Continuous Glucose Monitoring

Policy # 00019
Original Effective Date: 03/25/2002
Current Effective Date: 10/09/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider long-term continuous glucose monitoring (CGM) device monitoring of glucose levels in interstitial fluid in individuals with type 1 diabetes, as a technique of diabetic monitoring, to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for long-term CGM device monitoring of glucose levels in interstitial fluid in individuals with type 1 diabetes as a technique of diabetic monitoring will be considered when **ANY** of the following patient selection criteria are met:

- Individuals with type 1 diabetes who have demonstrated an understanding of the technology, are motivated to use the device correctly and consistently, are expected to adhere to a comprehensive diabetes treatment plan supervised by a qualified provider, and are capable of using the device to recognize alerts and alarms; **OR**
- Individuals with type 1 diabetes who despite use of best practices have recurrent, unexplained, severe (generally blood glucose levels <50 mg/dL) hypoglycemia or impaired awareness of hypoglycemia that puts the patient or others at risk; **OR**
- Individuals with poorly controlled type 1 diabetes despite use of best practices who are pregnant.

Note: Poorly controlled type 1 diabetes includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis.

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Based on review of available data, the Company may consider long-term continuous glucose monitoring (CGM) of glucose levels in interstitial fluid in individuals with type 2 diabetes to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility for long-term CGM of glucose levels in interstitial fluid in individuals with type 2 diabetes who are treated with insulin therapy will be considered when **ALL** of the following patient selection criteria are met:

- The individuals is willing and able to use the device, demonstrated an understanding of the technology, is motivated to use the device correctly and consistently, is expected to adhere to a comprehensive diabetes treatment plan supervised by a qualified provider, and is capable of using the device to recognize alerts and alarms; **AND**
- The individual has adequate medical supervision; **AND**
- The individual experiences recurrent, unexplained, severe (generally blood glucose levels <50 mg/dL) hypoglycemia or impaired awareness of hypoglycemia that puts the individual or others at risk **OR** has poorly controlled diabetes despite current use of best practices (see Policy Guidelines section) with persistent hyperglycemia, or hemoglobin A1c (HbA1c) levels above target.

Based on review of available data, the Company may consider long-term continuous glucose monitoring (CGM) of glucose levels in interstitial fluid using an implantable glucose sensor (i.e., Eversense®‡ E3 CGM) to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility may be considered for long-term CGM of glucose levels in interstitial fluid using an implantable glucose sensor (i.e., Eversense®‡ E3 CGM) when following criteria are met:

- The individual is ≥ 18 years old; **AND**
- Patient Selection Criteria for type 1 **OR** type 2 diabetes mellitus above are also met; **AND**
- The replacement of an implantable interstitial glucose sensor is in accordance with FDA approved indications for use.

Note: The use of Eversense®‡ E3 continuous glucose monitoring (CGM) system requires reporting of CPT®‡ Category III codes 0446T-0448T to be eligible for coverage.

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers other uses of long-term continuous glucose monitoring (CGM) of glucose levels in interstitial fluid as a technique of diabetic monitoring including use in gestational diabetes to be **investigational.***

The use of long-term continuous glucose monitoring (CGM) of glucose levels in interstitial fluid in individuals with type 2 diabetes when patient selection criteria are not met is considered to be **investigational.***

Based on review of available data, the Company considers continuous glucose monitoring (CGM) using an implantable glucose sensor (i.e., Eversense®‡ CGM system) for all other indications, including but not limited to when the criteria above have not been met, to be **investigational.***

Policy Guidelines

This policy only evaluates continuous (real time or intermittent) interstitial glucose monitors and does not evaluate insulin pumps.

Best practices in diabetes control include compliance with a self-monitoring blood glucose regimen of 4 or more fingersticks each day and use of an insulin pump or multiple daily injections of insulin. During pregnancy, 3 or more insulin injections daily could be considered best practice for individuals not on an insulin pump prior to the pregnancy. Prior short-term (72-hour) use of an intermittent glucose monitor would be considered a part of best practices for those considering long-term use of a continuous glucose monitor.

