Association of
Diabetes Care & Education
Specialists

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VIA ELECTRONIC SUBMISSION: BGMLCDCOMMENTS@cgsadmin.com

January 29, 2021

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

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

Dear Drs. Brennan, Gurk, Hoover, and Mamuya:

The Association of Diabetes Care & Education Specialists (ADCES) appreciates the opportunity to offer comments in response to the "Proposed Local Coverage Determination (LCD): Glucose Monitors (DL33822)", released by the DME MACs on December 17, 2020.

ADCES is an interdisciplinary professional membership organization dedicated to improving prediabetes, diabetes, and cardiometabolic care through innovative education, management, and support. With more than 12,000 professional members including nurses, dietitians, pharmacists, and others, ADCES has a vast and diverse network of practitioners working to optimize care and reduce complications. ADCES supports an integrated care model that lowers the cost of care, improves experiences, and helps its members lead so better outcomes follow.

ADCES commends the DME MACs for the changes outlined in the proposed LCD (DL33822) and urges the timely adoption of the proposed changes. We specifically express our support for the following:

- *Removal of the four times per day testing requirement*

  ADCES strongly supports the removal of the requirement that Medicare beneficiaries demonstrate the use of four or more finger stick tests per day to qualify for coverage of a continuous glucose monitoring (CGM) system. There is no evidence to suggest that requiring four or more finger stick tests per day significantly impacts the outcomes of CGM therapy. Additionally, this requirement creates unnecessary barriers to care for beneficiaries, as Medicare only covers three test strips per day for insulin-using beneficiaries. Removing this coverage requirement would allow for increased access to CGM systems and improved health outcomes for beneficiaries with diabetes by improving glycemic control. This also represents a step towards addressing the disparities that exist around diabetes technology under the Medicare program.

- *Use of "administration" to describe insulin usage*

  ADCES supports the use of the word "administration" instead of "injection" in the requirement related to insulin usage. ADCES believes this change will allow individuals who use inhaled insulin to benefit from CGM therapy. We also hope that updating this terminology will help to expediate coverage as future innovations in insulin delivery methods come to market.

Additional recommended changes to the coverage criteria for CGM systems:

In addition to our support for the changes outlined above, ADCES also urges the DME MACs to further revise the clinical coverage criteria for CGM systems. Our proposed changes are detailed below:

- *Broaden the coverage criteria for CGM systems*

  CGM systems serve an important function in helping people with type 1 and type 2 diabetes achieve time-in-range goals, decrease time spent in hypoglycemia and hyperglycemia, lower HbA1c levels, and reduce diabetes-related complications.[1][2] We urge the DME MACs to reconsider the coverage criteria for CGM therapy to ensure that more beneficiaries who can benefit from these devices are able to receive them.

ADCES recommends that a CGM system be covered for a Medicare beneficiary if they meet any one of the following four criteria as well as meeting the fifth criterion:

- Diagnosed with type 1 diabetes.
  - ADCES believes that any individual who has been diagnosed with type 1 diabetes, at any time in their life, should qualify for CGM coverage, without having to meet any other requirements except for the fifth criterion (visit with a health care professional).
- Diagnosed with type 2 diabetes and using any insulin.
  - The current evidence examining individuals with type 2 diabetes demonstrates that there is a significant benefit to CGM therapy in both those treated with multiple daily injections and those treated with less intensive regimens.[3][4] We urge the DME MACs to provide coverage for CGM systems for those diagnosed with type 2 diabetes, regardless of the type of insulin therapy they may use.
- Diagnosed with type 2 diabetes with documented hypoglycemia, regardless of diabetes therapy. Specifically, that the beneficiary has a history of at least one incidence of:
  - Level 2 (moderate) hypoglycemia, characterized by glucose levels $\leq$54 mg/dL.

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[1] Ruedy KJ, Parkin CG, Riddlesworth TD, Graham C, for the DIAMOND Study Group. Continuous glucose monitoring in older adults with type 1 and type 2 diabetes using multiple daily injections of insulin: results from the DIAMOND trial. J Diabetes Sci Technol 2017;11(6):1138-1146.

