BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Continuous Glucose Monitoring

Policy #: 038
Latest Review Date: August 2022
Category: DME

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

For continuous glucose monitoring, refer to refer to LCD 33822 and Article A52464.

For implantable continuous glucose monitoring, refer to L38743 and A58277.

Blue Advantage will treat **intermittent monitoring, i.e., 72 hours, of glucose levels in interstitial fluid** as a **covered benefit** in patients with **Type 1 diabetes mellitus whose diabetes is documented in the medical records as *poorly controlled despite current use of **best practices.**

*Poorly controlled Type 1 diabetes mellitus includes the following clinical situations:

- Unexplained hypoglycemic episodes;
- Hypoglycemic unawareness;
- Suspected postprandial hyperglycemia;
- Recurrent diabetic ketoacidosis.

Blue Advantage will treat **intermittent monitoring of glucose levels in interstitial** as a **covered benefit** in patients with Type 1 diabetes **prior to insulin pump initiation to determine basal insulin levels.**

Intermittent monitoring is generally conducted in 72-hour periods. It may be repeated at a subsequent time depending on the patient's level of diabetes control.

For dates of service prior to April 18, 2021:

Continuous Monitoring

For CPT codes A9276, A9277, A9278, K0553 and K0554, refer to LCD 33822 and Article 52464.

Blue Advantage will treat the use of **implantable continuous glucose monitoring devices (i.e. Eversense Continuous Glucose Monitoring System)** as a **non-covered benefit** and as **investigational.**

Intermittent Monitoring

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Intermittent monitoring is generally conducted in 72-hour periods. It may be repeated at a subsequent time depending on the patient's level of diabetes control.

Coverage for non-medical items, even when the items may be used to serve a medical purpose, such as smart devices (smart phones, tablets, personal computers, etc.) are non-covered. This includes smart devices used in conjunction with Continuous Glucose Monitors.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Tight glucose control in patients with diabetes has been associated with improved 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 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.

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 (i.e., before meals and at bedtime), a commitment that some patients may find difficult to meet. The goal of tight glucose control has to be balanced with an associated risk of hypoglycemia. Hypoglycemia is known to be a risk in patients with type 1 diabetes. While patients with insulin-treated type 2 diabetes may also experience severe hypoglycemic episodes, there is a lower relative likelihood of severe hypoglycemia compared with patients who had type 1 diabetes. An additional limitation of periodic self-measurements of blood glucose is that glucose levels are seen in isolation, and trends in glucose levels are undetected. For example, while a diabetic patient's fasting blood glucose level might be within normal values, hyperglycemia might be undetected postprandially, leading to elevated HbA1c levels.

Management

Measurements of glucose in the interstitial fluid have been developed as a technique to measure glucose values automatically throughout the day, producing data that show the trends in glucose levels. Although devices measure glucose in the interstitial fluid on a periodic rather than a continuous basis, this type of monitoring is referred to as continuous glucose monitoring (CGM).

Currently, CGM devices are of two designs; real-time CGM (rtCGM) provide 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. The devices must be calibrated twice daily with blood glucose measurements from fingersticks, and are less reliable when used after exercise or post-prandial. Devices may be used intermittently (i.e., for periods of 72 hours) or continuously (i.e., on a long-term basis).

KEY POINTS:

The most recent literature search was performed through June 10, 2022. Following is a summary of the key literature to date.

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 CGM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, 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 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 2 RCTs prespecified hypoglycemia-related outcomes and reported that time spent in hypoglycemia was significantly less in the CGM group. One RCT in pregnant women with type 1 diabetes, which compared real-time CGM with self-monitoring of blood glucose, 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 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 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.

