Anthem

Clinical UM Guideline

Subject: Continuous Glucose Monitoring Devices
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Description

This document addresses the use of continuous glucose monitoring devices (CGMs, also referred to as continuous *interstitial* glucose monitoring devices) for the management of diabetes mellitus.

CGMs are devices that continuously measure glucose concentrations in the interstitial space of the skin, allowing for indirect blood glucose measurements and avoidance of some or all fingersticks to access capillary blood. CGMs have been shown to assist in the management of some individuals with diabetes mellitus. Such devices come in a variety of configurations, including "flash" devices allowing on-demand measurements and devices that provide a continuous display of readings.

Note: This document does not address CGM devices approved for use without a prescription.

Note: For additional information regarding diabetes care, please see:

- CG-DME-50 Automated Insulin Delivery Systems
- CG-DME-51 External Insulin Pumps
- CG-SURG-79 Implantable Infusion Pumps

Clinical Indications

Medically Necessary:

I. *Non-Implanted* Continuous Interstitial Glucose Monitoring Devices for Personal Use

Use of a *non-implanted* continuous interstitial glucose monitoring device for personal use is considered **medically necessary** for individuals who meet the following criteria:

A. Individual has been diagnosed with diabetes mellitus (any type); **and**
B. Insulin injections are required multiple times daily or an insulin pump is used for maintenance of blood sugar control; **and**
C. Both of the following (1 and 2):
    1. The individual or caregiver(s) demonstrates the following:
        a. An understanding of the technology, including use of the device to recognize alerts and alarms; **and**
        b. Motivation to use the device correctly and consistently; **and**
        c. Continued participation in a comprehensive diabetes treatment plan; **and**
    2. *Any* of the following are present, despite ongoing management using self-monitoring and insulin administration regimens to optimize care:
        a. Inadequate glycemic control, demonstrated by HbA1c measurements above target; **or**
        b. Persistent fasting hyperglycemia; **or**
        c. Recurring episodes of hypoglycemia (blood glucose <54 mg/dL); **or**
        d. Hypoglycemia unawareness that puts the individual or others at risk; **or**
        e. In children and adolescents with type 1 diabetes who have achieved HbA1c levels below 7.0%, when treatment is intended to maintain target HbA1c levels and limit the risk of hypoglycemia.

Continued use of a non-implanted continuous interstitial glucose monitoring device for personal use is considered **medically necessary** when there is documentation that the device has resulted in clinical benefit (for example, improved or stabilized HbA1c control or fewer episodes of symptomatic hypoglycemia or hyperglycemia).

Replacement of a non-implanted continuous interstitial glucose monitoring device for personal use is considered **medically necessary** when the following criteria have been met:

A. The device is out of warranty; **and**
B. The device is malfunctioning; **and**
C. The device cannot be refurbished.

II. *Implanted* Continuous Interstitial Glucose Monitoring Devices for Personal Use

Use of an *implanted* continuous interstitial glucose monitoring device for personal use is considered **medically necessary** when the criteria below have been met:

A. The individual is 18 years of age or older; **and**
B. The individual meets the medical necessity criteria above for a non-implanted continuous interstitial glucose monitoring device for personal use.

Continued use of an implanted continuous interstitial glucose monitoring device for personal use is considered **medically necessary** when there is documentation that the device has resulted in clinical benefit (for example, improved or stabilized HbA1c control or fewer episodes of symptomatic hypoglycemia or hyperglycemia).

Replacement of an implantable continuous interstitial glucose monitoring device for personal use is considered **medically necessary** in accordance with FDA approved indications for use.

III. Professional, Intermittent, Short-Term Continuous Interstitial Glucose Monitoring Devices

Use of a continuous interstitial glucose monitoring device for professional, intermittent, short-term use is considered **medically**

necessary when **all** of the following criteria are met:

A. Individual meets medically necessary criteria for a non-implanted continuous interstitial glucose monitoring devices above;**and**
B. Monitoring and interpretation are under the supervision of a physician;**and**
C. The device is only used for a maximum of 14 consecutive days on an appropriate, periodic basis.

Not Medically Necessary:

Use of continuous interstitial glucose monitoring devices is considered **not medically necessary** when the criteria above have not been met.

Continued use of a continuous interstitial glucose monitoring device is considered **not medically necessary** when continued use criteria above have not been met.

Replacement of currently functional and warrantied continuous interstitial glucose monitoring devices is considered **not medically necessary** when the replacement criteria above have not been met.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation

HCPCS

A4238	Supply allowance for adjunctive non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277	Transmitter; external, for use with non-durable medical equipment interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with non-durable medical equipment interstitial continuous glucose monitoring system
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified
E2102	Adjunctive, non-implanted continuous glucose monitor or receiver
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver [that is, a device that does not require a finger stick, e.g., Dexcom G5]
G0308	Creation of subcutaneous pocket with insertion of 180 day implantable interstitial glucose sensor, including system activation and patient training
G0309	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180 day implantable sensor, including system activation
S1030	Continuous noninvasive glucose monitoring device, purchase
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor

ICD-10 Diagnosis

E08.00-E13.9	Diabetes mellitus
O24.011-O24.93	Diabetes mellitus in pregnancy, childbirth and the puerperium
P70.2	Neonatal diabetes mellitus

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for all other diagnoses not listed; or when the code describes a procedure, device or situation designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

According to the American Diabetes Association (ADA, 2024), diabetes is one of the most common chronic diseases in the United States (U.S.), with approximately 37 million Americans with diagnosed disease. Another 8.5 million are believed to have undiagnosed disease. Diabetes mellitus, the fourth leading cause of death in the U.S., is a chronic condition, marked by impaired metabolism of carbohydrate, protein and fat. The underlying problem in diabetes is in the production or utilization of insulin, the hormone secreted by the pancreas that controls the level of blood sugar by regulating the transfer of glucose from the blood into the cells. Diabetes mellitus, if poorly controlled, can cause cardiovascular disease, retinal damage that could lead to blindness, damage to the peripheral

nerves, and injury to the kidneys. Management of diabetes mellitus involves normalization of blood sugar without potentially dangerous hypoglycemia, or low blood sugar. Type 1 diabetes can occur at any age, but is most commonly diagnosed from infancy to late 30s. In type 1 the pancreas produces little to no insulin, and the body's immune system destroys the insulin-producing cells in the pancreas. Type 2 diabetes typically develops after age 40, but has recently begun to appear with more frequency in children. If a person is diagnosed with type 2 diabetes, the pancreas still produces insulin, but the body does not produce enough or is not able to use it effectively.

Adequate glycemic control is critical for directing therapy in individuals with diabetes. Ideal blood sugar concentration ranges between 70 mg/dL to 180 mg/dL. Hyperglycemia, defined as blood glucose concentrations above 200 mg/dL 1 to 2 hours following a meal, is associated with headaches, thirst, fatigue, blurred vision, hunger, difficulty concentrating, and coma. Long-term exposure to hyperglycemia has been associated with organ damage (including loss of function of the kidney, liver, heart, and eyes), peripheral nerve damage, and high blood pressure. Hypoglycemia is defined as an episode of an abnormally low plasma glucose concentration (with or without symptoms) that exposes the individual to harm. A blood glucose concentration between 54 mg/dL and 69 mg/dL, considered mild hypoglycemia, may include hunger or nausea, elevated heart rate, fatigue, difficulty concentrating, and tingling of the oral area. Serious hypoglycemia, defined as a blood glucose concentration < 54 mg/dL, has been associated with confusion, loss of coordination, blurry vision, loss of consciousness, and seizures. As noted by the Endocrine Society (2023), blood glucose concentrations < 54 mg/dL is associated with increased risk for cognitive dysfunction and mortality. Individuals with persistent fasting hyperglycemia, hypoglycemia unawareness that puts the individual or others at risk, or recurrent episodes of serious hypoglycemia (< 54 mg/dL) may benefit from use of continuous interstitial glucose monitoring devices and automated insulin delivery devices if ongoing management using self-monitoring and insulin administration regimens to optimize care has not resulted in adequate glycemic control.

For individuals with diabetes, a universal clinical indicator of adequate blood sugar control is the measurement of glycosylated hemoglobin, also known as hemoglobin A1c, or HbA1c. Measurement of HbA1c provides information regarding the concentration of a specific type of modified hemoglobin in the blood that is directly associated with blood sugar metabolism and is used to ascertain the level of blood glucose control over the previous three to four months before testing. Individuals with diabetes should have a "target" HbA1c measurement value to reach to demonstrate treatment compliance as well as attainment of treatment goals. The ADA has stated that an appropriate target for HbA1c concentrations in individuals with diabetes is 7% or lower.