[2] https://diabetesresearchconnection.org/evaluating-the-benefits-of-continuous-glucose-monitor-use/

[3] Vigersky RA, Fonda SJ, Chellappa M, Walker MS, Ehrhardt NM. Short- and long-term effects of real-time continuous glucose monitoring in patients with type 2 diabetes. Diabetes Care. 2012;35(1):32-38.

[4] Majithia AR, Kusiak CM, Lee AA, et al. Glycemic Outcomes in Adults With Type 2 Diabetes Participating in a Continuous Glucose Monitor–Driven Virtual Diabetes Clinic: Prospective Trial. J Med Internet Res. 2020 Aug; 22(8): e21778. Published online 2020 Aug 28. doi: 10.2196/21778.

  - Level 3 (severe) hypoglycemia, characterized by physical/mental dysfunction requiring third-party assistance.
  - Nocturnal hypoglycemia.
- Chronic kidney disease
  - Individuals with chronic kidney disease face serious challenges with managing glucose levels and CGM systems can serve as useful tools to mitigate such challenges. ADCES believes the DME MACs should explore coverage for individuals with severe chronic kidney disease.
- A visit with a health care professional with authority to prescribe CGM within six months prior to initiating CGM therapy, and every six months thereafter to confirm continued use of CGM.
  - ADCES recommends that CMS allow the beneficiary the option of meeting this requirement through a telehealth visit. ADCES believes that allowing the initiation of CGM therapy through a virtual visit will reduce barriers associated with travel and difficulty accessing a trained provider that are experienced by Medicare beneficiaries.

- *Eliminate the requirement that beneficiaries use insulin at least three times per day*

ADCES urges the DME MACs to eliminate the requirement that beneficiaries use insulin at least three (3) times per day to qualify for CGM coverage. As noted above, the benefits of CGM therapy are well-documented for individuals treated with multiple daily injections and those on different treatment regiments. ADCES believes that requiring individuals to be treated with multiple (3) daily injections of insulin to be eligible for a CGM system creates a barrier to accessing these critical devices for Medicare beneficiaries who may not be able to afford insulin.

Many Medicare beneficiaries have difficulty affording insulin.[5] In such cases, individuals are often prescribed medications, such as sulfonylureas, as a more affordable treatment option. These non-insulin diabetes medications can be associated with higher rates of hypoglycemia.[6] In fact, one study found a correlation between the use of eight different non-insulin diabetes drugs and rates of hypoglycemia.[7] Additionally, a study looking at nearly 32,000 US adults with type 2 diabetes who were not treated with insulin found that more than 45% received intensive treatment that nearly doubled the chances of them experiencing severe hypoglycemia.[8] Despite facing an increased risk of hypoglycemia, these beneficiaries are not eligible for a CGM system due to the requirement to use insulin at least three times per day.[9]

[5] https://www.kff.org/medicare/issue-brief/how-much-does-medicare-spend-on-insulin/
[6] https://care.diabetesjournals.org/content/31/11/2086
[7] Leonard CE, Han X, Brensinger CM, Bilker WB, Cardillo S, Flory JH, Hennessy S. Comparative risk of serious hypoglycemia with oral antidiabetic monotherapy: A retrospective cohort study. Pharmacoepidemiol Drug Saf. 2017;1–10.
[8] McCoy RG, Lipska KJ, Yao X, Ross JS, Montori VM, Shah ND. Intensive Treatment and Severe Hypoglycemia Among Adults With Type 2 Diabetes. JAMA Intern Med. 2016;176(7):969-978. doi:10.1001/jamainternmed.2016.2275
[9] https://care.diabetesjournals.org/content/31/11/2086

There are other ways that the requirement to use insulin three times per day affects individuals who have difficulty affording their insulin. To help mitigate costs, a beneficiary may use synthetic human insulin, like NPH insulin, as these types of insulins are typically more affordable than the newer insulin analogs. NPH insulin is administered twice-daily, thus preventing the beneficiary from meeting the coverage criteria for a CGM system of administering insulin three times per day. The existing CGM coverage criteria creates an unbalanced and disparate system that excludes from coverage beneficiaries who could greatly benefit from a CGM system, but do not qualify due to issues with insulin affordability. As we work to improve health equity and access to diabetes care, ADCES urges the DME MACs to consider how this requirement perpetuates existing health disparities and recommends immediate changes to this coverage policy to ensure access to CGM systems for all Medicare beneficiaries who can benefit from these devices. ADCES recommends that CMS remove requirements limiting coverage to people who inject/administer insulin three times per day and allow coverage for any therapeutic regimen that has the potential of causing hypoglycemia.