Type 2 Diabetes

For individuals with type 2 diabetes who require multiple daily doses of insulin or an insulin pump who receive long-term CGM, the evidence includes RCTs. Relevant outcomes are

symptoms, morbid events, QOL, and treatment-related morbidity. 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. 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 (the primary outcome).On secondary glycemic control measures, HbA1c was reduced by 0.82% compared to 0.33% in the control group (P =.005) without an increase in the frequency of hypoglycemic events. At 6 months, there was no difference between groups in the primary outcome of change in HbA1c (p=.8222). However, results for secondary outcomes including time in hypoglycemia and treatment satisfaction favored the CGM group. No serious adverse events or severe hypoglycemic events were reported related to device use. At 12-month follow-up in one of the trials of the Freestyle Libre device, hypoglycemic events were reduced by 40.8% to 61.7% with a greater relative reduction in the most severe thresholds of hypoglycemia. 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 do not require multiple daily doses of insulin or an insulin pump who receive long-term CGM, the evidence includes 2 RCTs. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. The trials found statistically significant benefits of CGM regarding glycemic control. However, participant populations were heterogenous with regard to their diabetic treatment regimens, and participants might not have been receiving optimal therapy. In contrast to recommendations in individuals on intensive insulin regimens, guidelines are less clear on when to prescribe blood glucose monitoring and how often monitoring is needed in individuals using basal insulin only. 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.

For individuals with type 2 diabetes who receive short-term continuous 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 short-term 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. 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 (continuous) or short-term (intermittent) glucose monitoring, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. In the RCT, the type of CGM was unclear. Trial reporting was incomplete; however, there was no difference between the groups for the majority of the reported outcomes.

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 nonrandomized studies. There are no RCTs and no comparative observational studies of implantable CGM compared to SBMG. Nonrandomized prospective studies and post-marketing registry studies assessed the accuracy and safety of an implanted glucose monitoring system that provides continuous glucose monitoring for up to 4 insertion/removal cycles as an adjunct to home glucose monitoring devices. Accuracy measures included the mean absolute relative difference between paired samples from the implanted device and a reference standard blood glucose measurement. The accuracy tended to be lower in hypoglycemic ranges. The initial approval of the device has been expanded to allow the device to be used for glucose management decision making. The same clinical study information was used to support what the FDA considered a reasonable assurance of safety and effectiveness of the device for the replacement of finger stick blood glucose monitoring for diabetes treatment decisions. In February 2022, approval of the device for use up to 180 days. Approval was based on the FDA expanded PROMISE pivotal clinical trial, which assessed accuracy and safety but not glycemic outcomes. Limitations of the evidence base include lack of direct comparisons to SMBG, lack of differentiation in outcomes for type 1 diabetes versus type 2 diabetes, and variability in reporting of trends in secondary glycemic measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Association of Clinical Endocrinologists

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 Intermediate Strength of Evidence)

American Diabetes Association

The American Diabetes Association (2022) “Standards of Medical Care in Diabetes" made the following recommendations (level of evidence) on CGM devices:

"Real-time CGM (A) or intermittently scanned continuous glucose monitoring (B) should be offered for diabetes management in adults with diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs."

Real-time CGM (A) or intermittently scanned continuous glucose monitoring (C) can be used for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs."

Real-time CGM (B) or intermittently scanned continuous glucose monitoring (E) should be offered for diabetes management in youth with type 1 diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs."

When used as an adjunct to pre- and postprandial blood glucose monitoring, CGM can help to achieve A1c targets in diabetes and pregnancy (B)

Periodic use of real-time or intermittently scanned cCGM or use of professional CGM can be helpful for diabetes management in circumstances where continuous use of CGM is not appropriate, desired, or available (C).

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

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

"When choosing a (CGM) device:

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

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

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

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

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

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

Endocrine Society
The Endocrine Society (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 an early daily basis.

Use of continuous glucose monitoring in adults with type 2 diabetes mellitus [T2DM]

6.3 We suggest short-term, intermittent RT-CGM use in adult patients with T2DM (not on prandial insulin) who have A1C levels ≥7%and are willing and able to use the device."

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

KEY WORDS:
GlucoWatch®, wrist glucose monitor, Glucose Biographer, AutoSensor, and GlucoWatch® G2™ Biographer, continuous monitoring of glucose in the interstitial fluid, intermittent monitoring of glucose in the interstitial fluid, Continuous Glucose Monitoring System, CGMS, CGMS® System Gold™, Minimed, MiniMed Paradigm 522 or 722 insulin pumps, MiniMed Paradigm Real-Time Insulin Pump and Continuous Glucose Monitoring System, combined continuous subcutaneous insulin infusion and blood glucose monitoring device, DexCom STS Continuous Glucose Monitoring System, CGMS iPro Recorder, Freestyle Navigator® Continuous Glucose Monitoring System, Guardian® REAL-Time Continuous Glucose Monitoring System, CGM, Dexcom G5, Abbott® Freestyle Libre Flash, Dexcom G6, Eversense, implantable , Freestyle® Libre 2, Eversense E3

APPROVED BY GOVERNING BODIES:
Multiple continuous glucose monitoring systems have been approved by the FDA through the premarket approval process:

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.

