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 Review: 6/2024

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 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.

Tight glucose control requires multiple daily measurements of blood glucose (i.e., before meals and at bedtime), a commitment that some patients may find difficult to meet. 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 with patients who had type 1 diabetes. 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 HbA1c levels.

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).

Currently, CGM devices are of 2 designs; real-time CGM (rtCGM) provides real-time data on glucose level, glucose trends, direction, and rate of change, and intermittently viewed (iCGM) devices that show continuous glucose measurements retrospectively. These devices are also known as flash-glucose monitors.

Continuous Monitoring of Glucose in the Interstitial Fluid

Approved devices now include devices indicated 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 to10 minutes and stored data for download and retrospective evaluation by a clinician. With currently available devices, the intervals at which interstitial glucose is measured range 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, according to the U.S. Food and Drug Administration (FDA) labeling, some marketed 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 while other devices are factory calibrated and do not require fingerstick blood glucose calibration.

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 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	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
Dexcom® G6 Continuous Glucose Monitoring System	Dexcom	2018	Children, adolescents, and adults > 2 years; indicated for the management of diabetes in persons age ≥2 years. Intended to replace fingerstick blood glucose testing for diabetes treatment decisions.

			Intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems with 10-day wear
Dexcom® G7 Continuous Glucose Monitoring System	Dexcom	2022	Children, adolescents, and adults >2 years, including pregnant women
Freestyle Libre® Flash Glucose Monitoring System Abbott		2017	Adults ≥18 y. Indicated for the management of diabetes and can be worn up to 10 days It is designed to replace blood glucose testing for diabetes treatment decisions.
		2018	Adults ≥18 y. Extended duration of use to 14 days
Freestyle Libre® 2 Flash Glucose Monitoring System	Abbott	2020	Children, adolescents, and adults >2 years, including pregnant women
FreeStyle Libre® 3 Continuous Glucose Monitoring System	Abbott	2022	Children, adolescents, and adults >2 years, including pregnant women
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 Continuous Glucose Monitoring System	Senseonics	2019	Adults ≥18 y. Continually measuring glucose levels up to 90 days. Use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. Adults ≥18 y. Continually measuring glucose levels up to 90 days. Indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions. Historical data from the system can be interpreted to aid in providing therapy adjustments.
Eversense E3 Continuous Glucose Monitoring System	Senseonics	2022	Adults ≥18 y. Continually measuring glucose levels up to 180 days. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions. The system is intended to provide real-time glucose readings, provide glucose trend information, and provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time.

Eversense 365	Senseonics	2024	Adults ≥18 y. Continually measuring glucose levels up to 365 days. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions. The system is intended to provide real-time glucose readings, provide glucose trend information, and provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time.

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.

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, with non-implanted or implantable device, 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 for individuals not 18 years of age or older.

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 (i.e., long-term) monitoring.

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 A1c (HbA1c) 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 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. One RCT in pregnant women with type 1 diabetes, which compared real-time CGM with self-monitoring of blood glucose (SMBG), has also reported a difference in change in HbA1c 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 to determine that the technology results in an improvement in the net health outcome.

For individuals with type 1 diabetes who receive short-term continuous glucose monitoring, the evidence includes RCTs and systematic reviews. 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 of glycemic control is mixed, and there was no consistency in HbA1c levels. Some trials have reported improvements in glucose control for the short-term 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 are 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Type 2 Diabetes

