

# **The Increasing Cost of Truvada: An Increase in the Contraction Rate of HIV: A Policy Alternative**

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## **Abstract**

There is a growing population of individuals who cannot afford the prevention treatment, Truvada (PrEP), for HIV infection. Those insured with private health care are able to afford this treatment as it is taken from deductibles allotted in the plan. Mostly seen in areas of low income, individuals who need this treatment for life saving reasons, are unable to have access to programs or doctors who can provide the medication. This paper evaluates the effect that the increasing cost of HIV prevention treatment has on individuals with no private insurance. Arguments for different policy alternatives needed to allow equity transparency within the pharmaceutical industry is also examined.

## **Keywords**

Healthcare Policy, Alternative policy, HIV/AIDS, pharmaceuticals, PrEP, Social Justice

## **PrEP as a Prevention Tool**

Findings from the Center for Disease Control (CDC) (2020) conclude that transmission rate modeling estimated 49% of HIV transmissions were from 20% of person(s) living with HIV who were unable to treat

the disease. The increase in infections shows a decrease in the percentage of persons with viral suppression who can be linked to care. Roughly 1.1 million people in the U.S. are currently living with HIV, and nearly 40,000 Americans become infected with the virus each year (CDC Report, 2020). Improving all stages of HIV care will substantially reduce transmission rates and one key part of this care is the use of Truvada (PrEP), or Pre-exposure Prophylaxis, to act as an aid in prevention. Those who need prevention fall in two categories: high risk individuals and individuals with partners who have HIV. High-risk individuals consist of gay and bisexual men of all races and ethnicities, African Americans, Latinos, injection drug users, and transgender individuals (CDC, 2020). These categories all represent individuals who are severely and disproportionately affected by this epidemic (CDC, 2020). High risk individuals account for more than 70% of the use of PrEP, these individuals are mostly a part of the LGBTQ community and are a target group for taking this treatment. HIV is not selective; it is a virus that can transmit to anyone and everyone. Unfortunately, the climbing cost of PrEP has now become a barrier for HIV negative individuals seeking treatment to remain uninfected.

## **Current Barriers to PrEP**

According to the CDC, PrEP is more than 90% effective in HIV prevention when taken daily (2019). Studies show that among high-risk men who have intercourse with other men, PrEP reduced the absolute risk of acquiring HIV infection from 5.3% to 2.9% (Coutinho & Prasad, 2013). One in 5 people who have partners with HIV say that they cannot afford the high price of PrEP and are subject to the possibility of HIV transmission. Those who cannot afford PrEP are in a state of despair, living a life full of fear that they might contract this debilitating disease.

Gilead Sciences, a research-based biopharmaceutical company who developed Tenofovir Disoproxil Fumarate with Emtricitabine (TDF-FTC), the main ingredient in PrEP, carried their drug with a list price of close to \$2,000 for a 30-day supply (Coutinho & Prasad, 2013). From

2012 to 2014, about 3,200 people filled prescriptions for PrEP in the first two years after its approval. That number is in comparison with the nearly 40,000 people a year in the United States who contract HIV (CDC, 2020). Those lucky enough to have private health insurance pay little or nothing for their monthly treatment but the same cannot be said about individuals who have public insurance or utilize financial assistance programs.

## **Low Capacity to Pay**

Individuals with public insurance (Medicaid or Medicare) or those who utilize financial assistance are among the ones with the lowest capacity to pay the high cost of PrEP. There are various financial assistance programs available to those who do not hold insurance, such as Gilead Sciences Advancing Access Medication Assistance Program (Gilead, 2020). This program covers a portion of the out-of-pocket costs for Truvada, mostly up to \$7,200 per year, which only covers a full 30-day-supply for four months. Since the price of Truvada is around \$2,000 monthly, this leaves those who do not qualify for financial assistance or public insurance to continue to pay the demanding price of this prescription. The average price of a 30-day supply rose from \$1,350 in 2014 to \$1,630 (5% compound annual growth rate [CAGR]) in a matter of 4 years (Furukawa, 2020). The wholesale price of PrEP has increased by 45% from 2014 to 2018 at average Wholesale Acquisition Cost (WAC) of \$48.51 (Vázquez, 2020). This means that a 30-day-supply of PrEP would be \$1,755.30, direct to consumer. This creates a barrier to access for this product, which results in the restricted exclusion of PrEP only to those who can afford it. Given the necessity of this drug to help curb the transmission of HIV, the out-of-pocket cost paid by the consumer needs to be decreased to allow for larger consumption of the treatment. This drastic increase in price has left hundreds, if not thousands, of individuals without treatment due to their lower capacity to pay.