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
		2014	Expanded to include patients with diabetes 2-17 y
Dexcom® G5 Mobile CGM	Dexcom	2016a	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 readings5,

Device	Manufacturer	Approval	Indications
Dexcom® G6 Continuous Glucose Monitoring System	Dexcom	2018	Indicated for the management of diabetes in person's 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	Adult's ≥18 y. Extended duration of use to 14 days
Freestyle® Libre 2 Flash Glucose Monitoring System	Abbott	June 2020	Children ≥ 4 years of age, adolescents and adults
Guardian Connect	Medtronic MiniMed	2018	Adolescents and adults (14-75 years) Continuous or periodic monitoring of interstitial glucose levels. Provides real-time glucose values, trends, and alerts through a Guardian Connect app installed on a compatible consumer electronic mobile device
Eversense Continuous Glucose Monitoring System	Senseonics	2018 2019	Adult's ≥18 y. Continually measuring glucose levels up to 90 days.

Device	Manufacturer	Approval	Indications
			Use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. Adult's ≥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.

CGM: continuous glucose monitoring.

a As a supplement to the G4 premarketing approval.

Food and Drug Administration product codes: MDS, PQF, QCD

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report
99091	Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time

REFERENCES:

1. Aleppo G, Beck RW, Bailey R, et al. The Effect of Discontinuing Continuous Glucose Monitoring in Adults With Type 2 Diabetes Treated With Basal Insulin. Diabetes Care. Dec 2021; 44(12): 2729-2737.
2. Agrawal P, Zhong A, Welsh JB, et al. Retrospective analysis of the real-world use of the threshold suspend feature of sensor-augmented insulin pumps. Diabetes Technol Ther. May 2015; 17(5):316-319.
3. Ajjan, RR, Abougila, KK, Bellary, SS, Collier, AA, Franke, BB, Jude, EE, Rayman, GG, Robinson, AA, Singh, BB. Sensor and software use for the glycaemic management of insulin-treated type 1 and type 2 diabetes patients. Diab Vasc Dis Res, 2016 Mar 24;13(3).
4. merican Association of Clinical Endocrinology and American College of Endocrinology. Comprehensive Type 2 DiabetesManagement Algorithm. 2020. https://pro.aace.com/disease-state-resources/diabetes/clinical-practice-guidelines-treatment-algorithms/comprehensive. Accessed November 2, 2020.
5. American Diabetes Association. Standards of Medical Care in Diabetes. 2022. https://professional.diabetes.org/content-page/practice-guidelines-resources.
6. American Diabetes A. 6. Glycemic Targets: Standards of Medical Care in Diabetes-2018. Diabetes Care. Jan 2018;41(Suppl 1):S55-S64.
7. American Diabetes Association. 7. Approaches to glycemic treatment. Diabetes Care. Jan 2015; 38 (suppl: S41-48).

