

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 7th 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