LOUISIANA BLUE

Policy # 00019
Original Effective Date: 03/25/2002
Current Effective Date: 04/01/2025

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.

For Coverage under the Medical Benefit Only

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) monitoring for individuals with diabetes treated with insulin (at least once a day) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility may be considered for long-term CGM monitoring for individuals with diabetes treated with insulin (at least once a day) when **ANY** of the following patient selection criteria are met:

- Individual has 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; **OR**
- Individual is willing and able to use the device and meets **ONE** of the following requirements:
    - Individual who despite use of best practices has 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**
    - Individual 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) using an implantable glucose sensor (i.e., Eversense®‡) for individuals with diabetes treated with insulin (at least once a day) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility may be considered for long-term CGM monitoring using an implantable glucose sensor (i.e., Eversense®‡) for individuals with diabetes treated with insulin (at least once a day) when **ALL** of the following patient selection criteria are met:

- The individual is ≥ 18 years old; **AND**
- Individual has 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**
- Individual with type 2 diabetes meets **ONE** of the following requirements:
    - Individual who despite use of best practices has 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**
    - Individual has poorly controlled diabetes despite current use of best practices (see Policy Guidelines section) with persistent hyperglycemia, or hemoglobin A1c (HbA1c) levels above target; **AND**
- The replacement of an implantable interstitial glucose sensor is in accordance with FDA approved indications for use.

Note: The use of Eversense CGM requires reporting of CPT®‡ Category III codes 0446T-0448T to be eligible for coverage.

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 and when the patient selection criteria are not met to be **investigational.***

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

For Coverage under the Pharmacy Benefit Only

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 Dexcom®‡, Freestyle®‡, and Guardian®‡ continuous glucose monitoring (CGM) systems to be **eligible for coverage**** when the below patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility will be considered for the following continuous glucose monitoring systems, including their system components (e.g., receiver, transmitter/reader, and sensor), as a technique of diabetic monitoring when **EITHER** of the patient selection criteria are met for the requested product:

- For Dexcom®‡ CGM System requests only:
  - Patient must use concurrently with insulin therapy. This includes patients on a basal insulin regimen, prandial insulin regimen, basal and prandial insulin regimen, or continuous subcutaneous insulin infusion (i.e., insulin pump); **OR**
- For Freestyle®‡ CGM System and Guardian®‡ CGM System requests only:
  - Patient must use concurrently with insulin therapy. This includes patients on a basal insulin regimen, prandial insulin regimen, basal and prandial insulin regimen, or continuous subcutaneous insulin infusion (i.e., insulin pump); **AND**
  - Patient has failed treatment with a Dexcom CGM System unless there is clinical evidence or patient history that suggests the product will be ineffective or cause an adverse reaction or event for the patient.
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

Note: Continuous glucose monitoring products which are used for in office monitoring by a health care professional (e.g., Freestyle Libre®‡Pro products) or implanted by a provider (e.g., Eversense sensors) are not covered under the pharmacy benefit.

Note: Over-the-counter (OTC) CGM's are NOT targeted by this policy and are not covered under the pharmacy or medical benefit. Coverage criteria apply to prescription CGM products only.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Freestyle and Guardian continuous glucose monitoring (CGM) Systems when the patient has NOT failed treatment with a Dexcom CGM System to be **not medically necessary.****

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 the use of Dexcom, Freestyle, and Guardian continuous glucose monitoring (CGM) Systems when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary****) 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 HbA1c levels should range between 6.0% to 6.5%; an HbA1c level less than 6% may be optimal as the pregnancy progresses.

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
Eversense Continuous Glucose Monitoring Systems are the only implantable CGMs FDA cleared for use in the US. Implanted in the subcutaneous skin layer, the system provides continuous glucose measurements over a 40 to 400 mg/dL range, providing real-time glucose values, glucose trends, and alerts for hypoglycemia and hyperglycemia through a mobile application installed on a compatible mobile device platform. Two models are currently available, Eversense E3 CGM System which is indicated for continually measuring glucose levels for up to 180 days after insertion and Eversense®‡ 365 CGM System which is indicated for continually measuring glucose levels for up to one year. Both systems are prescription devices indicated for use in adults (age 18 and older) with diabetes and are indicated for use to replace fingerstick blood glucose (BG) measurements for diabetes treatment decisions. Eversense E3 CGMs Fingerstick BG measurements are still required for calibration primarily one time a day after day 21, and when symptoms do not match CGM information or when taking medications of the tetracycline class. When using an Eversense 365 CGM, fingerstick BG measurements are required for calibration one time a week after day 13, and when symptoms do not match CGM information or when taking medications of the tetracycline class. 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 (e.g., 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. On September 16, 2024, the FDA cleared the Eversense 365 CGM system, and it became the first and

only CGM with a 365-day sensor. Eversense CGM systems 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 devices and insofar as the sale and distribution of the devices are restricted to practitioners who are enrolled in, undergoing, or have completed the specific training identified in the product 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	
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