8. American Diabetes Association. Standards of medical care in diabetes—2010. Diabetes Care 2010; 33(suppl 1):S11-61.
9. American Diabetes A. Standards of medical care in diabetes--2013. Diabetes Care 2013; 36 Suppl 1:S11-66.
10. American Diabetes Association. Standards in Medical Care in Diabetes, 2014. 2014; www.care.diabetesjournals.org/content/37/Supplement_1/S14.full.pdf+html American Diabetes Association (ADA). Glycemic Targets. Diabetes Care. Jan 2017; 40(Suppl 1):S48-S56.
11. American Diabetes Association. 7. Diabetes Technology: Standards of Medical Care in Diabetes-2019. Diabetes Care, 2018 Dec 19;42(Suppl 1).
12. American DA. Executive summary: standards of medical care in diabetes—2011. Diabetes Care 2011; 34(Suppl 1):S4-S10.
13. American Diabetes Association. Standards of Medical Care in Diabetes. 2020. https://professional.diabetes.org/content-page/practice-guidelines-resources.
14. American Diabetes Association. Standards of Medical Care in Diabetes. 2021. https://professional.diabetes.org/content-page/practice-guidelines-resources.
15. Bailey KJ, Little JP, Jung ME. Self-monitoring using continuous glucose monitors with real-time feedback improves exercise adherence in individuals with impaired blood glucose: a pilot study. Diabetes Technol Ther. Mar 2016; 18(3):185-193.
16. Battelino T, Conget I, Olsen B et al. The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy: a randomized controlled trial Diabetologia 2012; 55(12):3155-3162.
17. Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation:Recommendations From the International Consensus on Time in Range. Diabetes Care. Aug 2019; 42(8): 1593-1603.
18. Beck RW, Riddlesworth TD, Ruedy K, et al. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections: a randomized trial. Ann Intern Med. Sep 19 2017; 167(6):365-374.
19. Beck RW, Riddlesworth T, Ruedy K, et al. Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: The DIAMOND randomized clinical trial. Jama. Jan 24 2017; 317(4):371-378.
20. Benkhadra K, Alahdab F, Tamhane S, et al. Real-time continuous glucose monitoring in type 1 diabetes: a systematic review and individual patient data meta-analysis. Clin Endocrinol (Oxf). Mar 2017; 86(3):354-360.
21. Bergenstal RM, Klonoff DC, Garg SK et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia. N Engl J Med 2013; 369(3):224-32.
22. Blue Cross Blue Shield Association Technology Evaluation Criteria (TEC) Assessment. Use of intermittent or continuous interstitial fluid glucose monitoring in patients with diabetes mellitus. TEC Assessments 2003; Volume 18, Tab 16.
23. Christiansen, MM, Klaff, LL, Brazg, RR, Chang, AA, Levy, CC, Lam, DD, Denham, DD, Atiee, GG, Bode, BB, Walters, SS, Kelley, LL, Bailey, TT. A Prospective

Multicenter Evaluation of the Accuracy of a Novel Implanted Continuous Glucose Sensor: PRECISE II. Diabetes Technol. Ther., 2018 Jan 31;20(3).

24. Christiansen, MM, Klaff, LL, Bailey, TT, Brazg, RR, Carlson, GG, Tweden, KK. A Prospective Multicenter Evaluation of the Accuracy and Safety of an Implanted Continuous Glucose Sensor: The PRECISION Study. Diabetes Technol. Ther., 2019 Mar 30;21(5).
25. Deiss D, Irace C, Carlson G, et al. Real-World Safety of an Implantable Continuous Glucose Sensor Over Multiple Cycles ofUse: A Post-Market Registry Study. Diabetes Technol Ther. Jan 2020; 22(1): 48-52.
26. Erhardt NM, Chellapa M, Walker MS et al. The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. J Diabetes Sci Technol 2011; 5(3):668-75.
27. Feig DS, Donovan LE, Corcoy R, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. Lancet. Nov 25 2017; 390(10110):2347-2359.
28. Floyd B, Chandra P, Hall S et al. Comparative analysis of the efficacy of continuous glucose monitoring and self-monitoring of blood glucose in type 1 diabetes mellitus. J Diabetes Sci Technol 2012; 6(5):1094-1102.
29. Food and Drug Administration (FDA). Summary of Safety and Effectiveness (SSED): Dexcom G5 Mobile Continuous Glucose Monitoring System. 2016; www.accessdata.fda.gov/cdrh_docs/pdf12/P120005S041b.pdf. Accessed May 31, 2017.
30. Food and Drug Administration (FDA). News Release: Freestyle Libre Flash Glucose Monitoring System. 2017; www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577890.htm. Accessed January 11, 2018.
31. Food and Drug Administration. Summary of Safety and Effectiveness Data: Eversense Continuous Glucose Monitoring System(2019). https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048B.pdf. Accessed October November 2, 2020.
32. Furler J, O'Neal D, Speight J, et al. Use of professional-mode flash glucose monitoring, at 3-month intervals, in adults with type2 diabetes in general practice (GP-OSMOTIC): a pragmatic, open-label, 12-month, randomised controlled trial. Lancet DiabetesEndocrinol. Jan 2020; 8(1): 17-26.
33. Gandhi GY, Kovalaske M, Kudva Y et al. Efficacy of continuous glucose monitoring in improved glycemic control and reducing hypoglycemia: a systematic review and meta-analysis of randomized trials. J Diabetes Sci Technol 2011; 5(4):952-65.
34. Garber, AA, Abrahamson, MM, Barzilay, JJ, Blonde, LL, Bloomgarden, ZZ, Bush, MM, Dagogo-Jack, SS, DeFronzo, RR, Einhorn, DD, Fonseca, VV, Garber, JJ, Garvey, WW, Grunberger, GG, Handelsman, YY, Hirsch, II, Jellinger, PP, McGill, JJ, Mechanick, JJ, Rosenblit, PP, Umpierrez, GG. CONSENSUS STATEMENT BY THE AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY ON THE COMPREHENSIVE TYPE 2

