# Medical Coverage Policy | Glucose Monitoring-Continuous

**EFFECTIVE DATE:** 06|01|2021
**POLICY LAST UPDATED:** 02|18|2021

## 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

**Medicare Advantage Plans**

Implantable continuous glucose monitors (I-CGM) may be considered medically necessary when the following criteria is met:

1. The device has received United States Food and Drug Administration (FDA) approval and device indications include use as a therapeutic CGM; and
2. The member has diabetes mellitus; and
3. The member is insulin-treated with multiple (three or more) daily administrations of insulin or the member uses a Medicare covered continuous subcutaneous insulin infusion (CSII) pump; and
4. The member's insulin treatment regimen requires frequent adjustment by the member on the basis of BGM or CGM testing results; and
5. Within six months prior to ordering the I-CGM, the treating physician had an in-person visit with the member to evaluate their diabetes control and determined that criteria 2 – 4 above are met.

## PRIOR AUTHORIZATION

**Medicare Advantage Plans**

Prior authorization is required for Medicare Advantage Plans for use of implantable continuous glucose monitoring and is obtained via the online tool for participating providers. See the Related Policies section.

**Commercial Products**

Not applicable

## POLICY STATEMENT

**Medicare Advantage Plans**

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.

Implantable continuous glucose monitors (I-CGM) may be considered medically necessary when the medical criteria above are met.

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

The use of implantable CGM devices is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

**Medicare Advantage Plans 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.

**Modifiers**
Per Centers for Medicare and Medicaid Services (CMS) guidelines, for blood glucose monitoring equipment and related supplies, the following modifiers must be added to the HCPCS supply code(s) on every claim submitted to ensure claim reimbursement:

- Use modifier KX if the beneficiary is insulin treated; or,
- Use modifier KS if the beneficiary is non-insulin treated.

The KX modifier must not be used for a beneficiary who is not treated with insulin injections.

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. Please see the Related Policies Section.

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

Tight glucose control in patients with diabetes has been associated with improved health 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 or replacements for traditional self-monitoring of blood glucose levels. Devices can be used on a long-term (continuous) or short-term (often referred to as intermittent) basis.

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 find difficult to meet. 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**
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.

Currently, CGM devices are of two designs: real-time CGM (rtCGM) provides real-time data on glucose level, glucose trends, direction, and rate of change and, intermittently viewed (iCGM) devices that show continuous glucose measurements retrospectively. These devices are also known as flash-glucose monitors (FGM).

Approved devices now include devices indicated 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 Food and Drug Administration (FDA) labeling, some marketed 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. The devices must be calibrated twice daily with blood glucose measurements from fingersticks and are less reliable when used after exercise or post-prandial. Devices may be used intermittently (ie, for periods of 72 hours) or continuously (ie, on a long-term basis).

Mulitple CGM systems have been approved by FDA through the premarket approval process:

- Continuous Glucose Monitoring System (CGMS®) (MiniMed) in 1999 (approved for 3-day use in a physician's office).
- GlucoWatch G2® Biographer in 2001. Of note, the GlucoWatch has not been available since 2008
- Guardian®-RT (Real-Time) CGMS (MiniMed, now Medtronic) in 2005.
- Dexcom® STS CGMS system (DexCom) in 2006.
- Paradigm® REAL-Time System (MiniMed, now Medtronic) in 2006. This system integrates a CGM with a Paradigm insulin pump. The second-generation system is called Paradigm Revel System.
- FreeStyle Navigator® CGM System (Abbott) in 2008.
- Dexcom G4 Platinum (Dexcom) CGM in 2012 for use in adults 18 years and older. 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.
- Dexcom G5 Mobile CGM (Dexcom) 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.

- Dexcom G6 Continuous Glucose Monitoring System (Dexcom) in 2018 and is indicated for the management of diabetes in persons 2 years and older. It is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. It is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems, with 10-day wear.
- Freestyle Libre® Flash Glucose Monitoring System (Abbott) in 2017 for use in adults 18 years and older. It is indicated for the management of diabetes and can be worn up to 10 days. It is designed to replace blood glucose testing for diabetes treatment decisions. In 2018, the duration of use was extended to 14 days.
- Guardian Connect (Medtronic MiniMed) in 2018 for adolescents and adults age 14 – 75 years. It is used for continuous or periodic monitoring of interstitial glucose levels. It provides real-time glucose values, trends, and alerts through a Guardian Connect app installed on a compatible consumer electronic mobile device.
- Eversense Continuous Glucose Monitoring System (Senseonics) in 2018 for use in adults age 18 years and older. It continually measures glucose levels up to 90 days. The device was initially approved as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. In 2019, FDA expanded use to replace fingerstick blood glucose measurements for diabetes treatment decisions. Historical data from the system can be interpreted to aid in providing therapy adjustments.

**Medicare Advantage Plans**
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.

**Medicare Advantage Plans 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.

## CODING

**Modifiers**
Per Centers for Medicare and Medicaid Services (CMS) guidelines, for blood glucose monitoring equipment and related supplies, the following modifiers **MUST BE** added to the HCPCS supply code(s) on every claim submitted to ensure claim reimbursement:

- Use modifier KX if the member is insulin treated; or,
- Use modifier KS if the member is non-insulin treated.

The KX modifier must not be used for a member who is not treated with insulin injections.

**Diabetic Testing Supply Limits – Test Strips (A4253) and Lancets (A4259)**

| Insulin Dependency | Unit Limit | Timeframe |
|---|---|---|
| Insulin Dependent | 500 | 3 months |
| Non-Insulin Dependent | 200 | 3 months |

**Medicare Advantage Plans**
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 CGM System
- Abbott Freestyle Libre Flash Glucose Monitoring System

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.

The following code is considered medically necessary when the medical criteria above are met:
**0446T** Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training

The following code is considered medically necessary when the medical criteria above and the medical criteria found in the Removal of Implantable Devices policy are met:
**0448T** Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation

For the following code, please refer to the Related Policy Removal of Implantable Devices.
**0447T** Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision

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
**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
**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)

**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 codes are not medically necessary:
**0446T** Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training

For the following code, please refer to the Related Policy Removal of Implantable Devices.
**0448T** Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation

For the following code, please refer to the Related Policy Removal of Implantable Devices.
**0447T** Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision

**Medicare Advantage Plans 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
Removal of Implantable Devices

## PUBLISHED

Provider Update, April 2021
Provider Update, June 2020
Provider Update, July 2019
Provider Update, November 2018
Provider Update, June 2017

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