

Medical Coverage Policy | Glucose Monitoring Systems



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OVERVIEW

This policy addresses several methods of monitoring blood glucose: the glucometer, continuous glucose monitoring of the interstitial fluid, real time continuous glucose monitoring of the interstitial fluid, and the closed-loop system. 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.

PRIOR AUTHORIZATION

Commercial

Prior authorization is recommended for Commercial products only and is obtained via the online tool for participating providers. See the Related Policies section.

Prior authorization is also recommended when there is concurrent use of a continuous glucose monitor **AND** an external insulin infusion pump. Both services separately require prior authorization via the web-based tool.

BlueCHiP for Medicare

Not Applicable.

POLICY STATEMENT

Commercial

Continuous long-term monitoring for diabetic monitoring of glucose levels is **covered** when the medical criteria below are met.

Intermittent monitoring (up to 72 hours) for diabetic glucose monitoring is **covered** when the medical criteria below are met.

The glucose monitor is a purchased item.

BlueCHiP for Medicare

The use of long-term continuous glucose monitor is **not covered**.

The use of intermittent monitoring for diabetic glucose monitoring is **not covered**.

Diabetic equipment and supplies are provided in accordance with Rhode Island General Law §27-20-30. The details of the law can be found in the *Diabetes Self-Management Education* Mandate policy.

BlueCHiP for Medicare and Commercial

Other uses (e.g., Type 2 diabetes) of continuous monitoring of glucose levels in interstitial fluid as a technique of diabetic monitoring are considered **not medically necessary** because there is insufficient evidence in the published medical literature to demonstrate the efficacy of the service.

MEDICAL CRITERIA

Continuous Glucose Monitoring

Continuous, i.e., long-term, monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique of diabetic monitoring, is considered **medically necessary** for Commercial products when the following situations occur despite use of best practices**:

Clinical documentation is required to support the following:

- 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 post-prandial hyperglycemia, and recurrent diabetic ketoacidosis.

*In some patients with Type 2 diabetes, as the need for insulin rises, the pancreas gradually loses its ability to produce insulin thus resulting in Type 1 diabetes. Clinical documentation to support this (i.e., documentation of islet cell antibodies) must be submitted.

Intermittent Glucose Monitoring

Intermittent monitoring, i.e., up to 72 hours, of glucose levels in interstitial fluid is considered **medically necessary** for Commercial products in patients with type I diabetes whose diabetes is poorly controlled despite current use of best practices**. Poorly controlled type I diabetes includes the following clinical situations: unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected post-prandial hyperglycemia, and recurrent diabetic ketoacidosis.

Intermittent monitoring of glucose levels in interstitial fluid is considered **medically necessary** for Commercial products in patients with type I diabetes prior to insulin pump initiation to determine basal insulin levels.

****Best Practices** in diabetes control for patients with type I diabetes include:

- Compliance with a regimen of 4 or more fingersticks each day (with appropriate adjustments) and which may include the 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.

BACKGROUND

Glucometer (blood glucose monitor) is a portable battery-operated meter used to determine blood glucose level by exposing a reagent strip to a small blood sample. The monitor reads color changes on treated reagent strips by glucose concentration in the patient's blood. The patient uses a disposable lancet, draws a drop of blood, places it on the reagent strip and inserts it into the monitor which provides the patient with a direct measurement of their blood glucose level. Glucometers are available in many models with features such as memory, printable memory and downloadable memory. There is a blood glucose monitoring system for use by visually impaired patients. These monitors differ from the standard blood glucose monitor as they have voice synthesizers, timers, and specific placement of supplies to enable the patient to utilize the system independently.

Tight glucose control in patients with diabetes has been associated with improved outcomes. Several devices are available to measure glucose levels automatically and frequently (eg, every 5-10 minutes). The devices measure glucose in the interstitial fluid and are approved as adjuncts to traditional self-monitoring of blood glucose levels.

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. Although devices measure glucose in interstitial fluid on a periodic rather than a continuous basis, this type of monitoring is referred to as continuous glucose monitoring (CGM).

One **continuous glucose monitoring** (CGM) system provides long-term (more than 72 hours) real-time information allowing the individual to take action based on data; and another used for intermittent short-term use (less than 72 hours) for diagnostic or professional use which stores information for review at a later time.

