INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain standard Cigna benefit plans. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2017 Cigna

Coverage Policy

Coverage for home blood glucose monitors may be subject to the terms, conditions and limitations of the applicable benefit plan’s Durable Medical Equipment (DME) benefit and schedule of copayments. In addition, coverage for home blood glucose monitors may be governed by state mandates. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

Home Blood Glucose Monitor

If coverage is available for a home blood glucose monitor, Cigna covers as medically necessary EITHER of the following devices when used for the management of diabetes mellitus:

- standard home blood glucose monitor (HCPCS Code E0607)
- enhanced feature glucose monitor (e.g., large readout, audio monitor, integrated lancing/blood sample) for an individual who is able to both self-monitor and self-administer insulin, but has a visual or physical impairment that precludes the successful use of a standard home blood glucose monitor (HCPCS Code E2100, E2101)

Continuous Glucose Monitoring System (CGMS)

Cigna covers a minimally invasive, continuous glucose monitoring system (CGMS) as medically necessary for up to 14 days under the core medical benefits of the plan for the management of difficult to control insulin-treated diabetes mellitus (e.g., hypo- or hyperglycemic episodes unresponsive to
adjustments in therapy, asymptomatic nocturnal hypoglycemia) for up to six separate sessions in any given 12-month period (CPT® code 95250, 95251).

Cigna covers a minimally invasive continuous glucose monitoring system (CGMS) (HCPCS code A9277, A9278) as medically necessary for the management of type 1 or type 2 diabetes mellitus when used according to the U.S. Food and Drug Administration (FDA) approved indications and ALL of the following criteria have been met:

- completion of a diabetes self-management education program
- treatment program including at least three insulin injections per day with frequent self-adjustments of insulin dose for at least three months
- documented blood glucose self-testing an average of at least four times per day during the two months prior to initiation of the insulin pump
- ANY of the following while on the multiple daily injection regimen:
  - glycated hemoglobin level (HbA1c) > 7.0%
  - history of recurring hypoglycemia
  - wide fluctuations in blood glucose before mealtime
  - dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
  - history of severe glycemic excursions

Replacement of a Continuous Glucose Monitoring System and Components

Cigna covers the replacement of an existing continuous glucose monitoring system or component as medically necessary for an individual managing type 1 or type 2 diabetes mellitus on a continuous glucose monitor when BOTH of the following criteria are met:

- documentation confirming that the monitor/component is malfunctioning, is no longer under warranty and cannot be repaired
- evidence of an evaluation by the health care provider managing the diabetes within the last six months that includes a recommendation supporting continued use of a continuous glucose monitor

Not Covered

Cigna does not cover ANY of the following because each has not demonstrated an improvement to health outcomes and is therefore, considered not medically necessary and/or a convenience item.

- additional software or hardware required for downloading data to a device such as personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus
- combination devices that include a home blood glucose monitor combined with a cellular telephone or other device not specifically indicated for the management of diabetes mellitus (e.g., blood pressure monitor, cholesterol screening analyzer)
- remote glucose monitoring device (e.g., mySentry)
- hypoglycemic wristband alarm (e.g., Diabetes Sentry™)

General Background

Blood glucose monitors (BGMs) measure blood glucose concentration using a reagent strip, cartridge or cuvette and a drop of capillary blood from a finger puncture. Some devices measure glucose level in the interstitial space on a continuous basis. Used at home, portable glucose monitors allow diabetics to detect and treat fluctuations in blood glucose levels. The normal fasting blood glucose concentration ranges from 70–100 milligrams (mg) per deciliter (dL) in blood serum or plasma, although capillary blood glucose concentrations may be higher (e.g., by 10–15%). A person with diabetes can adjust insulin dosage, food intake, and exercise in response to the monitor's readings to achieve normoglycemia. Frequent blood glucose monitoring to maintain normoglycemia facilitates treatment designed to reduce the incidence and severity of diabetes-related microvascular and neurological complications.
Standard Home Blood Glucose Monitoring
The American Diabetes Association (ADA) recommends fingerstick self-monitoring of blood glucose (SMBG) as an integral component of diabetes therapy for type 1 and type 2 diabetics, as well as diabetes during pregnancy (maternal diabetes) or diabetes that develops during pregnancy (i.e., gestational diabetes). ADA stresses that the patient/caregiver should receive instructions in, and routine follow-up of, SMBG technique and their capability to use the data to adjust therapy. The ADA reports that clinical trials assessing the impact of glycemic control on diabetes complications have included SMBG as part of multifactorial interventions, suggesting that SMBG is a component of effective therapy. SMBG allows patients to evaluate their individual response to therapy and assess whether glycemic targets are being achieved (ADA, 2017).

The ADA’s 2017 recommendations for home blood glucose testing include:

- Most patients on multiple-dose insulin (MDI) or insulin pump therapy should consider SMBG prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving.
- When prescribed as part of a broader educational context, SMBG results may help to guide treatment decisions and/or patient self-management for patients using less frequent insulin injections or noninsulin therapies.
- When prescribing SMBG, ensure that patients receive ongoing instruction and regular evaluation of SMBG technique and SMBG results, as well as their ability to use SMBG data to adjust therapy.

Features that may be considered when purchasing a home glucose monitor include: analytical ranges; reproducibility of test results; performance reliability; ease of use; size of displays and buttons; safety features; memory and data management capabilities; warnings and alarms; type of batteries needed; and durability.

U.S. Food and Drug Administration (FDA): The standard glucose monitor and test strips are approved under the Class II, 510(k) process for the purpose of providing quantitative measurement of glucose in whole blood by people with diabetes at home. Examples of home blood glucose meters approved by the FDA include: Accu-Chek® (Roche Diagnostics, Indianapolis, IN), Freestyle® (Therasense, Inc., Alameda, CA), Ascensia® (Bayer HealthCare, Mishawaka, IN), and One Touch® (LifeScan, Inc., Milpitas, CA). The Sidekick blood glucose test system (Home Diagnostics, Inc., Fort Lauderdale, FLA) is a disposable system in which the meter is attached to the cap of the vial of strips. Being disposable, calibration of the meter is not required.

Some of the more recently approved glucose meters have the ability to transmit data from the glucose meter to an on-line account. An example is the Genesis Health Technologies (GHT) Blood Glucose Monitoring system, model TD-4123 (TaiDoc Technology Corp., New Taipei City, Taiwan), originally FDA 510(k) approved in 2012. The Genesis Health Record System (GHR), an optional accessory, is an internet browser-based software system that receives test results from the glucose meter (Genesis BGM) by secure cellular transmission over the Verizon wireless network and stores the results in a secured database. After the glucose reading is measured, the cellular transmission technology automatically uploads the tests results to the patient’s account on the Verizon cellular network. Patients and physicians can access the stored data from a computer. The data management system is 510(k) approved for use by adult diabetic patients in the home and healthcare professionals in the professional setting (FDA, 2013; FDA, 2012).

