Medical Coverage Policy | Glucose Monitoring-Continuous

EFFECTIVE DATE: 01|01|2023
POLICY LAST REVIEWED: 12|06|2023

OVERVIEW

This policy addresses coverage guidelines for Implantable and Non-Implantable Continuous Glucose Monitors (CGM)

Home blood glucose monitors are not addressed in this policy. Please see the Related Policies Section for information related to home blood glucose monitors.

MEDICAL CRITERIA

Implantable Continuous Glucose Monitors

Medicare Advantage Plans

Blue Cross & Blue Shield of Rhode Island (BCBSRI) follows the medical necessity criteria from the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations (NCD/LCD) for Implantable Continuous Glucose Monitors (I-CGM). Please use the medical criteria in the online tool for participating providers. See the Related Policies section for additional information.

Commercial Products

Not applicable as I-CGM's are not medically necessary for Commercial Products. Refer to the Policy Statement section for additional information.

Non-Implantable Continuous Glucose Monitors

Medicare Advantage Plans and Commercial Products

Not applicable

PRIOR AUTHORIZATION

Implantable Continuous Glucose Monitors

Medicare Advantage Plans

Prior authorization is required for Medicare Advantage Plans for use of (I-CGM) and is obtained via the online tool for participating providers. See the Related Policies section.

Commercial Products

Not applicable

Non-Implantable Continuous Glucose Monitors

Medicare Advantage Plans

Prior authorization is not required for non-implantable continuous glucose monitors for Medicare Advantage Plans.

Commercial Products

Dexcom and Abbott FreeStyle Libre branded non-implantable continuous glucose monitoring devices obtained from a retail pharmacy require authorization through Blue Cross & Blue Shield of Rhode Island's (BCBSRI) Pharmacy Benefit Management Program vendor. Clinical guidelines for review and approval of continuous

glucose monitoring systems are found in the BCBSRI Pharmacy Benefit Management vendor's website at **covermymeds.com**. Members should contact customer service and providers can contact the provider call center for more information.

Dexcom and Abbott FreeStyle Libre devices obtained from a Durable Medical Equipment Provider, or other non-implantable continuous glucose monitors that have been approved by the Food and Drug Administration (FDA) do not require authorization.

POLICY STATEMENT

Implantable Continuous Glucose Monitors

Medicare Advantage Plans
I-CGM may be considered medically necessary when the criteria in the web-based tool has been met.

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

Non-Implantable Continuous Glucose Monitors

Medicare Advantage Plans
Non-Implantable CGM devices defined as "adjunctive" or "non-adjunctive" CGMs are covered.

NOTE: *Adjunctive CGMs are CGMs that individuals use to check their glucose levels and trends which must be verified by use of a blood glucose monitor to make diabetes treatment decisions. A nonadjunctive CGM can be used to make treatment decisions without the need for a stand-alone home blood glucose monitor to confirm testing results.*

Medicare approved continuous glucose monitoring devices:

- Do not require authorization, and
- Can be obtained through either the Durable Medical Equipment (DME) or Pharmacy benefit (if the member has pharmacy benefits through BCBSRI).

Commercial Products
The use of a non-implantable CGM device defined as "adjunctive" or "nonadjunctive" is a covered service.

NOTE: *Adjunctive CGMs are CGMs that individuals use to check their glucose levels and trends which must be verified by use of a blood glucose monitor to make diabetes treatment decisions. A nonadjunctive CGM can be used to make treatment decisions without the need for a stand-alone home blood glucose monitor to confirm testing results.*

Dexcom and Abbott FreeStyle Libre branded non-implantable continuous glucose monitoring devices can be obtained through retail pharmacies with authorization through BCBSRI's Pharmacy Benefit Management Program vendor. Coverage will be through the member's pharmacy benefit. These glucose monitoring devices may also be obtained through a DME provider, authorization not required and are covered under the member's Durable Medical Equipment benefit.

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), when used in conjunction with a CGM, are not covered.
- 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 this type of monitor does 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.

BCBSRI 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, Diabetic equipment/supplies benefits/coverage, and Pharmacy 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 (CGM).

