

Pre-Exposure Prophylaxis for HIV Remains Inaccessible for Those Most in Need

Introduction

The U.S. Food and Drug Administration (FDA) approved the use of Truvada as pre-exposure prophylaxis (PrEP) for HIV over a decade ago.¹ PrEP continues to be the safest and most effective way to prevent HIV infection. Despite this, PrEP remains inaccessible to those most at risk for HIV. PrEP disparities are glaring on the urban-rural continuum; rural residents are far less likely to initiate and adhere to PrEP than their urban counterparts. Lack of providers, high cost, and stigma are often cited as key barriers to PrEP access among rural residents.

Background

The Human Immunodeficiency Virus (HIV) pandemic has changed greatly since the first domestic reports of the disease appeared in 1981. Novel advances in therapies have prevented tens of thousands of new HIV cases and AIDS-related deaths in the United States to date.² Given access to sustained treatment, a person living with HIV (PLWH) in the United States can expect an average lifespan which is on par with the general population.³

Pre-Exposure Prophylaxis (PrEP) for HIV is a crucial part in the effort to reduce HIV globally. PrEP is a form of medication that can be taken by an individual to reduce their likelihood of contracting HIV.⁴ Two forms of PrEP are currently approved by the Food and Drug Administration for use in the United States: daily oral (approved in 2012) and long-acting injectable (approved in 2021). PrEP is highly effective at preventing HIV infection and has minimal side-effects, such as nausea and fatigue, which tend to fade over time. Studies indicate that, when taken as prescribed, PrEP is 99% effective at preventing HIV acquisition through sex and at least 74% effective at preventing HIV acquisition through injection drug use.

Despite the effectiveness of PrEP, disparities in use have continued since its initial rollout a decade ago. A 2020 report by KFF estimates that only a quarter of people with a clinical indication for PrEP are currently taking the preventative medication.⁵ In 2014, the New York State Department of Health set a goal to increase the number of individuals filing a prescription for PrEP to 65,000 by 2020 as part of the *Ending the Epidemic* initiative. As of 2022, only 55,000 individuals have filed a prescription for PrEP in New York State.⁶ Nationally, HIV rates have increased among racial and ethnic minorities, women, and people living in rural communities. However, these groups are less likely to be prescribed PrEP.

Barriers to Accessing PrEP

Availability of Providers

Though the number of PrEP providers in the United States has increased steadily, demand still outpaces growth.⁷ Consequently, many individuals who could benefit from PrEP live in areas without a provider, known as 'PrEP deserts'. Studies estimate that nearly 20% of PrEP-eligible men who have sex with men (MSM) live more than a 30-minute drive from the nearest provider.⁷ Rural communities make up the majority of these deserts. Given that follow-up appointments are required every 2-3 months, travel time to appointments is a key determinant of PrEP initiation. MSM residing in PrEP deserts are far less likely to take PrEP than those living near a provider.⁷

Cost

The cash cost of initiating daily oral PrEP is estimated to be nearly \$3000, approximately half of which is attributed to laboratory tests and medical visits.⁸ Similar costs are incurred indefinitely throughout an individual's time on PrEP. Since 2021, federal regulations set by the Affordable Care Act require most commercial health insurance plans and Medicaid programs to cover PrEP and associated costs.⁹ Despite this, the true out-of-pocket cost can vary greatly by insurer and state policy. Some commercial insurers may only cover costs associated with one type of PrEP or prescriptions filled at certain pharmacies,¹⁰ leaving patients without a choice.¹¹ Gilead and ViiV, the pharmaceutical companies which manufacture the three available PrEP medications, have created assistance programs to address the high out-of-pocket costs that some patients may face. However, these programs have an expenditure ceiling and most do not cover clinical fees.¹² Thirteen states have established PrEP assistance programs to help cover costs for insured individuals.¹³

Stigma & Discrimination

PrEP use, like other sexual health practices, has been highly stigmatized. There is a belief, for example, that PrEP use promotes promiscuity and sexual 'risk taking'. Additionally, there is a misconception that people who take PrEP are HIV positive, compounding negative views of PrEP and HIV.¹⁴ This layering of biases with PrEP use has been observed with other forms of discrimination, namely racism, homophobia, and transphobia.¹⁵ Institutionalized and interpersonal stigma negatively impacts an individual's ability and willingness to engage with PrEP. A person may be unwilling to initiate PrEP because they fear that their friends, family, partners, or healthcare providers¹⁰ may view them negatively.

National and State Policies related to PrEP Access

Expanding access to PrEP is a key component to national and state HIV control programs. Typically, these programs aim to make PrEP more affordable for both insured and uninsured

patients. The U.S. Department of Health and Human Services launched the *Ready, Set, PrEP* program in 2019, which provides full coverage for PrEP medication to eligible uninsured patients across the country. While this program covers the cost of medication, it does not always cover clinical fees. Payments for these costs are dependent on patient income.¹⁶

As previously discussed, regulatory changes require most commercial insurers and Medicaid programs to cover the cost of PrEP medications and associated clinical costs. However, the continuation of these revisions remains uncertain. The 2023 ruling in *Braidwood Management v Becerra* removes the PrEP coverage requirement for insurers based on religious objections. The Biden administration appealed this decision, and an administrative stay was issued by the 5th circuit Court of Appeals in May 2023.¹⁷ As of February 2024, a final decision in this case has not been made.

Similarly, New York State has prioritized expanding access to PrEP as part of the *Ending the Epidemic* initiative. The states expanded Medicaid program provides full coverage for PrEP medication and clinical costs for enrollees.¹⁸ Additionally, New York has established a statewide PrEP assistance program (PrEP-AP) to cover clinical costs for uninsured PrEP patients. Importantly, PrEP-AP does not cover the cost of PrEP medication.¹⁹ Uninsured patients utilizing PrEP-AP resources must rely on existing patient assistance programs created by PrEP manufacturers to cover the cost of medications.

Summary

Improving access to PrEP is vital to HIV prevention efforts. Current estimates indicate that a national expansion in PrEP access could save \$2.27 billion over a 10-year period. These cost savings are crucial in rural communities which already face shortages in HIV/AIDS care services. However, the National Rural Health Association (NRHA) has yet to adopt a policy position on making PrEP more available. Organizations which advocate for rural health must join other public health lobbying groups, such as American Pharmacists Association and the American Medical Association, to call for eliminating barriers to PrEP initiation. Doing so will ensure that rural residents are not left out of future HIV prevention programs.

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