Employers that utilize private insurance companies (Anthem, United Healthcare) as a part of their benefit package have allowed the use of

co-pay coupons to help offset the cost of prescription medication and, specifically, they have used it to cut the cost of the monthly supply cost of PrEP. On average, an individual with private health insurance, using a co-pay coupon, will spend around \$94 a month to prevent transmission of HIV (Kates, 2021, par. 11). With the current rollback of co-pay coupons by Gilead Sciences, those who hold private insurance are subjected to the same price of PrEP as individuals with public health care, nearly \$2,000 for a 30-day-supply (Gilead, 2020). In the long run, in order to keep a constant supply of PrEP every month, the consumer is expected to pay roughly \$20,000 a year for prevention treatment (Vázquez, 2020). Luckily, there are some options available to help with the costs of PrEP for public insurance holders, but even with assistance these individuals are still expected to pay upwards of \$300 for a 30-day supply each month.

## **Effect of No Treatment**

The American Psychological Association termed the word “displaced” when describing individuals who cannot receive prevention treatment to help curb this disease (Lordan, 2011). Those with public insurance have little to no assistance resources when it comes to funding for PrEP. These individuals are living in a state of fear, concerned when and if they are going to contract this deadly virus. Those who are lucky enough to afford PrEP state that they “have little fear of contracting HIV” (Luthra, 2018). How does society combat the fear in persons who cannot afford this treatment? How can society increase the life expectancy of individuals while also decreasing a worldwide epidemic? Creating further policy alternatives and recommendations are needed for these individuals to get the prevention treatment they deserve.

## **Policy Options**

### **Reimbursement Plans for Public Insurance**

When it comes to being able to afford PrEP for prevention treatment of HIV for those who hold public insurance, there are a few policy options that need to become available. One of those is a reimbursement plan needed for public insurance.

With the increasing cost of PrEP, those insured under public insurance are more than likely not to continue with their treatment after the first month. Currently, law makers are working to reconstruct Medicare Part D by decreasing the government's share of coverage from 80% to 20% over four years, creating more cost for patients (McDermott, 2016). This would shift the out-of-pocket (OOP) cost from the insured to the insurer, in this case Medicare/Medicaid. AARP urged lawmakers to adopt reforms to keep lower OOP, including the Bipartisan Budget Act of 2018. When looking at the 60% delta (the change from original OPP to adjusted OPP) availability left to the states after this federal mandate, the states will have more funding to be able to provide those who have public insurance the means to have access to this preventative care.

To understand how HIV treatment and price affect an individual has to look at the Quality Adjusted Life Year (QALY). QALY is a generic measure of disease burden, including both the quality and the quantity of life lived. Essentially, an economic evaluation to assess the value of medical interventions. HIV interventions intended to improve and/or extend the lives of HIV positive or negative persons is evaluated to determine QALY index. The QALY index of those who take PrEP daily is seen to be increasingly higher than those who have no care at all. According to the CDC, programs with a conservative threshold are more likely to benefit from the cost-effectiveness of the treatment, specifically when it comes to prevention of HIV. Those who do not receive treatment for prevention essentially become less involved in society and essentially have a lower QALY compared to those who receive treatment.

Since public reimbursement programs are prospective to the states, speculation can be placed to state ran public health insurance programs. Creating a reimbursement plan for individuals with public insurance will give these insurance programs the power to negotiate with pharmaceutical manufacturers of PrEP. This leads to higher reimbursements to persons who hold public insurance, and they will no longer feel the effect of not having treatment.

## **Fixed-Price for PrEP**

The current status quo of having a higher price for prescription drugs, allowing a higher profit margins for pharmaceutical companies, is disproportionately affecting the individuals requiring treatment. Creating a price-cap for PrEP will not only reveal transparency between Gilead Sciences and the consumer but it will also allow the company to lower the cost of PrEP. If the federal government were to create a price cap on a PrEP, then private insurances and public insurances would still be able to set their own individual price of the drug. With a price-cap, the money that is spent over the cap would then have to be distributed back to beneficiaries in the form of reimbursement, leading to a lower cost of PrEP in the long run (Anderson, 2019, par. 1). The lower the cost, the more accessible this prescription is to those who need it. Medicare Part D and Medicare Advantage demonstrates the successes possible when consumer choice and private sector innovation are used to lower the cost of PrEP. A fixed price for PrEP will decrease costs for taxpayer-funded programs such as Medicare and Medicaid, and those individuals affected by HIV may feel more comfortable with the way states charge individuals who hold public health insurance. Lowering the price of PrEP will lead to more generic options being produced, which will essentially lead to more competition within the industry. This increased market competition will drive price down drastically, making PrEP more accessible to everyone. Competition in this industry regarding a more generic option could lead companies to stop shifting money into their research and development aspects (Congressional Budget Office, 2021). If this were the case in terms of PrEP, then we should expect one company, most likely Gilead Sciences, to take the lead in production and distribution and fall out of market competition by being one of the only companies to supply PrEP.

Fixed pricing is intended to attract more customers and clients because it offers them assurances. With the consistency of PrEP being a fixed price, consumers without private insurance will have access to start the prevention treatment and will allow the business model for the companies creating this treatment to benefit as well. This price-cap will also

allow sales forecasting and profit estimates to be simpler for the manufacturer. Rather than wasting taxpayer dollars counting and revising hours needed to develop new ways for prevention treatment, the manufacturer can focus on the results to be delivered. With a fixed-price prescription, the burden of administrative costs significantly decreases, allowing time to be spent where it should be – creating and developing better prevention options.

