Medical Policy

BlueCross BlueShield of Kansas
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Title: Continuous Glucose Monitoring System (CGMS)

Professional
Original Effective Date: June 27, 2001
Revision Date(s): September 3, 2003; January 26, 2004; April 21, 2005; November 2, 2006; July 17, 2007
Current Effective Date: September 3, 2008

Institutional
Original Effective Date: July 1, 2005
Revision Date(s): November 2, 2006; July 17, 2007
Current Effective Date: September 3, 2008

DESCRIPTION

Measurements of glucose in the interstitial fluid have been developed as a technique of automatically measuring glucose values throughout the day, producing data that show the trends in glucose measurements, in contrast to the isolated glucose measurements of the traditional blood glucose measurements. Two devices have received U.S. Food and Drug Administration (FDA) approval: 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.

The Continuous Glucose Monitoring System (CGMS) (MiniMed) and the upgraded version, the Guardian CGMS, consist of a subcutaneously implanted sensor that is attached to a small plastic disk the size of a dime and 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, which records glucose levels every 5 minutes, some 288 values per day.

The FDA-approved labeling for the CGMS states, in part: The CGMS is currently intended for occasional rather than everyday use, and is to be used only as a supplement to, and not a replacement for, standard invasive measurement. The CGMS is not intended to change patient management based on the numbers generated, but to guide future management of the patient based on response to trends noticed. That is, these trends or patterns may be used to suggest when to take the fingerstick glucose measurements to better manage the patients.

POLICY

Continuous glucose monitoring system (CGMS – up to 72 hours) may be considered a covered benefit when a patient is compliant with a prescribed intensive insulin program/therapy (multiple daily injections (MDI) of 4-5 injections of insulin per day or insulin pump). Prior approval is encouraged. The following conditions will be considered to determine medical necessity:

1. Unexplained large fluctuations in daily pre-prandial glucose values,
2. Unexplained frequent hypoglycemic attacks,
3. Unexplained episodes of ketoacidosis or hospitalization for glucose out of control,
4. Unexplained suboptimal glycemic control as reflected by a glycohemoglobin (HbA1c) value of greater than 7.0 percent.

Repeat testing for continuous glucose monitoring system (CGMS):

1. Prior approval is encouraged, and
2. Patient is compliant on a prescribed intensive insulin program/therapy, and
3. May occur four to six weeks following the initial study.

Purchase or rental of continuous glucose monitoring devices and related supplies is considered deluxe, patient responsibility/non-covered.

DOCUMENTATION

1. Use of a basal or long-acting insulin to simulate normal basal insulin secretion from the pancreas and very short-acting (bolus) insulin dosed several times per day to cover meal or snack related rises in blood sugar.
2. Appropriate and detailed education consisting of seven hours taught by a physician, ARNP, dietitian or diabetes educators. Education will pertain to:
   a. When to bolus,
   b. How much to bolus depending on meal content,
   c. How much to adjust basal rates,
   d. Meal boluses depending on projected activity levels,
   e. Use of sick day guidelines

CODING

CPT/HCPCS (Covered)

95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording (do not report 95250 in conjunction with 99091)
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; physician interpretation and report (Do not report 95250, 95251 in conjunction with 99091)

CPT/HCPCS (Non-Covered)

A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
S1030	Continuous non-invasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)
S1031	Continuous non-invasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)

