Open Access to HIV Medicines

Open & Unrestricted Access to HIV Treatment Medications Is Essential for Patients

Protecting access to antiretroviral therapy (ART) in state Medicaid programs and commercial plans is an essential safeguard for people living with HIV (PLWH). At the federal level, the 6PC Policy in Medicare Part D ensures PLWH have access to all HIV medicines without the burden of prior authorization or step therapy.

By ensuring that all patients can access the right HIV medications based on their individual needs, open access policies keep individuals healthy, reduce inequities, and move the nation closer to ending the HIV epidemic.

What is Open Access?

Open Access policies provide unrestricted access to all HIV treatment medications without barriers imposed by insurers like prior authorization or step therapy, which limits patient access to prescribed antiretroviral medications (ARVs) until they try one or more alternative, potentially inferior, HIV treatments.

Why is Open Access Essential?

Open Access policies help to ensure that PLWH have unrestricted access to ARVs that most effectively meet their needs. These policies provide vital protections for patients against risks, complications, and negative outcomes that result from restrictions and delays in access. HIV ARVs have unique qualities (clinical and pharmacological) that need to be considered when selecting the most appropriate treatment regimens for patients.

To end the HIV epidemic, people living with HIV should be able to quickly and easily start and remain on the HIV treatment regimen that best meets their needs.

Open Access Saves Lives

- Requires insurance plans to cover all HIV medicines.
- Prevents insurers from imposing barriers, like prior authorization and step therapy, on life-saving HIV therapies.
- Ensures that doctors and patients are empowered to make the best medical decisions for each patient.
- Brings policymakers one step closer to addressing existing disparities and ensuring all people can live successfully with HIV.

Providers and Patients Know Best

Safe & Effective Regimens

Choosing a safe, effective HIV regimen is complex. Providers consider many factors: drug resistance, other illnesses or conditions, potential drug interactions, and how life circumstances may impact the patient's ability to follow a drug regimen.

"**Selection of a regimen should be individualized for a particular patient** based on factors such as virologic efficacy, toxicity, potential adverse effects, pill burden, dosing frequency, drug–drug interaction potential, resistance-test results, comorbid conditions, and childbearing potential."

-The Department of Health and Human Services (DHHS)

Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents

Comprehensive Treatment Options

Studies show that as people with HIV age they are more likely to develop additional health issues and tend to develop them earlier than people who do not have HIV.[1] This often means taking additional multiple medications for other non-HIV comorbidities with the potential for adverse drug-drug interactions, which underscores the importance of access to a wide range of HIV treatment options.

Choice is Key

Limiting providers and patients to options pre-selected by an insurance company can be particularly dangerous for PLWH because it can lead to lower rates of medication adherence and persistence, complications, poorer health outcomes and increased likelihood of drug resistance and HIV transmission.[2,3,4]

Better Health, Lower Costs

Healthier Outcomes

Outcomes improve when providers and patients can select the most appropriate ARV regimen.[5] This results in better medication adherence and persistence, thereby increasing a patient's ability to achieve and sustain viral suppression.[6,7,8,9] By using ARVs as prescribed and sustaining viral suppression, PLWH cannot transmit the virus. This is referred to as TasP (Treatment as Prevention) and U=U (Undetectable = Untransmittable).

Prompt Access Leads to Lower Costs

By improving treatment and adherence patients can better control their HIV, resulting in decreased rates of hospitalization and lower healthcare costs. Utilization management can delay or compromise treatment, potentially endangering individual and public health. Ultimately, suboptimal therapy selection could lead to the progression of costly resistant viruses.

Rapid Start

Patients who begin ARV treatment within a week of diagnosis – preferably the same day – are more likely to stay in care and to achieve viral suppression.[10] Prompt access to the right treatment helps PLWH live healthier and longer lives and can dramatically reduce the risk of HIV transmission to others.[11,12]

Avoiding one new HIV infection can result in an average of $850,557 in lifetime healthcare cost savings[13]

Average annual and cumulative healthcare costs are estimated to be up to seven times higher for people living with HIV compared to those without HIV.

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March 13, 2024

The Honorable Tina Liebling, Chair, Health Finance and Policy Committee
Minnesota Health Finance and Policy Committee Members
Minnesota House of Representatives
477 State Office Building
St. Paul, MN 55155

Re: **HF 2466 – Pharmacists authorized to prescribe, dispense, and administer drugs to prevent the acquisition of HIV**

PCMA Testimony - Concerns with Prohibition on Use of Step Therapy and Prior Authorization for Antiretroviral Drugs

Dear Chair Liebling and Members of the Health Finance and Policy Committee:

The Pharmaceutical Care Management Association, commonly referred to as PCMA is the national trade association for pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 275 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs.

PBMs exist to make drug coverage more affordable by aggregating the buying power of millions of enrollees through their plan sponsor/payer clients. PBMs help consumers obtain lower prices for prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and using lower-cost dispensing channels. Though employers, health plans, and public programs are not required to use PBMs, most choose to because PBMs help lower the costs of prescription drug coverage.

