Medical Coverage Policy | Continuous Glucose Monitoring



EFFECTIVE DATE: 10 | 01 | 2015

POLICY LAST UPDATED: 09 | 01 | 2015

OVERVIEW

This policy addresses coverage of continuous and short-term (also known as intermittent) glucose monitoring for BlueCHiP for Medicare members. Home blood glucose monitors are not addressed in this policy, as they are a covered service.

For Commercial products, please see the Preauthorization via Web-Based Tool for Durable Medical Equipment (DME) policy, referenced in the Related Policies section below.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

BlueCHiP for Medicare

Not applicable

POLICY STATEMENT

Commercial Products

Not applicable

For Commercial products, please see the Preauthorization via Web-Based Tool for Durable Medical Equipment (DME) policy, referenced in the Related Policies section below.

BlueCHiP for Medicare

The use of continuous and short-term (also known as intermittent) 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.

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 Benefit Booklet, 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.

BACKGROUND

Tight glucose control in patients with diabetes has been associated with improved outcomes. Several devices are available to measure glucose levels automatically and frequently (e.g., 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.

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 adequecy of hyperglycemia control and to evaluate hypoglycemic episodes. The blood glucose monitor that requires fingersticks are meter devices that read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood. These home blood glucose monitors are not the focus of this policy.

Continuous glucose monitoring (CGM) uses a tiny sensor placed under the skin in the belly area. It can be implanted quickly and is usually not painful. The sensor measures the amount of glucose in interstitial fluid. A transmitter on the sensor then sends the information to a wireless, pager-like monitor that can be worn on a belt. The monitor displays glucose levels at 1-, 5- and 10-minute intervals. If the patient's glucose drops to a dangerously low level, or a high preset level, the monitor will sound an alarm.

In the past, only doctors could see the readings the CGM systems collected. Now, anyone can use the device as part of at-home diabetes care. The patient can download data on their computer, tablet or smartphone to see patterns and trends in their glucose levels. This information can help the patient and physician create the best diabetic management plan.

CGM is intended to complement, not replace, information obtained from fingerstick values. It can help unveil dynamic glucose patterns unseen with meters alone. Generally, the patient will need to continue to measure their blood glucose with a regular home meter a few times a day to ensure the monitor remains accurate. The sensor under the skin should be replaced every 3 to 7 days.

Intermittent (or short-term) monitoring is generally conducted in 72-hour periods and uses the same equipment as continuous monitoring.

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 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.

Medicare does not cover CGM devices or any other precautionary equipment. Since the CGM equipment isn't covered, supplies are also not covered.

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.

BlueCHiP for Medicare

The following codes are **not covered:**

S1030

S1031

A9276

A9277

A9278

RELATED POLICIES

Artificial Pancreas Device System

Diabetes Self-Management Education Mandate

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

PUBLISHED

Provider Update, November 2015

Provider Update, January 2015

Provider Update, March 2012

Provider Update, May 2011

Provider Update, July 2010

Provider Update, May 2009

Provider Update, July 2008

REFERENCES

- 1. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Home Blood Glucose Monitors (40.2)
- 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.

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