1.0 Durable Medical Equipment

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Description
Tight glucose control in patients with diabetes has been associated with improved outcomes. Several devices are available to measure glucose levels automatically and frequently (e.g., every 5-10 minutes). The devices measure glucose in the interstitial fluid and are approved as adjuncts to traditional self-monitoring of blood glucose levels.

Related Policies
- External Insulin Infusion Pump
- Artificial Pancreas Device Systems

Policy

Intermittent Monitoring of Glucose in Interstitial Fluid

Intermittent monitoring, (i.e., 72 hours), of glucose levels in interstitial fluid may be considered medically necessary for any of the following indications:

- Patients with type 1 diabetes mellitus or insulin-requiring type 2 diabetes mellitus whose diabetes is poorly controlled (including unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis), despite both of the following current use of best practices:
  - Compliance with a regimen of 4 or more fingersticks each day and
  - Use of an insulin pump
- During pregnancy, requiring 3 or more insulin injections daily for patients not on an insulin pump prior to the pregnancy
- Patients with type 1 diabetes mellitus or insulin-requiring type 2 diabetes mellitus prior to insulin pump initiation to determine basal insulin levels (See Blue Shield Medical Policy: External Insulin Infusion Pump)
- Women with poorly controlled type 1 diabetes mellitus taking insulin who are pregnant or about to become pregnant

Continuous Monitoring of Glucose in Interstitial Fluid

Continuous, i.e., long-term, monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique of diabetic monitoring, may be considered medically necessary when any of the following situations occur:
• Patients with type 1 diabetes mellitus who have recurrent, unexplained, severe hypoglycemia (generally blood glucose levels less than 50 mg/dL), for whom hypoglycemia puts the patient or others at risk despite compliance with a regimen of 4 or more fingersticks each day and either of the following:
  o Use of an insulin pump
  o Insulin injections at least four times a day with self adjusted dose changes for at least six months

• During pregnancy, if the patient was on 3 or more insulin injections daily (if not on an insulin pump) prior to the pregnancy. Prior use of an intermittent (72-hour) glucose monitor would be considered a part of best practices for those considering use of a continuous glucose monitor

• Patients with type 1 diabetes mellitus taking insulin who are pregnant or about to become pregnant with poorly controlled diabetes with any of the following:
  o Unexplained hypoglycemic episodes
  o Hypoglycemic unawareness
  o Suspected postprandial hyperglycemia
  o Recurrent diabetic ketoacidosis

Other uses of continuous monitoring of glucose levels in interstitial fluid as a technique of diabetic monitoring are considered investigational.

Sensor-augmented insulin pump therapy with the low glucose threshold suspend feature (e.g., MiniMed 530G with Enlite, Medtronic, Inc), may be considered medically necessary when all of the following have been met:

• Must be 16 years of age or older (in accordance with FDA guidelines)

• Medical necessity criteria for external insulin pumps have been met (see Blue Shield Medical Policy: External Infusion Pump)

• Medical necessity criteria for continuous glucose monitor (CGM) have been met

The following are considered not medically necessary:

• Equipment upgrades or accessories whose sole purpose is to integrate, through communication technology, an insulin pump and interstitial glucose monitor (e.g., patient has a functioning stand-alone insulin pump and a stand-alone continuous glucose monitoring system (CGMS) and requests integration)

• The replacement of an external insulin infusion pump, with or without an integrated continuous glucose monitor, for any of the following situations:
  o Device can be repaired or refurbished
  o Device is under warranty
  o Documentation of malfunction is not provided (e.g., repair logs, MD notes)

**Policy Guidelines**

Several insulin pump systems (e.g., Paradigm REAL-Time System) have a built-in continuous glucose monitor (CGM). This policy is evaluating the CGM-device only; the
policy does not evaluate insulin pumps. In the case of insulin pumps systems with a built-in CGM and a low glucose suspend (LGS) feature, the CGM device and the low glucose suspend feature are evaluated in the policy, not the insulin pump.

Best practices in diabetes control for patients with diabetes mellitus include compliance with a regimen of 4 or more fingersticks each day and use of an insulin pump. During pregnancy, 3 or more insulin injections daily could also be considered best practice for patients not on an insulin pump prior to the pregnancy. Prior use of an intermittent (72-hour) glucose monitor would be considered a part of best practices for those considering use of a continuous glucose monitor.

