Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

Policy # 00019
Original Effective Date: 03/25/2002
Current Effective Date: 01/11/2021

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

When Services Are 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 short-term continuous glucose monitoring (CGM) of glucose levels in interstitial fluid in patients with type 1 diabetes whose diabetes is poorly controlled, despite current use of best practices, to be **eligible for coverage**** (see Policy Guidelines section).
Note: Poorly controlled type 1 diabetes includes the following clinical situations: unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis.

Based on review of available data, the Company may consider short-term continuous glucose monitoring (CGM) of glucose levels in interstitial fluid in patients with type 1 diabetes prior to insulin pump initiation to determine basal insulin levels to be **eligible for coverage.****

Based on review of available data, the Company may consider short-term continuous glucose monitoring (CGM) of glucose levels in interstitial fluid in patients with type 2 diabetes who require multiple daily doses of insulin (e.g. 3 or more insulin injections per day or insulin pump) whose diabetes is poorly controlled, despite current use of best practices to be **eligible for coverage**** (see Policy Guidelines section).
Note: Poorly controlled type 2 diabetes includes the following clinical situations: unexplained hypoglycemic episodes, hypoglycemic unawareness, and persistent hyperglycemia and A1C levels above target.

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Based on review of available data, the Company may consider short-term continuous glucose monitoring (CGM) of glucose levels in interstitial fluid in patients with type 2 diabetes who require multiple daily doses of insulin prior to insulin pump initiation to determine basal insulin levels to be **eligible for coverage.****

Notes:
For short-term (72 hours to one week) CGM monitoring, no more than two CGM periods are considered medically necessary within a 12-month period.

Short-term CGM monitoring is only available through the medical benefit (NOT available on the pharmacy benefit)

When Services May Be Eligible for Coverage

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

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

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

Patient Selection Criteria

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

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

- Patients with poorly controlled type 1 diabetes who are pregnant.

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

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

Patient Selection Criteria

Coverage eligibility for long-term CGM of glucose levels in interstitial fluid in patients with type 2 diabetes who require multiple daily doses of insulin (e.g. 3 or more insulin injections per day or insulin pump) in the setting of insulin deficiency will be considered when **ALL** of the following patient selection criteria are met:

- The patient is willing and able to use the device, demonstrated an understanding of the technology, is motivated to use the device correctly and consistently, is expected to adhere to a comprehensive diabetes treatment plan supervised by a qualified provider, and is capable of using the device to recognize alerts and alarms; **AND**
- The patient has adequate medical supervision; **AND**
- The patient experiences recurrent, unexplained, severe (generally blood glucose levels <50 mg/dL) hypoglycemia or impaired awareness of hypoglycemia that puts the patient or others at risk.

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 short-term and long-term continuous glucose monitoring (CGM) of glucose levels in interstitial fluid as a technique of diabetic monitoring including use in gestational diabetes to be **investigational.***

The use of short-term continuous glucose monitoring (CGM) when patient selection criteria are not met is considered to be **investigational.***

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The use of long-term continuous glucose monitoring (CGM) when patient selection criteria are not met is considered to be **investigational.***

Based on review of available data, the Company considers continuous glucose monitoring (CGM) using an implantable glucose sensor (i.e., Eversense™‡ CGM system) to be **investigational.***

Policy Guidelines

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

Short-term intermittent monitoring is generally conducted over 72-hour periods. It may be repeated subsequently depending on the patient's level of diabetes control.

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 patients 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 patient or others at risk.

Women with type 1 diabetes taking insulin who are pregnant or about to become pregnant with poorly controlled diabetes are another subset of patients to whom the policy statement on intermittent monitoring may apply.

The strongest evidence exists for use of continuous glucose monitoring devices in patients age 25 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 CGM devices have FDA labeling related to age.

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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 A1c (HbA1c) level in the range of 7%, is now considered the standard of care for diabetic patients. 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 A1c in women with diabetes is also lower in pregnancy. The American Diabetes Association recommends that, if achievable without significant hypoglycemia, the A1c levels should range between 6.0% to 6.5%; an A1c 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
Recently, 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 two designs; real-time CGM (rtCGM) provides real-time data on glucose level, glucose trends, direction, and rate of change and, intermittently viewed (iCGM) devices that show continuous glucose measurements retrospectively. These devices are also known as flash-glucose monitors (FGM).

Approved devices now include devices indicated for pediatric use and those with more advanced software, more frequent measurements of glucose levels, or more sophisticated alarm systems. Devices initially measured interstitial glucose every 5 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 1-2 minutes to 5 minutes, and most provide measurements in real-time directly to patients. While CGM potentially eliminates or decreases the number of required daily fingersticks, it should be noted that, according to the Food and Drug Administration 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. Also, devices may be used intermittently (i.e., for periods of 72 hours) or continuously (i.e., on a long-term basis).

