Corporate Medical Policy

Continuous Monitoring of Glucose in the Interstitial Fluid

File Name: continuous_monitoring_of_glucose_in_the_interstitial_fluid
Origination: 10/2000
Last CAP Review: 6/2021
Next CAP Review: 6/2022
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Description of Procedure or Service

Tight glucose control in patients with diabetes has been associated with improved outcomes. Several devices are available to measure glucose levels automatically and frequently (e.g., every 5 to 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.

The advent of blood glucose monitors for use by patients in the home over 20 years ago revolutionized the management of diabetes. Using fingersticks, patients could monitor their blood glucose level both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. Tight diabetic control, defined as a strategy involving frequent glucose checks and a target hemoglobin A1c (HbA1c) 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 macrovascular complications such as stroke or myocardial infarction is less certain. The Diabetes Control and Complications Trial (2002) demonstrated that a relative HbA_{1c} level reduction of 10% is clinically meaningful and corresponds to approximately a 40% decrease in risk for progression of diabetic retinopathy and 25% decrease in risk for progression of renal disease. Due to an increase in turnover of red blood cells during pregnancy, HbA_{1c} levels are slightly lower in women with a normal pregnancy compared with nonpregnant women. The target A_{1c} in women with diabetes is also lower in pregnancy. The American Diabetes Association recommends that, if achievable without significant hypoglycemia, the A_{1c} levels should range between 6.0% to 6.5%; an A_{1c} levels less than 6% may be optimal as the pregnancy progresses.

Measurements of glucose in the 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 the 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 U.S. Food and Drug Administration (FDA) approval. 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 with an electric current (referred to as reverse iontophoresis).

Devices subsequently approved include those for pediatric use and those with 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 time intervals at which interstitial glucose is measured ranges from every 1-2 minutes to 5 minutes and most provide measurements in real-time directly to patients. While continuous glucose monitors potentially eliminate or decrease the number of required

daily fingersticks, it should be noted that, according to the FDA labeling, monitors are not intended to be an alternative to traditional self-monitoring of blood glucose levels but rather provide adjunct monitoring, supplying additional information on glucose trends that are not available from self-monitoring. In addition, devices may be used intermittently, i.e., for time periods of 72 hours, or continuously on a long-term basis.

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

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

DEVICE	MANUFAC-TURER	APPR OVAL	INDICATIONS
Continuous Glucose Monitoring System (CGMS®)	MiniMed	1999	3-d use in physician's office
GlucoWatch G2® Biographer		2001	Not available since 2008
Guardian®-RT (Real-Time) CGMS	MiniMed (now Medtronic)	2005	
Dexcom® STS CGMS system	Dexcom	2006	
Paradigm® REAL-Time System (second-generation called Paradigm Revel System)	MiniMed (now Medtronic)	2006	Integrates CGM with a Paradigm insulin pump
FreeStyle Navigator® CGM System	Abbott	2008	
Dexcom® G4 Platinum	Dexcom	2012	Adults ≥18 y; can be worn for up to 7 d
		2014	Expanded to include patients with diabetes 2-17 y
Dexcom® G5 Mobile CGM	Dexcom	2016[a]	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[5]
Dexcom® G6 Mobile CGM	Dexcom	2018	For determining blood glucose levels in children ages ≥2 and adults with diabetes
Freestyle Libre® Pro Flash Glucose Monitoring System	Abbott	2017	Adults ≥18 y. Readings only made available to patients in consultation with a health care professional. Does not require user calibration with blood glucose values.
Freestyle Libre® Flash Glucose Monitoring System	Abbott	2018	Adults ≥18 y. Extended duration of use to 14 days
Guardian Connect	Medtronic MiniMed	2018	Adolescents and adults (14-75 years) Continuous or periodic monitoring of interstitial glucose levels. Provides real-time glucose values, trends, and alerts through a Guardian

			Connect app installed on a compatible consumer electronic mobile device.
Eversense	Senseonics	2019	Fully implantable sensor, approved by FDA for non-adjunctive use in adults 18 years and older.

