Medical Coverage Policy | Glucose Monitoring Systems

EFFECTIVE DATE: 03|03|2009
POLICY LAST UPDATED: 01|17|2012

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

Prior authorization review is required for Commercial products.

POLICY STATEMENT

Commercial

Continuous long-term monitoring for diabetic monitoring of glucose levels is covered when the medical conditions above are met.
Intermittent monitoring (up to 72 hours) for diabetic glucose monitoring of type I diabetes is covered when the medical conditions above are met.

BlueCHiP for Medicare

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

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.

The combined use of a continuous glucose monitor **AND** an external insulin pump **both separately require preauthorization** (see policy *Insulin Infusion Pumps*for medically specific criteria).

Continuous glucose monitoring systems combined with an external insulin pump in a single closed-loop system are **not covered** as it has not been FDA approved.

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** for alll BCBSRI products because there is insufficient evidence in the published medical literature to demonstrate its efficacy.

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.

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.

There are several FDA approved continuous glucose monitoring systems available for adults, teenagers and children. According to FDA labeling, these devices are not intended as an alternative to traditional self monitoring of blood glucose levels, but rather to serve as a complement in supplying additional information on a patient's glucose trends that are not available solely 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.

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.

Types of continuous glucose monitoring devices (not an all inclusive list):

The **Continuous Glucose Monitoring System** (CGMS) by MiniMed uses an invasive, temporary sensor in the subcutaneous tissue (usually abdomen) to measure blood glucose values every five minutes for up to three days. While in operation, the device does not display glucose values and patients are still required to test their blood glucose levels several times per day using traditional methods.

The **FreeStyle Navigator CGM System** by 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. It can report glucose values continuously for up to 120 hours. As with other CGM devices, traditional blood glucose tests must be performed before adjusting therapy for diabetes management, and not based on the results and alarms from the FreeStyle Navigator system.

The **Paradigm® REAL-Time Insulin Pump and CGMS** (Medtronic, MiniMed) for adults, and the FDA has approved a version of Paradigm for children and teenagers ages 7 - 17. This system combines an external insulin pump with continuous monitoring of glucose levels via a subcutaneous sensor. The sensor communicates glucose readings to the pump using a radio transmitter. The pump can calculate recommended insulin doses, which the patient can accept or modify. A conventional blood glucose meter reading is recommended before making adjustments. There is limited research data available regarding the impact of the system on long-term glycemic control, prevention of diabetic complications, or quality of life.

The **Guardian-Real Time CGMS** (Medtronic, MiniMed) which provides real-time information, received approval in July 2005. The approval statement indicates its use for monitoring glucose levels in adults (ages 18 and older) with diabetes mellitus. The Guardian RT-CGMS have FDA approved pediatric versions. The Guardian system is similar to the Paradigm except it does not include the insulin pump.

The **DexCom SEVEN and SEVEN Plus** (DexCom) is FDA approved for up to 7 days of wear and is also for those with diabetes mellitus who are aged 18 and older. It is a glucose sensor that reports glucose values every 5 minutes. The system is indicated for use as an adjunctive device to complement, not replace information obtained from standard home glucose monitoring devices. The device provides short and long-term with real-time monitoring for adults (age 18 and older) with diabetes. The SEVEN Sensor has currently only been tested in adult persons with type 1 and type 2 diabetes. The System Plus has not been tested in children or adolescents, pregnant women, or persons on dialysis.

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):

I. The patient has diabetes (ICD-9 codes 249.00 - 250.93) which is being treated by a physician; and
II. 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
III. 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

IV. The patient (or the patient's caregiver) is capable of using the test results to assure the patient's appropriate glycemic control. and
V. 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.
I. The supplier of the test strips and lancets, or lens shield cartridge maintains in its records the order from the treating physician.
II. The beneficiary has nearly exhausted the supply of test strips and lancets, or useful life of one lens shield cartridge previously dispensed.
III. 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.
IV. 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.
V. 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, 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.

The monitor is a purchased item. Authorization for the monitor and supplies is typically approved for one year. After one year, the member must still meet the medical criteria "Best Practices" guidelines before they are approved for additional supplies, i.e., sensors for another year.

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.

CODING

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

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

Effective November 1, 2014: Claims for equipment and supplies should be submitted with the **KS modifier for non-insulin dependent members.**

Glucose monitoring devices used for a minimum of 72 hours are **covered** for all BCBSRI products

95250, 95251

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

99091

The following codes are **covered for all BCBSRI commercial products with prior authorization** and not medically necessary for **BlueCHiP for Medicare:**

S1030, S1031, A9276, A9277, A9278

The following battery 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

RELATED POLICIES

External Insulin Infusion Pumps
Artificial Pancreas Device System

PUBLISHED

Provider Update	Mar 2012
Provider Update	May 2011
Provider Update	Jul 2010
Provider Update	May 2009
Provider Update	Jul 2008
Policy Update	Aug 2007
Policy Update	Jul 2006

REFERENCES

1. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Home Blood GLUCOSE MONITORS (40.2)
2. CMS Pub. 100-3, (Medicare National Coverage Determinations Manual), Chapter 1, Section 40.2. Accessed 12/6/2011
3. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD) for Glucose Monitors (L11530) Accessed 12/6/2011

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