Glucose Monitors

DME.GC.100.A
v1.0.2025

Introduction

Glucose monitors are addressed by this guideline.

Criteria

Home Blood Glucose Monitors (BGMs)

A **home BGM** (HCPCS E0607) and related supplies are considered medically necessary when the individual meets **both** of the following coverage criteria:

- The individual has type 1 or type 2 diabetes mellitus.
- The individual or caregiver has received training to use a BGM.

Additional Criteria for BGMs

- A **BGM with special features** (HCPCS E2100, E2101) is considered medically necessary when the basic coverage criteria are met and the individual has a severe visual impairment (i.e., best corrected visual acuity of 20/200 or worse in both eyes) requiring use of this additional monitoring system.
- A **BGM with integrated lancing/blood sample** (HCPCS E2101) is considered medically necessary when the basic coverage criteria are met and the individual has a severe impairment of manual dexterity that requires the use of this additional monitoring system.

Initial Coverage of Continuous Glucose Monitors (CGMs) for Adults Greater Than 18 Years of Age

A **CGM and related supplies** (HCPCS E2102, E2103, E2104, A4238, A4239, A4271, A9276, A9277, A9278) are considered medically necessary for an individual (greater than 18 years of age) when the individual meets **all** of the following initial coverage criteria:

- The individual has type 1 or type 2 diabetes mellitus.
- The individual meets **any** of the following criteria:
  - The individual uses insulin to manage their diabetes.
  - The individual has a history of problems with low blood sugar levels.

730 Cool Springs Blvd, Franklin, TN 37067 (800) 918-8924

- The individual's glycated hemoglobin (HbA1c) is greater than 7%.
- The individual has ongoing participation in a diabetes management program.

Initial Coverage of Continuous Glucose Monitors (CGMs) for Individuals with Gestational Diabetes Mellitus

A **CGM and related supplies** (HCPCS E2102, E2103, E2104, A4238, A4239, A4271, A9276, A9277, A9278) are considered medically necessary for an individual with gestational diabetes when the individual meets **all** of the following initial coverage criteria:

- The individual has difficulty controlling blood sugar during pregnancy (gestational diabetes).
- The individual uses insulin to manage their diabetes.

Initial Coverage of Continuous Glucose Monitors (CGMs) for Pediatric Individuals (18 Years of Age or Younger)

A **CGM and related supplies** (HCPCS E2102, E2103, E2104, A4238, A4239, A4271, A9276, A9277, A9278) are considered medically necessary for a pediatric individual (18 years of age or younger) when the individual is capable of using the device safely (either independently or with a caregiver) and meets **any** of the following initial coverage criteria:

- The individual has type 1 diabetes mellitus.
- The individual uses insulin to manage their diabetes.

Supplies

- The supply allowance (HCPCS A4238 or A4239) is billed as one (1) unit of service per 30 days.
- The supply allowance for supplies used with a CGM system (HCPCS A4238, A4239) encompasses all items necessary for the use of the device and includes, but is not limited to, CGM sensors and transmitters.
  - Adjunctive CGMs (HCPCS E2102) do not replace a standard home BGM. The associated supply allowance (HCPCS A4238) does not include a home BGM and related BGM testing supplies. These items may be billed separately, in addition to HCPCS A4238.
  - Non-adjunctive CGMs (HCPCS E2103) replace standard home BGMs. Requests for a BGM and related supplies, billed in addition to a non-adjunctive CGM device and associated supply allowance (HCPCS A4239) are not covered.
- Lancets (HCPCS A4259), blood glucose test reagent strips (HCPCS A4253), glucose control solutions (HCPCS A4256), and spring powered devices for lancets (HCPCS

730 Cool Springs Blvd, Franklin, TN 37067 (800) 918-8924

A4258) are considered medically necessary for individuals for whom the glucose monitor is covered.
- More than one spring powered lancet (HCPCS A4258) per six months is considered not medically necessary.
- The quantity of test strips (HCPCS A4253) and lancets (HCPCS A4259) that are covered depends on the usual medical needs of the individual and whether or not the individual is being treated with insulin, regardless of their diagnostic classification as having type 1 or type 2 diabetes mellitus.

Not Covered

The following devices are considered not medically necessary, not medical in nature, and/or convenience items:

- disposable wearable on-demand insulin delivery devices with no wireless communication capability, such as the V-Go®
- home blood glucose disposable monitors, including test strips (HCPCS A9275)
- devices such as watches, smartphones, tablets, laptop computers, etc. used in conjunction with a durable CGM receiver
- glucose monitors that are not designed for use in the home
- urine test reagent strips or tablets (HCPCS A4250)
- alcohol or peroxide (HCPCS A4244, A4245), betadine, or hexachlorophene (pHisohex) (HCPCS A4246, A4247)

Note:

The FDA cautions that non-adjunctive, real time continuous glucose monitoring devices should not be used by individuals who are on dialysis or who critically ill.

