ENDOCRINE SOCIETY
Hormone Science to Health

January 4, 2021

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1738-P
P.O. Box 8013
Baltimore, MD 21244–1850

Re: CMS-1738-P; Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Policy Issues and Level II of the Healthcare Common Procedure Coding System

Dear Administrator Verma:

The Endocrine Society is pleased to offer the following comments on the revisions to the classification and payment for continuous glucose monitors (CGM) under Medicare Part B in the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) proposed rule. Founded in 1916, the Society represents approximately 18,000 physicians and scientists engaged in the treatment and research of all endocrine disorders, including diabetes. Our members are leaders in the treatment of diabetes and have authored Society clinical practice guidelines in diabetes technology, diabetes and pregnancy, and treatment of diabetes in older adults. As such, our members are knowledgeable about the challenges patients with diabetes face controlling their condition and have found that various types of diabetes technology have significantly improved the quality of their lives.

We appreciate that the Centers for Medicare & Medicaid Services (CMS) has taken an expeditious approach to ensure that innovative devices for diabetes management are available to Medicare beneficiaries. CGMs represent an innovative and beneficial device, as they have allowed for people with diabetes to measure glucose levels much more frequently than is feasible with self-testing using a blood glucose monitor and finger sticks. They allow people with diabetes to track glucose levels and trends in real time, as well as to receive alerts when glucose levels are outside of a predetermined range. These alerts assist people with diabetes in more accurately calculating insulin dosage for proper glycemic control. This helps people with diabetes avoid severe hypoglycemia and the medical costs associated with this such as emergency room visit, ambulance fee, and hospitalization.

As further advances are made in this technology, it is important that more CGM options be made available to patients with diabetes. For this reason, the Endocrine Society supports the creation of a new classification for CGM, the "non-therapeutic" CGM. This new category allows for a pathway to Medicare coverage for all FDA-approved CGMs that satisfy the medical necessity requirements. We believe that this new classification will improve patient access to appropriate care by providing more options for patients and their physicians to choose. However, we are concerned with several aspects of the proposed rule, namely the creation of the manual category of CGM, and the reduced access to supplies caused by low reimbursement rates.

Concern with Creation of the Manual Category

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The Endocrine Society is concerned about the new "manual" category the agency is proposing to create, particularly because the reduced reimbursement for this category will hinder patient access to this type of CGM. While we understand that the manual CGMs require the patient to manually hold a device over the sensor to display glucose readings, it is not clear from the proposed rule why it was necessary to create a separate category for reimbursement purposes.

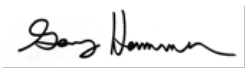
As an example, the Libre CGM would be classified as manual, and it is widely used among patients with diabetes due to the perceived ease of use. If the proposed rule is finalized, distributors could be disincentivized from carrying the Libre and other manual CGMs, which would hinder patient access. Patients may be forced to be retrained on a new CGM and this will disrupt the patients existing diabetes care plan.

Concern with Patient Access to CGM Supplies

The Endocrine Society is also concerned with the proposed monthly fee schedule amounts for the three different types of devices in the proposed rule. The proposed amounts are significantly below the current market prices for CGM transmitters and sensors in all three categories and this will likely lead to patient's bearing more of the financial responsibility for these supplies. The Medtronic CGM system includes one box of five sensors with an estimated retail price of about $400 per month and a transmitter, which lasts one year, with an estimated retail cost of approximately $1,000[1]. For the Dexcom CGM, the estimated retail price for one box of three sensors is approximately $500 per month, while the required transmitter has an estimated retail cost of about $500 and lasts 90 days[2]. These estimates are well above the proposed reimbursement for monthly supplies and equipment for automatic adjunctive and non-adjunctive devices. For the Libre CGM, the cost for the sensor/transmitter is approximately $200 per month, which again is well above the $52.01 included in the proposed rule for manual CGMs[3]. We request that the agency not finalize these reimbursement levels as proposed due to the negative impact on patient access to care.

Thank you for the opportunity to provide comments on the proposed rule. The Endocrine Society looks forward to working with you to ensure patient access to innovative diabetes technology. Please contact our Chief Policy Officer Mila Becker at mbecker@endocrine.org with any questions or if we can provide additional information.

Sincerely,



Gary D. Hammer, MD, PhD
President, Endocrine Society

[1] American Diabetes Wholesale. Retrieved from: www.adwdiabetes.com.
[2] Ibid.
[3] Ibid.