

September 7, 2018

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: Memo of August 7<sup>th</sup> Regarding Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage**

The undersigned organizations representing physicians thank the Centers for Medicare and Medicaid Services (CMS) for its attention to the negative impacts of high drug prices on Medicare and Medicaid beneficiaries, physicians, and the health care system. However, we have serious concerns about CMS's recent notification to Medicare Advantage plans that they will no longer be prohibited from utilizing step therapy protocols for physician administered drugs covered under Medicare Part B beginning in 2019. We find the growing trend towards the use of restrictive and burdensome utilization management tactics by payors concerning and urge CMS to reconsider its stance on this critical patient care issue.

Step therapy protocols that require patients to try and fail certain treatments before allowing access to other, potentially more appropriate treatments can both harm patients and undercut the physician-patient decision-making process. The most appropriate course of treatment for a given medical condition depends on the patient's unique clinical situation and the care plan developed by the physician in close consultation with that patient. While a particular drug or therapy might be generally considered appropriate for a condition, the presence of comorbidities, potential drug-drug interactions, or patient intolerances, for example, may necessitate the selection of an alternative drug as the first course of treatment. Step therapy requirements often fail to allow for such considerations, resulting in delays in getting patients the right treatments at the right time and unnecessary complications in the physician-patient decision-making process.

While step therapy protocols are problematic for many patients on a variety of therapies, they are particularly concerning where physician-administered drugs are concerned. In many cases, patients receiving drugs covered under Part B are especially vulnerable, many with serious or life-threatening conditions. Many cancer therapies, for example, are covered under Part B. For cancer patients, selecting the proper personalized treatment as quickly as possible can be critical to survival. For others, such as those suffering from conditions like autoimmune disorders and progressive blinding eye diseases, delays in getting appropriate treatments can mean prolonged symptomatic periods and irreversible damage, making a "fail first" approach to treatment inappropriate. Although the notification states that step therapy can only be applied to new prescriptions and administrations of Part B drugs, we have serious concerns about patients who will change Medicare Advantage plans being required to disrupt their current treatment to retry previously failed therapeutic regimens to meet step therapy requirements for a new plan. We also note that many Part B drugs are periodically infused, compared to being administered on a routine basis, which could easily lead to different interpretations between plans in what is considered a "newly prescribed" medication and to interruptions in ongoing therapy that could have devastating, permanent consequences for Medicare beneficiaries and their health.

Step therapy likewise places a significant administrative burden on physician practices. Physicians do not currently have ready access to patient benefit and formulary information, as there is currently no capability making this information available through electronic health records or other means at the point of prescribing. This lack of transparency makes it exceedingly difficult to determine what treatments are preferred by a particular payor at the point of care and places practices at financial risk for the cost of administered drugs if claims are later denied for unmet (yet unknown) step therapy requirements. Furthermore, payor exemption and appeals processes can be complicated and lengthy, making them burdensome for both busy physician practices and patients awaiting treatment. At a time when CMS has prioritized regulatory burden reduction in the patient-provider relationship through its Patients Over Paperwork initiative, it is our hope that another layer of administrative complication will not be added on to an already strained system.

As rising drug prices continue to place huge financial burdens on patients and the health care system, we recognize the significant difficulty of finding meaningful solutions that have the desired outcome of reducing costs for both. However, as we work towards finding policies to address this problem, we hope that solutions can be found that do not involve the creation of barriers to appropriate and timely treatment for some of our most critical patients. Given this, we urge CMS to reinstate its 2012 policy prohibiting Medicare Advantage plans from utilizing step therapy protocols for Part B physician administered medications. We look forward to working with CMS to find a better path forward for physicians and patients.

Sincerely,

American Medical Association  
American Academy of Allergy, Asthma & Immunology  
American Academy of Dermatology Association  
American Academy of Facial Plastic and Reconstructive Surgery  
American Academy of Hospice and Palliative Medicine  
American Academy of Neurology  
American Academy of Ophthalmology  
American Academy of Otolaryngic Allergy/Foundation  
American Academy of Pain Medicine  
American Academy of Physical Medicine and Rehabilitation  
American Association for Hand Surgery  
American Association of Clinical Endocrinologists  
American Association of Neurological Surgeons  
American College of Allergy, Asthma and Immunology and the Advocacy Council  
American College of Cardiology  
American College of Gastroenterology  
American College of Obstetricians and Gynecologists  
American College of Osteopathic Internists  
American College of Osteopathic Surgeons  
American College of Physicians  
American College of Rheumatology  
American Epilepsy Society  
American Gastroenterological Association  
American Glaucoma Society  
American Medical Women's Association

American Orthopaedic Foot & Ankle Society  
American Psychiatric Association  
American Society for Gastrointestinal Endoscopy  
American Society for Metabolic and Bariatric Surgery  
American Society for Radiation Oncology  
American Society for Surgery of the Hand  
American Society of Cataract & Refractive Surgery  
American Society of Clinical Oncology  
American Society of Hematology  
American Society of Plastic Surgeons  
American Society of Retina Specialists  
American Society of Transplant Surgeons  
American Urological Association  
College of American Pathologists  
Congress of Neurological Surgeons  
Heart Rhythm Society  
Medical Group Management Association  
Society for Cardiovascular Angiography and Interventions  
Society of Critical Care Medicine  
Society of Gynecologic Oncology

Medical Association of the State of Alabama  
Alaska State Medical Association  
Arizona Medical Association  
Arkansas Medical Society  
California Medical Association  
Colorado Medical Society  
Connecticut State Medical Society  
Medical Society of Delaware  
Medical Society of the District of Columbia  
Florida Medical Association Inc  
Medical Association of Georgia  
Hawaii Medical Association  
Idaho Medical Association  
Illinois State Medical Society  
Iowa Medical Society  
Kansas Medical Society  
Kentucky Medical Association  
Louisiana State Medical Society  
Maine Medical Association  
MedChi, The Maryland State Medical Society  
Massachusetts Medical Society  
Michigan State Medical Society  
Minnesota Medical Association  
Mississippi State Medical Association  
Missouri State Medical Association  
Montana Medical Association  
Nebraska Medical Association

Nevada State Medical Association  
New Hampshire Medical Society  
Medical Society of New Jersey  
New Mexico Medical Society  
Medical Society of the State of New York  
North Carolina Medical Society  
North Dakota Medical Association  
Ohio State Medical Association  
Oklahoma State Medical Association  
Oregon Medical Association  
Pennsylvania Medical Society  
South Carolina Medical Association  
South Dakota State Medical Association  
Tennessee Medical Association  
Texas Medical Association  
Utah Medical Association  
Vermont Medical Society  
Medical Society of Virginia  
Washington State Medical Association  
West Virginia State Medical Association  
Wisconsin Medical Society  
Wyoming Medical Society