Related Policy:
Artificial Pancreas Device Systems

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC may provide coverage for Continuous Monitoring of Glucose in the Interstitial Fluid when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.

When Continuous Monitoring of Glucose in the Interstitial Fluid is covered

A. Intermittent monitoring (72 hours) of glucose levels in interstitial fluid may be considered medically necessary in the following situations:

1. Patients with type 1 diabetes whose diabetes is poorly controlled, despite current use of best practices (see Policy Guidelines section). Poorly controlled type 1 diabetes includes the following clinical situations: unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis; or

2. Patients with type 1 diabetes prior to insulin pump initiation to determine basal insulin levels; or

3. Patients with type 2 diabetes who require multiple daily doses of insulin whose diabetes is poorly controlled, despite current use of best practices (see Policy Guidelines section). Poorly controlled type 2 diabetes includes the following clinical situations: unexplained hypoglycemic episodes, hypoglycemic unawareness, and persistent hyperglycemia and A1C levels above target; or

4. Patients with type 2 diabetes who require multiple daily doses of insulin to determine basal insulin levels prior to insulin pump initiation.

B. Continuous monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique in diabetic monitoring may be considered medically necessary in the following situations:

1. 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 be adherent to a comprehensive diabetes treatment plan supervised by a qualified provider, and are capable of using the device to recognize alerts and alarms; or

2. Patients with type 1 diabetes who have recurrent unexplained, severe, (generally blood glucose levels less than 50 mg/dl) hypoglycemia or impaired awareness of hypoglycemia that puts the patient or others at risk; or

3. Patients with poorly controlled type 1 diabetes who are pregnant. Poorly controlled type 1 diabetes includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis; or

4. Patients with type 2 diabetes who are willing and able to use the device and have adequate medical supervision and who experience significant hypoglycemia on multiple daily doses of insulin or an insulin pump in the setting of insulin deficiency.

NOTE: See Policy Guidelines section for the definition of "best practices" in diabetes.

When Continuous Monitoring of Glucose in the Interstitial Fluid is not covered

Other uses of continuous monitoring of glucose levels in interstitial fluid (including real-time monitoring) as a technique of diabetic monitoring are considered investigational.

Continuous glucose monitoring using an implantable glucose sensor (i.e., Eversense™ CGM system) is considered investigational.

Policy Guidelines

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

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

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

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

Providers board certified in endocrinology and/or providers with a focus on the practice of diabetes care may be considered qualified to evaluate and oversee individuals for continuous (ie, long-term) monitoring.

Summary of Evidence

Type 1 Diabetes
For individuals with 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 (QOL), 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. A 2017

individual patient data analysis, pooling data from 11 RCTs, found that reductions in hemoglobin A_{1c} (HbA_{1c}) levels were significantly greater with real-time CGM than with a control intervention. Two 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 HbA_{1c} levels than previous studies. One of the two RCTs prespecified hypoglycemia-related outcomes and reported that time spent in hypoglycemia was significantly less in the CGM group. One RCT in pregnant women with type 1 diabetes, which compared real-time CGM with self-monitoring of blood glucose, has also reported a difference in change in HbA_{1c} levels, an increased percentage of time in the recommended glucose control target range, a smaller proportion of infants who were large for gestational age, a smaller proportion of infants who had neonatal intensive care admissions lasting more than 24 hours, a smaller proportion of infants who had neonatal hypoglycemia requiring treatment, and reduced total hospital length of stay all favoring CGM.The evidence is sufficient that the long-term use of CGM provides an improvement in net health outcomes for persons with type 1 diabetes mellitus.