DIABETES MANAGEMENT ALGORITHM - 2019 EXECUTIVE SUMMARY. Endocr Pract, 2019 Feb 12;25(1).

35. Garg S, Brazg RL, Bailey TS et al. Reduction in duration of hypoglycemia by automatic suspension of insulin delivery: the in-clinic ASPORE study. Diab Technol Ther 2012; 14(3):205-9.
36. Garg SK, Liljenquist D, Bode B, et al. Evaluation of Accuracy and Safety of the Next-Generation Up to 180-Day Long-Term Implantable Eversense Continuous Glucose Monitoring System: The PROMISE Study. Diabetes Technol Ther. Feb 2022; 24(2): 84-92.
37. Gehlaut RR, Dogbey GY, Schwartz FL, et al. Hypoglycemia in type 2 diabetes--more common than you think: a continuous glucose monitoring study. J Diabetes Sci Technol. Sep 2015; 9(5):999-1005.
38. Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons with Diabetes Mellitus. Endocr Pract. Jun 2021; 27(6): 505-537.
39. Haak, TT, Hanaire, HH, Ajjan, RR, Hermanns, NN, Riveline, JJ, Rayman, GG. Flash Glucose-Sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-Treated Type 2 Diabetes: a Multicenter, Open-Label Randomized Controlled Trial. Diabetes Ther, 2016 Dec 22;8(1).
40. Haak, TT, Hanaire, HH, Ajjan, RR, Hermanns, NN, Riveline, JJ, Rayman, GG. Use of Flash Glucose-Sensing Technology for 12 months as a Replacement for Blood Glucose Monitoring in Insulin-treated Type 2 Diabetes. Diabetes Ther, 2017 Apr 13;8(3).
41. Ida, SS, Kaneko, RR, Murata, KK. Utility of Real-Time and Retrospective Continuous Glucose Monitoring in Patients with Type 2 Diabetes Mellitus: A Meta-Analysis of Randomized Controlled Trials. J Diabetes Res, 2019 Feb 19;2019:4684815.
42. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
43. Klonoff DC, Buckingham B, Christiansen JS et al. Continuous glucose monitoring: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2011; 96(10):2968-79.
44. Kropff, JJ, Choudhary, PP, Neupane, SS, Barnard, KK, Bain, SS, Kapitza, CC, Forst, TT, Link, MM, Dehennis, AA, DeVries, JJ. Accuracy and Longevity of an Implantable Continuous Glucose Sensor in the PRECISE Study: A 180-Day, Prospective, Multicenter, Pivotal Trial. Diabetes Care, 2016 Nov 7;40(1).
45. Laffel LM, Kanapka LG, Beck RW, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adolescents andYoung Adults With Type 1 Diabetes: A Randomized Clinical Trial. JAMA. Jun 16 2020; 323(23): 2388-2396.
46. Langendam M, Luijf YM, Hooft L et al. Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochran Database Syst Rev 2012; 1:CD0081010.
47. Lind M, Polonsky W, Hirsch IB, et al. Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: The GOLD randomized clinical trial. Jama. Jan 24 2017; 317(4):379-387.