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 while other devices are factory calibrated and do not require fingerstick blood glucose calibration. Devices may be used intermittently (ie, for periods of 72 hours) or continuously (ie, on a long-term basis).

Multiple CGM systems have been approved by FDA through the premarket approval process. The following is not an all-inclusive list:

- 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.
- Dexcom® D7 Continuous Glucose Monitoring System (Dexcom) in 2022 for children, adolescents, and adults age 2 years or older.
- 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. In 2020, approved for use in children, adolescents, and adults age 2 years and older, including pregnant women.
- FreeStyle Libre® 3 Continuous Glucose Monitoring System (Abbott) in 2022 for children, adolescents, and adults age 2 years and older, including pregnant women
- 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.
- Eversense E3 Continuous Glucose Monitoring System (Senseonics) in 2022 for use in adults age 18 years and older for continually measuring glucose levels up to 180 days. The system is indicated for use to replace finger stick blood glucose measurements for diabetes treatment decisions. The system is intended to provide real-time glucose readings, provide glucose trend information, and provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time.

Medicare Advantage Plans

Continuous Glucose Monitors (CGM)

A non-adjunctive CGM can be used to make treatment decisions without the need for a stand-alone BGM to confirm testing results. An adjunctive CGM requires the user verify their glucose levels or trends displayed on a CGM with a BGM prior to making treatment decisions. On February 28, 2022, CMS determined that both non-adjunctive and adjunctive CGMs may be classified as DME.

A CGM is intended for an individual that has been diagnosed with Diabetes mellitus. The treating practitioner should conclude that the individual or caregiver has sufficient training using a CGM, prescribed in accordance with the Food and Drug Administration (FDA) indications for use to improve glycemic control. A CGM may be prescribed for the following indications:

1. The individual is insulin-treated; or,
2. History of problematic, recurrent hypoglycemia that persists despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
3. History of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

Implantable Devices

As of March 1, 2020, there is only one Food and Drug Administration (FDA) approved implantable therapeutic continuous glucose monitoring system (I-CGM). The Eversense Continuous Glucose Monitoring System was approved by the FDA in June 2018, with expanded indications in June, 2019. This implantable CGM is a prescription device that provides real-time glucose monitoring every five minutes for up to 90 days at a time for people with diabetes.

The system consists of an implantable fluorescence-based sensor, a smart transmitter, and a mobile application for displaying glucose values, trends and alerts on the patient's compatible mobile device. It is designed to replace fingerstick blood glucose testing for diabetes treatment decisions as indicated in the FDA 2019 approval. The system is intended to provide real-time glucose readings, provide glucose trend information, and provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The FDA requires the specific training or experience practitioners need in order to use the device and insofar as the sale and distribution of the device are restricted to practitioners who are enrolled in, undergoing, or have completed the specific training identified in the labeling.

Commercial Products

For individuals with type 1 or type 2 diabetes who receive continuous glucose monitoring with an implantable device, the evidence includes an RCT and nonrandomized studies. The RCT compared implantable CGM with control (self-monitoring of blood glucose or intermittently scanned CGM). The RCT was conducted in

France and enrolled participants in 2 cohorts; cohort 1 (n=149) included participants with type 1 or type 2 diabetes withHbA1c >8.0% while cohort 2 (n=90) included participants with type 1 diabetes with time spent with glucose values below 70 mg/dL for more than 1.5 hours per day in the previous 28 days. In cohort 1, there was no difference in mean HbA1c, time in range, or patient-reported outcomes at day 180. In cohort 2, the mean difference in time spent below 54 mg/dL between days 90 and 120 was statistically significant favoring implantable CGM (difference=-1.6% [23 minutes]; 95% CI, -3.1 to -0.1; p=.04). There were no differences inpatient reported outcomes. Nonrandomized prospective studies and post-marketing registry studies assessed the accuracy and safety of an implanted glucose monitoring system. Accuracy measures included the mean absolute relative difference between paired samples from the implanted device and a reference standard blood glucose measurement. The accuracy tended to be lower in hypoglycemic ranges. The initial approval of the device has been expanded to allow the device to be used for glucose management decision making. The same clinical study information was used to support what the FDA considered a reasonable assurance of safety and effectiveness of the device for the replacement of fingerstick blood glucose monitoring for diabetes treatment decisions. In February 2022, the FDA expanded approval of the device for use up to 180 days. Approval was based on the PROMISE pivotal clinical trial, which assessed accuracy and safety but not glycemic outcomes. Limitations of the evidence base include limited comparisons to SMBG, lack of differentiation in outcomes for type 1 diabetes versus type 2 diabetes, and variability in reporting of trends in secondary glycemic measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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,
  - The KX modifier must not be used for a member who is not treated with insulin injections.
- Use modifier KS if the member is non-insulin treated.

