

DME MAC Medical Directors
26 Century Blvd., Ste ST610
Nashville, TN 37214-3685

Submitted electronically to GLULCDCOMMENTS@cgsadmin.com

Re: Glucose Monitors Proposed LCD (DL33822)

Dear DME MAC Medical Directors:

The Endocrine Society is pleased to offer the following comments on the proposed local coverage determination (LCD) for Continuous Glucose Monitors (CGM). 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 membership is also made up of over 11,000 clinicians who are the leaders in the treatment of diabetes. We have authored 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 patients' lives.

The Endocrine Society appreciates the efforts that the Centers for Medicare & Medicaid Services (CMS) and the MACs have taken to modify the coverage rules for CGMs. CGMs are important devices that allow people with diabetes to frequently monitor and track their glucose levels. Some CGMs provide alerts to users when their glucose levels are outside of the targeted range. The use of CGM helps people with diabetes avoid severe hypoglycemia and the associated medical costs, such as emergency room visits, ambulance fees, and hospitalization. The Endocrine Society has clinical practice guidelines available to practicing physicians on the use of CGMs which reflect evolving clinical science and offer practice recommendations for appropriate device use.

The proposed LCD would remove the requirement that a beneficiary with diabetes take "multiple daily administrations" of insulin to be eligible for CGM coverage. The proposal would also remove the requirement for frequent adjustment of the beneficiary's insulin treatment regimen. CMS proposes to replace the "multiple daily administrations" requirement with a requirement that the beneficiary with diabetes is insulin-treated with at least one daily administration of insulin. Under this change, CGM coverage would be expanded to Medicare beneficiaries living with type 2 diabetes treated with basal insulin. The Endocrine Society agrees with CMS's assessment that the certainty of evidence for

HbA1c reduction in patients taking one or two insulin injections a day is not "high". However, we recognize that a "moderate" certainty of evidence may be sufficient for CMS to recommend this expansion of coverage. We also note that other approaches to CGM coverage for people with type 2 diabetes, such as the NICE guideline in the United Kingdom, have proven to be useful.¹

The proposed LCD would also allow coverage of CGM for patients with diabetes who have a history of "Problematic Hypoglycemia". The Endocrine Society endorses this proposed change, which will be beneficial for people with type 2 diabetes who are having recurrent hypoglycemia. We also note that there is additional value of CGM coverage for patients with non-diabetes related causes of hypoglycemia.



Patients with diseases such as insulinoma or hypoglycemia following gastric bypass surgery often have both frequent hypoglycemia and neuroglycopenia. The availability of CGM for this group of patients would improve their medical care and help them avoid potentially life-threatening episodes of hypoglycemia.

The proposal would also clarify that the 6-month follow-up visit with the practitioner can be done via telehealth. The Society endorses this modification because it will provide greater flexibility for beneficiaries who use CGM. According to Medicare Part B claims data for 2021, endocrinologists delivered telehealth services at the highest rate outside of mental health providers. This is a testament to the value of telehealth services in the delivery of medically necessary services to patients while minimizing exposure to COVID-19. Last year, [the Society asked CMS](#) to consider ways to provide telehealth flexibilities for the 6-month visit and we are pleased that the agency wants to make this change. Our members have found that telehealth can be used effectively by patients and physicians, can help ensure compliance, and can reduce costs. For example, CGM data can be easily uploaded by the patient online and can be viewed by both the patient and provider during telehealth visits. Providing this flexibility will also be an effective tool to address health disparities. Studies show that expanded access to telehealth services often help patients from underserved communities receive care they need.

Thank you for the opportunity to comment on this proposal. We look forward to working with you to ensure patient access to diabetes technology. If we can be of further assistance, please contact Rob Goldsmith, Director of Advocacy and Policy, at rgoldsmith@endocrine.org.

Sincerely,

Ursula Kaiser, MD
President
Endocrine Society