For some individuals with diabetes, the use of multiple daily insulin injection therapy is insufficient to provide adequate control of blood sugar levels. In such cases, an external insulin pump may be recommended. These devices are worn externally and are attached to a temporary subcutaneous insulin catheter placed into the skin of the abdomen. The pump involves the use of a computer-controlled mechanism that can be set to administer the insulin at a set (basal) rate or provide injections (bolus) as needed. The pump typically has a syringe reservoir that has a 2- to 3-day insulin capacity. The purpose of the insulin pump is to provide an accurate, continuous, controlled delivery of insulin which can be regulated by the user to achieve intensive glucose control.

Whether an individual with diabetes uses injection therapy or an insulin pump, the individual needs to check blood glucose concentrations multiple times a day to make sure they are staying within normal blood glucose range. As with injection therapy, sometimes self-monitoring blood glucose management is also insufficient. In such circumstances, the use of a continuous interstitial glucose monitoring (CGM) device may be warranted.

Continuous Interstitial Glucose Monitoring Devices

CGM devices continuously monitor glucose concentrations in the fluid in between the body's cells, also known as interstitial fluid. Such devices have been proposed as an adjunct to routine blood-based glucose measurements in individuals with trouble maintaining appropriate blood glucose levels despite frequent blood-based monitoring or those with frequent undetected hypoglycemic events. They are designed to provide real-time glucose measurements, which have been found to accurately reflect blood glucose levels.

CGM devices have special features such as low and high glucose concentration alarms and data storage for later analysis. The stored data has been shown to be useful in identifying ways to improve individual care by altering diet, exercise, medication types, and timing of insulin administration.

There are a wide variety of interstitial glucose monitoring devices available. These devices can be divided into those intended for professional or personal use. Professional use involves periodic monitoring with retrospective review of the data by a medical provider and personal use involves longer-term real-time use by the individual. There are several devices on the market that allow for 6-, 7-, and 14-day monitoring intervals. Additionally, most CGMs are intended to be used as an adjunct to traditional monitoring of capillary blood glucose monitors. The U.S Food and Drug Administration (FDA) has approved devices for use without the need for blood glucose testing for diabetes treatment decisions, including the FreeStyle Libre Flash Glucose Monitoring System, Freestyle Libre 2, Freestyle Libre 3 (Abbott Diabetes Care Inc., Alameda, CA) as well as the Dexcom G6 and Dexcom G7 CGM systems (Dexcom, Inc. San Diego, CA). The Freestyle Libre Flash Glucose Monitoring System was the first CGM system approved by the FDA that did not require calibration by the user. The Freestyle Libre 2 and Freestyle Libre 3 devices which received FDA approval in November 2022 and April 2023, respectively, are comparable to the predicate Freestyle Libre Flash but have additional features. Similarly, the Dexcom G7 which received FDA approval in September 2022, has some additional features that are not found in the predicate Dexcom G6 CGM system.

As noted above, short-term use devices are intended to be used periodically, and are usually dispensed by the treating provider who then collects, analyzes and interprets the resultant data in a retrospective manner.

Personal CGM devices involve long-term use, are usually purchased by or for the individual for whom it has been prescribed, and are intended to be used continuously in real-time to help guide daily care. Periodic data downloading and analysis by the individuals and/or provider may also occur and provide additional data to guide care.

The FDA approved the Eversense implantable continuous interstitial glucose monitoring system on June 21, 2018, for continually measuring glucose levels in adults 18 years and older with diabetes for up to 90 days. Additional approval for use up to 180 days was granted on September 30, 2020. This device is implanted in the physician's office into the skin of the upper arm through a small incision. It is then removed when it expires and may be replaced with another sensor at a site on the contralateral arm to allow continued monitoring.

Meta-Analyses Data

The use of CGMs for the monitoring and treatment of type 1 diabetes has been the topic of many studies. These studies have investigated the use of these devices in several different populations, including children, individuals with difficulty with controlling their conditions, and pregnant women with diabetes. These studies have subsequently been subject to additional meta-analyses demonstrating significant benefits to (Benkhadra, 2017; Floyd, 2012; Gandhi, 2011; Langendam, 2012; Poolsup, 2013; Yeh, 2012).

With regard to individuals with type 2 diabetes specifically, the Gandhi study mentioned above included three RCTs that included subjects with type 2 diabetes. These studies involved heterogeneity with regard to inclusion of subjects who did and did not require insulin therapy. Their meta-analysis of the three trials indicated statistically significant reductions in HbA1c with CGM vs. self-monitoring blood glucose (SMBG). Likewise, the study by Poolsup previously described involved a meta-analysis of four trials including adults with type 2 diabetes. In their analysis, CGM appeared to result in improved HbA1c reductions compared to SMBG, with a pooled mean difference of -0.31% (p=0.04). These studies reported the use of different types of devices (for example, retrospective CGM vs. real-time CGM) and significant variability in frequency of CGM use.

Representative RCTs Addressing CGM for Type 1 Diabetes

Since the publication of the seminal article by the Juvenile Diabetes Research Foundation (JDRF) Continuous Glucose Monitoring Study Group (Tamborlane, 2008), a large number of studies have provided evidence demonstrating significant benefits to individuals with type 1 diabetes when treated with CGM. This study reported that when compared to the control group, the CGM group in this age group had significantly better results compared to the standard care group in regard to almost all measures of glycemic control, including: overall HbA1c change from baseline to 26 weeks (−0.71 to −0.35, p<0.001) improved, relative reduction in HbA1c of 10% or more (13% vs. 2%, p=0.003), number of subjects achieving target HbA1c goals less than 7.0% with no severe hypoglycemic events (15% vs. 3%, p=0.006), and higher percentage of time within normal blood glucose range (p<0.001). The data for the 8- to14-year-old age group demonstrated a significantly greater relative reduction in HbA1c of 10% or more (p=0.04) and a higher percentage of subjects achieving an HbA1c less than 7.0% (p=0.01). The 15- to 24-year-old group had no significant differences noted. The findings of this study suggest that CGM may provide benefit for adults over age 24 and, to a lesser degree, children, and adolescents under age 15. The authors note that the rate of sensor use between age groups may be related to the differences in clinical outcomes. The group with the least reported benefits, the 15-24 years-old, had only a 30% sensor use frequency. The group with the most benefit, those 25 years of age and older had the highest use of sensor frequency at 83%. The group with intermediate results, 8-14 years-old, had an intermediate frequency of use of 50%. The rate of parental supervision and support for CGM was greater for the 8-14 years age group than for the 15- to 24-year-old group, which may explain the higher rate of utilization and the significantly better results in younger children. The findings of this study suggest that significant benefits may be gained with CGM when a high level of compliance with therapy is achieved. It should be noted that this study population was composed of highly motivated individuals who measured their blood glucose levels 5 times a day or more and had a beginning HbA1c of 10% or less.

In an extension study of the study reported by Tamborlane, 214 of 219 (98%) control group subjects were followed for an additional 6 months and asked to use CGM daily (JDRF, 2010). This included 80 subjects who were at least 25 years old, 73 who were 15-24 years old, and 61 who were 8-14 years old. Among the 154 subjects with baseline HbA1c at least 7%, there was a significant decrease in HbA1c at 6 months after CGM use in the older age group (mean change in HbA1c, -0.4% ± 0.5%, p=0.003). There was a significant treatment group difference favoring the CGM group in mean HbA1c at 26 weeks adjusted for baseline values. The authors concluded that the weight of evidence suggests that CGM is beneficial for individuals with type 1 diabetes who have already achieved excellent control with HbA1c of less than 7.0% with SMBG.

Several studies have specifically focused on the use of CGM in pediatric populations. The results of the Diabetes Research in Children Network (DirecNet) Study Group RCT were published by Mauras in 2011. This study evaluated the use of CGM in the management of young children aged 4 to younger than 10 years with type 1 diabetes. In this study, 146 children were assigned to either CGM or usual care. At baseline, 30 children (42%) had an HbA1c of at least 8%. The primary outcome was reduction in HbA1c by at least 0.5% without the occurrence of severe hypoglycemia at 26 weeks. The authors reported that 19% in the CGM group and 28% in the usual care group (p=0.17) met this endpoint. Mean change in HbA1c, a secondary outcome, did not differ significantly between groups (-0.1 in each group, p=0.79).

