Is Insurance a Barrier to HIV Preexposure Prophylaxis? Clarifying the Issue

Clinical trials have demonstrated that preexposure prophylaxis (PrEP) protects against HIV infection; yet, even with its approval by the Food and Drug Administration (FDA) in 2012, less than 10% of eligible users in the United States are currently taking PrEP.

While there are multiple factors that influence PrEP uptake and pose barriers to PrEP implementation, here we focus on PrEP's cost in the United States, which, at the current list price of $2000 per month and with high levels of cost sharing, can leave insured users with more than $1000 in out-of-pocket costs every year. We discuss how patient deductibles, monthly premiums, copayments, and coinsurance vary widely and may increase the financial burden. Although drug payment-assistance programs have made PrEP more affordable to uninsured and underinsured users, lack of insurance is a barrier to PrEP accessibility. The FDA approved a generic version in 2017; however, that version has not been distributed to US consumers and may not be more affordable.

As other countries begin implementing PrEP programs, the extent of PrEP's availability as a tool in the global fight against HIV remains to be seen. (*Am J Public Health*. 2020;110:61–64. doi:10.2105/AJPH.2019.305389)

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See also Kapadia and Landers, p. 15; and the *AJPH* Ending the HIV Epidemic section, pp. 22–68.

Since 2012, Truvada, a combination of tenofovir and emtricitabine (commonly referred to as preexposure prophylaxis [PrEP]), has been recommended as an effective method of preventing HIV infection. Clinical trials have shown that, taken daily, it reduces the chance of HIV infection by up to 99% for those with higher rates of adherence and increased concentrations of PrEP.[1] The Centers for Disease Control and Prevention (CDC) estimate that among gay and bisexual men living in the United States, who are at increased risk for HIV and comprised 67% of all new infections in 2015,[2] more than 800 000 could potentially benefit from PrEP. Regrettably, only about 8% of all people who could benefit from PrEP are taking it.[3] One major barrier is the cost of PrEP, which is manufactured solely by its patent holder, Gilead Sciences Inc; its current list price is about $2000 per month. By contrast, antiretroviral therapy, which is prescribed to people living with HIV to suppress viral replication, has more than 20 US Food and Drug Administration (FDA)–approved medications, with generic options available. Having more drugs on the market increases competition, which may help lower the list price.

In November 2018, the US Preventive Services Task Force (USPSTF), an independent review panel of US disease-prevention experts, issued a draft recommendation for PrEP to be recognized as an A-grade preventive service against HIV infection. The USPSTF assigns an "A" to services for which there is "high certainty that the net benefit is substantial" (http://bit.ly/33BDRgS). Under the provisions of the Affordable Care Act (Pub L No. 111-148), insurance companies must provide these services to consumers without any cost sharing. Yet, it is not clear whether medical visits and laboratory tests, recommended by the CDC for ongoing PrEP users (HIV and other sexually transmitted infection tests, serum creatinine and calculated creatinine clearance, and pregnancy testing for females), will be restricted from cost sharing. The literature suggests that these additional costs may make PrEP too expensive for the populations for whom PrEP is most recommended, which include men who have sex with men (MSM), adolescents, persons with serodiscordant sexual partners, persons who inject drugs, and persons involved in commercial sex.[4–10] In this commentary, we discuss cost, lack of insurance, and other barriers to PrEP access. Though we focus on PrEP use in the United States, we also discuss PrEP uptake in other areas of the world and provide potential policy solutions to increase PrEP affordability.

