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Title

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

Description

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, which have demonstrated that decreasing diabetic complications are 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. In addition, the goal of tight glucose control has to be balanced with an associated risk of hypoglycemia. An additional limitation of periodic self-measurements of blood glucose is that glucose values are seen in isolation, and trends in glucose levels are undetected. For example, while a diabetic's fasting blood glucose level might be within normal values, hyperglycemia might be undetected postprandially, leading to elevated hemoglobin A1c values.

Recently, measurements of glucose in 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. 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. It is hoped that this information on glucose trends will lead to improved anti-diabetic regimens and, ultimately, normalization of hemoglobin A1c levels with a decreased risk of hypoglycemia.

Both devices rely on the same chemistry, i.e., the oxidation of glucose by glucose oxidase to produce hydrogen peroxide. Within the sensor, the hydrogen peroxide is further oxidized, ultimately producing electrons and generating a measurable electric current, which can be calibrated to the glucose concentration.

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. 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 CGMS sensors are capable of transmitting values for up to 3 days, after which time the sensor must be removed and replaced with another by the patient, if additional monitoring is needed. The Guardian CGMS can store up to 21 days of data. The data captured in the monitor can be downloaded to a personal computer for review and used by a physician or the patient. Unlike the GlucoWatch, the glucose values are not displayed on these systems. However, 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.

The FDA-approved labeling for the CGMS states, in part, that 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 patients.

Subsequently, additional devices have been approved by the FDA that provide real-time continuous glucose monitoring. The Guardian-RT (Real-Time) CGMS (Medtronic, MiniMed), which provides real-time information, received premarket approval in July 2005. The approval statement indicates its use for monitoring glucose levels in adults (ages 18 and older) with diabetes mellitus. It also states that values are not intended to be used directly for making therapy adjustments but to provide an indication of when a fingerstick may be required, and that all therapy adjustment would be based on measurements obtained using a home glucose monitor and not on Guardian values. (1) The DexCom STS CGMS system (DexCom) was approved by the FDA in March 2006, and is also for use in those with diabetes mellitus who are ages 18 and older. Information from the premarket approval indicates that the system is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices. (2) Other real-time CGM systems are being studied, including systems for the pediatric age group.

During review for the policy update in 2008, additional devices were identified that now have FDA approval. The FreeStyle Navigator CGM System (Abbott) was approved in March 2008. The sensor for this device can be worn on the back of the upper arm or on the abdomen. As with other CGM devices, information for this device also notes " Before adjusting therapy for diabetes management based on the results and alarms from the FreeStyle Navigator system, traditional blood glucose tests must be performed." The Paradigm REAL-Time System and Guardian REAL-Time System (Pediatric Versions) (Medtronic, MiniMed) were approved by the FDA in March 2007. These are pediatric versions of previously approved devices. The approval of these devices includes the wording "All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on the sensor glucose readings ..." This approval was based on the concordance of glucose results between those obtained with the sensor and with a glucose meter. The Paradigm system consists of an insulin infusion pump, the glucose sensor, and a transmitter.

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.

When services are covered for commercial products

We cover **intermittent monitoring**, i.e., up to 72 hours, of glucose levels in interstitial fluid in patients with type I diabetes prior to insulin pump initiation to determine basal insulin levels.¹

We cover **intermittent monitoring**, i.e., up to 72 hours, of glucose levels in interstitial fluid in patients with type I diabetes whose diabetes is poorly controlled.

We cover **intermittent monitoring**, i.e., up to 72 hours, of glucose levels in interstitial fluid in women with type I diabetes who are pregnant or about to become pregnant with poorly controlled diabetes.

Poorly controlled type I diabetes includes the following clinical situations:

- Unexplained hypoglycemic episodes,
- hypoglycemic unawareness,
- suspected postprandial hyperglycemia,
- and recurrent diabetic ketoacidosis.
- Intermittent monitoring of glucose levels in interstitial fluid in patients with type I diabetes prior to insulin pump initiation to determine basal insulin levels.

We cover **continuous, i.e., long-term**, monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique of diabetic monitoring, when the following situations occur despite use of best practices:

(See **Note** below for Best Practices information.)

- 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
- 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:

Best practices in diabetes control for patients with type I diabetes 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 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.

When services are not covered for commercial products

Other uses of continuous monitoring of glucose levels in interstitial fluid as a technique of diabetic monitoring are not covered.¹

When services are not covered for Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFSS PlusRx plans

We do not cover this service for the products listed above.

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

For services already billed

Blue Cross Blue Shield of Massachusetts
 Provider Appeals
 P. O. Box 986065
 Boston, MA 02298

Prior to performance of service

Blue Cross Blue Shield of Massachusetts
 Case Creation/Medical Policy
 One Enterprise Drive
 Quincy, MA 02171
 Tel: 1-800-327-6716
 Fax: 1-888-641-5330

Managed care guidelines

- Authorizations for intermittent or continuous glucose monitors are not required
- For Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorization is required for an inpatient admission.

Indemnity and PPO guidelines

All authorization requirements are determined by the individual's subscriber certificate, however:

- Authorizations for intermittent or continuous glucose monitors are not required
- Authorization is required for an inpatient admission.
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate.
- Referrals to a specialist are not required.

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

CPT codes:

- **95250:** Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
- **95251:** Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report

For 2008, HCPCS codes were added specifically for continuous glucose monitoring systems:

For DME Providers:

- **A9277:** Transmitter; external, for use with interstitial continuous glucose monitoring system
- **A9278:** Receiver (monitor); external, for use with interstitial continuous glucose monitoring system

For members with a pharmacy benefit:

- **A9276:** Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit=1 day supply

Note: If a member does not have a pharmacy benefit, the above noted item would be covered according to the member's benefit and certificate language.

Policy update history

New policy, effective 6/09. 6/2/09, Updated to include best practice statements from BCBSA policy # 1.01.20. 6/23/09, Updated to separate Best Practice statement from coverage information. 7/24/09, Updated to clarify prior authorization statements, formatting, and coding.

Footnotes

¹ References based upon BCBSA policy # 1.01.20, Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

References

References for footnote 1:

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