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Attention: Durable Medical Equipment Medicare Administrative Contractors (DMEMACs)

Re: Proposed LCD ID: DL33822  
Submitted via: [GLULCDCOMMENTS@cgsadmin.com](mailto:GLULCDCOMMENTS@cgsadmin.com)

Dear Medical Directors:

On behalf of the [Time in Range Coalition \(TIRC\)](#), thank you for the opportunity to comment on the proposed Local Coverage Determination (LCD) to modify the coverage criteria for Continuous Glucose Monitors (CGMs). We appreciate your recognition of the need to update Medicare coverage and payment policy for CGMs based on the best available evidence. Improving Medicare payment policy for CGMs will help expand access to care, advance equity, reduce disparities, and decrease health care costs. Moreover, we are grateful that all four DMEMACs are working together to promulgate this change so that there will be a consistent approach to CGM coverage across the nation and all Medicare beneficiaries, irrespective of geography, will benefit from the change.

### **About Time in Range Coalition**

TIRC is a global effort led by The diaTribe Foundation and comprised of 27 nonprofit associations, patient advocacy organizations, professional societies, and industry members committed to driving awareness and adoption of Time in Range (TIR) (including times above and below) as an actionable metric for daily diabetes management and a means to improve long-term health outcomes. TIR is the percentage of time a person spends within a target blood glucose range, as measured by a CGM. The Coalition works to achieve this by educating patients, health care providers, and regulators about the science of TIR and by working to establish TIR as an essential part of diabetes management and to make TIR accessible to all people with diabetes.

### **CGMs & Diabetes Management are Inextricably Linked**

CGMs are an essential tool in the utilization of TIR as a daily diabetes management metric<sup>1</sup> as reflected in the American Diabetes Association's Standards of Care<sup>2</sup>. To that end, we commend you for proposing an LCD that will expand Medicare coverage of CGMs to include use by beneficiaries taking insulin at least once a day and/or who experience recurring level two or three hypoglycemic events. Thirty-seven million Americans are impacted by diabetes, a chronic condition that requires proactive daily management of one's glucose levels. Within the Medicare

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<sup>1</sup> Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) Diabetes Care <https://doi.org/10.2337/dci22-0034>

<sup>2</sup> American Diabetes Association Standards of Medical Care in Diabetes—2022 Diabetes Care 2022;45(Suppl. 1):S97 S112, Chapter 7. Diabetes Technology. <https://doi.org/10.2337/dc22-S007>

population, the Centers for Medicare and Medicaid Services (CMS) reports that “one in every three Medicare beneficiaries has diabetes, and over 3.3 million Medicare beneficiaries use one or more of the common forms of insulin.”<sup>3</sup>

High blood glucose levels can lead to serious and life-threatening acute complications, such as coma or death. Further, over time, severe long-term complications including heart and kidney disease, stroke, amputations, and even blindness. On the opposite end of the spectrum is hypoglycemia, or low blood glucose levels, which in severe cases can include disorientation, seizures, difficulty speaking, loss of consciousness, coma or death. As such, ensuring that people with diabetes have access to the information they need to manage this disease can help prevent and reduce negative health outcomes. TIR is a tool that can provide actionable information to improve people’s daily diabetes management. People with diabetes can use the data generated by a CGM, including alarms to avoid dangerous blood sugar levels, to help make real-time adjustments to stay within a healthy range. According to the “Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials”<sup>4</sup> study lead by Drs. Roy Beck and Rich Bergenstal, as one’s TIR increases, the risk of microvascular complications decreases.

### **Expanded Access to CGMs Will Advance Equity and Reduce Disparities**

As outlined in the proposed LCD’s Summary of Evidence, we very much appreciate the acknowledgment of the racial, income, and geographic disparities that exist in diabetes prevalence and in access to CGM technologies. Minority communities bear a disproportionate burden of diabetes. Black (12.1%), Hispanic (11.8%), and Asian (9.5%) adults have higher prevalence rates than whites<sup>5</sup> (7.4%) and Indigenous Peoples are twice as likely as whites to have diabetes.<sup>6</sup> Diabetes also is disproportionately found among Americans with lower education and income levels. More than 13% of adults with less than a high school education have diagnosed diabetes compared to 9.2% of those with a high school education and 7.1% of those with more than a high school education.<sup>5</sup> Adults with family incomes below the federal poverty level have the highest diabetes prevalence for both men (13.7%) and women (14.4%).<sup>5</sup>

