Prior authorization and HIV medications: Considerations for state policymakers

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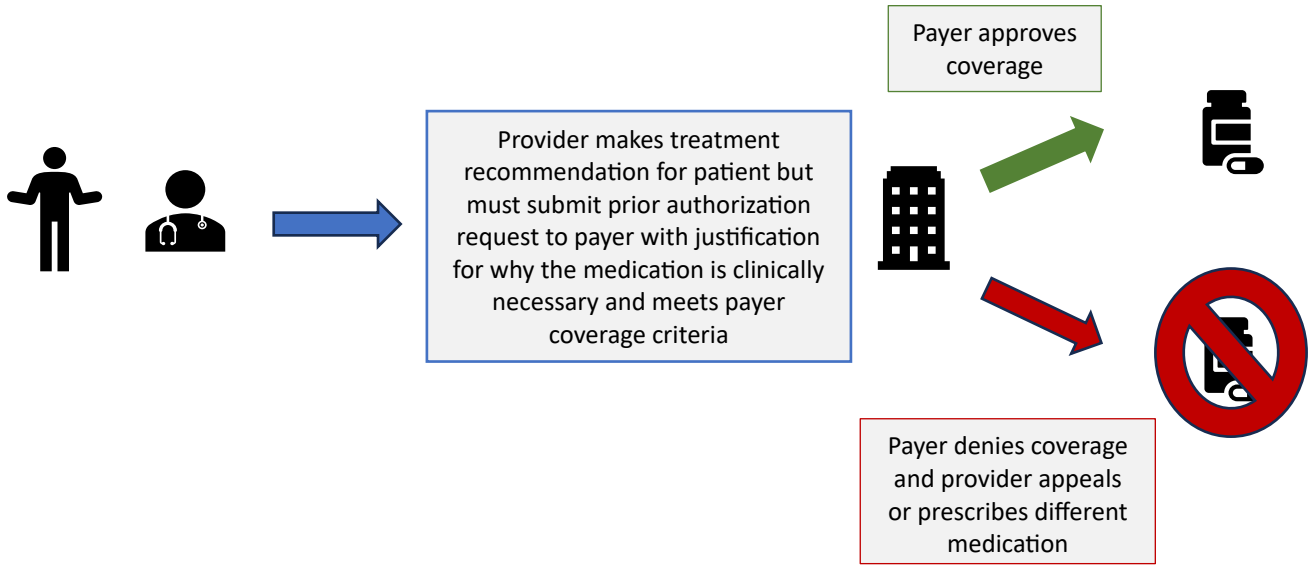
Prior authorization for HIV medications

Prior authorization is deployed by health insurers to manage the utilization of prescription drugs. It requires providers to seek approval from a health insurance plan before the plan will cover an item, service or medication for a specific patient (see Figure 1). Insurance plans place prior authorization requirements on covered services and require providers to prove or demonstrate that a patient meets certain criteria for coverage. Prior authorization is widely used across public and private payers, including Medicaid managed care, Medicare Advantage, the individual market and commercial insurance.

Figure 1: Prior authorization for medication in action



Insurers contend that prior authorization can be an important and simple check to ensure patients are getting appropriate, safe and cost-effective treatment.[1] However, a growing number of providers and patients report that prior authorization adds administrative burden, resulting in care and treatment delays. Further, many of the criteria used by health plans are out of date and often at odds with clinical standards of care.[2]

Effective HIV treatment saves lives and prevents HIV transmissions

For HIV medications, timely access is essential not only for an individual's health, but also for population health as regular access to antiretroviral medications reduces HIV transmissions. Rapid initiation of HIV treatment has been found to improve the likelihood of viral suppression, which is when the virus is undetectable in a person's blood, meaning that the person both derives maximal individual benefit and cannot transmit HIV to others.[3] [4] Burdensome and inefficient prior authorization processes cause dangerous delays and disruptions in care.[5] [6] [7] This hampers early access to HIV treatment and impacts HIV outcomes. The same is true for pre-exposure prophylaxis – antiretroviral medications that, when taken regularly, prevent someone from acquiring HIV.[8]