CGM Implanted Device for Long-Term Use
The Eversense Continuous Glucose Monitoring System is implanted in the subcutaneous skin layer and provides continuous glucose measurements over a 40-400 mg/dL range. The system provides real-time glucose values, glucose trends, and alerts for hypoglycemia and hyperglycemia and low glucose through a mobile application installed on a compatible mobile device platform. The Eversense CGM System is a prescription device indicated for use in adults (age 18 and older) with diabetes for up to 90 days. The device was initially approved as an adjunctive glucose monitoring

device to complement information obtained from standard home blood glucose monitoring devices. Prescribing providers are required to participate in insertion and removal training certification.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Multiple CGM systems have been approved by the Food and Drug Administration through the premarket approval process (see Table 1).

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

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

Device	Manufacturer	Approval	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

Device	Manufacturer	Approval	Indications
		2014	Expanded to include patients with diabetes 2-17 y
Dexcom®‡ G5 Mobile CGM	Dexcom	2016[a]	Replacement for fingerstick blood glucose testing in patients ≥2 y. System requires at least 2 daily fingerstick tests for calibration purposes, but additional fingersticks are not necessary because treatment decisions can be made based on device readings
Dexcom® G6 Continuous Glucose Monitoring System	Dexcom	2018	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
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	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.

CGM: continuous glucose monitoring.
[a] As a supplement to the G4 premarketing approval.
Food and Drug Administration product codes: MDS, PQF, QCD.

Rationale/Source

Tight glucose control in patients with diabetes has been associated with improved health outcomes. Several devices are available to measure glucose levels automatically and frequently (e.g., every 5-10 minutes). The devices measure glucose in the interstitial fluid and are approved as adjuncts to or replacements for traditional self-monitoring of blood glucose levels. Devices can be used on a long-term (continuous) or short-term(often referred to as intermittent) basis.

The following conclusions are based on a review of the evidence, including but not limited to, published evidence and clinical expert opinion, solicited via BCBSA's Clinical Input Process.

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. Systematic reviews have generally found that at least in the short-term, long-term CGM resulted in significantly improved glycemic control for adults and children with type 1 diabetes, particularly highly compliant patients. A 2017 individual patient data analysis, pooling data from 11 RCTs, found that reductions in hemoglobin A1c (HbA1c) levels were significantly greater with real-time CGM than with a control intervention. 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 HbA1c levels than previous studies. One of the two 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, has also reported a difference in change in HbA1clevels, 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 that the long-term use of CGM provides an improvement in net health outcomes for persons with type 1 diabetes mellitus.

For individuals with type 1 diabetes who have poor control of diabetes despite the use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation who receive short-term glucose monitoring, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity as well as intermediate outcomes related to measures of glucose control such as frequency and time in hypoglycemia and hyperglycemia. The evidence for short-term monitoring of glycemic control is mixed, and there was no consistency in HbA1c levels. Some trials have reported improvements in glucose control for the intermittent monitoring group but limitations in this body of evidence preclude conclusions. The definitions of control with short-term CGM use, duration of use and the specific monitoring protocols varied. In some studies, short-term monitoring was part of a larger strategy aimed at optimizing glucose control, and the impact of monitoring cannot be separated from the impact of other interventions. Studies have not shown an advantage for intermittent glucose monitoring in reducing severe hypoglycemia events but the number of events reported is generally small and effect estimates imprecise. The limited duration of use may preclude an assessment of any therapeutic effect. Two RCTs of short-term CGM use for monitoring in pregnancy included women

with both type 1 and 2 diabetes, with most having type 1 diabetes. One trial reported a difference in HbA1c levels at 36 weeks; the proportion of infants that were large for gestational age (>90th percentile) favored CGM while the second trial did not. The differences in the proportions of infants born via cesarean section, gestational age at delivery, and infants with severe hypoglycemia were not statistically significant in either study. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through 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 the use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Type 2 Diabetes
For individuals with type 2 diabetes who receive long-term CGM, the evidence includes RCTs. The relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. Most RCTs of CGM in patients with type 2 trials found statistically significant benefits of CGM regarding glycemic control. However, the degree of HbA1c reduction and the difference in HbA1c reduction between groups might not be clinically significant. Moreover, additional evidence would be needed to show what levels of improvements in HbA1c levels over the short-term would be linked to meaningful improvements over the long-term in health outcomes such as diabetes-related morbidity and complications. Also, the variability in entry criteria as well as among interventions makes it difficult to identify an optimal approach to CGM use; the studies used a combination of intermittent and continuous monitoring with a review of data in real-time or at study visits only. Only the DIAMOND RCT (n=158) has used real-time CGM in type 2 diabetes. Selected patients were highly compliant during a run-in phase. The difference in change in HbA1clevels from baseline to 24 weeks was -0.3% favoring CGM. The difference in the proportion of patients with a relative reduction in HbA1c level by 10% or more was 22% favoring CGM. There were no differences in the proportions of patients with an HbA1c level of less than 7% at week 24. There were no events of severe hypoglycemia or diabetic ketoacidosis in either group. The treatment groups did not differ in any of the QOL measures. RCTs using flash glucose-sensing technology as a replacement for self-monitoring of blood glucose for the management of insulin-dependent treated type 2diabetes found no difference in HbA1c change at 6 and 12 months between groups. However, time in severe hypoglycemia (<45mg/dL) was reduced for intervention participants. Two trials of CGM have enrolled pregnant women with type 2 diabetes, but the total number of women with type 2 diabetes

