about the value of PrEP and encouraging people who would benefit most from the medications to get a prescription and begin care.

"PrEP can be prescribed by any licensed health care provider with prescriptive authority, including physicians, nurse practitioners, physician assistants, and—in a growing number of states—pharmacists," said Murphy.

"Access to injectable options may be more limited due to cost and barriers to health care–administered medications," said Murphy. "Pharmacists in many states can fill this gap by administering injectable PrEP. However, it is important that patients' health insurance cover the costs associated with administering the medication."

For individuals who may want to be on PrEP but who may not understand their options or see a way to pay for their care, Barnett noted that pharmacists should be able to talk with their patients and let them know that patient assistance programs for uninsured and financially qualified patients are available.

"Also, some states have grants to cover the uninsured that pays for labs, provider visits, and PrEP medication, and some HIV prevention clinics offer sliding fee discount programs for the provider visit and labs to accompany the patient assistance medication programs," Barnett said.

Given the important role that pharmacists can and do play in HIV prevention care, it is important that their contribution and value is recognized and that they are paid accordingly by insurers for providing these services.

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In these states, pharmacists can independently prescribe and initiate PrEP, often through statewide protocols. Some pharmacists also may be providing these services in clinics or in community pharmacies.

"Because community pharmacies are so accessible across the country, pharmacist-prescribed HIV PrEP at those locations serves as a great entry point to get patients integrated into the HIV preventative care system," said Murphy.

Pharmacists can also help spread the word about cabotegravir and now lenacapavir and, most importantly, provide access to patients who may not be able to get to their physician or another health care clinic for their injections.

"A growing number of Medicaid and commercial plans are doing so, but we need consistency across all payers in covering and paying for pharmacists' services to ensure that all patients can use their health insurance to receive these important preventative services," said Murphy.

With the advancements in PrEP as well as a growing range of treatment options, the ability to conquer HIV seems closer at hand than ever. Pharmacists can play an invaluable role in helping to get these groundbreaking medications into the hands of the people who need them most, saving lives in ways that were unimaginable in the earliest, darkest days of this ongoing epidemic. ■