Several devices have received U.S. Food and Drug Administration (FDA) approval. The first 2 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, with currently available devices the time intervals at which interstitial glucose is measured ranges from every 1 to 2 minutes to 5 minutes. While CGMs 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, eg, time periods of 72 hours, or on a longterm basis.

In addition to stand-alone CGMs, several insulin pump systems have included a built-in CGM. This policy only addresses continuous glucose monitoring devices, not the insulin pump portion of these systems.

Several continuous glucose monitoring systems have been approved by 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 FDA in March 2006.
- The Paradigm® REAL-Time System (Medtronic, MiniMed) was approved by FDA in 2006. This system integrates a CGM 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 OmniPod® Insulin Management System (Insulet Corporation), integrating the Freestyle Navigator CGM system with the Pod insulin pump, was approved in December 2011.
- 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.

Despite the availability of increasingly effective treatment modalities a substantial proportion of patients with diabetes cannot achieve adequate glycemic control. Many experts believe that the best therapeutic option for the treatment of diabetes is a system (termed an artificial pancreas or closed-loop) that can mimic normal pancreatic beta cell function thereby restoring normal metabolic homeostasis without causing hypoglycemia. At this time, there are no FDA approved systems that demonstrate satisfactory characteristics in terms of reliability and/or accuracy.

The 2011 Standards of Medical Care in Diabetes: [Glucose Monitoring Recommendations](#)

According to American Diabetes Association (ADA) standards. *Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (age ≥25 years) with type 1 diabetes. Although the evidence for A1C lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. CGM may be a supplemental tool to self-monitored SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes.*

Blue Cross & Blue Shield of Rhode Island covers Glucometers according to Medicare^{1,2,3} guidelines:

To be eligible for coverage of home blood glucose monitors and related accessories and supplies, the member must meet all of the following basic criteria (1) - (5):

1. The patient has diabetes (ICD-9 codes 249.00 - 250.93) which is being treated by a physician; and
2. The glucose monitor and related accessories and supplies have been ordered by the physician who is treating the patient's diabetes and the treating physician maintains records reflecting the care provided including, but not limited to, evidence that the prescribed frequency of testing is reasonable and necessary; and
3. The patient (or the patient's caregiver) has successfully completed training or is scheduled to begin training in the use of the monitor, test strips and lancing devices; and
4. The patient (or the patient's caregiver) is capable of using the test results to assure the patient's appropriate glycemic control. and
5. The device is designed for home use

If an E2100 or E2101 glucose monitor is provided and basic coverage criteria (1)-(5) are not met, the items it will be denied as not reasonable and necessary.

Home blood glucose monitors with special features (E2100, E2101) are covered when the basic coverage criteria (1)-(5) above are met and the treating physician certifies that the patient has a severe visual impairment (i.e., best corrected visual acuity of 20/200 or worse in both eyes).

It is also covered for those with impairment of manual dexterity when the treating physician certifies that the patient has an impairment of manual dexterity severe enough to require the use of the special monitoring system.

The standard models of home glucose monitors, defined as those including downloadable memory features, are **covered** for all BCBSRI products for patients diagnosed with **Type I or II diabetes**.

Special reimbursement guidelines for the home glucose monitor and related supplies:

Quantity limits for supplies:

The quantity of test strips (A4253), lancets (A4259), and replacement lens shield cartridges (A4257) are covered according to the following guidelines and the criteria below are met:

Members not currently being treated with insulin injections, up to 100 test strips and up to 100 lancets or one lens shield cartridge every 3 months are covered if criteria (a)-(c) below are met.

Members currently being treated with insulin injections, up to 100 test strips and up to 100 lancets or one lens shield cartridge every month are covered if criteria (a)-(c) below are met.

Members not currently being treated with insulin injections, more than 100 test strips and more than 100 lancets or one lens shield cartridge every 3 months are covered if criteria (a)-(f) below are met.
Members currently being treated with insulin injections, more than 100 test strips and more than 100 lancets or one lens shield cartridge every month are covered if criteria (a)-(f) below are met.

When quantity limits are exceeded:

For a member currently being treated with insulin injections, more than 100 test strips and more than 100 lancets or one lens shield cartridge every month are covered if criteria (a)-(f) below are met:

Coverage criteria (1)-(5) listed above in the description section for a glucose monitor are met.