Significant hypoglycemia may include recurrent, unexplained, severe (generally blood glucose levels <50 mg/dL) hypoglycemia or impaired awareness of hypoglycemia that puts the individual or others at risk.

Individuals with type 1 diabetes taking insulin who are pregnant or about to become pregnant with poorly controlled diabetes are another subset of individuals to whom the policy statement on short-term continuous glucose monitoring may apply.

The strongest evidence exists for use of continuous glucose monitoring devices in individuals age 25 years and older. However, age may be a proxy for motivation and good control of disease, so it is also reasonable to select patients based on their ability to self-manage their disease, rather than their age. Multiple continuous glucose monitoring (CGM) devices have U.S. Food and Drug Administration labeling related to age.

Providers board-certified in endocrinology and/or providers with a focus on the practice of diabetes care may be considered qualified to evaluate and oversee individuals for continuous (i.e., long-term) monitoring.

Background/Overview

Blood Glucose Control

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 A_{1c} (HbA1c) level in the range of 7%, is now considered the standard of care for patients with diabetes. Randomized controlled trials assessing tight control have demonstrated benefits for patients with type 1 diabetes in decreasing microvascular complications. The impact of tight control on type 1 diabetes and macrovascular complications such as stroke or myocardial infarction is less certain. The Diabetes Control and Complications Trial (2002) demonstrated that a relative HbA1c level reduction of 10% is clinically meaningful and corresponds to approximately a 40% decrease in risk for progression of diabetic retinopathy and a 25% decrease in risk for progression of renal disease.

Due to an increase in turnover of red blood cells during pregnancy, HbA1c levels are slightly lower in women with a normal pregnancy compared with nonpregnant women. The target HbA1cin women with diabetes is also lower in pregnancy. The American Diabetes Association recommends that, if achievable without significant hypoglycemia, the HbA1clevels should range between 6.0% to 6.5%; an HbA1clevel less than 6% may be optimal as the pregnancy progresses.

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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 levels.

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 than a continuous basis, this type of monitoring is referred to as continuous glucose monitoring (CGM).

Currently, CGM devices are of 2 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.

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 to10 minutes and stored data for download and retrospective evaluation by a clinician. With currently available devices, the intervals at which interstitial glucose is measured range 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, according to the U.S. 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 (i.e., for periods of 72 hours) or continuously (i.e., on a long-term basis).

Continuous Glucose Monitoring Implanted Device
One implantable CGM device (Eversense) is FDA cleared for use in the US. The Eversense Continuous Glucose Monitoring System is implanted in the subcutaneous skin layer and provides continuous glucose measurements over a 40 to 400 mg/dL range. The system provides real-time glucose values, glucose trends, and alerts for hypoglycemia and hyperglycemia and through a mobile application installed on a compatible mobile device platform. The Eversense CGM System is a prescription device indicated for use in adults (age 18 and older) with diabetes for up to 180 days. The device was initially approved as an adjunctive glucose monitoring device to complement information obtained from standard home blood glucose monitoring devices. Prescribing providers are required to participate in insertion and removal training certification.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Multiple CGM systems have been approved or cleared by the FDA (see Table 1). FDA product codes: [PMA] QCD, MDS, PQF; [510(k)] QBJ, QLG.

CGM devices labeled as "Pro" for specific professional use with customized software and transmission to health care professionals are not enumerated in this list.

The Flash glucose monitors (eg FreeStyle Libre, Abbott) use intermittent scanning. The current version of the FreeStyle Libre device includes real-time alerts, in contrast to earlier versions without this feature.