Women with type 1 diabetes mellitus taking insulin who are pregnant or about to become pregnant with poorly controlled diabetes are another subset of patients to whom the policy statement on intermittent monitoring may apply.

Intermittent monitoring is generally conducted in 72-hour periods. It may be repeated at a subsequent time depending on the patient’s level of diabetes control.

The strongest evidence exists for use of CGM devices in patients age 25 and older. However, age may be a proxy for motivation and good control of disease, so it is also reasonable to select patients based on their ability to self-manage their disease, rather than age.

Coding

In 2009, the language of the CPT codes that specifically describe monitoring of glucose levels in the interstitial fluid using implanted devices was revised to state that the devices are used for a minimum of 72 hours:

- **95250**: 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
- **95251**: Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report

CPT code **99091** might also be used for this monitoring:

- **99091**: Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified healthcare professional, requiring a minimum of 30 minutes of time

For 2008, HCPCS codes were added specifically for continuous glucose monitoring systems:

- **A9276**: Sensor, invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply
- **A9277**: Transmitter, external, for use with interstitial continuous glucose monitoring system
- **A9278**: Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Rationale**

The advent of blood glucose monitors for use by patients in the home over 20 years ago revolutionized the management of diabetes. Using fingersticks, patients could monitor their blood glucose level both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. Tight diabetic control, defined as a strategy involving frequent glucose checks and a target hemoglobin A1c (HgA1c) in the range of 7% is now considered standard of care for diabetic patients. Randomized controlled trials of tight control have demonstrated benefits for type 1 diabetics in decreasing microvascular complications. The impact of tight control on type 1I diabetic patients and on macrovascular complications such as stroke or myocardial infarction is less certain.

However, tight glucose control requires multiple measurements of blood glucose each day (i.e., before meals and at bedtime), a commitment that some patients may be unwilling or unable to meet. In addition, the goal of tight glucose control has to be balanced with an associated risk of hypoglycemia. An additional limitation of periodic self-measurements of blood glucose is that glucose values are seen in isolation, and trends in glucose levels are undetected. For example, while a diabetic patient’s fasting blood glucose level might be within normal values, hyperglycemia might be undetected postprandially, leading to elevated HgA1c values.

Recently, measurements of glucose in interstitial fluid have been developed as a technique of automatically measuring glucose values throughout the day, producing data that show the trends in glucose measurements, in contrast to the isolated glucose measurements of the traditional blood glucose measurements. Although devices measure glucose in interstitial fluid on a periodic rather than a continuous basis, this type of monitoring is referred to as CGM.

Several devices have received FDA approval. The first 2 approved devices were the Continuous Glucose Monitoring System (CGMS®) (MiniMed), which uses an implanted temporary sensor in the subcutaneous tissues, and the GlucoWatch G2® Biographer, an external device worn like a wristwatch that measures glucose in interstitial fluid extracted through the skin with an electric current (referred to as reverse iontophoresis).

Additional devices that have subsequently been approved include those for pediatric use and those with more advanced software, more frequent measurements of glucose levels, more sophisticated alarm systems, etc. Devices initially measured interstitial glucose every 5 to 10 minutes and, with currently available devices, the time intervals at which interstitial glucose is measured ranges from every 1 to 2 minutes to 5 minutes. While CGMs potentially eliminate or decrease the number of required daily fingersticks, it should be noted that, according to the FDA labeling, monitors are not intended to be an
alternative to traditional self-monitoring of blood glucose levels but rather provide adjunct monitoring, supplying additional information on glucose trends that are not available from self-monitoring. In addition, it is important to note that devices may be used intermittently, e.g., time periods of 72 hours, or on a long-term basis.

In addition to stand-alone CGMs, several insulin pump systems have included a built-in CGM. This policy addresses continuous glucose monitoring devices, not the insulin pump portion of these systems.

