Submitted to: ***BGMLCDCOMMENTS@cgsadmin.com***

January 25, 2021

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

Re: Comments on Proposed Local Coverage Determination (LCD): Glucose Monitors (DL33822)

Dear Medical Directors:

Introduction

The American Association for Homecare (AAHomecare) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the Local Coverage Determination (LCD) and Policy Article (PA) for Glucose Monitors (DL33822). AAHomecare is the national association representing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare community. Our members are proud to be part of the continuum of care that assures Medicare beneficiaries receive cost effective, safe and reliable home care products and services. Our membership services diabetic patients across the nation by supplying both traditional blood glucose monitors and continuous blood glucose monitors. In light of our membership's expertise, we are uniquely qualified to comment on this opportunity.

Detailed Comments

DMEPOS Proposed Rule (CMS-1738-P)

In the proposed rule that was published on November 4, 2020 (85 *Fed. Reg.* 70358), CMS proposed to expand coverage for continuous glucose monitors (CGMs) by extending coverage to adjunctive CGMs and classifying all CGMs as routinely purchased DME. In the comments submitted on December 22, 2020, AAHomecare supported the expansion of CGM coverage. However, CMS has yet to finalize the proposals and it is uncertain at this time whether the proposals would be finalized as is. If the proposals are finalized, should the industry expect another proposed LCD to reflect the changes made in regulation? The proposed LCD currently

does not have any references to adjunctive and non-adjunctive CGMs. If the proposed rule is finalized, the DME MACs would need to reflect the changes within the Glucose Monitors LCD. Specifically, the LCD would need to include clinical coverage for both adjunctive and non-adjunctive CGMs, and list proposed codes and associated modifiers. As we highlighted in our letter to the proposed rule, we request that CGM suppliers be included in the conversation as coverage for adjunctive CGMs is being implemented. Working with suppliers that provide CGMs would help ensure the LCD and PA will provide clear documentation requirements. Generally, AAHomecare supports CMS' efforts to recognize and establish coverage for new technology, but we believe stakeholder involvement is crucial in ensuring a smooth implementation process.

Guidance on Switching from CGM Back to Test Strips

AAHomecare recommends that the DME MACs update the LCD with guidance for allowing beneficiaries to switch from CGMs to traditional blood glucose monitors. Our membership has experienced a great deal of issues trying to help beneficiaries who have tried CGMs and wish to switch back to traditional blood glucose monitors. We would like the DME MACs to confirm than when a CGM is provided to a beneficiary, that the Medicare program will allow that patient the ability to go back to test strips should they and their physician determine CGM is not working for them.

Elimination of Four or More Tests Per Day Requirement

AAHomecare supports the proposed change to remove the four or more finger pricks a day requirement for CGMs. The elimination of this requirement will improve beneficiary access.

Concerns with Documentation Requirements

Although we support the removal of the ≥4 testing a day requirement, we strongly encourage Medicare to implement objective coverage criteria. Subjective criteria are greatly disconcerting for suppliers, especially when claims are under review. With subjective criteria, a supplier may believe all the documentation requirements are met, but in an audit, the contracted auditor's subjective judgement ultimately determines if the claim met coverage criteria. One of the criteria under the CGM section states: "The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results…" It is not clear what would pass as "frequent adjustments." This type of subjective language reduces efficacy of the requirements. AAHomecare recommends removing this criterion. When LCDs only have subjective coverage criteria, it is unclear to the beneficiary, referral agent and supplier what documentation is necessary to support medical need and then it is unclear, in the event of an audit, what the DME MACs or other auditors would be reviewing in the medical record. AAHomecare requests more clarity on what needs to be documented by the prescriber. To limit ambiguity of meeting coverage requirements, AAHomecare recommends that the Medical Directors update LCDs to include objective criteria. However, the objective requirements should not increase burden or hinder beneficiary access. To do this, we recommend the Medical Directors engage suppliers in the discussion.

Change "Injection" to "Administration" of Insulin

Under the “Home Blood Glucose Monitor” section of the proposed LCD, the term “insulin injections” was switched out with “insulin administrations.” AAHomecare supports this wording change as it will now recognize technology besides traditional blood glucose monitors. We believe this change would be inclusive of future technologies that may have a new form of insulin delivery.

Support Clinical Community

AAHomecare supports LCD and PA changes based on clinical studies and literature. Coverage criteria should be based on available clinical evidence and any criteria that is not supported by clinical evidence should be reconsidered or removed. We are in support of comments submitted by the clinical community.

Conclusion

We appreciate the opportunity to provide comments on the proposed LCD for glucose monitors. Please contact us with any questions, or if you would like additional information.

Sincerely,

Kimberley S. Brummett
VP, Regulatory Affairs