- *Eliminate the requirement that beneficiaries be frequently adjusting insulin based on blood glucose measurements or CGM readings to have their CGM therapy covered.*

  ADCES urges the DME MACs to remove the requirement that beneficiaries be frequently adjusting insulin based on blood glucose meters (BGM) or CGM readings to have their CGM therapy covered. We have outlined our concerns below:

  - For those beneficiaries who have not yet begun CGM therapy, this requirement perpetuates the requirement that they be using multiple finger sticks per day, the exact requirement the DME MACs are proposing to remove due to lack of evidence supporting such a practice.
  - ADCES believes that evidence supports use of CGM by beneficiaries who do not frequently adjust insulin dosing.
  - This requirement creates an unnecessary administrative burden for beneficiaries, providers, and suppliers. If an individual is using insulin multiple times per day, they will be checking their glucose levels to dose correctly. Requiring them to prove they have used their BGM/CGM readings to dose their insulin serves no clinical function and creates additional paperwork.
  - ADCES is concerned over the ambiguity of the term "frequent". It is not clear what "frequent" means in this case nor how it should be documented. This ambiguity makes it difficult for suppliers and providers to confidently and appropriately document. This creates additional challenges and exposes them to an audit risk.

- *Facilitate communications between DME MACS and suppliers.*

  ADCES urges the Medicare contractors to work with the DME suppliers who provide significant numbers of CGM systems to beneficiaries to ensure the changes to the clinical coverage criteria proposed in this LCD translate to simple and concise documentation requirements at the supplier level. Currently, providers, including primary care providers, are overwhelmed with burdensome documentation requirements when prescribing CGM systems. This creates a barrier to care on both the beneficiary and provider side.

ADCES looks to the DME MACs to provide updated, clear, and concise direction to the DME suppliers to minimize confusion and inconsistencies and ensure beneficiaries can easily access their prescribed CGM system.

The importance of DSMES in supporting enduring CGM utilization

ADCES wishes to underscore the importance of diabetes self-management education and support (DSMES) to help the person with diabetes persist with use of a CGM system and maximize the health outcomes associated with the device. As noted in this letter, there are significant benefits to CGM utilization among people with type 1 and type 2 diabetes. These individuals may also face challenges as they adjust to a new device. In 2020, ADCES joined the American Diabetes Association, the Academy of Nutrition and Dietetics, the American Academy of Family Physicians, the American Academy of PAs, the American Association of Nurse Practitioners, and the American Pharmacists Association to develop a consensus report outlining the four critical times to refer to DSMES.[10] The consensus report outlines the importance for providers to refer to DSMES when a transition in life or care, including the initiation of or changes to a CGM device, occurs. DSMES, referred to by CMS as diabetes self-management training (DSMT), is a covered yet vastly underutilized Medicare benefit with only an estimated 5% of Medicare beneficiaries with newly diagnosed diabetes using this service.[11] As the DME MACs seek to remove barriers to CGM access, we also urge them to ensure beneficiaries are supported once they are prescribed a device by promoting awareness of the DSMES/DSMT benefit for beneficiaries.

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ADCES appreciates the opportunity to comment on this proposed LCD. Please contact Kate Thomas, Chief Advocacy and External Affairs Officer, by phone at 312-601-4821 or via email at kthomas@adces.org should you have any questions regarding ADCES' comment letter.

Sincerely,

Charles Macfarlane, FACHE, CAE
Chief Executive Officer

[10] Diabetes Self-management Education and Support in Adults With Type 2 Diabetes: A Consensus Report of the American Diabetes Association, the Association of Diabetes Care & Education Specialists, the Academy of Nutrition and Dietetics, the American Academy of Family Physicians, the American Academy of PAs, the American Association of Nurse Practitioners, and the American Pharmacists Association
[11] https://pubmed.ncbi.nlm.nih.gov/25616412/