**Regulatory Status**

Several continuous glucose monitoring systems have been approved by FDA through the premarket approval process:

- The Continuous Glucose Monitoring System (CGMS®) (MiniMed) in 1999 (approved for 3-day use in a physician's office).
- The GlucoWatch G²® Biographer in 2001. Of note, neither the GlucoWatch nor the autosensors have been available after July 31, 2008.
- The Guardian®-RT (Real-Time) CGMS (Medtronic, MiniMed) in July 2005. (MiniMed was purchased by Medtronic.)
- The DexCom® STS CGMS system (DexCom) was approved by FDA in March 2006.
- The Paradigm® REAL-Time System (Medtronic, MiniMed) was approved by FDA in 2006. This system integrates a CGM with a Paradigm insulin pump. The second generation integrated system is called the MiniMed Paradigm Revel System.
- The FreeStyle Navigator® CGM System (Abbott) was approved in March 2008.
- The DexCom G4 Platinum (DexCom) CGM was approved for use in adults 18 years and older in October 2012. The device can be worn for up to 7 days. In February 2014, FDA expanded use of the Dexcom Platinum CGM to include patients with diabetes, age 2 to 17 years old.

**Continuous Glucose Monitoring Systems**

Most of the following discussion focuses on the clinical utility of continuous glucose monitoring (CGM) systems. That is, their ability to provide either additional information on glucose levels, leading to improved glucose control or to improve the morbidity/mortality associated with clinically significant severe and acute hypoglycemic or hyperglycemic events. Because diabetic control encompasses numerous variables including the diabetic regimen and patient self-management, randomized controlled trials (RCTs) are important to isolate the contribution of interstitial glucose measurements to the overall diabetic management. Data on patients with type 1 diabetes and type 2 diabetes are discussed separately.

**Type 1 Diabetes**

Several meta-analyses of RCTs have been published; they have focused on slightly different populations, e.g., age and/or type of diabetes, and different study designs, e.g., by length of follow-up. Two 2011 meta-analyses included studies on adults and/or children. The study by Gandhi et al identified studies conducted among patients with
type 1 and/or type 2 diabetes and stratified findings by type of diabetes. The investigators identified 19 RCTs evaluating CGM interventions lasting at least 8 weeks and conducted in the outpatient setting. Mean baseline hemoglobin A1c (HbA1c) was at least 7.0% in all studies but included one in which the mean baseline HbA1c was 6.4%. Overall, compared with self-monitoring of blood glucose, CGM was associated with a statistically significant reduction in mean HbA1c (weighted mean difference [WMD], -0.27%; 95% confidence interval [CI], -0.44% to -0.10%). When stratified by age and type of diabetes, there was a statistically significant reduction in HbA1c in adults with type 1 diabetes and adults with type 2 diabetes, but not in studies of children and adolescents with type 1 diabetes.

Another 2011 meta-analysis of RCTs on CGM included trials conducted in adults and children with type 1 diabetes who were on an intensive insulin regimen (studies of type 2 diabetes were not included). This meta-analysis required a minimum of 12 weeks of follow-up in the studies (as compared with at least 8 weeks in the Gandhi meta-analysis). Studies compared CGM with self-monitored blood glucose (SMBG); there was no restriction related to type of CGM device, but the CGM readings had to be used to adjust insulin dose or modify diet. A total of 14 RCTs met eligibility criteria. In a pooled analysis, there was a statistically significant reduction in HbA1c with CGM compared with SMBG (WMD, -0.26%; 95% CI: -0.34% to -0.19%). In a subgroup analysis by age, there were significant reductions in HbA1c with CGM in studies of adults (n=5) (WMD, -0.33; 95% CI: -0.46 to -0.20) and in studies with children and/or adolescents (n=8) (WMD, -0.25; 95% CI: -0.43 to -0.08).

Two 2012 meta-analyses evaluating the efficacy of CGM in patients with type 1 diabetes had similar findings: overall, use of CGM to result in significantly greater reductions in HbA1c compared with SMBG. Most recently, a 2013 systematic review by Poolsup et al included RCTs that compared CGM with SMBG, had interventions lasting at last 8 weeks, and reported HbA1c as an outcome. For type 1 diabetes, only studies in children were included. Ten RCTs including pediatric patients with type 1 diabetes met inclusion criteria and were included in a meta-analysis. Overall, the investigators did not find that CGM had a significantly greater impact on HbA1c than SMBG. The pooled estimate of the difference in HbA1c between groups was -0.13% (95% CI: -0.38% to 0.11%). In a subgroup analysis by approach to CGM, devices that provided data retrospectively (retrospective CGM) did not result in better glucose control than SMBG (5 studies; pooled mean difference, -0.05%; 95% CI: 0.46% to 0.35%). However, real-time CGM was superior to SMBG in terms of improving glycemic control (5 studies; pooled mean difference, 0.18%; 95% CI: 0.35% to 0.02%).

