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April 22, 2024

Tamara Syrek Jensen
Director, Coverage and Analysis Group
Centers for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Medicare Program; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee— May 21, 2024

Dear Ms. Syrek Jensen,

On behalf of the Advanced Medical Technology Association (AdvaMed), we are submitting written comments regarding the May 21, 2024 meeting of the Medicare Evidence Development & Coverage Advisory Committee meeting entitled "Devices for Self-management of Type 1 and Insulin-Dependent Type 2 Diabetes." We are pleased to see CMS take up the issue of evaluating appropriate and meaningful endpoints in the Medicare population as a foundation for future updates to coverage requirements for devices used to manage diabetes. The prevalence of diabetes in the Medicare population and the costs associated with ineffective management of the disease argue for action as soon as possible.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. These technologies include advanced diabetes technologies, such as continuous glucose monitors (CGMs), insulin pumps, and closed loop systems. These technologies enable patients with diabetes to manage more effectively their condition, avoiding serious complications from the disease and improved and sustained care outcomes. AdvaMed is committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

In February of 2022, AdvaMed member companies and diabetes patient advocates submitted Requests for Reconsideration of National Coverage Determination (NCD) 280.14 for continuous subcutaneous insulin pumps (CSII). The requests argue that reconsideration is necessary because of significant new evidence that has been published since the existing NCD was completed. Unfortunately, CMS informed our companies that their reconsideration requests were accepted but that action needed to be postponed due to internal capacity restraints. All current insulin pumps on the market today operate with a CGM, and for this reason, we believe that coverage criteria for both devices should reflect the most current clinical evidence.

We recognize that when considering whether a device is medically reasonable and necessary, CMS is focusing on Medicare beneficiaries and the ultimate health outcomes associated with the technologies. We are encouraged that the discussion at the MEDCAC meeting remains focused on clinical endpoints considered important for older adults and suggested instruments for measuring those endpoints. We trust that this process will allow for swift action on ensuring critical updates to NCDs for these innovative devices used to manage diabetes.

AdvaMed's member companies are available to provide any additional information you may need as you take up this important work. Please contact me at tburke@advamed.org with any questions. Thank you for the opportunity to submit comments.

Sincerely,

TLR

Vice President, Payment & Healthcare Delivery Policy
AdvaMed