Experimental, Investigational, or Unproven

- A laser skin piercing device (HCPCS E0620) and related lens shield cartridge (HCPCS A4257) that uses a laser instead of a lancet to perforate the skin to obtain a blood sample for glucose measurement are considered experimental, investigational, or unproven.

Definitions

Hypoglycemia in individuals with diabetes mellitus is defined as abnormally low plasma glucose concentration <70 mg/dL (3.9 mmol/L).

Diabetes mellitus (DM) describes diseases of abnormal carbohydrate metabolism that are characterized by hyperglycemia. DM is associated with a relative or absolute

impairment in insulin secretion, along with varying degrees of peripheral resistance to the action of insulin.

According to the Centers for Disease Control and Prevention (CDC) National Diabetes Statistics Report of 2024, the estimated prevalence of DM for 2021 in the United States (US) was 38.4 million people or approximately 11.6% of the population. The percentage of adults with DM increases with age, estimated to be close to 30% in those aged 65 years or older.

Type 1 diabetes mellitus (T1DM) is a condition of insulin deficiency resulting from autoimmune destruction of the insulin-producing beta cells in the islets of Langerhans. T1DM is one of the most common chronic diseases in childhood. In addition to the clinical presentation and history, laboratory tests such as pancreatic beta-cell (β-cell) autoantibodies or insulin and C-peptide levels may assist in the diagnosis of T1DM. Management involves measuring blood glucose and urine ketone concentrations, administering insulin, and recognizing and treating hypoglycemia.

Type 2 diabetes mellitus (T2DM) is a heterogeneous disease characterized by hyperglycemia, insulin resistance, and relative impairment in insulin secretion. Management of individuals with T2DM includes education, evaluation for microvascular and macrovascular complications, achievement of target glycemia, treatment of cardiovascular risk factors, and avoidance of drugs that can aggravate abnormalities of glucose or lipid metabolism. Weight reduction, diet modification, oral medication, or insulin administration may be needed to maintain glycemic targets.

Gestational diabetes mellitus (GDM) develops in pregnant individuals whose pancreatic function is insufficient to overcome the insulin resistance associated with the pregnant state. The American Diabetes Association (ADA) notes that GDM is diagnosed in the second or third trimester, and is not present prior to conception.

Time in range (TIR) is the time in the target glucose range of 70 to 180 mg/dL (3.9 to 10 mmol/L) over a 14-day period. TIR is used as a measure of diabetes control, and low TIR is correlated with long-term microvascular complications.

Glycated hemoglobin (HbA1c) is a blood test that reflects average glycemia over the lifespan of the red blood cell (100 to 120 days), however 50% of HbA1c is determined by glycemia during the month preceding measurement. HbA1c monitors long-term glycemic control and provides an indication of the average of blood glucose levels over the preceding three months. Increased HbA1c is associated with an increased risk of long-term complications.

The primary mechanisms for **insulin delivery** include:

- **Injection**: Injecting insulin with a syringe or pen is the delivery method used by most people with insulin dependent diabetes mellitus.

- **Inhalation**: Inhaled insulin is available only as rapid-acting insulin, and is typically used for mealtime dosing. It is used in conjunction with an insulin injection regimen for individuals with T1DM and T2DM on intensive therapy, or as an alternative to injected mealtime bolus injections for individuals with T2DM with no other insulin requirement.
- **Infusion**: An insulin pump, also known as a continuous subcutaneous insulin infusion (CSII) pump, is an external ambulatory infusion device used for managing insulin dependent diabetes mellitus. It works by continuous administration of short-acting insulin at preselected rates.

Blood glucose monitoring (BGM) devices measure the glucose level of a small amount of blood (usually from the fingertip), typically three to four times per day. BGM readings look at specific glucose values at specific points in time, generating a pattern of variability.

Continuous glucose monitoring (CGM) devices measure the glucose content of interstitial fluid every five to 15 minutes, depending on the device. CGM systems provide visualization of the current glucose value as well as trend arrow analysis, which indicates the direction of changing glucose. This technology can help individuals fine-tune diabetic treatment.

Evidence Discussion

Purpose of technology/description of device

Continuous glucose monitors (CGMs) are designated by the United States Food and Drug Administration (FDA) as either adjunctive or non-adjunctive. Adjunctive CGMs require stand-alone home blood glucose monitoring (BGM) for verification prior to diabetes treatment decisions. Non-adjunctive CGMs can be used to make treatment decisions without the need for a stand-alone home BGM to confirm testing results. There are two main types of CGM systems: real-time CGM (rtCGM) and devices that require intermittent scanning (isCGM), also known as flash continuous glucose monitoring.

An rtCGM device measures glucose levels in the interstitial fluid through the use of a sensor, the exterior of which adheres to the skin while the sensor component pierces and remains under the skin. A transmitter sends information about glucose levels to a wireless monitor attached externally. These devices display glucose levels at either one- or five-minute intervals with the option to set alarms alerting the individual to abnormal glucose levels. Many rtCGM devices have technology which allows integration for sensor-augmented pump therapy (i.e., sends glucose readings to an insulin pump system to guide user-initiated adjustments), as well as automated insulin delivery systems (i.e., insulin delivery is automatically suspended or adjusted based on glucose information from the CGM).