Regulating prior authorization

As prior authorizations increase, there has been a growing sense of urgency to act to rein in the practice, both from state and federal policymakers. At the federal level, the Centers for Medicare and Medicaid Services finalized a rule in 2024 that includes specific timelines for prior authorization decisions, transparency requirements for coverage criteria and denial reasons, and interoperability requirements to increase use of electronic and streamlined prior authorization processes for Medicaid managed care, the Children's Health Insurance Program, Medicare Advantage and Qualified Health Plans.[9] That rule applies to medical items and services (e.g., diagnostic imaging) but does not address prescription drugs. States have also worked to implement reforms that govern the state-regulated private insurance market and Medicaid, including guardrails about how plans use prior authorization, ensuring that the prior authorization process is fair and transparent and individuals have access to clinically recommended care and treatment. This issue brief articulates the major challenges for prior authorization use for HIV medications as well as policy considerations to address those challenges.

HIV medication prior authorization challenges

The following challenges represent common provider and patient experiences with prior authorization applied to HIV medications.

Interference with clinically recommended HIV care

Prior authorization processes that limit access to certain medications can make it difficult for providers to make individualized decisions about the best treatment regimen for their patients. Prior authorization for HIV medications typically puts in place a set of criteria that a provider must attest (sometimes through the submission of medical records) that a patient meets. Typically, a prior authorization requirement is placed on a non-preferred treatment regimen (i.e., a regimen that is covered by the plan but requires plan approval for access over other options and often comes with higher cost sharing). For providers and patients, prior authorization requirements can limit the regimens available to patients and make it difficult for providers to make individualized treatment decisions with their patients that are in line with federal HIV treatment guidelines.[10] This problem is exacerbated when plans rely on providers who are not versed in the specifics of the ARV class, including potential drug interactions, to review prior authorization requests.

Prior authorization is more likely to be required for newer agents that can also be more expensive.[11] The HIV antiretroviral medication pipeline is dynamic, with recent approvals of long-acting injectable regimens that help with adherence to both HIV treatment and PrEP. These medications are seen by many as "game changers" and present a viable path to ending the HIV epidemic.

Burdensome prior authorization requirements, which are common for these medications, can derail these efforts.

Example 1: In some cases prior authorization may require demonstration of failure to tolerate older multi-tablet regimens before a plan will cover a single-tablet regimen or require failure to tolerate oral PrEP regimens before a plan will cover a long-acting injectable product.

Example 2: A semi-retired radiologist could be employed by an insurance plan to conduct a "peer" review of a denial of plan's initial prior authorization request for a particular ARV for the treatment of HIV. This specialist does not have the requisite knowledge of HIV treatment, including the ARV class and potential drug interactions associated with particular regimens, to accurately review whether a medication is medically necessary for a particular patient.

Dangerous medication delays or interruptions for patients

The administrative burdens associated with prior authorization can also lead to delayed medication access and disruptions in treatment that can result in increased likelihood of drug resistance and disease progression. This can be a frustrating experience for patients who go to a pharmacy to pick up the medication their doctor prescribed, only to be told that the medication has not yet been approved by their insurance plan. A patient facing a high out-of-pocket cost for a medication for which prior authorization approval was denied is likely to abandon the prescription at the pharmacy.[12] Without medications, these patients remain at high risk for complications of HIV, including severe, life-threatening infections and hospitalizations.

Example 3: If an initial prior authorization request for a particular ARV is denied, it can take weeks to get a decision on the appeal, which can result in missed ARV doses. This can have negative consequences that could compromise the long-term health of people with HIV, such as the development of drug resistance or delayed viral suppression. For individuals on a PrEP regimen, breaks in PrEP access can create risk of HIV acquisition as the intervention only offers protection if taken regularly.

Example 4: Prior authorization policies that require a patient's health status to deteriorate before a new regimen is approved can result in irreversible harm for people with HIV. As an example, a provider recommends a patient with HIV and type 2 diabetes switch to a new HIV regimen that is safer for his kidneys because of renal dysfunction. The patient was apprehensive to switch from a regimen he had been on for many years but was willing to switch based on his doctor's advice. When he went to pick up the new regimen at the pharmacy, he was informed the prior authorization had been denied and that if he wanted the medication that day, he would need to pay over $1,000 out of pocket.

