Policy Statement

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 four or more finger sticks each day
  - Use of an insulin pump
- During pregnancy, requiring three 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 of California 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, despite use of best practices:

- Patients with type 1 diabetes who have demonstrated an understanding of the technology, are motivated to use the device correctly and consistently, are expected to adhere to a comprehensive diabetes treatment plan supervised by a qualified provider, and are capable of using the device to recognize alerts and alarms
- Patients with type 1 diabetes mellitus who have recurrent, unexplained, severe hypoglycemia (generally blood glucose levels less than 50 mg/dL), for whom hypoglycemia or impaired awareness of hypoglycemia that puts the patient or others at risk despite compliance with a regimen of four or more finger sticks each day and either of the following:
  - Use of an insulin pump
  - 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 three 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:
  - Unexplained hypoglycemic episodes
  - Hypoglycemic unawareness
  - Suspected postprandial hyperglycemia
  - 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:
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- 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 of California Medical Policy: External Insulin 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:
  - Device can be repaired or refurbished
  - Device is under warranty
  - Documentation of malfunction is not provided (e.g., repair logs, Medical Doctor [MD] notes)

**Policy Guidelines**

Several insulin pump systems (e.g., Paradigm® REAL-Time System) have a built-in continuous glucose monitor (CGM). This policy only evaluates the continuous glucose monitor (CGM); it does not evaluate insulin pumps. Insulin pumps systems with a built-in continuous glucose monitor and a low glucose suspend feature are addressed in Blue Shield of California Medical Policy: Artificial Pancreas Device Systems.

Best practices in diabetes control for patients with diabetes mellitus include compliance with a regimen of four or more fingersticks each day and use of an insulin pump. During pregnancy, three 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 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 over 72-hour periods. It may be repeated subsequently depending on the patient’s level of diabetes control.

The strongest evidence exists for use of continuous glucose monitoring (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 their age.

**Coding**

The language of the CPT codes that specifically described 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; physician-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
- **95251**: Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report
Effective January 1, 2018, the following CPT code specifically describes glucose monitoring on equipment provided by the patient:

- **95249**: Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording

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

HCPCS codes are available specifically for continuous glucose monitoring systems:

- **A9276**: Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = one-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

### Description

Tight glucose control in patients with diabetes has been associated with improved health 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. Devices can be used on an intermittent (short-term) basis or a continuous (long-term) basis.

### Related Policies

- Artificial Pancreas Device Systems
- External Insulin Infusion Pump

### 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]) prohibits 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.

### Regulatory Status

Several CGM systems have been approved by the FDA through the premarket approval process (see Table 1).

### Table 1. CGM Systems Approved by the Food and Drug Administration

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Approval</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous Glucose Monitoring System (CGMS®)</td>
<td>MiniMed</td>
<td>1999</td>
<td>3-d use in physician's office</td>
</tr>
<tr>
<td>GlucoWatch G2® Biographer®</td>
<td></td>
<td>2001</td>
<td></td>
</tr>
<tr>
<td>Device</td>
<td>Manufacturer</td>
<td>Approval</td>
<td>Indications</td>
</tr>
<tr>
<td>--------</td>
<td>--------------</td>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Guardian®-RT (Real-Time) CGMS</td>
<td>Minimed (now Medtronic)</td>
<td>2005</td>
<td>System integrates a CGM with a Paradigm insulin pump</td>
</tr>
<tr>
<td>Dexcom® STS CGMS System</td>
<td>Dexcom</td>
<td>2006</td>
<td></td>
</tr>
<tr>
<td>Paradigm® REAL-Time System</td>
<td>Minimed (now Medtronic)</td>
<td>2006</td>
<td>Adults ≥18 y; can be worn for up to 7 d;</td>
</tr>
<tr>
<td>(second generation called Paradigm Revel System)</td>
<td></td>
<td></td>
<td>Expanded use to include patients with diabetes 2-17 y</td>
</tr>
<tr>
<td>FreeStyle Navigator® CGM System</td>
<td>Abbott</td>
<td>2008</td>
<td></td>
</tr>
<tr>
<td>Dexcom® G4 Platinum</td>
<td>Dexcom</td>
<td>2012, 2014</td>
<td>Replacement for fingerstick blood glucose testing in patients ≥2 y. System requires at least 2 daily fingerstick tests for calibration purposes, but additional fingersticks are not necessary because treatment decisions can be made based on device readings.</td>
</tr>
<tr>
<td>Dexcom® G5 Mobile CGM</td>
<td></td>
<td>2016</td>
<td></td>
</tr>
</tbody>
</table>

CGM: continuous glucose monitoring.

FDA product codes: MDS, PQF.

**Rationale**

**Background**

The advent of blood glucose monitors for use by patients in the home revolutionized the management of diabetes. Using fingersticks, patients can monitor their blood glucose levels 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 level in the range of 7%, is now considered standard of care for diabetic patients. Randomized controlled trials assessing tight control have demonstrated benefits for patients with type 1 diabetes in decreasing microvascular complications. The impact of tight control on type 1 diabetes and on macrovascular complications such as stroke or myocardial infarction is less certain.

