

June 1, 2022

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 asking that the agency 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 of denials are ultimately reversed by MA organizations, negative consequences from avoidable delays in medically necessary care are not absolved.<sup>1</sup> 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.

Our groups were disappointed by the rescission of this important prohibition by the previous administration. Since step therapy has been allowed for Part B drugs since 2019 there have been multiple cases of patient harm. 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, 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.**

Part B drugs treat some of the most vulnerable Medicare beneficiaries, which makes step therapy a health equity issue. Recent analysis of Medicare beneficiary demographic characteristics shows that MA

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<sup>1</sup> 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>

enrollees are disproportionately lower-income, Black or Latino, and dually enrolled in Medicaid when compared to traditional fee-for-service enrollees.<sup>2</sup> As long as Medicare Advantage plans are allowed to use step therapy, patients treated under these private for-profit MA plans are deprived of the same health care that those in fee-for-service receive.

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 Plans<sup>3</sup>, 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](mailto:bkeys@aao.org) or via phone at 202-737-6662.

CC: Meena Seshamani, MD, PhD, Deputy Administrator and Director of the Center for Medicare; Cheri Rice, Deputy Director, Parts C and D, of the Center for Medicare

Sincerely,

Accessia Health  
aHUS Action Network  
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 Association of Neurological Surgeons  
American Academy of Ophthalmology

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<sup>2</sup> Analysis by the by the Office of the Assistant Secretary for Planning and Evaluation on 2019 enrollment data shows that beneficiaries enrolled in MA were more likely to report incomes below 100% FPL (17.6 percent vs. 14.6 percent), be 75 or older (39.6 percent vs. 37.5 percent), and have educational attainment less than high school (17.5 percent vs. 12.3 percent). MA included a higher percent of Black and Latino beneficiaries (13.7 percent and 10.6 percent) than in FFS Parts A and B (8.5 percent and 5.2 percent, respectively). MA enrollees were more likely than FFS enrollees to be dually enrolled (20.1 percent vs. 16.5 percent) and to have multiple health conditions (34.2 percent vs. 25.4 percent).

HHS Office of the Assistant Secretary for Planning and Evaluation. (2022, March 2). *Medicare Beneficiary Enrollment Trends and Demographic Characteristics*.  
<https://aspe.hhs.gov/sites/default/files/documents/f81aafbb0b331c71c6e8bc66512e25d/medicare-beneficiary-enrollment-ib.pdf>

<sup>3</sup> 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.

Kaiser Family Foundation. (2021, June 21). *Medicare Advantage in 2021: Enrollment Update and Key Trends*.  
<https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2021-enrollment-update-and-key-trends/>

American College of Allergy, Asthma and Immunology  
American College of Gastroenterology  
American College of Osteopathic Family Physicians  
American College of Rheumatology  
American Gastroenterological Association  
American Glaucoma Society  
American Liver Foundation  
American Macular Degeneration Foundation  
American Medical Association  
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  
Association of Black Cardiologists  
Association of Gastrointestinal Endoscopy  
Asthma and Allergy Foundation of America  
Autoimmune Association  
Caregiver Action Network  
Center for Medicare Advocacy  
Chronic Disease Coalition  
Coalition of Skin Diseases  
Coalition of State Rheumatology Organizations  
Community Oncology Alliance  
Congress of Neurological Surgeons  
Crohn's & Colitis Foundation  
Digestive Health Physicians Association  
Epilepsy Alliance America  
Fabry Support & Information Group  
GBS|CIDP Foundation International  
Glaucoma Research Foundation  
Hemophilia Federation of America  
Hypersomnia Foundation  
Infusion Access Foundation  
Infusion Providers Alliance  
International Foundation for Autoimmune & Autoinflammatory Arthritis  
International Foundation for Gastrointestinal Disorders  
International Topical Steroid Access Network  
Large Urology Group Practice Association  
Louisiana Hemophilia Foundation  
Lupus and Allied Diseases Association, Inc.  
Maryland Society of Eye Physicians & Surgeons  
Medical Group Management Association  
Medicare Rights Center  
Multiple Sclerosis Association of America  
National Alopecia Areata Foundation

National Association for Continence  
National Eczema Association  
National Infusion Center Association  
National Multiple Sclerosis Society  
National Organization for Rare Disorders  
National Pancreas Foundation  
National Psoriasis Foundation  
National Scleroderma Foundation  
Physician Advocacy Institute  
Prevent Blindness  
Project Sleep  
Pulmonary Hypertension Association  
Restless Legs Syndrome Foundation  
Spondylitis Association of America  
The Glaucoma Foundation  
The Michael J. Fox Foundation for Parkinson's Research  
The US Oncology Network  
U.S. Pain Foundation  
United for Charitable Assistance  
US Hereditary Angioedema Association  
Vision Health Advocacy Coalition  
wAIHA Warriors