Administrative burden

Providers have described the administrative burden of prior authorization as consuming valuable time and resources, with individual prior authorization requests taking up hours of staff time depending on the complexity of the request. Many providers have reported that prior authorization requests for HIV medications are typically granted, making the administrative burden and costs associated with the approval all the more frustrating. There is some anecdotal evidence to suggest that smaller public health and private practice clinics and rural providers may be disproportionately impacted by prior authorization requirements simply because they lack infrastructure and staff to process them. Ultimately, this both harms patient care and increases provider burnout in an already overburdened system.

Example 5: A large safety-net clinic in Atlanta, Georgia, has two full-time employees devoted to managing prior authorizations. Rural providers face unique challenges because they do not have the same resources as larger urban practices to deal with prior authorizations. This frequently means that clinical staff must take time away from patient care to manage prior authorization processes.

Example 6: As an example, a provider prescribes an antiretroviral regimen to a patient, who then goes to the pharmacy and is told the medication cannot be dispensed because it requires a prior authorization. The provider, however, is not notified about this prior authorization requirement. By the time the provider is aware, many days may have passed, resulting in a significant delay of the ultimate approval and receipt by the patient of the medication.

Barriers to newer regimens

Prior authorization is more likely to be used with newer treatment regimens that are more expensive. The HIV antiretroviral medication pipeline is dynamic, with recent approvals of long-acting injectable regimens that may help with adherence for both HIV treatment and PrEP. Burdensome prior authorization requirements for these newer regimens that fail to take patient adherence challenges into account may create unnecessary barriers to these products.

Example 7: Prior authorization for PrEP increases the likelihood of HIV acquisition for patients. A provider prescribes a long-acting injectable for preventing HIV that is administered every six months and requires two oral tablets be given as a loading dose. The health insurer approves the injection but not the oral dose and then subsequently advises that the patient needs to try and fail on an oral medication first. Failure puts the patient at risk for HIV acquisition. The provider, pharmacy tech and medical assistant spend two weeks working to resolve the case.

Prior authorization policy considerations

In addition to federal rulemaking, states have ramped up legislative approaches to prior authorization reforms.[13] The considerations below should inform federal and state prior

authorization policies in ways that ensure timely access to HIV prevention, care and treatment services.

1. Require prior authorization criteria to be based on HIV clinical guidelines and that prior authorization denials be reviewed by an infectious diseases or HIV clinician.
2. Collect more granular data on how plans are using prior authorization and publish public reports that break down prior authorization approvals and denials by drug class.
3. Standardize prior authorization processes across payers.
4. Place guardrails around the use of artificial intelligence in prior authorization decisions.
5. Approach "gold carding" and other provider-focused programs with caution.
6. Policies that address prior authorization should be pursued in tandem with broader medication coverage and access reforms.
7. Reform manufacturer pricing and pharmacy benefit manager rebate gaming to reduce the price of medications.

1) Require prior authorization criteria to be based on HIV clinical guidelines and that adverse decisions be reviewed by an infectious diseases or HIV clinician.

Policymakers should consider legislative reforms that require prior authorization criteria to reflect up-to-date clinical standards, including the federal or professional society HIV Treatment Guidelines. *See Table 1*. This could include prohibiting prior authorization requirements for first-line treatment regimens. As an additional safeguard to make sure that coverage is based on clinically recommended care, reforms should require that peer-to-peer review of prior authorization requests for HIV antiretroviral medications be conducted by clinicians with experience in HIV treatment. The criteria that plans use to adjudicate a prior authorization request as well as the specific reasons for a prior authorization denial should also be available to both patients and providers.

2) Collect more granular data on how plans are using prior authorization and publish public reports that break down prior authorization approvals and denials by drug class.

While data reporting is not a substitute for substantive legislative protections, more transparency into the historically opaque prior authorization process can provide lawmakers and other policymakers with important information about what reforms to enact. For instance, if prior authorization requests for a particular medication or drug class are approved at a rate of close to 100%, it could signal that use of prior authorization is inappropriate, adds unnecessary delays in treatment access and administrative costs and should be prohibited.

