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January 25, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses [CMS–4180–P]

Dear Administrator Verma:

The American Society for Gastrointestinal Endoscopy (ASGE) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Service's (CMS) proposals to control drug spending within Part D and Medicare Advantage, as published in the *Federal Register* on November 30, 2018.

As ASGE commented last year on the Administration's Blueprint for bringing down the price of drugs and reducing out-of-pocket costs, the high cost of drugs has fueled an elaborate system designed to control and manipulate costs, which imposes excessive burden on physicians. ASGE is grateful the Administration is committed to addressing the cost of drugs, but we are deeply disappointed that CMS is proposing to incorporate step therapy protocols in the Medicare Advantage program. Step therapy, a form of prior authorization, means physicians will spend even more time dealing with third-party intermediaries and less time providing patient care.

Gastroenterologists treat disorders of the bowel that produce an inflammatory response and for which biologics, oftentimes administered in the physician's office and reimbursed under Part B, are the primary treatment. CMS' proposal to allow Medicare Advantage plans to apply step therapy as a utilization management tool for Part B drugs will result in excessive burden on physicians who are trying to provide the best and most appropriate care to their patients.

Throughout the proposed rule, CMS makes reference to Part D policies, including the use of Pharmacy and Therapeutics committees to review and approve step therapy programs; step therapy parameters; and appeals timelines and processes. ASGE opposes CMS' proposal to allow Medicare Advantage plans to use step therapy on the basis of gastroenterologists' experiences with Part D plans and their imposition of utilization controls that interfere with physician-patient decision making.

Under Part D and other private insurance plans, complex drugs, including biologics, are uniformly subject to complex authorization processes that involve substantial delays in treatment. Gastroenterologists routinely have to utilize specialty pharmacies or authorization specialists to navigate the authorization requirements.

ASGE members also frequently must prove that a patient failed other therapies, including sometimes one or more drugs in the same category, before the requested therapy will be approved. Physicians are not given rules or indications of how these authorizations will be adjudicated. Based on the experiences gastroenterologists have had with utilization controls under Part D, we have no confidence that CMS' proposal to allow Medicare Advantage plans to impose step therapy requirements for Part B drugs will not result in the same tremendous burden on physicians and impediments to timely patient access to appropriate therapies.

CMS states in the rule that a Medicare Advantage organization "may," but is not required to, establish an evaluation process for the appropriateness of enforcing its step therapy protocols when a health care provider's assessment of medical necessity for the Part B drug indicates that the lower or earlier steps in the step therapy protocol are not clinically appropriate for a patient. ASGE is disappointed that CMS has proposed allowing Medicare Advantage plans to use step therapy without also establishing clear guardrails to ensure that barriers to care do not result.

Consistent with bipartisan legislation — the *Restoring the Patient's Voice Act of 2017*, H.R. 2077 — introduced in the House during the 115th Congress and supported by the ASGE, CMS should require Medicare Advantage plans to implement a clear process for a beneficiary or prescribing health care provider to request an exception to a medication step therapy protocol. CMS should also establish under which circumstances coverage for a prescription drug, including a Part B drug, would receive expedited approval without regard to a medication step therapy protocol.

Those circumstances, as delineated in the above referenced legislation, should, at a minimum include the following:

- The treatment otherwise required under the protocol, or a drug or drugs in the same pharmacological class, are contraindicated or have been ineffective in the treatment of the disease or condition of the patient.

- The treatment otherwise required under the protocol is reasonably expected to be ineffective based upon the known physical or mental characteristics of the patient, including medical history; and the known characteristics of such treatment.

- The treatment otherwise required under the protocol will cause or is likely to cause an adverse reaction or other physical harm to the patient.

- The treatment otherwise required under the protocol is not in the best interest of the patient, based on medical necessity, because the patient's use of such treatment is expected to decrease the patient's ability to achieve or maintain reasonable and safe functional ability in performing daily activities or occupational responsibilities; or to adhere to the treatment plan as defined by the prescribing health care provider.

- The patient is stable for his or her disease or condition on the prescription drugs selected by the prescribing health care provider.

It is particularly important that Medicare Advantage plans or their P&T committees justify each step in a step therapy protocol by the best data for relative effectiveness and not on short-term cost alone. We believe this review must be done annually and based on scientific literature. For many diseases there are multiple therapies, but not all are equal in providing short- and long-term remission and prevention of relapse, particularly as it relates to chronic disease. When insurance companies demand that a patient first try a less effective treatment, it may be several months before a more expensive but much more

effective agent is approved, during which time long-term damage may result. For example, in Crohn's disease it might be demanded that a patient fail an immunomodulator (MTX or azathioprine) before a biologic will be covered. The real-world effectiveness of biologics is more than twice that of immunomodulators and the onset of remission is also generally much quicker. The long-term cost effectiveness is also better with biologics as they truly can delay or prevent surgery. The short-term cost, however, is much higher.

When it is clear that lower or earlier steps in a step therapy protocol are not clinically appropriate for a patient, it is important for Medicare Advantage organizations to have processes in place that eliminate the need to file a request for an organization determination. Well-documented cases of medical necessity should not be encumbered by utilization control mechanisms that burden physicians and delay treatment.

CMS has proposed this change to reduce spending in the Medicare program which will undoubtedly shift cost onto providers who are uncompensated for the administrative time and staff required for authorization and appeals when coverage of the prescribed treatment is denied. When denial of prescribed treatment or step therapy requirements lead to a delay of appropriate medical care, insurers should be required to compensate physicians for the time associated with seeking appropriate authorizations. As proposed, these requirements are one-sided with no disincentive for plans to deny or delay care. Medicare Advantage plans must accept some level accountability for their policies if appropriate treatment is withheld or delayed.

Imposing step therapy and other utilization management tools to drive down drug spending is an expedient short-term solution that tacitly acknowledges the complexity and lack of transparency of drug pricing in this country that impedes reform. We respectfully request the reconsideration of your proposal to allow Medicare Advantage plans to use step therapy for Part B drugs, or, at a minimum, revise your proposal to include the important patient protections recommended in this letter.

Should you require additional information, please contact Lakitia Mayo, ASGE's Senior Director, Health Policy and Education, at lmayo@asge.org or (630) 570-5641.

Sincerely,

Steven A. Edmundowicz, MD, FASGE
President
American Society for Gastrointestinal Endoscopy