With an intermittently scanned (flash) CGM (isCGM), reporting of glucose data is user-initiated by scanning the device. Intermittently scanning CGM devices measure glucose every minute and record measurements every 15 minutes. They can be worn for up to 14 days. The newest generation of these devices has an optional alarm or alert feature for abnormal glucose levels. These devices also have wireless capability that allows communication with other devices, such as an insulin pump, for user-initiated dosing adjustments.

Sensor-augmented pump (SAP) therapy combines the use of an rtCGM or isCGM with a compatible insulin pump to communicate data to the pump. The user must access the CGM data to manually adjust the insulin dosing with SAP. When the CGM transmits information to the pump software to suspend insulin dosing, the sensor-augmented pump is referred to as a "low glucose suspend" system.

Automated insulin delivery (AID) systems are more advanced integrated systems, where CGM sensor data is used by the pump to directly adjust insulin infusion, as well as suspend it when necessary. AID systems may be referred to as hybrid closed-loop systems, integrated CGMs (iCGMs), or artificial pancreas systems.

Medical Background

The United States Food and Drug Administration (FDA) approved the first adjunctive professional continuous glucose monitor (CGM) in 1999. With this device, blood glucose values were downloaded to the health care provider's office for review every three days. The first rtCGM was Cygnus's (Redwood City, CA) Glucowatch Biographer, a noninvasive device worn as a wristwatch.

Medtronic® (Northridge, CA) introduced the Guardian® REAL-Time CGM system in 2004, which had the ability to notify users of potentially dangerous blood glucose measurements. In 2006, Medtronic® released the first integrated pump and sensor. In 2006, Dexcom® (San Diego, CA) introduced the Short-Term Sensor (STS), the company's first rtCGM. Abbott® (Alameda, CA) introduced its FreeStyle® Navigator in 2008. All of these initial devices were adjunctive CGMs. In 2013, Medtronic® released the MiniMed 530G Enlite® sensor, the first pump with threshold suspend for hypoglycemia. Dexcom® released the G5 Mobile in 2015, which allowed data to be transmitted to the user's cell phone.

In December 2016, the FDA approved the Dexcom® G5 Mobile Continuous Glucose Monitoring System as the first non-adjunctive CGM able to replace fingerstick blood glucose testing for treatment decisions in diabetics aged two and older.

The Guardian® Sensor 3 was introduced by Medtronic® in 2017, and was the company's first hybrid closed-loop device, automating insulin delivery by combining a CGM sensor with an insulin pump.

730 Cool Springs Blvd, Franklin, TN 37067 (800) 918-8924

The Eversense® CGM system was approved by the FDA in June 2018 for use in diabetics aged 18 and older. The Eversense® was the first FDA approved CGM with a fully implantable sensor that was able to be worn for up to 90 days.

The FDA approved the Dexcom Stelo® Glucose Biosensor system in March 2024. The Stelo is the first over-the-counter CGM. It is an integrated CGM (iCGM), and is approved for use by anyone over the age of 18.

All current CGMs have mobile integration and can be used with a smart phone with Bluetooth and internet access for data uploads and tracking. Some CGMs can be used with a receiver rather than a smartphone. CGM apps are available on Android and iOs devices. Non-adjunctive CGM use is not recommended for patients who cannot or will not perform self-monitoring of blood glucose at least twice daily.

Literature review

Continuous glucose monitoring (CGM) for individuals with type 1 diabetes mellitus (T1DM):

- Diciembrini et al., (2021) conducted a meta-analysis to evaluate the effectiveness of continuous glucose monitoring (CGM) compared with self-monitoring of blood glucose (BGM) on glucose control in individuals with type 1 diabetes mellitus (T1DM). Twenty-one articles were included in the review. The primary endpoint was glycated hemoglobin (HbA1c) at the end of the trial. A secondary endpoint was severe hypoglycemia. In addition, the following secondary endpoints were explored, using the same methods: time in range, health-related quality of life, and treatment satisfaction.The authors noted that treatment satisfaction and quality of life were not measured or reported in the majority of studies. However, the authors concluded that for individuals with T1DM, CGM was associated with a reduction in HbA1c and a lower risk of severe hypoglycemia compared with BGM.
- Pratley et al., (2020) reported on a randomized controlled trial which evaluated whether CGM is effective in reducing hypoglycemia compared with standard BGM in 203 older adults with type 1 diabetes mellitus (T1DM). The primary outcome was CGM-measured percentage of time that glucose values were less than 70 mg/dL during six months of follow-up. There were 31 prespecified secondary outcomes, including metrics of hypoglycemia, hyperglycemia, and glucose control; glycated hemoglobin (HbA1c); and cognition and patient-reported outcomes. At six-month follow-up, the results of the study demonstrated that 83% of participants used a CGM at least six days per week. In addition, median time with glucose levels less than 70 mg/dL was 5.1% (73 minutes per day) at baseline and 2.7% (39 minutes per day) during follow-up in the CGM group vs 4.7% (68 minutes per day) and 4.9% (70 minutes per day), respectively, in the standard BGM group. Thus, the authors observed a small but significant reduction in time spent in hypoglycemia in the CGM group, most notably in individuals with worse baseline levels of hypoglycemia.

