ENDOCRINE SOCIETY
Hormone Science to Health

January 29, 2021

Liz Richter
Acting Administrator
Centers for Medicare and Medicaid Services
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Baltimore, MD 21244

Stacey V. Brennan, MD
Robert D. Hoover, Jr., MD
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Submitted electronically to BGMLCDCOMMENTS@cgsadmin.com

Re: Proposed Glucose Monitors LCD (DL 33822)

Dear Acting Administrator Richter, Dr. Brennan, Dr. Hoover, Dr. Mamuya, and Dr. Gurk:

The Endocrine Society is pleased to offer the following comments on the proposed local coverage determination (LCD) for glucose monitors. 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 patients' lives.

The Endocrine Society appreciates the efforts that the Centers for Medicare & Medicaid Services (CMS) has taken to review and modify the local coverage determination (LCD) for continuous glucose monitors (CGM). CGMs are an important device that allow people with diabetes to frequently monitor and track their glucose levels and 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.

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Self-Monitoring Blood Glucose Frequency Requirement

CMS currently requires a self-monitoring blood glucose (SMBG) frequency of four or more times a day prior to initiating CGM coverage. In the proposed LCD, CMS has recommended removing this requirement because there is no evidence to support that SMBG at least four times a day results in improved health outcomes. The Endocrine Society supports the removal of this requirement because we agree there is no evidence of improved health outcomes, and because it is burdensome for people with diabetes who need access to a CGM. According to our members, many of the patients they serve have trouble meeting this requirement on a daily basis, and some have trouble accessing fingersticks because of current coverage policies. In addition, there are circumstances that make the readings from fingersticks inaccurate (such as peripheral ischemia, vasculitis, uremia and severe hypertriglyceridemia). Currently, these conditions are not recognized as exceptions to the rule and patients are required to still monitor 4 time daily and present the data despite knowing the results are inaccurate, causing wastage in the system. Also, CMS's current coverage policy creates challenges in accessing the required number of glucose test strips needed to test four times a day. As CMS noted in the proposed LCD, the Society's clinical practice guidelines, which CMS cited in the proposed coverage policy, do not mention or provide evidence to support this requirement prior to use of a CGM. While it is important to have appropriate guardrails to ensure CGMs are not overly prescribed, it is our determination that the SMBG requirement is a barrier (and in some instances even causing harm and wastage in the system) that is preventing people who need a CGM from being able to get one.

Use of Inhaled Insulin as Substitute for Insulin Injections

The proposed LCD recommends updating the coverage criterion that Medicare beneficiaries "inject" insulin to allow multiple (three or more) daily "administrations" of insulin, whether via injections or inhalation. The Endocrine Society supports modifying this criterion to allow for the administration of inhaled insulin. As noted in the proposal, there is both evidence and clinical guidelines that support the use of inhaled insulin as an alternative to injected insulin when appropriate, which includes Medicare beneficiaries with diabetes who use CGM. The Society supports this modification to allow for those using a CGM to include inhalable insulin as part of their daily administration.

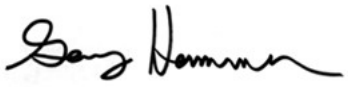
Telehealth Considerations

The COVID-19 pandemic has resulted in an increase of the number of services provided via telehealth. We appreciate CMS's quick action to expand telehealth flexibilities for many services during the public health emergency as they have been critical to ensuring patients with diabetes and other chronic conditions continue to receive medically necessary care

while minimizing exposure to COVID-19. Regarding CGM coverage, CMS currently requires an in-person visit within six months of the initial order for a CGM followed by in-person visits every six months after the initial prescription. We recognize the importance of these face-to-face visits for Medicare beneficiaries who use CGMs, particularly because they may lead to discussion of other issues with the patient regarding their care. However, we ask that you consider ways to provide telehealth flexibilities for beneficiaries who use CGMs for one of their two allowed visits each year. Our members treat patients who are vulnerable to COVID-19 infection or may have to travel significant distances to see their endocrinologist and telehealth flexibilities will ensure greater protection from being exposed to this deadly virus. Our members have also found during the pandemic that telehealth can be used effectively by patients and physicians, can help ensure compliance, and can reduce costs. For example, when using CGM patients and providers are able to upload their sensor data online. This data can be viewed by both the patient and provider during telehealth visits. Our members have also been able to troubleshoot any CGM issues that patients experience via telehealth with the help of diabetes educators. We ask that you consider telehealth flexibilities during the ongoing pandemic.

Thank you for the opportunity to comment on the proposed LCD for continuous glucose monitors. 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,



Gary D. Hammer, MD, PhD
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