INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. 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.

Coverage Policy

Coverage for Durable Medical Equipment including home blood glucose monitors varies across plans. Please refer to the customer’s benefit plan document for coverage details.

Home Blood Glucose Monitor

If coverage is available, a home blood glucose monitor is considered medically necessary for EITHER of the following 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)

A minimally invasive, continuous glucose monitoring system (CGMS) is considered medically necessary 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 14 days under the core medical benefits of the plan, for up to six separate sessions in any given 12-month period (CPT® code 95250, 95251).
The Freestyle Libre Flash Glucose Monitoring System (HCPCS code K0553, K0554) is considered medically necessary for the management of type 1 or type 2 diabetes mellitus when ALL of the following criteria have been met:

- age 18 years or older
- completion of a diabetes self-management education program
- documented blood glucose self-testing an average of at least four times per day
- treatment program including at least three insulin injections per day with frequent self-adjustments of insulin dose for at least two months

A minimally invasive continuous glucose monitoring system (CGMS) (HCPCS code A9277, A9278, K0553, K0554) is considered 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

Replacement of an existing continuous glucose monitoring system or component is considered 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
Each of the following 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™)

Overview
This Coverage Policy addresses the various types of home glucose monitors and the indications for use of these monitors.

**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 (GHRS), 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. CGM systems can be used by a healthcare provider for diagnostic purposes or continuously by the patient for ongoing self-monitoring of the blood glucose levels.

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 therapeutical 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).

A newer CGM system has been proposed for replacement of finger-stick glucose monitoring and the sensor can be worn for up to 10 days. An example of this type of CGM is the FreeStyle Libre (Abbott Diabetes Care Inc., Alameda, CA). The FreeStyle Libre CGM is a sensor-based continuous glucose monitoring system that uses an ambulatory glucose profile (AGP) to assess glycemic levels on a 24-hour basis through a minimally invasive method called flash glucose monitoring. The System includes a Sensor kit, Reader Kit and software. The Sensor kit includes the sensor and the sensor applicator. 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 10 days. About one hour after insertion, the sensor begins reading glucose levels and stores data every fifteen minutes trending the information. The Reader is used to obtain glucose readings from the Sensor. Data are transferred by radiofrequency identification to the reader when it is brought into close proximity to the sensor. The Reader displays the current sensor glucose level, a glucose trend arrow, and glucose readings over the preceding eight hours at fifteen minute intervals. Scanning can be done as often as is needed for current glucose concentration. The Reader can store up to 90 days of glucose history data and has a built-in meter that can be used to test blood glucose and blood ketone levels. Notes can be entered into the Reader by the user. The data in the reader memory can be uploaded using the device software to generate summary glucose reports (including an ambulatory glucose profile). 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 is calibrated at the point of manufacture (i.e., factory-calibrated) and does not require or accept any user-entered calibration (Abbott Laboratories, 2017; Haak, et al., 2017; Bolinder, et al., 2016; Edge, et al., 2016; Bailey, et al., 2015; Karla and Gupta, 2015).
Other CGM systems are used with finger-stick blood glucose monitoring and should never be used alone. 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. CGM may be used on a long-term basis for the treatment of a subtype of type 1 or type 2 diabetics. The ADA and a 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). 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.

The Freestyle Libre continuous glucose monitoring system (Abbott Diabetes Care Inc., Alameda, CA) is FDA PMA approved “for the management of diabetes in persons age 18 years and older. It is designed to replace blood glucose testing for diabetes treatment decisions” (FDA, 2017). It is a sensor-based continuous glucose monitoring system that uses an ambulatory glucose profile (AGP) that assesses glycemic levels on a 24-hour basis through a minimally invasive method called flash glucose monitoring. This device is factory-calibrated and is never calibrated by the patient.

CGMS are used only as an adjunct to SMBG and should never replace or be used instead of SMBG. Examples of FDA approved adjunctive CGMs include 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. These systems provide data for up to five to seven days.

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). The Dexcom requires calibration by the patient every 12 hours.

