CALIFORNIA
HIV / AIDS POLICY
RESEARCH CENTERS

# *Evaluating the Impact of Prior Authorization Requirements for PrEP and PEP in California*

## Executive Summary

In response to California Senate Bill 159, the Southern California HIV/AIDS Policy Research Center conducted a rapid response study, interviewing clinical providers and navigators of pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) to investigate the impact of prior authorization requirements on access and patient adherence to PrEP and PEP in California. We interviewed a total of eight PrEP/PEP clinical providers and navigators from June to August 2019. Findings from our study illustrate that key informants perceive prior authorization as a barrier to HIV prevention. All eight providers interviewed had experiences with prior authorization requirements for PrEP; three out of eight providers had experiences with prior authorizations for PEP. Generally, participants expressed concerns about prior authorization and its consequences. In their estimation, prior authorization delays access to PrEP and PEP and reduces patient adherence to PrEP. Participants' perspectives indicate that state legislation, which removes prior authorization requirements, may facilitate PrEP and PEP access and patient adherence.

## Background

### *Pre-Exposure Prophylaxis and Post-Exposure Prophylaxis*

Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are widely accepted as critical tools to ending the HIV epidemic in California and across the country. PrEP is a method of HIV prevention in which HIV-negative individuals take antiretroviral medications before coming into contact with the virus to reduce their risk of becoming infected. PrEP is proven extremely effective, reducing the risk of contracting HIV from sexual intercourse by 99% and from injection drug use by 74% (Harawa, et al., 2018).

PEP is an HIV prevention strategy in which HIV-negative individuals take antiretroviral drugs after a potential exposure to prevent HIV infection (CDC, 2018). PEP is only used in emergency situations and must be administered within 72 hours. Every hour counts when it comes to PEP.

Despite the importance of these biomedical prevention interventions, recent analyses suggest that less than 25 percent of individuals who could benefit from PrEP are currently taking it (National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 2019). PrEP uptake has been lowest among populations most affected by HIV, including Black and Latinx individuals, women, and youth (California HIV/AIDS Research Program, 2018). Medical providers and patient advocates have cited insurance prior authorization requirements as a key barrier to PrEP access and adherence (Petroll, A. E. et al, 2017; Rumohr, 2017).

## *Prior Authorization*

Prior authorization (PA) is the practice of requiring that a medication receive special approval by an insurance company before it can be dispensed by a pharmacy. Health insurers sometimes use PA to protect patient safety when a medication is contraindicated for certain individuals. However, health insurers are increasingly using PA as a cost-saving measure to limit use of high-cost medications (Soumerai, 2004). Truvada®, currently the only medication approved for PrEP in the United States, can cost anywhere from $1,600 to $2,000 for a 30-day supply.

Use of PA as a cost containment strategy has been highly successful. One study by the Government Accountability Office estimated that PAs saved Medicare as much as $1.9 billion from 2012-2017 (U.S. Government Accountability Office, 2018). From a patient care perspective, however, the perceived benefits are not as explicit. Theoretically, the clinical benefit of PA lies in preventing the over-prescription of medicines (Mendelowitz, 2019). However, prior research indicates that the overwhelming effects of PA requirements have been fewer prescriptions filled and negative impacts on medication adherence (Abdelgawad et al, 2006; Ridley et al, 2006; Wilson et al., 2005). PA for HIV treatment has also been shown to significantly delay access to medications and increase costs for health care providers (Raper et. al, 2017). While few studies have examined the impact of PA for PrEP and PEP, a recent study identified PA as a significant barrier to PrEP prescription by medical providers (American Medical Association, 2018).

Medi-Cal, California's Medicaid program, removed a requirement that doctors complete a Treatment Authorization Request (TAR) when prescribing Truvada® in 2014. According to the Department of Health Care Services, Medi-Cal does not require a TAR for PrEP and PEP as the department "understands the consequence of delaying or denying access to these life-altering medications" (State of California, 2007). This policy shift reflects the general understanding that any additional administrative processes required in the dispensing of PrEP and PEP is a potential barrier to PrEP/PEP access.

A recent review of Covered California health plans by CHPRC found that four out of eleven insurers currently require PA for Truvada®. These insurance providers include Chinese Community Health Plan, LA Care Health Plan, Oscar Health Plan of California, and Valley Health Plan. According to the Centers for Disease Control and Prevention, the preferred regimen for PEP includes Truvada® plus Isentress® or Tivicay™. Our review did not identify any Covered California health plans that currently require PA for Isentress® and Tivicacy™.