Tight glucose control requires multiple daily measurements of blood glucose (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. Hypoglycemia is known to be a risk in patients with type 1 diabetes. While patients with insulin-treated type 2 diabetes may also experience severe hypoglycemic episodes, there is a lower relative likelihood of severe hypoglycemia compared to patients with type 1 diabetes.1,2 An additional limitation of periodic self-measurements of blood glucose is that glucose levels 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 hemoglobin A1c values.

Recently, measurements of glucose in interstitial fluid have been developed as a technique to measure glucose values automatically throughout the day, producing data that show the trends in glucose levels. Although devices measure glucose in interstitial fluid on a periodic rather than a continuous basis, this type of monitoring is referred to as continuous glucose monitoring (CGM).
Several devices have received approval from the U.S. Food and Drug Administration (FDA). The first approved devices were the Continuous Glucose Monitoring System (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 by electric current (referred to as reverse iontophoresis).

Devices subsequently approved include those for pediatric use and those with, e.g., more advanced software, more frequent measurements of glucose levels, or more sophisticated alarm systems. Devices initially measured interstitial glucose every 5 to 10 minutes and stored data for download and retrospective evaluation by a clinician. With currently available devices, the intervals at which interstitial glucose is measured ranges from every 1 to 2 minutes to 5 minutes and most provide measurements in real-time directly to patients. While CGM potentially eliminates or decreases the number of required daily fingersticks, it should be noted that, according to the FDA labeling, monitors are not intended as an alternative to traditional self-monitoring of blood glucose levels but rather as adjuncts to monitoring, supplying additional information on glucose trends not available from self-monitoring. In addition, devices may be used intermittently (i.e., for periods of 72 hours) or continuously (i.e., on a long-term basis). In addition to stand-alone continuous glucose monitors, several insulin pump systems have a built-in CGM. This evidence review addresses CGM devices, not the insulin pump portion of these systems.

Literature Review
This evidence review was created in August 2000 and it incorporated findings of a TEC Assessment published in 2003. The most recent literature review was performed through April 25, 2017.

Most of our discussion focuses on the clinical utility of continuous glucose monitoring (CGM) systems. That is, their ability either to provide additional information on glucose levels, leading to improved glucose control, or to improve the morbidity and 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 overall diabetes management. Data on patients with types 1 or 2 diabetes are discussed separately. The following is a summary of the key literature to date.

Type 1 Diabetes
This evidence review assesses RCTs that have reported on outcomes of CGM devices. We categorized CGM devices as continuous, long-term, monitoring devices by the patient to direct insulin regimens, and intermittent (i.e., 72 hour), short-term monitoring used by the provider to optimize management.

The evidence review combines discussion of the first 2 indications because several of the systematic reviews and RCTs provided information relevant to both indications. Separate section summaries address each indication.

Continuous Glucose Monitoring Devices for Long-Term Use
Systematic Reviews
A number of systematic reviews and meta-analyses of RCTs evaluating CGM for long-term, daily use in treating type 1 diabetes have been published. These systematic reviews have focused on slightly different populations, and some did not separate long-term CGM from intermittent glucose monitoring. The most recent meta-analysis, which was also the only analysis that used individual patient data, was published by Benkhadra et al in 2017. The meta-analysis evaluated data from 11 RCTs that enrolled patients with type 1 diabetes and compared real-time CGM to a control intervention. Studies in which patients used insulin pumps or received multiple daily insulin injections were included. Reviewers contacted corresponding study authors requesting individual patient data; data were not obtained for 1 trial. Mean baseline hemoglobin A1c
(HbA₁c) levels were 8.2% in adults and 8.3% in children and adolescents. The overall risk of bias in the studies was judged to be moderate. In pooled analyses, there was a statistically significantly greater decrease in HbA₁c levels with real-time CGM vs control conditions. Overall, the degree of difference between groups was 0.26%. In subgroup analyses by age, there was significantly greater change in HbA₁c levels among individuals 15 years and older, but not among the younger age groups. There were no significant differences between groups in the time spent in hypoglycemia or in the incidence of hypoglycemic events. Key findings are shown in Table 2.