For individuals with type 2 diabetes who are treated with insulin therapy who receive long-term CGM, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. RCTs have included individuals on intensive insulin therapy and individuals on basal insulin. Three RCTs have evaluated CGM compared to SMBG in individuals with type 2 diabetes on intensive insulin therapy; 1 using real-time CGM and 2 using an intermittently scanned device. One RCT evaluated CGM in patients treated with basal insulin. All found either improved glycemic outcomes or no difference between groups with no increase in hypoglycemic events. In the DIAMOND trial, the adjusted difference in mean change in HbA1c level from baseline to 24 weeks was -0.3% (95% CI, -0.5% to 0.0%; p=.022) favoring CGM. The adjusted difference in the proportion of patients with a relative reduction in HbA1c level of 10% or more was 22% (95% CI, 0% to 42%; p=.028) favoring CGM. There were no events of severe hypoglycemia or diabetic ketoacidosis in either group. Yaron et al (2019) reported higher treatment satisfaction with CGM compared to control (the primary outcome). At 12-month follow-up in one of the trials of the Freestyle Libre device, hypoglycemic events were reduced by 40.8% to 61.7% with a greater relative reduction in the most severe thresholds of hypoglycemia. In the Martens trial of individuals treated with basal insulin without prandial insulin, there was a statistically significantly greater decrease in mean HbA1c in the CGM group (adjusted difference, -0.4%; 95% CI -0.8% to -0.1%; p=.02), with 1

hypoglycemic event in each group. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with type 2 diabetes who are not treated with insulin therapy who receive long-term CGM, the evidence includes 4 RCTs. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. Results were mixed regarding benefits of CGM with respect to glycemic control. Participant populations were heterogenous with regard to their diabetic treatment regimens, and participants might not have been receiving optimal therapy. In individuals on oral antidiabetic agents only, routine glucose monitoring may be of limited additional clinical benefit. Additional evidence would be needed to show what levels of improvement in blood glucose excursions and HbA1c levels over the short-term in this population would be linked to meaningful improvement in long-term health outcomes such as diabetes-related morbidity and complications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with type 2 diabetes who receive short-term continuous glucose monitoring, the evidence includes RCTs and systematic reviews. 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 of glycemic control is mixed, and there was no consistency in HbA1c levels. Some trials have reported improvements in glucose control for the short-term 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 are imprecise. The limited duration of use may preclude an assessment of any therapeutic effect. Three 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 other trials 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 studies in which these outcomes were reported. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Implantable CGM

For individuals with type 1 or type 2 diabetes who receive continuous glucose monitoring with an implantable device, the evidence includes an RCT and nonrandomized studies. The RCT compared implantable CGM with control (self-monitoring of blood glucose or intermittently scanned CGM). The RCT was conducted in France and enrolled participants in 2 cohorts; cohort 1 included participants with type 1 or type 2 diabetes with HbA1c >8.0% while cohort 2 included participants with type 1 diabetes with time spent with glucose values below 70 mg/dL for more than 1.5 hours per day in the previous 28 days. In cohort 1, there was no difference in mean HbA1c, time in range, or patient-reported outcomes at day 180. In cohort 2, the mean difference in time spent below 54 mg/dL between days 90 and 120 was statistically significant favoring implantable CGM (difference=-1.6% [23 minutes]; 95% CI, -3.1 to -0.1; p=.04). There were no differences in patient reported outcomes. Nonrandomized prospective studies and post-marketing registry studies assessed the accuracy and safety of an implanted glucose monitoring system. Accuracy measures included the mean absolute relative difference between paired samples from the implanted device and a reference standard blood glucose measurement. The accuracy tended to be lower in hypoglycemic ranges. The initial approval of the device has been expanded to allow the device to be used for glucose management decision making. The same clinical study information was used to support what the FDA considered a reasonable assurance of safety and effectiveness of the device for the replacement of fingerstick blood glucose monitoring for diabetes treatment decisions. In February 2022, the FDA expanded approval of the device for use up to 180 days. Approval was based on the PROMISE pivotal clinical trial, which assessed accuracy and safety but not glycemic outcomes. Limitations of the evidence base include limited comparisons to SMBG, lack of differentiation in outcomes for type 1 diabetes versus

type 2 diabetes, and variability in reporting of trends in secondary glycemic measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Gestational Diabetes
For individuals who are pregnant with gestational diabetes who receive long-term CGM or short-term (intermittent) glucose monitoring, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. In the RCTs, trial reporting was incomplete; however, there was no difference between the groups for most reported outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The American Diabetes Association (2023) "Standards of Medical Care in Diabetes" made the following recommendations (**level of evidence**) on CGM devices:

- "Real-time CGM (**A)** or intermittently scanned continuous glucose monitoring (**B**) should be offered for diabetes management in adults with diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs."
- "Real-time CGM (**A**) or intermittently scanned continuous glucose monitoring (**C**) should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs."
- "Real-time CGM (**B**) or intermittently scanned continuous glucose monitoring (**E**) should be offered for diabetes management in youth with type 1 diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs."
- "Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring should be offered for diabetes management in youth with type 2 diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs." **(E)**
- When used as an adjunct to pre- and postprandial blood glucose monitoring, CGM can help to achieve A1c targets in diabetes and pregnancy **(B).**
- Periodic use of real-time or intermittently scanned cCGM or use of professional CGM can be helpful for diabetes management in circumstances where continuous use of CGM is not appropriate, desired, or available **(C)**.

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, A4239, A9276, A9277, A9278, E2103, G0564, G0565, S1030, S1031*

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

Blue Cross NC considers Implantable CGM (Eversense) codes 0446-0448T to represent the procedure only, while A9276 represents the device. A9276 units are required to match implantable device life expectancy (e.g., 180 days = 180 units).

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

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Medical Director review 6/2023

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Food and Drug Administration (FDA). Summary of Safety and Effectiveness (SSED): Dexcom G5 Mobile Continuous Glucose Monitoring System. 2016; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120005S041.

American Diabetes Association. Standards of Medical Care in Diabetes. 2022. https://professional.diabetes.org/content-page/practice-guidelines-resources.

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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)
1/11/22	References updated. Following statement was added to "When Not Covered" section, The use of intermittently scanned (flash) CGM devices is considered investigational. Medical Director review 1/2022. (tt)
3/8/22	Following statement was removed from "When Not Covered" section, The use of intermittently scanned (flash) CGM devices is considered investigational. Medical Director review 2/2022. (tt)
7/12/22	References updated. Specialty Matched Consultant Advisory Panel review 6/2022. Medical Director review 6/2022. Added codes G0308 and G0309 to Billing/Coding section, effective 7/1/2022. Updated FDA approved device list to include Freestyle Libre 3. No change to policy statement. (tt)
12/30/22	Added the following statement to When Not Covered section, "The use of d-Nav technology for automated, intermittent glucose monitoring and insulin titration is considered investigational." Updated Billing/Coding section to add 0740T, 0741T, A4239, and E2103, effective 1/1/2023; removed G0308 and G0309. Medical Director review 11/2022. (tt)
6/30/23	Policy Guidelines updated. References updated. Updated FDA approved device list to include Dexcom® G7 Mobile CGM. Specialty Matched Consultant Advisory Panel review 6/2023. Medical Director review 6/2023. No change to policy statement. (tt)

7/17/24 Description, Policy Guidelines, FDA approved device list, and References updated. Updated Billing/Coding section to remove deleted codes K0553 and K0554. Specialty Matched Consultant Advisory Panel review 6/2024. Updated When Covered "B" as follows: Continuous monitoring of glucose levels in interstitial fluid, with non-implanted or implantable device, including real-time monitoring, as a technique in diabetic monitoring may be considered medically necessary. Updated When Not Covered as follows: Continuous glucose monitoring using an implantable glucose sensor (i.e., Eversense™ CGM system) is considered investigational for individuals not 18 years of age or older. Medical Director review 6/2024. (tt)

10/1/24 Removed the following statement from When Not Covered section, "The use of d-Nav technology for automated, intermittent glucose monitoring and insulin titration is considered investigational" as it is addressed in Artificial Pancreas Device Systems medical policy. Updated Billing/Coding section to removed 0740T and 0741T. Remove the following statement from Benefits Application section: "The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement." (tt)

10/30/24 Updated the FDA approved device list. Added the following statement to Billing/Coding section: "Blue Cross NC considers Implantable CGM (Eversense) codes 0446-0448T to represent the procedure only, while A9276 represents the device. A9276 units are required to match implantable device life expectancy (e.g., 180 days = 180 units)." (tt)

12/31/24 Updated Billing/Coding section to add G0564, G0565, effective 1/1/2025. (tt)