Literature Review: As recommended by the ADA, the use of SMBG is an established, primary technique available for diabetic patients to assess blood glucose levels. The evidence in the published peer-reviewed scientific literature including meta-analysis, systematic reviews, randomized controlled trials and case series reported statistically significant decreases in hemoglobin A1c (HbA1c) in SMBG subjects, increased regularity of medication usage, improved glucose control and better metabolic control in type 1 and type 2, insulin and non-insulin treated diabetics (Schutt, et al., 2006; Sarol, et al., 2005; Welschen, et al., 2005; Soumerai, et al., 2004).

Enhanced Feature Glucose Monitors
Audio monitors are available for the patient who has severe visual impairment. The monitor gives instructions and results verbally, allowing the patient to use the equipment without assistance. Monitors are also available with large readouts for those with impaired vision. BGMs may have various other features, such as speaking in Spanish and data management systems. The Prodigy Voice™ Glucose Meter (Diagnostic Devices, Inc., Deerfield, IL) is an example of an FDA-approved audio blood glucose monitor.
Home Continuous Glucose Self-Monitoring (CGM)

A proposed alternative to intermittent SMBG is continuous glucose monitoring (CGM). CGM devices provide ongoing, real-time monitoring and recording of blood glucose levels by continuous measurement of interstitial fluid which generally lags from three to 20 minutes behind finger-stick values. Therefore, CGM is only to be used with finger-stick blood glucose monitoring. The continuous glucose monitoring system (CGMS) consists of a sensor, transmitter and receiver. Some monitors provide real-time information, while others require that data be downloaded and reviewed retrospectively. Depending on the device, a sensor may be worn for 3–7 days before it must be changed.

Short-term CGM may be used by the treating physicians as a one-time evaluation tool for up to fourteen days for type 1 and type 2 insulin-treated individuals who are experiencing hypo- or hyperglycemic episodes unresponsive to adjustments in therapy (e.g., insulin administration and nutrition). CGM may also be used to detect asymptomatic nocturnal hypoglycemia and for lowering A1c levels without risking severe hypoglycemia (Behrman, 2004). The recording can identify fluctuations in blood glucose levels that were not detected by intermittent fingersticks. This data allows adjustments to be made in the therapeutic regimen (e.g., oral medication, insulin therapy, diet, exercise) to minimize glucose excursion. Repeat short-term assessments may be needed periodically until the individual stabilizes and achieves ideal treatment targets (Inzucchi and Sherwin, 2007).

It has also been proposed that CGM be used on a long-term basis for the treatment of type 1 diabetics. The ADA and a recent clinical trial by the Juvenile Diabetes Research Foundation (JDRF) support the use of long-term CGM in type 1 diabetics age 25 years or older. A reduction of up to 1.0% in the A1c level has been reported. One of the reasons for better outcomes in older individuals is because they are typically more compliant in the use of CGM than adolescents and children. In individuals less than age 25 years, CGM has been shown to be effective in those who experience severe episodes of hypoglycemia with a blood glucose level < 50mg/dL not corrected by adjustments in conventional therapies (e.g., SMBG four or times per day, insulin therapy). Although the limited number of clinical trials with short-term follow-ups are lacking in strong, definitive conclusions, the evidence is suggestive of improved clinical outcomes including normalization of A1c levels and a reduction of hypoglycemic episodes. Professional societies and organizations (e.g., American Association of Clinical Endocrinologists, ADA and NICE) state that CGM may have a role in the ongoing assessment and management of this subgroup of type 1 diabetics. Long-term use of CGM may also be indicated in a subgroup of type 2 diabetics whose diabetes is not being controlled (e.g., A1C >7.0%, recurring hypo- and/or hyperglycemic episodes) despite frequent adjustments in therapy and adherence to treatment regimens including daily self-management of blood glucose levels and three or more daily injections of insulin for three or more months.

U.S. Food and Drug Administration (FDA): Continuous glucose monitors (CGMs) require FDA premarket approval (PMA). CGMS are used only as an adjunct to SMBG and should never replace or be used instead of SMBG. Some monitors provide a sensor that records data for a limited period of time and are intended for occasional use by the health care profession rather than everyday use by the patient. The Medtronic’s iPro2™ Professional CGM (Medtronic MiniMed, Inc., Northridge, CA) and the Freestyle Libre Pro Flash Glucose Monitoring System (Abbott Diabetes Care, Inc., Alameda, CA) are examples of CGM systems for professional use only. The Medtronic iPro2 system received FDA approval for use with the Elite sensor which records data for up to six days (FDA, 2016).

The Freestyle LibrePro is indicated for use in persons age 18 years and older and records data for up to 14 days. The FDA labeling notes that the device may inaccurately indicate hypoglycemia. Per the FDA, the results of the clinical study conducted for this device showed that 40% of the time when the device indicated that user sensor glucose values were at or below 60 mg/dL, user glucose values were actually in the range of 81-160 mg/dL. Therefore, interpretation of the FreeStyle Libre Pro Flash Glucose Monitoring System readings should only be based on the trends and patterns analyzed through time using the reports available per the intended use. However, the FDA benefit-risk assessment of the FreeStyle Libre Pro System concluded that the potential benefits to patients using this device outweigh the potential risks. The data in the FreeStyle Libre Pro cannot be viewed by the patient. At this time, the FreeSyle Libre for patient use is not FDA approved (FDA, 2016).

Other CGMs are used by the patients for continuous use and provide data for up to five to seven days and, such as the DexCom™ G4 Platinum Continuous Glucose Monitoring System (DexCom, Inc., San Diego, CA),
DexCom G4 Platinum (Pediatric) Continuous Glucose Monitoring System (ages 2–7 years), and the Medtronic Guardian REAL-Time Continuous Glucose Monitoring System.

In July 2016 Dexcom received FDA PMA supplemental approval for the Dexcom G5 Mobile Continuous Glucose Monitoring System. The FDA approval states that “the Dexcom G5 Mobile Continuous Glucose Monitoring System (Dexcom G5) is a glucose monitoring system indicated for the management of diabetes in persons age 2 years and older. The Dexcom G5 is designed to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the Dexcom G5 results should be based on the glucose trends and several sequential readings over time. The Dexcom G5 also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. The Dexcom G5 is intended for single patient use and requires a prescription” (FDA, 2016). Per Dexcom this is the first CGM proposed to replace fingerstick testing.