Device	Manufacturer	Approval or Clearance	Indications
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
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

Device	Manufacturer	Approval or Clearance	Indications
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 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®‡ G7 Continuous Glucose Monitoring System	Dexcom	2022	Children, adolescents, and adults ≥2 years
Eversense E3 Continuous	Senseonics	2022	Adults ≥18 y. Continually measuring glucose levels up to 180 days. The system is indicated for

Device	Manufacturer	Approval or Clearance	Indications
Glucose Monitoring System			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 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.
Eversense 365 Continuous Glucose Monitoring System	Senseonics	2024	Adults ≥18 y. Continually measuring glucose levels for up to 365 days, significantly reducing the frequency of sensor replacements. The system is indicated for use to replace fingerstick blood glucose (BG) measurements for diabetes treatment decisions. Fingerstick BG measurements are required for calibration one time a week after day 13, and when symptoms do not match CGM information or when taking medications of the tetracycline class. The system is a prescription device

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 regulations, other plan medical policies, and accredited national guidelines.

Description

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 admission 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 2023, the American Association of Clinical Endocrinology (AACE) published an updated consensus statement on an algorithm for type 2 diabetes management. A subset of the statements regarding CGM are below.

- "CGM is highly recommended to assist persons with diabetes in reaching goals safely. CGM has provided a major advance in the treatment of persons with all forms of DM."
- "The use of CGM is recommended for persons treated with insulin to optimize glycemic control while minimizing hypoglycemia."

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 [type 1 diabetes], 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 [type 2 diabetes] 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)**.

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 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 the Eversense CGM System With Enhanced Features	350	Sep 2025
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.

References

1. Writing Team for the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. Effect of intensive therapy on the microvascular complications of type 1 diabetes mellitus. JAMA. May 15 2002; 287(19): 2563-9. PMID 12020338
2. American Diabetes Association. 13. Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes-2018. Diabetes Care. Jan 2018; 41(Suppl 1): S137-S143. PMID 29222384
3. Gehlaut RR, Dogbey GY, Schwartz FL, et al. Hypoglycemia in Type 2 Diabetes--More Common Than You Think: A Continuous Glucose Monitoring Study. J Diabetes Sci Technol. Apr 27 2015; 9(5): 999-1005. PMID 25917335
4. Food and Drug Administration (FDA). Summary of Safety and Effectiveness (SSED): Dexcom G5 Mobile Continuous Glucose Monitoring System. 2016; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120005S041.
5. Floyd B, Chandra P, Hall S, et al. Comparative analysis of the efficacy of continuous glucose monitoring and self-monitoring of blood glucose in type 1 diabetes mellitus. J Diabetes Sci Technol. Sep 01 2012; 6(5): 1094-102. PMID 23063035