The FDA approved the Eversense implantable continuous interstitial glucose monitoring system on June 21, 2018, for continually measuring glucose levels in adults 18 years and older with diabetes for up to 90 days. Additional approval for use up to 180 days was granted on September 30, 2020. On February 10, 2022 FDA approved to market Eversense E3 Continuous Glucose Monitoring System for adults 18 years and older with diabetes for monitoring glucose levels up to 180 days. The system consists of an implantable fluorescence-based sensor, a transmitter, and a mobile app for displaying glucose values, trends and alerts on the patient's compatible mobile device (smart phone,

tablet, etc.). Sensor is implanted in the physician's office into the skin of the upper arm through a small incision. It is then removed when it expires and may be replaced with another sensor at a site on the contralateral arm to allow continued monitoring. 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.

Table 1. CGM Systems Approved by the U.S. Food and Drug Administration

Device	Manufacturer	Approval or Clearance	Indications
Continuous Glucose Monitoring System (CGMS®‡)	MiniMed	1999	3-d use in physician's office
GlucoWatch G2® Biographer		2001	Not available since 2008
Guardian®‡-RT (Real-Time) CGMS	MiniMed (now Medtronic)	2005	
Dexcom®‡ STS CGMS system	Dexcom	2006	
Paradigm®‡ REAL-Time System (second-generation called Paradigm Revel System)	MiniMed (now Medtronic)	2006	Integrates CGM with a Paradigm insulin pump
FreeStyle Navigator®‡ CGM System	Abbott	2008	

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Device	Manufacturer	Approval or Clearance	Indications
Dexcom®‡ G4 Platinum	Dexcom	2012	Adults ≥18 y; can be worn for up to 7 d
		2014	Expanded to include patients with diabetes 2-17 y
Dexcom®‡ G5 Mobile CGM	Dexcom	2016[a]	Replacement for fingerstick blood glucose testing in patients ≥2 y. 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	2018	Children, adolescents, and adults ≥ 2 years; indicated for the management of diabetes in persons age ≥2 years. Intended to replace fingerstick blood glucose testing for diabetes treatment decisions. 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	2017	Adults ≥18 y. 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.
Freestyle Libre®‡ Flash Glucose Monitoring System	Abbott	2018	Adults ≥18 y. Extended duration of use to 14 days

Device	Manufacturer	Approval or Clearance	Indications
Freestyle Libre®‡ 2 Flash Glucose Monitoring System	Abbott	2020	Children, adolescents, and adults ≥2 years, including pregnant women
Guardian Connect	Medtronic MiniMed	2018	Adolescents and adults (14-75 years) Continuous or periodic monitoring of interstitial glucose levels. 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	2018/2019	Adults ≥18 y. Continually measuring glucose levels up to 90 days. Use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. Adults ≥18 y. Continually measuring glucose levels up to 90 days. Indicated for 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	2022	Adults ≥18 y. Continually measuring glucose levels up to 180 days. The system is indicated for use to replace fingerstick 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

Device	Manufacturer	Approval or Clearance	Indications
			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.
FreeStyle Libre®‡ 3 Continuous Glucose Monitoring System	Abbott	2022	Children, adolescents, and adults ≥2 years, including pregnant women
Dexcom®‡ D7 Continuous Glucose Monitoring System	Dexcom	2022	Children, adolescents, and adults ≥2 years

CGM: continuous glucose monitoring.
[a] As a supplement to the G4 premarketing approval.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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 to 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.

Summary of Evidence

Type 1 Diabetes

For individuals with type 1 diabetes who are willing and able to use the device, and have adequate medical supervision, who receive long-term continuous glucose monitoring (CGM), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life (QOL), and treatment-related morbidity. RCTs have evaluated both real-time and intermittently scanned CGMs. Long-term CGM resulted in significantly improved glycemic control for adults and children with type 1 diabetes, particularly highly compliant patients. Two RCTs in patients who used multiple daily insulin injections and were highly compliant with CGM devices during run-in phases found that CGM was associated with a larger reduction in hemoglobin HbA1c levels than previous studies. One of the 2 RCTs prespecified hypoglycemia-related outcomes and reported that time spent in hypoglycemia was significantly less in the CGM group. One RCT in pregnant women with type 1 diabetes, which compared real-time CGM with self-monitoring of blood glucose (SMBG), has also reported a difference in change in HbA1c levels, an increased percentage of time in the recommended glucose control target range, a smaller proportion of infants who were large for gestational age, a smaller proportion of infants who had neonatal intensive care admissions lasting more than 24 hours, a smaller proportion of infants who had neonatal hypoglycemia requiring treatment, and reduced total hospital length of stay all favoring CGM. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Type 2 Diabetes

