Medical Policy

BlueCross BlueShield of Kansas
An Independent Licensee of the Blue Cross and Blue Shield Association

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

Professional
Original Effective Date: June 27, 2001
Revision Date(s): September 3, 2003; January 26, 2004; April 21, 2005; November 2, 2006; July 17, 2007; September 3, 2008
Current Effective Date: September 9, 2009

Institutional
Original Effective Date: July 1, 2005
Revision Date(s): November 2, 2006; July 17, 2007, September 3, 2008
Current Effective Date: September 9, 2009

DESCRIPTION

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. The importance of tight diabetic control has been validated over the past 10 years by several published randomized clinical trials, which have demonstrated that decreasing diabetic complications are associated with tight glucose control, defined as a hemoglobin A1c measurement of less than 7%.

However, tight glucose control may require 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'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 of 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. These measurements use implanted temporary sensors in the subcutaneous tissues. While the time intervals at which interstitial glucose is measured range from every 5 minutes to every 10 minutes this of monitoring has been referred to as continuous glucose monitoring. These devices potentially eliminate or decrease the number of required daily fingersticks, it should be noted that, according to the FDA labeling, they are not intended to be an alternative to traditional self-monitoring of blood glucose levels but rather serve as an adjunct, supplying additional information

on glucose trends that are not available from self-monitoring. It is hoped that this information on glucose trends will lead to improved anti-diabetic regimens and, ultimately, normalization of hemoglobin A1c levels with a decreased risk of hypoglycemia.

Interstitial glucose monitoring relies on the oxidation of glucose by glucose oxidase to produce hydrogen peroxide. Within the sensor, the hydrogen peroxide is further oxidized, ultimately producing electrons and generating a measurable electric current, which can be calibrated to the glucose concentration.

The Continuous Glucose Monitoring System (CGMS) (MiniMed) and the upgraded version, the Guardian CGMS, consist of a subcutaneously implanted sensor that is attached to a small plastic disk the size of a dime and is taped to the skin to hold the sensor in place. A thin wire connects the sensor to a pager-sized glucose monitor, which records and stores glucose values in memory. An electrical signal is continuously relayed to the glucose sensor, which records glucose levels every 5 minutes, some 288 values per day. For calibration purposes, the manufacturer recommends that the patient enter the results of 4 fingerstick blood glucose measurements per day into the monitor. For the Guardian CGMS, it is recommended that the device be calibrated with fingerstick blood glucose levels every 12 hours at a minimum. The CGMS sensors are capable of transmitting values for up to 3 days, after which time the sensor must be removed and replaced with another by the patient, if additional monitoring is needed. The Guardian CGMS can store up to 21 days of data. The data captured in the monitor can be downloaded to a personal computer for review and used by a physician or the patient. The glucose values are not displayed on these systems. However, the Guardian CGMS features an audible alarm that sounds when glucose levels become too high or too low per parameters set by the patient and physician. The alarm is intended to prompt the patient to perform a fingerstick blood glucose measurement, since a level is not provided with the sounding of the alarm.

The FDA-approved labeling for the CGMS states, in part, that the CGMS is currently intended for occasional rather than everyday use, and is to be used only as a supplement to, and not a replacement for, standard invasive measurement. The CGMS is not intended to change patient management based on the numbers generated but to guide future management of the patient based on response to trends noticed. That is, these trends or patterns may be used to suggest when to take the fingerstick glucose measurements to better manage patients.

Additional devices have been approved by the FDA that provide real-time continuous glucose monitoring. The Guardian-RT (Real-Time) CGMS (Medtronic, MiniMed), which provides real-time information, received premarket approval in July 2005. The approval statement indicates its use for monitoring glucose levels in adults (ages 18 and older) with diabetes mellitus. It also states that values are not intended to be used directly for making therapy adjustments but to provide an indication of when a fingerstick may be required, and that all therapy adjustment would be based on measurements obtained

using a home glucose monitor and not on Guardian values. (1) The DexCom STS CGMS system (DexCom) was approved by the FDA in March 2006, and is also for use in those with diabetes mellitus who are ages 18 and older. Information from the premarket approval indicates that the system is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices. (2) Other real-time CGM systems are being studied, including systems for the pediatric age group.

