ENDOCRINE SOCIETY
Hormone Science to Health

June 12, 2020

Novitas Solutions, LLC
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re: Proposed Local Coverage Determination (LCD): Implantable Continuous Glucose Monitors (I-CGM) (DL38617)

The Endocrine Society is pleased to offer the following comments on the proposed local coverage determination (LCD) on implantable continuous glucose monitors (I-CGM), DL38617. 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 and Medicaid Services (CMS) has taken an expeditious approach to ensure that innovative devices for diabetes management are available to Medicare beneficiaries. Continuous Glucose Monitors (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. CGMs 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.

As further advances are made in this technology, it is important that more CGM options be made available to patients with diabetes. The Endocrine Society recommends CGM systems as the gold standard for managing type 1 diabetes, and the technology also can be useful for some people with type 2 diabetes.[1] CGMs are also included in the American Diabetes Association's (ADA) Standards of Medical Care for the treatment of patients with diabetes who require insulin. The Standards state that "when used properly, real-time continuous glucose monitors in conjunction with intensive insulin regiments is a useful tool to lower A1c in adults with type 1 diabetes who are not meeting glycemic targets."[2] The

[1] https://www.endocrine.org/news-and-advocacy/news-room/2018/streamlined-method-helps-people-with-diabetes-act-on-cgm-data
[2] https://care.diabetesjournals.org/content/43/Supplement_1/S77

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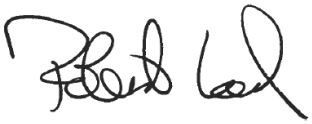
Standards also recommend that real-time CGMs be used on a daily basis if possible, for maximum benefit to the patient.

We agree that the proposed LCD includes proposed coverage criteria for I-CGMs that is aligned with the CGM class of devices. However, we recommend that you change the blood glucose self-testing requirements for I-CGMs in coverage criteria #2 from at least four times per day to at least three times per day. This is consistent with current Medicare coverage policy for test strips and with the scientific and clinical recommendations from experts in diabetes care. Requiring testing four times per day will limit patients who currently use other CGM systems, and this requirement is not supported by data to be a predicate requirement for coverage. Furthermore, the Society would like to see language added to the coverage criteria to account for patients who have adopted other CGM systems and may have had trouble complying, managing them, and cases when the CGM might not be appropriate anymore in light of other CGM options, like I-CGM.

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



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