Regarding the secondary endpoints, there were statistically significant differences for all nine CGM metrics, six of seven of the HbA1c outcomes, and none of the 15 cognitive and patient-reported outcomes. HbA1c decreased in the CGM group compared with the standard BGM group. Moreover, ten participants in the BGM group experienced severe hypoglycemia requiring assistance as compared with one individual in the CGM group. In summary, the investigators concluded that among older adults with T1DM, CGM resulted in a small but statistically significant improvement in hypoglycemia over six months compared to BGM.

- Laffel et al., (2020) performed a randomized controlled trial that compared CGM to standard BGM in adolescents and young adults (ages 14 to 24 years old) with type 1 diabetes mellitus (T1DM). The study included 142 individuals who were randomized to a CGM group (n = 74) or usual care using a BGM (n = 79). The primary outcome was change in glycated hemoglobin (HbA1c) from baseline to 26 weeks. There were 20 secondary outcomes, including CGM and HbA1c metrics, and patient-reported outcomes. At six-month follow-up, 68% of participants in the CGM group used CGM at least 5 days per week. Mean HbA1c was 8.9% at baseline and 8.5% at 26 weeks in the CGM group and 8.9% at both baseline and 26 weeks in the BGM group. Regarding the secondary outcomes, there were statistically significant differences in three of seven binary HbA1c metrics, eight of nine CGM metrics, and one of four patient-reported outcomes. The authors concluded that continuous glucose monitoring resulted in a small but statistically significant reduction in mean HbA1c over 26 weeks among adolescents and young adults with T1DM compared with standard blood glucose monitoring.
- Aleppo et al., (2017) conducted the REPLACE-BG randomized trial to determine whether the use of CGM without confirmatory BGM measurements was as safe and effective as using CGM adjunctive to BGM in adults with well-controlled type 1 diabetes mellitus (T1DM). Participants were randomly assigned 2:1 to the CGM only group (n = 149) or CGM and BGM group (n = 77). The primary outcome was TIR (70-180 mg/dL) over the 26-week trial. Mean TIR was 63 ± 13% at both baseline and 26 weeks in the CGM-only group and 65 ± 13% and 65 ± 11% in the CGM and BGM group. No severe hypoglycemic events occurred in the CGM-only group, and one event occurred in the CGM and BGM group. In conclusion, the investigators opined that the of CGM without regular use of confirmatory BGM for insulin dosing is as safe and effective as using CGM with BGM in adults with well-controlled T1DM at low risk for severe hypoglycemia.

Continuous glucose monitoring (CGM) for individuals with type 2 diabetes mellitus (T2DM) administering insulin 1-2 times daily:

- Ehrhardt et al., (2011) conducted a randomized trial which examined the use of real-time continuous glucose monitoring (rtCGM) in individuals with type 2 diabetes mellitus (T2DM) not taking prandial insulin. The study randomized 100 individuals with T2DM not taking prandial insulin with an initial glycated hemoglobin (HbA1c) ≥

7% to either a rtCGM group (n = 50) or a self-monitoring of blood glucose (SMBG) group (n = 50). HbA1c decreased by 1.0% (±1.1%) for the rtCGM group and 0.5% (±0.8%) for the SMBG group at 12 weeks (p= 0.006).The rtCGM group had an adjusted decline in HbA1c of 0.60% greater than the SMBG group (p =0.002). Thus, Ehrhardt and colleagues concluded that rtCGM significantly improved HbA1c compared with SMBG in individuals with T2DM not taking prandial insulin at 12 weeks. Moreover, a 40-week follow-up study performed by Vigersky et al. (2012) showed the improvement in HbA1c demonstrated in the rtCGM group was sustained during the 40-week follow-up period. Thus, the Vigersky and colleagues opined that there is a lasting effect on HbA1c from short-term (12 weeks) exposure to rtCGM.

- Martens et al., (2021) reported on a randomized, multicenter, clinical trial which evaluated the effectiveness of continuous glucose monitoring (CGM) (n=116) versus self-monitoring of blood glucose (SMBG) (n=59) in individuals with type 2 diabetes mellitus (T2DM) treated with basal insulin. The primary outcome was glycated hemoglobin (HbA1c) at eight months. An additional secondary outcome was CGM-measured time in target glucose range of 70 to 180 mg/dL (TIR). At eight-month follow-up, the mean HbA1c levels decreased in the CGM group (9.1% to 8.0%) and the SMBG group (9.0% to 8.4%). The mean percentage of TIR was 59% in the CGM group versus 43% in the SMBG group. A six-month extension study conducted by Aleppo et al. (2021) aimed to determine the long-term benefits of continued CGM use or the detriments of discontinuing CGM. At 14 weeks, mean TIR decreased from 62% to 50% in the group that discontinued the CGM. In the group that continued CGM use, little change was found in TIR from eight to 14 months. Thus, the authors concluded that in adults with T2DM treated with basal insulin who had been using real-time CGM for eight months, discontinuing CGM resulted in a loss of about one-half of the initial gain in TIR that had been achieved during CGM use.
- Ida et al., (2019) performed a systematic review to examine the effectiveness of continuous glucose monitoring (CGM) use compared to self-monitoring of blood glucose (SMBG) in individuals with type 2 diabetes mellitus (T2DM). Seven randomized controlled trials (669 participants) were included in the meta-analysis. Three trials used rtCGM (which confirms the blood glucose profile in real-time), and four trials used retrospective CGM (which is used for retrospective examination of the blood glucose profile over several days). The mean age of the participants was 58.0 years. The authors reported that CGM was associated with a significant reduction in HbA1c levels. Moreover, the CGM group exhibited shorter time spent with hypoglycemia than the SMBG group.

