Medical Coverage Policy | Glucose Monitoring-Continuous

EFFECTIVE DATE: 01|01|2017
POLICY LAST UPDATED: 07|30|2019

OVERVIEW
This policy addresses coverage of continuous (also called long-term) and short-term (also known as intermittent, monitoring for up to 72 hours) glucose monitoring.

Home blood glucose monitors are not addressed in this policy. Please see the Related Policies Section.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
BlueCHiP for Medicare and Commercial Products
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare
Continuous glucose monitoring (CGM) devices defined as "therapeutic" CGMs are covered.

NOTE: Therapeutic CGMs provide information that can be used to make diabetes treatment decisions, such as changing one's diet or insulin dosage, based solely on the readings of the CGM. They are intended to replace information obtained from blood glucose monitors.

CGMs that are used as adjunctive devices to complement, not replace, information obtained from a separate blood glucose monitor are referred to as "non-therapeutic" CGMs, and are therefore not covered.

Commercial Products
The use of continuous glucose monitoring is a covered service.

BlueCHiP for Medicare and Commercial Products
The following are not covered:

- Alcohol or peroxide (A4244, A4245), betadine or phisoHex (A4246, A4247) are not covered since these items are not required for the proper functioning of the device.
- Urine test reagent strips or tablets (A4250) are not covered 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 not covered (no benefit category).
- Home blood glucose disposable monitor, including test strips (A9275) is not covered 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.

Blue Cross Blue Shield of Rhode Island maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to BCBSRI upon request. Failure to produce the requested information may result in denial or retraction of payment.

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

The advent of blood glucose monitors for use by patients in the home revolutionized the management of diabetes. Using fingersticks, patients can monitor their blood glucose levels both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. Tight glucose control, defined as a strategy involving frequent glucose checks and a target hemoglobin A1c (HbA1c) level in the range of 7%, is now considered standard of care for diabetic patients.

Tight glucose control requires multiple daily measurements of blood glucose (ie, before meals and at bedtime), a commitment that some patients may be unwilling or unable to meet. Also, the goal of tight glucose control has to be balanced with an associated risk of hypoglycemia. Hypoglycemia is known to be a risk in patients with type 1 diabetes. While patients with insulin-treated type 2 diabetes may also experience severe hypoglycemic episodes, there is a lower relative likelihood of severe hypoglycemia compared with patients who had type 1 diabetes. An additional limitation of periodic self-measurements of blood glucose is that glucose levels are seen in isolation, and trends in glucose levels are undetected. For example, while a diabetic patient's fasting blood glucose level might be within normal values, hyperglycemia might be undetected postprandially, leading to elevated HbA1c values.

Management

Recently, measurements of glucose in the interstitial fluid have been developed as a technique to measure glucose values automatically throughout the day, producing data that show the trends in glucose levels. Although devices measure glucose in the interstitial fluid on a periodic rather that a continuous basis, this type of monitoring is referred to as continuous glucose monitoring.

Several devices have received approval from the U.S. Food and Drug Administration (FDA). The first approved devices were the Continuous Glucose Monitoring System (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 by electric current (referred to as reverse iontophoresis).

Devices subsequently approved include those for pediatric use and those with more advanced software, more frequent measurements of glucose levels, or more sophisticated alarm systems. Devices initially measured interstitial glucose every 5 to 10 minutes and stored data for download and retrospective evaluation by a clinician. With currently available devices, the intervals at which interstitial glucose is measured ranges from every 1 to 2 minutes to 5 minutes, and most provide measurements in real-time directly to patients. While CGM potentially eliminates or decreases the number of required daily fingersticks, it should be noted that, according to the FDA labeling, monitors are not intended as an alternative to traditional self-monitoring of blood glucose levels but rather as adjuncts to monitoring, supplying additional information on glucose trends not available from self-monitoring. Also, devices may be used intermittently (ie, for periods of 72 hours) or continuously (ie, on a long-term basis).

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, the GlucoWatch has not been available since 2008.
- The Guardian®-RT (Real-Time) CGMS (MiniMed, now Medtronic) in 2005.
- The Dexcom® STS CGMS system (DexCom) was approved by FDA in 2006.
- The Paradigm® REAL-Time System (MiniMed, now Medtronic) 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 2008.
- The Dexcom G4 Platinum (Dexcom) CGM was approved for use in adults 18 years and older in 2012. The device can be worn for up to 7 days. In 2014, FDA expanded use to include patients with diabetes, age 2 to 17 years old.
- The Dexcom G5 Mobile CGM (Dexcom) was approved in 2016 as a replacement for fingerstick blood glucose testing in patients 2 years and older. System requires at least 2 daily fingerstick tests for calibration purposes, but additional fingersticks are not necessary because treatment decisions can be made based on device readings.
- The Freestyle Libre® Pro Flash Glucose Monitoring System (Abbott) was approved in 2017 for use in adults 18 years and older. Readings are only made available to patients through consultation with a health care professional. The system does not require user calibration with blood glucose values.
- The Dexcom G6 Mobile CGM (Dexcom) was approved in 2018 for determining blood glucose levels in children ages ≥2 and adults with diabetes.

