August 17, 2020

Jane Beyer
Office of the Insurance Commissioner
302 Sid Snyder Ave., SW
Olympia WA 98504

RE: Comments on CR-101 for R 2020-13 Prescription Drug Utilization Management (ESHB 1879)

Dear Ms. Beyer,

The undersigned organizations thank you for the opportunity to comment on the consolidated health care rulemaking of inquiry on CR-101. CR-101 impacts prescription drug utilization management, by establishing how notice is given to participating providers and patients under the new standard process requirements and external review options established in ESHB 1879. Our organizations represent thousands of Washingtonian's living with serious, complex, chronic conditions and the providers who care for them. Our organizations and the individuals we represent are intimately familiar with utilization management practices in prescription drug benefits and come to you with a diversity of perspectives on how these policies impact care, health outcomes, and the overall well-being of thousands of Washingtonians.

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

Guiding Principles for Utilization Management

1. ***Guarantee that patients and providers have access to a clearly disclosed list of drugs when utilization management 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 their 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 utilization management protocols are based on clinical guidelines that are crafted by currently practicing clinical specialists so that medicine expertise, not cost, dictate requirements.***

Utilization management 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] This is why we encourage OIC to extend their standards for clinical guidelines to prescription drug utilization management enforceable in current Revised Codes of Washington and when absent providers and insurers use generally accepted medical practices and/or additional resources, such as peer-reviewed publications.

3. ***Maintain the exception process laid out in EHB 1879 section 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 utilization management practice 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. A study found that adherence to medication declined due to formulary restrictions [4].

Further, 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 step therapy caused the 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

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[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.
[2] Yokoyama, K., et al., 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.
[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.
[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*

received continuous therapy at 6 months.[5,6] Similarly, a study found that adherence to medication declined due to formulary restrictions and total costs increased with formulary restrictions due to increased inpatient and medical costs as well as increased pharmacy costs for bipolar disorder. [7]

We encourage the OIC to require prescription drug utilization management entities to meet the process response timelines of 72 hours or 24 hours in urgent circumstances and ensure determinations be based on the five criteria for granting an exception outlined in section three of the legislation to help the system work for all stakeholders.

One concern we encourage the OIC to address is the lack of clarity in WAC 284-43-2023 regarding timeframes for exception and substitution requests, specifically section 3, *"A carrier may establish a specific reasonable time frame for submission of the additional information, and may deny the request if the information is not received within that time frame."* We believe there should be a backstop on what a "reasonable time frame" should be to ensure all stakeholders have a clear understanding of the process and time frame allotted for decisions. We encourage OIC to use the time frames in WAC 284-43-2050 10aii(B) for standard exceptions or substitutions, and 10bii(B) for expedited exceptions or substitutions, which is four calendar days of the receipt of the information of the deadline for receiving information, whichever is sooner. This would create uniformity in the time frames and provide clarity to patients and providers.

Commonsense guardrails on prescription drug utilization management protocols recognize the primacy of the patient-provider relationship while maintaining the ability for insurers to use these tools to manage cost. Our organizations represent thousands of patients, caregivers, and families whose lives depend on access to the best treatment option available. We appreciate the opportunity to provide comments on the preproposal statement. We welcome the opportunity to further discuss these solutions.

Thank you for your time and consideration. If you have questions or concerns, please contact Brittany Duffy-Goche, State Government Relations Manager with the National Psoriasis Foundation, at bduffy-goche@psoriasis.org

Sincerely,

Allergy & Asthma Network
American Diabetes Association
Arthritis Foundation
Chronic Disease Coalition
Coalition of State Rheumatology Organizations
Crohn's and Colitis Foundation
Epilepsy Foundation Washington
Hero House NW

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[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.
[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*
[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*

Lupus and Allied Diseases Association
Lupus Foundation of America
Multiple Sclerosis Association of America
National Eczema Association
National Infusion Center
National Multiple Sclerosis Society
National Organization of Rare Diseases
National Psoriasis Foundation
Washington Rheumatology Alliance