Continuous glucose monitoring (CGM) for individuals with type 2 diabetes mellitus (T2DM) not administering insulin (oral hypoglycemic agents only):

- Raj et al., (2022) conducted a systematic review to examine the association between time in range (TIR) derived from continuous glucose monitoring (CGM) and microvascular complications in individuals with type 2 diabetes mellitus (T2DM). The

authors noted that glycated hemoglobin (HbA1c) is the primary tool for monitoring long-term glycemic control and assessing the risk of diabetes-related complications; however, HbA1c is affected by multiple factors such as anemia, recent blood transfusion, or chronic kidney disease, which results in discrepancies between measured HbA1c and true glycemic control. CGM-derived metrics, such as TIR have been examined as surrogate markers of glycemic control and may be predictors of diabetes-related microvascular complications. This systematic review included 11 studies with a total of 13,987 participants. Four studies evaluated the relationship between CGM-derived TIR and diabetic retinopathy and nephropathy. Seven studies evaluated the relationship between CGM-derived TIR and diabetic peripheral neuropathy. The authors found that a 10% increase in TIR was associated with a reduction in albuminuria, severity of diabetic retinopathy, and prevalence of diabetic peripheral neuropathy and cardiac autonomic neuropathy. In addition, an association was observed between the urinary albumin to creatinine ratio, but not with estimated glomerular filtration rate.

- A 2020 randomized trialconducted by Wada and colleagues evaluated the effects of flash glucose monitoring (isCGM) and self-monitoring of blood glucose (SMBG) on glycated hemoglobin (HbA1c) in individuals with non-insulin-treated type 2 diabetes mellitus (T2DM). The study randomly assigned participants to the isCGM (n=49) or SMBG (n=51) groups. The primary outcome was change in HbA1c level. The mean HbA1c levels were 7.83% in the isCGM group and 7.84% in the SMBG group at baseline, and the values were reduced in both isCGM and SMBG groups at 12 weeks. Moreover, at 24 weeks, HbA1c was significantly decreased from baseline values in the isCGM group, but not in the SMBG group. The authors concluded that while both isCGM and SMBG had a comparable effect in improving glycemic control in individuals with non-insulin-treated T2DM during 12-week glucose monitoring, glycemic control was better with isCGM than with SMBG at 24 weeks after the cessation of glucose monitoring. The authors opined that isCGM use in individuals with non-insulin-treated T2DM had the potential to provide a sustained improvement in glycemic control after discontinuation of use.

Continuous glucose monitoring (CGM) for individuals with diabetes mellitus and chronic kidney disease (CKD) stage 3-5:

- Coca et al., (2012) performed a systematic review and meta-analysis to evaluate the benefits of intensive versus conventional glucose control on kidney-related outcomes for adults with type 2 diabetes mellitus (T2DM). Seven randomized clinical trials including 28,065 participants were included in the analysis. The investigators examined the effect on outcomes of: median date of enrollment, years since diagnosis, duration of therapy, and difference between achieved glycated hemoglobin (HbA1c) and median achieved HbA1c. The meta-analysis concluded that intensive glucose control reduces the risk for microalbuminuria and macroalbuminuria, but evidence is lacking that intensive glycemic control reduces the risk for significant

clinical renal outcomes, such as doubling of the serum creatinine level, end-stage renal disease (ESRD), or death from renal disease during the years of follow-up after the trials. The meta-analysis did not compare the use of self-monitoring of blood glucose (SMBG) to continuous glucose monitoring (CGM) and thus was considered indirect evidence of the effectiveness of CGM in adults with T2DM.

