

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: 7/2011
Next CAP Review: 7/2012
Last Review: 7/2011

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.

The advent of blood glucose monitors for use by patients in the home over 20 years ago revolutionized the management of diabetes. Using fingersticks, patients could monitor their blood glucose level both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. The importance of tight diabetic control has been validated over the past 10 years by several published randomized clinical trials (RCTs), which have demonstrated that decreasing diabetic complications is associated with tight glucose control, defined as a hemoglobin A1c measurement of less than 7%. However, tight glucose control may require multiple measurements of blood glucose each day (i.e., before meals and at bedtime), a commitment that some patients may be unwilling or unable to meet. 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). While the time intervals at which interstitial glucose is measured range from every 5 minutes (CGMS) to every 10 minutes (GlucoWatch), both types of monitoring have been referred to as continuous glucose monitoring (CGM). While both devices potentially eliminate or decrease the number of required daily fingersticks, it should be noted that, according to the FDA labeling, neither is intended to be an alternative to traditional self-monitoring of blood glucose levels but rather serve as an adjunct, supplying additional information on glucose trends that are not available from self-monitoring. Additional devices have been approved in recent years. These include devices for pediatric use and devices with more advanced software, more frequent measurements of glucose levels, more sophisticated alarm systems, etc.

In evaluating the continuous glucose monitoring systems, it is important to recognize that they may be used intermittently, e.g., time periods of 72 hours, or continuously. In addition, it is important to note that all FDA-approved CGM systems are indicated as adjuncts to traditional self-monitoring of blood glucose and should not be used instead of self-monitoring.

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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.

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

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

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

The data supporting use of continuous (long-term) glucose monitoring are still limited. Studies by the Juvenile Diabetes Research Foundation suggest that more frequent use of continuous glucose monitors may result in better outcomes, but this has not been tested prospectively. Using rationale similar to that noted above for intermittent monitoring, continuous monitoring can also be used, and can be considered medically necessary, to provide additional data for management of those who have recurrent, unexplained, severe symptomatic hypoglycemia, despite use of current best practices, that puts the patient or others at risk and for pregnant patients with type I diabetes.

Data to support use (that show improved outcomes) of devices that allow wireless connectivity between a continuous monitoring device and insulin pump are still limited. Moreover, there is limited evidence on use of continuous glucose monitors by patients with type 2 diabetes and on use of integrated continuous glucose monitors and insulin pump systems; randomized trials are underway that will provide additional data.

The American Diabetes Association (ADA) makes the following recommendations concerning continuous glucose monitoring in its 2011 standards of medical care in diabetes: Continuous glucose monitoring in conjunction with intensive insulin regimens can be 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.

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CGM may be a supplemental tool to self-monitoring of blood glucose in those with hypoglycemic unawareness and/or frequent hypoglycemic episodes.

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, A9276, A9277, A9278, S1030, S1031

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://bluweb.bcbs.com/global_assets/special_content/medical_policy/policymanual/policy.html?pnunm=10120.

American Diabetes Association. (2004, January) Position Statement: Tests of glycemia in diabetes. *Diabetes Care*. 27(Supp. 1), S91-S93. Retrieved on 6/10/04 from http://care.diabetesjournals.org/cgi/content/full/27/suppl_1/s91.

Specialty Matched Consultant Advisory Panel - 6/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.20, 9/27/2005.

Specialty Matched Consultant Advisory Panel - 5/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.20, 12/13/07

American Diabetes Association. (2008, January) Position Statement: Standards of medical care in diabetes - 2008. *Diabetes Care*. 31:S12-S54. Retrieved 5/29/08 from

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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

American Diabetes Association (2010, January) Executive Summary: Standards of Medical Care in Diabetes. Diabetes Care 33:S4-S10; doi:10.2337/dc10-S004. Retrieved on July 22, 2010 from http://care.diabetesjournals.org/content/33/Supplement_1/S4.full.pdf+html

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

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

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.

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- 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

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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)

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.