



November 16, 2022

DME MAC Medical Directors
26 Century Blvd., Ste ST610
Nashville, TN 37214-3685
GLULCDCOMMENTS@cgsadmin.com

**RE: CMS Pub. 100-03, (Medicare National Coverage Determinations Manual), Chapter 1, Section 40.2,
Proposed Local Coverage Determination (LCD) ID DL33822; Proposed LCD Title Glucose Monitors**

[Submitted electronically to GLULCDCOMMENTS@cgsadmin.com]

To whom it may concern:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments on the Local Coverage Determination (LCD) Title Glucose Monitors proposed by the Centers for Medicare & Medicaid Services (CMS) on October 6, 2022.

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. APhA's members strive to improve medication use, advance patient care, and enhance public health.

APhA supports the removal of multiple daily injections (MDI) as a criterion for continuous glucose monitoring (CGM) coverage for Medicare beneficiaries, to allow coverage of CGM for beneficiaries with diabetes mellitus who are insulin treated or have a history of problematic hypoglycemia. Per APhA policy introduced in 2013 and updated in 2018, "APhA encourages the inclusion of medications, medical devices, and their associated services provided under FDA's defined conditions of safe use within health benefit coverage."^{1,2} Further, in 2020, APhA passed policy supporting pharmacists applying digital health technologies to optimize patient care outcomes.³

CGM can improve monitoring of safety and efficacy of diabetes regimens, including diabetes self-management skills and clinical decision making. The enhanced monitoring of CGM results in improved health outcomes, including better glucose management (reduced hemoglobin A1C and increased time in range) and reduced complications and adverse events—specifically hypoglycemia, co-morbidities, emergency department visits,

¹ American Pharmacists Association. Report of the 2013 APhA House of Delegates. *JAPhA*. 2013;53(4):P365–67.

² American Pharmacists Association. Actions of the 2018 APhA House of Delegates. *JAPhA*. 2018;58(4):P356–65.

³ American Pharmacists Association. Actions of the 2020 House of Delegates—Special session. *JAPhA*. 2020;60(5):e–e16.

hospitalizations, and death. According to the 2022 American Diabetes Association (ADA) Standards of Medical Care, “Individuals on a variety of insulin regimens can benefit from CGM . . . Use of CGM devices should be considered from the outset of the diagnosis of diabetes that requires insulin management. This allows for close tracking of glucose levels with adjustments of insulin dosing and lifestyle modifications and removes the burden of frequent blood glucose monitoring.”⁴ In addition to informing adjustment of insulin doses, the real-time biofeedback of CGM helps inform individual patients of the impact of their lifestyle choices, based on enhanced detection of hypoglycemia unawareness or elevated glucose levels that may be difficult to otherwise identify.^{4,5} APhA believes there is value in the use of CGM for patients with diabetes regardless of MDI.

Many studies and national diabetes guidelines support the benefits and use of CGM in patients with type 2 diabetes who are on less intensive insulin regimens and not on MDI. There is evidence for the benefits of CGM in improving glycemic control in adults with type 2 diabetes treated with basal insulin only without bolus/prandial insulin.⁶ In addition, clinical research supports that when CGM is interrupted or discontinued in patients with diabetes mellitus, clinical outcomes decline, highlighting the importance of consistent access to CGM for these patients.^{7,8} The 2022 American Diabetes Association (ADA) “Standards of Medical Care in Diabetes” upholds CGM as an integral part of diabetes self-management. ADA’s standards state that “real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring can be used for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely.”⁴

In addition, the 2021 American Association of Clinical Endocrinology (AACE) “Advanced Diabetes Technology Guideline” states that “CGM may be recommended for individuals with type 2 diabetes who are treated with less intensive insulin therapy.”⁹ The 2022 AACE “Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan” states, “[a]ll persons who use insulin should use CGM or perform blood glucose monitoring a minimum of twice daily,” and “CGM is recommended for persons with type 2 diabetes who are treated with insulin therapy or who have high risk for hypoglycemia and/or with hypoglycemia unawareness.” AACE’s guideline references the body of evidence that “CGM is efficacious in reducing hyperglycemia and A1C levels in insulin-treated persons with type 2 diabetes, including those taking 1 or 2 doses of basal insulin.”¹⁰

By removing the requirement for MDI, more patients will have access to the benefits of CGM. The restrictive practice of Medicare coverage for CGM only for beneficiaries taking MDI does not promote optimal diabetes management and care. Based on the clinical experience of APhA’s members, there are many patients who benefit from CGM who are on less intensive insulin regimens. However, to see the benefits of using CGM, these patients need to pay out of pocket for a continuous glucose monitor and related supplies, which reduces access to care. Coverage for CGM regardless of insulin regimen can improve clinical outcomes for patients before they may progress to needing MDI insulin.

