



## Corporate Medical Policy

# Continuous Monitoring of Glucose in the Interstitial Fluid

**File Name:** continuous\_monitoring\_of\_glucose\_in\_the\_interstitial\_fluid  
**Policy Number:** DME0027  
**Origination:** 10/2000  
**Last CAP Review:** 5/2008  
**Next CAP Review:** 5/2010  
**Last Review:** 6/2009

### Description of Procedure or Service

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Blood glucose monitors for use by patients in the home have been available for over 20 years and have revolutionized the management of diabetes. The use of fingersticks allows patients to monitor their own blood glucose levels to determine the adequacy of their hyperglycemic control and to evaluate hypoglycemic episodes. Tight diabetic control has been proven over the past 10 years to decrease diabetic complications. Tight glucose control is 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. These data are able to show trends in glucose measurements, in contrast to isolated glucose readings of traditional blood glucose measurements. These devices rely on the oxidation of glucose by glucose oxidase to produce hydrogen peroxide. Within the sensor, the hydrogen peroxide is further oxidized, which produces electrons and generates a measurable electric current that can be calibrated to the glucose concentration.

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.

The FDA approved the Continuous Glucose Monitoring System (CGMS) (MiniMed) in 1999 and the upgraded version, the Guardian CGMS in 2005. Both use an implanted sensor in the subcutaneous tissue. This is attached to a small plastic disk the size of a dime that is taped to the skin to hold the sensor in place. A thin wire connects the sensor to a pager-sized glucose monitor, which records and stores glucose values in memory. An electrical signal is continuously relayed to the glucose sensor to record glucose levels every 5 minutes. The Guardian CGMS features an audible alarm that sounds when glucose levels become too high or too low per parameters set by the patient and physician. The alarm is intended to prompt the patient to perform a fingerstick blood glucose measurement, since a level is not provided with the sounding of the alarm.

According to FDA labeling, the above devices are not intended to be an alternative to traditional self-monitoring of blood glucose levels (SMBG), but rather serve as an adjunct to supply additional information on glucose trends that are not available from self-monitoring. They are intended for occasional rather than everyday use. The data are to be used to guide future management of the patient based on response to trends noted. Patterns observed may be used to suggest when to take the fingerstick glucose measurements to better manage patients.

More recently, several devices have been approved by the FDA to provide real-time glucose monitoring

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such as the Guardian-RT (Real-Time) CGMS (Medtronic, MiniMed). The DexCom STS Continuous Glucose Monitoring System (Dexcom) received pre-market approval in March 2006 is indicated for use as an adjunctive device to complement, not replace, information obtained from home glucose monitoring devices. The FreeStyle Navigator Continuous Glucose Monitoring System (Abbott) has sensors that can be worn either on the back of the upper arm or on the abdomen. All are to be used as an adjunct to therapy and any adjustments should be based on the glucose measurements obtained by the use of a home glucose monitor and not on the sensor readings. The Paradigm REAL-Time System consists of an insulin infusion pump, the glucose sensor, and a transmitter

Continuous glucose monitoring devices display interstitial glucose readings frequently (every 1-5 minutes depending on the device). The goal of this continuous close monitoring is to provide better management to improve both hemoglobin A1C and to decrease acute glucose fluctuations. Ongoing clinical trials should help assess how this technology impacts health outcomes.

The GlucoWatch G2 Biographer is an external device worn like a wristwatch that measures glucose in the [interstitial](#) fluid extracted through the skin with an electric current was one of the first CGMS developed. However, this product is no longer available as of July 31, 2008.

### **Policy**

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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**

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Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

### **When Continuous Monitoring of Glucose in the Interstitial Fluid is covered**

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- 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
  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

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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

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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

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Best practices in diabetes control are those patients with type I diabetes who are compliant with a regimen including 4 or more fingersticks each day and use of an insulin pump. 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 2008 Standards of Care from the American Diabetes Association (ADA) include a recommendation that "CGMS may be a supplemental tool to self monitoring blood glucose (SMBG) for selected patients with type I diabetes, especially those with hypoglycemia unawareness." This recommendation was based on expert consensus or clinical experience.

The available studies demonstrate that intermittent glucose monitoring provides a different type of data than results from fingerstick 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.

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

### Billing/Coding/Physician Documentation Information

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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](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 95250, 95251, 99091, A9276, A9277, A9278, S1030, S1031*

### Medical Term Definitions

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#### **Interstitial**

pertaining to or situated between parts or in the interspaces of a tissue.

### Scientific Background and Reference Sources

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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](http://blueweb.bcbs.com/global_assets/special_content/medical_policy/policymanual/policy.html?pnum=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](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 [http://care.diabetesjournals.org/cgi/content/full/31/Supplement\\_1/S12#SEC5](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

## Policy Implementation/Update Information

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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.

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- 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)

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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.