## *California Senate Bill 159*

Currently pending in the California State legislature is Senate Bill 159 sponsored by Senator Scott Wiener (D-San Francisco). Among other provisions, the bill would prohibit health plans and insurers from requiring PA or step therapy for PrEP and PEP (CA S.B. 159, 2019). The bill would also allow a pharmacist to furnish a 60-day supply of PrEP and a full course of PEP provided certain conditions are met.[1]

A recent analysis by the California Health Benefits Review Program found that "there is insufficient evidence that prohibiting [PA] increases the likelihood that health professionals with prescribing

1 See Koester, et al., 2019 for more information relating to the feasibility of pharmacists to deliver PrEP and PEP in the state of California. Findings suggest that pharmacists who were interviewed in the study perceive themselves to be capable of prescribing and administering PrEP and PEP to patients. Medical providers that were also interviewed voiced support and concern. While pharmacist driven delivery increases access, some medical providers see the lack of intensive training for diagnosis and medical condition management to be a challenge.

authority will prescribe PrEP or PEP, improve adherence to PrEP or PEP, or improve health outcomes for people taking PrEP or PEP. However, there is limited evidence that [PA] requirements for medications used to treat HIV delay receipt of care." The analysis concluded, "It is possible that prohibiting [PA] would enable people to obtain PrEP or PEP more quickly, which is especially important for PEP because PEP is only effective if it is initiated within 72 hours of known or suspected exposure to HIV" (California Health Benefits Review Program, 2019).

## Aims of the Study

Given the paucity of data regarding the impact of PA on PrEP and PEP uptake, , the Southern California HIV/AIDS Policy Research Center sought to better understand the impact of PA on PrEP and PEP access and adherence from the perspective of providers. Specifically, the study aimed to:

1. Examine the impact of PA on timely access to PrEP and PEP; and

2. Determine whether PA impacts patients' PrEP and PEP adherence[2].

## Methods

From June through August 2019, we collected data through semi-structured qualitative interviews with clinical providers of PrEP/PEP and PrEP/PEP navigators who work at state-funded enrollment sites for the PrEP-Assistance Program (AP). The PrEP-AP provider network is comprised of clinical service providers contracted by the State Office of AIDS to provide PrEP-related medical services (California Department of Public Health, 2019). Clinical and social services sites that are part of the PrEP-AP Provider Network across California also provide access to PrEP navigators, individuals that facilitate access to no and low-cost PrEP services. To be eligible for the study, participants needed to work in an enrollment, provider, or administrative capacity focused on the delivery of PrEP and/or PEP. Participants also needed to be familiar with health insurance PA requirements and health insurance plans that specifically require PA for PrEP and/or PEP. The study did not enroll individuals from pharmaceutical or insurance companies.

Eight interviews were conducted and audio-recorded through *Zoom*, an online meeting platform. Quotes from interviews were transcribed verbatim and narrative reports were created for data analysis. We followed the Rapid Assessment Process (RAP) at the conclusion of each interview (Hamilton, 2013). Through this process, study staff drafted summaries of the interview, debriefed after each interview to identify common themes among providers' experiences and drafted a narrative report for each interview. After completing all reports, data from the interviews were coded to highlight main themes according to the frequency of similar narrative responses to interview questions.

Of the eight providers interviewed, three worked at clinical sites in Northern California and five worked at clinical sites in Southern California. Participants were compensated $50 for their time in the form of an electronic gift card.

## Results

Our analysis of the California PrEP-AP providers perspectives yielded **three themes**: (1) prior authorization negatively affecting **access** to PrEP; (2) prior authorization negatively affecting **adherence** to PrEP; and (3) prior authorization for PEP as undermining HIV prevention efforts.

2 This study did not evaluate the impact of step therapy requirements on PrEP and PEP access because we did not determine that any health insurance providers in California currently require step therapy for PrEP and/or PEP.

## *Prior Authorization Delays Access to PrEP*

All 8 of the providers interviewed were familiar with situations in which PA delayed access to PrEP. Six of these providers had personally worked with patients where PrEP access was delayed. Another two had colleagues with a similar experience.

All 8 providers interviewed noted that prior authorization is a barrier for patients to access PrEP. One Southern California provider expressed their frustration with the following anecdote.

***"You have a patient who might be traditionally considered high risk for HIV acquisition, who leaves your clinic expecting to get their refill today, and then having to deal with a prior authorization that could sometimes last up to a couple of weeks before approval, which leaves 14 possible days for seroconversion… [wait times] can be a little scary as someone who is providing these services just because you understand your patient's needs."***

***All 8 of the providers interviewed were familiar with situations in which prior authorization delayed access to PrEP***

The provider was familiar with situations where patients had asked friends with PrEP prescriptions to borrow medication during the interim to circumvent this barrier.

Another provider explained,

***"when…the prior authorization process does not go smoothly, a lot of clients will give up on the process in getting PrEP."***

Due to the complexities of prior authorization, patients at risk may feel discouraged and ultimately stop attempting to access HIV prevention medication. This comment reveals the provider's belief that prior authorizations do not align with patient-centered care. Rather, these policies economically benefit insurance companies, ignore the provider's competency and create another barrier to administering quality care.

## *Prior Authorization Reduces Patient Adherence to PrEP*

A majority (6 out of 8) of providers interviewed were familiar with situations in which prior authorizations presented a barrier to adherence to PrEP. Of these 6 providers, 4 of them had personally worked with patients who were at risk of medication non-adherence as a result of delays in accessing medication.

