Is High Cost Hindering Access to Truvada for PrEP?

Total payments for the HIV prevention pill exceeded $2 billion in 2018.

September 18, 2020 By Liz Highleyman

The rising price of Truvada—including an increase in out-of-pocket costs—may be limiting wider access to pre-exposure prophylaxis (PrEP), according to a recent study by researchers at the Centers for Disease Control and Prevention (CDC). But relief could come in a matter of weeks with the launch of the first generic version of the HIV prevention pill.

Truvada (tenofovir disoproxil fumarate/emtricitabine) was approved for HIV prevention in 2012. Studies have shown that it reduces the risk of HIV acquisition for gay and bisexual men by around 99% if taken consistently.

Since then, PrEP use has risen dramatically, but it is still not reaching everyone who could benefit. CDC researchers have estimated that more than 1 million people in the United States are at substantial risk for HIV and therefore eligible for PrEP, but only around a third of gay and bi men are using it. Usage rates are lower among women, and there are considerable disparities based on age, race/ethnicity, location and access to care.

Advocates have argued that the cost of PrEP is one of the barriers to wider access, and lawsuits have challenged Gilead Sciences' PrEP patents. Truvada typically sells for around $1,600 to $1,800 per month. Gilead offers a patient assistance program for low-income people and a co-pay card to cover out-of-pocket drug costs for those with private insurance. Some state Medicaid programs cover PrEP, and some city and state public health departments provide it for free, but this imposes considerable cost on the health system as a whole.

As described in the Annals of Internal Medicine, Nathan Furukawa, MD, MPH, and colleagues with the CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention looked at national trends in PrEP drug payments from 2014 through 2018.

The researchers used the large IQVIA pharmacy database, which covers more than 90% of retail pharmacy prescriptions, to estimate out-of-pocket and third-party payments—for example, by private insurers or public payers such as Medicaid—for Truvada for PrEP. The database doesn't include prescriptions from closed health systems such as Kaiser Permanente or government systems such as the Veterans Health Administration.

Between 2014 and 2018, annual PrEP prescriptions increased from 73,739 to 1,100,684. Over that period, the average total payment for 30 Truvada tablets—a month's supply using the once-daily regimen approved by the Food and Drug Administration (FDA)—increased from $1,350 to $1,638.

What's more, the average out-of-pocket payment rose from $54 to $94 per month. While the total cost of PrEP increased by 5% per year, the out-of-pocket cost rose by 15% annually. Out-of-pocket payments made up about 6% of the total cost of PrEP, with third-party payers picking up the remaining 94%. Out-of-pocket payments were lower for Medicaid recipients ($3) than for Medicare recipients ($80) or those with commercial insurance ($107).

In 2018, total payments for PrEP added up to $2.08 billion, up from the $114 million spent in 2014. The largest share, $1.68 billion (81%), came from prescriptions for people with commercial insurance. This was followed by $200 million (10%) for those with Medicaid, $48 million (2%) for those with Medicare and $127 million (6%) for those using Gilead's assistance programs.

"The $2.08 billion in PrEP medication payments in 2018 is an underestimation of national costs," wrote the study authors. "High costs to the health care system may hinder PrEP expansion."

This analysis did not include the cost of Descovy (tenofovir alafenamide/emtricitabine), which the FDA approved last year as a second daily PrEP option for some people. The newer formulation of tenofovir (TAF) in Descovy is associated with less kidney and bone toxicity—but more weight gain and blood lipid abnormalities—than the older version (TDF) in Truvada. However, the small differences in kidney biomarkers and bone density may have little clinical relevance for the vast majority of PrEP users who are not at risk for kidney or bone problems.

As the Truvada patent expiration draws near, Gilead has encouraged people to switch from Truvada to Descovy for PrEP, but experts question the cost effectiveness of such a shift.

In a cost-benefit analysis presented at this years Conference on Retroviruses and Opportunistic Infections and published in Annals of Internal Medicine, researchers calculated that Descovy PrEP would be worth no more than a premium of $370 annually—or about $31 a month—over the cost of a generic version of Truvada costing about $700 a month.

"The arrival of generic Truvada will soon present us with an extraordinary opportunity to expand PrEP access to some of our most vulnerable populations," Rochelle Walensky, MD, MPH, of Massachusetts General Hospital and Harvard Medical School, a coauthor of that study, told POZ when that study came out. "Our results indicate that both the rush to transition patients to Descovy and the price being charged for that drug are not justified by its possible benefits. If the manufacturer succeeds in driving out generic Truvada, PrEP expansion in the U.S. could stall."

Walensky also coauthored an editorial accompanying the new study, along with Kevin Ard, MD, MPH, also of Mass General and Harvard.

The 204,720 people who received prescriptions for PrEP in 2018 represent only about 20% of the estimated number of Americans who could benefit from the prevention method, they noted.

In order to reach the national "Ending the HIV Epidemic" goal of reducing new diagnoses by 90% in 10 years, the effort "must start by releasing the cost noose that is strangling its own success," Wallensky and Ard wrote. "Pre-exposure prophylaxis is a potent tool to prevent HIV, but only if we—patients, public and insurers alike—can afford it."

Click here to read the study abstract.

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