

October 1, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage

Dear Secretary Azar,

The undersigned organizations, representing millions of Medicare beneficiaries with complex, chronic conditions and the providers who care for them, write today in response to the recent announcement that Medicare will permit the use of step therapy protocols for Part B drugs in Medicare Advantage (MA) plans beginning this coming year. Our organizations and the individuals we represent are intimately familiar with step therapy practices across the country and come to you with a diversity of perspectives on how these policies impact care, health outcomes, and the overall well-being of millions of Americans. We recognize the administration's efforts to explore methods for controlling healthcare spending. However, we seek to share our significant experience with this topic and put forward some proven solutions to ensure any Part B step therapy protocols allow for appropriate utilization management while recognizing the primacy of the patient-physician relationship for MA beneficiaries.

Each day, our patients and providers face the reality of step therapy and its impact on care, 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, step therapy exacerbates administrative burdens as they help patients navigate complicated and often opaque coverage determination processes. Step therapy protocols are not required to follow clinical practice guidelines, creating unnecessary and harmful hurdles to accessing accepted standards of care. Such experiences have made us experts on the impacts of step therapy policies and prompted us to advocate for a more patient- and provider-friendly system. This advocacy work has resulted in a consensus model of step therapy protections that is already in place in numerous state insurance markets across the country. Additionally, this model is currently being considered in Congress for application to health plans governed under the Employee Retirement Income Security Act (ERISA). Due to the nature of the Medicare population, reasonable guardrails are especially important to include as MA plans gain this additional authority to implement step therapy protocols. We think including specific beneficiary protections and guardrails are necessary and that such protections should be instituted on day one.

Specifically, when faced with step therapy, it is critical that patients can receive an exception to one of the required steps when the plan-directed medication is inappropriate. Too often, step therapy protocols create a one-size-fits-all approach to treatment that runs counter to the growing movement for patient-centered care. Additionally, a recent study shows that step therapy protocols are inconsistent across plans, creating additional confusion and frustration for patients and the providers acting on their behalf.¹ Therefore, step therapy policies should be explicit regarding the circumstances that warrant and the processes for requesting an exception. We recognize that balance needs to be struck so the exceptions process is not overly prescriptive. However, we believe beneficiaries should have access to a patient- and provider-friendly exception process when:

¹ 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.

- (1) the treatment is contraindicated;
- (2) the treatment is expected to be ineffective based on the physical or mental characteristics of the patient or the nature of the treatment;
- (3) the treatment will cause or is likely to cause an adverse reaction to the individual;
- (4) the treatment is not in the best medical interest of the patient because the provider is already following applicable clinical practice guidelines or because the treatment is expected to decrease the individual's ability either to perform daily activities, occupational responsibilities, or adhere to the treatment plan; or
- (5) the individual is stable on another drug to treat his or her condition.

We commend CMS for their actions to require MA plans to exclude beneficiaries with existing prescriptions from step therapy requirements. We greatly appreciate CMS's recognition of the need for stable patients to remain on their course of treatment and request clarity on whether this protection will extend to those enrolling in a Medicare plan for the first time. The undersigned organizations believe this protection should extend to both new and existing Medicare beneficiaries who are stable on their medications.

We also encourage CMS to require plans to meet the Part D appeals process response timeline of 72 hours or 24 hours in life-threatening cases. 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 conditions. We appreciate that CMS is "strongly encouraging" MA plans to follow this timeline but feel patients would be best served if it were an explicit requirement. Lastly, reforms should require plans to make the appeals process transparent and straightforward so patients and physicians can easily access the information they need to meet the plan's documentation requirements.

As mentioned, this step therapy reform model is already in place in numerous states across the country, including Indiana, Texas, Iowa, and West Virginia. In 2018 alone, two additional states enacted robust step therapy protection laws. These commonsense guardrails on step therapy recognize the primacy of the patient-provider relationship while maintaining the ability for insurers to use this tool to manage utilization, and we think CMS would be well-served by basing the MA step therapy appeals process on this model.

We welcome the opportunity to further discuss these solutions with you and how they can best be translated to the Medicare population. For additional information, please contact Patrick Stone, Vice President of Government Relations and Advocacy with the National Psoriasis Foundation, at pstone@psoriasis.org.

Sincerely,

Alliance for Patient Access
Alliance for the Adoption of Innovations in Medicine (Aimed Alliance)
American Academy of Dermatology Association
American Academy of Neurology
American Autoimmune Related Diseases Association (AARDA)
American College of Rheumatology
American Gastroenterological Association
American Liver Foundation
American Society of Clinical Oncology
Arthritis Foundation
Chronic Disease Coalition
Crohn's & Colitis Foundation
Dermatology Nurses Association
Digestive Disease National Coalition
Dystonia Advocacy Network
Dystonia Medical Research Foundation

Epilepsy Foundation
GBS|CIDP Foundation International
Global Healthy Living Foundation
Hemophilia Federation of America
Interstitial Cystitis Association
ITSAN (International Topical Steroid Addiction Network)
Lupus and Allied Diseases Association
Mental Health America
METAvivor
National Alliance on Mental Illness
National Eczema Association
National Infusion Center Association
National MS Society
National Organization for Rare Disorders
National Patient Advocate Foundation
National Psoriasis Foundation
NephCure Kidney International
Patients Rising Now
Pulmonary Hypertension Association
Scleroderma Foundation
The Marfan Foundation
United Spinal Association
US Hereditary Angioedema Association
US Pain Foundation