The FreeStyle Navigator CGM System (Abbott) was approved in March 2008. The sensor for this device can be worn on the back of the upper arm or on the abdomen. As with other CGM devices, information for this device also notes "Before adjusting therapy for diabetes management based on the results and alarms from the FreeStyle Navigator system, traditional blood glucose tests must be performed." The Paradigm REAL-Time System and Guardian REAL-Time System (Pediatric Versions) (Medtronic, MiniMed) were approved by the FDA in March 2007. These are pediatric versions of previously approved devices. The approval of these devices includes the wording "All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on the sensor glucose readings …." This approval was based on the concordance of glucose results between those obtained with the sensor and with a glucose meter. The Paradigm system consists of an insulin infusion pump, the glucose sensor, and a transmitter.

Continuous glucose monitoring systems may be used intermittently, e.g., time periods of 72 hours, or continuously.

POLICY

Intermittent monitoring, i.e., up to 72 hours, of glucose levels in interstitial fluid may be considered **medically necessary** in patients with type I diabetes whose diabetes is poorly controlled despite current use of best practices (see Policy Guidelines). Poorly controlled type I diabetes includes the following clinical situations: unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis.

Intermittent monitoring of glucose levels in interstitial fluid may also be considered **medically necessary** in patients with type I diabetes prior to insulin pump initiation to determine basal insulin levels.

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 the following situations occur despite use of best practices (see Policy Guidelines):

- Patients with type I diabetes who have recurrent, unexplained, severe, symptomatic (generally blood glucose levels less than 50 mg/dl) hypoglycemia for whom hypoglycemia puts the patient or others at risk; or

- Patients with type I diabetes who have recurrent diabetic ketoacidosis (DKA) requiring emergency room visits and admissions.

- Patients with type I diabetes who are pregnant whose diabetes is poorly controlled. Poorly controlled type I diabetes includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis.

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

Note: Hypoglycemia unawareness is reversible. Meticulous avoidance of hypoglycemic for several weeks is sufficient to restore awareness of hypoglycemia. Hypoglycemia Anticipation, Awareness and Treatment Training/Blood Glucose Awareness Training (HAATT/BGAT) has been proven to reduce the occurrence of severe hypoglycemia.

POLICY GUIDELINES
Best practices in diabetes control for patients with type I diabetes include compliance with a regimen of 4 or more fingersticks each day and use of an insulin pump. Compliance will also be required for other aspects of diabetic management including insulin bolusing and diet. 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 I diabetes 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 four weeks depending on the patient's level of diabetes control and medical necessity.

RATIONALE

Data presented to the U.S. Food and Drug Administration (FDA) advisory committee meeting consisted of studies validating the correlation between the measurements of glucose in interstitial fluid with the blood glucose measurements made with home monitoring devices. (3-5) While the individual values between the two may vary, in general, the panel found that the overall trends in glucose levels detected by frequent measurements produced potentially clinically important information. However, there were no clinical data presented regarding improvements in hemoglobin A1c measurements or a decreasing incidence of hypoglycemic episodes in those whose antidiabetic medications were managed based on more frequent readings of interstitial fluid glucose. However, members of the advisory panel felt that more frequent measurements should extrapolate

to improved diabetic management. For example, prior studies have shown that hemoglobin A1c levels are lowest among patients who have the highest frequency of daily blood glucose measurements. (6) Nevertheless, the use of trends of daily glucose levels implies a different type of diabetic management compared to traditional methods of serial fingerstick glucose methods. The following clinical applications were suggested by the FDA advisory panels:

- Hypoglycemic episodes can be identified more readily by the use of an alarm. This may be particularly helpful in patients with hypoglycemic unawareness or overnight hypoglycemia. In addition, patients with adequate glucose control, as measured by hemoglobin A1c (HbA1c) levels, may undergo monitoring to ensure that this control does not come at the expense of unrecognized hypoglycemia.

- Unsuspected postprandial hyperglycemia may be detected, which contributes to elevated HbA1c concentrations in patients whose HbA1c levels are considered adequate. Postprandial hyperglycemia has been related to increased cardiovascular risks. Both fast-acting insulin (insulin lispro) and fast-acting oral hypoglycemics (i.e., repaglinide) may be particularly effective in treating postprandial hyperglycemia.

- The devices may be used periodically to confirm the status of current antidiabetic therapy. Currently, some patients may perform 7–9 fingersticks a day on a periodic basis to confirm the success of diabetic management.

