

April 22, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Step Therapy for Part B Drugs in Medicare Advantage

Dear Secretary Becerra,

The undersigned organizations, representing millions of Medicare beneficiaries with life-threatening, complex, chronic conditions and 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 write to you today regarding the implementation of utilization management protocols and specifically the reinstatement of an important patient protection for beneficiaries in Medicare Advantage (MA) plans.

On August 7, 2018 CMS issued a memo to MA plans that rescinded the September 17, 2012 HPMS memo *Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services* and issued new guidance allowing MA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. We were disappointed that the previous administration removed this important patient protection. 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.

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. 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.

Step therapy 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 can also be administratively burdensome on a physician and their staff as they help patients navigate complicated and often opaque coverage determination processes. Furthermore, payor exemption and appeals processes can be complicated and lengthy, making them onerous for busy physician practices and patients awaiting treatment.

While we do appreciate that CMS included some safeguards intended to protect beneficiaries and ensure timely access to medically necessary Part B drugs in the final policy, those safeguards do not go far enough to protect patients. **To protect our patients, we urge CMS to reinstate the step therapy prohibition in Medicare Advantage plans for Part B drugs as laid out in the original September 17, 2012 HPMS memo *Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services*.**

We hope that the new administration will consider immediately reversing the harmful decision to allow step therapy. At the same time, we encourage CMS to continue its work with patients, physicians, and other key stakeholders to develop other solutions that will ensure Medicare beneficiaries continue to have timely access to the clinical treatments they need while lowering the cost of medications for patients and the Medicare program. This is an urgent first step in ensuring a broad, evidence based pharmaceutical benefit for the beneficiaries.

We would welcome the opportunity to discuss implementation of the reversal of this policy in greater detail. As patient and physician advocacy organizations representing millions of beneficiaries and their health care providers, we are keenly aware of the challenges that can arise from poorly structured and implemented step therapy protocols. 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 Kayla L. Amodeo, PhD, American Academy of Ophthalmology's Director of Health Policy at kamodeo@aaoo.org or via phone at 202-210-1797.

CC: Elizabeth Richter, Acting Administrator, Centers for Medicare and Medicaid Services

Sincerely,

Aimed Alliance
Alliance for Patient Access
American Academy of Allergy Asthma and Immunology (AAAAI)
American Academy of Dermatology Association
American Academy of Neurology
American Academy of Ophthalmology
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American Autoimmune Related Diseases Association, Inc.
American College of Gastroenterology
American College of Rheumatology
American Gastroenterological Association
American Glaucoma Society
American Society for Gastrointestinal Endoscopy
American Society for Radiation Oncology
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
Cancer Support Community
Caregiver Action Network
Chronic Disease Coalition
Coalition of State Rheumatology Organizations
Color of Crohn's & Chronic Illness, Inc.
Community Oncology Alliance (COA)
Congress of Neurological Surgeons
Crohn's & Colitis Foundation
Cure SMA
Digestive Disease National Coalition
Digestive Health Physicians Association (DHPA)
Endocrine Nurses Society
Global Healthy Living Foundation
Hemophilia Federation of America
Infusion Access Foundation (IAF)
Infusion Providers Alliance
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)

Large Urology Group Practice Association (LUGPA)
Lupus and Allied Diseases Association, Inc.
Medical Group Management Association
Multiple Sclerosis Association of America
National Comprehensive Cancer Network
National Eczema Association
National Infusion Center Association (NICA)
National Osteoporosis Foundation
National Psoriasis Foundation
North American Spine Society
Oncology Nursing Society
Prevent Blindness
Pulmonary Hypertension Association
Society of Gynecologic Oncology
Spondylitis Association of America
The Oley Foundation
The US Oncology Network
U.S. Pain Foundation
Vision Health Advocacy Coalition