***A majority of providers interviewed were familiar with situations in which prior authorizations presented a barrier to adherence to PrEP***

Decreased patient motivation was cited as one effect of prior authorization. A provider from Northern California stated:

***"[prior authorization] is just a hassle and a lot of interacting with pharmacies and your provider just to stay on the medication."***

A provider from Southern California reported that prior authorizations might not consider nor accommodate patients' busy schedules.

***"There are patients who are super busy, who forget they have an appointment or miss an appointment, and they'll call me the day of, and they'll be like 'hey can you do my prior authorization for my Truvada? I'm completely out today.' Well, unfortunately, insurance companies don't process prior authorizations as fast as we would like them to. Even submitting it under urgent or hopefully under a 24-hour turn-around time will not ensure the patient will not miss a dose and I've definitely seen that."***

## *Prior Authorization Requirements for PEP Were Viewed as Counterintuitive to HIV Prevention Efforts*

Some of the providers interviewed (3 out of 8) were familiar with health insurance plans imposing prior authorization requirements for PEP. They expressed extreme concern in light of the short window frame (e.g. 72 hours) people have to take PEP after exposure to prevent HIV.

***Some of the providers interviewed were familiar with health insurance plans imposing prior authorization requirements for PEP***

One provider from Northern California described a scenario where a client came into the clinic on a weekend for PEP. While the provider was able to reach an insurance agent on the phone, they were told that because it was a weekend, there was nothing they could do to resolve the situation until the following Monday. The provider was only able to issue PEP because the program was housed in a specialty clinic for HIV care, a factor that may not be true of other clinics. When asked if they had experienced specific instances where prior authorization requirements delayed access to PEP, the provider replied,

***All 8 providers interviewed viewed prior authorization for PEP as a needless barrier to accessing care***

***"We've had some insurance companies say that it will be a turnaround time of two to four days. And we're like 'No, this is a time-sensitive medication, we need it to go through today.'"***

Even providers not familiar with health insurance plans imposing prior authorization requirements for PEP expressed dismay regarding the potential delay in access. One provider in Southern California noted:

***"If someone has to sit there and wait three business days…it would be the complete antithesis of why we're even doing this work. It would basically put a stop to them acquiring the medication within 72 hours because it would probably take even longer considering if it was the weekend if that was the situation… I can only imagine the frustrations and the issues that we could encounter..."***

Thus, all 8 providers interviewed viewed prior authorization for PEP as a needless barrier to accessing care.

## Policy Recommendations

Findings from this study suggest that prior authorization requirements for both PrEP and PEP in California were largely viewed among the surveyed PrEP/PEP providers and navigators as a barrier to quality care.

**Policymakers should consider the negative impact of prior authorization requirements for PrEP and PEP.** California Senate Bill 159 prohibits health plans from subjecting PrEP and PEP to prior authorization. However, if the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of HIV, a health plan is only required to cover at least one of the therapeutically equivalent versions without prior authorization. (CA S.B. 159, 2019). This amendment provides health plans with a mechanism to control costs when lower-cost, therapeutically equivalent medications for PrEP and PEP become available. Participant narratives suggest that eliminating prior authorization requirements for PrEP and PEP would facilitate the prescription process and improve medication adherence, creating better patient-centered care environments.

## Conclusion

This study offers an initial look into PrEP/PEP service providers' perspectives on how prior authorization presents barriers to medication access and adherence to PrEP and PEP. Prior authorization requirements for PrEP and PEP not only induce frustration among PrEP-AP providers, but can result in dangerous delays in patients' initial and continued access to medication to prevent HIV acquisition. Prior authorization requirements therefore run counter to the state's robust efforts to increase access and uptake to PrEP and PEP.

Given the state's efforts to prioritize and increase HIV prevention efforts, Senate Bill 159 aligns with the overarching mission to end the HIV epidemic in California. The passage of California Senate Bill 159 would help to eliminate existing barriers to HIV prevention and prioritize patient health. Timeliness is central to the effectiveness of this specific biomedical HIV prevention innovation. Therefore, reducing administrative burdens that might cause delays will facilitate greater uptake and adherence to PrEP and PEP. Failure to address prior authorization as a significant challenge to care will result in greater hardship for providers to provide quality care, putting their patients at greater risk for HIV. Furthermore, because the U.S Preventive Services Task Force recently finalized a Grade A recommendation for PrEP, state and federal regulators will be looking to draft further regulations on how to implement the recommendation. The dearth of data on the impact of PA requirements and potential step therapy requirements on PrEP and PEP will need to be addressed to ensure that any regulations stemming from this recommendation ensures broad and unhindered access to PrEP and PEP.

## Citation

Paneda C, Ochoa AM, Pulsipher C, Maxwell K, Danly J, Holloway IW. Evaluating the Impact of Prior Authorization Requirements for PrEP and PEP in California. California HIV/AIDS Policy Research Centers. September 2019.

## Acknowledgements

Thank you to all of our study participants who provided us with their narratives about their life and work experiences, without whom this project would not be possible.

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