

October 26, 2020

Mandy Weeks-Green  
Office of the Insurance Commissioner  
302 Sid Snyder Ave., SW  
Olympia WA 98504

**RE: Comments on CR-102 (R 2019-11) Prescription drug utilization management proposed rule**

Dear Ms. Weeks-Green,

Thank you for the opportunity to submit comments on Washington state's prescription drug utilization management proposed rule language on (R-2019-11) which is a result of passage of ESHB 1879 during the 2019 legislative session.

The undersigned organizations represent thousands of Washingtonian's living with serious, complex chronic health conditions and the providers who care for them. Our organizations have a well-earned perspective on what people with pre-existing conditions and their families need to prevent disease progression, cure illness, and preserve health and well-being over their lifetimes. We are intimately familiar with utilization management practices in prescription drug benefits and come to you with a diversity of informed perspectives. We support the Office of the Insurance Commissioner's (OIC) effort to set fair and responsible standards for drug utilization review practices, including a prescription drug utilization management exception and substitution process to foster quality health care and better access to care for patients' and consumers'.

The proposed rule delivers a strong and balanced approach, including the following items of interest to our organizations:

- Clear and transparent posting of clinical review criteria and information to consider an exception request.
- Prescription drug utilization management exception or substitution process.
- Establishment of timelines for a drug utilization exception request determination at 1 business day for urgent and 3 business days for nonurgent.
- 60 day posting for formulary changes.

**Clinical Review Criteria**

Our organizations fully support OIC's position on the expansion of WAC 284-43-2020, section (2) which requires issuers or any entity performing administration on the issuer's behalf to post the drug utilization management exception process and clinical review criteria used, including the specific information and documentation to consider an exception request.

Many issuers do not make it clear to health care providers and patients that they have the ability to ask for an exception to drug utilization management, nor do they make the process on how to make that request and/or what information is needed in order to get an exception granted clear or easily accessible. The rule would require issuers to improve that and also clarifies that issuers can use their existing authorization process, if they exist – they just need to be more transparent about the process and improve their communications.

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.<sup>1</sup> We believe alleviating administrative burden for providers will help avoid costly episodes of care that often arise from unnecessary delays in treatment, side effects, and/or drug abandonment that can be a result of lack of transparency to the utilization management and clinical review criteria.

### **Establishment of a Prescription Drug Utilization Management Exception and Substitution Process**

Each day, our patients and providers face the reality of barriers to health care through onerous 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.

It is critical that patients can receive an exception to the required drug 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<sup>2</sup>.

Establishment of WAC 284-43-2021 provides providers and patients with an exception or substitution process, for both nonurgent and urgent exception request procedures, for the drug utilization management process. We commend OIC throughout this WAC including:

- Section (5)(a) through (e). Which determines the clarity and transparency for the exception request.
- Section (8) (a) through (f). Establishes the criteria to grant an exception. Our organizations support the addition of including “dosage that differs from a carrier’s formulary dosage limitation” to the criteria for granting an exception request.
- Section (9) (a) and (b). Directions for requesting an emergency fill to keep the enrollee stable while the exception request is being processed.

### **Timeframes**

Delays in treatment can have devastating health implications that are avoidable when patients and providers receive timely responses to their exception requests. Having access to the right medication quickly for certain patients can mean life or death. These delays can also create unnecessary costs to the system when individuals need to seek additional medical care to properly manage their condition.

Our organizations support WAC 284-43-2022 that establishes time frames for an exception or substitution request determination, including three business days for nonurgent and one business day for an urgent exception. We believe the back and forth clarity that is provided in section (1)-(3) will assure delays for granting an exception will not be because a lack of documentation is needed to make a determination.

### **Notification of Formulary Change**

Patients, especially chronic disease patients, need predictably when it comes to accessing their treatments. If there is a change in formulary design that would force a patient to suspend or discontinue

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<sup>1</sup> 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.

<sup>2</sup> 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

treatment advanced notification is needed for the patient and provider to seek an alternative or request an exception to the formulary change, especially once a patient is stable on their treatment plan. WAC 284-43-5100 provides patient and providers with a 60 day written notice of formulary changes. We believe this extension from 30 days to 60 days will provide patients and providers with adequate time to find solutions to formulary changes with minimal negative consequences to treatment plans.

**Conclusion**

We appreciate the complexity that goes into the rulemaking process and applaud OIC for doing its due diligence on the matter and are pleased with the proposed rule to put common sense guardrails on prescription drug utilization management protocols. Thank you for allowing us to provide comments, we hope to continue work with you on access to care issues.

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](mailto:bduffy-goche@psoriasis.org)

Sincerely,

**Allergy and Asthma Network**

**Alliance for Patience Access**

**Arthritis Foundation**

**Association for Clinical Oncology**

**Chronic Disease Coalition**

**Coalition of State Rheumatology Organizations**

**Crohns and Colitis Foundation**

**Epilepsy Foundation of Washington**

**Hemophilia Federation of America**

**Infusion Access Foundation**

**Lupus and Allied Diseases Association**

**Lupus Foundation of America**

**Multiple Sclerosis Association of America**

**National Infusion Center Association**

**National Multiple Sclerosis Society**

**National Organization for Rare Diseases**

**National Psoriasis Foundation**

**Washington State Medical Association**

**Washington State Medical Oncology Society**