**Literature Review:** The evidence in the published peer-reviewed literature supports CGM when used in conjunction with SMBG to aid in the management of insulin dependent diabetics who are difficult to control and not achieving treatment targets. Studies including type 1 and type 2 adult and child diabetics have been in the form of systematic reviews and meta-analysis, randomized controlled trials and case series (Chetty, et al., 2008; Golicki, et al., 2008; Yoo, et al., 2008; Weber, et al., 2007; Zisser, et al., 2007; Deiss, et al., 2006a; Garg, et al., 2006; Lagarde, et al., 2006; Chico, et al., 2003; Ludvigsson, et al., 2003; Chase, et al., 2001).

Evidence also supports the safety and efficacy of long-term CGM in the management of type 1 diabetics age 25 years or older, a subgroup of type 1 diabetics who are less than age 25 years, and type 2 diabetics with uncontrolled blood glucose levels despite appropriate management and adherence to a prescribed diabetic regimen. Systematic reviews, meta-analysis, randomized controlled trials, comparative studies and case series typically reported reductions in A1c levels that were maintained throughout the studies, as well as fewer hypo- and hyperglycemic events (Poolsup, et al., 2013; Langendam, et al., 2012; Battelino, et al., 2011; Hoeks, et al., 2011; Chase et al., 2010; Juvenile Diabetes Research Foundation [JDRF], 2009a; JDRF, 2009b; Newman, et al., 2009; Rodbard, et al., 2009; JDRF, 2008; Mazze, et al., 2008; Weinzimer, et al., 2008b; Deiss, et al., 2006b; Wilson, et al., 2007; Bailey, et al., 2007; Diabetes Research in Children Network [DirecNet] Study Group, 2007; Garg, et al., 2007; Ludvigsson, et al., 2003).

Gandhi et al. (2011) conducted a systematic review and meta-analysis to assess the efficacy of CGM in improving glycemic control and reducing hypoglycemia compared to self-monitored blood glucose (SMBG) in patients with type 1 (T1DM) and type 2 (T2DM) diabetic mellitus. Nineteen randomized controlled trials (n=1801) met inclusion criteria. The baseline HbA1C was typically greater than 7.0%. Compared to SMBG, meta-analysis showed that CGM was associated with a significant reduction in mean HbA1c in adult type 1 and type 2 diabetics, but no significant effect was noted in children and adolescents. Inconsistencies across studies with children and adolescents were significant. Subgroup analysis showed no effect based on the type of CGM used (real-time vs. non-real-time). No significant adverse effects related to the device were reported in any trial. Meta-analysis of patient satisfaction was not possible due to heterogeneity of outcome assessments and reporting methods. Reasons for not using the device included inconvenience and problems sleeping, bathing and participating in sports. The authors stated that the current body of literature had several limitations including the following: overall, device studies were structured to demonstrate a maximal difference in the outcome and often provided more education, visits, support, feedback and access to patients resulting in co-intervention effect and bias that exaggerated the treatment effect; heterogeneity of the documentation of hypoglycemia and hyperglycemia; changing technology; small number of randomized controlled trials using currently available devices; adult populations tended to be fairly young; and the number of T2DM patients was low. Many studies with children and adolescents used the Glucowatch and they may have used CGM less frequently.

**Technology Assessment:** The Agency for Healthcare Research and Quality (AHRQ) (2012) conducted a comparative effectiveness systematic review on insulin delivery and glucose monitoring. The objective was to determine if CSII compared to MDI (at least three injections per day) resulted in “better glycemic control, less hypoglycemia, improved quality of life (QOL), and improved clinical outcomes” in individuals with type 1, type 2 or pre-existing diabetes in pregnancy. AHRQ also wanted to assess if the outcomes differed if real-time CGM (rt-CGM) was used compared to SMBG (at least three fingersticks a day). Randomized controlled trials and observational studies were included in the assessment. Only randomized controlled trials were used in combined estimates for HbA1c and severe hypoglycemia. Meta-analysis was conducted when two or more studies were sufficiently homogeneous in the key variables. No studies were found that compared rt-CGM with...
SMBG that reported frequency of adjusting insulin therapy, adherence to therapy, health visits, or microvascular and macrovascular disease. The authors noted that the studies were “small”, and of “fair to poor quality”. Studies were heterogeneous in terms of definitions of nonsevere hypoglycemia, hyperglycemia, and weight gain. Few studies included children age ≤ 12 years, adults age ≥ 65 years, or pregnant women with pre-existing type 2 diabetes. Therefore, conclusion could not be made regarding these populations. None of the studies included data on the microvascular and macrovascular complications associated with long-term diabetes. None of the studies in women with pre-existing type 1 diabetes examined the effect of rt-CGM on maternal and fetal outcomes. Other than the rt-CGM studies, few studies reported data on treatment adherence. AHRQ noted that the results of this report were not generalizable to nonspecialty settings or all patients with diabetes mellitus, as the initiation, instruction, monitoring, and therapeutic changes rt-CGM use are often limited to expert settings and highly motivated patients and families. AHRQ reported the following findings:

- Only comparative effectiveness studies of rt-CGM versus SMBG in type 1 children, adolescents, and adults were found. No studies have made this comparison in type 2 diabetics or pregnant women with diabetes.
- Compared with the SMBG group, the rt-CGM group achieved lower HbA1c levels.
- rt-CGM was associated with lower HbA1c in individuals age ≤ 18 years which supports recent clinical practice recommendations suggesting rt-CGM use in children and adolescents over the age of 8 years.
- “rt-CGM is superior to SMBG in lowering HbA1c, without increasing or decreasing the risk of severe hypoglycemia, in nonpregnant individuals with type 1 diabetes, particularly those who are compliant with wearing the monitoring device”.
- The rt-CGM vs. SMBG groups “did not differ in the rate of severe hypoglycemia; however, there was a significant reduction in the time spent in the hyperglycemic range” favoring rt-CGM.
- No differences were reported in QOL between the groups.
- “Sensor-augmented pump use resulted in a statistically and clinically significantly greater reduction in HbA1c compared with MDI/SMBG use in nonpregnant individuals with type 1 diabetes”. The evidence was insufficient to draw definitive conclusions about severe hypoglycemia or QOL.

**Professional Societies/Organizations:** The ADA’s 2017 clinical practice recommendations for the treatment and management of diabetes mellitus include the following recommendations for CGM:

- “When used properly, continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1c in selected adults (age ≥ 25 years) with type 1 diabetes.
- Although the evidence for A1c lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device.
- CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes.”

