

Continuous Glucose Monitoring

Policy # 00019

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Current Effective Date: 05/01/2026

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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

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 less than 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.

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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 greater than or equal to 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 less than 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 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**.*

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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.

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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 less than 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.

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Key changes in the American Diabetes Association (ADA) “Standards of Medical Care in Diabetes” include broader recommendations for CGM use, increased emphasis on time in range (TIR), and expanded access to CGM technology for various populations (see Supplemental Information).

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} (HbA_{1c}) level in the range of 7%, is now considered the goal for most adults 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 HbA_{1c} 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, HbA_{1c} levels are slightly lower in women with a normal pregnancy compared with nonpregnant women. The target HbA_{1c} in women with diabetes is also lower in pregnancy. The American Diabetes Association (ADA) recommends that the A1C goal in pregnancy is <6% (<42 mmol/mol) if this can be achieved without significant hypoglycemia, but the goal may be relaxed to <7% (<53 mmol/mol) if necessary to prevent hypoglycemia.

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 HbA_{1c} levels.

Gestational diabetes (GDM) is a form of glucose intolerance that is first recognized during pregnancy. The standard of care is to screen asymptomatic individuals at 24-28 weeks gestation using a non-fasting 50g oral glucose load with 1 hour blood glucose measurement. Abnormal results are followed up with additional testing as clinically appropriate. Early pregnancy screening may be appropriate to identify undiagnosed T2 diabetes mellitus in individuals with diabetic risk factors

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including a history of prior gestational diabetes. Postpartum evaluation for resolution of glucose intolerance is recommended. GDM often represents previously undiagnosed prediabetes, type 2 diabetes, maturity-onset diabetes of the young, or developing type 1 diabetes.

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 scanned (isCGM) 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 to 10 minutes and stored data for download and retrospective evaluation by a clinician. With currently available devices, the intervals at which interstitial glucose is measured 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

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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.

Some CGM devices might no longer be on the market, or the manufacturers associated with these systems may have changed.

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 (now Medtronic)	1999	3-d use in physician's office

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Device	Manufacturer	Approval or Clearance	Indications
GlucoWatch G2 [®] †Biographer	Cygnus	2001	Not available since 2008
Guardian [®] †-RT (Real-Time) CGMS	MiniMed (now Medtronic)	2005	Not available; it was a predecessor to Guardian Connect system (see below) which offered more advanced features.
Dexcom [®] † STS CGMS system	Dexcom	2006	Not available; discontinued by Dexcom in 2020.
Paradigm [®] † REAL-Time System (second-generation called Paradigm Revel System)	MiniMed (now Medtronic)	2006	Integrates CGM with a Paradigm insulin pump. Not available; replaced by newer Medtronic models.
FreeStyle Navigator [®] † CGM System	Abbott	2008	Not available since 2011
Dexcom [®] † G4 Platinum	Dexcom	2012	Adults ≥ 18 y; can be worn for up to 7 d; Not available; Dexcom stopped selling the G4 Platinum and G5 Mobile systems and their components in 2020, and all support and software for these older systems ceased by the end of that year. Individuals needed to transition to newer systems, such as the Dexcom G6 or Dexcom G7, to continue using a CGM from Dexcom.
		2014	Expanded to include patients with diabetes 2-17 y; Not available (see above)
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; Not available since 2020 (see above)
Dexcom [®] † G6 Continuous	Dexcom	2018	Children, adolescents, and adults ≥ 2 years; indicated for the management of diabetes in

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Device	Manufacturer	Approval or Clearance	Indications
Glucose Monitoring System			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. Dexcom G6 system is still available, but Dexcom is in the process of transitioning users to the Dexcom G7 system (see below); availability may be limited or change over time.
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; The FreeStyle Libre 2 and FreeStyle Libre 3 systems are being discontinued and replaced with the FreeStyle Libre 3 Plus and Freeestyle Libre 2 Plus sensors. The current FreeStyle Libre 2 and 3 sensors will be available until September 30, 2025. After this date, users will need a new prescription for the updated Plus versions.
		2018	Adults ≥ 18 y. Extended duration of use to 14 days. Not available (see above)
Freestyle Libre [®] 2 Flash Glucose Monitoring System	Abbott	2020	Children, adolescents, and adults ≥ 2 years, including pregnant women; FreeStyle Libre 2 system is being discontinued and replaced with the Plus sensor (see above).
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; Not available; being discontinued by Medtronic, with the last transmitter sale on April 25, 2025, and the app removed from app stores on October 24, 2025.