For individuals with type 2 diabetes who are treated with insulin therapy who receive long-term CGM, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. RCTs have included individuals on intensive insulin therapy and individuals on basal insulin. Three RCTs have evaluated CGM compared to SMBG in individuals with type 2 diabetes on intensive insulin therapy; 1 using real-time CGM and 2 using an intermittently scanned device. One RCT evaluated CGM in patients treated with basal insulin. All found either improved glycemic outcomes or no difference between groups with no increase in hypoglycemic events. In the DIAMOND trial, the adjusted difference in mean change in HbA1c level from baseline to 24 weeks was -0.3% (95% CI, -0.5% to 0.0%; p=.022) favoring CGM. The

adjusted difference in the proportion of patients with a relative reduction in HbA1c level of 10% or more was 22% (95% CI, 0% to 42%; p=.028) favoring CGM. There were no events of severe hypoglycemia or diabetic ketoacidosis in either group. Yaron et al (2019) reported higher treatment satisfaction with CGM compared to control (the primary outcome). At 12-month follow-up in one of the trials of the Freestyle Libre device, hypoglycemic events were reduced by 40.8% to 61.7% with a greater relative reduction in the most severe thresholds of hypoglycemia. In the Martens trial of individuals treated with basal insulin without prandial insulin, there was a statistically significantly greater decrease in mean HbA1c in the CGM group (adjusted difference, -0.4%; 95% CI -0.8% to -0.1%; p=.02), with 1 hypoglycemic event in each group. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with type 2 diabetes who are not treated with insulin therapy who receive long-term CGM, the evidence includes 4 RCTs. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. Results were mixed regarding benefits of CGM with respect to glycemic control. Participant populations were heterogenous with regard to their diabetic treatment regimens, and participants might not have been receiving optimal therapy. In individuals on oral antidiabetic agents only, routine glucose monitoring may be of limited additional clinical benefit. Additional evidence would be needed to show what levels of improvement in blood glucose excursions and HbA1c levels over the short-term in this population would be linked to meaningful improvement in long-term health outcomes such as diabetes-related morbidity and complications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Gestational Diabetes

For individuals who are pregnant with gestational diabetes who receive long-term CGM or short-term (intermittent) glucose monitoring, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. In the RCTs, trial reporting was incomplete; however, there was no difference between the groups for most reported outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Continuous Glucose Monitoring with an Implantable Device (Eversense)

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 with HbA1c >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 in patient 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.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2019 Input

Clinical input was sought to help determine whether the use of continuous or intermittent monitoring of glucose in the interstitial fluid would provide a clinically meaningful improvement in net health

outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 3 respondents, including 3 physician-level responses identified through 1 specialty society, including 2 physicians with academic medical center affiliations.

Type 1 Diabetes
For individuals who have type 1 diabetes who receive short-term glucose monitoring, clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice when used in specific situations such as poor control of Type 1 diabetes despite the use of best practices and to help determine basal insulin levels prior to insulin pump initiation.

Type 2 Diabetes
For individuals who have type 2 diabetes who do not require insulin who receive long-term continuous glucose monitoring (CGM), clinical input does not support a clinically meaningful improvement in net health outcome and does not indicate this use is consistent with generally accepted medical practice.

For individuals with type 2 diabetes who are willing and able to use the device and have adequate medical supervision and who experience significant hypoglycemia on multiple daily doses of insulin or an insulin pump in the setting of insulin deficiency who receive long-term continuous glucose monitoring, clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice.

