

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On August 7, 2018 CMS issued a memo to MA plans that rescinded the September 17, 2012 HPMS memo *Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services* and issued new guidance allowing MA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