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April 22, 2024

Tara Hall  
MEDCAC Coordinator

Letter sent via email: [Tara.Hall@cms.hhs.gov](mailto:Tara.Hall@cms.hhs.gov)

Cc: [MedCACpresentations@cms.hhs.gov](mailto:MedCACpresentations@cms.hhs.gov)

**RE: MEDCAC Meeting, Devices for Self-management of Type 1 and Insulin-Dependent Type 2 Diabetes: May 21, 2024**

Dear Ms. Hall:

The American Diabetes Association® (ADA) is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) regarding the examination of clinical endpoints in studies of new devices for self-management of type 1 and insulin-dependent type 2 diabetes in adults.

**About ADA**

The ADA is the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic. Founded in 1940, the ADA has been driving discovery and research to treat, manage, and prevent diabetes, while working relentlessly for a cure. We help people with diabetes thrive by fighting for their rights and developing programs, advocacy, and education designed to improve their quality of life. The ADA also reviews and authors the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes<sup>1</sup> and publishes the most influential professional journals concerning diabetes research and treatment.<sup>2</sup>

**Comments**

In its MEDCAC meeting notice, CMS states that the goal of its May 21, 2024, meeting will be to provide recommendations to CMS regarding a guidance document on the topic, to be issued under the Clinical Endpoints Guidance program...“this need has arisen because the available devices for monitoring and controlling glucose levels have been studied and used primarily in individuals with type 1 diabetes, who historically have

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<sup>1</sup> American Diabetes Association: Standards of Medical Care in Diabetes 2023, Diabetes Care 46: Supp.1 (January 2023).

<sup>2</sup> The Association publishes five professional journals with widespread circulation: (1) Diabetes (original scientific research about diabetes); (2) Diabetes Care (original human studies about diabetes treatment); (3) Clinical Diabetes (information about state-of-the-art care for people with diabetes); (4) BMJ Open Diabetes Research & Care (clinical research articles regarding type 1 and type 2 diabetes and associated complications); and (5) Diabetes Spectrum (review and original articles on clinical diabetes management).



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not been Medicare-age adults. Although type 2 diabetes is much more common than type 1 diabetes among older adults, better management of type 1 diabetes is leading to more prolonged survival among patients with type 1 diabetes and, thus, greater numbers of these individuals are among the Medicare population. Furthermore, the prevalence of insulin-dependent type 2 diabetes, especially among older adults, is rising. Relevant clinical endpoints for assessing the effectiveness and safety of diabetes management devices may be unique for older adults.”<sup>3</sup>

### ***General Diabetes Technology Principles***

The ADA publishes the *Standards of Care in Diabetes* (Standards of Care), which is updated annually by a committee of U.S. experts in diabetes care, and it includes vital new and updated practice guidelines to care for people with diabetes and prediabetes. It is the gold-standard for professionals in the medical field. Chapter 7, entitled “Diabetes Technology,”<sup>4</sup> states that diabetes technology, when coupled with diabetes self-management and education and support, can improve the lives and health of people with diabetes,<sup>5</sup> and has transformed the diabetes management landscape by improving outcomes and making the condition easier to live and thrive with. People with diabetes who have been using CGM, insulin pumps, also known as continuous subcutaneous insulin infusion (CSII), and/or automated insulin delivery (AID) for diabetes management should have continued access across third-party payers, regardless of age or A1C levels.<sup>6</sup>

Further, technology is rapidly changing, but there is no one-size-fits-all approach to technology use in people with diabetes. Insurance coverage can lag behind device availability, people’s interest in devices and willingness for adoption can vary, and health care teams may have challenges in keeping up with newly released technology.

We acknowledge the troubling trend of the time delay between when a device is approved by the FDA and the period of time it takes to receive Medicare coverage; and note that the ADA broadly supports measures that will expand access to technology for beneficiaries with diabetes, whether this refers to technologies on the market today or in the future. We urge that CMS take extra care to avoid making choices that would limit access for people with diabetes, especially once a device has already been thoroughly tested and proven safe and effective like CGM, CSII, and AID systems, where CGM-informed algorithms modulate insulin delivery, as well as diabetes self-management support software serving as medical devices.

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<sup>3</sup> [MEDCAC Meeting - Devices for Self-management of Type 1 and Insulin-Dependent Type 2 Diabetes \(05/21/2024\) \(cms.gov\)](https://www.cms.gov/medcarac/meetings/2024/05212024)

<sup>4</sup> [https://diabetesjournals.org/care/issue/47/Supplement\\_1](https://diabetesjournals.org/care/issue/47/Supplement_1)

<sup>5</sup> American Diabetes Association: Standards of Medical Care in Diabetes 2023, Diabetes Care 47: Supp.1, p.S126, (January 2024).