3) Standardize prior authorization processes across payers.

In addition to policies that reduce unnecessary prior authorization, prior authorization reforms should require insurers to standardize their prior authorization processes to alleviate administrative burden for providers and patients. The federal CMS rule requires more standardization for prior authorization, including electronic interoperability standards and specific time standards for decisions, but only reaches some of the private insurance market and does not include prescription drug prior authorization requests. Additional state and federal policies should capture prescription drug prior authorization as well, as that is the source of the largest prior authorization burden for HIV.

4) **Place guardrails around the use of artificial intelligence in prior authorization decisions.**

The increasing use of AI to augment insurer claims adjudication processes and utilization management review necessitates additional guardrails.[14] While AI has the potential to support more efficient prior authorization approvals, policymakers should consider additional protections that ensure a qualified human is the ultimate arbiter of a prior authorization denial as well as periodic audits to ensure that AI algorithms and machine learning systems are not using biased datasets or faulty assumptions about utilization or treatment patterns that could disproportionately impact protected classes of patients.[15]

5) **Approach "gold carding" and other provider-focused programs with caution.**

A more recent approach to prior authorization reform has included "gold carding" programs that exempt certain providers with high prior authorization approval rates from prior authorization requirements. While gold carding and similar provider-focused programs could ease prior authorization burden in some settings, without broader reforms these types of programs could exacerbate existing health care disparities.[16] For instance, HIV providers without the infrastructure and staff of a large consolidated health care system, including practices in rural areas, may not be able to achieve the prior authorization approval rates needed to get gold card status, not because they aren't following the same clinical recommendations as those large systems, but because they simply do not have the capacity to process those requests in the same way.

6) **Policies that address prior authorization should be pursued in tandem with broader medication coverage and access reforms.**

As policymakers pursue prior authorization reforms, they should closely evaluate potential unintended consequences of a narrow focus on one-payer activity to rein in health care costs and limit access. For instance, more onerous prior authorization reforms could prompt payers to exclude medications from formularies altogether, subjecting those medications to a much more burdensome and much less regulated formulary exclusion appeals process. Prior authorization reforms should be pursued in tandem with coverage and access standards that ensure plans cover the range of HIV medications individuals need and that are recommended by federal or professional society clinical guidelines.

7) **Reform manufacturer pricing and pharmacy benefit manager rebate gaming to reduce the price of medications.**

Policymakers should acknowledge the underlying drivers of many prior authorization and utilization management policies: the high price of prescription drugs in the United States.[17] With relatively few state and federal mechanisms to rein in the prices of HIV medications, prior authorization is a tool that payers use to negotiate for rebates and discounts. Any state or federal effort to address utilization management reform should also assess policy levers to drive down the exorbitantly high price of brand-name and specialty medications.

Table 1: HIV prevention and treatment guidelines

Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV	clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/
HIV Clinical Guidelines: Adult and Adolescent Opportunistic Infections	clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections
HIV Clinical Guidelines: Pediatric HIV Treatment	clinicalinfo.hiv.gov/en/guidelines/pediatric-arv/
HIV Clinical Guidelines: Pediatric Opportunistic Infections	clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-pediatric-opportunistic-infections/
Perinatal HIV Guidelines	clinicalinfo.hiv.gov/en/guidelines/perinatal/
2021 CDC PrEP Clinical Practice Guideline	stacks.cdc.gov/view/cdc/112360
Clinical Recommendation for the Use of Injectable Lenacapavir as HIV Pre-Exposure Prophylaxis – United States, 2025	www.cdc.gov/mmwr/volumes/74/wr/mm7435a1.htm
Pre-Exposure Prophylaxis for HIV: Updated Recommendations From the 2024 International Antiviral Society – USA Panel	jamanetwork.com/journals/jama/fullarticle/2835835
Antiretroviral Drugs for Treatment and Prevention of HIV in Adults: 2024 Recommendations of the International Antiviral Society – USA Panel	jamanetwork.com/journals/jama/fullarticle/2827545

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