ADA stresses the importance of assessing individual readiness for use of CGM and ensuring that the user receives robust education, training and support.

Regarding continuous glucose monitoring (CGM) in adults, the 2016 Endocrine Society guidelines for CGM include the following:

- Recommend real-time continuous glucose monitoring (RT-CGM) devices for adult type 1 diabetics who have A1C levels above target and are willing and able to use the devices on a nearly daily basis (strong recommendation; high level of evidence).
- Recommend RT-CGM for well-controlled adult type 1 diabetics who are willing and able to use these devices on a nearly daily basis (strong recommendation; high level of evidence).
- Suggest short-term real-time continuous glucose monitoring (RT-CGM) use in adult type 2 diabetics not on prandial insulin who have A1C levels ≥ 7% and are willing and able to use the device (weak recommendation; weak level of evidence). Although the number of studies is limited, results showed a significant improvement in A1C compared to baseline with CGM.

In a 2017 Choosing Wisely statement, the Society of General Internal Medicine did not recommend daily home finger glucose testing in Type 2 diabetics who are not on hypoglycemic medications or insulin. According to the Society, there is no benefit to SMBG in this subpopulation and potential negative clinical impact is possible. SMBG should be reserved for use during titration of medication doses or periods of change in diet and exercise.
routines. The Endocrine Society and American Association of Clinical Endocrinologists (2013) recommend avoiding routine SMBG in adults with stable type 2 diabetes on hypoglycemic agents when target control is achieved. Exceptions include acute illness, change in medication, significant change in weight, A1c drifts off course and any other time when SMBG is needed to maintain targets and/or needed for learning.

In the 2016 consensus statement on outpatient glucose monitoring, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) made the following recommendations for CGM in diabetics:

- Type 1 adults: CGM is 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 patients: Recommendation same as for type 1 adults. However, the authors noted that prevalence and persistent use of CGM is lower in children and more in-depth training and follow up is recommended to ensure successful use of this technology.
- Type 2 diabetics using insulin/ sulfonylureas, glinides: Data on CGM for this population are limited and trials are ongoing.
- Type 2 diabetics with low risk of hypoglycemia: No recommendation was made.
- Gestational diabetics: Based on current data, the benefit of CGM in pregnant women with preexisting diabetes is unclear. CGM can be used during pregnancy as a teaching tool, to evaluate glucose patterns, and to fine-tune insulin dosing. CGM can also supplement blood glucose monitoring, especially for monitoring nocturnal hypoglycemia or hyperglycemia and postprandial hyperglycemia.

In their consensus statement on glycemic control for type 2 diabetics, the AACE and ACE (Rodbard, et al., 2009) stated that CGM may be considered for the management of type 2 diabetics who are receiving insulin and the disease is otherwise difficult to control. CGM may help to "educate the patient regarding the glycemic effects of various foods, help the patient titrate insulin, and provide warnings when the patient is experiencing hyperglycemia or hypoglycemia."

**Continuous Glucose Monitoring in Pregnancy**

Management of diabetes during pregnancy (maternal diabetes) is essential for healthy outcomes for the mother and the infant. An individual with preexisting type 1 or type 2 diabetes mellitus may become pregnant or a woman can develop diabetes during the pregnancy (i.e., gestational diabetes). Gestational diabetes typically subsides following delivery. Uncontrolled diabetes during pregnancy can be associated with miscarriage, pre-eclampsia, preterm labor, stillbirth, congenital malformations and other complications. Both 72-hour and long-term CGM have been proposed for use during pregnancy (Kitzmiller, et al., 2008; NICE, 2015).

**Literature Review:** Secher et al. (2013) conducted a randomized controlled trial including 123 type 1 and 31 type 2 women with pregestational diabetes. Patients were randomized to CGM (n=79) for six days at 8, 12, 21, 27, and 33 weeks in addition to routine care or routine care only (n=75). Routine care included self-monitored blood glucose seven times per day. Twenty-seven type 1 diabetics were on insulin pump therapy, most initiated prior to pregnancy. Forty-nine women used real-time CGM per protocol. At 33 weeks, there was no significant difference in HbA1c (p=0.64), episodes of severe hypoglycemia (p=0.91) and prevalence of large-for-gestational-age infants (p=0.19) between the groups. Other perinatal outcomes were also comparable. Intermittent use of CGM did not improve outcomes in this patient population. A limitation of the study is the low number of CGM users who followed protocol.

Murphy et al. (2008) conducted a randomized controlled trial to compare the outcomes of type 1 (n=46) and type 2 (n=25) diabetic women, age range 16–45 years, who used CGMS (n=38) compared to SMBG (n=33) during pregnancy. CGM was performed for up to seven days at 4–6 week intervals, between 8–32 weeks’ gestation. Data were downloaded and reviewed during follow-up visits and, in correlation with SMBG values, adjustments were made to diet, exercise and insulin therapy as indicated. The CGMS was used 0–8 times, mean 4.2 times, with 80% of the women wearing the monitor at least once per trimester. No significant differences were found in the mean A1c level between the two groups prior to week 32, but the CGM group had a consistently lower A1c level. A significant difference in A1c was seen between 32–36 weeks’ gestation with the CGMS group having a lower mean A1c (p=0.007). Although not statistically significant, the CGMS group had a trend toward reduced emergency caesareans (p=0.08). There was no significant difference in infant morbidity.
between the two groups. Compared with healthy singletons of women in the SMBG group (n=30), women in the CGMS group (n=32) had significantly decreased mean birth weight standard deviation scores (p=0.05) and median birth weight centiles (p=0.02). Thirteen infants in the CGMS group compared to 18 infants in the SMBG group were macrosomic (p=0.05). The study suggested that the use of CGMS during pregnancy was associated with third-trimester improved glycemic control, lower birth weights and reduced risk of macrosomia. Author-noted limitations of the study included: the health professionals were not blinded, the small patient population, women were predominantly of white European ethnicity, and differences in the maternal characteristics with longer duration of diabetes in the intervention group.

Kestilä et al. (2007) conducted a randomized controlled trial to compare CGM (n=36) to SMBG (n=37) in detecting patients with gestational diabetes mellitus (GDM) who needed antidiabetic drug treatment. High-risk pregnant women at 22–34 gestational weeks who had at least two abnormally high glucose values on oral glucose tolerance testing were included in the study. The mean CGM period was 47.4 ± 2.5 hours. SMBG was performed at least five times per day. Treatment modalities were offered within five days of monitoring. As a result of CGMS, 11 women were treated with either oral agents or insulin compared to three patients in the SMBG group (p=0.0149). Within the CGM group, SMBG values were compared to the CGM values, and five SMBG patients were identified with indications for antihyperglycemic treatment compared to 16 CGM patients.