- Patients may use the devices in specific circumstances when the normal routine is upset, i.e., changes in work shifts or while traveling.

- The devices may be used to monitor changes in insulin therapy, i.e., the initiation of an insulin pump.

- The device may be used as an educational tool to more easily illustrate how glucose levels vary with activities and meal choices.

- Quality of life may be improved by decreasing the number of fingersticks.

The key clinical outcomes regarding the clinical utility of interstitial measurements of glucose relates to 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 are important to isolate the contribution of interstitial glucose measurements to the overall diabetic management. This policy is based on a 2003 TEC Assessment (7), which reviewed the published controlled trials and offered the following discussion.

Continuous Glucose Monitoring Systems (CGMS)
Results of 4 randomized trials have been reported. The largest of them, which enrolled 128 adult patients with type 1 diabetes, was initially available in abstract only. (10) Among the 109 patients completing the 3-month trial (the dropout rate was 15%), there was no statistically significant difference in HbA1c levels. Mean HbA1c levels in both the control and study groups declined from 9% at baseline to 8.3% at 3 months. Similarly, in another randomized study of 75 patients, there was no statistical difference in HbA1c levels after the 3-month intervention. (11) The other randomized studies included only 11 and 27 patients, respectively (12, 13). In 2004, Tanenberg and colleagues reported on a study of 128 patients (reported previously in abstract form (10)) randomized to insulin therapy adjustments using data from either the CGMS or self-monitoring of blood glucose (SMBG) using a home blood glucose monitor over a 12-week period. (14) At 12 weeks, HbA1c levels and hyperglycemic event frequency and duration did not differ with any statistical significance in the treatment groups. However, at 12 weeks, events of hypoglycemia (glucose < or = 60 mg/dL) were found to be significantly shorter in the CGMS group than in the SMBG group (49.4 +/- 40.8 vs. 81.0 +/- 61.1 minutes per event, p = .009). The authors concluded that durations of hypoglycemia can be further reduced by adjusting insulin therapy with data from the CGMS rather than using SMBG data alone. Nevertheless, the biochemically defined measurements of hypoglycemia (without accompanying evidence of symptoms and/or a clinically significant hypoglycemic event) are not compelling outcomes. The clinical significance of these test results has not been established, i.e., there is insufficient evidence showing the link between increased duration of asymptomatic hypoglycemia and subsequent clinical outcomes.

2006-2007 Update
Additional studies continue to evaluate continuous glucose monitoring systems. Lagarde and colleagues found a slight improvement in HbA1c levels using CGMS compared to controls in children with type 1 diabetes. (15) However, the difference did not reach statistical significance (p = 0.13). In a European study using a crossover design, Deiss and colleagues reported that CGMS did not decisively influence glycemic control of the total study cohort of children and adolescents with type 1 diabetes. (16) They suggested that more frequent use of CGMS at shorter intervals may be of greater value. A recent review raised questions about the accuracy of these systems. (17)

Garg reported that in 91 patients with diabetes (75 were type 1) real-time continuous glucose monitoring was able to reduce glycemic excursions by reducing hyperglycemia without increasing the risk of hypoglycemia. (18) They also indicated that this type of monitoring may reduce long-term complications of diabetes. Recently, Deiss reported on a 3-month study of 81 children and 81 adults with stable type 1 diabetes who had HbA1c levels of 8.1% or greater. (19) Patients were randomized to continuous real-time monitoring, continuous monitoring for 3 days every 2 weeks, or self-monitoring of blood glucose. At 3 months, 50% of patients with continuous real-time monitoring had a decrease in HbA1c of at least 1% compared to 37% of those with intermittent continuous monitoring, and 15 % of controls. These results suggest that continuous

glucose monitoring may have potential for improving control in patients with diabetes; however, as the authors note, additional work is needed to determine long-term efficacy, clinical feasibility in patients with varying levels of glycemic control, and effect on rates of hypoglycemia.

April 2008 Update

The policy was updated with a literature review using MEDLINE from January 2007 through February 2008. No publications were identified that present results from randomized trials that show an impact of long-term continuous glucose monitoring on relevant patient outcomes. Recent publications continue to report results on case series and often do not clearly link to patient outcomes.