48. Little SA, Leelarathna L, Walkinshaw E, et al. Recovery of hypoglycemia awareness in long-standing type 1 diabetes: a multicenter 2 x 2 factorial randomized controlled trial comparing insulin pump with multiple daily injections and continuous with conventional glucose self-monitoring (HypoCOMPaSS). Diabetes Care. Aug 2014; 37(8):2114-2122.
49. Ly TT, Nicholas JA, Retterath A, et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycemia in patients with type 1 diabetes: a randomized clinical trial. JAMA. Sep 25 2013; 310(12):1240-1247.
50. Martens T, Beck RW, Bailey R, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 DiabetesTreated With Basal Insulin: A Randomized Clinical Trial. JAMA. Jun 08 2021; 325(22): 2262-2272.
51. Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes-2018. Diabetes Care. Jan 2018; 41(Suppl 1):S137-s143.
52. Mauras N, Beck R, Xing D et al. A randomized clinical trial to assess the efficacy and safety of real-time continuous glucose monitoring in the management of type 1 diabetes in young children aged 4 to <10 years. Diabetes Care 2012; 35(2):204-210.
53. National Center for Health and Care Excellence (NICE). Type 1 diabetes in adults: diagnosis and management. www.nice.org.uk/guidance/ng17?unlid=382286372016220232952. Accessed November 2, 2020
54. National Institute for Health and Care Excellence. (2022) Type 1 Diabetes in Adults: Diagnosis and Management.https://www.nice.org.uk/guidance/ng17/chapter/Recommendations#blood-glucose-management. Accessed July 1, 2022
55. National Institute for Health and Care Excellence. 2022. Type 2 Diabetes in Adults: Management.https://www.nice.org.uk/guidance/ng28. Accessed June 30, 2022
56. National Institute for Health and Care Excellence. Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system). Diagnostics guidance [DG21]. Feb 2016. https://www.nice.org.uk/guidance/dg21/chapter/1-Recommendations. Accessed October 21, 2016.
57. Pazos-Couselo M, Garcia-Lopez JM, Gonzalez-Rodriguez M, et al. High incidence of hypoglycemia in stable insulin-treated type 2 diabetes mellitus: continuous glucose monitoring vs. self-monitored blood glucose. Observational prospective study. Can J Diabetes. Oct 2015; 39(5):428-433.
58. Perkins BA, Bebu I, de Boer IH, et al. Risk Factors for Kidney Disease in Type 1 Diabetes. Diabetes Care. 2019 42(5):883-890.
59. Peters AL, Ahmann AJ, Battelino T, et al. Diabetes technology-continuous subcutaneous insulin infusion therapy and continuous glucose monitoring in adults: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. Nov 2016; 101(11):3922-3937.