Several studies have addressed the use of CGM in adult populations. Beck and colleagues (2017a) reported on the results of the DIAMOND RCT. This study included 158 adults with type 1 diabetes using multiple daily insulin injections and with HbA1c levels of 7.5% to 9.9%. All subjects were randomized in a 2:1 fashion to receive treatment with either CGM (n=105) or standard care (n=53). HbA1c level, the primary outcome measure, was measured in a centralized lab from baseline to 24 weeks. A total of 155 (98%) of subjects completed the study (n=102 for the CGM group [97%], n=53 for the control group [100%]). Median CGM use in the experimental group was 7 days a week at a 4, 12, and 24 weeks, with only 2 subjects discontinuing CGM use prior to 24 weeks. In the CGM group, mean HbA1c was reduced 1.1% at 12 weeks and 1.0% at 24 weeks. In the control group mean HbA1c reduction 0.5% and 0.4%, respectively (between group difference at 24 weeks, p<0.001). The adjusted difference in mean change in HbA1c level from baseline to 24 weeks in the CGM group was -0.6% (p<0.001). The median duration of hypoglycemia at a blood glucose concentration of < 70 mg/dL was 43 min/day in the CGM group vs. 80 min/day in the control group (p=0.002). Additional significant differences between groups at 24 months in favor of the CGM group were noted for glucose variability (coefficient of variation 36 vs. 42, p<0.001), minutes per day with blood glucose concentration within range (736 minutes vs. 650, p=0.005), and median duration of hypoglycemia at blood glucose concentration less than > 180 mg/dL (638 minutes vs. 740, p=0.03). The occurrence of severe hypoglycemia events did not differ between groups, with two events reported in each group. The authors concluded that, “Among adults with type 1 diabetes who used multiple daily insulin injections, the use of CGM compared with usual care resulted in a greater decrease in HbA1c level during 24 weeks.” They further commented that, “Further research is needed to assess longer-term effectiveness, as well as clinical outcomes and adverse effects.”

Also in 2017, Lind and colleagues published the results of the GOLD trial. This RCT involved an open-label crossover randomized study design. The study involved 161 subjects with type 1 diabetes and HbA1c (HbA1c) of greater than or equal to 7.5% who were treated with multiple daily insulin injections. All subjects were assigned to receive their initial treatment with a CGM or standard care for a period of 26 weeks followed by a washout period of 17 weeks and then another 26 weeks with the alternate treatment. Complete data for analysis was available for a total of 142 subjects (88/2%). Mean HbA1c was 7.92% during the CGM phase and 8.35% during the control treatment phase (p<0.001). Overall mean use time during the CGM phase was 87.8% (range 86.5-91.9%). In subjects using the CGM greater than 70% if the time, HbA1c was reduced by 0.46% compared to no reduction in those using CGM less than 70% of the time. Mean self-measurement of blood glucose was performed 2.75 times a day in the CGM group vs. 3.66 times per day in the control group. The mean percentage of time in a hypoglycemic state (< 70 mg/dL) was 2.97% in the CGM phase vs. 4.79% in the control phase. A second lower hypoglycemic threshold for blood glucose concentration of < 54 mg/dL also reported, with the mean percentage of time below that threshold reported as 0.79% for the GICM phase vs. 1.89% for the control phase. Severe hypoglycemic events were reported in 1 subject in the CGM phase vs. 5 subjects in the control phase (p=ns). There were no significant differences between groups with regard to the rate of serious adverse events. The 19 subjects without full data available were younger, had significantly higher HbA1c and had a history of hypoglycemic events. The authors made similar conclusions those of the DIAMOND study:

> Among patients with inadequately controlled type 1 diabetes treated with multiple daily insulin injections, the use of continuous glucose monitoring compared with conventional treatment for 26 weeks resulted in lower HbA1c. Further research is needed to assess clinical outcomes and longer-term adverse effects.

The results from the DIAMOND and GOLD trials are supportive of the use of CGM in individuals with type 1 diabetes. However, it

should be noted that the benefits were modest, with mean HbA1c reductions between 0.4 and 0.6% and showed no significant difference between CGM and standard care with regard to the incidence of severe hypoglycemic events. Additionally, it must be noted that these study results involved highly motivated and monitored subjects under the care of endocrinologists in the framework of a clinical trial.

Battelino (2017) reported the results of an unblinded, randomized, parallel, controlled trial involving children 8 to 18 years of age with type 1 diabetes being treated with insulin pump therapy. Subjects were assigned in a 1:1 fashion to treatment with the Medtronic 640G system with the predictive low glucose management (PLGM) either on (n=47) or off (n=49). The trial period was 2 weeks in duration. A significant difference between groups was noted with regard to the number of hypoglycemic events (glucose concentrations < 65 mg/dL; ≥ 20 minutes long) with the PLGM ON group experiencing 4.4 episodes vs. 7.4 for the PLGM OFF group (p=0.008). Similar findings were reported when the data were stratified by day (2.9 vs. 4.6, respectively, p=0.022) and night (1.5 vs. 2.8, respectively, p=0.025). However, the number of hypoglycemic events below 50 mg/dL was not significantly different. The time spent below 65 mg/dL, 60 mg/dL, and 50 mg/dL was less in the PLGM ON group (p=0.0106, p=0.089, and p=0.0203, respectively). The time spent above 140 mg/dL was significantly higher in the PLGM ON group (p=0.0165), but time spent above 180 mg/dL and 250 mg/dL was not (p-value not provided). The time spent within range, 70-140 mg/dL was significantly shorter in the PLGM ON group (p=0.0387), but time spent within the 70-180 mg/dL range was not. Mean and median sensor glucose measurements, sensor glucose measurements at 7:00 AM, mean and median blood glucose measurements, blood glucose measurements at 7:00 AM, and morning ketones were not significantly different between groups. No device-related serious adverse events were reported. However, the device was replaced on three occasions, and multiple sensor-related problem were reported, mostly due to lost connectivity.

Abraham (2018) described an RCT involving pediatric subjects aged 8 to 20 years old with type 1 diabetes assigned to treatment with either standard sensor-augmented therapy or the MiniMed 640G system with predictive low glucose suspend (PLGS) feature. The low glucose threshold was set for 61 mg/mL for the duration of the study. Subjects were selected on the basis of having at least one hypoglycemic event (serum glucose < 3.5 mmol/L) or three episodes of being at risk of hypoglycemia (4.4 mmol/L) during a 2-week assessment period. All subjects were required to use their assigned device for a minimum 80% of the time and followed for 6 months following randomization. At the end of the study the low threshold group 18 subjects (21%) lost to follow-up and the 640G group had 6 subjects (7%) lost to follow-up. The intent-to-treat population included 154 subjects, 74 in the sensor-augmented therapy group and 80 in the 640G group. Both groups demonstrated significant reductions in time spent in hypoglycemia (sensor-augmented therapy group, 3% to 2.6%, p=0.03 vs. 640G group 2.8% to 1.4%, p<0.0001, respectively). The 640G group results were more significant vs. the sensor-augmented therapy group (p<0.0001). The low threshold suspend group did not have any significant reductions in time spent in daytime hypoglycemia (2.5% vs. 2.3%, p=0.07), but did have significant nocturnal reductions (p=0.04). The 640G group had significant reductions in both day and nighttime hypoglycemia (day 2.4% vs. 1.3, p<0.001 and night 3.4% vs. 1.6%, p<0.0001, respectively). Compared to the sensor-augmented therapy group, the 640G group had significantly fewer hypoglycemic events (227 vs. 139, p<0.001). Interestingly, a significant increase in time with > 270 mg/dL was reported in both groups (p<0.0001 for both). No significant changes in HbA1c were noted in either group. The authors concluded that use of the 640G device with PLGS d feature reduced hypoglycemia without deterioration in glycemic control.