<sup>6</sup> American Diabetes Association: Standards of Medical Care in Diabetes 2023, Diabetes Care 47: Supp.1, p.S127, (January 2024).



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We are grateful to the DME MAC Medical Directors for expanding access to CGM technology for Medicare beneficiaries by making important coverage criteria changes to the LCD for Glucose Monitors (L33822).<sup>7</sup> We appreciate the elimination of the “four or more times per day” blood glucose monitoring (BGM) testing requirement in 2021, as well as the April 16, 2023 expansion, allowing all insulin-dependent people with diabetes, and others who have a history of problematic hypoglycemia to have access to this important technology.

Each of these changes has removed significant barriers for Medicare beneficiaries with diabetes and we respectfully caution the agency against erecting additional barriers to devices and technology that have been rigorously tested in people with all types of diabetes, and at all ages.

### ***Diabetes Technology Recommendations and Data from Randomized Controlled Trials***

The ADA recommends that real-time CGM (rtCGM) or intermittently scanned CGM (isCGM) should be offered for diabetes management in adults with diabetes on multiple daily injections (MDI), CSII, or basal insulin who are capable of using the devices safely, as well as for youth with type 1 diabetes or type 2 diabetes on MDI.<sup>8</sup> Additionally, AID systems should be offered for diabetes management to youth and adults with type 1 diabetes and other types of insulin deficient diabetes. Insulin pump therapy can be offered for diabetes management to youth and adults on MDI with type 2 diabetes and can be successfully started at the time of diagnosis. Based on the agency’s comments in the MEDCAC issue brief about diabetes technologies and older people, we draw your attention to our recommendation that older individuals with type 1 diabetes benefit from ongoing insulin pump therapy, and access to insulin pump therapy, including AID systems, and should be allowed or continued in older adults as it is in younger people.<sup>9</sup>

Multiple randomized controlled trials (RCTs) have been performed using real time CGM devices, and the results have largely been positive in terms of reducing A1C levels and/or episodes of hypoglycemia, as long as participants regularly wore the devices. The initial studies were done primarily in adults and youth with type 1 diabetes on insulin pump therapy and/or MDI.<sup>10</sup> The primary outcome was met and showed benefit in adults of all ages<sup>11</sup> including seniors.<sup>12</sup> Data in children show that rtCGM use in young children with type 1 diabetes reduced hypoglycemia; in addition, behavioral support of parents of

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<sup>7</sup> <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822>

<sup>8</sup> American Diabetes Association: Standards of Medical Care in Diabetes 2023, Diabetes Care 47: Supp.1, p.S129 - S130, (January 2024).

<sup>9</sup> American Diabetes Association: Standards of Medical Care in Diabetes 2023, Diabetes Care 47: Supp.1, p. S134, (January 2024).

<sup>10</sup> American Diabetes Association: Standards of Medical Care in Diabetes 2023, Diabetes Care 47: Supp.1, p. S130, (January 2024).

<sup>11</sup> American Diabetes Association: Standards of Medical Care in Diabetes 2023, Diabetes Care 47: Supp.1, p. S130, (January 2024).

<sup>12</sup> American Diabetes Association: Standards of Medical Care in Diabetes 2023, Diabetes Care 47: Supp.1, p. S130, (January 2024).



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young children with diabetes using real time CGM showed the benefits of reducing hypoglycemia concerns and diabetes distress.<sup>13</sup> Similarly, A1C level reduction was seen in adolescents and young adults with type 1 diabetes using rtCGM.<sup>14</sup> RCT data on rtCGM use in individuals with type 2 diabetes on MDI,<sup>15</sup> mixed therapies,<sup>16</sup> and basal insulin<sup>17</sup> have consistently shown reductions in A1C levels and increases in time in range (TIR) (70–180 mg/dL [3.9–10 mmol/L]).