### Table 2. Main Findings From a 2017 Individual Patient Data Meta-Analysis on Real-Time CGM

<table>
<thead>
<tr>
<th>No. of Trials</th>
<th>N</th>
<th>Outcomes</th>
<th>Point Value</th>
<th>95% Confidence Intervals</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change in HbA₁c levels, %</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>1371</td>
<td>Overall</td>
<td>-0.258</td>
<td>0.464 to -0.052</td>
<td>0.014</td>
</tr>
<tr>
<td>7</td>
<td>902</td>
<td>Age &gt;15 y</td>
<td>-0.356</td>
<td>0.551 to -0.160</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>7</td>
<td>178</td>
<td>Age 13-15 y</td>
<td>-0.039</td>
<td>-0.320 to 0.242</td>
<td>0.787</td>
</tr>
<tr>
<td>7</td>
<td>291</td>
<td>Age ≤12 y</td>
<td>-0.047</td>
<td>0.217 to 0.124</td>
<td>0.592</td>
</tr>
<tr>
<td><strong>Time spent in hypoglycemia &lt;60 mg/dL, min</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>706</td>
<td>Overall</td>
<td>-8.549</td>
<td>-31.083 to 13.985</td>
<td>0.457</td>
</tr>
<tr>
<td>4</td>
<td>467</td>
<td>Age &gt;15 y</td>
<td>-8.095</td>
<td>-32.615 to 16.425</td>
<td>0.518</td>
</tr>
<tr>
<td>3</td>
<td>109</td>
<td>Age 13-15 y</td>
<td>-13.966</td>
<td>31.782 to 3.852</td>
<td>0.124</td>
</tr>
<tr>
<td>3</td>
<td>130</td>
<td>Age ≤12 y</td>
<td>-9.366</td>
<td>19.898 to 1.167</td>
<td>0.081</td>
</tr>
<tr>
<td><strong>Incidence of hypoglycemic events &lt;70 mg/dL, mean no. events</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>351</td>
<td>Overall</td>
<td>0.051</td>
<td>-0.314 to 0.416</td>
<td>0.785</td>
</tr>
<tr>
<td>3</td>
<td>277</td>
<td>Age &gt;15 y</td>
<td>0.074</td>
<td>-0.517 to 0.368</td>
<td>0.742</td>
</tr>
<tr>
<td>2</td>
<td>47</td>
<td>Age 13-15 y</td>
<td>0.536</td>
<td>0.243 to 1.316</td>
<td>0.177</td>
</tr>
<tr>
<td>2</td>
<td>27</td>
<td>Age ≤12 y</td>
<td>0.392</td>
<td>0.070 to 0.854</td>
<td>0.097</td>
</tr>
</tbody>
</table>

CGM: continuous glucose monitoring; HbA₁c: hemoglobin A₁c.

A systematic review by Yeoh et al (2015) addressed a broad range of interventions to restore hypoglycemia awareness in adults with type 1 diabetes (i.e., educational, technologic, and pharmacologic interventions) and did not identify any RCTs focusing on CGM for hypoglycemia unawareness.

Earlier meta-analyses of glucose monitoring devices for type 1 diabetes tended to combine studies of intermittent glucose monitoring with studies of long-term CGM. Several reported separate subgroup analyses for long-term CGM. A 2012 Cochrane review of CGM in type 1 diabetes in adults and children included RCTs comparing CGM with conventional self-monitored blood glucose (SMBG). In pooled analysis (6 studies; n=963 patients) of studies of long-term CGM, the average decline in HbA₁c levels 6 months after baseline was statistically significantly larger for CGM users than for SMBG users (mean difference [MD] change, -0.2% 95% confidence interval [CI], -0.4% to -0.1%), but there was no difference in decline in HbA₁c levels at 12 months (1 study, n=154 patients; MD change, 0.1; 95% CI, -0.5 to 0.7). In a meta-analysis of 4 RCTs (n=689 patients), there was no significant difference in the risk of severe hypoglycemia between CGM and SMBG users and the confidence interval for the relative risk (RR) was wide (RR=1.05; 95% CI, 0.63 to 1.77), indicating lack of precision in estimating the effect of CGM on hypoglycemia risk. Reviewers were unable to compare longer term change in HbA₁c levels or hypoglycemia outcomes for real-time CGM. Trials reporting results by compliance subgroups found larger treatment effects in highly compliant patients.

A 2011 systematic review of RCTs on CGM included trials conducted in adults and children with type 1 diabetes. Reviewers selected studies having a minimum of 12 weeks of follow-up and requiring patients be on intensive insulin regimens. Studies compared CGM to SMBG; there was no restriction on type of CGM device, but CGM readings had to be used to adjust insulin dose or modify diet. Fourteen RCTs met eligibility criteria. Study durations ranged from 3 to 6 months. Baseline mean HbA₁c levels ranged from 6.4% to 10%. Five included studies found a statistically significant decrease in HbA₁c levels favoring CGM, while 9 did not. In a pooled analysis, there was a statistically significant reduction in HbA₁c levels with CGM compared with SMBG (weighted mean difference [WMD], -0.26%; 95% CI, -0.34% to -0.19%). For the subgroup of 7 studies that reported on long-term CGM, this difference was statistically significant (WMD = -0.26; 95% CI, -
0.34 to -0.18). In a subgroup analysis by age, there were significant reductions in HbA1c levels 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). Four of the studies provided data on the frequency of hypoglycemic episodes. Pooled results showed a significant reduction in hypoglycemic events for CGM vs SMBG (standardized mean difference, -0.32; 95% CI, -0.52 to -0.13). In 5 studies reporting the percentage of patients with severe hypoglycemic episodes, there were no differences in the percentage of patients with severe hypoglycemic episodes using CGM and SMBG in any of them.

**Randomized Controlled Trials**

Recent RCTs not included in the meta-analyses are described next.