Continuous glucose monitoring (CGM) for pregnant individuals including those with gestational diabetes mellitus (GDM):

- Feig et al., (2017) performed a randomized controlled trial to examine the effectiveness of continuous glucose monitoring (CGM) on maternal glucose control and obstetric and neonatal health outcomes. Three hundred twenty-five women (215 pregnant, 110 planning pregnancy) with type 1 diabetes mellitus (T1DM) for a minimum of 12 months were randomly assigned to glucose monitoring with a CGM (CGM group) or no device (control group). The study found a small difference in glycated hemoglobin (HbA1c) in pregnant women using CGM (mean difference −0.19%; p=0.0207). Pregnant CGM users spent more time in target range (68% versus 61%; p=0.0034) and less time hyperglycemic (27% versus 32%; p=0.0279) than did pregnant control participants, with comparable severe hypoglycemia episodes (18 in the CGM group and 21 in the control group) and time spent hypoglycemia (3% vs 4%; p=0.10). Moreover, neonatal health outcomes were significantly improved, with lower incidence of large for gestational age infants (p=0.0210), fewer neonatal intensive care admissions lasting more than 24 hours (p=0.0157), fewer incidences of neonatal hypoglycemia (p=0.0250), and one-day shorter length of hospital stay (p=0.0091). Of note, the authors reported no benefit of CGM use in women planning pregnancy. In conclusion, the authors reported that CGM use during pregnancy is associated with improved neonatal outcomes, likely secondary to reduced exposure to maternal hyperglycemia. Thus, the authors recommended that CGM should be offered to all pregnant women with T1DM using intensive insulin therapy.
- García-Moreno et al., (2022) conducted a systematic review to evaluate the effect of continuous glucose monitoring (CGM) on maternal and neonatal outcomes in gestational diabetes mellitus (GDM). The study included six randomized controlled trials that compared the effects of CGM and blood glucose monitoring (BGM) in women with GDM. A total of 482 individuals were included in the meta-analysis. The use of CGM was associated with lower glycated hemoglobin (HbA1c) levels at the end of pregnancy compared to BGM. Women using CGM also had less gestational weight gain and their children had lower birth weight. No differences were observed in the other outcomes evaluated. In summary, the authors reported that CGM use was slightly more effective in improving glycemic control than BGM use, but the impact on maternal or fetal outcomes was inconclusive. The authors recommended that CGM could be recommended to improve glycemic control in women with GDM; however,

additional larger clinical trials were needed to better understand the effects of CGM in GDM.

Professional organizations/societies:

- The CDC Diabetes Care Schedule recommends individuals with diabetes visit their physician every three months if not meeting their treatment goals, and every six months when they are meeting their treatment goals.
- The American Diabetes Association (ADA)'s 2024 clinical practice recommendations for the treatment and management of diabetes mellitus recommended that real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM) should be offered for diabetes management in adults with diabetes on basal insulin, multiple daily injections (MDI), or continuous subcutaneous insulin infusion (CSII), or in youth with type 1 or type 2 diabetes mellitus on multiple daily injections or continuous subcutaneous insulin infusion 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. Moreover, the ADA stated that, when used as an adjunct to pre- and postprandial blood glucose monitoring, CGM can help to achieve glycated hemoglobin (HbA1c) targets in diabetes and pregnancy.
- The American Diabetes Association (ADA) Standards of Medical Care in Diabetes-2022 Abridged for Primary Care Providers recommended that real-time continuous glucose monitoring (rtCGM) (Level of Evidence: A (clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered)) or intermittently scanned continuous glucose monitoring (isCGM) (Level of Evidence: B (Supportive evidence from well-conducted cohort studies)) should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely (either by themselves or with a caregiver). The guideline noted that the choice of device should be made based on individual circumstances, desires, and needs.
- The 2021 American Association of Clinical Endocrinology (AACE) Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons with Diabetes Mellitus (Grunberger et al.) recommended continuous glucose monitoring (CGM) for the following populations: individuals with diabetes treated with intensive insulin therapy, defined as three or more injections of insulin per day or the use of an insulin pump; individuals with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness); children/adolescents with type 1 diabetes mellitus (T1DM); pregnant women with T1DM or type 2 diabetes mellitus (T2DM) treated with intensive insulin therapy; and women with gestational diabetes mellitus (GDM) on insulin therapy.
- The 2022 American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan (Blonde et al.) recommended:

  - 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) of insulin, persons not at HbA1c 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.
  - Real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM) is recommended for all persons with type 1 diabetes mellitus (T1DM), regardless of insulin delivery system, to improve glycated hemoglobin (HbA1c) levels and to reduce the risk for hypoglycemia and diabetic ketoacidosis (DKA).
  - rtCGM or isCGM is recommended for persons with type 2 diabetes mellitus (T2DM) who are treated with insulin therapy, or who have high risk for hypoglycemia and/or hypoglycemia unawareness.
- In a 2023 review and update to the diabetes-specific parts of the 2009 Evaluation and Management of Adult Hypoglycemic Disorders, the Endocrine Society recommended:
  - continuous glucose monitoring (CGM) rather than self-monitoring of blood glucose (SMBG) by fingerstick for patients with type 1 diabetes mellitus (T1DM) receiving multiple daily injections (MDIs).
  - real-time continuous glucose monitoring (rtCGM) 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 mellitus (T1DM).
  - real-time continuous glucose monitoring (rtCGM) be used rather than no continuous glucose monitoring (CGM) for outpatients with type 2 diabetes mellitus (T2DM) who take insulin and/or sulfonylureas (SUs) and are at risk for hypoglycemia.
- The 2020 Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guidelines for Diabetes Management stated that daily glycemic monitoring with continuous glucose monitoring (CGM) or self-monitoring of blood glucose (SMBG) may help prevent hypoglycemia and improve glycemic control when antihyperglycemic therapies associated with risk of hypoglycemia are used.