Representative RCTs follow.

In 2008, the Juvenile Diabetes Research Foundation (JDRF) published results of a study that randomly assigned 322 adults and children with type 1 diabetes to CGM or self-(home) monitoring. With HbA1c as the primary outcome measure, there was a significant difference among patients 25 years of age or older that favored continuous monitoring (mean HbA1c difference, 0.53%), while the difference between groups was not statistically significant for those ages 15 to 24 years or 8 to 14 years. The population in this study had relatively well-controlled diabetes in that entry criterion was glycated Hb of 7% to 10%, but approximately 70% had levels between 7% and 8% in addition, more than 70% of patients were using an insulin pump. No significant differences were noted in rates of hypoglycemic events, but the study was likely not sufficiently large to detect potential differences. The authors also reported that monitor use was greatest in those patients ages 25 or older, the group in which 83% of patients used the monitor 6 or more days per week. The investigators also conducted a nonblinded single-arm 6-month extension to
the randomized trial in which patients in the control group were offered a CGM device. A total of 214 of 219 (98%) in the control group participated in the extension. This included 80 (37%) who were at least 25 years old, 73 (34%) who were 15-to-24 years old, and 61 (29%) who were 8-to-14 years old. The mean HbA1c level at the time of initiation of CGM use was 7.4%±0.7%. Patients were instructed to use the device on a daily basis. Among the 154 patients with baseline A1c at least 7%, there was a significant decrease in A1c 6 months after initiating device use in the older age group (mean change in A1c, -0.4%±0.5%; p<0.001). HbA1c did not decrease significantly in the 15- to 24-year-olds (0.01%±0.7%, p=0.95) or in the 8- to 14-year-olds (0.02±0.7%, p=0.85). Greater decrease in HbA1c was associated with more frequent use of the CGM device (p=0.001, adjusted for age group). Frequency of device use tended to decrease over time, with less of a decrease in the older age group. At month 6, median use of CGM devices was 6.5 days per week among the older age group, 3.3 days among the 15- to 24-year-olds, and 3.7 days per week among the children. During the 6-month extension, the rate of severe hypoglycemic events was 15 per 100 person-years of follow-up.

An additional randomized trial by JDRF, published in 2009, studied the potential benefits of CGM in the management of adults and children with well-controlled type 1 diabetes. In this study, 129 adults and children with intensively treated type 1 diabetes (age range, 8-69 years) and HbA1c less than 7.0% were randomly assigned to either continuous or standard glucose monitoring for 26 weeks. The main study outcomes were time with biochemical hypoglycemia (≤70 mg/dL, HbA1c level, and severe hypoglycemic events. At 26 weeks, biochemical hypoglycemia (≤70 mg/dL) was less frequent in the CGM group than in the control group (median, 54 vs. 91 min/d, respectively), but the difference was not statistically significant (p=0.16). Time out of range (≤70 or >180 mg/dL) was significantly lower in the CGM group than in the control group (377 vs. 491 min/d, respectively, p=0.003). There was a significant treatment group difference favoring the CGM group in mean HbA1c at 26 weeks adjusted for baseline values. One or more severe hypoglycemic events occurred in 10% and 11% of the 2 groups, respectively (p=NS). The authors concluded that the weight of evidence suggests that CGM is beneficial for individuals with type 1 diabetes who have already achieved excellent control with HbA1c of less than 7.0%. This is a relatively small study. In addition, the clinical significance of some of these findings is not certain. Some of the patients in this group would likely meet policy statements for use of CGM.

