



March 21, 2024

The Honorable Melissa Wiklund, Chair, Health and Human Services Committee
Minnesota Senate Health and Human Services Committee Members
Minnesota Senate
Room 1100 Minnesota Senate Building
St. Paul, MN 55155

Re: **SF 2320 – 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 Wiklund and Members of the Health and Human Services 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 SF 2320 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] PROHIBITION 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-authorization/what-you-need-to-know>.



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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 as 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 drugs⁴, 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

² IQVIA@ LAAD Weekly, through April 2023. https://www.descovychp.com/renal-and-bone-over-time?gclid=Cj0KCQiAoKeuBhCoARIsAB4WxtdBGi9XwwwPXviHMAoDrWfuUnmY-Uf2fkqWz0AG_v6L9k9YJx4DzegaApk0EALw_wcB&qclsrc=aw.ds

³ Drugs.com. Emtricitabine/tenofovir alafenamide interactions. <https://www.drugs.com/search.php?searchterm=emtricitabine+%2F+tenofovir+alafenamide>

⁴ Federal Drug Administration. "Generic Drug Facts." <https://www.fda.gov/drugs/generic-drugs/generic-drug-facts>.

⁵ US GAO. July 2019. "Medicare Part D: Use of PBMs and Efforts to Manage Drug Expenditures and Utilization," Citing multiple studies showing improvement in medication adherence and a reduction in adverse drug events. <https://www.gao.gov/assets/gao-19-498.pdf>. Also, see Visante. 2023. "Increased Costs Associated with Proposed State Legislation Impacting PBM Tools." <https://www.pcmnet.org/wp-content/uploads/2023/01/Increased-Costs-Associated-With-Proposed-State-Legislation-Impacting-PBM-Tools-January-2023.pdf>.



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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,

A handwritten signature in blue ink, appearing to read "Michelle Mack".

Michelle Mack
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Phone: (202) 579-3190
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A handwritten signature in black ink, appearing to read "Johnny Garcia".

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Copy: Sen. Scott Dibble

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>.

⁸ See discussion in 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>.