Codes

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee

of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

HCPCS Code	Description
A4233	Replacement battery, alkaline (other than j cell), for use with medically necessary home blood glucose monitor owned by patient, each
A4234	Replacement battery, alkaline, j cell, for use with medically necessary home blood glucose monitor owned by patient, each
A4235	Replacement battery, lithium, for use with medically necessary home blood glucose monitor owned by patient, each
A4236	Replacement battery, silver oxide, for use with medically necessary home blood glucose monitor owned by patient, each
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
A4244	Alcohol or peroxide, per pint
A4245	Alcohol wipes, per box
A4246	Betadine or phisohex solution, per pint
A4247	Betadine or iodine swabs/wipes, per box
A4250	Urine test or reagent strips or tablets (100 tablets or strips)
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4255	Platforms for home blood glucose monitor, 50 per box
A4257	Replacement lens shield cartridge for use with laser skin piercing device, each
A4258	Spring-powered device for lancet, each
A4259	Lancets, per box of 100
A4271	Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per month
A9275	Home glucose disposable monitor, includes test strips

730 Cool Springs Blvd, Franklin, TN 37067 (800) 918-8924

HCPCS Code	Description
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial continuous glucose monitoring system, one 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
E0607	Home blood glucose monitor
E0620	Skin piercing device for collection of capillary blood, laser, each
E2100	Blood glucose monitor with integrated voice synthesizer
E2101	Blood glucose monitor with integrated lancing/blood sample
E2102	Adjunctive, non-implanted continuous glucose monitor or receiver
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver
E2104	Home blood glucose monitor for use with integrated lancing/blood sample testing cartridge

References

1. Medicare Local Coverage Determination (LCD): Glucose Monitors (L33822) / LCA (A52464) **https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33822**
2. United States Food and Drug Administration (FDA). Integrated continuous glucose monitoring system Class II regulatory classification (2018). Accessed May 4, 2023. **https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170088.pdf**
3. United States Food and Drug Administration (FDA). Dexcom G4 Platinum Continuous Glucose Monitoring System - P120005/S059 (2017). Accessed May 4, 2023. **https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120005S031A.pdf**
4. United States Food and Drug Administration (FDA). Dexcom G5 Mobile Continuous Glucose Monitoring System - P120005/S033 (2015). Accessed May 4, 2023. **https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120005S033**
5. United States Centers for Disease Control and Prevention (CDC). National Diabetes Statistics Report. 2024. Accessed July 24, 2024. **https://www.cdc.gov/diabetes/php/data-research/?CDC_AAref_Val=https://www.cdc.gov/diabetes/data/statistics-report/index.html**
6. ElSayed N, Aleppo G, Aroda V, et al. 2. Classification and diagnosis of diabetes: standards of care in diabetes-2023. Diabetes Care. 2023;46(Suppl 1):S19-S40. doi:10.2337/dc23-S002
7. Aleppo G, Ruedy K, Riddlesworth T, et al. REPLACE-BG: a randomized trial comparing continuous glucose monitoring with and without routine blood glucose monitoring in adults with well-controlled type 1 diabetes. Diabetes Care. 2017;40(4):538-545. doi:10.2337/cd22-as01
8. Liebl A, Henrichs H, Heinemann L, et al. Continuous glucose monitoring: evidence and consensus statement for clinical use. J Diabetes Sci Technol. 2013;7(2):500-519. doi:10.1177/193229681300700227