The MITRE trial, published by Newman et al in 2009, was conducted to evaluate whether the additional information provided by use of minimally invasive glucose monitors resulted in improved glucose control in patients with poorly controlled insulin-requiring diabetes. This was a 4-arm RCT conducted at secondary care diabetes clinics in 4 hospitals in England. In this study, 404 people aged older than 18 years, with insulin-treated diabetes mellitus (types 1 or 2) for at least 6 months, who were receiving 2 or more injections of insulin daily, were eligible. Most participants, 57%, had type 1 diabetes, 41% had type 2 diabetes, and 2% were classified as “other.” Participants had 2 HbA1c values of at least 7.5% in the 15 months before entry and were randomized to 1 of 4 groups. Two groups received minimally invasive glucose monitoring devices (GlucoWatch Biographer or MiniMed Continuous Glucose Monitoring System, CGMS). Intermittent CGM was used, i.e., monitoring was performed over several days at various points in the study. These groups were compared with an attention control group (standard treatment with nurse feedback sessions at the same frequency as those in the device groups) and a standard control group (reflecting common practice in the clinical management of diabetes). Change in HbA1c from baseline to 3, 6, 12, and 18 months was the primary indicator of short- to long-term efficacy in this study. At 18 months, all groups demonstrated a decline in HbA1c levels from baseline. Mean percentage
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changes in HbA1c were -1.4 for the GlucoWatch group, -4.2 for the CGMS group, -5.1 for the attention control group, and -4.9 for the standard care control group. In the intention-to-treat analysis, no significant differences were found between any of the groups at any of the assessment times. There was no evidence that the additional information provided by the devices resulted in any change in the number or nature of treatment recommendations offered by the nurses. Use and acceptability indicated a decline in use of both devices, which was most marked in the GlucoWatch group by 18 months (20% still using GlucoWatch vs. 57% still using the CGMS). In this study of unselected patients, use of CGMs (CGMS on an intermittent basis) did not lead to improved clinical outcomes.

In 2011, Mauras et al published an analysis from the Diabetes Research in Children Network (DirecNet) Study Group that evaluated CGM in the management of young children aged 4 to younger than 10 years with type 1 diabetes.11 A total of 146 children (mean age, 7.5 years) were randomized to CGM or usual care. At baseline, 30 children (42%) had an HbA1c of at least 8%. The primary outcome was clinical success, as defined as reduction in HbA1c by at least 0.5% without the occurrence of severe hypoglycemia at 26 weeks. Clinical success was attained by 19% in the CGM group and 28% in the usual care group (p=0.17). Mean change in HbA1c, a secondary outcome, did not differ significantly between groups (-0.1 in each group, p=0.79).

Section Summary
There are numerous RCTs and several systematic reviews of RCTs evaluating CGM in patients with type 1 diabetes. Systematic reviews generally found that CGM use resulted in improved glycemic control for adults with type 1 diabetes and for children with type 1 diabetes who used real-time CGM devices.

Type 2 Diabetes
Two of the systematic reviews previously described in the section on type 1 diabetes also reported on the efficacy of CGM in patients with type 2 diabetes. Gandhi et al identified 3 RCTs that included patients with type 2 diabetes (one of these included patients with either type of diabetes). There was a mixture of patients with type 2 diabetes who did and did not require insulin. In a meta-analysis of the 3 trials, there was a statistically significant reduction in HbA1c with CGM compared with SMBG in adults with type 2 diabetes (WMD, -0.70; 95% CI: -1.14 to -0.27). In 2013, Poolsup et al conducted a meta-analysis of 4 trials conducted with adults with type 2 diabetes. In a pooled analysis, CGM had greater efficacy in terms of HbA1c than usual care. The pooled mean difference in HbA1c was -0.31% (95% CI: -0.6 to 0.02, p=0.04). Because of a lack of statistical heterogeneity among studies, subgroup analyses (e.g., by type of CGM device) were not performed. However, there were some differences among studies; 1 used retrospective CGM and 2 used real-time CGM. Also, there was variability in the frequency of CGM use, making it difficult to determine the optimal frequency of use.

A representative study included in the 2013 meta-analysis evaluated intermittent use of a CGM device in 100 patients with type 2 diabetes who did not use prandial insulin.12,13 Eligible participants were 18 or older, had type 2 diabetes for at least 3 months, and had an initial HbA1c of at least 7% but not more than 12%. The study compared real-time continuous monitoring with the DexCom device used for four 2-week cycles (2 weeks on/1 week off) with SMBG. The primary efficacy outcome was mean change in HbA1c. The mean decline from baseline in HbA1c in the CGM versus the SMBG group was 1.0% versus 0.5% at 12 weeks, 1.2% versus 0.5% at 24 weeks, 0.8% versus 0.5% at 38 weeks, and 0.8% versus 0.2% at 1 year, respectively. Over the course of the study, the reduction in HbA1c was significantly greater than in the SMBG group (p=0.04). After adjusting for
potential confounding variables including age, sex, baseline therapy, and whether the individual started taking insulin during the study, the difference between groups over time remained statistically significant (p<0.001).