For individuals with type 1 diabetes who have poor control of diabetes despite the use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation who receive short-term glucose monitoring, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity as well as intermediate outcomes related to measures of glucose control such as frequency and time in hypoglycemia and hyperglycemia. The evidence for short-term monitoring on glycemic control is mixed, and there was no consistent in HbA1c levels. 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 control with short-term CGM use, duration of use and the specific monitoring protocols varied. In some studies, short-term 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. 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 limited duration of use may preclude an assessment of any therapeutic effect. Two RCTs of short-term CGM use for monitoring in pregnancy included women with both type 1 and 2 diabetes, with most having type 1 diabetes. One trial reported a difference in HbA1c levels at 36 weeks; the proportion of infants that were large for gestational age (>90th percentile) favored CGM while the second trial did not. The differences in the proportions of infants born via cesarean section, gestational age at delivery, and infants with severe hypoglycemia were not statistically significant in either study. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice when used in specific situations such as poor control of diabetes despite the use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Type 2 Diabetes

For individuals with type 2 diabetes who receive long-term CGM, the evidence includes RCTs. The relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. Most RCTs of CGM in patients with type 2 trials found statistically significant benefits of CGM regarding glycemic control. However, the degree of HbA1c reduction and the difference in HbA1c reduction between groups might not be clinically significant. Moreover, additional evidence would be needed to show what levels of improvements in HbA1c levels over the short-term would be linked to meaningful improvements over the long-term in health outcomes such as diabetes-related morbidity and complications. Also, the variability in entry criteria as well as among interventions makes it difficult to identify an optimal approach to CGM use; the studies used a combination of intermittent and continuous monitoring with a review of data in real-time or at study visits only. Only the DIAMOND RCT (n=158) has used real-time CGM in type 2 diabetes. Selected patients were highly compliant during a run-in phase. The difference in change in HbA1c levels from baseline to 24 weeks was -0.3% favoring CGM. The difference in the proportion of patients with a relative reduction in HbA1c level by 10% or more was 22% favoring CGM. There were no differences in the proportions of patients with an HbA1c level of less than 7% at week 24. There were no events of severe hypoglycemia or diabetic ketoacidosis in either group. The treatment groups did not differ in any of the QOL measures. RCTs using flash glucose-sensing technology as a replacement for self-monitoring of blood

glucose for the management of insulin-dependent treated type 2 diabetes found no difference in HbA1c change at 6 and 12 months between groups. However, time in severe hypoglycemia (<45mg/dL) was reduced for intervention participants. Two trials of CGM have enrolled pregnant women with type 2 diabetes, but the total number of women with type 2 diabetes included in both trials is only 58. One study reported a difference in HbA1c levels at 36 weeks, and the proportion of infants that were large for gestational age (>90th percentile) favored CGM while the second study did not. Neither trial reported analyses stratified by diabetes type. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input for long-term (continuous) CGM in patients with type 2 diabetes who do not require insulin did not provide strong support of a safety benefit and clinically meaningful improvement in net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with type 2 diabetes who are willing and able to use the device and have adequate medical supervision and who experience significant hypoglycemia on multiple daily doses of insulin or an insulin pump in the setting of insulin deficiency who receive long-term (continuous) glucose monitoring, the evidence includes a systematic review and non-randomized study with 12-month follow-up. The relevant outcomes are the frequency of and time spend in hypoglyceima, the incidence of hypoglycemic episodes, complications of hypoglycemia, and QOL. The available studies demonstrate that CGM can significantly reduce time in hypoglycemia and frequency of hypoglycemia events both during the day and at night. At 12-month follow-up, hypoglycemic events were reduced by 40.8% to 61.7% with a greater relative reduction in the most severe thresholds of hypoglycemia. The published evidence supports a meaningful improvement in the net health outcome. Evidence reported through clinical input provides additional clinical context and based on both the published evidence and clinical input the following patient selection criteria are associated with a clinically meaningful improvement in net health outcome and are consistent with generally accepted medical practice: selected patients with type 2 diabetes who are (1) willing and able to use the CGM device and have adequate medical supervision and (2) experiencing significant hypoglycemia on multiple daily doses of insulin or an insulin pump in the setting of insulin deficiency. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with type 2 diabetes who require multiple daily doses of insulin and have poor control of diabetes despite the use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation who receive short-term CGM monitoring, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. Systematic reviews of three to four RCTs have found statistically significant benefits from CGM regarding glycemic control. However, the degree of HbA1c reduction and the difference in HbA1c reductions between groups may not be clinically significant. Also, the limited number of RCTs and variability among interventions make it difficult to identify an optimal approach to CGM or a 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 issues of severe hypoglycemia and diabetic complications. Very few pregnant women with type 2 diabetes have been included in RCTs. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input for use of short-term CGM in patients with type 2 diabetes who require multiple daily doses of insulin supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice when used in specific situations such as poor control of diabetes despite use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Implantable CGM