In addition, the most severe diabetes-related health complications are prevalent among minority populations. Black, Indigenous, and Hispanic individuals with diabetes have higher rates of blindness, end-stage kidney disease, and amputations than non-Hispanic white individuals with diabetes<sup>7</sup>. Deaths from diabetes are also significantly higher among these populations – Indigenous Americans are three times more likely, Non-Hispanic Black Americans are 2.3 times more likely, and Hispanic Americans are 1.5 times more likely to die from diabetes than white individuals.<sup>7</sup>

Significant racial and income disparities also exist in access to CGM technologies. Among people with type 1 diabetes, 71% of non-Hispanic white people use a CGM, while only 37% of Hispanic and 28% of Black individuals use CGMs.<sup>8</sup> Lack of comprehensive health insurance coverage for CGM means people may pay \$150-500 out of pocket each month for the device. As a result, CGM use is [lowest](#) among people with lower incomes.<sup>9</sup> The proposed

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<sup>3</sup> <https://innovation.cms.gov/innovation-models/part-d-savings-model>

<sup>4</sup> Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials. Beck RW, Bergenstal RM, Riddlesworth TD, Kollman C, Li Z, Brown AS, Close KL. Diabetes Care 2019 Mar;42(3):400-405. doi: 10.2337/dc18-1444. Epub 2018 Oct 23.

<sup>5</sup> <https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-diabetes.html>

<sup>6</sup> <https://www.cdc.gov/vitalsigns/aian-diabetes/index.html>

<sup>7</sup> [Spanakis E](#) and Golden, S. Race/Ethnic Difference in Diabetes and Diabetic Complications. Current Diabetes Reports. D2013; 13(6): 814-823.

<sup>8</sup> [Agarwal S](#), Schechter C, Gonzalez J, Long J. Racial-Ethnic Disparities in Diabetes Technology use Among Young Adults with Type 1 Diabetes. Diabetes technology & therapeutics. 2021; 23(4): 306-313.

<sup>9</sup> [Addala A](#), et al. A Decade of Disparities in Diabetes Technology Use and HbA1c in Pediatric Type 1 Diabetes: A Transatlantic Comparison. Diabetes Care. 2021; 44(1): 133-140.

LCD, if finalized, will help improve access to CGMs, particularly for lower-income Medicare beneficiaries, which in turn, will help advance equity and reduce disparities.

### **Diabetes Management Must Be Patient-Centered**

Diabetes is unique to every individual and a patient-centric approach to care is critical to ensuring optimal disease management. People with diabetes have reported improved psychosocial outcomes and quality of life when using CGM and CGM data, demonstrating patient satisfaction and success with the device.<sup>10,11</sup> In addition, 67% of people with diabetes who use CGM reported time in range as simple and intuitive for them to understand, and over half reported that the metric provides information needed to individualize care.<sup>12</sup> With regard to the proposed requirement for an in-person treating practitioner visit every six months to assess adherence, we appreciate the allowance for telehealth visits. However, we urge consideration of a more flexible approach to allow for patients and providers to engage in shared decision making as to how frequently an in-person visit needs to occur.

### **Conclusion**

The TIRC appreciates your recognition of the need to expand Medicare CGM coverage to include beneficiaries taking insulin at least once a day and/or who experience recurring level two or three hypoglycemic events. Increased access to the data these CGMs provide has been proven to enable more stable management of glucose levels and reduced complications. Again, we are grateful that you are collaborating on the promulgation of this LCD, which will ensure that all Medicare beneficiaries who qualify will be able to benefit from expanded access to a CGM. If we can be of any assistance to you as you finalize the proposed policy, please do not hesitate to contact me at any time (412.552.0889/[julie.heverly@diaTribe.org](mailto:julie.heverly@diaTribe.org)).

Sincerely,



Julie Heverly  
Senior Director, Time in Range Coalition  
The diaTribe Foundation

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<sup>10</sup> [Pinsker JE](#), Müller L, Constantin A, Leas S, Manning M, McElwee Malloy M, Singh H, Habif S. Real-world patient-reported outcomes and glycemic results with initiation of control-IQ technology. *Diabetes technology & therapeutics*. 2021; 23(2): 120-7.

<sup>11</sup> [Polonsky WH](#), Fortmann AL. The influence of time in range on daily mood in adults with type 1 diabetes, *Journal of Diabetes and Its Complications*. 2020;34(12):107746.

<sup>12</sup> Sainz N, Sommi A, Asamoia E, Shoger E, Wood R, Alexander C. Perceived benefits of TIR varies between patient CGM users vs HCPs, presented at the 58<sup>th</sup> European Association for the Study of Diabetes Conference (EASD). September 2022.