PCMA appreciates the opportunity to provide written testimony on HF 2466 and applaud the legislature and bill sponsor to provide coverage for an enrollee for HIV prevention drugs at the lowest cost share. However, we would request one of the following two options which is either removing or amending the language in Section 1 to allow health plans to still be able to perform step therapy and prior authorization based on clinical evidence and rationale. After our suggested options, we have included our rationale and reasoning for the options.

Option 1:

Remove lines 1.10 thru 1.23 - Section 1, [62Q.1842] PROHIBTION ON USE OF STEP THERAPY FOR ANTITROVIRAL DRUGS.

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Option 2:

Amend Section 1, as follows in red:

1.18 (c) "Step therapy protocol" has the meaning given in section 62Q.184.
1.19 Subd. 2. **Prohibition on use of step therapy protocols.**(a) A health plan that covers
1.20 antiretroviral drugs that are medically necessary for the prevention of HIV/AIDS, including
1.21 preexposure prophylaxis and postexposure prophylaxis, must not limit or exclude coverage
1.22 for the antiretroviral drugs by requiring prior authorization or by requiring an enrollee to
1.23 follow a step therapy protocol~~.~~, except as provided in paragraph (b).

(b) If the United States Food and Drug Administration has approved one or more drugs, devices, or products for the prevention of AIDS/HIV, a health plan is not required to cover all such therapies without a prior authorization or a step therapy protocol requirement so long as at least one alternative drug, device or product is covered without requiring prior authorization or the use of a step therapy protocol.

(c) A health plan company may require prior authorization for an antiretroviral drug if prior authorization is medically necessary. The health plan company or utilization review organization must make a determination on the prior authorization request and notify the requesting provider within 36 hours of receipt of the request, or prior authorization is deemed to be approved.

Rationale and Reasoning:

Utilization management, such as prior authorization, is needed operationally to ensure the medication is clinically justified and appropriate to treat the patient's medical condition. The prior authorization process requires a prescriber to provide updated clinical information to the plan about the appropriateness of a drug. Drugs that require prior authorization typically have dangerous side effects and are harmful when combined with other drugs. Prior authorization is important as there are also equally effective, less costly drugs that would work.[1]

PCMA supports coverage of medication for pre-exposure prophylaxis (PrEP) for HIV based on clinical evidence and rationale. Prior authorizations ensure the provider performed the correct clinical evaluations before providing a patient with a potentially dangerous medication. **This class of medications requires a patient to receive a HIV test every 3 months and testing for sexually transmitted infections (STIs) every 3-6 months** These medications are not used for patients who test positive for HIV since there is viral resistance to some medications used for PrEP, and if untreated, could cause life threatening complications for a patient.

[1] GoodRx. 2020. "What is Prior Authorization? A Look at the Process and Tips for Approval." https://www.goodrx.com/insurance/health-insurance/prior-authorizationwhat-you-need-to-know.

PrEP also requires routine kidney function tests every 6 months. According to one drug's prescribing guidelines, "**approximately 39% of men on PrEP medications are greater than, or equal to, 40 years old, an age when kidney function may be declining… and 62% of PrEP users had one or more risk factors for kidney concerns.**"[2] These statistics warrant the use of prior authorizations to ensure there are safeguards to protect patients.

These medications may also have serious drug-drug or drug-disease contraindications, thus putting a patient at greater risk of kidney and liver disease. **Medications such as ibuprofen (NSAIDs) and Prilosec (PPIs) are contraindicated with the use of PrEP medications** due to increased risk of kidney disease. Diabetics and people with high blood pressure are also advised not to take PrEP medications due to concerns of potential kidney function issues.

> ***"[One medication lists] 230 drugs known to interact with [it], along with 7 disease interactions, and 1 alcohol/food interaction. Of the total drug interactions, 133 are major, 94 are moderate, and 3 are minor."***[3]

Prior authorization is an important tool used by PBMs because they have insight into all medications billed to a patient's insurance and they can spot harmful interactions or contraindications.

PCMA is also concerned that no longer requiring step therapy for any class of medications, such PrEP, could raise drug costs. Step therapy ensures that the patient gets the safest, most cost-effective drug, by requiring the patient to try proven, more affordable therapies before drugs that cost more. Generic drugs cost less than brand-name drugs[4], and step therapy is designed to capture those savings while achieving the desired therapeutic outcome. **For instance, there is a generic alternative for Truvada ($21 per 30 days) compared to brand name Descovy ($2484 per 30 days) which contains similar ingredients. Step therapy would encourage an eligible patient to try the generic alternative for Truvada before Descovy.**

As indicated above, utilization management tools are associated with financial savings and improved health indicators.[5] Studies demonstrate that prior authorization has generated savings of up to 50% for targeted drugs or drug categories, and step therapy has generated savings of

