



NATIONAL  
PSORIASIS  
FOUNDATION®

**Our Mission:** To drive efforts to cure psoriatic disease and improve the lives of those affected.

May 15, 2020

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Send via email: [MDHHSCommonFormulary@michigan.gov](mailto:MDHHSCommonFormulary@michigan.gov)

**RE: Michigan Medicaid Health Plan Common Formulary and Utilization Management Tools**

Dear Ms. VanCamp:

Thank you for the opportunity to comment on the Michigan Medicaid Health Plan Common Formulary, the drugs included or not included on the Common Formulary, prior authorization criteria, and step therapy criteria under the Common Formulary.

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 over 250,000 Michigan 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 Michiganders.

We appreciate the complexity that goes into the formulary process and oversight of the Managed Care Organizations (MCOs). NPF applaud the Michigan Department of Health and Human Services (MDHHS) for doing its due diligence in ensuring patients and providers are heard regarding critical access to care issues. We are writing to offer the following principles, which draw on our patients' collective experiences with utilization management, especially around 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 especially in prescription drug step therapy practices.

**Step Therapy Guiding Principles**

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***1. Guarantee that patients and providers have access to a clearly disclosed list of drugs when step therapy protocols are used.***

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.<sup>1,2</sup>

NPF requests the list of drugs used in a step therapy protocol be clear and transparent. MDHHS utilizes the [Step Therapy Criteria](#) and the [Drug PA Criteria](#) to establish its Common Formulary step therapy process. Psoriasis (PsO) and Psoriatic Arthritis (PsA) are not listed in the Step Therapy Criteria document; however, [Appendix A](#) in the Common Formulary and the Drug PA Criteria set out the differing expectations for step therapy for PsO and PsA patients. NPF request MDHHS review the conflicting step therapy processes for PsO and PsA so patients and providers understand the expectations for obtaining the treatments needed to treat his or her disease.

**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, which creates 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.<sup>3</sup>

MDHHS clearly states on its website that the Department is maximizing drug manufacturer rebates to generate additional budgetary savings surrounding the Medicaid program. However, NPF respectfully requests that when establishing utilization management tools, such as step therapy protocols, these protocols should be based on widely accepted medical and clinical guidelines, and not solely based on cost.

**3. *Establish an exceptions process and include the required documentation and related information needs to submit a completed exceptions request.***

While step therapy is often an appropriate utilization tool, it can be particularly difficult when applied towards complicated, heterogenous diseases like psoriasis. Failure to take into consideration the unique nature of a diseases like psoriasis and psoriatic arthritis can be detrimental for patients and can lead to:

- disease progression,
- higher overall costs of care,
- irreversible damage (specifically joint), or
- development of other comorbidities.

It is likely an individual with psoriasis will have at least one, if not multiple, significant comorbidities including: arthritis, cardiovascular disease, metabolic syndrome (diabetes), inflammatory bowel disease and depression.<sup>4</sup> These associated comorbidities emphasize the importance for tailored and efficacious treatment plans.

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<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</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>4</sup> (WHO). WHO. Global Report on Psoriasis. Geneva: World Health Organization;

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.

The Common Formulary should include a clear process for a health care provider or patient to submit an exceptions request to the step therapy protocol if at least one of the following criteria are met:

- is contraindicated or will likely cause an adverse reaction of physical or mental harm
- is expected to be ineffective
- was previously tried and discontinued due to lack of effectiveness
- is not in the best interest of the patient based on medical necessity
- the patient is currently stable on a medication while under the patient's current or previous health benefit plan

Further, the Common Formulary and the MCOs should make the utilization management process transparent and straightforward so patients and providers can easily access the information they need to meet the documentation requirements to request an exception.

#### **4. Establish timelines for granting or denying an exception submission.**

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 \$0.06 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.<sup>5,6</sup> 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.<sup>7</sup>

We highly encourage MDHHS to require all MCOs to meet a process response timeline of twenty-four (24) hours in urgent circumstances, and seventy-two (72) in non-urgent circumstances for exception requests submitted by the patient or on behalf of the patient.

Commonsense guardrails on prescription drug step therapy protocols recognize the primacy of the patient-provider relationship while maintaining the ability for the MCOs to use these tools to manage cost.

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<sup>5</sup> 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.