For individuals with diabetes who receive an implantable CGM (eg Eversense), the evidence consists of noncomparative cohort studies with small numbers and short follow-up. Relevant outcomes include symptoms, morbid events, quality of life and treatment-related morbidity. Studies have shown accuracy comparable to other CGMs, as measured by comparison to venous or finger stick glucose measurements, but there is uncertainty about the accuracy across a range of glucose values. The use of different outcome measures and glucose levels used in the various studies limits the ability to draw conclusions across studies.

There is insufficient evidence showing clinical utility. In addition, there are remaining safety concerns about repeated insertion and removal and the possibility of scar tissue formation affecting sensor accuracy. Due to the limited number of currently existing studies and trials, there is a small and weak body of evidence to support the use of Eversense as an adjunct or non-adjunctive device. The evidence is insufficient to determine the effects of the technology on health outcomes.

Gestational Diabetes
For individuals who are pregnant with gestational diabetes who receive long-term CGM or short-term (intermittent) glucose monitoring, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. In the RCT, the type of glucose monitoring was unclear. Trial reporting was incomplete; however, there was no difference between the groups for most reported outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

The 2021, The American Diabetes Association (ADA) "Standards of Medical Care in Diabetes on Diabetes Technology" includes the following recommendations on continuous glucose monitoring:

- When prescribing continuous glucose monitoring (CGM) devices, robust diabetes education, training, and support are required for optimal CGM device implementation and ongoing use. People using CGM devices need to have the ability to perform self-monitoring of blood glucose in order to calibrate their monitor and/or verify readings if discordant from their symptoms. Level of evidence=**B**

- When used properly, continuous glucose monitoring in conjunction with multiple daily injections and continuous subcutaneous insulin infusion (Level of evidence= **A**) and other forms of insulin therapy (Level of evidence=**C)** are a useful tool to lower and/or maintain A1C levels and/or reduce hypoglycemia in adults and youth with diabetes.

- When used properly, intermittently scanned continuous glucose monitors in conjunction with multiple daily injections and continuous subcutaneous insulin infusion (Level of evidence=**B)** and other forms of insulin therapy (Level of Evidence=**C)** can be useful and may lower A1C levels and/or reduce hypoglycemia in adults and youth with diabetes to replace self-monitoring of blood glucose.

- In patients on multiple daily injections and continuous subcutaneous insulin infusion, real-time continuous glucose monitoring (CGM) devices should be used as close to daily as possible for maximal benefit. (Level of evidence=A). Intermittently scanned CGM devices should be scanned frequently, at a minimum once every 8 h.