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

Non-Adjunctive, Non-Implantable Continuous Glucose Monitoring
The following HCPCS codes represent non-adjunctive devices and supplies and are covered for Medicare Advantage Plans and Commercial Products:

A4239 Supply allowance for non-adjunctive, non-implanted 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 A4239 may be billed and is reimbursable by BCBSRI.

E2103 Non-adjunctive, non-implanted continuous glucose monitor or receiver

NOTE: The following are classified as "non-adjunctive" CGM devices. Therefore, claims for the devices and associated supplies must be filed with HCPCS codes A4239 and E2103.

- Dexcom G5 Mobile CGM
- Dexcom G6 CGM System

- Abbott Freestyle Libre Flash Glucose Monitoring System

NOTE FOR COMMERCIAL PRODUCTS: Abbott Freestyle Libre and Dexcom branded glucose monitoring devices are covered and require authorization through BCBSRI's Pharmacy Benefit Management Program vendor, when obtained under a Pharmacy benefit. They are also available through a Subscribers DME benefit. Please note that not all BCBSRI Subscribers hold pharmacy benefits through BCBSRI.

It is considered incorrect to file claims for the above non-adjunctive devices and associated supplies with HCPCS codes A9276 – A9278. BCBSRI requires that these devices and their associated supplies be billed under HCPCS codes A4239 and E2103.

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 E2103 will not be covered.

Adjunctive, Non-Implantable Continuous Glucose Monitoring

The following HCPCS codes represent adjunctive devices and supplies and are covered for Medicare Advantage Plans and Commercial Products:

A4238 Supply allowance for adjunctive, non-implanted 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 A4238 may be billed and is reimbursable by BCBSRI.

E2102 Adjunctive, non-implanted continuous glucose monitor or receiver

It is considered incorrect to file claims for the above adjunctive devices and associated supplies with HCPCS codes A9276 – A9278. BCBSRI requires that these devices and their associated supplies be billed under HCPCS codes E2102 and A4238.

Supplies

The following HCPCS codes are not covered for Medicare Advantage Plans according to CMS, and they are covered for Commercial Products. However, HCPCS codes A9276 - A9278 are not used to bill for supplies used with codes E2102 (adjunctive, non-implanted CGM or receiver) and E2103 (non-adjunctive, non-implanted CGM or receiver).

A9276 Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial continuous glucose monitoring system, one unit = 1 day supply

A9277 Transmitter; external, for use with non-durable medical equipment interstitial continuous glucose monitoring system

A9278 Receiver (monitor); external, for use with non-durable medical equipment 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)

Implantable Continuous Glucose Monitors

The following code(s) are medically necessary for Medicare Advantage Plans when the criteria in the web-based tool has been met. These code(s) are not medically necessary for Commercial Products.

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 for Medicare Advantage Plans and Commercial Products when the criteria in the Removal of Implantable Devices policy is met. Please see Related Policies section.

0447T Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision

The following code is considered medically necessary for Medicare Advantage Plans when the medical criteria above and the medical criteria in the Removal of Implantable Devices policy are met. For Commercial Products, the following code may be considered medically necessary according to medical criteria in the Removal of Implantable Devices policy. Please see Related Policies section.

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

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

Medicare Advantage Plans National and Local Coverage Determinations
Artificial Pancreas Device System
Diabetes Self-Management Education Mandate
Durable Medical Equipment
Glucose Monitoring – Home
Prior Authorization via Web Based Tool for Procedures
Removal of Implantable Devices

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