⁴ American Diabetes Association Professional Practice Committee. 7. Diabetes technology: Standards of medical care in diabetes—2022. *Diabetes Care*. 2022;45(Suppl 1):S97–S112.

⁵ American Diabetes Association. Health equity and diabetes technology: A study of access to continuous glucose monitors by payer and race. Arlington, VA: American Diabetes Association. Available at: <https://diabetes.org/sites/default/files/2021-10/ADA%20CGM%20Utilization%20White%20Paper.pdf>. Accessed November 10, 2022.

⁶ Martens T, Beck RW, Bailey R, et al. Effect of continuous glucose monitoring on glycemic control in patients with type 2 diabetes treated with basal insulin: A randomized clinical trial. *JAMA*. 2021;325(22):2262–72.

⁷ Aleepo G, Beck RW, Bailey R, et al. The effect of discontinuing continuous glucose monitoring in adults with type 2 diabetes treated with basal insulin. *Diabetes Care*. 2021;44(12):2729–37.

⁸ Addala A, Maahs DM, Scheinker D, et al. Uninterrupted continuous glucose monitoring access is associated with a decrease in HbA1c in youth with type 1 diabetes and public insurance. *Pediatr Diabetes*. 2020;21(7):1301–9.

⁹ Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology clinical practice guideline: The use of advanced technology in the management of persons with diabetes mellitus. *Endocr Pract*. 2021;27(6):505–37.

¹⁰ Blonde L, Umpierrez G, Reddy SS, et al. American Association of Clinical Endocrinology clinical practice guideline: Developing a diabetes mellitus comprehensive care plan—2022 update. 2022;28(10):923–1049.

Additionally, APhA supports the removal of frequent insulin adjustments on the basis of CGM testing results as a criterion for CGM coverage for Medicare beneficiaries. Insulin adjustments are part of the standard of care for patients with diabetes mellitus who are using CGM.⁴ CGM testing results are used by the health care team to adjust medication doses and used by the patient to aid in treatment decisions (e.g., to be alerted of low blood glucose levels in real time to prompt treatment of hypoglycemia). However, the requirement to demonstrate frequent insulin adjustments places undue administrative burden on the health care team, through additional communication and documentation steps that can lead to delays in patients obtaining a continuous glucose monitor and related supplies.

Lastly, APhA supports the expansion of CGM coverage for Medicare beneficiaries to allow a patient's six-month visit to be conducted via Medicare-approved telehealth. In today's health care environment, telehealth is becoming an increasingly common standard of care. During the COVID-19 pandemic, telehealth has expanded and improved access to care, particularly for vulnerable patients in rural areas, those in areas with health care professional shortages, and those with transportation barriers. CGM data is conducive to and facilitates telehealth. When patients use the corresponding mobile applications, data is continuously transmitted and available for real-time viewing. The option for telehealth follow-up visits supports more timely and convenient care for patients with diabetes.

In conclusion, there is a substantial body of evidence demonstrating that CGM is associated with improved glycemic control for patients with diabetes. However, CGM remains underutilized, and disparities in care are evident.^{5,11} The proposed changes brought forth to expand CGM access for Medicare beneficiaries are a positive step for diabetes care and help to improve clinical outcomes and mitigate the burden of morbidity and mortality in patients with diabetes on insulin therapy.

Thank you for the opportunity to provide these comments in support of CMS's proposed Local Coverage Determination (LCD) Title Glucose Monitors. If you have any questions or require additional information, please contact Paria Sanaty Zadeh, Associate Director of Practice and Science Programs at psanatzadeh@aphanet.org.

Sincerely,



Brigid K. Groves, PharmD, MS
Senior Director, Practice & Professional Affairs

¹¹ American Diabetes Association. The cost of access to diabetes technologies. Arlington, VA: American Diabetes Association. Available at: <https://diabetes.org/advocacy/cost-access-diabetes-technologies>. Accessed November 10, 2022.