- When used as an adjunct to pre- and postprandial self-monitoring of blood glucose, continuous glucose monitoring can help to achieve A1C targets in diabetes and pregnancy. Level of Evidence=**B**

- Use of professional continuous glucose monitoring (CGM) and/or intermittent real-time or intermittently scanned CGM can be helpful in identifying and correcting patterns of hyper- and hypoglycemia and improving A1C levels in people with diabetes on noninsulin as well as basal insulin regimens. Level of Evidence=**C**

- Skin reactions, either due to irritation or allergy, should be assessed and addressed to aid in successful use of devices. Level of Evidence=**E**

- People who have been using continuous glucose monitors should have continued access across third-party payers. Level of Evidence=**E**

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *95249, 95250, 95251, 99091, 0446T, 0447T, 0448T, A9276, A9277, A9278, S1030, S1031, K0553, K0554*

CPT code 95251 is eligible for reimbursement once every three months.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual - 8/18/00; 1.01.20

Specialty Matched Consultant Advisory Panel - 9/2000

Medical Policy Advisory Group - 10/2000

BCBSA Medical Policy Reference Manual - 12/15/00; 1.01.20

BCBSA Medical Policy Reference Manual - 2/15/02; 1.01.20

BCBSA Medical Policy Reference Manual - 5/15/02; 1.01.20

BCBSA TEC Assessment, Volume 17, No. 2, 6/2002

Specialty Matched Consultant Advisory Panel - 7/2002

BCBSA Medical Policy Reference Manual. 1.01.20. 12/17/03. Retrieved on 4/8/04 from http://blueweb.bcbs.com/global_assets/special_content/medical_policy/policymanual/policy.html?pnum=10120.

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Specialty Matched Consultant Advisory Panel - 6/2004

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Specialty Matched Consultant Advisory Panel - 5/2006

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American Diabetes Association. (2008, January) Position Statement: Standards of medical care in diabetes - 2008. Diabetes Care. 31:S12-S54. Retrieved 5/29/08 from http://care.diabetesjournals.org/cgi/content/full/31/Supplement_1/S12#SEC5

Specialty Matched Consultant Advisory Panel - 5/2008

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.20, 10/7/08

Senior Medical Director Review - 11/17/08

Senior Medical Director Review - 6/24/09

Specialty Matched Consultant Advisory Panel 8/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.20, 4/08/10

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BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.20, 3/10/11

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.20, 3/8/12

Specialty Matched Consultant Advisory Panel 7/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.20, 3/14/13

Specialty Matched Consultant Advisory Panel 7/2013

FDA approval of MiniMed 530G. Available at http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/recently-approveddevices/ucm372176.htm . Last accessed 10/28/2013.

Medtronic MiniMed 530G. Available at http://www.medtronicdiabetes.com/treatment-and-products . Last accessed 10/28/2013.

American Diabetes Association: Standards of Medical Care in Diabetes 2013. Available at: http://care.diabetesjournals.org/content/36/Supplement_1/S11.full.pdf+html

Senior Medical Director review – 10/28/13

Senior Medical Director review – 12/3/13

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.20, 3/13/14

American Diabetes A. Standards of medical care in diabetes--2013. Diabetes Care 2013; 36 Suppl 1:S11-66

American Diabetes Association. Diabetes Care. Standards of Medical Care in Diabetes – 2014. Diabetes Care January 2014 vol. 37 no. Supplement 1 S14-S80.

Specialty Matched Consultant Advisory Panel – 7/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.20, 12/11/14

Specialty Matched Consultant Advisory Panel – 7/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.20, 6/16/2016

American Diabetes Association (ADA). 6. Glycemic Targets. Diabetes Care. Jan 2017;40(Suppl 1):S48-S56. PMID 27979893

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.20, 7/13/2017

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BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.20, 7/11/2019

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Deiss D, Szadkowska A, Gordon D, et al. Clinical Practice Recommendations on the Routine Use of Eversense, the First Long-Term Implantable Continuous Glucose Monitoring System. *Diabetes Technol Ther*. 2019;21(5):254–264. doi:10.1089/dia.2018.0397

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Medical Director review 6/2021

Policy Implementation/Update Information

10/2000	Original policy issued.
10/2000	Medical Policy Advisory Group - Approved.
5/2001	Policy key word added and changes in formatting.
11/2001	Coding format change.

