

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On August 7, 2018 CMS issued a memo to MA plans that rescinded the September 17, 2012 HPMS memo *Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services* and issued new guidance allowing MA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 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