Professional Societies/Organizations: The 2013 Endocrine Society’s practice guideline on diabetes and pregnancy recommended SMBG testing in all pregnant women with gestation or overt diabetes prior to meals and 1–2 hours after the start of each meal. The Society suggested that CGM be used during pregnancy with overt or gestational diabetes when SMBG levels or HbA1cs are not sufficient to assess glycemic control.

Replacement of a Continuous Glucose Monitoring System and Components
Replacement of a Continuous Glucose Monitoring System (CGM) and/or components is indicated when the device malfunctions, cannot be repaired and is no longer under warranty. Warranties for continuous glucose monitor and various components range from six months to three year. There is a lack of evidence to support improved outcomes due to advanced technology for CGM. Diabetics should be routinely followed by a health care provider and seen by their provider within six months of a request for a replacement monitor to ensure compliance to the management of their diabetes and the continued need for CGM.

Data Management Systems
Although data management systems offer convenience in tracking test results and glucose levels, disadvantages of some of the management systems include the complexity, time and labor intensiveness of downloading the data. There is insufficient evidence in the peer-reviewed literature to support that data management systems improve diabetic management. Due to the limitations of the available studies (e.g., lack of randomization, heterogeneous patient populations, various outcome measures, participant attrition) the benefits of data management systems in overall health outcomes in the treatment of diabetes mellitus is unknown (Costa, et al., 2009; Russell-Minda, 2009). Additional software or hardware for downloading data to computers, iPhones®, iPad® or iPods® for data management are not medically indicated.

U.S. Food and Drug Administration (FDA): Data management systems are approved as an FDA 510(k) Class II device. An example is the Animas ezManager® Max Diabetes Management Software (Animal Corporation, West Chester, PA) which is intended for use with Animas glucose meters to support diabetes management by the patient and/or health professional to allow for review, analysis and evaluation of blood glucose history information.

Literature Review: Lafl el et al. (2007) conducted a randomized controlled trial (n=205) to evaluate glycemic control in insulin-treated patients who utilized an integrated glucose meter and electronic logbook compared to patients who used a conventional glucose meter and paper logbook. Type 1 and type 2 adult and pediatric patients (n=70) were recruited from seven centers to participate in the study. Participants were either using continuous insulin infusion or multiple daily injections of insulin, performing SMBG two or more times a day, and had an A1c ≥ 8% with stable glycemic control. During the first four weeks, all patients used their glucose monitor and written logbooks. At week four, patients were randomized to either a glucose monitor and written logs (i.e., paper group) (n=92) or to an integrated glucose meter/logbook (i.e., electronic group) (n=113). Follow-up visits occurred at four, eight, 12, 16 and 20 weeks. Upon completion of the study, mean A1c decreased -0.27% in the paper group compared to -0.35% in the electronic group (p=0.022). Pediatric patients also demonstrated similar results (p=0.024). The electronic group reported performing more average daily SMBG checks than the paper
group (p=0.03). There was no significant difference in the mean amplitude of glycemic excursion between the two groups, but the rate of reported hypoglycemic events was lower in the paper group (p<0.0001). A total of 104 patients were available for a follow-up visit at 66 weeks, and patients were identified by four subgroups (i.e., group 1a had continued with meter/paper log since the 20-week visit; group 1b switched to integrated meter/electronic log; group 2a continued with integrated meter/electronic log; and group 2b switched to meter/paper log). Between the four-week follow-up visit and the 66-week follow-up visit, mean A1c decreased significantly in those who continued using the electronic logbook (p=0.008) compared to the other three subgroups who experienced an increase. A1c levels returned to the pre-trial level in these three groups. There was a statistically significant difference in mean A1c in those who used paper logbooks the entire time compared to those who used the electronic logbooks (p=0.006). The same trend was seen among the pediatric patients (p=0.053). From the last study visit to the 66-week visit, A1c increased in all groups. Limitations noted by the authors included short-term follow-up, neither patients or providers could be fully blinded, the “greater reduction in A1c in the electronic group may have yielded a greater number of measured hypoglycemic episodes,” the increased recognition of hypoglycemic episodes in the electronic users may have resulted from more frequent monitoring and detection of events, and the choice of switching was made by the patient and provider. The authors noted that, although statistically significant, the differences between the two study groups from the end of the RCT and the absolute reductions in A1c were modest and stated that additional studies were needed to confirm the outcomes of this study.

Remote Glucose Monitoring Device
mySentry (Medtronic MiniMed, Inc., Northridge, CA) is a remote glucose monitor that can be placed at the bedside of a parent or guardian to allow monitoring of glucose information throughout the night. The system consists of a monitor, power source and radio-frequency operated Outpost that transmits information from a Medtronic MiniMed Paradigm REAL-Time Revel insulin pump. The Outpost allows monitoring from 50 feet away or greater. The monitor displays the same information and sounds the same alarms as the pump itself if the alarm silence option is off. The device is not used for making therapy adjustments nor does it control the insulin pump in any way (Medtronic, 2013). Remote glucose monitoring devices purely for the intent of surveillance of the original device, like the mySentry, are considered a convenience item and not medically necessary in the treatment of diabetes mellitus.

mySentry was FDA approved as a supplement to the original premarket agreement (PMA) for the Medtronic continuous glucose monitoring system. The approval order included a monitor and a remote outpost for use with the paradigm real-time system (FDA, 2011).

Hypoglycemic Alarm Wristband
Alarm devices that can be worn on the wrist or ankle have been proposed for use by a diabetic to detect changes in skin conditions as an alert for hypoglycemia. The FDA approved Diabetes Sentry (Diabetes Sentry Products, LLC. Fort Worth, TX) is an example of a hypoglycemic alarm that can be worn on the wrist, ankle or bicep. The device is proposed to detect an increase in perspiration and/or drop in skin temperature and alert the wearer. The Sentry does not measure glucose levels (Diabetes Sentry, 2017). This type of device is not used for making decision regarding treatment and is considered a convenience item and not medically necessary.

GlucoWatch® G2™ Biographer
The GlucoWatch® G2™ Biographer (Cygnus, Inc., Redwood, CA) was an FDA, PMA CGMS that was worn on the wrist like a watch and took noninvasive glucose measurements through the skin every 10 minutes for up to 13 hours at a time. It was approved for use in patients seven years and older. After a two-hour warm-up period and calibration, the GlucoWatch began monitoring by producing an electrical current that pulled fluid from the skin and measured the glucose in the fluid. It has a high/low glucose alarm feature. This device is no longer available.

