



February 7, 2023

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Re: Comments on Proposed LCD – Glucose Monitors (DL33822) Regarding the End of the COVID-19 Public Health Emergency

Dear Medical Directors:

AAHomecare is the national association representing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare/home medical equipment (HME) 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 patients living with diabetes and provides medical equipment such as continuous glucose monitors (CGMs) across the nation.

In light of the recent announcement by the Biden Administration on ending the COVID-19 public health emergency (PHE), the industry requests that the DME MACs finalize the Proposed Glucose Monitors Local Coverage Determination (DL33822) prior to the end of the PHE on May 11, 2023. To ensure Medicare beneficiaries do not have a lapse in their coverage, it is critical that the LCD be finalized no later than March 27, 2023, to align the effective date of the new policy with the PHE end date.

During the COVID-19 PHE, CMS issued waivers of clinical conditions for coverage associated with CGMs.¹ Pursuant to this waiver, DME suppliers have provided CGMs to Medicare beneficiaries who use insulin less than three times per day (as required under the existing glucose monitoring LCD), or in some cases individuals who use no insulin at all, if the beneficiary's provider has demonstrated the medical necessity

¹ 85 Fed. Reg. 27595 (May 8, 2020).

for the CGM. Waivers applied to CGMs along with many other PHE waivers and flexibilities are slated to end when the PHE is over on May 11.

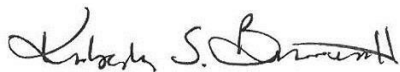
This past October, the DME MACs proposed to modify the CGM policy criteria to expand coverage such as patients not using any insulin but are experiencing problems managing their glucose levels. Finalizing the policy changes proposed in the DL33822 prior to the end of the PHE would ensure patients that accessed CGMs during the PHE will continue to have access to this critical device and related supplies. If the PHE ends prior to the DME MACs finalizing this proposed LCD, many beneficiaries who have accessed CGMs during the PHE may experience a gap in coverage of their therapy.

On January 30, 2023, the Biden Administration announced that the COVID-19 PHE will end May 11, 2023, providing 101-day advance notice to the public. The industry strongly encourages DME MACs to take this time to prepare for a smooth transition out of the PHE to ensure that beneficiaries do not experience any challenges in receiving their treatments. When DME MACs finalize the Glucose Monitors LCD, there will be a 45-day waiting period before the finalized LCD goes into effect. DME MACs must publish the finalized LCD by March 27, 2023, to ensure that CGM patients who obtained their devices under the waiver will be able to continue to meet coverage criteria after May 11

Overall, AAHomecare and its members strongly support the DME MACs' proposed coverage expansion of CGMs. The COVID-19 pandemic has enabled a broader array of beneficiaries to access this exciting new technology, and to be able to better manage their diabetes and health. We therefore strongly encourage the DME MACs to finalize this LCD by March 27, 2023.

AAHomecare appreciates the opportunity to submit this request. If you have any questions or would like further information, please contact me at kimb@aahomecare.org.

Sincerely,



Kim Brummett
Senior V.P., Regulatory Affairs
American Association for Homecare