Van Beers et al (2016) published a crossover RCT comparing CGM with SMBG and focusing on patients with impaired hypoglycemia awareness. Eligible patients were 18 to 75 years old, were treated with insulin infusion pumps or multiple daily insulin injections, undertook at least 3 SMBG measurements per day, and had impaired awareness of hypoglycemia (i.e., Gold score ≥4). The trial used an artificial pancreas device system without using the low glucose suspend feature. After a 6-week run-in phase (during which patients received education about diabetes management), 52 patients received both 16 weeks of CGM and 16 weeks of SMBG, in random order. There was a 12-week washout period between interventions. All patients were included in the primary intention-to-treat analysis. Six patients withdrew from the study early.

The primary outcome, time spent in normoglycemia (4-10 mmol/L), was significantly higher in the CGM phase than in the SMBG phase. The percentage of time spend in normoglycemia was 65.0% in the CGM phase and 55.4% in the SMBG group (MD=9.6%; p<0.001). The sequence allocation did not have an effect on the primary end point. Most other CGM-derived outcomes (e.g., number and duration of nocturnal hypoglycemia events) also significantly favored the CGM group. The total number of severe hypoglycemic events (i.e., those needing third-party assistance) was 14 in the CGM phase and 34 in the SMBG phase, which differed significantly between groups (p=0.033). The number of patients with 1 or more severe hypoglycemic event during the intervention period, however, did not differ significantly between phases 10 in the CGM phase and 18 in the SMBG phase (p=0.062). HbA1c outcomes did not differ significantly; e.g., change in HbA1c levels from baseline was -0.1% in both phases (p=0.449). In terms of hypoglycemia awareness, one of 4 variables, Gold score at the study end point differed significantly (mean, 4.6 for the CGM phase vs 5.0 for the SMBG phase, p=0.035); 3 other variables related to hypoglycemia awareness did not differ between groups.

Two 2017 RCTs evaluated long-term CGM in patients with type 1 diabetes treated with multiple daily insulin injections. Both trials used the Dexcom G4 CGM device. Lind et al (2017) reported on a crossover study with 142 adults ages 18 and older who had baseline HbA1c levels of 7.5% or higher (mean baseline HbA1c level, ≈8.5%). There was a 6-week run-in period using a CGM device with masked data and patients were excluded from further participation if they did not believe they would use the device more than 80% of the time or did not perform an adequate number of calibrations during the run-in period. Enrolled patients underwent 26-week treatment periods with a CGM device and conventional therapy using SMBG, in random order. There was a 17-week washout period between intervention phases. The primary end point was the difference in HbA1c levels at the end of each treatment period. Mean HbA1c levels were 7.9% during CGM use and 8.4% during conventional therapy (mean difference, -0.4% p<0.01). There were a large number of secondary end points. A portion of them were prespecified and analyses took into consideration the statistical impact of multiple comparisons; the remaining secondary outcomes were considered descriptive and p values were not reported. Among the prespecified secondary outcomes, treatment satisfaction (measured by the Diabetes Treatment Satisfaction Questionnaire) was significantly higher in the CGM phase than in the conventional treatment phase (p<0.001). Hypoglycemia outcomes were secondary descriptive outcomes. There was 1 (0.7%) severe hypoglycemic event during the CGM phase and 5 (3.5%) events...
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Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

Section Summary: Continuous Glucose Monitoring Devices for Long-Term Use in Type 1 Diabetes

Numerous RCTs and several systematic reviews of RCTs have evaluated CGM in patients with type 1 diabetes. A 2017 individual patient data analysis, using data from 11 RCTs, found that reduction in HbA1c levels was significantly greater with real-time CGM compared with a control intervention. In addition, a 2012 meta-analysis of 6 RCTs found a significantly larger decline in HbA1c levels at 6 months in CGM users than in the SMBG group. There are few studies beyond 6 months. Two recent RCTs in patients who used multiple daily insulin injections and were highly compliant with CGM devices during run-in phases found that CGM was associated with a larger reduction in HbA1c levels than previous studies. Reductions were 0.4% and 0.6%, respectively, compared with approximately 0.2% to 0.3% in previous analyses. One of the 2 RCTs prespecified hypoglycemia-related outcomes, and time spent in hypoglycemia was significantly less in the CGM group.

Section Summary: Continuous Glucose Monitoring Devices for Long-Term Use in Type 1 Diabetes and Impaired Hypoglycemia Awareness and/or History of Recurrent Unexplained Severe Hypoglycemia

Although meta-analyses of RCTs on CGM have generally not shown a significant difference in hypoglycemia outcomes between CGM and SMBG, those RCTs included a variety of patients and did not focus in patients at highest risk of hypoglycemia. A 2016 crossover RCT included only patients with impaired awareness of hypoglycemia and found significantly improved hypoglycemia outcomes during the phase that a long-term CGM device was used compared with SMBG. Findings from this trial can be extrapolated to a related group of patients at increased risk of severe hypoglycemia—those patients with a history of recurrent, severe unexplained hypoglycemia.