For individuals with type 2 diabetes who require multiple daily doses of insulin who receive short-term CGM, clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice when used in specific situations such as poor control of diabetes despite use of best practices and to help determine basal insulin levels prior to insulin pump initiation.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given

to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Clinical Endocrinologists
In 2022, the American Association of Clinical Endocrinology (AACE) published clinical practice guideline for developing diabetes care plans and made the following recommendations (level of evidence) on CGM:

- "All persons who use insulin should use continuous glucose monitoring (CGM) or perform blood glucose monitoring (BGM) a minimum of twice daily and ideally before any insulin injection." **(Grade A; Best Evidence Level 1)**
- "Real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM) is recommended for all persons with T1D, regardless of insulin delivery system, to improve A1C levels and to reduce the risk for hypoglycemia and DKA." **(Grade A; Best Evidence Level 1)**
- "rtCGM or isCGM is recommended for persons with T2D who are treated with insulin therapy, or who have high risk for hypoglycemia and/or with hypoglycemia unawareness." **(Grade A; Best Evidence Level 1)**

In 2021, the American Association of Clinical Endocrinology (AACE) published recommendations on the use of advanced technology in the management of diabetes and made the following recommendations (level of evidence) on CGM:

- CGM is strongly recommended for all persons with diabetes treated with intensive insulin therapy, defined as 3 or more injections of insulin per day or the use of an insulin pump. (**Grade A; High Strength of Evidence**)
- CGM is recommended for all individuals with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness). (**Grade A; Intermediate-High Strength of Evidence**)
- CGM is recommended for children/adolescents with T1D. (**Grade A; Intermediate-High Strength of Evidence**)
- CGM is recommended for pregnant women with T1D and T2D treated with intensive insulin therapy. (**Grade A; Intermediate-High Strength of Evidence**)
- CGM is recommended for women with gestational diabetes mellitus (GDM) on insulin therapy. (**Grade A; Intermediate Strength of Evidence**)

- CGM may be recommended for women with GDM who are not on insulin therapy. (**Grade B; Intermediate Strength of Evidence**)
- CGM may be recommended for individuals with T2D who are treated with less intensive insulin therapy. (**Grade B; Intermediate Strength of Evidence**)

American Diabetes Association
The American Diabetes Association (2023) "Standards of Medical Care in Diabetes" made the following recommendations (**level of evidence**) on CGM devices:

- "Real-time CGM (**A)** or intermittently scanned continuous glucose monitoring (**B**) should be offered for diabetes management in adults with diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs."
- "Real-time CGM (**A**) or intermittently scanned continuous glucose monitoring (**C**) should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs."
- "Real-time CGM (**B**) or intermittently scanned continuous glucose monitoring (**E**) should be offered for diabetes management in youth with type 1 diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs."
- "Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring should be offered for diabetes management in youth with type 2 diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs." **(E)**
- When used as an adjunct to pre- and postprandial blood glucose monitoring, CGM can help to achieve A1c targets in diabetes and pregnancy **(B).**
- Periodic use of real-time or intermittently scanned cCGM or use of professional CGM can be helpful for diabetes management in circumstances where continuous use of CGM is not appropriate, desired, or available **(C)**.

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National Institute for Health and Care Excellence
In 2022, the National Institute for Health and Care Excellence (NICE) updated its guidance on management of type 1 and type 2 diabetes. The guidance included the following updated recommendations on CGM (refer to source documents for complete guidance):

Type 1 Diabetes

- "Offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash'), based on their individual preferences, needs, characteristics, and the functionality of the devices available. "

"When choosing a (CGM) device:

- use shared decision making to identify the person's needs and preferences, and offer them an appropriate device
- if multiple devices meet their needs and preferences, offer the device with the lowest cost"

Type 2 Diabetes
"Offer intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') to adults with type 2 diabetes on multiple daily insulin injections if any of the following apply:

- they have recurrent hypoglycaemia or severe hypoglycaemia
- they have impaired hypoglycaemia awareness
- they have a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them)
- they would otherwise be advised to self-measure at least 8 times a day."

