Continuous Monitoring of Glucose in the Interstitial Fluid

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. 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. The goal of tight glucose control has to be balanced with the associated risk of hypoglycemia. An additional limitation of periodic self-measurements of blood glucose (SMBG) is that glucose values are seen in isolation, and trends in glucose levels are undetected.

Measurement of glucose in the interstitial fluid is a technique that has been developed to automatically measure glucose values throughout the day, producing data that show trends in glucose measurements, in contrast to isolated glucose readings of traditional blood glucose measurements.

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

Additional devices that have subsequently been approved include those for pediatric use and those with more advanced software, more frequent measurements of glucose levels, more sophisticated alarm systems, etc. Devices initially measured interstitial glucose every 5 to 10 minutes and 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, it is important to note that devices may be used intermittently, i.e., for time periods of 72 hours, or continuously on a long-term basis.
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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:

- The Continuous Glucose Monitoring System (CGMS®) (MiniMed) in 1999 (approved for 3-day use in a physician's office).
- The GlucoWatch G2® Biographer in 2001. Of note, neither the GlucoWatch nor the autosensors have been available after July 31, 2008.
- The Guardian®-RT (Real-Time) CGMS (Medtronic, MiniMed) in July 2005. (MiniMed was purchased by Medtronic).
- The DexCom® STS CGMS system (DexCom) was approved by the FDA in March 2006.
- The Paradigm® REAL-Time System (Medtronic, MiniMed) was approved by the FDA in 2006. This system integrates a continuous glucose monitor with a Paradigm insulin pump. The second generation integrated system is called the MiniMed Paradigm Revel System.
- The FreeStyle Navigator® CGM System (Abbott) was approved in March 2008.
- The DexCom® G4 Platinum (DexCom) CGM was approved for use in adults 18 years and older in October 2012. The device can be worn for up to 7 days. In February 2014, FDA expanded use of the Dexcom Platinum CGM to include patients with diabetes, age 2 to 17 years-old.
- DexCom® G5 Mobile CGM, approved in 2016 as a supplement to the G4 premarketing approval and indicated as a replacement for fingerstick BG testing in patient over age 2. The 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.

***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 when the criteria are met:

1. Patients with type I 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, hypoglycemic unawareness, suspected postprandial hyperglycemia, or recurrent diabetic ketoacidosis.
Continuous Monitoring of Glucose in the Interstitial Fluid

2. Patients with type I diabetes prior to insulin pump initiation to determine basal insulin levels.

3. Women with type I 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 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 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; or

3. 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.

*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.

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.

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.

The patient must meet the FDA age indications for the specific device.

For individuals who have type 1 diabetes who are willing and able to use the device, and have adequate medical supervision who receive long-term CGM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Systematic reviews have generally found that, at least in the short-term, long-term CGM resulted in significantly improved glycemic control for adults and children with type 1 diabetes, particularly highly compliant patient. Most recently, a 2017 individual patient data analysis, using data from 11 RCTs, found that reduction in HbA1c levels was significantly greater with real-time CGM compared with a control intermention. There are few data on the effectiveness of CGM beyond
Continuous Monitoring of Glucose in the Interstitial Fluid

6 months. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

The evidence is also insufficient to determine the effects of the technology on health outcomes for individuals with type 1 diabetes who received short-term (intermittent) glucose monitoring and for pregnant individuals with diabetic complications who received long-term CGM.

In 2017, The American Diabetes Association (ADA) position statement on diabetes includes the following recommendations on continuous glucose monitoring:

- When used properly, continuous glucose monitoring in conjunction with intensive insulin regimens is a useful tool to lower A1c in selected adults (age at least 25 years) with type 1 diabetes.

- Although the evidence of A1c lowering is less strong in children, teens, and younger adults, CGM may be helpful in those groups. Success correlates with adherence to ongoing use of the device.

- CGM may be a useful tool in those with hypoglycemic unawareness and/or frequent hypoglycemic episodes.

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

**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: 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

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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


Senior Medical Director Review - 11/17/08

Senior Medical Director Review - 6/24/09


American Diabetes Association: Standards of Medical Care in Diabetes 2011. Available at: http://care.diabetesjournals.org/content/34/Supplement_1/S11.full


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Specialty Matched Consultant Advisory Panel 7/2012


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


Policy Implementation/Update Information

10/2000 Original policy issued.


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."
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3/04  Benefits Application and Billing/Coding sections updated for consistency.

1/19/06  Added 2006 CPT code 95251 to "Billing/Coding" section.


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.


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."

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.
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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."


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)


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)
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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)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.