January 27, 2020

Mark V. Afable
Office of the Commissioner of Insurance
125 S. Webster St.
Madison, WI 53703


Dear Commissioner Afable,

Thank you for the opportunity to comment on the Statement of Scope on SS: 123-19, relating to step therapy protocols for prescription drug coverage, grievance procedure amendments and affecting small business, which will begin the process of developing rules to establish how notice would be given to participating providers and patients given the new standard process requirements and external review options that passed under WI Act 12.

The National Psoriasis Foundation (NPF) is a non-profit organization with a mission to drive efforts to cure psoriatic disease and improve the lives of those affected. The NPF is the leading patient advocacy group for more than 8.3 million Americans and the roughly 146,053 Wisconsin residents living with psoriasis and psoriatic arthritis. The NPF is intimately familiar with utilization management practices in prescription drug benefits and come to you with a unique perspective on how these policies impact care, health outcomes, and the overall well-being of thousands of Wisconsinites.

We appreciate the complexity that goes into the rulemaking process and applaud the Office of the Commissioner of Insurance (OCI) for doing its due diligence on the matter. We are writing to offer the following principles, which draw on our patients’ collective experiences with step therapy practices. These guiding principles emphasize the importance of allowing appropriate access to care while also recognizing the primacy of the patient-physician relationship in prescription drug step therapy practices.

Guiding Principles

1. **Guarantee that patients and providers have access to a clearly disclosed list of drugs when step therapy is used in prescription drugs, along with required documentation and related information that needs to be submitted for a completed exception request.**

   Each day, our patients and providers face the reality of barriers to health care through utilization management practices that impact treatment, health, and well-being. When these policies interfere with the patient-physician relationship, they can result in delayed treatment, increased disease activity, loss of function, and potentially irreversible disease progression.
For providers, utilization management exacerbates administrative burdens as they help patients navigate complicated and often opaque coverage determination processes. Several studies have found that the time and administrative burden associated with step therapy presents an obstacle to access that may lead to unnecessary breaks in treatment. These findings show that 17% to 22% of patients did not submit any prescription claim to their insurance provider following a step therapy edit. Instead, these patients ended up forgoing treatment.\(^1,2\)

Payers should make the process transparent and straightforward so patients and providers can easily access the information they need to meet the plan’s documentation requirements and have that information be explicit regarding the circumstances that warrant a potential exception.

2. **Ensure prescription drug step therapy protocols are based on clinical guidelines that are crafted by currently practicing clinical specialists so that medicine expertise, not cost, dictate requirements.**

Step therapy protocols are not required to follow clinical practice guidelines, published by experts in the field of specialty creating unnecessary and harmful hurdles to accessing accepted standards of care. A recent study shows that these utilization management protocols, specifically step therapy protocols, are inconsistent across payers, creating additional confusion and frustration for patients and their providers acting on their behalf.\(^3\)

3. **Maintain the exception process laid out in WI Act 12 subsection 3, including timelines for granting or denying a submission and the five criteria for granting an exception.**

It is critical that patients can receive an exception to the required step therapy protocol when the plan-directed medication is inappropriate. Too often, utilization management protocols create a one-size-fits-all approach to treatment that runs counter to the growing movement for patient-centered care.

Delays in treatment can have devastating health implications that are avoidable when patients and providers receive timely responses to their exception requests. These delays can also create unnecessary costs to the system when individuals need to seek additional medical care to properly manage their condition. One analysis looked at the impact of step therapy on anti-depressants and total Medicaid costs, drug costs and drug utilization. The study found that total Medicaid costs increased by $0.32 per member per month (PMPM) while drug costs decreased by $0.26 PMPM (an overall increased spend of $.06 PMPM). The same study also found that due to step therapy requirements, more patients switched medications within 6 months and fewer patients received continuous therapy at 6 months.\(^4,5\)

Similarly, a study found that adherence to medication declined due to formulary restrictions

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\(^3\) Chambers JD, Kim DD, Pope EF, Graff JS, Wilkinson OL, Neumann PJ. Specialty Drug Coverage Varies Across Commercial Health Plans In The US. Health Affairs. 2018;37(7):1041-47.


and total costs increased with formulary restrictions due to increased inpatient and medical costs as well as increased pharmacy costs for bipolar disorder.  

We encourage the OCI to require prescription drug utilization management entities to meet the process response timelines of three (3) business days or in urgent circumstances, by the end of the next business day after receipt of complete, clinically relevant written documentation, and ensuring determinations be based on the five criteria for granting an exception outlined in subsection three of WI Act 12 to help ensure the system works for all stakeholders.

Commonsense guardrails on prescription drug step therapy protocols recognize the primacy of the patient-provider relationship while maintaining the ability for insurers to use these tools to manage cost. The NPF represents thousands of patients, caregivers, and families whose lives depend on the best treatment option available with limited barriers to care. We appreciate the opportunity to provide comments on the statement of scope.

Thank you for your time and consideration. If you have questions or concerns, please contact Kristen Stiffler, State Government Relations Manager – Central Region with the National Psoriasis Foundation, at kstiffler@psoriasis.org.

Sincerely,

Kristen Stiffler
State Government Relations Manager, Central Region

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