THE COST OF PREEXPOSURE PROPHYLAXIS

Someone without insurance drug coverage or qualification for drug-assistance programs would pay about $8000 for a year's worth of PrEP.[11] Even before 2012, when the FDA approved PrEP for HIV prevention, its high list price prompted discussions about cost that continue today. Stakeholders have questioned which programs ought to provide oversight and financial assistance; in the past, PrEP as prevention was thought to fall "somewhere between HRSA's [Health Resources and Services Administration's] and CDC's responsibilities."[12] However, for several years, PrEP provision has primarily fallen under the purview of insurance programs and pharmaceutical companies. To help those eligible for PrEP navigate their insurance and payment options, the CDC has compiled a resource guide, *Paying for PrEP* (http://bit.ly/2ITPyHL), which provides information for those who fall into one of the following categories: insured, uninsured or eligible for insurance, uninsured or not eligible for insurance, or insurance denies claim. Table 1 provides examples of PrEP

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TABLE 1—Preexposure Prophylaxis Payment Options and Associated Costs

Health Payer	Health Payer Type	Eligibility	Average Cost or Rebate Per Year
Medicaid	State-administrated public insurance program	Medicaid expansion states only: ≤138% of the FPL for adults aged 18–65 y All states Low-income parents and their children Pregnant women People with disabilities Low-income seniors aged ≥65 years	Nearly free for Medicaid enrollees with incomes <150% FPL
Medicare	Federal public health insurance program	Aged ≥65 years Receives Social Security Disability Insurance	Varies by state or county and plan Prescription drug plan example: $2276–$2430 (including deductibles, monthly premiums, copays, and coinsurance)
Private insurance	For-profit insurance plans sold by health insurance companies	Enrolled in a commercial insurance plan Spouse or dependent of someone enrolled in a commercial insurance plan	Varies by state or county and plan Low deductible plan example: $162–$243 for year's supply $500 deductible 20% coinsurance fee after deductible
Gilead Advancing Access	Federal drug assistance program	Uninsured Commercially insured	Free for uninsured individuals Up to $4800 rebate for commercially insured individuals per year
Patient Advocate Foundation's Co-Pay Relief Program	501(c)(3) nonprofit drug assistance program	Insured individuals with annual incomes <400% FPL	Up to $7500 rebate for drug costs per year
PrEP Drug Assistance Program	State drug assistance program	Uninsured or underinsured PrEP users living in Washington, Colorado, New York, Illinois, or Massachusetts	Free for low-income individuals (FPL limit varies by state)

Note. FPL = federal poverty level; PrEP = preexposure prophylaxis. Total costs for insured users may vary by state, county, and plan.

insurance and drug assistance program payment options along with their estimated yearly average cost, each discussed here.

Medicaid covers PrEP and, because federal laws limit copayments to "nominal amounts" for individuals with annual incomes under 150% of the federal poverty level (FPL), PrEP is nearly free for low-income individuals. However, states may set their own copayment standards for people with incomes over 150% of the FPL. Furthermore, eligibility criteria vary from state to state because of unequal Medicaid expansion. In expansion states, adults aged younger than 65 years are eligible for Medicaid if their annual income is less than or equal to 138% of the FPL. However, in nonexpansion states, adults without children or disabilities, even with the lowest incomes (below 100% FPL), are not eligible for either Medicaid or subsidized private health insurance. These individuals fall into the "coverage gap"; their incomes are, perversely, too low to meet enrollment eligibility criteria.

Medicare coverage for PrEP is even more inconsistent. For example, the prescription drug–pricing Web site GoodRx (https://www.goodrx.com) lists the postdeductible copay range for Truvada as between $42 and $2078. The "Medicare Plan Finder" function on Medicare's Web site helps narrow the expected price range, though the price varies on the basis of a number of criteria, including whether enrollees have "original Medicare" or a Medicare health plan and whether they also have Medicaid, Supplemental Security Income, or a Medicare savings program. Using this search function, we estimated out-of-pocket PrEP costs for Medicare enrollees in our zip code (48109). We found 55 plans available: 24 prescription drug plans, 27 Medicare health plans with drug coverage, and 4 Medicare health plans without drug coverage.[11] Including deductibles, monthly premiums, copays, and coinsurance, the total annual cost for PrEP for someone with a prescription drug plan would come to between $2276 and $2430. For someone with a Medicare health plan with drug coverage, the annual cost for PrEP would range from $1354 to $2277. As this one example shows, there are many possible Medicare plans, but without additional insurance or payment assistance, PrEP costs more than $1000 a year.