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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. Now called Eversense 365 (see below).
FreeStyle Libre [®] 3 Continuous Glucose Monitoring System	Abbott	2022	Children, adolescents, and adults ≥ 2 years, including pregnant women; FreeStyle Libre 2 and FreeStyle Libre 3 sensors will be available until September 30, 2025; being transitioned to FreeStyle Libre 3 Plus or FreeStyle Libre 2 Plus sensor
Dexcom [®] G7 Continuous Glucose Monitoring System	Dexcom	2022	Children, adolescents, and adults ≥ 2 years, including pregnant women
Dexcom [®] Stelo Glucose	Dexcom	2024	Over-the-counter (OTC) Adults 18 years and older not on insulin

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Device	Manufacturer	Approval or Clearance	Indications
Biosensor System (OTC)			Helps to detect normal (euglycemic) and low or high (dysglycemic) glucose levels. May also help the user better understand how lifestyle and behavior modification, including diet and exercise, impact glucose excursion. The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional.
Eversense 365 Continuous Glucose Monitoring (CGM) System	Senseonics	2024	Indicated for continually measuring glucose levels for up to 1 year in people (18 years or older) with diabetes. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.
Abbott Lingo and Libre Rio Continuous Glucose Monitoring (CGM) Systems (OTC)	Abbott	2024	Abbott Lingo is designed for individuals 18 years and older for overall health and wellness. Libre Rio is for adults with Type 2 diabetes who do not use insulin and typically manage their diabetes through lifestyle modifications.
Dexcom G7 15-Day Continuous Glucose Monitoring (CGM) System	Dexcom	2025	Adults over the age of 18 with type 1, type 2, and gestational diabetes, offering 15.5 days of wear time (including a 12-hour grace period).

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.

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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 A1c (HbA1c) levels than previous studies. One RCT 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%

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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 heterogeneous 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. Evidence suggests CGM offers better detection of glycemic fluctuations, improved time in range (TIR), and enhanced maternal and neonatal outcomes. RCTs found CGM to be preferred by individuals and at least comparable to SMBG for TIR and glycemic control. Overall, CGM demonstrates potential benefits in GDM management to optimize glucose control. The evidence is sufficient 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

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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. In September 2024, Eversense was FDA approved for use up to 1 year based on the ENHANCE pivotal clinical trial, a prospective, multicenter, nonrandomized study involving study participants with diabetes ≥ 18 years of age at four clinical sites in the United States. These studies indicate that the device provides accuracy comparable to laboratory blood glucose testing, aligning with established standards. The latest American Diabetes Association (ADA) Standards of Care in Diabetes (2025) recognize implantable devices as equivalent to non-implantable devices. The evidence is sufficient 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.

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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.

The 2025 American Diabetes Association (ADA) "Standards of Medical Care in Diabetes" support the use of CGM to help achieve glycemic targets, including TIR and time above range, as well as A1C goals during pregnancy for individuals with type 1 diabetes. CGM may also benefit those with other types of diabetes during pregnancy. This guidance is informed by a evidence review which includes 1 multicenter international RCT (Feig et al, 2017 discussed in the previous section); 3 observational studies (published between 2017 and 2024) for type 1 diabetes; and 2 qualitative systematic reviews (from 2021 and 2022) focused on type 2 diabetes. The American Association of Clinical Endocrinology (AACE, 2021) also supports CGM use for women with gestational diabetes who are either on insulin therapy or not on insulin therapy (see below).