5/2002	Policy reaffirmed. Reference sources added. Codes 95250, 99091, S1030, S1031 added to Billing and Coding section and the following statement was removed: "There is no specific CPT or HCPCS coding for this service. E1399 may be used."
8/2002	Specialty Matched Consultant Advisory Panel review 7/1/2002. No criteria changes. Format changes.
3/04	Benefits Application and Billing/Coding sections updated for consistency.
1/19/06	Added 2006 CPT code 95251 to "Billing/Coding" section.
6/19/06	Specialty Matched Consultant Advisory Panel review 5/18/2006. No changes to policy statement. Rationale added to "Policy Guidelines" section. References added.
11/13/06	"Description of Procedure or Service" was updated to include information related to integrated continuous glucose monitoring systems and insulin pumps. Added statement to the "When not covered" section to indicate, "Glucose sensors and transmitters associated with an integrated insulin pump are non-covered due to the investigational status of the continuous glucose monitoring system." The "Policy Guidelines" section was updated to reference ongoing clinical trials. Added the names various continuous glucose monitors to the "Policy Key Words" section.
12/31/07	Added new 2008 HCPCS codes; "A9276, A9277, and A9278" to "Billing/Coding" section.
6/30/08	Specialty Matched Consultant Advisory Panel review 5/29/08. No changes to policy statement. Updated rationale in "Policy Guidelines" section. References added.
12/8/08	Reviewed policy with Senior Medical Director 11/17/2008. Updated "Description" section. Changed "Policy" statement to; "BCBSNC may provide coverage for Continuous Monitoring of Glucose in the Interstitial Fluid when it is determined to be medically necessary because the medical criteria and guidelines shown below are met." Added criteria to the "When Covered" section indicating; "A. Intermittent monitoring (72 hours) of glucose levels in interstitial fluid may be considered medically necessary in the following situations when the criteria are met: 1. Patients with type 1 diabetes who despite current use of best practices have poorly controlled diabetes, including hemoglobin A1c not in acceptable target range for the patient's clinical situation, unexplained hypoglycemic episodes, evidence suggesting postprandial hyperglycemia, or recurrent diabetic ketoacidosis. 2. Patients with hypoglycemic unawareness. 3. Patients with type 1 diabetes prior to insulin pump initiation to determine basal insulin levels. 4. Women with type 1 diabetes who are pregnant or about to become pregnant and have poorly controlled diabetes. B. Continuous monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique in diabetic monitoring may be considered medically necessary in the following situations: 1. Patients with recurrent unexplained severe symptomatic hypoglycemia for whom hypoglycemia puts the patient or others at risk; or 2. Pregnant women with type 1 diabetes complicated by recurrent hypoglycemia, which is not resolved by current use of best practices. ***NOTE: See Policy Guidelines section for the definition of "best practices" in diabetes." Under "When Not Covered" section added; "1. Glucose sensors and transmitters associated with an integrated insulin pump are not medically necessary unless the patient meets criterion B.1. above AND does not already have an adequately functioning insulin pump. 2.Other uses of continuous monitoring of glucose levels in interstitial fluid (including real-time monitoring) as a technique of diabetic monitoring, are considered investigational." Updated "Policy Guidelines" section. References added.
8/3/09	Added the following statement to the "Description" section; "***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician." Moved "A.2. Patients with

hypoglycemic unawareness." into "A.1." in the "When Covered" section. Added "type I diabetes who have" to "B.1." and "severe, symptomatic (generally blood glucose levels less than 50 mg/dl)". Changed "B.2." to indicate; "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." In the "When Not Covered" section removed "A. Glucose sensors and transmitters associated with an integrated insulin pump are not medically necessary unless the patient meets criterion B.1. above AND does not already have an adequately functioning insulin pump." Reviewed by Senior Medical Director 6/24/09. Notice given 8/3/2009. Policy effective date 11/9/2009 (btw)

6/22/10 Policy Number(s) removed (amw)