included in both trials is only 58. One study reported a difference in HbA1c levels at 36 weeks, and the proportion of infants that were large for gestational age (>90th percentile) favored CGM while the second study did not. Neither trial reported analyses stratified by diabetes type. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input for long-term (continuous) CGM in patients with type 2 diabetes who do not require insulin did not provide strong support of a safety benefit and clinically meaningful improvement in net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

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, the evidence includes a systematic review and non-randomized study with 12-month follow-up. The relevant outcomes are the frequency of and time spend in hypoglycemia, the incidence of hypoglycemic episodes, complications of hypoglycemia, and QOL. The available studies demonstrate that CGM can significantly reduce time in hypoglycemia and frequency of hypoglycemia events both during the day and at night. At 12-month follow-up, hypoglycemic events were reduced by 40.8% to 61.7% with a greater relative reduction in the most severe thresholds of hypoglycemia. The published evidence supports a meaningful improvement in the net health outcome. Evidence reported through clinical input provides additional clinical context and based on both the published evidence and clinical input the following patient selection criteria are associated with a clinically meaningful improvement in net health outcome and are consistent with generally accepted medical practice: selected patients with type 2 diabetes who are (1) willing and able to use the CGM device and have adequate medical supervision and (2) experiencing significant hypoglycemia on multiple daily doses of insulin or an insulin pump in the setting of insulin deficiency. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with type 2 diabetes who require multiple daily doses of insulin and have poor control of diabetes despite the use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation who receive short-term CGM monitoring, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. Systematic reviews of three to four RCTs have found statistically significant benefits from CGM regarding glycemic control. However, the degree of HbA1c reduction

and the difference in HbA1c reductions between groups may not be clinically significant. Also, the limited number of RCTs and variability among interventions make it difficult to identify an optimal approach to CGM or a subgroup of type 2 diabetes patients who might benefit. Moreover, studies of CGM in patients with type 2 diabetes have generally not addressed the clinically important issues of severe hypoglycemia and diabetic complications. Very few pregnant women with type 2 diabetes have been included in RCTs. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input for use of short-term CGM in patients with type 2 diabetes who require multiple daily doses of insulin 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 or when basal insulin levels need to be determined prior to insulin pump initiation. The evidence is sufficient to determine that the technology results in a meaningful 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 an RCT. The relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. In the RCT, the type of glucose monitoring was unclear. Trial reporting was incomplete; however, there was no difference between the groups for most reported outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Tight glucose control in patients with diabetes has been associated with improved health outcomes. Several devices are available to measure glucose levels automatically and frequently (e.g., every 5-10 minutes). The devices measure glucose in the interstitial fluid and are approved as adjuncts to or replacements for traditional self-monitoring of blood glucose levels. Devices can be used on an intermittent (short-term) basis or a continuous (long-term) basis.

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
In response to requests, while this policy was under review in 2019, clinical input on the use of continuous or intermittent monitoring of glucose in the interstitial fluid was received from 3 respondents, including 3 physician-level responses identified through one specialty society including 2 physicians with academic medical center affiliations.

2008
In response to requests, input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review in 2008. Input concurred that continuous glucose monitoring, particularly intermittent glucose monitoring, was helpful in a subset of patients with diabetes. Reviewers commented that this monitoring can improve diabetes care by reducing glucose levels (and improving hemoglobin A_{1c}levels) and/or by reducing episodes of hypoglycemia. Reviewers argued that there is persuasive data from case reports to demonstrate the positive impact of intermittent glucose monitoring.

Practice Guidelines and Position Statements

American Association of Clinical Endocrinologists and the American College of Endocrinology
The AACE and the ACE (2016) published a consensus statement on outpatient glucose monitoring.

Their recommendations on continuous glucose monitoring (CGM) included:
Type 1 diabetes, adults: "CGM recommended, especially for patients with history of severe hypoglycemia, hypoglycemia unawareness and to assist in the correction of hyperglycemia in patients not at goal. CGM users must know basics of sensor insertion, calibration and real-time data interpretation."