Literature Review: The overall evidence in the published peer-reviewed literature in the form of randomized controlled trials (Newman, et al., 2010; Chase, et al., 2005; Chase, et al., 2003) indicated that the use of the GlucoWatch resulted in minimal or no significant improvements in glycemic control or in a reduction in the occurrence of hypoglycemic attacks. Use of the device was associated with skin irritation, edema, erythema, skipped readings, false alarms, and inaccurate results (Weinzimer, et al. 2008a; Ellis, et al., 2007).

Other Home Blood Glucose Monitors
Some monitors combine a standard finger-stick blood glucose meter with non-medical devices and/or non-diabetic testing capabilities. Examples of these monitors include a finger-stick meter combined with a cellular telephone (glucophone), (e.g., GlucoPack™, HealthPia America Corp., Newark, NJ), a blood pressure monitor (e.g., Advocate DUO, Diabetic Supply of Suncoast, Taipei County, Taiwan), and a cholesterol screening analyzer (e.g., CardioChek PA Analyzer, Polymer Technology Systems, Inc. Indianapolis, IN). These devices are considered convenience items for the individual and not medically necessary in the treatment of diabetes mellitus.

Use Outside of the US

Different systems for standard and continuous glucose monitoring (CGM) are available outside of the United States. Examples of standard finger-stick blood glucose monitors offered in various countries throughout the world include the Accu-Chek and the One Touch. The Navigator Continuous Glucose Monitor (Abbott Diabetes Care, Alameda, CA) is available in Europe and other countries such as Israel and Australia. The Optical Glucose Monitor CGM system (C8 MediSensors, Inc., San Jose, CA) is Conformité Européenne (CE) Mark approved for marketing in Europe.

FreeStyle Libre: Ambulatory glucose profile (AGP) assesses glycemic levels on a 24-hour basis through a minimally invasive method called flash glucose monitoring. The flash glucose monitoring system is calibrated at the factory and does not require fingerstick calibration by the user. The data are extrapolated using inbuilt software that summarizes the glycemic variability over a two week period of time. The interstitial system is proposed as a replacement for the capillary fingerstick blood glucose measurement (Kalra and Gupta, 2015; Thomas, et al., 2008).

The FreeStyle Libre™ Flash Glucose Monitoring System (Abbott Diabetes Care, Alameda, CA) for individual use is currently available in Austria, Belgium, France, Germany, Italy, Netherlands, Norway, Spain, Sweden and the United Kingdom. The FreeStyle is approved for use by children and teens with diabetes aged 4-17 years old as well as adults. The System includes a Sensor kit, Reader Kit and software. The Sensor kit includes the sensor and the sensor applicator. The Reader is used to get glucose readings from the Sensor. It can store up to 90 days of glucose history data. The Reader has a built-in meter and can be used to test blood glucose and blood ketone levels. Notes can be entered into the Reader by the user. The glucose sensor is worn under the skin and connected to a plastic patch worn on the back of the upper arm for up to 14 days. About one hour after insertion, the sensor begins reading glucose levels and stores data every fifteen minutes trending the information. The hand-held reader with the built-in FreeStyle Precision BG meter is used to scan the sensor to receive a real-time glucose level along with historic results at 15-minute intervals for up to eight hours. Data are transferred by radiofrequency identification from the sensor to the reader memory. This data can be uploaded using the device software to generate summary glucose reports (including an ambulatory glucose profile) for review. The Libre is proposed for use instead of fingerstick glucose measurements except when the user is hypoglycemic, experiencing rapid changes in glucose readings and/or when symptoms do not match the Libre’s readings. There are no alarms on the system and it does not require a prescription. The system is currently not available in the US (Abbott Laboratories, 2017; Haak, et al., 2017; Edge, et al., 2016; Bailey, et al., 2015; Karla and Gupta, 2015).

Haak et al (2017) conducted a multicenter randomized controlled trial (n=224) to assess the safety and efficacy of the flash glucose-sensing technology using the (FreeStyle Libre; Abbott Diabetes Care, Witney, UK). Subjects were randomized at a 2:1 ratio into the intervention group (n=149) or the control group (n=75). The control group self-managed their glucose levels utilizing a standard blood glucose device (Abbott Diabetes Care, Witney, UK) and a glucose diary. Inclusion criteria were: age ≥ 18 years; type 2 diabetes; treated with insulin for at least six months on their current regimen of prandial only or prandial and basal intensive insulin therapy or CSII therapy for at least three months; an A1C of 7.5%–12.0%; SMBG more than 10 times per week for at least two months; and capable of using the system. The primary outcome measure was the difference in A1C at six months following usage. Secondary outcomes included time in hypoglycemia, effect of age, and patient satisfaction. Following two weeks of blinded sensor wear, subjects were randomized into the study group or the control group. At six months there was no significant difference in the change in A1C between the two groups (p=0.8222). A similar drop in A1C was detected in both groups comparing study end to baseline values. There were significant differences in favor of the study group vs. the control group in time spent in hypoglycemia (p=0.0014), nocturnal hypoglycemia (p=0.0001), daytime hypoglycemia (p=0.0374), reduction in frequency of hypoglycemic events (p=0.0098) and treatment satisfaction (p<0.0001). In subjects age < 65 years, the A1C drop was significant in the intervention group compared to the control group (p=0.0301). In subjects age ≥ 65
years the drop in A1C was more pronounced for the controls compared to the intervention group (p=0.0081) but the time in hypoglycemia (< 70 mg/dL) was reduced significantly more in the study group than the control group (p=0.0083). There were no differences in time in range (70–180 mg/dL) (p=0.7925) or time in hyperglycemia (>180 mg/dL). When the study group was able to see sensor glucose readings, their blood glucose testing frequency fell to around one test every three days and 57% of participants tested less than once every ten days. The control group remained concordant with regular blood glucose testing throughout the study (averaging 3–4 tests daily) but did not benefit from a reduction in hypoglycemia. No serious adverse events were reported. Nine sensor-adhesive reactions were reported. Author-noted limitations included: the absence of a treatment algorithm for modifying insulin therapy; inclusion of only adults with intensive insulin therapy performing regular glucose testing; and non-masked sensor intervention for the study group.