9. Hirsch I. Introduction: history of glucose monitoring. ADA Clinical Compendia. 2018;2018(1):1. doi:10.2337/db20181-1
10. FDA expands indication for continuous glucose monitoring system, first to replace fingerstick testing for diabetes treatment decisions. December 20, 2016, Accessed March 15, 2024. **https://www.fda.gov/news-events/press-announcements/fda-expands-indication-continuous-glucose-monitoring-system-first-replace-fingerstick-testing**
11. FDA approves first continuous glucose monitoring system with a fully implantable glucose sensor and compatible mobile app for adults with diabetes. June 21, 2018, Accessed March 15, 2024. **https://www.fda.gov/news-events/press-announcements/fda-approves-first-continuous-glucose-monitoring-system-fully-implantable-glucose-sensor-and**
12. FDA clears first over-the-counter continuous glucose monitor. March 05, 2024, Accessed March 15, 2024. **https://www.fda.gov/news-events/press-announcements/fda-clears-first-over-counter-continuous-glucose-monitor**
13. Abbott. FreeStyle Libre: easy to use, easy to prescribe, and more affordable. Accessed March 15, 2024. **https://www.freestyleprovider.abbott/us-en/freestyle-libre-2.html?gclid=101760dc82071876b46d05284f102970&gclsrc=3p.ds&msclkid=101760dc82071876b46d05284f102970&utm_source=b%20%7C%20BR%20%7C%20FreeStyle%20Libre%202&utm_term=freestyle%20libre%202%20com&utm_content=Website**
14. Dicembrini I, Cosentino C, Monami M, Mannucci E, Pala L. Effects of real-time continuous glucose monitoring in type 1 diabetes: a meta-analysis of randomized controlled trials. Acta Diabetologica. 2021;58(4):401-410. doi:10.1007/s00592-020-01589-3
15. Pratley R, Kanapka L, Rickels M, et al. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: a randomized clinical trial. JAMA. 2020;323(23):2397-2406. doi:10.1001/jama.2020.6928
16. Laffel L, Kanapka L, Beck R, et al. Effect of continuous glucose monitoring on glycemic control in adolescents and young adults with type 1 diabetes: a randomized clinical trial. JAMA. 2020;323(23):2388-2396. doi:10.1001/jama.2020.6940
17. Ehrhardt N, Chellappa M, Walker M, Fonda S, Vigersky R. The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. J Diabetes Sci Technol. 2011;5(3):668-675. doi:10.1177/193229681100500320
18. Vigersky R, Fonda S, Chellappa M, Walker M, Ehrhardt N. Short- and long-term effects of real-time continuous glucose monitoring in patients with type 2 diabetes. Diabetes Care. 2012;35(1):32-38. doi:10.2337/dc11-1438
19. Martens T, Beck R, Bailey R, et al. Effect of continuous glucose monitoring on glycemic control in patients with type 2 diabetes treated with basal insulin: a randomized clinical trial. JAMA. 2021;325(22):2262-2272. doi:10.1001/jama.2021.7444
20. Aleppo G, Beck R, Bailey R, et al. The effect of discontinuing continuous glucose monitoring in adults with type 2 diabetes treated with basal insulin. Diabetes Care. 2021;44(12):2729-2737. doi:10.2337/dc21-1304
21. Ida S, Kaneko R, Murata K. Utility of real-time and retrospective continuous glucose monitoring in patients with type 2 diabetes mellitus: a meta-analysis of randomized controlled trials. J Diabetes Res. 2019;2019:4684815. doi:10.1155/2019/4684815
22. Raj R, Mishra R, Jha N, Joshi V, Correa R, Kern P. Time in range, as measured by continuous glucose monitor, as a predictor of microvascular complications in type 2 diabetes: a systematic review. BMJ Open Diabetes Res Care. 2022;10(1):e002573. doi:10.1136/bmjdrc-2021-002573
23. Wada E, Onoue T, Kobayashi T, et al. Flash glucose monitoring helps achieve better glycemic control than conventional self-monitoring of blood glucose in non-insulin-treated type 2 diabetes: a randomized controlled trial. BMJ Open Diabetes Res Care. 2020;8(1):e001115. doi:10.1136/bmjdrc-2019-001115
24. Coca S, Ismail-Beigi F, Haq N, Krumholz H, Parikh C. Role of intensive glucose control in development of renal end points in type 2 diabetes mellitus: systematic review and meta-analysis. Arch Intern Med. 2012;172(10):761-769. doi:10.1001/archinternmed.2011.2230
25. Feig D, Donovan L, Corcoy R, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. Lancet. 2017;390(10110):2347-2359. doi:10.1016/S0140-6736(17)32400-5
26. García-Moreno R, Benítez-Valderrama P, Barquiel B, et al. Efficacy of continuous glucose monitoring on maternal and neonatal outcomes in gestational diabetes mellitus: a systematic review and meta-analysis of randomized clinical trials. Diabet Med. 2022;39(1):e14703. doi:10.1111/dme.14703

27. United States Centers for Disease Control and Prevention (CDC). Your diabetes care schedule. Accessed April 28, 2022, **https://www.cdc.gov/diabetes/managing/care-schedule.html**
28. American Diabetes Association Professional Practice Committee. 7. Diabetes Technology: Standards of Care in Diabetes—2024. Diabetes Care. 2024;47(Supplement_1):S126-S144. doi:10.2337/dc24-S007
29. American Diabetes Association. Standards of medical care in diabetes-2022 abridged for primary care providers. Clin Diabetes. 2022;40(1):10-38. doi:10.2337/cd22-as01
30. Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology clinical practice guideline: the use of advanced technology in the management of persons with diabetes mellitus. Endocr Pract. 2021;27(6):505-537. doi:10.1016/j.eprac.2021.04.008
31. Blonde L, Umpierrez G, Reddy S, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan-2022 Update. Endocr Pract. 2022;28(10):923-1049. doi:10.1016/j.eprac.2022.08.002
32. McCall A, Lieb D, Gianchandani R, et al. Management of individuals with diabetes at high risk for hypoglycemia: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2023;108(3):519-562. doi:10.1210/clinem/dgac596
33. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2020 clinical practice guideline for diabetes management in chronic kidney disease. Kidney Int. 2020;98(4S):S1-S115. doi:10.1016/j.kint.2020.06.019