Glucose Monitoring Devices for Short-Term (Intermittent) Use

Meta-analyses of glucose monitoring devices for type 1 diabetes tend to combine studies of intermittent glucose monitoring with studies of long-term CGM. For this body of evidence, there is variability in the definitions of intermittent monitoring and the specific monitoring protocols used. In addition, many of the trials of intermittent monitoring have included additional interventions to optimize glucose control (e.g., education, lifestyle modifications).

Two meta-analyses were identified that reported separate subgroup analyses for intermittent monitoring. In the 2012 Cochrane review, 4 studies (total N=216 patients) compared real-time intermittent glucose monitoring systems to SMBG, and the pooled effect estimate for change in
HbA1c levels at 3 months was not statistically significant (MD change, -0.18; 95% CI, -0.42 to 0.05). The 2011 meta-analysis of RCTs on CGM (described previously) also included a separate analysis of 8 RCTs of intermittent monitoring. On pooled analysis, there was a statistically significant reduction in HbA1c levels with intermittent glucose monitoring compared with SMBG (WMD = -0.26; 95% CI, -0.45 to -0.06).

The largest RCT was the 2009 Management of Insulin-Treated Diabetes Mellitus (MITRE) trial, published by Newman et al; it evaluated whether use of the additional information provided by minimally invasive glucose monitors improved glucose control in patients with poorly controlled insulin-requiring diabetes. This 4-arm RCT was conducted at secondary care diabetes clinics in 4 hospitals in England. This trial enrolled 404 people over the age of 18 years, with insulin-treated diabetes (types 1 or 2) for at least 6 months, who were receiving 2 or more injections of insulin daily. Most (57%) participants had type 1 diabetes (41% had type 2 diabetes, 2% were classified as “other”). Participants had to have 2 HbA1c values of at least 7.5% in the 15 months before trial 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 glucose monitoring was used (i.e., monitoring was performed over several days at various points in the trial). 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 levels from baseline to 3, 6, 12, and 18 months was the primary indicator of short- to long-term efficacy. At 18 months, all groups demonstrated a decline in HbA1c levels from baseline. Mean percentage changes in HbA1c levels 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 groups at any 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 for 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 trial of unselected patients, glucose monitoring (CGMS on an intermittent basis) did not lead to improved clinical outcomes.

Section Summary: Glucose Monitoring Devices for Short-Term (Intermittent) Use in Type 1 Diabetes
For short-term (intermittent) monitoring of type 1 diabetes, there are few RCTs and systematic reviews. Some trials have reported improvements in glucose control for the intermittent monitoring group, but limitations in this body of evidence preclude conclusions. The definitions of intermittent control and the specific monitoring protocols varied. In some studies, intermittent monitoring was part of a larger strategy aimed at optimizing glucose control, and the impact of monitoring cannot be separated from the impact of other interventions.

Type 2 Diabetes
Two systematic reviews (previously described) also reported on the efficacy of CGM in patients with type 2 diabetes. Gandhi et al (2011) identified 3 RCTs studying patients with type 2 diabetes (1 study included both types of diabetes). There was a mix of patients with type 2 diabetes who did and did not require insulin. Two of the 3 trials evaluated retrospective CGM of different lengths and durations and the third evaluated real-time intermittent CGM. Patients in the trials had baseline HbA1c levels greater than 8%. In a meta-analysis of the 3 trials, there was a statistically significant reduction in HbA1c levels 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 evaluating adults with type 2 diabetes. Three trials in Poolsup overlapped with those of Gandhi; the remaining trial also evaluated real-time CGM but with a longer period of use (2 weeks on and 1 week off for 3 months). In a pooled analysis, CGM had greater efficacy in terms of HbA1c levels than SMBG. The pooled mean difference in HbA1c level 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.
Ehhardt and colleagues published 2 studies (2011, 2012) reporting on the largest sample size (N=100) in the Poolsup systematic review (accounting for 45% of the weight in the pooled analysis of HbA1c levels). The trial evaluated intermittent use of a CGM device in adults with type 2 diabetes treated with diet/exercise and/or glycemia-lowering medications but not prandial insulin who had an initial HbA1c level of at least 7% but not more than 12%. The study compared real-time CGM 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 levels. Mean (SD) HbA1c levels in the CGM group were 8.4% (1.5%) at baseline, 7.4% (1.0%) at 12 weeks, 7.3% (1.1%) at 24 weeks, and 7.7% (1.1%) at 52 weeks. In the SMBG group, these values (SD) were 8.2% (1.1%) at baseline, 7.7% (1.2%) at 12 weeks, 7.6% (1.3%) at 24 weeks, and 7.9% (1.4%) at 52 weeks. During the study, the reduction in HbA1c levels was significantly greater in the CGM group than in the SMBG group (p=0.04). After adjusting for potential confounders (e.g., age, sex, baseline therapy, whether the individual started taking insulin during the study), the difference between groups over time remained statistically significant (p<0.001). The investigators also evaluated SMBG results for both groups. The mean proportions of SMBG tests less than 70 mg/dL were 3.6% in the CGM group and 2.5% in the SMBG group (p=0.06).