In 2018, Little and colleagues reported the results of the HypoCOMPaSS study, a 2 x 2 RCT comparing the following treatment methods: 1) MDI with self-monitoring of blood glucose, 2) MDI with self-monitoring of blood glucose and real-time CGM, 3) continuous insulin infusion with self-monitoring of blood glucose, and 4) continuous insulin infusion with self-monitoring of blood glucose and real-time CGM. Subjects all had type 1 diabetes and were aged 18 -74. The intervention period consisted of 24 weeks where subjects were treated per assignment, followed by reversion to routine care with additional data collection and visits at 12, 18 and 24 months. During the follow-up period, subjects were given the option to change their insulin delivery method and the CGM group was allowed continued use of the device while the self-monitoring of blood glucose group continued with that methodology. A total of 96 subjects were randomized and 76 (79%) completed the 24-month study period. The MDI group contained 50 subjects, with 39 (78%) completing the study period. Only 26% were still using this treatment method at end of the study. The insulin pump group began with 48 subjects, with 39 (81%) completing the study. A total of 68% were still using their pump at the end of the study. The CGM group involved 48 subjects, with 37 (77%) completing the study, and 30% were still using the devices at the end of the study. The self-monitoring of blood glucose group began with 48 subjects. It was not clear how many of these subjects completed the study from the study publication. No significant differences were noted between the daily injection and pump groups with regard to hypoglycemia awareness over the 24-month study period. Likewise, no differences were reported between the self-monitoring of blood glucose group and the CGM group with regard to hypoglycemia awareness, severe hypoglycemia or any secondary outcomes. Only 30% of CGM subjects continued to use their devices for the full 24 months. In the overall population, there was improvement in hypoglycemia awareness, sustained throughout the study period (Gold score 5.1 vs. 3.7, p<0.0001). Similar results were reported for the severe hypoglycemia rate (8.9 episodes/person-year vs. 0.4, (p<0.0001) and HbA1c (8.2 vs. 7.7; p=0.003). This study found no differences between the use of CGMs and serial monitoring of blood glucose, which warrants closer investigation.

Overall, the available RCT evidence addressing the use of CGM devices in individuals with type 1 diabetes is mixed but skewed to beneficial outcomes with the use of CGM devices. Data from meta-analyses supports this conclusion and indicates that the use of CGM results in improved glycemic control for adults with type 1 diabetes and for children with type 1 diabetes who used real-time CGM devices.

Implantable Interstitial Glucose Monitors

Multiple well-designed trials have demonstrated the accuracy of implantable CGMs when compared to both blood glucose measurements and non-implantable CGMs (Aronson, 2019; Boscari, 2021a and 2021b; Christiansen, 2018 and 2019; Jafri, 2020; Sanchez, 2019). Additional studies have demonstrated significant impact of the Eversense device on HbA1c concentrations and the effectiveness of alerts for hypoglycemia (Irace , 2020; Kropff, 2017; Tweden, 2020). The rate of adverse events and durability of the sensors have also been investigated and shown to be within acceptable range (Deiss, 2019). A study by Renard (2021) demonstrated a significant decrease in time below range (< 55 mg/dL) as a result of Eversense use when compared to self-monitoring or non-implantable CGM use.

The results of these trials demonstrate reasonable accuracy relative to laboratory blood glucose measures, with results being within accepted standards. Additionally, the available data demonstrate acceptable long-term performance out to 180 days for the Eversense device. Use of this device has been accepted as equivalent to non-implantable devices in the most recent version of the ADA Standards of Care in Diabetes (2024).

Real-time CGM use in Individuals with Type 2 Diabetes

Real-time CGM devices utilize an interstitial glucose sensor device attached to the skin, which is linked to a monitoring device which constantly provides up-to-date glucose concentration data which can be read and utilized by the treated individual or their caregiver. Such devices also store data for analysis at a later date to evaluate trends. Multiple studies have demonstrated significant benefit from these types of devices (Beck 2017b; Blackberry, 2014 and 2016; Sierra, 2017; Yoo, 2008).

Most recently, Furler (2020) published a report of an open-label RCT involving 299 subjects with type 2 diabetes assigned to care

with a flash CGM set to professional mode (n=149) vs. standard care (n=150). Subjects in the professional CGM group were not able to view the CGM data and were asked to wear the device for 5-14 days every 3 months over a 12-month period to capture data. At the end of each recording period the data was downloaded by their healthcare professional and discussed with the subject. Control subjects wore the professional CGM device at baseline and 12 months only and the results were not discussed with them. There were no significant differences reported between groups with regard to the primary outcome measure, mean HbA1c at 12 months (-0.3% vs -0.5%, p=0.59). However, at 6 months there was a significant difference reported (8.1% vs. 8.6%, p=0.001). The mean percentage time in target range was significantly better in the CGM group (54.8% vs. 46.9%, p=0.0043). The authors reported this difference was more pronounced between 6 a.m. and midnight, with the CGM group having a 9.2% higher mean percent time within target range (p=0.0021). No differences between groups was reported for this measure for midnight to 6 a.m. (p=0.06). From baseline to 9 months CGM use fell to 78%. Mean between-group difference in HbA1c results did not change when device non-users were removed from the analysis. No significant changes in median number of non-insulin drugs used, subjects using insulin, or median total insulin dose were reported. The authors concluded that professional CGM use in individuals with type 2 diabetes did not improve HbA1c concentrations over 12 months. However, it did improve time in range (TIR) at 12 months and HbA1c at 6 months. While the results suggest a potential benefit of professional CGM use in individuals with type 2 diabetes, the authors note that the TIR outcome at 12 months findings were “exploratory and need to be interpreted with caution, particularly in the context of an open label trial in which the primary outcome was negative”.

Martens (2021) reported on an RCT involving 175 subjects with type 2 diabetes with basal insulin assigned to management with either CGM (n=116) or standard blood glucose monitoring (n=59). The authors reported that at 8 months follow-up the mean HbA1c concentrations decreased significantly in the CGM group when compared to the blood monitoring group (9.1% to 8.0% in the CGM group vs. 9.0% to 8.4% in the blood monitoring group, p=0.02). Additionally, the mean percentage of time in the target glucose range (70 to 180 mg/dL) was 59% in the CGM group vs. 43% in the blood monitoring group (p<0.001). The mean percentage of time at greater than 250 mg/dL was also significantly improved in the CGM group (11% vs 27%, respectively; p<0.001).

Overall, the existing evidence addressing the use of CGM individuals with type 2 diabetes is weaker than that for individuals with type 1 diabetes. The available meta-analyses report significant variability in the literature with regard to the types of interventions investigated, the frequency of use, and populations involved. Although the meta-analyses available to date have found a statistically significant benefit of CGM in terms of glycemic control, the small number of RCTs and the variability among interventions makes it difficult to identify an optimal approach to CGM use or subgroup of individuals with type 2 diabetes who might benefit. Nonetheless, the data does indicate significant benefits for individuals with type 2 diabetes with regard to short-term HbA1c concentrations, TIR, lowered BMI, and recognition of post-prandial hypoglycemia. On the basis of these findings the use of CGMs in this population has become an accepted practice and is currently recommended by the American Diabetes Association (2023), and for all insulin-using individuals, regardless of diabetes type, by the American Association of Clinical Endocrinologists and American College of Endocrinology (Grunberger, 2018).

Flash-CGM use in Individuals with Type 2 Diabetes

Flash CGM devices (for example, FreeStyle Libre Flash Glucose Monitoring System, Abbott Laboratories, Abbott Park, Ill) utilize an interstitial glucose sensor device attached to the skin for up to 14 days. This sensor takes measurements every 15 minutes, which may be accessed in real-time by triggering a separate reader/scanner unit, which wirelessly links to the sensor. Such devices also store data for analysis at a later date to evaluate trends. Multiple large, well conducted trials have demonstrated significant benefit from use of these types of devices (Al Hayek, 2017; Bolinder, 2016; Dunn, 2018; Ehrhardt, 2011; Haak, 2017a and 2017b; Saboo, 2018; Vigersky, 2012)

Most recently, in 2020 Yaron and colleagues reported the results of an unblinded RCT involving 101 subjects with type 2 diabetes to 10 weeks of treatment with a flash glucose device (n=53) or standard care (n=48). Flash group subjects were asked to use the flash scanner every 8 hours and the data was downloaded every 2-4 weeks. During inpatient visits, data from the flash device (Flash group) and the standard blood glucose monitor (Control Group) was used to counsel subjects in self-care. In the ITT analysis the mean (SD) change in HbA1c was demonstrated to have decreased -0.82% in the Flash group vs. -0.33 in the control group (p=0.005). HbA1c reduction, with adjustment for HbA1c values at baseline, was -0.85% in the Flash group vs. -0.32% in the control group (p<0.0001). The frequency of hypoglycemic episodes was not significantly different between groups and no severe hypoglycemic or serious adverse events were reported.