6. Gandhi GY, Kovalaske M, Kudva Y, et al. Efficacy of continuous glucose monitoring in improving glycemic control and reducing hypoglycemia: a systematic review and meta-analysis of randomized trials. J Diabetes Sci Technol. Jul 01 2011; 5(4): 952-65. PMID 21880239
7. Langendam M, Luijf YM, Hooft L, et al. Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochrane Database Syst Rev. Jan 18 2012; 1(1): CD008101. PMID 22258980
8. Poolsup N, Suksomboon N, Kyaw AM. Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. Diabetol Metab Syndr. 2013; 5: 39. PMID 23876067
9. Wojciechowski P, Ryś P, Lipowska A, et al. Efficacy and safety comparison of continuous glucose monitoring and self-monitoring of blood glucose in type 1 diabetes: systematic review and meta-analysis. Pol Arch Med Wewn. Oct 2011; 121(10): 333-43. PMID 22045094
10. Yeoh E, Choudhary P, Nwokolo M, et al. Interventions That Restore Awareness of Hypoglycemia in Adults With Type 1 Diabetes: A Systematic Review and Meta-analysis. Diabetes Care. Aug 2015; 38(8): 1592-609. PMID 26207053
11. Benkhadra K, Alahdab F, Tamhane S, et al. Real-time continuous glucose monitoring in type 1 diabetes: a systematic review and individual patient data meta-analysis. Clin Endocrinol (Oxf). Mar 2017; 86(3): 354-360. PMID 27978595
12. Lind M, Polonsky W, Hirsch IB, et al. Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults With Type 1 Diabetes Treated With Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. JAMA. Jan 24 2017; 317(4): 379-387. PMID 28118454
13. Beck RW, Riddlesworth T, Ruedy K, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. JAMA. Jan 24 2017; 317(4): 371-378. PMID 28118453
14. Riddlesworth T, Price D, Cohen N, et al. Hypoglycemic Event Frequency and the Effect of Continuous Glucose Monitoring in Adults with Type 1 Diabetes Using Multiple Daily Insulin Injections. Diabetes Ther. Aug 2017; 8(4): 947-951. PMID 28616804
15. Polonsky WH, Hessler D, Ruedy KJ, et al. The Impact of Continuous Glucose Monitoring on Markers of Quality of Life in Adults With Type 1 Diabetes: Further Findings From the DIAMOND Randomized Clinical Trial. Diabetes Care. Jun 2017; 40(6): 736-741. PMID 28389582
16. Laffel LM, Kanapka LG, Beck RW, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adolescents and Young Adults With Type 1 Diabetes: A Randomized Clinical Trial. JAMA. Jun 16 2020; 323(23): 2388-2396. PMID 32543683
17. Pratley RE, Kanapka LG, Rickels MR, et al. Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults With Type 1 Diabetes: A Randomized Clinical Trial. JAMA. Jun 16 2020; 323(23): 2397-2406. PMID 32543682
18. Leelarathna L, Evans ML, Neupane S, et al. Intermittently Scanned Continuous Glucose Monitoring for Type 1 Diabetes. N Engl J Med. Oct 20 2022; 387(16): 1477-1487. PMID 36198143
19. Yan J, Zhou Y, Zheng X, et al. Effects of intermittently scanned continuous glucose monitoring in adult type 1 diabetes patients with suboptimal glycaemic control: A multi-centre randomized controlled trial. Diabetes Metab Res Rev. May 2023; 39(4): e3614. PMID 36670050

20. Roussel R, Riveline JP, Vicaut E, et al. Important Drop in Rate of Acute Diabetes Complications in People With Type 1 or Type 2 Diabetes After Initiation of Flash Glucose Monitoring in France: The RELIEF Study. Diabetes Care. Jun 2021; 44(6): 1368-1376. PMID 33879536
21. Riveline JP, Roussel R, Vicaut E, et al. Reduced Rate of Acute Diabetes Events with Flash Glucose Monitoring Is Sustained for 2 Years After Initiation: Extended Outcomes from the RELIEF Study. Diabetes Technol Ther. Sep 2022; 24(9): 611-618. PMID 35604792
22. Feig DS, Donovan LE, Corcoy R, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. Lancet. Nov 25 2017; 390(10110): 2347-2359. PMID 28923465
23. Voormolen DN, DeVries JH, Sanson RME, et al. Continuous glucose monitoring during diabetic pregnancy (GlucoMOMS): A multicentre randomized controlled trial. Diabetes Obes Metab. Aug 2018; 20(8): 1894-1902. PMID 29603547
24. Beck RW, Riddlesworth TD, Ruedy K, et al. Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial. Ann Intern Med. Sep 19 2017; 167(6): 365-374. PMID 28828487
25. Haak T, Hanaire H, Ajjan R, et al. Flash Glucose-Sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-Treated Type 2 Diabetes: a Multicenter, Open-Label Randomized Controlled Trial. Diabetes Ther. Feb 2017; 8(1): 55-73. PMID 28000140
26. Yaron M, Roitman E, Aharon-Hananel G, et al. Effect of Flash Glucose Monitoring Technology on Glycemic Control and Treatment Satisfaction in Patients With Type 2 Diabetes. Diabetes Care. Jul 2019; 42(7): 1178-1184. PMID 31036546
27. Martens T, Beck RW, Bailey R, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial. JAMA. Jun 08 2021; 325(22): 2262-2272. PMID 34077499
28. Aleppo G, Beck RW, Bailey R, et al. The Effect of Discontinuing Continuous Glucose Monitoring in Adults With Type 2 Diabetes Treated With Basal Insulin. Diabetes Care. Dec 2021; 44(12): 2729-2737. PMID 34588210
29. Guerci B, Roussel R, Levrat-Guillen F, et al. Important Decrease in Hospitalizations for Acute Diabetes Events Following FreeStyle Libre System Initiation in People with Type 2 Diabetes on Basal Insulin Therapy in France. Diabetes Technol Ther. Jan 2023; 25(1): 20-30. PMID 36094418
30. Haak T, Hanaire H, Ajjan R, et al. Use of Flash Glucose-Sensing Technology for 12 months as a Replacement for Blood Glucose Monitoring in Insulin-treated Type 2 Diabetes. Diabetes Ther. Jun 2017; 8(3): 573-586. PMID 28401454
31. Machry RV, Rados DV, Gregório GR, et al. Self-monitoring blood glucose improves glycemic control in type 2 diabetes without intensive treatment: A systematic review and meta-analysis. Diabetes Res Clin Pract. Aug 2018; 142: 173-187. PMID 29857093
32. Ehrhardt NM, Chellappa M, Walker MS, et al. The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. J Diabetes Sci Technol. May 01 2011; 5(3): 668-75. PMID 21722581