Private insurance plans have varying costs, and copay ranges are difficult to estimate. Using one of our personal plans as an example, 200 to 300 milligrams of PrEP could cost between $40 and $60 for a 90-day supply (and $162–$243 for year's supply). Yet, even in this case, there are additional costs beyond the copay: a $500 deductible and, once that amount is reached, a 20% coinsurance fee for the medical visits and laboratory tests that are required every three months for ongoing PrEP use. For plans with higher deductibles, which are rapidly increasing in the United States, patients must pay for more services out of pocket before the deductible applies, which may cost prohibitive for some PrEP users.

Drug payment-assistance options are available for uninsured or underinsured PrEP users, although these do not cover laboratory or medical-visit costs. The Gilead Advancing Access program offers a rebate of up to $4800 per year to commercially insured individuals (provided enrollees do not receive any federally funded assistance such as Medicare or Medicaid), while uninsured individuals may receive PrEP for free. The Patient Advocate Foundation's Co-Pay Relief Program, a 501(c)(3) nonprofit organization that provides medical financial aid, will also cover up to $7500 in drug costs per year for insured PrEP users with annual incomes of less than 400% of the FPL.

PrEP Drug Assistance Programs are modeled after the Ryan White HIV/AIDS Program (RWHAP), which provides medical care and social services to uninsured and underinsured people living with HIV. However, RWHAP does not cover medical services for individuals who are HIV-negative and therefore does not provide payment assistance for PrEP. In a 2016 policy notice, the Health Resources and Services Administration's HIV/AIDS Bureau "strongly [encouraged] Ryan White HIV/AIDS Program (RWHAP) recipients and providers to leverage the RWHAP infrastructure to support PrEP services within the parameters of the RWHAP legislation" (http://bit.ly/2OMpcei). Since then, several states have created programs like the RWHAP's AIDS Drug Assistance Programs. For example, using the AIDS Drug Assistance Program model, Washington, New York, Colorado, Illinois, and Massachusetts have created PrEP drug-assistance programs using state or local funds. In these five states, uninsured or underinsured PrEP users can apply for help from the programs, which will cover the cost of PrEP and associated laboratory visits.

LACK OF INSURANCE NOT THE ONLY BARRIER TO ACCESS

We recently conducted a search of the literature with previously described search criteria[13] and found eight papers that discussed funding, insurance, or both as potential barrier to PrEP implementation in the United States. By looking at the trajectory of these PrEP implementation barriers over a decade, we can see how cost-related concerns have been identified at different times.

In articles published between 2007 and 2017, a period that included the inception of PrEP implementation, the prevalent anticipated barriers concerned young individuals covered by their caregivers' health insurance who might be unable to access PrEP services if a prescription required parental or guardian consent.[4–6] Other barriers identified by MSM and transgender women were expensive insurance copays,[14] lack of insurance, and limited transportation or work-schedule constraints that made accessing services difficult.[15–17] Medical providers noted insurance as an anticipated barrier to prescribing PrEP for their patients.[18]

In articles published in the past year, insurance is not cited as frequently as a barrier to PrEP implementation. Current articles are more likely to describe actual, instead of anticipated, barriers. In one study of young Black MSM, even when PrEP was offered for free, PrEP uptake remained lower than expected. The authors hypothesized that this was likely because participants' perceptions of their own HIV risk were low.[19] Three articles suggested that insurance and cost were not significant barriers to PrEP implementation among MSM, the majority of whom had insurance,[20,21] or transgender women,[7] who discussed how they were able to access PrEP for free.