Furthermore, containing the price of PrEP to a single margin will allow a copay from public insurances for the consumer. Public health insurance plans only allot a certain number of pharmaceuticals to be counted towards the deductible in the plan, and until recently PrEP was not one of them. Due to this, individuals with public insurance do not have the ability to use their deductible to pay for PrEP, instead, they have to pay the full amount. Allowing PrEP to be taken from a copay, whether public or private insurance, it will alleviate the burden given to the consumer for a prescription that is essentially life or death. Hopefully, this strategy will allow more individuals to take a daily treatment of PrEP for prevention as it will become more affordable.

## **Optional State Mandates**

Throughout the country, many state mandates are placed on prescriptions, especially when it comes to the opioid pandemic. Prescription drug monitoring programs (PDMPs) are operated and mandated at the state level to ensure practitioners and prescribers have the information they need to identify those most at need for certain prescriptions (Wickramatilake & Zur, 2017). With the benefit of doctor-patient confidentiality, patients will not have to worry about having their sexual orientation being used to determine their eligibility for the PDMP. The advent of state-mandated formularies provides clarity on which medications have proven efficacy for treatment. All studies show that PrEP is more than 90% effective when taken daily compared to those who have taken it sporadically or have no preventative treatment at all (Coutinho & Prasad, 2013). By allowing a state mandate for PrEP,

the federal government would have no intervention in the price of the drug, which means that production and distribution responsibility will be that of the state. Without federal intervention, we will see that more research and development can be made in companies in different states allowing companies to expand on their efforts to provide a medication that has a proven efficacy for treatment.

The adverse effect of conservative states not having policies to support this position is possible, as states have the benefit of creating programs based on their Medicaid expansion. The benefit of having a state ran program is that the state can set a price for the prescription based the needs of the population. Certain states such as California and New York will provide citizens with a cheaper option for PrEP as they have expanded Medicaid to provide for the ever-expanding at-risk population. States that are not as progressive as these will more than likely take influence and shape policies or procedures based around the actions taken by progressive states. As stated before, PrEP benefits everybody and it is not selective based off of your sexual orientation. Individuals who have a high amount of sexual intercourse with unknown partners or partners who are not regularly tested are considered at-risk as well (Wickramatilake & Zur, 2017).

Having state mandated pharmacy benefits will allow the federal government to set broad requirements for public health insurance to decrease the cost of their prescription with the incentive of a tax cut or benefit package from the state. If PrEP were to be pushed for those at high-risk of the contraction of HIV, public health insurance will have the ability to regulate the prescription when it comes to copays and insurance benefits. State mandates allow the consumers to feel that they have the necessary access to prevention treatment and will decrease their disability-adjusted life year (DALY) and increase their QALY. This option will show an efficient and effective use of health care resources and result in decreased medical costs, increase patient access to care, and increase quality of care.



## Policy Recommendations

Individuals with public insurance, or no insurance at all, cannot afford to continue to pay more than anyone else for the same prescription drug. Only 18% of patients requiring PrEP had coverage and almost half did not continue the medication for the entire year due to the increasing cost (Coutinho & Prasad, 2013). The World Health Organization stated in their 2025 vision that health care is a right to everyone. Having a prescription drug that exceeds one's capability to pay, interferes with this right. Creating more acquirable means to access this prevention medication is necessary in order to decrease the rate of transmission of HIV and it will promote the lives of patients and their loved ones.

## Conclusion

The HIV epidemic has shown that pharmaceutical companies are creating a disadvantage for individuals who cannot afford the prevention treatment PrEP. The most displaced of these individuals are gay and bisexual males who have become the most at risk for contracting HIV. By creating policy initiatives to decrease the price of the prescription, then the barrier for these individuals will slowly diminish. Creating reimbursement plans for public insurance, setting a fixed price for PrEP and allowing state mandates will create the incentive for more people to start treatment for the prevention of HIV. This will drastically change the numbers we see in the increase of HIV positive patients and it will provide for a better life for the consumer in the long run.

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## **Appendix**

### *Key findings for the use of PrEP as a prevention treatment for HIV*

- **Prescriptions rose from 73,739 in 2014 to 1,100,684 in 2018**
- **TDF-FTC tablets dispensed rose from 2,534,309 in 2014 to 37,988,487 in 2018**
- **Patients receiving PrEP increased from 20,315 in 2014 to 204,720 in 2018**
- **Average price rose from \$1350 to \$1638 (21.3%, or 5% compound annual growth rate (CAGR))**
- **Average OOP payment rose from \$54 to \$94 (74.1%, or 14.9% CAGR)**

DALY: Disability-Adjusted Life Year is a measure of overall disease burden, expressed as the number of years lost due to ill-health, disability or early death. In comparison to QALY, DALY gives the measure of an individual's life in terms of years lost while QALY gives a measure of an individual's life based upon a disease. DALY is a quantitative measure while QALY is a qualitative measure.