<sup>6</sup> 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

<sup>7</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

## **Additional Concerns Regarding the Common Formulary**

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### **1. *Formulary Review***

Psoriasis is an immune-mediated disease that affects approximately 3 percent of the adult U.S. population.<sup>8</sup> Up to 30 percent of individuals with psoriasis may also develop psoriatic arthritis, an inflammatory form of arthritis that can lead to irreversible joint damage if left untreated.<sup>9</sup> Due to the heterogeneous characteristics of this chronic immune-mediated disease, psoriatic disease requires sophisticated medical care. Treatments that work for one person may not work for others, and many patients cycle through numerous accepted treatment options.<sup>10</sup> Without the tools to control their symptoms, people with psoriatic disease cycle through periods of intense pain; fatigue; unbearable itch; whole-body inflammation; flaking and bleeding of large swaths of the skin; and joint degradation.

NPF requests the Common Formulary provide a diverse formulary with multiple drugs and multiple mechanisms of action. The Common Formulary should also include multiple drugs for varying severity of PsO and PsA diagnoses. In 2016, the Institute for Clinical and Economic Review analyzed the effectiveness and value of targeted immunomodulators for the treatment of moderate-to-severe plaque psoriasis and found incremental cost-effectiveness ratios across all agents that were well-aligned with commonly-accepted thresholds for cost-effectiveness.<sup>11</sup> The ICER found the immunomodulators drugs reviewed were a “good value”; therefore, NPF reiterates its request for a robust formulary for PsO and PsA Medicaid Managed Care patients.

### **2. *MDHHS MCO Common Formulary Workgroup Members***

NPF respectfully requests a review of the membership of the MDHHS MCO Common Formulary Work Group. Patient and provider groups offer a unique and valuable perspective regarding the patients that receive services through the Medicaid Managed Care program, especially those representing and treating the chronic disease community. Chronic disease patients tend to have greater utilization of high cost and specialty drugs and should be allowed to participate with other stakeholders in the implementation of the Common Formulary and utilization management protocols.

### **3. *Oversight***

NPF applauds MDHHS for the continuous and diligent oversight of the Medicaid Managed Care program. NPF requests MDHHS continue its oversight and transparency of the implementation of the Common Formulary and the utilization management tools, including step therapy, used with Medicaid Managed Care recipients.

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 Common Formulary and the utilization management tools used in the Medicaid Managed Care program. NPF hopes to continue this conversation surrounding utilization management

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<sup>8</sup> Helmick CG, Lee-Han H, Hirsch SC, Baird TL, Bartlett CL. Prevalence of Psoriasis Among Adults in the U.S: 2003–2006 and 2009–2010 National Health and Nutrition Examination Surveys. *American journal of preventive medicine*. 2014;47(1):37-45. doi:10.1016/j.amepre.2014.02.012.

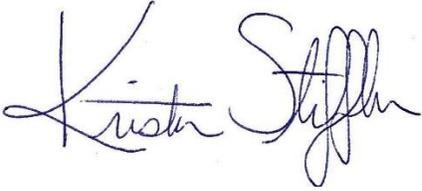
<sup>9</sup> Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis*. 2005;64(suppl 2):ii14–ii17. - See more at: <http://www.rheumatologynetwork.com/psoriatic-arthritis/classification-criteria-psoriatic-arthritis-caspar#sthash.Or6zBLgM.dpuf>

<sup>10</sup> Stern RS, Nijsten T, Feldman SR, Margolis DJ, Rolstad T. Psoriasis is common, carries a substantial burden even when not extensive, and is associated with widespread treatment dissatisfaction. *Journal of Investigative Dermatology Symposium Proceedings*. 2004 Mar; 9(2):136-9

<sup>11</sup> [https://icer-review.org/wp-content/uploads/2016/08/NECEPAC\\_Psoriasis\\_Draft\\_Report\\_092916.pdf](https://icer-review.org/wp-content/uploads/2016/08/NECEPAC_Psoriasis_Draft_Report_092916.pdf)

tools for psoriatic patients and would like the opportunity to follow up with additional information. Thank you for your time and consideration. If you have questions or concerns, please contact me at [kstiffler@psoriasis.org](mailto:kstiffler@psoriasis.org).

Sincerely,

A handwritten signature in black ink that reads "Kristen Stiffler". The signature is written in a cursive style with a large initial "K" and "S".

Kristen Stiffler  
State Government Relations Manager, Central Region