Type 1 diabetes, children: Same as adults, except that more training and follow-up are needed.

Type 2 diabetes receiving insulin, sulfonylureas, or glinides: "Data on CGM in T2DM [type 2 diabetes mellitus] are limited at this time. Trials assessing the use of CGM in T2DM are ongoing."

The AACE and the ACE (2018) published a consensus statement on a T2D management algorithm. It is recommended that therapy be evaluated regularly including the results of A1C, SMBG records (fasting and postprandial) or continuous glucose monitoring tracings.

In 2019, the AACE and the ACE 2015 Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan further supplemented by an AACE/ACE Consensus Statement on Comprehensive Type 2 Diabetes Management. The statement supports consideration of the use of personal CGM devices for those patients who are on intensive insulin therapy (three to four injections/day or on an insulin pump), for those with a history of hypoglycemia unawareness, or those with recurrent hypoglycemia. Regarding the duration of use the statement reads; "While these devices could be used intermittently in those who appear stable on their therapy, most patients will need to use this technology on a continual basis."

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence (2016) updated its guidance on the diagnosis and management of type 1 diabetes in adults. The guidance stated that real-time CGM should not be offered "routinely to adults with type 1 diabetes" but that it can be considered in the following:

"...adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring:

- More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
- Complete loss of awareness of hypoglycaemia.
- Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.
- Extreme fear of hypoglycaemia.
- Hyperglycaemia (HbA1c [hemoglobin A_{1c}] level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more."

American Diabetes Association
The American Diabetes Association (2019) “Standards of Medical Care in Diabetes: Diabetes Technology" included the following statement:

"SMBG or CGM is especially important for insulin-treated patients to monitor for and prevent hypoglycemia and hyperglycemia. Most patients using intensive insulin regimens (MDI or insulin pump therapy) should assess glucose levels using SMBG or a CGM prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving"

The Standards (2019) also state that data provided by CGM "offers opportunities to analyze data more granularly than was previously possible, providing additional information to aid in achieving glycemic targets," and note that metrics have been proposed that may include the following:

1. average glucose
2. percentage of time in hypoglycemic ranges (i.e. <54 mg/dL [level 2], 54-70 mg/dL [level 1])
3. percentage of time in target range (i.e. 70-180 mg/dL)
4. percentage of time in hyperglycemic range (≥180 mg/dL)

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

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

International Consensus on Time in Range
In 2019, consensus recommendations on clinical targets for CGM data interpretation were published and endorsed by the American Diabetes Association, American Association of Diabetes Educators, European Association for the Study of Diabetes, Foundation of European Nurses in Diabetes, International Society for Pediatric and Adolescent Diabetes, JDRF, and Pediatric Endocrine Society.

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 Food and Drug Administration 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 Food and Drug Administration 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.

For CY 2020, Medicare has 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 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			
NCT03908125[a]	A Post- Approval Study to Evaluate the Long-term Safety and Effectiveness of the	400	Mar 2023

	Eversense® Continuous Glucose Monitoring (CGM) System		
NCT03808376[a]	PROMISE Study: A Prospective, Multicenter Evaluation of Accuracy and Safety of an Implantable Continuous Glucose Sensor Lasting up to 180 Days	180	Mar 2020
NCT03445065[a]	Benefits of a Long Term Implantable Continuous Glucose Monitoring System for Adults With Diabetes - France Randomized Clinical Trial	324	Jun 2020
Unpublished			
NCT03263494	CGM Intervention in Teens and Young Adults With T1D (CITY): A Randomized Clinical Trial to Assess the Efficacy and Safety of Continuous Glucose Monitoring in Young Adults 14-<25 With Type 1 Diabetes	200	Jul 2019
NCT02838147	Effect of a Continuous Glucose Monitoring on Maternal and Neonatal Outcomes in Gestational Diabetes Mellitus: A Randomized Controlled Trial	200	Jul 2019

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

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Policy History

Original Effective Date: 03/25/2002
Current Effective Date: 01/11/2021

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. Adopted BCBSA format, title 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 to primarily track BCBSA policy 1.01.20.
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.

Next Scheduled Review Date: 12/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of

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descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana 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 Blue Cross Blue Shield of Louisiana 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 Blue Cross Blue Shield of Louisiana 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, 95249, 95250, 95251
HCPCS	A9276, A9277, A9278, E0784, K0553, K0554, S1030, S1031, S1034, S1035, S1036, S1037 Codes added eff 1/1/2020: A4226, E0787
ICD-10 Diagnosis	E08.3-E08.9, E09.3-E09.9, E10.3-E10.9, E11.3-E11.9, E13.3-E13.9

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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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.