DIAGNOSIS

These diagnoses are otherwise subject to medical policy as stated above

250.01	Diabetes mellitus without mention of complication, type I (juvenile type), not stated as uncontrolled
250.03	Diabetes mellitus without mention of complication, type I (juvenile type), uncontrolled
250.11	Diabetes with ketoacidosis, type I (juvenile type), not stated as uncontrolled
250.13	Diabetes with ketoacidosis, type I (juvenile type), uncontrolled
250.21	Diabetes with hypertension, type I (juvenile type), not stated as uncontrolled
250.23	Diabetes with hypertension, type I (juvenile type), uncontrolled
250.31	Diabetes with other coma, type I (juvenile type), not stated as uncontrolled
250.33	Diabetes with other coma, type I (juvenile type), uncontrolled
250.41	Diabetes with renal manifestations, type I (juvenile type), not stated as uncontrolled
250.43	Diabetes with renal manifestations, type I (juvenile type), uncontrolled
250.51	Diabetes with ophthalmic manifestations, type I (juvenile type), not stated as uncontrolled
250.53	Diabetes with ophthalmic manifestations, type I (juvenile type), uncontrolled
250.61	Diabetes with neurologic manifestations, type I (juvenile type), not stated as uncontrolled
250.63	Diabetes with neurologic manifestations, type I (juvenile type), uncontrolled
250.71	Diabetes with peripheral circulatory disorders, type I (juvenile type), not stated as uncontrolled
250.73	Diabetes with peripheral circulatory disorders, type I (juvenile type), uncontrolled
250.81	Diabetes with other specified manifestations, type I (juvenile type), not stated as uncontrolled
250.83	Diabetes with other specified manifestations, type I (juvenile type), uncontrolled
250.91	Diabetes with other unspecified complications, type I (juvenile type), not stated as uncontrolled
250.93	Diabetes with other unspecified complications, type I (juvenile type), uncontrolled

REVISIONS

01-26-2004	Deleted "Certain diabetic and newly pregnant or who are about to conceive" and "Patients who are about to start insulin for the first time using an insulin pump regimen"
	Added "Suboptimal glycemic control as reflected by a glycohemoglobin (HbA1c) value of greater than 7.0 percent."
	Added "Repeat testing for Continuous Glucose Monitoring System® (CGMS®): a. Prior Approval is recommended; and b. Patient is compliant on a prescribed intensive insulin program/therapy; and c. May occur four to six weeks following the initial study."
	Added "Use of noninvasive continuous glucose monitoring devices (e.g. Gluco Watch Biographer®) and related supplies is considered experimental/investigational for all indications."
04-21-2005	Added the definition of "intensive insulin therapy".
	Added, "The use of combined insulin, such as 70/30 insulin did not meet the criteria for "program involvement" of multiple daily injections."
11-02-2006 effective 01-02-2007	In "Description" section, deleted the paragraph starting with "The GlucoWatch is similar in appearance to a wristwatch that is worn on the inner or" as recommended by the Medical Director.
	In "Description" section, deleted the paragraph starting with "Although the noninvasiveness is an attractive quality of the device, it should be…" as recommended by the Medical Director..
	In "Description" section, deleted "For calibration purposes, the manufacturer recommends that the patient enter the results of 4 fingerstick blood glucose measurements per day into the monitor. For the Guardian CGMS, it is recommended that the device be calibrated with fingerstick blood glucose levels every 12 hours at a minimum. The Guardian CGMS does feature an audible alarm that sounds when glucose levels become too high or too low per parameters set by the patient and physician." as recommended by the Medical Director.
	In "Description" section, deleted the paragraph starting with "The definition of 'Intensive Insulin Therapy' is the use of an insulin regimen that…" as recommended by the Medical Director..
	In "Policy" section, first paragraph, added "(multiple daily injections (MDI) of 4-5 injections of insulin per day or insulin pump)." as recommended by the Medical Director.
	In "Policy" section, deleted "and one of the following conditions have been met:" and the "or" at the end of #1, #2, and #3 sentences per November MAC.
	In "Policy" section, added to the end of the opening sentence "The following conditions will be considered to determine medical necessity:" per November MAC.
	In "Policy" section, added "Unexplained" to the beginning of #3 and #4 per November MAC.
	In "Documentation" section, deleted "Program Involvement (all required):" as recommended by the Medical Director.
	In "Documentation" section, deleted #2 "Basal insulin usually involves "Ultralente" and "Lantus" insulin." as recommended by the Medical Director.

