# Medical Coverage Policy | Glucose Monitoring-Continuous

**EFFECTIVE DATE:** 01|01|2017
**POLICY LAST UPDATED:** 04|18|2017

## 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

**BlueCHiP for Medicare and Commercial Products**
The use of short-term (also known as intermittent), glucose monitoring for a minimum of 72 hours is a covered service.

**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**
Effective January 1, 2017, The Dexcom G5® Mobile CGM System is the only continuous glucose monitoring (CGM) that is covered replace finger stick blood glucose monitor (BGM) testing for diabetes. All other CGM devices are not covered.

In addition to the the DME receiver included in the Dexcom G5® Mobile CGM System, an alternative option for displaying the received data is with a smart device using the Dexcom G5® app on a member - owned smart device such as a smart phone or tablet. Smart phones or tablets are not covered.

**BlueCHiP for Medicare and Commercial Products**
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.

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.

## 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 adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. The blood glucose monitors that require 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.

**Blue CHiP for Medicare**
On December 20, 2016 the Food & Drug Administration (FDA) granted premarket approval to Dexcom, Inc. for an expanded indication for their Dexcom G5® Mobile Continuous Glucose Monitoring (CGM) System. The Dexcom G5® Mobile CGM System is now indicated to replace fingerstick blood glucose monitor (BGM) testing for diabetes treatment decisions, referred to by the FDA as "non-adjunctive" use. **T**he Dexcom G5® Mobile CGM System is currently the only FDA-approved device with a "non-adjunctive" indication.

On January 12, 2017 the Centers for Medicare & Medicaid Services (CMS) issued CMS Ruling 1682R addressing the benefit category for non-adjunctive CGM systems. CMS Ruling 1682R classified CGM systems into therapeutic and non-therapeutic systems. Therapeutic CGM are defined as CGM used as a replacement for fingerstick blood glucose testing for diabetes treatment decisions i.e., non-adjunctive use. Non-therapeutic CGM are devices used as an adjunct to BGM testing (i.e., primary therapeutic decisions regarding diabetes treatment must be made with a standard home BGM, not the CGM).

Medicare does not cover any other CGM devices and the supplies associated with these devices.

## 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**
**For claims prior to 7/1/2017**
The DME component for the Dexcom G5® Mobile CGM system is the receiver. The receiver must be billed using the following code:
• E1399 - Durable Medical Equipment, Miscellaneous
Note when billing this code, suppliers must enter "Dexcom G5® Receiver" in the narrative field of the claim.
The supply allowance for supplies used with the Dexcom G5® Mobile CGM System encompasses all items necessary for the use of the device and
includes, but is not limited to: CGM sensor, CGM transmitter, home blood glucose monitor and related BGM supplies (test strips, lancets, lancing device,and calibration solutions) and all batteries. The supply allowance must be billed using the following code:
• A9999 – Durable Medical Equipment, Miscellaneous Supply

Note : Claims for A9999 must be billed as one (1) unit of service per month. When billing this code, suppliers must enter "Supplies used with Dexcom G5® Receiver" in the narrative field on the claim.

**For claims with date of service 7/1/2017 claims must be filed with the following new HCPCS code**
K0553 Supply allowance for therapeutic continuous glucose monitor (CGM) system, includes all supplies and accessories, 1 month supply = 1 unit of service.
K0554 Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system

**The following codes are not covered as these are for use with other CGM systems:**
**S1030** Continuous non-invasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)
**S1031** Continuous non-invasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)
**A9276** Sensor; invasive (e.g. subcutaneous) disposable, for use with interstitial continuous glucose monitoring system, on unit=1 day supply
**A9277** Transmitter; external, for use with interstitial continuous glucose monitoring system
**A9278** Receiver (monitor); external, for use with interstitial continuous glucose monitoring

**BlueCHiP for Medicare and Commercial Products**
The following codes are covered:
**95250** Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, 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

The following code is not medically necessary:
**0446T** Creation of a subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training (New code effective 1/1/2017)

## RELATED POLICIES
Artificial Pancreas Device System
Diabetes Self-Management Education Mandate
Preauthorization via Web-Based Tool for Durable Medical Equipment (DME)

## PUBLISHED
Provider Update June 2017
Provider Update, July 2016
Provider Update, November 2015
Provider Update, January 2015
Provider Update, March 2012
Provider Update, May 2011
Provider Update, July 2010
Provider Update, May 2009

## REFERENCES

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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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