A 2016 RCT, published by Sato et al, included 34 patients with type 2 diabetes who were at least 20 years old and on insulin injection therapy, had HbA1c levels between 6.9% and 11.0% during the previous 3 months, with HbA1c fluctuations within 0.5%. All patients conducted SMBG and used CGM devices that do not have data available in real-time (i.e., data are viewed retrospectively by physicians). Devices were used for 4 to 5 days before each of 3 clinic visits, 2 months apart. At clinic visits, patients were evaluated and suggestions made to improve glucose control by lifestyle changes and by changing medication doses. In the intervention group, but not the control group, patients and physicians had access to CGM data at the clinic visits. The primary end point was change in HbA1c levels from baseline, which did not differ significantly between groups at the end of the trial, between the first and second visits, or between the second and third visits. HbA1c levels changed little in either group. In the intervention group, the mean (SD) baseline HbA1c level was 8.2% (1.2%) and the mean final HbA1c level was also 8.2% (1.3%). Comparable percentages in the control group were 8.2% (0.9%) and 7.9% (0.8%). In this trial, conducted in Japan, decisions on medication doses were made only by the physician at clinic visits and practices may differ in other countries.

**Section Summary: Type 2 Diabetes**

There are fewer RCTs assessing CGM in patients with type 2 diabetes than in patients with type 1. Systematic reviews of 3 to 4 trials found statistically significant benefits of CGM in terms of glycemic control. However, the degree of HbA1c reduction and the difference in HbA1c reduction between groups may not be clinically significant. In addition, the small number of RCTs and variability among interventions make it difficult to identify an optimal approach to CGM use or subgroup of type 2 diabetes patients who might benefit. Moreover, studies of CGM in patients with type 2 diabetes generally do not address the clinically important issue of severe hypoglycemia.

**Pregnant Women with Diabetic Complications**

In 2013, Voormolen et al published a systematic review of the literature on CGM during pregnancy. They identified 11 relevant studies. Two were RCTs. The 11 studies included a total of 534 women; the largest was an RCT (N=154). Seven used CGMs that do not have data available in real-time; the remaining 4 studies used real-time CGM. Reviewers did not pool study findings; they concluded that the evidence was 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 with type 1 (n=123) and type 2 (n=31) diabetes to real-time CGM in addition to routine pregnancy care (n=79) or routine pregnancy care alone (n=75). 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 levels were 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 trial had low baseline HbA1c levels, which might explain the lack of impact of CGM on outcomes. Other factors potentially contributing to the negative findings included the intensive SMBG routine in both groups and the relatively low compliance rate (64%) in the CGM group.

In 2008, Murphy et al in the U.K. randomized 71 pregnant women with type 1 ($n=46$) and 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 weeks 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 (SD) levels were 7.2% (0.9%) in the CGM group and 7.4% (1.5%) in the usual care group. The primary study outcome was maternal glycemic control during the second and third trimesters. Mean HbA1c (SD) levels were consistently lower in the intervention arm, but differences between groups were not statistically significant at any time point. For example, between 28 weeks and 32 weeks of gestation, mean HbA1c levels were 6.1% (0.6%) in the CGM group and 6.4% (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 (35%) of 37 infants in the CGM group were large-for-gestational age compared with 18 (60%) of 30 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; $p=0.05$).

In addition, Wei et al (2016) published an RCT on CGM evaluating 120 women with gestational diabetes at 24 to 28 weeks. Patients were allocated to prenatal care plus CGM ($n=58$) or to SMBG ($n=62$). The investigators assessed a number of end points and did not specify primary outcomes; a significance level of $p$ less than 0.05 was used for all outcomes. The groups did not differ significantly in change in most outcomes, including change in maternal HbA1c, levels, rates of preterm delivery before the 35th gestational week, cesarean delivery rates, proportions of large-for-gestational age infants, or rates of neonatal hypoglycemia. Women in the CGM group gained significantly less weight than those in the SMBG group.

**Section Summary: Pregnant Women with Diabetic Complications**

Only a few RCTs have been published on use of CGM in pregnancies complicated by diabetes. Two of 3 RCTs that assessed large-for-gestational age infants as a primary or a secondary outcome did not find significantly lower rates in women who used CGM. Other outcomes, such as maternal glycemic control and neonatal hypoglycemia, tended not to be significantly improved with CGM.