Guillod reported on a retrospective study that described findings from a group of 88 patients with type I diabetes who underwent a CGMS exam. (20) The prevalence of nocturnal hypoglycemia (NH) was 67% (32% of them unsuspected). A measured hypoglycemia at bedtime (22–24 hr) had a sensitivity of 37% to detect NH, while a single measure 4 mmol/l or less at 03-hour had a sensitivity of 43%. In this study, NH measurements were not associated with morning hyperglycemias but with morning hypoglycemias. After 6–9 months, suspicions of NH decreased from 60% to 14% ($p<0.001$). The authors concluded that NH was highly prevalent and often undetected. Self-monitoring blood glucose at bedtime, which detected hypoglycemia, had sensitivity almost equal to that of 03-hour and should be preferred because it is easier to perform. Tubiana-Rufi reported on an uncontrolled study of 182 patients (children and adults) with poorly controlled type I diabetes. (21) Using the Guardian RT system, which the authors indicated required 3 calibrations a day, resulted in improvement in HbA1c levels over 3 months. The DirecNet Study Group reported results of another non-comparative study of 30 patients with type I diabetes who used an insulin pump with the FreeStyle Navigator CGM system for 13 weeks. (22) During this time, the mean HbA1c levels improved from 7.1% to 6.8% and the percentage of glucose values between 71 and 180 mg/dl increased from 52% to 60%. Two patients had severe skin reactions related to the sensor mount adhesive. Wilson and colleagues, as part of the Diabetes Research in Children Network (DirecNet), evaluated the accuracy and precision of the FreeStyle Navigator CGMS in 30 children with type 1 diabetes (mean age 11.2 years). (23) The Navigator glucose values were compared with reference serum glucose values of blood samples obtained in an inpatient clinical research center and measured in a central laboratory and in an outpatient setting with a FreeStyle meter. Median absolute difference (AD) and median relative absolute difference (RAD) were computed for sensor-reference and sensor-sensor pairs. The median AD and RAD were 17 mg/dl and 12%, respectively, for 1,811 inpatient sensor-reference pairs, and 20 mg/dl and 14%, respectively, for 8,639 outpatient pairs. The median RAD between two simultaneous Navigator measurements (n = 1,971) was 13%. Ninety-one percent of sensors in the inpatient setting and 81% of sensors in the outpatient setting had a median RAD of 20% or less. The authors concluded that the Navigator's accuracy does not yet approach the accuracy of current-generation home glucose meters, but it is sufficient to believe that

the device has the potential to be an important adjunct to treatment of youth with type 1 diabetes.

Several authors note that these results provide a compelling rationale for conducting a randomized controlled trial (RCT) of use of continuous glucose monitoring in type 1 diabetes. Recent advances in technology now allow linkage between the CGM device and an insulin pump. Halvorson reported on an uncontrolled pilot trail of 10 children with type 1 diabetes. The small size and lack of control group limit the ability to draw any conclusions from this study. (24) Publications are also beginning to report on early trials of use of these devices in patients with type 2 diabetes. Wolpert discussed the skills needed for diabetes management using real-time monitoring and commented specifically on the role of calibration as well as understanding the lag between capillary and interstitial glucose levels. (25) Given the lack of scientific data about the impact of CGM on clinical outcomes, this is considered investigational.

October 2008 Update

The policy was updated in October 2008 with a literature search using MEDLINE.

A recent systematic review of randomized studies identified 7 studies with 335 patients that fulfilled their inclusion criteria. (26) Study duration varied from 12 to 24 weeks. This review concluded that compared with self-monitoring, CGMS was associated with a non-significant reduction in HbA1c levels and that evidence is insufficient to support the notion that CGMS provides a superior benefit over self-monitoring for HbA1c reduction. There was some indication from this review of improved detection of asymptomatic nocturnal hypoglycemia in the CGMS group.