60. Polonsky WH, Hessler D, Ruedy KJ, et al. The impact of continuous glucose monitoring on markers of quality of life in adults with type 1 diabetes: further findings from the DIAMOND randomized clinical trial. Diabetes Care. Jun 2017; 40(6):736-741.
61. Poolsup N, Suksomboon N, Kyaw AM. Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. Diabetol Metab Syndr 2013; 5(1):39.
62. Pratley RE, Kanapka LG, Rickels MR, et al. Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults WithType 1 Diabetes: A Randomized Clinical Trial. JAMA. Jun 16 2020; 323(23): 2397-2406.
63. Phillip M, Battelino T, Atlas E et al. Nocturnal glucose control with an artificial pancreas at a diabetes camp. N Engl J Med 2013; 368(9):824-33.
64. Riddlesworth T, Price D, Cohen N, et al. Hypoglycemic event frequency and the effect of continuous glucose monitoring in adults with type 1 diabetes using multiple daily insulin injections. Diabetes Ther. Aug 2017;8(4):947-951.
65. Sanchez P, Ghosh-Dastidar S, Tweden KS, et al. Real-World Data from the First U.S. Commercial Users of an ImplantableContinuous Glucose Sensor. Diabetes Technol Ther. Dec 2019; 21(12): 677-681.
66. Sato J, Kanazawa A, Ikeda F, et al. Effect of treatment guidance using a retrospective continuous glucose monitoring system on glycaemic control in outpatients with type 2 diabetes mellitus: A randomized controlled trial. J Int Med Res. Feb 2016; 44(1):109-121.
67. Secher AL, Ringholm L, Andersen HU et al. The Effect of Real-Time Continuous Glucose Monitoring in Pregnant Women with Diabetes: a randomized controlled trial. Diabetes care 2013 Jul 2013; 36(7):1877-1883.
68. Secher AL, Pedersen-Bjergaard U, Svendsen OL, et al. Flash glucose monitoring and automated bolus calculation in type 1 diabetestreated with multiple daily insulin injections: a 26 week randomised, controlled, multicentre trial. Diabetologia. Dec 2021; 64(12): 2713-2724.
69. Sequeira PA, Montoya L, Ruelas V, et al. Continuous glucose monitoring pilot in low-income type 1 diabetes patients. Diabetes Technol Ther. Oct 2013; 15(10):855-858.
70. Tweden KS, Deiss D, Rastogi R, et al. Longitudinal Analysis of Real-World Performance of an Implantable Continuous GlucoseSensor over Multiple Sensor Insertion and Removal Cycles. Diabetes Technol Ther. May 2020; 22(5): 422-427.
71. Tweden KS, Deiss D, Rastogi R et al. Longitudinal Analysis of Real-World Performance of an Implantable Continuous Glucose Sensor Over Multiple Sensor Insertion and Removal Cycles.. Diabetes Technol. Ther., 2019 Nov 8.
72. van Beers CA, DeVries JH, Kleijer SJ, et al. Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycemia (IN CONTROL): a randomized, open-label, crossover trial. Lancet Diabetes Endocrinol. Nov 2016; 4(11):893-902.
73. Vigersky RA, Fonda SJ, Chellappa M et al. Short-and long-term effects of real-time continuous glucose monitoring in patients with type 2 diabetes. Diabetes Care 2012; 35(1):32-38.

74. Voormolen DN, Devries JH, Frax A et al. Effectiveness of continuous glucose monitoring during diabetic pregnancy (GlucoMOMS trial); a randomised controlled trial. BMCPrgnancy Childbirth 2012; 12(1):164.
75. Voormolen DN, Devries JH, Evers IM et al. The efficacy and effectiveness of continuous glucose monitoring during pregnancy: a systematic review. Obstet Gynecol Surv 2013; 68(11):753-63.
76. Wei Q, Sun Z, Yang Y, et al. Effect of a CGMS and SMBG on maternal and neonatal outcomes in gestational diabetes mellitus: a randomized controlled trial. Sci Rep. 2016; 6:19920.
77. Wojcichowski P, Rys P, Lipowska A et al. Efficacy and safety comparison of continuous glucose monitoring and self-monitoring of blood glucose in type 1 diabetes. Pool Arch Med Wewn 2011; 121(10):333-343.
78. Yeoh E, Choudhary P, Nwokolo M, et al. Interventions that restore awareness of hypoglycemia in adults with type 1 diabetes: a systematic review and meta-analysis. Diabetes Care. Aug 2015; 38(8):1592-1609.

POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 12-June 27, 2005
Medical Policy Group, March 2006
Medical Policy Group, June 2006
Available for comment July 15-August 28, 2006
Medical Policy Group, January 2007
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Medical Policy Group, July 2007
Medical Policy Group, October 2007
Available for comment October 20-December 3, 2007
Medical Policy Group, June 2008
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Medical Policy Group, January 2009
Medical Policy Group, May 2010
Medical Policy Group, December 2012
Medical Policy Group, June 2013
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Medical Policy Group, April 2014
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Medical Policy Group, May 2014
Medical Policy Group, February 2015
Medical Policy Group, July 2016
Medical Policy Group, December 2016
Medical Policy Group, February 2017
Medical Policy Group, July 2017
Medical Policy Group, December 2017
Medical Policy Group, January 2018

Medical Policy Group, May 2018
Medical Policy Group, August 2019
Medical Policy Group, December 2019: Annual Coding Update
Medical Policy Group, December 2019
Medical Policy Group, June 2020; Added keyword Freestyle® Libre 2.
Medical Policy Group, December 2020
Medical Policy Group, December 2021
Medical Policy Group, June 2022: Quarterly Coding Update. Added HCPCS codes G0308-G0309 to Current Coding Section.
Medical Policy Group, August 2022
Medical Policy Group, November 2022
Medical Policy Group, December 2022