Section Summary

There are fewer RCTs on CGM in patients with type 2 diabetes than for patients with type 1 diabetes. Systematic reviews that included 3 to 4 RCTs found that there was variability in the intervention, e.g., type of CGM device, frequency of use and patient populations, e.g., adults and/or children. Although systematic reviews have found a statistically significant benefit of CGM in terms of glycemic control, the small number of RCTs and variability among interventions makes it difficult to identify an optimal approach to CGM use or subgroup of type 2 diabetes patients who might benefit.

Pregnant Women With Diabetes

In 2013, Voormolen et al published a systematic review of the literature on CGM during pregnancy. The authors identified 11 relevant studies (i.e., published in peer-review journals and evaluating the utility of CGM in pregnancy). Two of the studies were RCTs. The 11 studies included a total of 534 women; the largest study was an RCT that had 154 participants. Seven of the studies used retrospective CGM, and the remaining 4 studies used real-time CGM. The authors did not pool study findings; they concluded that evidence is limited on the efficacy of CGM during pregnancy. The 2 published RCTs are described next:

The larger RCT was published in 2013 by Secher et al in Denmark. The investigators randomized 154 women to real-time CGM in addition to routine pregnancy care (n=79) or routine pregnancy care alone (n=75). There were 123 women with type 1 diabetes and 31 with type 2 diabetes. Patients in the CGM group were instructed to use the CGM device for 6 days before each of 5 study visits and were encouraged to use the devices continuously. Participants in both groups were instructed to perform 8 daily self-monitored plasma glucose measurements for 6 days before each visit. Baseline mean HbA1c was 6.6% in the CGM group and 6.8% in the routine care group. The 154 pregnancies resulted in 149 live births and 5 miscarriages. The prevalence of large-for-gestational age infants (at least 90th percentile), the primary study outcome, was 45% in the CGM group and 34% in the routine care group. The difference between groups was not statistically significant (p=0.19). In addition, no statistically significant differences were found between groups for secondary outcomes, including the prevalence of preterm delivery and the prevalence of severe neonatal hypoglycemia. Women in this study had low baseline HbA1c, which might help explain the lack of impact of CGM on outcomes. Other factors potentially contributing to the negative findings include the intensive SMBG routine in both groups and the relatively low compliance rate (64%) in the CGM group with the instruction of use the CGM devices for 6 days before each of 5 study visits.

In 2008, Murphy et al in the U.K. randomized 71 pregnant women with type 1 (n=46) or type 2 (n=25) diabetes to CGM or usual care. The intervention consisted of up to 7 days of CGM at intervals of 4 to 6 weeks between 8 and 32 weeks of gestation. In addition to CGM, the women were advised to measure blood glucose levels at least 7 times a day. Baseline HbA1c was 7.2% (SD=0.9) in the CGM group and 7.4% (SD=1.5) in the usual care group. The primary study outcome was maternal glycemic control during the second and third trimesters. Mean HbA1c levels were consistently lower in the intervention arm, but differences between groups were not statistically significant at any time point. For example, between 28 and 32 weeks’ gestation, mean HbA1c levels were 6.1% (SD=0.60) in the CGM group and 6.4% (SD=0.8) in the usual care group (p=0.10). The prevalence of large-for-gestational age infants (at least 90th percentile) was a secondary outcome.
Thirteen of 37 (35%) infants in the CGM group were large-for-gestational age compared with 18 of 30 (60%) in the usual care group. The odds ratio for reduced risk of a large-for-gestational age infant with CGM was 0.36 (95% CI, 0.13 to 0.98; p=0.05).

Neither RCT found a statistically significant difference in their primary outcome. The Murphy study found a borderline statistically significantly lower rate of large-for-gestational age infants in women who used CGM while pregnant. Taken together, 2 published RCTs on CGM in pregnancy do not provide strong evidence that routine CGM during pregnancy is beneficial. However, it is difficult to draw definitive conclusions from this limited evidence.

Other Diabetic Subgroups

CGM has been proposed for specific diabetic subgroups such as patients with poor diabetic control, as evidenced by recurrent hypoglycemia, hypoglycemia unawareness, postprandial hyperglycemia, and/or recurrent diabetic ketoacidosis. For these groups, CGM provides different types of information than single glucose measurements, such as trends in glucose and rates of change. There is only anecdotal evidence for the efficacy of this approach; there is no high-quality evidence available to evaluate the impact of this approach on health outcomes.