Overall, the data regarding the impact of flash CGM devices for individuals with type 2 diabetes is indicative of significant benefits with regard to decreased HbA1c concentrations and decreased overall and nocturnal time in the hypoglycemic range.

Other use in Individuals with Type 2 Diabetes

The use of CMGs has been proposed for the management of glycemic control in individuals with type 2 diabetes not on an intensive insulin regimen. Such therapy involves the use of a CGM to help guide dietary and activity decisions to drive behavioral changes and self-management to improve outcomes. Such use has been referred to as “patient-driven lifestyle modification.” At this time, there is limited evidence to support such use.

Choe (2022) published the results of a non-blinded RCT involving 126 subjects with type 2 diabetes treated with anti-diabetes medication, including oral agents and basal insulin, but not prandial insulin, assigned to standard treatment (n=63) vs. education support with behavior modification and self-management with the use of intermittently scanned CGM (FreeStyle Libre) (n=63). The authors reported mean HbA1c levels were significantly improved in the intervention group vs. the control group (7.3 ± 0.6 in the CGM group vs. 7.8 ± 0.9% the control group at 12 weeks, p<0.001). Additionally, the proportion of participants achieving HbA1c < 7.0% was significantly lower in the CGM group (24.1% vs. 8.1%, p=0.016). Mean fasting glucose level was also lower in the CGM group vs. the control group at 12 months (136 mg/dL vs. 154 mg/dL, p=0.017). No significant differences between groups were reported with regard to body weight, waist circumference, or lipid profiles.

Aronson (2023) reported the results of another RCT involving 116 subjects with type 2 diabetes, HbA1c of 7.5% or higher, and at least one non-insulin anti-diabetes medication. Subjects were assigned to diabetes self-management education (n=52) vs. education with behavior modification and self-management with the use of intermittently scanned CGM (FreeStyle Libre) (n=53). Randomized treatment lasted for 16-weeks and was followed by another 16-week extension phase. The extension phase data are not provided in this report. The primary outcome was TIR, and the results at the last timepoint indicated that the percentage TIR was significantly better in the CGM vs. the control group (p<0.01). Percentage time in glycemic range and percentage time above range were significantly better in the CGM group vs. the control group (p=0.042 and p=0.037, respectively). No differences between groups were found with regard to time below range or mean glucose concentrations. Both groups had significant improvements in mean HbA1c. However, no between group comparisons were provided. No differences between groups were found for weight, waist circumference, or hypoglycemic events.

These findings are of interest, but further investigation is warranted to understand the wider impact of such CGM use in the general population outside the investigational setting.

Non-Prescription Devices

On March 5, 2024, the FDA granted 510K clearance to Dexcom to market their Stelo Glucose Biosensor system to individuals over the age of 18 who do not use insulin, such as individuals with diabetes using oral drug management therapy. The purpose of the device is to allow individuals to access glucose concentrations in real time without need for a needle stick for blood glucose monitoring. Additionally, the FDA states, “Importantly, this system is not for individuals with problematic hypoglycemia (low blood sugar) as the system is not designed to alert the user to this potentially dangerous condition.”

Major Specialty Medical Society Recommendations

The ADA Standards of Medical Care in Diabetes-2024 has recommendations regarding the use of continuous glucose monitoring. These recommendations state:

7.2 Initiation of continuous glucose monitoring (CGM) should be offered to people with type 1 diabetes early in the disease, even at time of diagnosis. A.
7.4 The type(s) and selection of devices should be individualized based on a person’s specific needs, preferences, and skill level. In the setting of an individual whose diabetes is partially or wholly managed by someone else (e.g., a young child or a person with cognitive impairment or dexterity, psychosocial, and/or physical limitations), the caregiver’s skills and preferences are integral to the decision-making process. E
7.5 When prescribing a device, ensure that people with diabetes and caregivers receive initial and ongoing education and training, either in person or remotely, and ongoing evaluation of technique, results, and the ability to utilize data, including uploading/sharing data (if applicable), to monitor and adjust therapy. C
7.6 People with diabetes who have been using CGM, 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. E
7.8 Initiation of CSII and/or AID early, even at diagnosis, in the treatment of diabetes can be beneficial depending on a person’s or caregiver’s needs and preferences. C
7.9 People with diabetes should be provided with blood glucose monitoring (BGM) devices as indicated by their circumstances, preferences, and treatment. People using CGM devices must also have access to BGM at all times. A
7.14 Real-time CGM (rtCGM) A or intermittently scanned CGM (isCGM) B should be offered for diabetes management in adults with diabetes on multiple daily injections (MDI) or CSII who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual’s circumstances, preferences, and needs.
7.15 rtCGM A or isCGM B should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual’s circumstances, preferences, and needs.
7.16 rtCGM A or isCGM E should be offered for diabetes management in youth with type 1 diabetes on MDI or CSII who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual’s circumstances, preferences, and needs.
7.17 rtCGM or isCGM should be offered for diabetes management in youth with type 2 diabetes on MDI or CSII who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual’s circumstances, preferences, and needs. E
7.18 In people with diabetes on MDI or CSII, rtCGM devices should be used as close to daily as possible for maximal benefit. A isCGM devices should be scanned frequently, at a minimum once every 8 h to avoid gaps in data. A People with diabetes should have uninterrupted access to their supplies to minimize gaps in CGM. A
7.19 When used as an adjunct to preprandial and postprandial BGM, CGM can help to achieve A1C targets in diabetes and pregnancy. B
7.20 Periodic use of rtCGM or isCGM or use of professional CGM can be helpful for diabetes management in circumstances where consistent use of CGM is not desired or available. C
7.31 Individuals with diabetes may be using systems not approved by the FDA, such as do-it-yourself closed-loop systems and others; health care professionals cannot prescribe these systems but should assist in diabetes management to ensure the safety of people with diabetes. E
14.7 Frequent glucose monitoring before, during, and after exercise, via blood glucose meter or continuous glucose monitoring (CGM), is important to prevent, detect, and treat hypoglycemia and hyperglycemia associated with exercise. C
14.17 All youth with type 1 diabetes should monitor glucose levels multiple times daily (up to 6–10 times/day by blood glucose meter or CGM), including prior to meals and snacks, at bedtime, and as needed for safety in specific situations such as physical activity, driving, or the presence of symptoms of hypoglycemia. B
14.18 Real-time CGM A or intermittently scanned CGM E should be offered for diabetes management at diagnosis or as soon as possible in youth with diabetes on multiple daily injections or insulin pump therapy who are capable of using the device safely (either by themselves or with caregivers). The choice of device should be made based on the individual’s and family’s circumstances, desires, and needs.
14.22 A1C goals must be individualized and reassessed over time. An A1C of <7% (<53 mmol/mol) is appropriate for many children and adolescents. B
14.23 Less stringent A1C goals (such as <7.5% [<58 mmol/mol]) may be appropriate for youth who cannot articulate symptoms of hypoglycemia; have hypoglycemia unawareness; lack access to analog insulins, advanced insulin delivery technology, and/or CGM; cannot check blood glucose regularly; or have nonglycemic factors that increase A1C (e.g., high glycators). B
14.24 Even less stringent A1C goals (such as <8% [<64 mmol/mol]) may be appropriate for individuals with a history of severe hypoglycemia, limited life expectancy, or where the harms of treatment are greater than the benefits. B
14.25 Health care professionals may reasonably suggest more stringent A1C goals (such as <6.5% [<48 mmol/mol]) for selected individuals if they can be achieved without significant hypoglycemia, negative impacts on well-being, or undue burden of care or in those who have nonglycemic factors that decrease A1C (e.g., lower erythrocyte life span). Lower goals may also be appropriate during the honeymoon phase. B
14.26 CGM metrics derived from continuous glucose monitor use over the most recent 14 days (or longer for youth with more glycemic variability), including time in range (70–180 mg/dL [3.9–10.0 mmol/L]), time below range (<70 mg/dL [<3.9 mmol/L] and <54 mg/dL [<3.0 mmol/L]), and time above range (>180 mg/dL [>10.0 mmol/L] and >250 mg/dL [>13.9 mmol/L]), are recommended to be used in conjunction with A1C whenever possible. E
14.58 Real-time CGM or intermittently scanned CGM should be offered for diabetes management in youth with type 2 diabetes on multiple daily injections or insulin pumps who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on an individual’s and family’s circumstances, desires, and needs. E
14.60 A reasonable A1C goal for most children and adolescents with type 2 diabetes is <7% (<53 mmol/mol). More stringent A1C goals (such as <6.5% [<48 mmol/mol]) may be appropriate for selected individuals if they can be achieved without significant hypoglycemia or other adverse effects of treatment. Appropriate individuals might include those with a short

duration of diabetes and lesser degrees of β-cell dysfunction and individuals treated with lifestyle or metformin only who achieve significant weight improvement. E