10/12/10 Specialty Matched Advisory Panel review 8/2010. Added the MiniMed Paradigm Revel System to the "Description" section. Added the following statements to the Policy Guidelines section: "The patient must meet the FDA age indication for the specific device." and "CPT code 95251, (Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report,) is only eligible for reimbursement once every three months." References updated. (mco)

8/30/11 Description section and Policy Guidelines sections updated. No change in medical coverage criteria. Specialty Matched Advisory Panel review 7/27/11. (adn)

8/7/12 Related guideline added. Information on OmniPod Insulin Management System added. Policy Guidelines section updated. No change in coverage criteria. Specialty Matched Consultant Advisory Panel review 7/18/12. (sk)

5/14/13 Reference added. Policy statement added that artificial pancreases are considered investigational. Senior Medical Director review. (sk)

11/12/13 Specialty Matched Consultant Advisory Panel review 7/17/13. Information added about MiniMed 530G artificial pancreas system. No change to Policy statement. (sk)

12/10/13 Removed the phrase "with low glucose suspend (LGS) features" from the When Not Covered section. (sk)

6/10/14 References added. Senior Medical Director review. No change to Policy statement. (sk)

7/1/14 Codes S1034, S1035, S1036, S1037 added to Billing/Coding Section. (sk)

8/29/14 Specialty Matched Consultant Advisory Panel review 7/29/2014. No change to Policy statement. (sk)

10/28/14 Added the following statement to the Benefits Application section: "The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement." (mco)

9/1/15 Reference added. Material on artificial pancreas device systems, including the policy statement, removed from policy. Other policy statements unchanged. OmniPod removed from policy as it does not have a CGM included. Specialty Matched Consultant Advisory Panel review 7/29/2015. (sk)

9/30/16 Specialty Matched Consultant Advisory Panel review 7/27/2016. Minor changes in the Description section. Added rationale for type 2 diabetes to the Policy Guidelines section. No change to policy statement or intent. (an)

12/30/16 For 2017 coding update, added codes 0046T, 0047T, 0048T to Billing/Coding section. (an)

1/27/17 Correction to coding update. New codes are 0446T, 0447T, 0448T. (an)

6/30/17 Added new codes effective 7/1/2017: K0553 and K0554. (an)

8/11/17 Description and Policy Guidelines sections updated. The following statement was added to the "When Covered" section, Item B 1: Continuous monitoring of glucose levels in interstitial fluid may be considered medically necessary in 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 be adherent to a comprehensive diabetes treatment plan supervised by a qualified provider, and are capable of using the device to recognize alerts and alarms. Item B 2 was revised to read: …patients with type I diabetes who have recurrent unexplained, severe, (generally blood glucose levels less than 50 mg/dl) hypoglycemia **or impaired awareness of hypoglycemia** that puts the patient or others at risk. Specialty Matched Consultant Advisory Panel review 7/26/2017. (an)

12/15/17 Added new code 95249 effective 1/1/2018 to Billing/Coding section. (an)

7/27/18 Description and Policy Guidelines sections updated. Specialty Matched Consultant Advisory Panel review 6/27/2018. No change to policy statement. (an)

7/16/19 Description Section updated. Minor changes to Covered and Non-Covered Sections for clarity. No change to medical criteria. Policy Guidelines updated. References added. Specialty Matched Consultant Advisory Panel review 6/19/2019. (eel)

7/30/19 Description section updated for Eversense FDA approval. Added clarifying statement to "When not covered" section to include implantable CGM. (eel)

9/10/19 References added and evidence summary updated to include type 2 diabetes and Eversense CGM. Policy statement updated to include type 2 diabetes as medically necessary for continuous and intermittent monitoring. (eel)

7/14/20 References updated. Specialty Matched Consultant Advisory Panel review 6/17/2020. No change to policy statement. (eel)

7/1/21 Description, Policy Guidelines, References updated. Specialty Matched Consultant Advisory Panel review 6/16/2021. No change to policy statement. (lpr)