- a. The supplier of the test strips and lancets, or lens shield cartridge maintains in its records the order from the treating physician.
- b. The beneficiary has nearly exhausted the supply of test strips and lancets, or useful life of one lens shield cartridge previously dispensed.
- c. The treating physician has ordered a frequency of testing that exceeds the utilization guidelines and has documented in the patient's medical record the specific reason for the additional materials for that particular patient.
- d. The treating physician has seen the patient and has evaluated their diabetes control within 6 months prior to ordering quantities of strips and lancets, or lens shield cartridges that exceed the utilization guidelines.
- e. If refills of quantities of supplies that exceed the utilization guidelines are dispensed, there must be documentation in the physician's records (e.g., a specific narrative statement that adequately documents the frequency at which the patient is actually testing or a copy of the beneficiary's log) or in the supplier's records (e.g., a copy of the beneficiary's log) that the patient is actually testing at a frequency that corroborates the quantity of supplies that have been dispensed. If the patient is regularly using quantities of supplies that exceed the utilization guidelines, new documentation must be present at least every six months.

If criteria (a)-(c) are not met, all testing supplies will be denied as not reasonable and necessary. If quantities of test strips, lancets or lens shield cartridges that exceed the utilization guidelines are provided and criteria (d)-(f) are not met, the amount in excess will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a three (3)-month quantity at a time.

The following are not covered:

Alcohol or peroxide (A4244, A4245), betadine or phisoHex (A4246, A4247) are noncovered since these items are not required for the proper functioning of the device.

Urine test reagent strips or tablets (A4250) are noncovered since they are not used with a glucose monitor.

Reflectance colorimeter devices used for measuring blood glucose levels in clinical settings are not covered as durable medical equipment for use in the home because their need for frequent professional re-calibration makes them unsuitable for home use.

Glucose monitors that are not designed for use in the home must be coded A9270 and will be denied as statutorily noncovered (no benefit category).

Home blood glucose disposable monitor, including test strips (A9275) is noncovered because these monitors do not meet the definition of DME.

COVERAGE

Benefits may vary by groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable office visit benefits/coverage, Diagnostic Imaging, Lab, and Machine Tests benefits/coverage, Medical Equipment, Medical Supplies and Prosthetic Devices benefits/coverage and Diabetic equipment/supplies benefits/coverage.

CODING

Modifiers:

Claims for equipment and supplies should be submitted with the KX modifier for insulin dependent members.

Claims for equipment and supplies should be submitted with the KS modifier for non-insulin dependent members.

Commercial

The following codes are **covered** when medical criteria is met.

Note: These HCPCS codes are also used for intermittent glucose monitoring.

S1030, S1031

The following items are covered when the associated glucose monitoring device has been approved.

A9276, A9277, A9278, 95250, 95251

BlueCHiP for Medicare

The following codes are **not medically necessary**:

S1030, S1031, A9276, A9277, A9278, 95250, 95251

BlueCHiP for Medicare and Commercial

The following supply codes are **covered** under the member's diabetic equipment and supplies or pharmacy benefit, depending on where the supplies are obtained and **do not require prior authorization**:

E0607, E2100, E2101, A4250, A4253, A4256, A4258, A4259

The following codes are **not covered** and are the member's responsibility as they are non-prescription items and are not included in the "Diabetes Mandate":

A4233, A4234, A4235, A4236, A4244, A4245, A4246, A4247, A4255

The following code for glucose downloads is covered though **not separately reimbursed**.

99091

RELATED POLICIES

Artificial Pancreas Device System

Preauthorization via Web-Based Tool for Durable Medical Equipment (DME)

PUBLISHED

Provider Update	Jan	2015
Provider Update	Mar	2012
Provider Update	May	2011
Provider Update	Jul	2010
Provider Update	May	2009
Provider Update	Jul	2008

REFERENCES

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2. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD) for Glucose Monitors (L11530)
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4. Gandhi GY, Kovalaske M, Kudva Y et al. Efficacy of continuous glucose monitoring in improved glycemic control and reducing hypoglycemia: a systematic review and meta-analysis of randomized trials. *J Diabetes Sci Technol* 2011; 5(4):952-65.
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