Edge et al. (2016) conducted a single center, prospective case series (n=89) to determine the safety and accuracy of the FreeStyle Libre Flash in pediatric patients. Subjects were age 4–17 years with type 1 diabetes, who were being treated with multiple daily injections (MDI) of insulin or continuous subcutaneous insulin infusion (CSII), and testing capillary blood glucose levels (BG) at least two times per day. Baseline A1Cs were 5.6%–10.4%. The device was used for 14 days and the Freestyle results were compared to capillary blood glucose measurements. Sensor results were masked to the patients. Subjects attended clinic three times during the 14 day period. A FreeStyle Sensor was worn on the back of the upper arm. Subjects were asked to perform four capillary BG tests daily using the BG strip-port on the FreeStyle Libre (FreeStyle Optium test strips, Abbott Diabetes Care), immediately followed by an interstitial fluid (ISF) glucose sensor measurement (data masked to participants) to allow comparison of results between the sensor and BG. Consensus error grid (CEG) analysis demonstrated 83.8% of Freestyle results in Zone A and 99.4% of results in Zones A and B (considered clinically accurate). Sensor results were in good agreement with BG results. Lag effect (sensor results higher/lower than BG when glucose was decreasing/increasing) was not evident with the FreeStyle. The sensor detected hypoglycemia (when capillary BG <3.9 mmol/L) on 70% (438/622) of occasions, increasing to 84% when pending alerts (i.e., sensor results within ±10% of the hypoglycemic threshold) were included. For the 30% of subjects when hypoglycemia measured in capillary testing was not detected by the FreeStyle sensor, further analysis showed that 164 of the results were in Zones A and B (clinically acceptable) and 20 were in Zone C (altered clinical action was likely to affect clinical outcome). The sensor detected hyperglycemia (when BG >13.3 mmol/L) on 85% of occasions, increasing to 94% when pending alerts were included (n=999). User experience with sensor application and sensor wear was favorable compared to SMBG. Adverse events included: allergic reaction, blister, pink mark/scabbing and abrasion on sensor removal. All were resolved at study completion. Limitations of the study include: single-center study; small patient population; and short-term follow-up.

Bailey et al. (2015) conducted a prospective, single arm study (n=72) to evaluate and compare the FreeStyle Libre Flash glucose measurements to capillary blood glucose levels. Subjects were type 1 or type 2 diabetics, age 18–71 years with an A1C 5.5%–11.5% and performed SMBG 4.0–9.6 times per day. Thirty-three subjects were on insulin therapy. The FreeStyle sensor was worn on the back of each upper arm for up to fourteen days. During the 14-day period subjects had three clinic visits during which venous blood samples were collected every 15 minutes over an eight hour period. The first clinic visit was between day one and three, the second clinic visit was between day four and nine, and the third clinic visit was between day 10 and 14. Twenty-four of 14 sensors that were dislodged prior to the second clinic visit were replaced; sensors that were dislodged after that time were not replaced. At least eight capillary tests using the FreeStyle Reader were required to be performed on each day of the sensor wear at home and in the clinic. In total, 13,195 capillary and 12,172 venous results were paired with sensor glucose results. The percentages of FreeStyle sensor results in Zones A and B (considered clinically accurate) of the Consensus and Clarke Error Grids were 99.7% and 99.0%, respectively. Continuous glucose error grid analysis versus venous reference showed 96.5% (11,232/11,640) of the data were categorized as clinically accurate, and 2.4% (274/11,640) were classified as benign errors. The percentage of readings within Consensus Error Grid Zone A (within 10% of capillary results) on Days 2, 7, and 14 was 88.4%, 89.2%, and 85.2%, respectively showing consistency in result across the 14 days. There was no significant difference in values between the left and right arm sites (p=0.5950). The FreeStyle results were highly correlated to the capillary blood glucose results. Patient questionnaire showed an overall satisfaction with the FreeStyle of ≥97.2% on day 1 and ≥94.4% on day 15. Adverse events included, itching, moderate erythema, bruising, bleeding and insertion pain. Three subjects were lost to follow-up. Author-noted limitations of the study included: the single body site used for data collection; limited venous reference data over the 14-day wear due to practical limitation of obtaining blood, and a limited number of sensor lots used in the study. Another limitation is that the total number of sensors dislodged was not reported.
Thomas et al. (2008) conducted a randomized controlled trial (n=202) to compare the accuracy and precision (exactness of replication) of five fingerstick blood glucose (BG) meters. Patients were type 2 diabetics, age 38–76, and 101 patients were on insulin. Diabetic patients undergoing venipuncture for glucose testing were randomized to one of two groups. Group 1 (n=101) included: FreeStyle Flash, Accu-Chek Advantage, and Accu-Chek Compact Plus. Group 2 (n=100) included the FreeStyle Flash, Ascensia Contour and BD Logic (BD Diabetes Care, Franklin Lake, NJ). Within five minutes following venipuncture BG samples, duplicate finger BG measurements from three ipsilateral fingers were taken. Accuracy was assessed by comparing the glucose results of the first fingerstick obtained with each meter with the laboratory reference value. Meter precision was determined by calculating the absolute mean percentage differences in glucose values between the first and second finger test results. Blood samples were obtained over a 15-day period. There were no statistically significant differences among the meters in their ability to obtain glucose values in Zones A and B (clinically acceptable) (p>0.1 in group 1; p>0.3 in group 2). Analysis of Zone A results (representing less than a 20% deviation from the true blood glucose) demonstrated greater accuracy in the FreeStyle in group 1 (p<0.001) and greater accuracy of the FreeStyle and Contour in group 2 (p<0.001). In group 1 there was a significant difference in meter accuracy (p=0.014) between the FreeStyle (44% of results falling within 10% of the reference range) and the Advantage. There was no significant difference between the meters in group 2. In group 2, the BD Logic was significantly less accurate (p=0.021) than the Contour and the FreeStyle Flash. There was no difference in precision among the meters. In an analysis of meter results of venipuncture glucose levels of ≤110 mg/dL all meters read, on average, 9–21 mg/dL higher than the 89 mg/dL mean venous result. There were no significant variations between fingerstick values compared to venous results with regards to time of the patient’s previous meal or insulin administration. Author-noted limitations of the study included: small patient population; glucose testing was performed on different blood samples (venipuncture and four different fingersticks) and on different types of blood (venous and capillary); and the investigators were not blinded to the meter used.