Continuous Glucose Monitoring Systems Integrated With an Insulin Pump

Technology is now available that allows linkage between a CGM device and an insulin pump. In a randomized study of 132 adults and children from France reported in 2009, Raccah et al reported improved HbA1c levels (change in A1c of 0.96% vs. 0.55%, respectively) in patients who were fully protocol compliant for use of an insulin pump integrated with CGMS compared with those using a pump with standard glucose self-monitoring. In 2012, Battelino et al published findings of a multicenter crossover study conducted in several European countries that included 153 children and adults with type 1 diabetes. The study used the MiniMed Paradigm REAL-Time system, which integrates a CGM device and an insulin pump system. Patients were randomized to use of the system for 6 months with the sensor on and 6 months with the sensor off, in random order, with a washout period of 4 months between interventions. Baseline HbA1c ranged from 7.5% to 9.5%. After treatment, mean HbA1c was 8.04% in the sensor on arm and 8.47% in the sensor off arm. The mean difference in HbA1c between groups was -0.43% (95% CI: -0.32% to -0.55%; p<0.001). Neither of the above trials was blinded, and neither compared continuous with intermittent use of the CGM.

Summary of Evidence

The available studies demonstrate that glucose monitoring may improve glucose control in type 1 diabetic patients. However, the data on the impact of long-term continuous glucose monitoring are still limited. Studies such as that of the Juvenile Diabetes Research Foundation suggest that more frequent use of continuous glucose monitors (CGMs) may result in better outcomes, but this finding is not consistent across all available studies. In addition, the magnitude of effect is modest, suggesting that either the efficacy is of a small magnitude or that only a subset of patients benefit from this type of monitoring. Thus, the impact of CGM use on glucose control for the general diabetic population is uncertain, and CGM is considered investigational for the purpose of improving glucose control in the general diabetic population.

CGM provides more data points on glucose levels and also provides information about trends. This additional information is most likely to benefit subgroups of diabetic patients, i.e., those patients with type 1 diabetes who do not have adequate control, including episodes of hypoglycemia, despite use of current best practices including multiple (≥4)
daily checks of blood glucose and use of an insulin pump. Based on the available data and supported by strong clinical input, intermittent, i.e., 72-hour, glucose monitoring may be considered medically necessary in those whose type 1 diabetes is poorly controlled, despite use of best practices.

Using a rationale similar to that just noted for intermittent monitoring, continuous monitoring can also be used in diabetic subpopulations. Continuous glucose monitoring may be considered medically necessary to provide additional data for management of those who have recurrent, unexplained, severe hypoglycemia that puts the patient or others at risk, despite use of current best practices, and also for pregnant patients with type 1 diabetes.

The available literature suggests that CGM systems may improve glycemic control in patients with type 2 diabetes, but too few studies have focused on this population, and it is not clear what subset of patients with type 2 diabetes might benefit from intermittent or continuous glucose monitoring. Due to the limited evidence, use of CGM systems in patients with type 2 diabetes is considered investigational.

**Supplemental Information**

**Practice Guidelines and Position Statements**

In 2014, the American Diabetes Association made the following recommendations concerning continuous glucose monitoring:\(^1\):

- CGM in conjunction with intensive insulin regimens can be a useful tool to lower A1c in selected adults (age at least 25 years) with type 1 diabetes. (Level of evidence A)
- Although the evidence of A1c lowering is less strong in children, teens, and younger adults, CGM may be helpful in those groups. Success correlates with adherence to ongoing use of the device. (Level of evidence C)
- CGM may be a supplemental tool to SMBG in those with hypoglycemic unawareness and/or frequent hypoglycemic episodes. (Level of evidence E)

In 2011, the Endocrine Society published a clinical practice guideline developed by a task force that included the following recommendations on continuous glucose monitoring:\(^2\):

1.0 Real-time continuous glucose monitoring (RT-CGM) in adult hospital settings

1.1 We recommend against the use of RT-CGM alone for glucose management in the intensive care unit or operating room until further studies provide sufficient evidence for its accuracy and safety in those settings.