American Association of Clinical Endocrinology

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**)

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- "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 (ADA) "Standards of Medical Care in Diabetes", particularly regarding CGM, have evolved significantly over the past years. Key changes in 2025 include broader recommendations for CGM use, increased emphasis on time in range (TIR), and expanded access to CGM technology for various populations.

The ADA recommendations **(level of evidence)** regarding the use of CGM state:

7. Diabetes Technology: Standards of Care in Diabetes - 2025

- "7.2 Initiation of continuous glucose monitoring (CGM) should be offered to people with type 1 diabetes early in the disease, even at time of diagnosis. **(A)**
- 7.3 The type(s) and selection of devices should be individualized based on a person's specific needs, preferences, and skill level. In the setting of an individual whose diabetes is partially or wholly managed by someone else (e.g., a young child or a person with cognitive impairment or dexterity, psychosocial, and/or physical limitations), the caregiver's skills and preferences are integral to the decision-making process. **(E)**

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- 7.4 When prescribing a device, ensure that people with diabetes and caregivers receive initial and ongoing education and training, either in person or remotely, and ongoing evaluation of technique, results, and the ability to utilize data, including uploading/sharing data (if applicable), to monitor and adjust therapy. **(C)**
- 7.6 People with diabetes who have been using CGM, continuous subcutaneous insulin infusion (CSII), and/or automated insulin delivery (AID) for diabetes management should have continued access across third-party payors, regardless of age or A1C levels. **(E)**
- 7.8 Recommend early initiation, including at diagnosis, of CGM, CSII, and AID depending on a person's or caregiver's needs and preferences. **(C)**
- 7.15 Recommend real-time CGM (rtCGM) **(A)** or intermittently scanned CGM (isCGM) for diabetes management to youth **(C)** and adults **(B)** with diabetes on any type of insulin therapy. The choice of CGM device should be made based on the individual's circumstances, preferences, and needs.
- 7.16 Consider using rtCGM and isCGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals. The choice of device should be made based on the individual's circumstances, preferences, and needs. **(B)**
- 7.17 In people with diabetes on insulin therapy, rtCGM devices should be used as close to daily as possible for maximal benefit. **(A)** isCGM devices should be scanned frequently, at minimum once every 8 h, to avoid gaps in data. **A** People with diabetes should have uninterrupted access to their supplies to minimize gaps in CGM. **(A)**
- 7.18 CGM can help achieve glycemic goals (e.g., time in range and time above range) **(A)** and A1C goal **(B)** in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy. **(E)**
- 7.19 In circumstances when consistent use of CGM is not feasible, consider periodic use of personal or professional CGM to adjust medication and/or lifestyle. **C"**

14. Children and Adolescents: Standards of Care in Diabetes - 2025

- "14.8 Advise frequent glucose monitoring before, during, and after exercise, via blood glucose meter and/or continuous glucose monitoring (CGM), is important to prevent, detect, and treat hypoglycemia and hyperglycemia associated with exercise. **(C)**
- 14.18 All youth with type 1 diabetes should monitor glucose levels multiple times daily (up to 10 times/day by blood glucose meter or CGM), including prior to meals and snacks, at bedtime, and as needed for safety in specific situations such as physical activity, driving, or the presence of symptoms of hypoglycemia. **(B)**
- 14.19 Real-time CGM **(A)** or intermittently scanned CGM **(E)** should be offered for diabetes management at diagnosis or as soon as possible in youth with diabetes on multiple daily injections or insulin pump therapy who are capable of using the device safely (either by themselves or with caregivers). The choice of device should be made based on the individual's and family's circumstances, desires, and needs.
- 14.23 A1C goals must be individualized and reassessed over time. An A1C of <7% (<53 mmol/mol) is appropriate for many children and adolescents. **(B)**