"Offer isCGM to adults with insulin-treated type 2 diabetes who would otherwise need help from a care worker or healthcare professional to monitor their blood glucose."

"Consider real-time continuous glucose monitoring (rtCGM) as an alternative to isCGM for adults with insulin-treated type 2 diabetes if it is available for the same or lower cost."

The guidance and accompanying evidence review do not specifically mention implantable CGM devices.

Endocrine Society
The Endocrine Society (2022) published clinical practice guidelines of management of individuals at high risk of hypoglycemia and included the following recommendations on CGM:

- We recommend CGM rather than self-monitoring of blood glucose (SMBG) by fingerstick for patients with type 1 diabetes (T1D) receiving multiple daily injections (MDIs).
- We suggest real-time continuous glucose monitoring CGM be used rather than no CGM for outpatients with type 2 diabetes (T2D) who take insulin and/or sulfonylureas (SUs) and are at risk for hypoglycemia.

The Endocrine Society (2016) published clinical practice guidelines that included the following recommendations on CGM:

6. "Real-time continuous glucose monitors in adult outpatients
   6.1 We recommend real-time continuous glucose monitoring (RT-CGM) devices for adult patients with T1DM [type 1 diabetes mellitus] who have A1C levels above target and who are willing and able to use these devices on a nearly daily basis.
   6.2 We recommend RT-CGM devices for adult patients with well-controlled T1DM who are willing and able to use these devices on a nearly daily basis.
   Use of continuous glucose monitoring in adults with type 2 diabetes mellitus [T2DM]
   6.3 We suggest short-term, intermittent RT-CGM use in adult patients with T2DM (not on prandial insulin) who have A1C levels ≥7% and are willing and able to use the device."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
In January 2017, the Centers for Medicare & Medicaid Services (CMS) ruled that CGM devices (therapeutic CGMs) approved by the U.S. Food and Drug Administration (FDA) that can be used to make treatment decisions are considered durable medical equipment. A CGM is considered a therapeutic CGM if it is approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions such as changes in diet and insulin dosage. Initially, CMS did not

consider the smartphone application as a DME component and did allow payment for that part of the CGM system. Subsequently, in June 2018, CMS made an announcement that Medicare's published coverage policy for CGMs will be modified to support the use of CGMs in conjunction with a smartphone, including the important data sharing function they provide for patients and their families. Currently marketed therapeutic CGM systems are included in Table 1.

In 2020, Medicare assigned relative value units to the insertion, removal and removal/reinsertion codes uses for provision of the implantable glucose sensor device.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03981328	The Effectiveness of Real Time Continuous Glucose Monitoring to Improve Glycemic Control and Pregnancy Outcome in Patients With Gestational Diabetes Mellitus	372	Dec 2023
NCT03908125[a]	A Post- Approval Study to Evaluate the Long-term Safety and Effectiveness of the Eversense®‡ Continuous Glucose Monitoring (CGM) System	273 (Actual enrollment)	Mar 2023
NCT04836546	A Post Approval Study to Evaluate the Safety and Effectiveness of the Eversense®‡ Continuous Glucose Monitoring (CGM) System Used Non-adjunctively	925	Mar 2026
NCT05131139	Enhance Study: A Prospective, Multicenter Evaluation of Accuracy and Safety of	350	Sep 2025

	the Eversense CGM System With Enhanced Features		
Unpublished			
NCT04535830	The Effectiveness of Flash Glucose Monitoring System on Glycemic Control in Patients With New-onset Type 2 Diabetes#A Randomized Controlled Trial	200	Sep 2021 (unknown status)
NCT03445065[a]	Benefits of a Long Term Implantable Continuous Glucose Monitoring System for Adults With Diabetes - France Randomized Clinical Trial	239	Aug 2020