2.0 Children and adolescent outpatients

2.1 We recommend that RT-CGM with currently approved devices be used by children and adolescents with type 1 diabetes mellitus who have achieved HbA1c levels below 7.0%.

2.2 We recommend RT-CGM devices be used with children and adolescents with type 1 diabetes who have HbA1c levels 7.0% or higher who are able to use these devices on a nearly daily basis.

2.3 We make no recommendations for or against the use of RT-CGM by children with type 1 diabetes who are less than 8 yr of age.
2.4 We suggest that treatment guidelines regarding use of RT-CGM be provided to patients.

2.5 We suggest the intermittent use of CGM systems designed for short-term retrospective analysis in pediatric patients with diabetes in whom clinicians worry about nocturnal hypoglycemia, dawn phenomenon, and postprandial hyperglycemia; in patients with hypoglycemic unawareness; and in patients experimenting with important changes to their diabetes regimen.

3.0 Adult outpatients

3.1 We recommend that RT-CGM devices be used by adult patients with type 1 diabetes who have HbA1c levels of at least 7.0% and who have demonstrated that they can use these devices on a nearly daily basis.

3.2 We recommend that RT-CGM devices be used by adult patients with type 1 diabetes who have HbA1c levels less than 7.0% and who have demonstrated that they can use these devices on a nearly daily basis.

3.3 We suggest that intermittent use of CGM systems designed for short-term retrospective analysis may be of benefit in adult patients with diabetes to detect nocturnal hypoglycemia, the dawn phenomenon, and postprandial hyperglycemia, and to assist in the management of hypoglycemic unawareness and when significant changes are made to their diabetes regimen.

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force has not addressed continuous or intermittent glucose monitoring in patients with diabetes.

Medicare National Coverage

A 2006 national coverage determination (NCD) stated that home blood glucose monitors are covered for patients meeting the following criteria:

- The patient has been diagnosed with diabetes;
- The patient's physician states that the patient is capable of using the device appropriately; and
- The device is designed for home use.

The NCD did not specifically mention continuous versus intermittent use of home blood glucose monitors.

References


Documentation Required for Clinical Review

Initial Request:
- History and physical and/or consultation notes from referring physician including:
  - Type of diabetes and duration, reason for the request
  - Clinical findings supporting inadequate glycemic control
  - Frequency and severity of hypoglycemic episodes or glycemic excursions
  - Insulin therapy adjustments
  - Patient compliance with diabetes management
- Two serial HbA1c lab results, three months apart and prior to the current request
- Documented frequency of glucose self-testing and number of insulin injections per day or self adjustments on an insulin pump (i.e., blood sugar and insulin logs), for the past 30 days

Replacements and/or Repair:
- Clinical summary including:
  - Type of diabetes and insulin management
  - Past benefit from CGM device, including clinical findings
  - Reason for continued need of CGM device
  - Description of device malfunction
- Warranty information and repair log or repair history (if applicable)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<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></td>
<td>95251</td>
<td>Ambulatory continuous glucose monitoring of</td>
</tr>
</tbody>
</table>
### Medical Policy

<table>
<thead>
<tr>
<th>HCPC</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>S1030</td>
<td>Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use cpt code)</td>
</tr>
<tr>
<td>S1031</td>
<td>Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use cpt code)</td>
</tr>
</tbody>
</table>

### ICD-9 Procedure

None

### ICD-10 Procedure

For dates of service on or after 10/01/2015

None

### ICD-9 Diagnosis

All Diagnosis

### ICD-10 Diagnosis

For dates of service on or after 10/01/2015

All Diagnosis

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/23/2000</td>
<td>New Policy Adoption</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>10/10/2003</td>
<td>Policy Revision based on CTAF review</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>5/16/2008</td>
<td>Policy Revision Developed medically necessary position statement for use of CGMS in specific Type 1 Diabetics on an insulin pump. Policy Name changed from Continuous Glucose Monitoring.</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>3/1/2009</td>
<td>Coding Update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>6/26/2009</td>
<td>Policy Revision Policy updated, Medically Necessary criteria added for Long Term CGMS</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>11/4/2009</td>
<td>Coding Update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>10/7/2011</td>
<td>Policy revision with position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>11/12/2012</td>
<td>Policy statement clarification</td>
<td>Administrative Review</td>
</tr>
</tbody>
</table>
Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).

For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.

For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.
The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.