The 2007 Standards of Medical Care by the American Diabetes Association (ADA) does not mention this technology in the section on assessment of glycemic control. (27) Recommendations in this section are for self-monitoring of blood glucose 3 or more times daily for patient using multiple insulin injections. The 2008 Standards of Care from the ADA include a recommendation that "CGMS may be a supplemental tool to SMBG for selected patients with type 1 diabetes, especially those with hypoglycemia unawareness." (28) This recommendation is level E, based on expert consensus or clinical experience. The ADA guidelines explain continuous glucose monitoring systems "require calibration with SMBG reading, and the latter are still recommended for making treatment decisions. Continuous glucose sensors have alarms for hypoglycemia and hyperglycemia. Small studies in selected patient populations have shown good correlation of readings with SMBG and decreases in meantime spent in hypo- and hyperglycemic ranges compared with blinded sensor use. Although continuous glucose sensors would seem to show great promise in diabetes management, as yet no rigorous controlled trials have demonstrated improvement in long term glycemia."

In December 2007, the Juvenile Diabetes Research Foundation (JDRF) completed recruitment for a 6-month trial at 10 centers of real-time CGMS in patients with type 1

diabetes. (29) Results of this study, that randomly assigned 322 adults and children with type I diabetes to continuous glucose monitoring or self (home) monitoring, were released in 2008. (30) 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. Unlike many prior studies, this study was sufficiently large to detect a meaningful change in HbA1c levels between groups. The population in this study had relatively well-controlled diabetes in that entry criterion was glycated Hb of 7% to 10% but about 70% had levels between 7% and 8%; in addition, over 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 where 83% of patients used the monitor 6 or more days per week

Physician Specialty Society and Academic Medical Center Input
In response to requests, input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review. 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.

Those providing input concurred that this technique, 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 HbA1c) and/or by reducing episodes of hypoglycemia. Reviewers believed that there was persuasive information from case reports to demonstrate the positive impact of intermittent glucose monitoring.

Summary
In summary, the available studies demonstrate that intermittent glucose monitoring provides a different type of data than results from fingerstick glucose levels. In addition to providing more data points, it also provides information about trends (direction) in glucose levels. This additional information is most likely to benefit those patients with type I diabetes who do not have adequate control, including episodes of hypoglycemia, despite use of current best practices including multiple (4 or more) daily checks of blood glucose and use of an insulin pump. Thus, based on the available data and supported by clinical input, the policy statement is changed to indicate that intermittent, i.e., 72-hour, glucose monitoring may be considered medically necessary in those whose diabetes is poorly controlled despite use of best practices.

The data supporting use of continuous (long-term) glucose monitoring are still limited. Using rationale similar to that noted above for intermittent monitoring, continuous

monitoring can also be used, and can be considered medically necessary, to provide additional data for management of those who have recurrent, unexplained, severe symptomatic hypoglycemia, despite use of current best practices, that puts the patient or others at risk and for pregnant type I diabetics.

Data to support use (that show improved outcomes) of devices that allow wireless connectivity between a continuous monitoring device and insulin pump are still lacking.

A major limitation of CGMS is the durability and stability of the glucose sensors, which must be changed every three days. Another potential concern is the six to ten minute delay in interstitial glucose sensor response to changes in serum glucose levels. This delay appears to be most important when glucose levels are falling rapidly, since it might result in development of clinically significant hypoglycemia before it was reflected in the sensor reading.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

CPT/HCPCS

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
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 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
S1030	Continuous non-invasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)
S1031	Continuous non-invasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)

DIAGNOSIS

250.01	Diabetes mellitus without mention of complication, type I (juvenile type), not stated as uncontrolled
250.03	Diabetes mellitus without mention of complication, type I (juvenile type), uncontrolled
250.11	Diabetes with ketoacidosis, type I (juvenile type), not stated as uncontrolled

250.13	Diabetes with ketoacidosis, type I (juvenile type), uncontrolled
250.21	Diabetes with hypertension, type I (juvenile type), not stated as uncontrolled
250.23	Diabetes with hypertension, type I (juvenile type), uncontrolled
250.31	Diabetes with other coma, type I (juvenile type), not stated as uncontrolled
250.33	Diabetes with other coma, type I (juvenile type), uncontrolled
250.41	Diabetes with renal manifestations, type I (juvenile type), not stated as uncontrolled
250.43	Diabetes with renal manifestations, type I (juvenile type), uncontrolled
250.51	Diabetes with ophthalmic manifestations, type I (juvenile type), not stated as uncontrolled
250.53	Diabetes with ophthalmic manifestations, type I (juvenile type), uncontrolled
250.61	Diabetes with neurologic manifestations, type I (juvenile type), not stated as uncontrolled
250.63	Diabetes with neurologic manifestations, type I (juvenile type), uncontrolled
250.71	Diabetes with peripheral circulatory disorders, type I (juvenile type), not stated as uncontrolled
250.73	Diabetes with peripheral circulatory disorders, type I (juvenile type), uncontrolled
250.81	Diabetes with other specified manifestations, type I (juvenile type), not stated as uncontrolled
250.83	Diabetes with other specified manifestations, type I (juvenile type), uncontrolled
250.91	Diabetes with other unspecified complications, type I (juvenile type), not stated as uncontrolled
250.93	Diabetes with other unspecified complications, type I (juvenile type), uncontrolled