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

Original Effective Date: 03/25/2002
Current Effective Date: 10/09/2023

03/21/2002	Medical Policy Committee review
03/25/2002	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy.
01/29/2004	Medical Director Review
02/1720/04	Medical Policy Committee review. Format revision. No substance change to policy.
02/23/2004	Managed Care Advisory Council approval
02/01/2006	Medical Director review
02/15/2006	Medical Policy Committee review. Format revisions. Rationale updated.
02/23/2006	Quality Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged
03/14/2007	Medical Director review
03/21/2007	Medical Policy Committee approval. Real time monitoring added to policy statement. Coverage eligibility unchanged.
05/07/2008	Medical Director review
05/21/2008	Medical Policy Committee approval. 72 hour continuous glucose monitoring now eligible for coverage with criteria. The word "Continuous" was removed from the title.
12/03/2008	Medical Director review
12/17/2008	Medical Policy Committee approval. Separated criteria into type I and type II diabetes in the 72 Hour Glucose Monitoring coverage section. Added, "Type II diabetes in patients who are insulin dependent requiring three or more insulin injections per day." to the 72 Hour Glucose Monitoring coverage section. Format and coverage for chronic continuous glucose monitoring as follows: Based on review of available data, the Company may consider continuous monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique of diabetic monitoring, in the following situations to be **eligible for coverage**:

- Patients with type 1 diabetes on an insulin pump with recurrent unexplained severe symptomatic hypoglycemia for whom hypoglycemia puts the patients or others at risk; or

- Pregnant type 1 diabetics, when recurrent hypoglycemia cannot be resolved.

11/04/2010	Medical Policy Committee approval
11/16/2010	Medical Policy Implementation Committee approval. No change to coverage.
11/03/2011	Medical Policy Committee approval
11/16/2011	Medical Policy Implementation Committee approval. No change to coverage. Rationale rewritten.
03/01/2012	Medical Policy Committee approval
03/21/2012	Medical Policy Implementation Committee approval. Under the 72 hour glucose monitoring section, "Type 1" was removed and "as evidenced by four or more documented blood glucose checks per day with fasting blood glucose levels often greater than or equal to 150 and/or hypoglycemic levels of less than or equal to 50 for at least a month" was also removed from patient selection criteria.
09/06/2012	Medical Policy Committee approval
09/19/2012	Medical Policy Implementation Committee approval. Patient Selection Criteria for both 72 hour and chronic continuous glucose monitoring revised.
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Added "requiring 3 or more insulin injections per day or are" to the first bullet for Chronic Continuous Glucose Monitoring criteria.
06/05/2014	Medical Policy Committee review
06/18/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2015	Medical Policy Committee review
06/17/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2016	Coding update
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update
09/07/2017	Medical Policy Committee review

09/20/2017 Medical Policy Implementation Committee approval. Added "Intermittent" to the "72 Hour Glucose Monitoring" subtitle in the coverage section. Changed the first criteria bullet for "Intermittent 72 Hour Glucose Monitoring" as follows:

1. Insulin dependent diabetic using 3 or more insulin injections per day or insulin pump; AND
    - Despite current use of best practices (per Policy Guidelines), diabetes is poorly controlled as evidenced by unexplained or frequent hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia or recurrent diabetic ketoacidosis.

Changed the "Chronic Continuous Glucose Monitoring" subtitle in the coverage section to "Continuous Long-term Glucose Monitoring. Impaired awareness of hypoglycemia added to eligible for coverage statement on long-term CGM.

01/01/2018 Coding update

09/06/2018 Medical Policy Committee review

09/19/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

12/06/2018 Medical Policy Committee review

12/19/2018 Medical Policy Implementation Committee approval. For "Intermittent 72 Hour Glucose Monitoring" criteria, edited the 1st bullet for an insulin dependent diabetic using 3 or more insulin injections per day. Clarification that the 9/20/2017 Medical Policy Implementation Committee meeting addressed and approved "Continuous Long-term Glucose Monitoring" criteria bullets to include type 1 diabetes only, with policy effective date of 12/01/2017. Referenced the Policy Guidelines in the Patient Selection Criteria for Continuous Long-Term Glucose Monitoring and added a *"Note"* after the criteria.