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- 14.24 Less stringent A1C goals (such as <7.5% [<58 mmol/mol]) may be appropriate for youth who cannot articulate symptoms of hypoglycemia; have hypoglycemia unawareness; lack advanced insulin delivery technology and/or CGM; cannot check blood glucose regularly; or have nonglycemic factors that increase A1C (e.g., high glycaters). **(B)**
- 14.25 Even less stringent A1C goals (such as <8% [<64 mmol/mol]) may be appropriate for individuals with a history of severe hypoglycemia, limited life expectancy or where the harms of treatment are greater than the benefits. **(B)**
- 14.26 Health care professionals may reasonably suggest more stringent A1C goals (such as <6.5% [<48 mmol/mol]) for selected individuals if they can be achieved without significant hypoglycemia, excessive weight gain, negative impacts on well-being, or undue burden of care or in those who have nonglycemic factors that decrease A1C (e.g., lower erythrocyte life span). Lower goals may also be appropriate during the honeymoon phase. **(B)**
- 14.27 CGM metrics derived from continuous glucose monitor use over the most recent 14 days (or longer for youth with more glycemic variability), including time in range (70-180 mg/dL [3.9-10.0 mmol/L]), time below range (<70 mg/dL [<3.9 mmol/L] and <54 mg/dL [<3.0 mmol/L]), and time above range (>180 mg/dL [>10.0 mmol/L] and >250 mg/dL [>13.9 mmol/L]), are recommended to be used in conjunction with A1C whenever possible. **(E)**
- 14.58 Real-time CGM or intermittently scanned CGM should be offered for diabetes management in youth with type 2 diabetes on multiple daily injections or insulin pumps who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on an individual's and family's circumstances, desires, and needs. **(E)**
- 14.60 Consider setting an A1C goal of <6.5% (<48 mmol/mol)] for most children and adolescents with type 2 diabetes who have a low risk of hypoglycemia. For those at higher risk of hypoglycemia, A1C goals should be individualized as clinically appropriate. **(C)**"

15. Management of Diabetes in Pregnancy: Standards of Care in Diabetes - 2025

- "15.9 Due to increased red blood cell turnover, A1C is slightly lower during pregnancy in people with and without diabetes. Ideally, the A1C goal in pregnancy is <6% (<42 mmol/mol) if this can be achieved without significant hypoglycemia, but the goal may be relaxed to <7% (<53 mmol/mol) if necessary to prevent hypoglycemia. **(B)**
- 15.10 Continuous glucose monitoring (CGM) can help to achieve glycemic goals (e.g., time in range, time above range) **(A)** and A1C goal **(B)** in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy. **(E)**
- 15.11 Recommend CGM to pregnant individuals with type 1 diabetes. **(A)** In conjunction with aims to achieve traditional pre- and postprandial glycemic goals, real-time CGM can reduce the risk for large-for-gestational-age infants and neonatal hypoglycemia in pregnancy complicated by type 1 diabetes. **(A)**
- 15.12 CGM metrics may be used in combination with blood glucose monitoring to achieve optimal pre- and postprandial glycemic goals. **(E)**"

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Endocrine Society

The Endocrine Society (2023) published clinical practice guidelines of management of individuals at high risk of hypoglycemia and included the following recommendations on CGM:

- "Recommendation 1 - We recommend continuous glucose monitoring (CGM) rather than self-monitoring of blood glucose (SMBG) by fingerstick for patients with type 1 diabetes (T1D) receiving multiple daily injections (MDIs). (1 $\oplus\oplus\oplus$) (Strong recommendation, Low certainty of evidence)
- Recommendation 2 - We suggest using real-time continuous glucose monitoring (CGM) and algorithm-driven insulin pumps (ADIPs) rather than multiple daily injections (MDIs) with self-monitoring of blood glucose (SMBG) three or more times daily for adults and children with type 1 diabetes (T1D). (2 $\oplus\oplus\oplus$) (Conditional recommendation, Low certainty of evidence)
- Recommendation 3 - We suggest real-time continuous glucose monitoring (CGM) be used rather than no continuous glucose monitoring (CGM) for outpatients with type 2 diabetes (T2D) who take insulin and/or sulfonylureas (SUs) and are at risk for hypoglycemia. (2 $\oplus\oplus\oplus$) (Conditional recommendation, Very Low certainty of evidence)
- Recommendation 4 - We suggest initiation of continuous glucose monitoring (CGM) in the inpatient setting for select inpatients at high risk for hypoglycemia. (2 $\oplus\oplus\oplus$) (Conditional recommendation, Very Low certainty of evidence)
- Recommendation 5 - We suggest continuation of personal continuous glucose monitoring (CGM) in the inpatient setting with or without algorithm-driven insulin pump (ADIP) therapy rather than discontinuation. (2 $\oplus\oplus\oplus$) (Conditional recommendation, Very Low certainty of evidence)"