REVISIONS

07-17-2007	In Policy section: ▪ Added clarification to policy that continuous glucose monitoring system is limited to 72 hours. Extended use beyond 72 hours is considered patient deluxe, patient responsibility/non-covered. In Coding section: ▪ Removed code 99091.
01-01-2008	In Coding section: ▪ Added codes and nomenclature for A9276, A9277, A9278.
09-03-2008	In Coding section: ▪ Added codes and nomenclature for S1030, S1031. ▪ Corrected nomenclature for 95250.
	In Policy section: Revised wording from "requires prior approval" to "prior approval is encouraged".
09-09-2009	In Header: ▪ Revised title from Continuous Glucose Monitoring System (CGMS) to Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid.
	In Description section: ▪ Updated wording.

	In Policy section: ▪ Updated wording on intermittent monitoring, no change in policy position. ▪ Added indication of: 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 the following situations occur despite use of best practices: • Patients with type I diabetes who have recurrent, unexplained, severe, symptomatic (generally blood glucose levels less than 50 mg/dl) hypoglycemia for whom hypoglycemia puts the patient or others at risk; or • Patients with type I diabetes who have recurrent diabetic ketoacidosis (DKA) requiring emergency room visits and admissions. • Patients with type I diabetes who are pregnant whose diabetes is poorly controlled. Poorly controlled type I diabetes includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis. Other uses of continuous monitoring of glucose levels in interstitial fluid as a technique of diabetic monitoring are considered investigational.
	Added Rationale section.

REFERENCES

1. Guardian-RT CGMS: FDA Summary of Safety and Effectiveness: www.fda.gov/cdrh/pdf/p980022s011.html
2. DexCom STS CGMS: FDA Summary of Safetly and Effectiveness: www.fda.gov/cdrh/pdf5/p050012.html
3. CGMS: FDA Summary of Safety and Effectiveness: www.fda.gov/cdrh/pdf/p980022b.pdf
4. GlucoWatch G2 Biographer: FDA Summary of Safety and Effectiveness: www.fda.gov/cdrh/pdf/p990026S008b.pdf .
5. Tamada JA, Garg S, Jovanovic L et al. Noninvasive glucose monitoring: comprehensive clinical results. JAMA 1999; 282(19):1839-44.
6. Evans JM, Newton RW, Ruta DA et al. Frequency of blood glucose monitoring in relation to glycaemic control: observational study with diabetes database. BMJ 1999; 319(7202):83-6.
7. 2003 TEC Assessments; Tab 16.
8. Chase HP, Roberts MD, Wightman C et al. Use of the GlucoWatch Biographer in children with type 1 diabetes. Pediatrics 2003; 111(4):790-4.
9. Eastman RC, Leptien A, Chase HP. Cost effectiveness of use of the GlucoWatch Biographer in children and adolescents with type 1 diabetes: an analysis based on a randomized controlled trial. Abstracts from the American Diabetes Association's 63 rd Scientific Sessions, 2003, #398-P.
10. Bode B, Lane C, Levetan J et al. Therapy adjustments based on CGMS data lower HbA1c with less hypoglycemia than blood glucose meter data alone. Abstracts from the American Diabetes Association's 63 rd Scientific Sessions, 2003, #386-P.
11. Chico A, Vidal-Rios P, Subira M et al. The continuous glucose monitoring system is useful for detecting unrecognized hypoglycemias in patients with type 1 and type 2 diabetes but is not better than frequent capillary glucose measurements for improving metabolic control. Diabetes Care 2003; 26(4):1153-7.
12. Chase HP, Kim LM, Owen SL et al. Continuous subcutaneous glucose monitoring in children with type 1 diabetes. Pediatrics 2001; 107(2):222-6.