14.61 Less stringent A1C goals (such as 7.5% [58 mmol/mol]) may be appropriate if there is an increased risk of hypoglycemia. E

14.62 A1C goals for individuals on insulin should be individualized, taking into account the relatively low rates of hypoglycemia in youth-onset type 2 diabetes. E

15.8 Due to increased red blood cell turnover, A1C is slightly lower during pregnancy in people with and without diabetes. Ideally, the A1C goal in pregnancy is <6% (<42 mmol/mol) if this can be achieved without significant hypoglycemia, but the goal may be relaxed to <7% (<53 mmol/mol) if necessary to prevent hypoglycemia. B

15.9 When used in addition to pre- and postprandial blood glucose monitoring, continuous glucose monitoring (CGM) can help to achieve the A1C goal in diabetes and pregnancy. B

15.10 CGM is recommended in pregnancies associated with type 1 diabetes. A When used in addition to blood glucose monitoring, achieving traditional pre- and postprandial goals, real-time CGM can reduce the risk for large-for-gestational age infants and neonatal hypoglycemia in pregnancy complicated by type 1 diabetes. A

15.11 CGM metrics may be used in addition to but should not be used as a substitute for blood glucose monitoring to achieve optimal pre- and postprandial glycemic goals. E

The Endocrine Society also has recommendations for the use of CGM devices in their 2018 clinical practice guideline addressing this topic (Peters, 2018):

6. Real-time continuous glucose monitors in adult outpatients

6.1 We recommend real-time continuous glucose monitoring (RT-CGM) devices for adult patients with T1DM who have A1C levels above target and who are willing and able to use these devices on a nearly daily basis. (1⊕⊕⊕⊕)

6.2 We recommend RT-CGM devices for adult patients with well-controlled T1DM who are willing and able to use these devices on a nearly daily basis. (1⊕⊕⊕⊕)

6.3 We suggest short-term, intermittent RT-CGM use in adult patients with T2DM (not on prandial insulin) who have A1C levels 7% and are willing and able to use the device. (2⊕⊕○○)

Children and Adolescents (2011 guideline)

2.1 We recommend that RT-CGM with currently approved devices be used by children and adolescents with T1DM who have achieved glycosylated hemoglobin (HbA1c) levels below 7.0% because it will assist in maintaining target HbA1c levels while limiting the risk of hypoglycemia (1|⊕⊕⊕).

2.2 We recommend RT-CGM devices be used with children and adolescents with T1DM who have HbA1c levels ≤ 7.0% who are able to use these devices on a nearly daily basis (1|⊕⊕⊕○).

2.3 We make no recommendations for or against the use of RT-CGM by children with T1DM who are less than 8 years of age.

2.4 We suggest that treatment guidelines be provided to patients to allow them to safely and effectively take advantage of the information provided to them by RT-CGM (2|⊕○○○).

2.5 We suggest the intermittent use of CGM systems designed for short-term retrospective analysis in pediatric patients with diabetes in whom clinicians worry about nocturnal hypoglycemia, dawn phenomenon, and postprandial hyperglycemia; in patients with hypoglycemic unawareness; and in patients experimenting with important changes to their diabetes regimens [such as instituting new insulin or switching from multiple daily injections (MDI) to pump therapy] (2|⊕○○○).

It should be noted that recommendation 6.3 was graded “weak” and based on low quality evidence.

In 2023 the Endocrine Society published a clinical practice guideline addressing the management of individuals with diabetes at high risk for hypoglycemia (McCall, 2023). In this document they make the following recommendations:

Recommendation 1 We recommend continuous glucose monitoring (CGM) rather than self-monitoring of blood glucose (SMBG) by fingerstick for patients with type 1 diabetes (T1D) receiving multiple daily injections (MDIs). (1⊕⊕OO)

Recommendation 2 We suggest using real-time continuous glucose monitoring (CGM) and algorithm-driven insulin pumps (ADIPs) rather than multiple daily injections (MDIs) with self-monitoring of blood glucose (SMBG) three or more times daily for adults and children with type 1 diabetes (T1D). (2⊕⊕OO)

Recommendation 3 We suggest real-time continuous glucose monitoring (CGM) be used rather than no continuous glucose monitoring (CGM) for outpatients with type 2 diabetes (T2D) who take insulin and/or sulfonylureas (SUs) and are at risk for hypoglycemia. (2⊕OOO)

Recommendation 4 We suggest initiation of continuous glucose monitoring (CGM) in the inpatient setting for select inpatients at high risk for hypoglycemia. (2⊕OOO)

Recommendation 5 We suggest continuation of personal continuous glucose monitoring (CGM) in the inpatient setting with or without algorithm-driven insulin pump (ADIP) therapy rather than discontinuation. (2⊕OOO)

The Endocrine Society uses the following scheme to grade their recommendations (McCartney, 2022):

Certainty of evidence	Interpretation
High ⊕⊕⊕⊕	We are very confident that the true effect lies close to that of the estimate of the effect
Moderate ⊕⊕⊕○	We are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low ⊕⊕OO	Our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect
Very Low ⊕OOO	We have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

Strength of recommendation	Criteria	Interpretation by patients	Interpretation by healthcare providers	Interpretation by policy makers

1—Strong recommendation for or against	Desirable consequences CLEARLY OUTWEIGH the undesirable consequences in most settings (or vice versa).	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	Most individuals should follow the recommended course of action. Formal decision aids are not likely to be needed to help individual patients make decisions consistent with their values and preferences.	The recommendation can be adopted as policy in most situations. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator
2—Conditional recommendation for or against	Desirable consequences PROBABLY OUTWEIGH undesirable consequences in most settings (or vice versa).	The majority of individuals in this situation would want the suggested course of action, but many would not.	Clinicians should recognize that different choices will be appropriate for each individual and that clinicians must help each individual arrive at a management decision consistent with the individual's values and preferences. Decision aids may be useful in helping patients make decisions consistent with their individual risks, values and preferences.	Policy-making will require substantial debate and involvement of various stakeholders. Performance measures should assess whether decision making is appropriate

The American Association of Clinical Endocrinologist (AACE) and the American College of Endocrinology (ACE) produced a consensus statement addressing outpatient glucose monitoring in 2016 (Bailey, 2016). This document makes the following recommendations for the use of CGM:

- Type 1 Adult: CGM recommended, particularly for patients with history of severe hypoglycemia, hypoglycemia unawareness and to assist in the correction of hyperglycemia in patients not at goal. CGM users must know basics of sensor insertion, calibration, and real-time data interpretation.
- Type 1 – Pediatric: Same as Adult Type 1. Both prevalence and persistent use of CGM is lower in children than adults. More in-depth training as well as more frequent follow-up is recommended to enable children to adopt the technology more successfully.
- Type 2 – Receiving insulin/ sulfonylureas, glinides: Data on CGM in T2DM are limited at this time. Trials assessing the use of CGM in T2DM patients are ongoing.
- Type 2 – Low risk of hypoglycemia: No recommendation.
- Gestational: Benefits of CGM in pregnant females with pre-existing diabetes are unclear based on current data; additional studies are ongoing. CGM during pregnancy can be used as a teaching tool, to evaluate glucose patterns, and to fine-tune insulin dosing. CGM in pregnancy can supplement BGM, in particular for monitoring nocturnal hypoglycemia or hyperglycemia and postprandial hyperglycemia.