12/05/2019 Medical Policy Committee review

12/11/2019 Medical Policy Implementation Committee approval. Coverage section revised.

03/25/2020 Coding update

05/07/2020 Medical Policy Committee review

05/13/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

12/03/2020 Medical Policy Committee review

12/09/2020 Medical Policy Implementation Committee approval. Added a note clarifying that the coverage of short term CGM is only available on the medical benefit.

05/06/2021	Medical Policy Committee review
05/12/2021	Medical Policy Implementation Committee approval. Added "despite use of best practices" to 2nd and 3rd criteria bullets for long-term continuous glucose monitoring (CGM) device monitoring of glucose levels in interstitial fluid in patients with type 1 diabetes, as a technique of diabetic monitoring. Coverage eligibility unchanged.
05/05/2022	Medical Policy Committee review
05/11/2022	Medical Policy Implementation Committee approval. Title changed from "Continuous or Intermittent Monitoring of Glucose in the Interstitial Fluid" to "Continuous Glucose Monitoring". Removed the eligible for coverage section for short term (72-hour) continuous glucose monitoring. Removed references and statements on short term continuous glucose monitoring that no do not apply to the policy from the investigational statements and Policy Guidelines section.
06/09/2022	Coding update
10/06/2022	Medical Policy Committee review
10/11/2022	Medical Policy Implementation Committee approval. Replaced "patients" with "individuals" throughout the coverage section. Added "…**OR** has poorly controlled diabetes despite current use of best practices (see Policy Guidelines section) with persistent hyperglycemia, or hemoglobin A1c (HbA1c) levels above target." to the criteria for long-term continuous glucose monitoring for Type 2 diabetes mellitus. Added "…including use in individuals with type 2 diabetes not on intensive insulin therapy (i.e., on basal insulin or oral antidiabetic agents only) to the investigational statement for the use of long-term continuous glucose monitoring (CGM) when patient selection criteria are not met. Post MPC, "In the absence of frequent self-monitoring," was added to the Policy Guidelines at the beginning of the following statement:…"for prior short-term (72-hour) use of an intermittent glucose monitor would be considered a part of best practices for those considering long-term use of a continuous glucose monitor."
10/20/2022	Coding update
12/07/2022	Coding update
05/04/2023	Medical Policy Committee review
05/10/2023	Medical Policy Implementation Committee approval. Replaced "patients" with "individuals" in the coverage section. Added long-term continuous glucose monitoring (CGM) of glucose levels in interstitial fluid using an implantable glucose sensor (i.e., Eversense®‡ E3 CGM) to be eligible for coverage with criteria.

	Added a *Note* after the coverage criteria stating *"The use of Eversense®‡ E3 continuous glucose monitoring (CGM) system requires reporting of CPT®‡ Category III codes 0446T-0448T to be eligible for coverage."* Revised the investigational statement so that continuous glucose monitoring (CGM) using an implantable glucose sensor (i.e., Eversense™‡ CGM system) for all other indications, including but not limited to when the criteria have not been met is investigational.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Medically Necessary statement added for individuals with type 2 diabetes who are treated with insulin therapy. INV statement removed: "The use of long-term continuous glucose monitoring (CGM) when patient selection criteria are not met including use in individuals with type 2 diabetes not on intensive insulin therapy (i.e., on basal insulin or oral antidiabetic agents only) is considered to be investigational.*" INV statement added: " The use of long-term continuous glucose monitoring (CGM) of glucose levels in interstitial fluid in individuals with type 2 diabetes when patient selection criteria are not met is considered to be investigational.*"

Next Scheduled Review Date: 09/2024

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0446T, 0447T, 0448T
HCPCS	A9278, E2102, E2103, S1030, S1034, S1035, S1036, S1037 Delete code effective 11/01/2022: S1031 Delete codes effective 01/01/2023: A4226, A4238, A9276, A9277, E0787, G0308, G0309, K0553, K0554
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);

2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.