13. Ludvigsson J, Hanas R. Continuous subcutaneous glucose monitoring improved metabolic control in pediatric patients with type 1 diabetes: a controlled crossover study. Pediatrics 2003; 111(5 pt 1):933-8.
14. Tanenberg R, Bode B, Lane W et al. Use of the Continuous Glucose Monitoring System to guide therapy in patients with insulin-treated diabetes: a randomized controlled trial. Mayo Clin Proc 2004; 79(12):1521-6.
15. Lagarde WH, Barrows FP, Davenport ML et al. Continuous subcutaneous glucose monitoring in children with type I diabetes mellitus: a single-blind, randomized, controlled trial. Pediatr Diabetes 2006; 7(3):159-64.
16. Deiss D, Hartmann R, Schmidt J et al. Results of a randomized controlled cross-over trial on the effect of continuous subcutaneous glucose monitoring (CGMS) on glycemic control in children and adolescents with type 1 diabetes. Exp Clin Endocrinol Diabetes 2006; 114(2):63-7.
17. Continuous glucose monitoring. Med Lett Drugs Ther 2007; 49(1254):13-5.
18. Garg S, Zisser H, Schwartz S et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. Diabetes Care 2006; 29(1):44-50.
19. Deiss D, Bolinder J, Riveline JP et al. Improved glycemic control in poorly controlled patients with type-1 diabetes using real-time continuous glucose monitoring. Diabetes Care 2006: 29(12):2730-2.
20. Guillod L, Comte-Perret S, Monbaron D et al. Nocturnal hypoglycaemias in type 1 diabetic patients: what can we learn with continuous glucose monitoring? Diabetes Metab 2007; 33(5):360-5.
21. Tubiana-Rufi N, Riveline JP, Dardari D. Real-time continuous glucose monitoring using Guardian RT: from research to clinical practice. Diabetes Metab 2007; 33(6):415-20.
22. Diabetes Research in Children Network (DirectNet) Study Group; Buckingham B, Beck RW, Tamborlane WV et al. Continuous glucose monitoring in children with type 1 diabetes. J Pediatr 2007; 151(4):388-93.
23. Wilson DM, Beck RW, Tamborlane WV et al. The accuracy of the FreeStyle Navigator continuous glucose monitoring system in children with type 1 diabetes. Diabetes Care 2007; 30(1):59-64.
24. Halvorson M, Carpenter S, Kaiserman K et al. A pilot trial in pediatrics with the sensor-augmented pump: combining real-time continuous glucose monitoring with the insulin pump. J Pediatr 2007; 150(1):103-5.
25. Wolpert HA. The nuts and bolts of achieving end points with real-time continuous glucose monitoring. Diabetes Care 2008; 31(suppl 2):S146-9.
26. Chetty VT, Almulla A, Odueyungbo A et al. The effect of continuous subcutaneous glucose monitoring (CGMS) versus intermittent whole blood finger-stick glucose monitoring (SBGM) on hemoglobin A1c (HBA1c) levels in Type I diabetic patients: a systematic review. Diabetes Res Clin Pract 2008; 81(1):79-87.
27. American Diabetes Association. Standard of medical care in diabetes – 2007. Diabetes Care 2007; 30 (suppl 1):S4-41.
28. American Diabetes Association. Standard of medical care in diabetes – 2008. Diabetes Care 2008; 31(suppl 1):S12-54.
29. Tamborlane W, Ruedy K, Wysocki T et al.; JDRF CGM Study Group. JDRF randomized clinical trial to assess the efficacy of real-time continuous glucose monitoring in the management of type 1 diabetes: research design and methods. Diabetes Technol Ther 2008; 10(4):308-19.

30. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med 2008; 359(14):1469-76.
31. MCOP 2060-1645 Dec 15, 2008
32. Blue Cross and Blue Shield of Kansas Pediatric Liaison Committee, July 2008.
33. Blue Cross and Blue Shield of Kansas Internal Medicine Liaison Committee, August, 2008.
34. Blue Cross and Blue Shield of Kansas Family Practice Liaison Committee, July, 2009
35. Blue Cross and Blue Shield of Kansas Pediatric Liaison Committee, July 2009.
36. Blue Cross and Blue Shield of Kansas Internal Medicine Liaison Committee, August, 2009.