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[2] IQVIA® LAAD Weekly, through April 2023. https://www.descovyhcp.com/renal-and-bone-over-time?gclid=Cj0KCQiAoKeuBhCoARIsAB4WxtdBGi9XwwwPXvjHMAoDrWfuUnmY-Uf2fkgWz0AG_v6L9k9YJx4DzegaApk0EALw_wcB&gclsrc=aw.ds

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more than 10% in targeted categories.[6] The National Academies of Sciences, Engineering and Medicine has also indicated step therapy and similar PBM tools keep premiums lower, that formularies help "steer patients and prescribing clinicians toward generic substitutes, biosimilar drugs with similar therapeutic efficacy for the same disease, or other therapeutic options," and that without formulary controls, "insurance premiums would rise." [7] The Federal Trade Commission has also linked step therapy and prior authorization to cost savings.[8]

Lastly, plans and PBMs rely on independent Pharmacy and Therapeutics (P&T) Committees, comprised of physicians, pharmacists, and other medical professionals to develop evidence-based guidelines used in drug management programs, including prior authorization and other utilization management tools—to ensure that these management controls do not impair the quality of care.[9] After safety and quality are considered, cost is evaluated. Sometimes, there are many drugs—multiple brand name drugs, and/or generic drug options—that treat the same condition. Typically, a generic is more affordable than its associated brand name drug, and when there are multiple brands in the class, there is typically one that has a lower net cost than the other(s). In this case, a utilization management program may require a prescriber to provide an explanation about why the more expensive drug is necessary.

Again, I would like to thank the committee and bill sponsor's intent to improve patient care in Minnesota and we encourage the committee to consider our proposed changes.

Please feel free to contact me should you have any questions.

Sincerely,

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[6] Visante. 2023. "Increased Costs Associated with Proposed State Legislation Impacting PBM Tools." https://www.pcmanet.org/wp-content/uploads/2023/01/Increased-Costs-Associated-With-Proposed-State-Legislation-Impacting-PBM-Tools-January-2023.pdf.

[7] National Academies of Sciences, Engineering, and Medicine (NASEM). 2017. "Making Medicines Affordable: A National Imperative." https://nap.nationalacademies.org/catalog/24946/making-medicines-affordable-a-national-imperative.

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HIV ON THE HILL

Expand PrEP & PEP Access

HF2466 (Curran) SF2320 (Dibble)

Supporting HF2466/SF2320 expands HIV prevention medications prophylaxis (PrEP) and postexposure prophylaxis (PEP) especially for Minnesotans disproportionately at higher risk for HIV. The bill authorizes pharmacists to dispense PrEP and PEP without a prescription. – Helps End HIV in Minnesota by increasing the number of people who have access to HIV prevention medications and decreasing new HIV infection rates.

What is PrEP & PEP?

- When taken as prescribed Pre-Exposure Prophylaxis (PrEP), a once-a-day pill, is more than 99% effective in preventing HIV.
- Post-Exposure Prophylaxis (PEP) is prescribed to people who have had a possible exposure to HIV. PEP must be started within 72 hours of potential exposure.

Why is it needed?

- Provides access and availability to HIV prevention medications for people at high risk for new HIV infection.
- Expanding pharmacists prescribing authorities is the next huge leap to ending HIV in MN
- It is estimated that only about 10% of the total 1.2 million people nationwide who could benefit from PrEP & PEP are potentially receiving the medication.
- Reduce the number of new infections of HIV by 75% by the year 2035
- To help keep HIV negative people maintain a negative status through HIV prevention medications.

What does the bill do?

- Authorize pharmacists to dispense PrEP and PEP without a prescription.
- Authorizes, but not requires, a training program for pharmacists about PrEP & PEP by the Department of Human Services.

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SAFELY EXPANDING HIV PREVENTION & TREATMENT ACCESS

We can do more to end new infections & improve lives

9,700 Minnesotans live with HIV/AIDS with over 275 new cases diagnosed each year.

MN has a goal that by 2025 "new HIV diagnoses are rare and all people living with HIV—and those at high risk of HIV infection—will have access to high quality health care and the resources they need to live long healthy lives, free from stigma and discrimination."

To meet this goal we must expand timely and convenient community-based patient access to Pre-exposure (PrEP) and Post-exposure (PEP) prophylaxis.

HF 2466 (Curran)/SF 2320 (Dibble):

- Authorizes a pharmacist to prescribe, dispense, & administer drugs for preventing HIV.
- Authorizes ordering, conducting, & interpreting laboratory tests necessary for therapies that use drugs for preventing HIV.
- Provides for payment of services.

Patient access & speed are critical:

- Timely access is vital, especially with exposure—72 hours for treatment.
- Pharmacists are trained and will operate under a protocol from the Minnesota Board of Pharmacy.
- Most Minnesotans live within 5 miles of a pharmacy and see their pharmacist more times per year than any other provider.
- Other states have taken similar steps: AR, CA, CO, ID, IL, KY, ME, MO, NC, NM, NV, NY, OR, UT, VT.

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