

February 13th, 2023

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. **We are taking this opportunity to ask again for the agency to move swiftly to reinstate the step therapy prohibition in Medicare Advantage (MA) plans for Part B drugs as described in the September 17, 2012, HPMS memo *Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services*.**

Step therapy and prior authorization are both forms of utilization management, and we share the concerns for MA beneficiary access to care described by the HHS Office of Inspector General (OIG) in their report, *Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care*. As highlighted by the OIG report, although some denials are ultimately reversed by MA organizations, negative consequences from avoidable delays in medically necessary care are not absolved.¹ Critical delays in obtaining the best medicines for the best outcomes may ultimately lead to increased costs for the Medicare program and its beneficiaries as well.

Despite this past research by the OIG on step therapy, we are concerned that in the recent proposed rule on changes to Medicare, there is still language asserting that “The requirements in the 2019 rule, in combination with current MA program regulations, ensure access to Part B drugs and limit the potential for step therapy policies to interfere with medically necessary care”. As we have raised in the past, the current allowances made for Step Therapy in Medicare Part B are creating unnecessary burdens and consequences when it comes to the care of patients.

In September 2021, several groups presented CMS leaders with clear instances of patient harm that resulted in, but were not limited to, patients becoming legally blind, long-term hospitalizations,

¹ U.S. Department of Health and Human Services Office of Inspector General. (April 2022). *Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care*. <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>

infections, increased disease activity, and disability. We appreciate that CMS took the time to meet with patient and physician stakeholder groups and listen to our testimony; however, **we are concerned that step therapy remains permissible, and patients continue to be harmed by the practice.**

There have been numerous cases of patient harm due to the utilization of step therapy protocols and the beneficiaries receiving Part B covered drugs include some of the most vulnerable in the program. As enrollment in MA plans rapidly grows, including Special Needs Plans², the need to address this barrier to care becomes ever more urgent. With that in mind, **we urge the administration to protect patients' access to care and expeditiously reverse the harmful decision to allow MA plans to implement step therapy.**

We 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 Brandy Keys, MPH, American Academy of Ophthalmology's Director of Health Policy at bkeys@aao.org or via phone at 202-737-6662.

Sincerely,

Allergy & Asthma Network
Alliance for Aging Research
Alliance for Patient Access
American Academy of Allergy, Asthma, and Immunology
American Academy of Dermatology Association
American Academy of Neurology
American Academy of Ophthalmology
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Allergy, Asthma and Immunology (ACAAI)
American College of Gastroenterology
American College of Osteopathic Family Physicians
American College of Osteopathic Internists
American College of Rheumatology
American Glaucoma Society
American Macular Degeneration Foundation
American Medical Association
American Partnership for Eosinophilic Disorders (APFED)
American Society for Gastrointestinal Endoscopy
American Society of Cataract and Refractive Surgery
American Society of Retina Specialists
American Urological Association
Arthritis Foundation

² From 2000 to 2021 enrollment in Medicare Advantage Plans grew from 7 million to 26 million enrollees (73% increase). Special Needs Plans accounted for about 15% of total Medicare Advantage enrollment in 2021.

Association for Clinical Oncology
Association of Black Cardiologists
Asthma and Allergy Foundation of America
Autoimmune Association
Bone Health and Osteoporosis Foundation
Coalition of Skin Diseases
Coalition of State Rheumatology Organizations
Community Oncology Alliance (COA)
Congress of Neurological Surgeons
Crohn's & Colitis Foundation
Digestive Health Physicians Association (DHPA)
Epilepsy Alliance America
Global Healthy Living Foundation
Infusion Access Foundation
International Foundation for Autoimmune & Autoinflammatory Arthritis
Large Urology Group Practice Association (LUGPA)
Lupus and Allied Diseases Association, Inc.
Medical Group Management Association
Multiple Sclerosis Association of America
Multiple Sclerosis Foundation
National Eczema Association
National Infusion Center Association
National Psoriasis Foundation
Patients Rising Now
Physician Advocacy Institute
Prevent Blindness
Pulmonary Hypertension Association
Restless Legs Syndrome Foundation
Rheumatology Nurses Society (RNS)
Spondylitis Association of America
The Michael J. Fox Foundation for Parkinson's Research
The Oley Foundation
The US Oncology Network
U.S. Pain Foundation
US Hereditary Angioedema Association
Vision Health Advocacy Coalition