Other recent studies identified high costs and lack of insurance as barriers to PrEP implementation, both among PrEP users generally[22] and within specific populations. For example, in a survey of 138 persons who inject drugs, about one third reported lack of insurance as a barrier to PrEP use,[8] while another survey found that uninsured young MSM had lower rates of PrEP uptake than their insured counterparts.[9] Even the insured cited cost as a barrier to accessing PrEP. In a study that investigated reasons for PrEP discontinuation among gay and bisexual men, 30% of participants cited the high cost of prescription copays as a reason.[10] High deductibles and copays were also cited as key barriers among MSM and transgender women.[7] So, while insurance may certainly facilitate PrEP use, these studies indicate that insurance may also be cost prohibitive for some users. Given the steep price of PrEP and the eligibility criteria for payment-assistance plans, insured patients above certain income levels might be unable to afford PrEP.

INSURANCE-RELATED COSTS CAN HINDER ACCESS AND UPTAKE

In a seminal 2003 article in *Health Affairs*, Anderson et al. noted that the United States spends more on health as a percentage of gross domestic product than any other country in the world, even though its use of health care services remains lower than that in many industrialized nations.[23] With its pithy conclusion, "It's the prices, stupid,"[23] the article remains as relevant as ever. In 2017, persons in the United States spent $57.8 billion on out-of-pocket costs for prescription drugs, even as pharmaceutical companies and manufacturers were projected to enjoy a 2% to 5% net growth in profits by 2022.[24] It is expected that specialty medications, including those requiring long-term use, will make up a large portion of this growth.[24]

PrEP is, and will likely continue to be, a costly drug. Though the FDA approved a generic version of it in 2017, it has not yet been distributed to US consumers, and there is no guarantee that the generic version will be more affordable. For now, PrEP's high list price means that though insurance companies may technically cover a prescription, insured patients are still left with hundreds or even thousands of dollars in cost sharing. Effectively, PrEP may be more affordable for uninsured persons and those who qualify for payment-assistance programs than for those who are insured. So, while the cost of PrEP is a problem, insurance is not necessarily the solution. Cost is also not the only obstacle PrEP users may face: as described previously, barriers to PrEP implementation occur on many levels, and not in isolation.[12]

For example, the waiting period between providers' receipt of PrEP-associated laboratory results and ability to fill PrEP prescriptions may pose a barrier for vulnerable populations who

cannot access or advocate for condom use and who may become infected during this time. Insurance may pose a barrier for young adults who, under the Affordable Care Act, can stay on their parents' insurance until they are aged 26 years. Because Gilead's Advancing Access program provides free PrEP only to uninsured persons, young adults covered by their parents' insurance who are concerned about confidentiality and disclosure may be dissuaded from taking PrEP.

PrEP is still quite new, and many countries are just beginning to consider its implementation as part of their HIV-prevention plans. For example, in China, where antiretroviral therapy is freely available to people living with HIV, PrEP has not been as readily embraced by the health care system.[25] The European Union did not approve Truvada as an HIV-prevention drug until September 2016. In 2017, Brazil became the latest country to provide free PrEP prescriptions to eligible persons, a move that has inspired PrEP advocacy elsewhere in Latin American and Caribbean countries. The extent to which PrEP will be embraced in the global fight against HIV remains to be seen, and both attitudes toward and the stigma attached to vulnerable populations (e.g., sexual minority groups) will play a large role.

POTENTIAL POLICY SOLUTIONS

While there are many reasons why people eligible for PrEP may either opt out or be unable to take it, it is clear that cost—for both uninsured and insured PrEP users—is a key barrier for some. To increase PrEP's affordability for insured users, it is important that the USPSTF's draft recommendation for PrEP as an A-grade HIV prevention tool is upheld, and that the restriction on cost sharing applies to laboratory tests as well as medication costs. Having a generic version of PrEP on the market is also important, as it has the potential to drive down costs. For uninsured users, drug assistance programs are vital. However, unequal Medicaid expansion across states has left more people uninsured in nonexpansion states, therefore placing a strain on drug assistance programs that may not withstand higher number of PrEP users in the United States. Nationwide Medicaid expansion would likely increase PrEP access and affordability. AJPH

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Both authors co-developed the theme of the article. E. S. Kay was involved in the research and writing of the article, on which R. M. Pinto provided feedback.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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