Medical Coverage Policy | Glucose Monitoring Systems

EFFECTIVE DATE: 12|01|2014
POLICY LAST UPDATED: 11|18|2014

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.

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.

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.*

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, January 2015
Provider Update, March 2012
Provider Update, May 2011
Provider Update, July 2010
Provider Update, May 2009
Provider Update, July 2008
Policy Update, August 2007

REFERENCES:

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2. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD) for Glucose Monitors (L11530)

3. Blue Cross and Blue Shield Technology Evaluation Center (TEC). Use of Intermittent or Continuous Interstitial Fluid Glucose Monitoring in Patients with Diabetes Mellitus. TEC Assessments 2003; Volume 18, Tab 16.

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.

5. Wojciechowski P, Rys P, Lipowska A et al. Efficacy and safety comparison of continuous glucose monitoring and self-monitoring of blood glucose in type 1 diabetes. Pol Arch Med Wewn 2011; 121(10):333-43.

6. Langendam M, Luijf YM, Hooft L et al. Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochrane Database Syst Rev 2012; 1:CD008101.

7. Floyd B, Chandra P, Hall S et al. Comparative analysis of the efficacy of continuous glucose monitoring and self-monitoring of blood glucose in type 1 diabetes mellitus. J Diabetes Sci Technol 2012; 6(5):1094-102.

8. Poolsup N, Suksomboon N, Kyaw AM. Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. Diabetol Metab Syndr 2013; 5(1):39.

9. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med 2008; 359(14):1469-76.

10. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Effectiveness of continuous glucose monitoring in a clinical care environment. Diabetes Care 2010; 33(1):17-22.

11. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. The effect of continuous glucose monitoring in well-controlled type 1 diabetes. Diabetes Care 2009; 32(8):1378-83.