**Summary of Evidence**

For individuals who have type 1 diabetes who are willing and able to use the device, and have adequate medical supervision, who receive long-term continuous glucose monitoring (CGM), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Systematic reviews have generally found that, at least in the short-term, long-term CGM resulted in significantly improved glycemic control for adults and children with type 1 diabetes, particularly highly compliant patients. Recently published evidence has further demonstrated a clinically meaningful and significant benefit for use of long-term CGM in type 1 diabetics particularly for appropriately selected patients who are expected to adhere to use of the CGM. A 2017 individual patient data analysis, using data from 11 RCTs, found that reduction in hemoglobin A1c (HbA1c) levels was significantly greater with real-time CGM compared with a
control intervention. Two newly added RCTs in patients who used multiple daily insulin injections and were highly compliant with CGM devices during run-in phases found that CGM was associated with a larger reduction in HbA1c levels than previous studies. One of the 2 RCTs prespecified hypoglycemia-related outcomes and reported that time spent in hypoglycemia was significantly less in the CGM group. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have type 1 diabetes and impaired hypoglycemia awareness and/or a history of recurrent unexplained severe hypoglycemia who receive long-term CGM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Although meta-analyses of RCTs on CGM have generally not shown a significant difference in hypoglycemia outcomes between CGM and self-monitored blood glucose, those RCTs included a variety of patients and did not focus on patients at highest risk of hypoglycemia. A recently added 2016 crossover RCT that included only patients with impaired awareness of hypoglycemia found significantly improved hypoglycemia outcomes during the phase that a long-term CGM device was used compared with self-monitored blood glucose. Findings from this trial can be reasonably extrapolated to a related group of patients at increased risk of severe hypoglycemia (i.e., patients who have a history of recurrent, severe unexplained hypoglycemia) who would benefit from long-term CGM with alerts to provide earlier recognition of hypoglycemia to guide management that may improve health outcomes through avoided, reduced or less severe episodes of hypoglycemia. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have type 1 diabetes who receive short-term (intermittent) glucose monitoring, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. The evidence for intermittent short-term monitoring on glycemic control is mixed, and there is no definite improvement in HbA1c levels. Studies have not shown an advantage for intermittent glucose monitoring in reducing severe hypoglycemia events, but the number of events reported is generally small and effect estimates imprecise. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have type 2 diabetes who receive long-term CGM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Systematic reviews of 3 to 4 RCTs have found statistically significant benefits from CGM in terms of glycemic control. However, the degree of HbA1c reduction and the difference in HbA1c reduction between groups may not be clinically significant. In addition, the small number of RCTs and variability among interventions make it difficult to identify an optimal approach to CGM or subgroup of type 2 diabetes patients who might benefit. Moreover, studies of CGM in patients with type 2 diabetes have generally not addressed the clinically important issue of severe hypoglycemia. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are pregnant with diabetic complications who receive long-term CGM, the evidence includes several RCTs. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Only a few RCTs have been published on CGM in pregnancies complicated by diabetes. Two of 3 RCTs that assessed large-for-gestational age infants as a primary or a secondary outcome did not find a significantly lower rate of larger infants delivered by women who used CGM. Other outcomes (e.g., maternal glycemic control, neonatal hypoglycemia) tended not to be significantly improved with CGM. The evidence is insufficient to determine the effects of the technology on health outcomes.
Supplemental Information
Clinical Input from Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received from 1 physician specialty society and 4 academic medical centers in 2008. Those providing input concurred that continuous glucose monitoring, particularly intermittent glucose monitoring, was helpful in a subset of patients with diabetes. Reviewers commented that this monitoring can improve diabetes care by reducing glucose levels (and improving hemoglobin A1c levels) and/or by reducing episodes of hypoglycemia. Reviewers argued that there is persuasive data from case reports to demonstrate the positive impact of intermittent glucose monitoring.

Practice Guidelines and Position Statements
American Association of Clinical Endocrinologists and American College of Endocrinology
In 2016, the American Association of Clinical Endocrinologists and American College of Endocrinology published a consensus statement on outpatient glucose monitoring.24 Their recommendations on continuous glucose monitoring (CGM) included:

Type 1 diabetes, adults: “CGM recommended, especially 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 diabetes, children: Same as adults, except that more training and follow-up are needed.

Type 2 diabetes receiving insulin, sulfonylureas, or glinides: “Data on CGM in T2DM [type 2 diabetes mellitus] are limited at this time. Trials assessing the use of CGM in T2DM are ongoing.”

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence updated its guidance on diagnosis and management of type 1 diabetes in adults in 2016.25 The guidance stated that real-time CGM should not be offered routinely to adults with type 1 diabetes but that it can be considered in the following:

1.6.21 Do not offer real-time continuous glucose monitoring routinely to adults with type 1 diabetes.
1.6.22 ...adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimized use of insulin therapy and conventional blood glucose monitoring:
  • More than 1 episode a year of severe hypoglycemia with no obviously preventable precipitating cause
  • Complete loss of awareness of hypoglycemia
  • Frequent (more than 2 episodes a week) asymptomatic hypoglycemia that is causing problems with daily activities
  • Extreme fear of hypoglycemia
  • Hyperglycemia (HbA1c [hemoglobin A1c] 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.

American Diabetes Association
The 2017 American Diabetes Association position statement on diabetes includes the following recommendations on CGM (see Table 3).26
Table 3. Recommendations on Diabetes Care

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“When used properly, continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens is a useful tool to lower A1C in selected adults (aged ≥25 years) with type 1 diabetes.”</td>
<td>A</td>
</tr>
<tr>
<td>“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.”</td>
<td>B</td>
</tr>
<tr>
<td>“CGM may be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes.”</td>
<td>C</td>
</tr>
</tbody>
</table>

LOE: level of evidence.

