

November 23, 2021

The Honorable Chiquita Brooks-LaSure Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

*Via Electronic Delivery*

**Re: Step Therapy for Part B Drugs in Medicare Advantage**

Dear Administrator Brooks-LaSure,

The undersigned organizations, representing millions of Medicare beneficiaries with life-threatening, complex, chronic conditions and/or the physicians who care for them, are asking the Centers for Medicare and Medicaid Services (CMS) to ensure that beneficiaries enrolled in Medicare Advantage plans continue to have appropriate and timely access to the therapies they need to properly manage their conditions. **CMS was recently presented with current examples of patient harm due to the implementation of utilization management protocols and we are asking that the agency move swiftly to reinstate the step therapy prohibition in Medicare Advantage (MA) plans for Part B drugs.**

On August 7, 2018 CMS issued a memo to MA plans that rescinded the September 17, 2012 HPMS memo *Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services* and issued new guidance allowing MA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. In May 2019, CMS issued the *Medicare Advantage and Part D Drug Pricing Final Rule* codifying the change, allowing MA plans to impose step therapy on Part B drugs.

Step therapy, also known as “fail first,” is utilized by health plans to determine coverage and requires that patients fail on an insurer’s preferred medication before the therapy prescribed by their health care provider is covered. Step therapy frequently delays or disrupts continuity of care and threatens outcomes for patients. Stopping and restarting certain medicines may cause the treatments to fail due to immunogenicity or cause dangerous reactions when the medication is re-initiated.

Part B drugs treat some of the most vulnerable Medicare beneficiaries and while a drug or therapy might be generally considered appropriate for a condition, individual patient issues--the presence of comorbidities, potential drug-drug interactions, or patient intolerances - may necessitate the selection of an alternative drug as the first course of treatment. These policies also interfere with the patient – physician relationship, often resulting in delayed treatment, increased disease activity, disability, and in some cases irreversible disease progression. Step therapy requirements often fail to recognize such considerations, resulting in delays in getting patients the right treatment at the right time. A patient’s health care provider is in the best position to assess their patients’ medical needs.

Our groups were disappointed that this important prohibition was previously removed. Since step therapy was allowed in 2019 there have been multiple cases of patient harm. Recently, several groups presented CMS with clear instances of patient harm that resulted in, but was not limited to, patients becoming legally blind, long term hospitalizations, infections, increased disease activity, and

disability. We are pleased that CMS took the time to meet with patient and physician stakeholder groups. With open enrollment just around the corner it is important now more than ever to ensure beneficiaries have appropriate access to care when they are selecting their MA plan. **Given that there have been numerous cases of patient harm due to the utilization of step therapy protocols and the fact that beneficiaries receiving Part B covered drugs include some of the most vulnerable in the program, we urge the administration to take immediate action and reverse the harmful decision to allow MA plans to implement step therapy.**

Patients deserve timely access to the most clinically appropriate treatment, and we appreciate CMS taking the health of beneficiaries seriously with a focus on high quality healthcare. We welcome the opportunity to further discuss implementation of the reversal of this policy in greater detail and look forward to working with CMS to ensure Medicare beneficiaries have timely access to life changing therapies. To discuss this matter further or schedule a meeting, please have your staff contact Kayla L. Amodeo, PhD, American Academy of Ophthalmology's Director of Health Policy at [kamodeo@aao.org](mailto:kamodeo@aao.org) or via phone at 202-210-1797.

*CC: Cheri Rice, Deputy Director, Center for Medicare*

Sincerely,

Allergy & Asthma Network  
Alliance for Aging Research  
Alliance for Patient Access  
American Academy of Allergy, Asthma, and Immunology  
American Academy of Neurology  
American Academy of Ophthalmology  
American Association of Neurological Surgeons  
American College of Gastroenterology  
American College of Rheumatology  
American Gastroenterological Association  
American Glaucoma Society  
American Medical Association  
American Partnership for Eosinophilic Disorders  
American Society for Gastrointestinal Endoscopy  
American Society of Anesthesiologists  
American Society of Cataract and Refractive Surgery  
American Society of Retina Specialists  
American Urological Association  
Arthritis Foundation  
Association for Clinical Oncology  
Asthma and Allergy Foundation of America  
Autoimmune Association  
Campaign Urging Research for Eosinophilic Disease  
Cancer Support Community  
Coalition of Skin Diseases  
Coalition of State Rheumatology Organizations  
Color of Crohn's and Chronic illness  
Community Oncology Alliance  
Congress of Neurological Surgeons

Crohn's & Colitis Foundation  
Cure SMA  
Derma Care Access Network  
Diabetes Policy Collaborative  
Digestive Disease National Coalition  
Digestive Health Physicians Association  
EveryLife Foundation for Rare Diseases  
Hemophilia Federation of America  
IBDMoms  
Infusion Access Foundation  
International Foundation for Autoimmune & Autoinflammatory Arthritis  
Large Urology Group Practice Association  
Lupus and Allied Diseases Association, Inc.  
Maryland Society of Eye Physicians & Surgeons  
Medical Group Management Association  
National Eczema Association  
National Infusion Center Association  
National Organization of Rheumatology Management  
National Psoriasis Foundation  
Oncology Nursing Society  
Patient Services, Inc  
Patients Rising  
Physician Advocacy Institute  
Prevent Blindness  
Spondylitis Association of America  
The Sumaira Foundation  
The US Oncology Network  
U.S. Pain Foundation  
Vision Health Advocacy Coalition