**Literature Review – Freestyle Libra CGM:** Bolinder et al. (2016) conducted a multicenter, randomized controlled trial (n=241) to assess whether a factory-calibrated, sensor-based, flash glucose-monitoring system (Freestyle Libre) compared with self-monitored glucose testing reduced exposure to hypoglycemia in patients with type 1 diabetes. A total of 23 European diabetes centers were included. Subjects were age ≥ 18 years, diagnosed with type 1 diabetes for five years or longer, on their current insulin regimen for at least three months, had an HbA1c ≤ 58 mmol/mol (7.5%) or lower; reported self-monitoring of blood glucose levels ≥ 3 times per day for ≥ 2 months and were considered to be capable of using the Freestyle Libre. After two weeks of all participants wearing the blinded sensor, those with readings for at least 50% of the period were randomly assigned (1:1) to flash sensor-based glucose monitoring (n=120) or to self-monitoring of blood glucose with capillary strips (n=121) using the FreeStyle Lite meter and test strips (Abbott Diabetes Care, Witney, Oxon, UK). The primary outcome was time spent in hypoglycemia (<3.9 mmol/L [70 mg/dL]) for the 14 days preceding the end of the six-month study period (days 194-208). At six months there was a significant difference in the mean time in hypoglycemia in favor of the study group vs. the control group (p<0.0001). Mean time in hypoglycemia changed from 3.38 hours per day at baseline to 2.03 hours per day in the study group and from 3.44 hours per day to 3.27 hours per day in the control group. There was a 38% reduction in mean time in hypoglycemia in the study group compared to the control group. At six months, 77 (65%) study group subjects compared with 39 (33%) control group subjects reduced their time in hypoglycemia (<3.9 mmol/L) by at least 30% (p<0.0001). HbA1c concentrations in the study group were essentially unchanged compared with the control group. The mean number of self-monitored blood glucose tests performed per day by the study group immediately decreased from 5.5 tests per day during the 14 day baseline phase to 0.5 tests per day during the treatment phase of the trial. The mean number of sensor scans per day for the Freestyle group was 15.1 during the treatment phase. At the end of the study there were no differences in total daily doses of insulin or bolus/basal insulin ratios between the groups. Patient satisfaction was significantly higher in the study group compared to the control group (p<0.001). The total treatment satisfaction and perceived frequency of hyperglycemia were significantly improved (p<0.0001, each) in the Freestyle group compared. There was no difference in diabetes distress (p=0.7634) or hypoglycemia fear behavior (p=0.9834) or worry scores (p=0.4154). No device-related hypoglycemia or safety issues were reported. Ten adverse events related to the sensor included: four allergy events (one severe, three moderate); one mild itching; one mild rash; four severe insertion-site symptoms; two erythema events (one severe, one mild); and one moderate edema event. No hypoglycemic serious adverse events were considered device related. There were no reported events of diabetic ketoacidosis during the study. Limitations of the study include: short-term follow-up which means long-term compliance is unknown; loss to follow-up (n=9 in study group; n=19 in control group); subjects were adults with well controlled type 1 diabetes limiting generalizability of results to all diabetics; and lack of masking of sensor during the study period.

Haak et al. (2017a) conducted a multicenter randomized controlled trial (n=224) (“Novel Glucose-sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-treated Type 2 Diabetes [REPLACE]”) study) 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
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.

A total of 139 subjects from the Haak 2017 (above) Freestyle group completed an open-access phase and were followed for an additional six months. The primary outcomes were changes in sensor-derived glycemic measures between baseline and 12 month results. The sensor-derived glycemic measures were number and duration of hypoglycemic events (glucose < 70 mg/dL) and number and duration of hyperglycemic events (glucose > 240 mg/dL). At 12 months' follow-up, time in hypoglycemia was reduced by 50% compared to baseline (p=0.0002). Nocturnal hypoglycemia (2300 to 0600 hours) was reduced by 52% (p = 0.0002). There was no change in the time in glucose levels of 70-180 mg/dL. SMBG fell from a mean 3.9 times/day to 0.2 time/day. Average frequency of sensor scanning was 7.1 times per day and mean sensor utilization was 83.6 ± 13.8%. Adverse events included: infection, allergy, erythema, itching and rash (Haak, 2017b).

**Literature Review** – CGM used in conjunction with a standard home blood glucose monitor: The evidence in the published peer-reviewed literature supports the use of a 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 (Gandhi, et al., 2011; 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; Weinzierl, 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).

**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 non-specialty 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 conventional 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®, iPads® 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: Laffel 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. 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. Outside the US, the FreeStyle is approved for use by children and teens with diabetes aged 4-17 years old as well as adults.

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.

**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.

### 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.

#### Home Blood Glucose Monitor

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0607</td>
<td>Home blood glucose monitor</td>
</tr>
<tr>
<td>E2100</td>
<td>Blood glucose monitor with integrated voice synthesizer</td>
</tr>
<tr>
<td>E2101</td>
<td>Blood glucose monitor with integrated lancing/blood sample</td>
</tr>
</tbody>
</table>

#### Continuous Glucose Monitoring System (CGMS)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>95249</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up,</td>
</tr>
</tbody>
</table>
Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9276</td>
<td>Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply</td>
</tr>
<tr>
<td>A9277</td>
<td>Transmitter; external, for use with interstitial continuous glucose monitoring system</td>
</tr>
<tr>
<td>A9278</td>
<td>Receiver (monitor); external, for use with interstitial continuous glucose monitoring system</td>
</tr>
<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</td>
</tr>
<tr>
<td>K0554</td>
<td>Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system</td>
</tr>
</tbody>
</table>

Considered Convenience Item/Not Medically Necessary 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:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9279</td>
<td>Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified</td>
</tr>
<tr>
<td>A9280</td>
<td>Alert or alarm device, not otherwise classified</td>
</tr>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
</tbody>
</table>


References


21. Chico A, Vida K, Rios P, Sutra M, No vials A. The continuous glucose monitoring system is useful for detecting unrecognized hypoglycemia inpatients with type 1 and type 2 diabetes but is not better than


82. Rodbard, D, Jovanovic, L, and Garg, SK. Responses to continuous glucose monitoring in subjects with type 1 diabetes using continuous subcutaneous insulin infusion or multiple daily injections. Diabetes Technol Ther. 2009;11(12):757-765.


