

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.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.

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

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>

enrollees are disproportionately lower-income, Black or Latino, and dually enrolled in Medicaid when compared to traditional fee-for-service enrollees.² 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 Plans³, 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.

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

² 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>

³ 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