Further, RCT for isCGM in adults with type 1 diabetes showed that the use of isCGM with optional alerts and alarms resulted in reduction of A1C levels compared with BGM use.<sup>18</sup> The benefits of isCGM for adults with type 2 diabetes not using insulin were recently reported in an RCT, showing that the use of isCGM plus diabetes education versus diabetes education alone showed decreased A1C levels and increased TIR, as well as increased time in tight target range (70–140 mg/dL [3.9–7.8 mmol/L]) in the isCGM-plus-education group.<sup>19</sup> Additionally, real-world data on insulin pump use in individuals with type 1 diabetes show benefits in A1C levels and hypoglycemia reductions as well as total daily insulin dose reduction.<sup>20</sup>

A complement to A1c, TIR is an important measure that relates strongly to microvascular complications. Data is collected by CGM devices at 1–5 min intervals, which obtains data on glycemic excursions and periods of asymptomatic hypoglycemia or hyperglycemia (i.e., details of glycemic control that are not provided by A1c concentrations alone that are measured continuously and can be analyzed in daily, weekly, or monthly timeframes). These CGM-derived metrics are the subject of standardized, internationally agreed reporting formats and should, therefore, be considered for use in all clinical studies in diabetes.<sup>21</sup>

Use of CGM allows for the direct observation of glycemic excursions and daily profiles, which can inform immediate therapy decisions and/or lifestyle modifications and allows

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<sup>13</sup> American Diabetes Association: Standards of Medical Care in Diabetes 2023, *Diabetes Care* 47: Supp.1, p. S130, (January 2024).

<sup>14</sup> Laffel LM, Kanapka LG, Beck RW, et al.; CGM Intervention in Teens and Young Adults with T1D (CITY) Study Group; CDE10. Effect of continuous glucose monitoring on glycemic control in adolescents and young adults with type 1 diabetes: a randomized clinical trial. *JAMA* 2020;323:2388–2396

<sup>15</sup> Beck RW, Riddlesworth TD, Ruedy K, et al.; DIAMOND Study Group. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections: a randomized trial. *Ann Intern Med* 2017;167:365–374

<sup>16</sup> American Diabetes Association: Standards of Medical Care in Diabetes 2023, *Diabetes Care* 47: Supp.1, p. S130, (January 2024).

<sup>17</sup> American Diabetes Association: Standards of Medical Care in Diabetes 2023, *Diabetes Care* 47: Supp.1, p. S130, (January 2024).

<sup>18</sup> American Diabetes Association: Standards of Medical Care in Diabetes 2023, *Diabetes Care* 47: Supp.1, p. S131, (January 2024).

<sup>19</sup> Aronson R, Brown RE, Chu L, et al. Impact of flash glucose monitoring in people with type 2 diabetes inadequately controlled with non-insulin antihyperglycaemic therapy (IMMEDIATE): a randomized controlled trial. *Diabetes Obes Metab* 2023;25:1024–1031

<sup>20</sup> Aleppo G, DeSalvo DJ, Lauand F, et al. Improvements in glycemic outcomes in 4738 children, adolescents, and adults with type 1 diabetes initiating a tubeless insulin management system. *Diabetes Ther* 2023;14:593–610

<sup>21</sup> Batellino, Tadej, Alexander, Charles, et al. Continuous glucose monitoring and metrics for clinical trials: an international consensus statement: [https://www.thelancet.com/journals/landia/article/PIIS2213-8587\(22\)00319-9/abstract](https://www.thelancet.com/journals/landia/article/PIIS2213-8587(22)00319-9/abstract)



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clinicians and people with diabetes the ability to identify patterns of hypo- and hyperglycemia.<sup>22</sup> The ADA continues to advocate for increased recognition of TIR as an adjunct measure of glucose control, and we highlight its importance in clinical trial design, which is becoming more common and critical.

**Conclusion**

The ADA strongly encourages MEDCAC to closely examine the [ADA's Standards of Care, Chapter 7 on "Diabetes Technology,"](#) for a thorough review of the research for all diabetes technologies that continue to transform the diabetes management landscape by improving outcomes and making the condition easier to live and thrive with. We urge CMS not to pull back access to diabetes technologies and continue to focus on expanding access to populations who have far too often been left behind. Individuals on Medicare should have swift access to these necessary FDA-approved technologies as soon as possible to increase their opportunity for better health outcomes.

Should you have any questions or seek additional information regarding these comments, please reach out to Laura Friedman, Vice President, Regulatory Affairs at: [lfriedman@diabetes.org](mailto:lfriedman@diabetes.org).

Sincerely,

A handwritten signature in black ink, appearing to read "R. Gabbay".

Robert A. Gabbay, MD, PhD  
Chief Scientific & Medical Officer

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<sup>22</sup> Batellino, Tadej, Danne, Thomas, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range: <https://diabetesjournals.org/care/article/42/8/1593/36184/Clinical-Targets-for-Continuous-Glucose-Monitoring>