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 $\geq 7\%$ and are willing and able to use the device."

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):

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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.

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 not 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

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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 April 2023, the CMS expanded coverage for Continuous Glucose Monitors (CGMs) to include more individuals with diabetes (A52464). Medicare now covers CGMs for people with diabetes who use insulin, regardless of the type or amount of insulin used. Additionally, coverage is extended to those with diabetes who do not use insulin but have a history of problematic hypoglycemia. The CMS will cover any FDA-approved CGM device.

CGM with an Implantable Device

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

In 2024, the CMS issued a local coverage decision on Implantable Continuous Glucose Monitors (I-CGM) (L38743).

- Therapeutic I-CGMs are considered reasonable and necessary by Medicare when all of four coverage criteria (1-4) are met.
 - The beneficiary has diabetes mellitus (DM); **and**,
 - The beneficiary’s treating practitioner has concluded that the beneficiary (or beneficiary’s caregiver) has sufficient training using the I-CGM prescribed as evidenced by providing a prescription; **and**,
 - The I-CGM is prescribed in accordance with its FDA indications for use; **and**,
 - The beneficiary for whom an I-CGM is being prescribed, to improve glycemic control, meets at least 1 of the criteria below:
 - The beneficiary is insulin-treated; **or**,
 - The beneficiary has a history of problematic hypoglycemia with documentation of at least 1 (of 2) specified hypoglycemic events.

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
<i>Ongoing</i>			
NCT04836546 ^a	A Post Approval Study to Evaluate the Safety and Effectiveness of the Eversense [®] Continuous Glucose Monitoring (CGM) System Used Non-adjunctively	925	Mar 2026 (last update posted: Aug 2025)

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<i>Unpublished</i>			
NCT03981328	The Effectiveness of Real Time Continuous Glucose Monitoring to Improve Glycemic Control and Pregnancy Outcome in Patients With Gestational Diabetes Mellitus	375	Feb 2025
NCT03908125 ^a	A Post- Approval Study to Evaluate the Long-term Safety and Effectiveness of the Eversense ^{®‡} Continuous Glucose Monitoring (CGM) System	273	Feb 2024

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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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
02/17/2004	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.

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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

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12/19/2018	Medical Policy Implementation Committee approval. For “Intermittent 72 Hour Glucose Monitoring” criteria, edited the 1 st 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 “ <i>Note</i> ” 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 2 nd and 3 rd 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 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.”

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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 <i>Note</i> after the coverage criteria stating “ <i>The use of Eversense^{®†} E3 continuous glucose monitoring (CGM) system requires reporting of CPT^{®‡} Category III codes 0446T-0448T to be eligible for coverage.</i> ” 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 “ <u>For Coverage Under the Medical Benefit Only</u> ” 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 “ <u>For Coverage Under the Pharmacy Benefit Only</u> ”. 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

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

04/02/2026 Medical Policy Committee review

04/10/2026 Medical Policy Implementation Committee approval. For medical benefits, removed “as a technique of diabetic monitoring including use in gestational diabetes” from the investigational statement for other uses of long-term continuous glucose monitoring (CGM) of glucose levels in interstitial fluid. Added content to the Policy Guidelines section for key changes in the American Diabetes Association (ADA) “Standards of Medical Care in Diabetes”.

08/01/2026 Coding update

Next Scheduled Review Date: 04/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 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 Add code effective 08/01/2026: S1036
ICD-10 Diagnosis	All related Diagnoses

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***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.

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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.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.