33. Vigersky RA, Fonda SJ, Chellappa M, et al. Short- and long-term effects of real-time continuous glucose monitoring in patients with type 2 diabetes. Diabetes Care. Jan 2012; 35(1): 32-8. PMID 22100963
34. Price DA, Deng Q, Kipnes M, et al. Episodic Real-Time CGM Use in Adults with Type 2 Diabetes: Results of a Pilot Randomized Controlled Trial. Diabetes Ther. Jul 2021; 12(7): 2089-2099. PMID 34089138
35. Wada E, Onoue T, Kobayashi T, et al. Flash glucose monitoring helps achieve better glycemic control than conventional self-monitoring of blood glucose in non-insulin-treated type 2 diabetes: a randomized controlled trial. BMJ Open Diabetes Res Care. Jun 2020; 8(1). PMID 32518063
36. Aronson R, Brown RE, Chu L, et al. IMpact of flash glucose Monitoring in pEople with type 2 Diabetes Inadequately controlled with non-insulin Antihyperglycaemic ThErapy (IMMEDIATE): A randomized controlled trial. Diabetes Obes Metab. Apr 2023; 25(4): 1024-1031. PMID 36546594
37. Lai M, Weng J, Yang J, et al. Effect of continuous glucose monitoring compared with self-monitoring of blood glucose in gestational diabetes patients with HbA1c 6%: a randomized controlled trial. Front Endocrinol (Lausanne). 2023; 14: 1174239. PMID 37152928
38. Wei Q, Sun Z, Yang Y, et al. Effect of a CGMS and SMBG on Maternal and Neonatal Outcomes in Gestational Diabetes Mellitus: a Randomized Controlled Trial. Sci Rep. Jan 27 2016; 6: 19920. PMID 26814139
39. Renard E, Riveline JP, Hanaire H, et al. Reduction of clinically important low glucose excursions with a long-term implantable continuous glucose monitoring system in adults with type 1 diabetes prone to hypoglycaemia: the France Adoption Randomized Clinical Trial. Diabetes Obes Metab. May 2022; 24(5): 859-867. PMID 34984786
40. Kropff J, Choudhary P, Neupane S, et al. Accuracy and Longevity of an Implantable Continuous Glucose Sensor in the PRECISE Study: A 180-Day, Prospective, Multicenter, Pivotal Trial. Diabetes Care. Jan 2017; 40(1): 63-68. PMID 27815290
41. Christiansen MP, Klaff LJ, Brazg R, et al. A Prospective Multicenter Evaluation of the Accuracy of a Novel Implanted Continuous Glucose Sensor: PRECISE II. Diabetes Technol Ther. Mar 2018; 20(3): 197-206. PMID 29381090
42. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data: Eversense Continuous Glucose Monitoring System (2018). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160048.
43. Garg SK, Liljenquist D, Bode B, et al. Evaluation of Accuracy and Safety of the Next-Generation Up to 180-Day Long-Term Implantable Eversense Continuous Glucose Monitoring System: The PROMISE Study. Diabetes Technol Ther. Feb 2022; 24(2): 84-92. PMID 34515521
44. Sanchez P, Ghosh-Dastidar S, Tweden KS, et al. Real-World Data from the First U.S. Commercial Users of an Implantable Continuous Glucose Sensor. Diabetes Technol Ther. Dec 2019; 21(12): 677-681. PMID 31385732
45. Deiss D, Irace C, Carlson G, et al. Real-World Safety of an Implantable Continuous Glucose Sensor Over Multiple Cycles of Use: A Post-Market Registry Study. Diabetes Technol Ther. Jan 2020; 22(1): 48-52. PMID 31418587

