



September 10, 2018

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

**Re:** Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage

Dear Administrator Verma,

The American Association of Diabetes Educators (AADE) has reviewed and prepared comments in response to CMS' memorandum issued on August 7, 2018 to Medicare Advantage (MA) organizations addressing "Prior Authorization and Step Therapy for Part B Drugs in MA". This memo effectively rescinds CMS's 2012 HPMS memo "Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services," and provides new guidance to MA plans that they may use step therapy for Part B drugs, beginning January 1, 2019. AADE has significant concerns with this policy change and the negative implications this may have for people with diabetes and individuals with other complex chronic diseases.

Given these concerns, AADE strongly urges CMS to reconsider this change in policy and maintain the 2012 guidance prohibiting MA organizations from using step therapy as a mechanism to manage costs. AADE understands that CMS will initiate a rulemaking process to determine policies for subsequent years beginning with calendar year 2020. We implore that the agency withhold from implementing this step therapy policy change in 2019 until they can engage in a formal rulemaking process and collect stakeholder feedback to avoid complications and negative outcomes for individuals under these MA plans.

AADE is a multi-disciplinary association of healthcare professionals dedicated to integrated self-management as a key outcome in the care of people with diabetes and related chronic conditions. Representing over 14,000 professional members including nurses, dietitians, pharmacists, exercise specialists, and others, AADE has a vast network of practitioners working with people who have, are affected by, or are at risk for diabetes. Our members understand first-hand how such a problematic shift in policy may adversely impact people with diabetes. This impact includes limiting access to prescribed medication, delaying appropriate treatment, and directly contributing to negative patient outcomes.

### **Step Therapy as “Fail First”**

Step therapy is frequently referred to as “fail first” as this approach requires individuals to try and fail a less expensive alternative medication to the one prescribed by their physician. Only once the individual determines the medication (or medications) to be ineffective, will the insurance company cover the prescription as originally prescribed by the individual’s physician. This process takes time, which can significantly delay treatment of a disease. This can result in the worsening of the disease, severe complications, or uncontrolled symptoms.

### **Impact of Step Therapy on Diabetes Management**

In the case of diabetes management, Medicare Part B covers external durable insulin pumps and the insulin that the device uses if beneficiaries meet certain conditions. There are many different types of insulin, and many differences among the many types of insulin available to people with diabetes. Prescribing insulin is not a one size fits all approach, and it is critical that the person diagnosed with diabetes work with their prescribing physician to determine the right type of insulin to manage their diabetes. “Failing first” can have serious consequences for individuals with diabetes, where care management is best determined by the physician working in direct consort with the person with diabetes. Step therapy may result in a person with diabetes not using the medication provided (if it “fails”) or delaying important treatment as they try multiple medications.

Diabetes affects nearly every major body system. If a person with diabetes is untreated or faces a delay in treatment, they may face serious health complications, including kidney disease, amputations, and vision loss from diabetic retinopathy, as well as cardiovascular comorbidities, like heart disease. Though touted as a cost-savings measure, there is little evidence to suggest that step therapy saves on drug costs in the long term given these comorbidities.<sup>1</sup> There are considerable expenses associated with additional office visits, more and prolonged treatments, and in some cases, hospitalizations related to delaying treatment through trying and failing on multiple treatments or medications. Again, the decision about what medication an individual should take for their diabetes should be a decision made between the patient and provider, not by an executive at an MA organization or an insurance company.

### **AADE Requests Reconsideration of CMS’ Policy on Step Therapy for MA Plans**

Step therapy creates an unnecessary barrier to individuals accessing prescribed medications in a timely manner and can significantly delay treatment. Step therapy also undermines the unique treatment needs of individuals in order to reduce pharmacy costs, though the long-term cost savings of step therapy is largely unproven. In CMS’ August 7 memo to MA organizations, the agency indicates that MA plans should ensure that new step therapy requirement apply only to new prescriptions or administrations of Part B drugs for enrollees that are not actively receiving the affected medication. CMS also includes other recommendations to avoid creating undue access barriers for beneficiaries, like patient engagement and care coordination. Unfortunately, due to the inherent issues with step therapy, oftentimes such barriers are unavoidable and cause unnecessary harm to beneficiaries.

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<sup>1</sup> Institute for Patient Access: Diabetes Therapy Access Working Group (2018). *Protecting Access to Diabetes Care* [White Paper]. Retrieved August 23, 2018 from: [http://instituteforpatientaccess.org/wp-content/uploads/2018/07/IfPA\\_Protecting-Access-to-Diabetes-Care\\_June-2018.pdf](http://instituteforpatientaccess.org/wp-content/uploads/2018/07/IfPA_Protecting-Access-to-Diabetes-Care_June-2018.pdf)

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AADE advises CMS to reconsider this policy for CY 2019 and maintain the 2012 guidance and the prohibition on using step therapy for cost management. We believe that CMS should collect stakeholder feedback on the effects of step therapy through the formal rulemaking process to help minimize the risk of complications and the threats associated with delayed treatment for diabetes and other chronic diseases.

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AADE appreciates the opportunity to comment on the August 7, 2018 memo to the MA Organizations regarding step therapy. Please contact Kate Thomas, Director of Advocacy, by phone at 312-601-4821 or via email at [kthomas@aadenet.org](mailto:kthomas@aadenet.org) should you have any questions regarding AADE's comment letter.

Sincerely,

A handwritten signature in cursive script that reads "Donna Ryan".

Donna Ryan, MPH, RN, RD, CDE, FAADE, 2018 AADE President

A handwritten signature in cursive script that reads "Charles Macfarlane".

Charles Macfarlane, FACHE, CAE, Chief Executive Officer