

April 8<sup>th</sup>, 2019

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244  
Via e-mail: [Seema.Verma@cms.hhs.gov](mailto:Seema.Verma@cms.hhs.gov)

**RE: Patient Protections and Step Therapy**

Dear Administrator Verma:

On behalf of the millions of Americans living with chronic, disabling, and life-threatening medical conditions, the undersigned patient and provider organizations have joined together to advocate for policies addressing one of the greatest obstacles standing between patients and the treatments they need: high out-of-pocket costs. We write to you today regarding the important patient protections for Medicare Advantage (MA) plans implementing utilization management protocols.

On August 7, 2018 CMS issued a memo to MA plans that rescinded the September 17, 2012 HPMS memo *Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services* and issued new guidance allowing MA plans to use step therapy for Part B drugs, beginning January 1, 2019. Step therapy, also known as fail first protocols, limits therapeutic treatments based on payer preference. This may require a patient to try a treatment other than what the physician believes is best. Step therapy frequently disrupts continuity of care by requiring patients to stop an effective therapy and switch to another due to formulary or protocol changes. Stopping and restarting certain medicines may cause the treatments to fail due to immunogenicity or cause dangerous reactions when the medication is re-initiated. We appreciate that CMS listened to these concerns and proposed guardrails in the 2019 *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* proposed rule. Due to the timing of these regulatory guidance's and proposed rules we have grave concerns that there will be a year gap of protections for patients in 2019. The proposed guard rails would not go into effect until 2020 leaving vulnerable patients unprotected from harmful step therapy practices. For patients with severe or complex diseases, this can result in irreversible damage, disability, and even death. **We urge CMS to immediately publish guidance to plans that lays out, at minimum, the patient safeguards proposed in the *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* proposed rule so that beneficiaries have some protections in 2019.**

We applaud CMS for including these safeguards intended to protect beneficiaries and ensure timely access to medically necessary Part B drugs. Although we are pleased to see these safeguards, such as step therapy requirements only applying to new starts of medication, the safeguards do not go far

enough to protect patients. **In addition to publishing these safeguards for 2019 we also urge CMS to provide more details on exceptions and recommend that CMS make the following explicitly clear:**

- That the provider determines if a patient “fails” a treatment, not another entity such as the insurance company.
- Exception if the treatment is contraindicated.
- Exception if the provider determines the treatment is likely to be ineffective.
- Exception if the provider determines the treatment is likely to cause a harmful reaction.
- Exception for those whose life could be in jeopardy or physical or sensory function irreparably harmed.
- Exception if the provider and patient believe the treatment is likely to impede the patient’s ability to perform daily activities or responsibilities and/or adhere to the treatment plan.
- Preclude any unwritten, implicit step therapy that is handled through a different utilization management process such as prior authorization.

In conclusion, we hope that CMS will publish guidance to the plans as soon as possible so that patients will have safeguards for the 2019 plan year. We also welcome the opportunity to work with CMS to ensure that no patient is left without the ability to get the treatment that can improve or save their lives. Please contact Kayla L. Amodeo, Ph.D., at [kamodeo@rheumatology.org](mailto:kamodeo@rheumatology.org) or (202) 210- 1797 if you have questions or if we can be of assistance.

Sincerely,

Alliance for Patient Access  
American Academy of Dermatology Association  
American Academy of Neurology  
American College of Rheumatology  
American Gastroenterological Association  
American Society of Clinical Oncology  
Arthritis Foundation  
Beyond Celiac  
Chronic Disease Coalition  
Crohn’s & Colitis Foundation  
Digestive Disease National Coalition  
Digestive Health Physicians Association  
Global Healthy Living Foundation  
Hemophilia Federation of America  
Lupus and Allied Diseases Association, Inc.  
Lupus Foundation of America  
National Brain Tumor Society  
National Infusion Center Association  
National Psoriasis Foundation  
Pennsylvania Society of Gastroenterology  
Sjogren’s Syndrome Foundation  
Spondylitis Association of America  
The Sturge-Weber Foundation

U.S. Pain Foundation  
WomenHeart