The AACE and American College of Endocrinology (ACE) published a position statement on the integration of insulin pumps and continuous glucose monitoring in patients with diabetes mellitus (Grunberger, 2018). This document states the following:

> The AACE/ACE recommends that CGM be considered for all insulin-using patients, regardless of diabetes type. Insulin pump usage is recommended in patients with intensively managed insulin-dependent T1DM or T2DM (those who perform at least 4 insulin injections and 4 SMBG measurements daily). Integration of CGM and CSII may be considered in patients already on SII or appropriate for initiating CSII.
>
> Personal CGM should ideally be considered in all patients with T1DM, especially those with a history of severe hypoglycemia, hypoglycemia unawareness, and to assist in the correction of hyperglycemia in patients not at goal. Of note, usage and persistence of usage of CGM is lower in pediatric patients. The benefits of CGM in patients with T2DM have not been investigated to the same degree. A key aspect of successful glycemic control with CGM, however, is patients' ability to understand and respond to the data they receive in real time. Recent results show there is some variation in how patients adjust insulin therapy. Nonetheless, CGM users do rely on glucose rate of change arrows to adjust insulin delivery.

Appropriate candidates for pump therapy include:

- Patients with T1DM who are not at glycemic goal, despite adherence to maximum MDI, in particular
  - Those with erratic and wide glycemic excursions (including recurrent DKA)
  - Frequent severe hypoglycemia and/or hypoglycemia unawareness
  - Significant "dawn phenomenon," extreme insulin sensitivity
- T1DM special populations (including preconception, pregnancy, children, adolescents, and competitive athletes)
- Patients with T1DM who feel CSII would help achieve and maintain glycemic targets
- Select patients with insulin-dependent T2DM with any or all of the following:
  - C-peptide positivity with suboptimal control on maximal basal/bolus injections
  - Substantial "dawn phenomenon"
  - Erratic lifestyle (e.g., frequent long-distance travel, shift work, and unpredictable schedules)
  - Severe insulin resistance
- Select patients with other DM types (e.g., postpancreatectomy).

> Importantly, patients who are unable or unwilling to perform MDI, frequent SMBG, and carbohydrate counting; lack motivation to achieve tighter glucose control or have a history of nonadherence; have a history of serious psychological or psychiatric conditions; or have either substantial reservations or unrealistic expectations about pump therapy are not good candidates.

Use of CGM with integrated pump requires patient self-management. The ideal candidate must be willing and able to carry out tasks associated with using the system, self-monitor and react to collected data, and maintain frequent contact with the healthcare team. Intensive education is needed, and patients must be willing to complete the necessary training. Family support, particularly with pediatric patients, is paramount to success. The increased burden on patients and their families, as well as health-economic and ethical concerns, must be considered carefully, and this strategy may not be ideal for all patients.

Additionally, in 2018 the Endocrine Society published *Advances in Glucose Monitoring and Automated Insulin Delivery: Supplement to Endocrine Society Clinical Practice Guidelines* (Peters, 2018). In this document they make the following recommendations:

Follow-up visits. (1|⊕⊕OO)
6. Real-time continuous glucose monitors in adult outpatients
6.1 We recommend real-time continuous glucose monitoring (RT-CGM) devices for adult patients with T1DM who have A1C levels above target and who are willing and able to use these devices on a nearly daily basis. (1|⊕⊕⊕⊕)
6.2 We recommend RT-CGM devices for adult patients with well-controlled T1DM who are willing and able to use these devices on a nearly daily basis. (1|⊕⊕⊕⊕) Use of continuous glucose monitoring in adults with type 2 diabetes mellitus
6.3 We suggest short-term, intermittent RT-CGM use in adult patients with T2DM (not on prandial insulin) who have A1C levels 7% and are willing and able to use the device. (2|⊕⊕OO)

In 2021 the AACE published clinical practice guidelines addressing the use of advanced technology in the management of persons with diabetes mellitus (Grunberger, 2021). Their recommendations in that document include the following:

R2.1.3 CGM is recommended for all individuals with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness). Grade A; Intermediate-High Strength of Evidence; BEL 1
R2.1.4 CGM is recommended for children/adolescents with T1D. Grade A; Intermediate-High Strength of Evidence; BEL 1
R2.1.5 CGM is recommended for pregnant women with T1D and T2D treated with intensive insulin therapy. Grade A; Intermediate-High Strength of Evidence; BEL 1
R2.1.6 CGM is recommended for women with gestational diabetes mellitus (GDM) on insulin therapy. Grade A; Intermediate Strength of Evidence; BEL 1
R2.1.7 CGM may be recommended for women with GDM who are not on insulin therapy. Grade B; Intermediate Strength of Evidence; BEL 1
R2.1.8 CGM may be recommended for individuals with T2D who are treated with less intensive insulin therapy. Grade B; Intermediate Strength of Evidence; BEL 1
R2.2.1 The AGP may be utilized to assess glycemic status in persons with diabetes. Grade B; Low Strength of Evidence; BEL 1
R2.2.2 When using the AGP, a systematic approach to interpret CGM data is recommended:

1. Review overall glycemic status (eg, GMI, average glucose)
2. Check TBR, TIR, and TAR statistics, focusing on hypoglycemia (TBR) first. If the TBR statistics are above the cut-point for the clinical scenario (ie, for most with
3. T1D >4% <70 mg/dL; >1% <54 mg/dL), the visit should focus on this issue. Otherwise, move on to the TIR and TAR statistics.
4. Review the 24-hour glucose profile to identify the time(s) and magnitude(s) of the problem identified.
5. Review treatment regimen and adjust as needed.
   Grade B; Low Strength of Evidence; BEL 1

R2.3.1 Real-time continuous glucose monitoring (rtCGM) should be recommended over intermittently scanned continuous glucose monitoring (isCGM) to persons with diabetes with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness) who require predictive alarms/ alerts; however, the lifestyle of persons with diabetes and other factors should also be considered. Grade B; Low-Intermediate Strength of Evidence; BEL 1
R2.3.2 isCGM should be considered for persons with diabetes who meet 1 or more of the following criteria: Newly diagnosed with T2D Treated with nonhypoglycemic therapies Motivated to scan device several times per day at low risk for hypoglycemia, but desire more data than SMBG provides Grade D; Low Strength of Evidence/Expert Opinion of Task Force; BEL 4
R2.4.1 Diagnostic/professional CGM should be used in the management of persons with diabetes who meet 1 or more of the following criteria: Newly diagnosed with diabetes mellitus Not using CGM May have problematic hypoglycemia, but no access to personal CGM Persons with T2D treated with non-insulin therapies who would benefit from episodic use of CGM as an educational tool Persons who would like to learn more about CGM before committing to daily use Importantly, in those using “masked” or “blinded” diagnostic/professional CGM, they must have and continue using adjunctive SMBG to assist in daily diabetes self-care. Grade B; Intermediate Strength of Evidence; BEL 1
R2.9.1 Low-glucose suspend (LGS) is strongly recommended for all persons with T1D to reduce the severity and duration of hypoglycemia, whereas predictive low-glucose suspend (PLGS) is strongly recommended for all persons with T1D to mitigate hypoglycemia. Both systems do not lead to a rise in mean glucose, and lead to increased confidence and trust in the technology, more flexibility around mealtimes, and reduced diabetes distress for both persons with diabetes and caregivers. Therefore, anyone with frequent hypoglycemia, impaired hypoglycemia awareness, and those who fear hypoglycemia leading to permissive hyperglycemia should be considered for this method of insulin delivery. Grade A; High Strength of Evidence; BEL 1
R2.10.2 rtCGM is recommended for persons 65 years old with insulin-requiring diabetes to achieve improved glycemic control, reduce episodes of severe hypoglycemia, and improve QoL; however, glycemic goals should be individualized due to increased comorbidities and reduced capacity to detect and counter-regulate against severe hypoglycemia in this population. Grade A; Intermediate-High Strength of Evidence; BEL 1
R2.10.3 Clinicians should prescribe CGM as a tool to track glucose before, during, and after exercise in persons with diabetes; monitor the glycemic response to exercise; and help direct insulin and carbohydrate consumption to avoid hypoglycemia and hyperglycemia. When this technology is utilized as part of AID systems, it can reduce glycemic excursions during exercise. Grade A; Intermediate Strength of Evidence; BEL 1
R3.4.1 Clinicians should caution persons with diabetes who are using do-it-yourself systems that these devices have not undergone rigorous review by the FDA for safety and efficacy. Grade B; Low Strength of Evidence/Expert Opinion of Task Force; BEL 4

In 2022 the AACE published a new clinical practice guideline for developing a diabetes mellitus comprehensive care plan (Blonde, 2022). This document makes the following recommendations:

R 3.2 All persons who use insulin should use continuous glucose monitoring (CGM) or perform blood glucose monitoring (BGM) a minimum of twice daily and ideally before any insulin injection. More frequent BGM may be needed by persons who

are taking multiple daily injections (MDI) injections, persons not at A1C targets, or those with history of hypoglycemia. Persons who do not require insulin or insulin secretagogue therapy may often benefit from BGM, especially to provide feedback about the effects of their lifestyle choices (diet and physical activity), and to assess response to pharmacologic therapy. Grade A; BEL 1

R 3.3 Real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM) is recommended for all persons with T1D, regardless of insulin delivery system, to improve A1C levels and to reduce the risk for hypoglycemia and DKA (see Fig. 6). Grade A; BEL 1

R 3.4 rtCGM or isCGM is recommended for persons with T2D who are treated with insulin therapy, or who have high risk for hypoglycemia and/or with hypoglycemia unawareness Grade A; BEL 1

R 15.6 Although inpatient CGM has not received regulatory approval, CGM may be useful in inpatient settings, while complying with institutional policies and safety precautions. CGM may improve detection of severe hypoglycemic and hyperglycemic events, identify glucose trends and patterns, and improve satisfaction in persons with DM. Grade C; BEL 2

R 25 Persons with DM who are engaged in occupations with public safety implications, such as commercial drivers and pilots, have special management requirements for certification. CGM to predict hypoglycemia in real time and pharmacotherapy that minimizes hypoglycemia are recommended as effective strategies for persons with DM who work in these occupations. Grade A; BEL 1 and expert opinion of task force

In 2023 The AACE published a clinical endocrinology consensus statement on the comprehensive management algorithm for type 2 diabetes (Samson, 2023). This document stated “CGM is highly recommended to assist persons with diabetes in reaching goals safely.”

*FDA Authorized/Approved Devices**

Device Name	Vendor	FDA Links
Dexcom G6 CGM System	Dexcom	https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170088.pdf
Dexcom G7 CGM System	Dexcom	https://www.accessdata.fda.gov/cdrh_docs/pdf21/K213919.pdf
Eversense E3 CGM System	Senseonics	https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048S021A.pdf
FreeStyle Libre 14-day System	Abbott Diabetes Care	https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160030S017A.pdf
FreeStyle Libre 2	Abbott Diabetes Care	https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193371.pdf
FreeStyle Libre 3	Abbott Diabetes Care	https://www.accessdata.fda.gov/cdrh_docs/pdf21/K213996.pdf
Guardian Connect CGM System	Medtronic Diabetes	https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160007A.pdf

* This may not be an all-inclusive-list. Additional CGM devices may be FDA approved and available in the US.

Definitions

Continuous interstitial glucose monitoring (CGM) device: A device applied to the skin that contains a sensor implanted into the skin to measure glucose concentrations in the interstitial fluid. Such devices may be used to create a record of glucose concentrations over time to allow analysis by a medical professional. They may also measure and provide real-time glucose concentration data to allow an individual or automated insulin delivery system to adjust insulin delivery rates to provide better control of blood glucose concentrations.

External insulin infusion pumps: A device that is worn externally and attached to a temporary subcutaneous insulin catheter. An integrated computer controls a pump mechanism that administers insulin at a set rate or provide bolus injections as needed.

Flash CGM: A type of CGM device that requires the use of a device access glucose data from a sensor on a per-need basis. Glucose concentration data is not continuously visible with this type of device.

Glycemic: Having to do with blood sugar (glucose) levels.

Glycemic control: The ability of an individual’s body to control blood glucose concentrations within a specific physiologic range, either on its own or with the assistance of medical therapy.

Glycosylated hemoglobin (HbA1c) test: A laboratory test that provides the percentage of a specific type of modified hemoglobin in the blood. This test ascertains the level of diabetic blood glucose control over the past three to four months. The ADA has stated that an appropriate target for HbA1c concentrations in individuals with diabetes is 7% or lower.

Hyperglycemia: A condition characterized by excessively high blood glucose concentrations, generally considered greater than 150 mg/dL.

Hypoglycemia: : In patients with diabetes, defined as an episode of an abnormally low plasma glucose concentration (with or without symptoms) that expose the individual to harm. Serious hypoglycemia is generally considered a blood glucose level less than 54 mg/dL..

Interstitial glucose: Glucose present in the fluid present in spaces between the tissue cells of the body.

Real time CGM: A type of CGM device that provides real-time, continuously visible glucose concentration data to the user.

Type 1 diabetes: A condition characterized by the impaired or inability of the pancreas to produce insulin. Sometimes known as ‘juvenile diabetes.’

Type 2 diabetes: A condition characterized by a person’s body losing the ability to use insulin properly, a problem referred to as insulin resistance.

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised criteria related to blood glucose concentrations and self-monitoring. Revised Discussion, Definitions, References, and Websites sections.
Revised	11/09/2023	MPTAC. Revised document title. Moved content related to external insulin pumps to new document CG-DME-51 and automated insulin delivery systems to new document CG-DME-50. Revised formatting in Clinical Indications section. Revised existing MN and NMN statements. Revised Description, Coding, Discussion, Definitions, References, Websites, and Index sections. Updated Coding section to remove codes A9274, E0784 now addressed in CG-DME-51, and E0787, S1034 now addressed in CG-DME-50.
Revised	05/11/2023	MPTAC. Revised hierarchy and formatting of external infusion pump criteria. Revised MN criteria for external insulin infusion pumps (group A). Revised the MN criteria for *personal long-term use* of continuous interstitial glucose monitoring devices so that the HbA1c range of “7% to 10%” was changed to “7% or greater”. Added MN and NMN continued use criteria for external insulin pumps, continuous interstitial glucose monitoring devices, and open-loop or hybrid closed-loop automated insulin delivery systems. Updated Discussion, References, and Index sections.
	12/28/2022	Updated Coding section with 01/01/2023 HCPCS changes; added A4239, E2103 replacing K0553, K0554 deleted 12/31/2022, and revised descriptors for A4238, A9276, A9277, A9278, E2102.
Revised	05/12/2022	MPTAC. Revised title. Added MN statements addressing implantable CGM device implantation and replacement (formerly in MED.00121 Implantable Interstitial Glucose Monitors) to this document. Updated Description, Discussion, and References sections. Updated Coding section to add 0446T, 0448T previously addressed in MED.00121; also updated with 07/01/2022 HCPCS changes to add G0308, G0309.
	04/01/2022	Updated Coding section with 04/01/2022 HCPCS changes; added A4238, E2102.
Revised	05/13/2021	MPTAC. Clarified MN statement for external insulin pumps. Updated References section.
	01/11/2021	Corrected typographical error in references section.
	11/17/2020	Corrected criteria B in Clinical Indications section for personal long-term use of CGMs regarding type of diabetes.
Revised	11/05/2020	MPTAC review. Clarified type of diabetes throughout Clinical Indications section. Simplified blood glucose testing criteria throughout Clinical Indications section. Simplified hyper- and hypoglycemia criteria throughout Clinical Indications section. Added use of a CGM to insulin pump MN criteria. Simplified criteria for duration of professional CGM use. Lowered age criteria from > 24 y/o to > 14 y/o for use of CGMs by individuals in the absence of frequent hypoglycemic episodes. Expanded professional (short-term) and personal (long-term) CGM criteria to include treatment of individuals with all types of diabetes mellitus. Lowered MN age criteria for open-loop or hybrid closed-loop automated insulin delivery systems from 7 to 2 years of age. Updated Description, Discussion/General Information, References, and Index sections. Reformatted Coding section.

Revised	05/14/2020	MPTAC review. Relocated information regarding device details from Description section to the Websites section. Added additional example of disposable external insulin pump without wireless communication capability to NMN statement. Updated Discussion, Rationale and References sections.
	12/31/2019	Updated Coding section with 01/01/2020 HCPCS changes; added E0787.
Revised	06/06/2019	MPTAC review. Added notes to Description section addressing device types. Clarified and updated formatting in the Clinical Indications section. Updated Discussion, Definitions, References, and Index sections.
Reviewed	09/13/2018	MPTAC review. Updated Discussion and References sections.
New	01/25/2018	MPTAC review. Initial document development. Combined content from three documents into this document: CG-DME-01 External (Portable) Continuous Insulin Infusion Pumps, CG-DME-38 Continuous Interstitial Glucose Monitoring, and DME.00040 Automated Insulin Delivery Devices.