\* LOE: A: clear evidence from well-conducted, generalizable RCTs that are adequately powered; B: supportive evidence from well-controlled cohort studies; C: supportive evidence from poorly controlled or uncontrolled studies.

The Association also recommended that physicians assess individual readiness prior to prescribing CGM and that education, training, and support were needed for optimal CGM device implementation.

**Endocrine Society**

In 2016, the Endocrine Society published clinical practice guidelines that included the following recommendations on CGM:

6. Real-time continuous glucose monitors in adult outpatients
   6.1 We recommend real-time continuous glucose monitoring (RT-CGM) devices for adult patients with T1DM [type 1 diabetes mellitus] who have A1C levels above target and who are willing and able to use these devices on a nearly daily basis.
   6.2 We recommend RT-CGM devices for adult patients with well-controlled T1DM who are willing and able to use these devices on a nearly daily basis.

Use of continuous glucose monitoring in adults with type 2 diabetes mellitus

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

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

In January 2017, the Centers for Medicare & Medicaid Services (CMS) issued a ruling that CGM devices approved by the Food and Drug Administration that can be used to make treatment decisions are considered durable medical equipment. To date, 1 device has met these criteria, the Dexcom G5.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01787903*</td>
<td>The Effects of Real-time Continuous Glucose Monitoring on Glycemia and Quality of Life in Patients with Type 1 Diabetes Mellitus and Impaired Hypoglycemia Awareness</td>
<td>52</td>
<td>Apr 2016 (ongoing)</td>
</tr>
<tr>
<td>NCT02671968*</td>
<td>Real-Time Continuous Glucose Monitoring (RT-CGM) in Patients with Type 1 Diabetes at High Risk for Low Glucose Values Using Multiple Daily Injections (MDI) in Germany (HYPODE-STUDY)</td>
<td>190</td>
<td>Dec 2017</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

\* Denotes industry-sponsored or cosponsored trial.


**Documentation for Clinical Review**

**Please provide the following documentation (if/when requested):**

**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 including baseline A1C
  - Frequency and severity of hypoglycemic episodes or glycemic excursions
  - Insulin therapy adjustments
  - Patient compliance with diabetes management
- 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
1.01.20 Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

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)

Post Service
- Results/reports of tests performed

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product 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 services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be 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>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, calibration of monitor, patient training, and printout of recording (Code effective 1/1/2018)</td>
</tr>
<tr>
<td></td>
<td>95250</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording (Code revision effective 1/1/2018)</td>
</tr>
<tr>
<td></td>
<td>95251</td>
<td>Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report (Code revision effective 1/1/2018)</td>
</tr>
<tr>
<td></td>
<td>99091</td>
<td>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 health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time</td>
</tr>
<tr>
<td>HCPCS</td>
<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></td>
<td>A9277</td>
<td>Transmitter; external, for use with interstitial continuous glucose monitoring system</td>
</tr>
<tr>
<td></td>
<td>A9278</td>
<td>Receiver (monitor); external, for use with interstitial continuous glucose monitoring system</td>
</tr>
<tr>
<td></td>
<td>K0553</td>
<td>Supply allowance for therapeutic continuous glucose monitor (CGM) system, includes all supplies and accessories, 1-month supply = 1 unit of service</td>
</tr>
</tbody>
</table>
Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>K0554</td>
<td>Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system</td>
</tr>
<tr>
<td></td>
<td>S1030</td>
<td>Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)</td>
</tr>
<tr>
<td></td>
<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-10 Procedure  None

ICD-10 Diagnosis All Diagnoses

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>
</tr>
</thead>
<tbody>
<tr>
<td>02/23/2000</td>
<td>New Policy Adoption</td>
</tr>
<tr>
<td>10/10/2003</td>
<td>Policy Revision based on CTAF review</td>
</tr>
<tr>
<td>05/16/2008</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>
</tr>
<tr>
<td>03/01/2009</td>
<td>Coding Update</td>
</tr>
<tr>
<td>06/26/2009</td>
<td>Policy Revision Policy updated, Medically Necessary criteria added for Long Term CGMS</td>
</tr>
<tr>
<td>11/04/2009</td>
<td>Coding Update</td>
</tr>
<tr>
<td>10/07/2011</td>
<td>Policy revision with position change</td>
</tr>
<tr>
<td>11/12/2012</td>
<td>Policy statement clarification</td>
</tr>
<tr>
<td>06/28/2013</td>
<td>Policy revision with position change</td>
</tr>
<tr>
<td>09/30/2014</td>
<td>Policy title change from Continuous Glucose Monitoring System Policy revision with position change</td>
</tr>
<tr>
<td>11/26/2014</td>
<td>Policy statement clarification</td>
</tr>
<tr>
<td>01/01/2015</td>
<td>Coding Update</td>
</tr>
<tr>
<td>02/27/2015</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>10/30/2015</td>
<td>Documentation Required Update</td>
</tr>
<tr>
<td>09/01/2016</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>07/01/2017</td>
<td>Coding update</td>
</tr>
<tr>
<td>11/01/2017</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>02/01/2018</td>
<td>Coding update</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 (as applicable to your plan)

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 be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.