46. Tweden KS, Deiss D, Rastogi R, et al. Longitudinal Analysis of Real-World Performance of an Implantable Continuous Glucose Sensor over Multiple Sensor Insertion and Removal Cycles. Diabetes Technol Ther. May 2020; 22(5): 422-427. PMID 31697182
47. Blonde L, Umpierrez GE, Reddy SS, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan-2022 Update. Endocr Pract. Oct 2022; 28(10): 923-1049. PMID 35963508
48. Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus. Endocr Pract. Jun 2021; 27(6): 505-537. PMID 34116789
49. American Diabetes Association. Standards of Medical Care in Diabetes. 2022. https://professional.diabetes.org/content-page/practice-guidelines-resources.
50. Natiional Institute for Health and Care Excellence. (2022) Type 1 Diabetes in Adults: Diagnosis and Management. https://www.nice.org.uk/guidance/ng17/chapter/Recommendations#blood-glucose-management.
51. National Institute for Health and Care Excellence. 2022. Type 2 Diabetes in Adults: Management. https://www.nice.org.uk/guidance/ng28.
52. McCall AL, Lieb DC, Gianchandani R, et al. Management of Individuals With Diabetes at High Risk for Hypoglycemia: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. Feb 15 2023; 108(3): 529-562. PMID 36477488
53. Peters AL, Ahmann AJ, Battelino T, et al. Diabetes Technology-Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. Nov 2016; 101(11): 3922-3937. PMID 27588440
54. Centers for Medicare & Medicare Services. Durable Medical Equipment, Prosthetics/Orthotics & Supplies Fee Schedule. https://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposfeesched.
55. Centers for Medicare & Medicare Services. Durable Medical Equipment (DME) Center; https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.
56. FDA. (2018, June 21). *FDA approves first continuous glucose monitoring system with a fully implantable glucose sensor and compatible mobile app for adults with diabetes* [Press Release]. https://www.fda.gov/news-events/press-announcements/fda-approves-first-continuous-glucose-monitoring-system-fully-implantable-glucose-sensor-and#:~:text=The%20U.S.%20Food%20and%20Drug%20Administration%20today%20approved,can%20be%20worn%20for%20up%20to%2090%20days.
57. FDA. (2022, March 2). *Eversense E3 Continuous Glucose Monitoring System - P160048/S016.* https://www.fda.gov/medical-devices/eversense-e3-continuous-glucose-monitoring-system-p160048s016.
58. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) for Implantable Continuous Glucose Monitors (I-CGM). L38617. (2022) https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38617&ver=26
59. Food and Drug Administration (FDA). Summary: Eversense 365 Continuous Glucose Monitoring System (2024). https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=241335.

Policy History

Original Effective Date: 03/25/2002
Current Effective Date: 04/01/2025

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 o 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.*"
07/02/2024 Medical Policy Committee review
07/10/2024 Medical Policy Implementation Committee approval. Added the heading **"For Coverage Under the Medical Benefit Only**" for coverage with criteria and the investigational sections that fall under the medical benefit. Completely revised the "**When Services May Be Eligible for Coverage"** section. Added "and when patient selection criteria are not met" to the investigational statement for long-term continuous glucose monitoring in interstitial fluid as a technique of diabetic monitoring including use in gestational diabetes. Removed the investigational statement for 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. Added the heading **"For Coverage Under the Pharmacy Benefit Only**". Added subsections for "**When Services May Be Eligible for Coverage"** and "**When Services Are Considered Not Medically Necessary"** for content that falls under the pharmacy benefit.
12/10/2024 Coding update
03/06/2025 Medical Policy Committee review
03/12/2025 Medical Policy Implementation Committee approval. Under the Medical Benefit Only section, replaced Eversense E3 CGM with Eversense CGM. Under the Pharmacy Benefit Only section, added "When Services Are Considered

Investigational" section. Added new product Eversense 365 CGM System to the policy.

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 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.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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, S1037 Delete codes effective 10/01/2024: S1035, S1036 Delete codes effective 04/01/2025: G0564, G0565
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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.