BlueCHiP for Medicare
Effective for claims with dates of service on or after January 12, 2017, Medicare covers therapeutic CGM devices under the DME benefit. CGM devices covered by Medicare are defined in CMS Ruling 1682R as therapeutic CGM. CGM devices that do not meet the definition of a therapeutic CGM as defined in CMS Ruling 1682R will be denied as non-covered (no benefit).

CMS Ruling 1682R
Medicare does not cover CGMs approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors. Such devices are not used for making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM, and therefore, have not been covered under Medicare because they are not considered to serve the medical purpose of making diabetes treatment decisions.

All CGMs that are for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions are referred to as "non-therapeutic" CGMs.

Therapeutic CGMs provide information that can be used to make diabetes treatment decisions, such as changing one's diet or insulin dosage, based solely on the readings of the CGM. They are intended to replace information obtained from blood glucose monitors. Therefore, claims for BGM and related supplies, billed *in addition to an approved therapeutic CGM device*, and associated supply allowance will be denied as not covered.

BlueCHiP for Medicare and Commercial Products
Insulin-treated means that the member is receiving insulin injections to treat their diabetes. Insulin does not exist in an oral form and therefore members taking oral medication to treat their diabetes are not insulin treated.

Blue Cross Blue Shield of Rhode Island follows the Centers for Medicare and Medicaid Services (CMS) Medically Unlikely Edits (MUEs) regarding the number of test strips and lancets that are covered. Per CMS, the quantity of test strips (code A4253) and lancets (code A4259) that are covered depends on the usual medical needs of the member and whether or not the member is being treated with insulin. Coverage of testing supplies is based on the following guidelines:

Usual utilization for a member who is not currently being treated with insulin injections can be up to 100 test strips and up to 100 lancets every 3 months.
Usual utilization for a member who is currently being treated with insulin injections can be up to 300 test strips and up to 300 lancets every 3 months.

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 HCPCS codes are covered:
K0553 Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
Note: Up to a 90-day supply of HCPCS code K0553 may be billed and is reimbursable by BCBSRI.
K0554 Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system

NOTE: The following are classified as therapeutic CGM devices. Therefore, claims for the devices and associated supplies must be filed with HCPCS codes K0554 and K0553.

- Dexcom G5 Mobile CGM
- Dexcom G6 Mobile CGM
- Abbott Freestyle Libre

It is considered incorrect to file claims for the above therapeutic devices and associated supplies with HCPCS codes A9276 – A9278. BCBSRI requires that these devices and their associated supplies be billed under HCPCS codes K0554 and K0553.

Please note that BCBSRI also requires Pricing, Data Analysis and Coding contractor (PDAC) approval for devices and supplies to be considered covered. Continuous Glucose Monitor systems that have not been reviewed and listed on the Product Classification List for HCPCS code K0554 will not be covered.

The following HCPCS codes are not covered, as they fail to meet the definition of "therapeutic" according to CMS. Additionally, codes A9276 and A9277 are not used to bill for supplies used with code K0554.
A9276 Sensor; invasive (e.g. subcutaneous) disposable, for use with interstitial continuous glucose monitoring system, 1 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 system
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)

Commercial Products

The following HCPCS codes are covered:
A9276 Sensor; invasive (e.g. subcutaneous) disposable, for use with interstitial continuous glucose monitoring system, 1 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 system
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K0554 Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system
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Please note that BCBSRI also requires Pricing, Data Analysis and Coding contractor (PDAC) approval for devices and supplies to be considered covered. Continuous Glucose Monitor systems that have not been reviewed and listed on the Product Classification List for HCPCS code K0554 will not be covered.

BlueCHiP for Medicare and Commercial Products
The following codes are covered:
95249 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
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

RELATED POLICIES
Artificial Pancreas Device System
Diabetes Self-Management Education Mandate
Glucose Monitoring - Home

PUBLISHED
Provider Update, July 2019
Provider Update, November 2018
Provider Update, June 2017
Provider Update, July 2016
Provider Update, November 2015

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