Our Mission: To drive efforts to cure psoriatic

disease and improve the lives of those affected.

July 27, 2020

Honorable Chair Yvanna D. Cancela

Committee to Conduct an Interim Study Concerning the Costs of Prescription Drugs (SB276)

Nevada Legislature

Carson City, NV

**RE: August 10th Work Session ---Step Therapy**

Dear Chair Cancela and members of the committee,

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 over than 74,000 Nevada residents living with psoriasis and psoriatic arthritis. We write to you today to express our support for legislation in 2021 to reform step therapy protocol.

Step therapy is a form of prior authorization where health carriers approve a prescription drug or class of drugs for a medical condition based on cost effectiveness and treatment best practices. Step therapy requires the patient to begin treatment with the approved drug. If the patient fails to respond to the drug or experiences an adverse effect, then coverage is generally allowed for another drug prescribed by the patient's health care provider. Due to the heterogeneous nature of psoriatic disease, patients need access to a broad range of treatment choices, making a one-size-fits-all approach harmful for patients.

We are writing to offer the following principles, when considering legislation on step therapy reform for 2021. These guiding principles emphasize the importance of allowing appropriate access to care while also recognizing the primacy of the patient-physician relationship when accessing treatment and care.

**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]](#footnote-1), [[2]](#footnote-2)

Carriers 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.

1. ***Ensure 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. Currently, carriers may design their prescription drug benefit plan and often time base their tiering and placement or preferred verse non-preferred drugs off economics rather than science. A recent study shows that these protocols, specifically step therapy protocol, are inconsistent across payers, creating additional confusion and frustration for patients and their providers acting on their behalf. [[3]](#footnote-3) This is why we encourage the legislature to set the standards for clinical guidelines and review criteria used to establish step therapy protocol be evidence-based and updated on a regular basis through review of new evidence, research, and newly developed treatments.

1. ***Create an exception process for step therapy protocol, including timelines for granting or denying a submission.***

It is critical that patients can receive an exception to the required step therapy drug when the plan-directed medication is inappropriate. Too often, step therapy creates a one-size-fits-all approach to treatment that runs counter to the growing movement for patient-centered care. A study found that adherence to medication declined due to formulary restrictions [[4]](#footnote-4). We encourage the legislature to include five criteria for carriers to grant an exception to step therapy protocol if the required prescription drug is:

* contraindicated or will likely cause an adverse reaction or physical or mental harm to the patient.
* Expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen.
* The patient has tried the required prescription drug, or another prescription drug in the same pharmacologic class, while covered by their current or previous health insurer, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
* Not in the best interest of the patient based on medical necessity.
* The patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration while covered by their current or previous health insurer.

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.[[5]](#footnote-5),[[6]](#footnote-6) Similarly this study found that total costs increased with formulary restrictions due to increased inpatient and medical costs as well as increased pharmacy costs for bipolar disorder. [[7]](#footnote-7) This is why we believe carriers must disclose all rules and criteria related to the step therapy process to all participating providers, including the information and documentation that must be submitted by a health care provider or patient for an exemption request to be considered complete. With the disclosure of the process we encourage the legislature to require carriers meet the process response timelines of 72 hours or 24 hours in emergency circumstances.

Without proper treatment, patients with chronic conditions like psoriatic disease may experience otherwise preventable health events, resulting in more doctor visits or hospitalization. Common sense guardrails on step therapy protocol are needed to ensure patients have access to the best treatment options. Our solutions seek to balance patient’s health and well-being with appropriate use of tools to manage healthcare costs. We welcome the opportunity to further discuss these solutions.

Thank you for your time and consideration. If you have any questions, please reach out at [bduffy-goche@psoriasis.org](mailto:bduffy-goche@psoriasis.org).

Sincerely,

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Brittany Duffy-Goche

State Government Relations Manager

1. Delate, T., et al., Clinical and financial outcomes associated with a proton pump inhibitor prior-authorization program in a Medicaid population. Am J Manag Care, 2005. 11(1): p. 29-36. [↑](#footnote-ref-1)
2. Yokoyama, K., et aI., Effects of a step-therapy program for angiotensin receptor blockers on antihypertensive medication utilization patterns and cost of drug therapy.) Manag Care Pharm, 2007. 13(3): p. 235-44. [↑](#footnote-ref-2)
3. Chambers JD, Kim DD, Pope EF, Graff JS, Wilkinson CL, Neumann PJ. Specialty Drug Coverage Varies Across Commercial Health Plans In The US. Health Affairs. 2018;37(7):1041-47. [↑](#footnote-ref-3)
4. Seabury SA, Goldman DP, Kalsekar I, Sheehan J, Laubmeier K, Laubmeier K (2014). Formulary Restrictions on Atypical Antipsychotics: Impacts on Costs for Patients with Schizophrenia and Bipolar Disorder in Medicaid. *American Journal of Managed Care, 20(2), pages e52-e60* [↑](#footnote-ref-4)
5. Panzer PE, Regan TS, Chiao E, Sarnes MW. Implications of an SSRI generic step therapy pharmacy benefit design: an economic model in anxiety disorders. Am J Manag Care. 2005;11(12 suppl):S370-S379.  [↑](#footnote-ref-5)
6. Carlton, R.I.; Bramley, T.J.;Nightengale, B.;Conner, T.M. & Zacker, C. (2010) Review of outcomes associated with formulary restrictions: Focus on step therapy. *The American Journal of Pharmacy Benefits 2(1). 50-58* [↑](#footnote-ref-6)
7. Seabury SA, Goldman DP, Kalsekar I, Sheehan J, Laubmeier K, Laubmeier K (2014). Formulary Restrictions on Atypical Antipsychotics: Impacts on Costs for Patients with Schizophrenia and Bipolar Disorder in Medicaid. *American Journal of Managed Care, 20(2), pages e52-e60* [↑](#footnote-ref-7)