Rivers et al. (2006) compared two alternative-site glucose monitors in 105 patients to assess the accuracy and precision of finger and forearm blood glucose measures. The FreeStyle Flash was used for forearm samples and the One Touch Ultra (LifeScan, Milpitas, CA) was used for the fingersticks. Nonpregnant adults (age ≥ 18 years) who were schedule for a venipuncture glucose measure were included in the study. Seven patients were not diabetics. The testing sequences for finger and forearm readings were randomized before study initiation. Within five minutes of the venipuncture, finger and forearm glucose measurements were taken. Accuracy was assessed by comparing the finger and forearm results to the venipuncture results. Two outcomes were used: error-grid analysis of meter results compared to venipuncture results and comparison of the percentage of results obtained with each meter falling within 10% of the laboratory values. An error grid with five Zones was used for analysis with Zones A and B considered clinically accurate. Values in Zone A did not vary by more than 20% from the venipuncture value and Zone B results were greater than 20% of the venipuncture results. Decisions based on Zone B would not lead to serious consequences for the patient. Values in Zones C, D and E could lead to serious consequences. Of the fingerstick results obtained with the FreeStyle, 96 were in Zone A and four were in Zone B compared with 91 in Zone A and 19 in Zone B with the One Touch. Adequate forearm samples for glucose testing were obtained in 99 Freestyle patients and 74 One Touch patients (p<0.001). Of the forearm results 89 FreeStyle were in Zone A, nine were in Zone B and one was in Zone D. The one Touch forearm readings showed 62 in Zone A and 12 in Zone B. Overall, use of the FreeStyle resulted in significantly greater values in Zone A vs. the One Touch (p=0.002). Compared to venipuncture samples, the FreeStyle had an average absolute percent error of 7.2% in the finger and 9.3% in the forearm results and the One Touch had an error rate of 10.8% in the finger and 12.8% in the forearm. Statistical comparison of sequential samples showed that the first fingerstick results were on average 7 mg/dL and 5 mg/dL lower than the second for the FreeStyle and One Touch, respectively (p=0.003, each). There was no variation in the forearm sequential samples. The differences among the number of patients who obtained a forearm glucose reading with one stick, the number of patients unable to obtain at least one forearm glucose measure despite repeated attempts and the total number of forearm sticks between the two groups were statistically significant in favor of the FreeStyle (p<0.001). These results showed that the FreeStyle and the One Touch were clinically accurate 99.5% and 100% of the time, respectively. The comparison of meter results falling within 10% of the venipuncture values showed that the FreeStyle was more accurate than the One Touch. Five patients were lost to follow-up. Limitations of the study include the small patient population and lack of blinding to the devices being used.

Professional Societies/Organizations: Based on a review of the evidence-based literature, the Working Group Diabetes Technology of the German Diabetes Association published a consensus statement (Liebl, et al., 2013) that included the following indications for CGM for type 1 diabetics:
• hypoglycemia, i.e., frequent, severe hypoglycemic episodes (requiring assistance from third parties), severe nocturnal hypoglycemia, and/or proven hypoglycemia unawareness;
• unsatisfactory metabolic control if, despite the use of all available forms of treatment (including also CSII), good compliance and the exclusion of severe psychological/psychiatric problems, the target HbA1c level cannot be achieved;
• before/during pregnancy with inadequate metabolic control using conventional forms of treatment; and
• the need to perform more than 10 blood glucose measurements per day to achieve the target HbA1c level.

The Scottish Intercollegiate Guidelines Network (SIGN) recommendations on the management of diabetes (2010) stated that CGM may be a useful adjuvant to conventional self-monitoring in selected adults with type 1 diabetes who have persistent problems with glycemic control. However further research is required to identify individuals who will gain the most benefit. Although there is limited evidence that continuous glucose monitoring may be of benefit to women during pregnancy, CGM may be considered for type 1 and type 2 diabetics in pregnancy.

The National Institute for Clinical Excellence (NICE) (United Kingdom) (2015; updated 2016) recommended self-monitoring of blood glucose levels for all adults with type 1 diabetes at least four times a day, including before each meal and before bed. Testing may be performed up to ten times per day in various situations including the following: A1C isn’t achieved; the frequency of hypoglycemic episodes increases; before, during and after sports; when planning pregnancy, during pregnancy and while breastfeeding; or during illness. NICE stated that CGM could be considered for adults with type 1 diabetes who commit to using CGM at least 70% of the time and who have any of the following despite optimized insulin therapy and conventional blood glucose monitoring:

• More than one episode a year of severe hypoglycemia with no obviously preventable precipitating cause.
• Complete loss of awareness of hypoglycemia.
• Frequent asymptomatic hypoglycemia (more than two episodes a week) that is causing problems with daily activities.
• Extreme fear of hypoglycemia.
• Hyperglycemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.

Regarding pregnancy, NICE (2015) recommended that CGM not be routinely offered to pregnant women with diabetes. CGM may be considered for pregnant women on insulin therapy who have problematic severe hypoglycemia or have unstable blood glucose levels or to gain information about variability in blood glucose levels. The role of CGM in helping women achieve blood glucose targets before pregnancy needs further research.

Summary
Self-monitoring of blood glucose (SMBG) is an integral component of diabetes management, provided that the patient or caregiver is given instruction in technique and is capable of using the data to adjust therapy. While conventional monitors are adequate for most individuals, continuous self-monitoring of glucose is appropriate for a carefully selected subset of individuals.

The replacement of an existing continuous glucose monitor with newer models and additional features when the device is fully functional is primarily for convenience or ease of use and not medically necessary for the treatment of diabetes. The use of data management systems has not been shown to improve health outcomes. Finger-stick blood glucose monitors combined with non-medical devices (e.g., cellular phones) or non-diabetes related testing capabilities (e.g., blood pressure monitor) are considered a convenience and not medically necessary in the treatment of diabetes mellitus.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Covered when medically necessary:**

<table>
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<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<td>95250</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording</td>
</tr>
<tr>
<td>95251</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum 72 hours; interpretation and report</td>
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<td>Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply</td>
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<tr>
<td>A9277</td>
<td>Transmitter; external, for use with interstitial continuous glucose monitoring system</td>
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<tr>
<td>A9278</td>
<td>Receiver (monitor); external, for use with interstitial continuous glucose monitoring system</td>
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<td>E0607</td>
<td>Home blood glucose monitor</td>
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<tr>
<td>E2100</td>
<td>Blood glucose monitor with integrated voice synthesizer</td>
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<tr>
<td>E2101</td>
<td>Blood glucose monitor with integrated lancing/blood sample</td>
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<tr>
<td>K0553</td>
<td>Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service (Code effective 07/01/2017)</td>
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<tr>
<td>K0554</td>
<td>Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system (Code effective 07/01/2017)</td>
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**Convenience/Not Medically Necessary/Not Covered when used to report the use of additional software or hardware required for downloading data to a device, combination devices, remote glucose monitoring devices and/or hypoglycemic wristband alarm:**

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<td>Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified</td>
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<td>Alert or alarm device, not otherwise classified</td>
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<tr>
<td>E1399</td>
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**References**


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