	In "Documentation" section, deleted #3 "Bolus insulin (insulin analogue) usually involves "Humalog" or "Novolog" insulin." as recommended by the Medical Director.
	In "Coding" Covered Diagnosis, deleted ICD-9 codes (for type II) 250.00, 250.02, 250.10, 250.12, 250.20, 250.22, 250.30, 250.32, 250.40, 250.42, 250.50, 250.52, 250.60, 250.62, 250.70, 250.72, 250.80, 250.82, 250.90, and 250.92 as recommended by the Medical Director.
	In "Reference" Government Agency; Medical Society; and Other Authoritative Publications section, added new #3 through #7.
07-17-2007	In Policy section: ▪ Added clarification to policy that continuous glucose monitoring system is limited to 72 hours. Extended use beyond 72 hours is considered patient deluxe, patient responsibility/non-covered. In Coding section: ▪ Removed code 99091.
01-01-2008	In Coding section: ▪ Added codes and nomenclature for A9276, A9277, A9278.
09-03-2008	In Coding section: ▪ Added codes and nomenclature for S1030, S1031. ▪ Corrected nomenclature for 95250.
	In Policy section: Revised wording from "requires prior approval" to "prior approval is encouraged".

REFERENCES

1. Chase HP, Roberts MD, Wightman C et al. Use of the GlucoWatch Biographer in children with type 1 diabetes. Pediatrics 2003;111(4):790-4.
2. Chico A, Vidal-Rios P, Subira M et al. The continuous glucose monitoring system is useful for detecting unrecognized hypoglycemias in patients with type 1 and type 2 diabetes but is not better than frequent capillary glucose measurements for improving metabolic control. Diabetes Care 2003; 26(4): 1153-7.
3. Eastman RC, Leptien A, Chase HP. Cost effectiveness of use of the GlucoWatch Biographer in children and adolescents with type 1 diabetes: an analysis based on a randomized controlled trial. Abstracts from the American Diabetes Association's 63rd Scientific Sessions, 2003, #398-P.
4. Evans JM, Newton RW, Ruta DA et al. Frequency of blood glucose monitoring in relation to glycemic control: observational study with diabetes database. BMJ 1999; 319(7202):83-6.
5. Ludvigsson J, Hanas R. Continuous subcutaneous glucose monitoring improved metabolic control in pediatric patients with type 1 diabetes: a controlled crossover study. Pediatrics 2003; 111(5 pt 1):933-8.
6. Tamada JA, Garg S, Jovanovic L et al. Noninvasive glucose monitoring: comprehensive clinical results. JAMA 1999; 282(19): 1839-44.
7. BCBSKS Medical Director, July 17, 2007.

Government Agency; Medical Society; and Other Authoritative Publications

1. 2003 TEC Assessment: Continuous or Intermittent Monitoring of Interstitial Glucose.

2. Bode B, Lane C, Levetan J et al. Therapy adjustments based on CGMS data lower HbA1c with less hypoglycemia than blood glucose meter data alone. Abstracts from the American Diabetes Association's 63rd Scientific Sessions, 2003, #386-P.
3. Blue Cross and Blue Shield of Kansas Family Practice Liaison Committee, July 11, 2006 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC–03-06).
4. Blue Cross and Blue Shield of Kansas Internal Medicine Liaison Committee, August 30, 2006 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC–03-06).
5. Blue Cross and Blue Shield of Kansas Pediatric Liaison Committee, August 2, 2006 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC–03-06).
6. Blue Cross and Blue Shield of Kansas Medical Advisory Committee (MAC) meeting, November 2, 2006 (see Blue Cross and Blue Shield of Kansas Newsletter, Blue Shield Report. MAC–03-06).
7. BCBSKS Medical Consultant, Practicing Board Certified Endocrinologist (107), July 20, 2006.
8. National Medical Consultant, Board Certified in Internal Medicine and Pediatrics with sub-certification in Endocrinology, Diabetes and Metabolism and Pediatric Endocrinology, October 22, 2007, (ID-1076-5188).

Web site

1. CGMS: FDA Summary of Safety and Effectiveness: www.fda.gov/cdrh/pdf/p980022b.pdf
2. GlucoWatch G2 Biographer: FDA Summary of Safety and Effectiveness: www.fda.gov/cdrh/pdf/p990026S008b.pdf.