BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Continuous or Intermittent Monitoring of Glucose in the Interstitial Fluid

Policy #: 038
Category: DME

Latest Review Date: December 2020
Policy Grade: B

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 dates of service on or after April 18, 2021:

Continuous Monitoring

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

For CPT codes 0446T, 0447T and 0448T, refer to LCD L38743 and Article A58277.

Intermittent Monitoring

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.**

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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 an intermittent (short-term) basis or a continuous (long-term) 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 DiabetesControl 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 is 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 should range between 6.0 to 6.5%; an A1C 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 October 28, 2020. 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. The 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 inHbA1c 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 receive short-term glucose monitoring, the evidence includes RCTs and systematic reviews. The 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 on 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.

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 HbA1c levels 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 SMBG for the management of insulin-dependent treated type 2 diabetes 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 spent 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.

For individuals with type 2 diabetes who receive short-term CGM monitoring, the evidence includes RCTs and systematic reviews.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.

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.

Practice Guidelines and Position Statements

American Association of Clinical Endocrinologists and American College of Endocrinology

In 2020, the AACE and the ACE 2015 Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan was supplemented by an AACE/ACE Consensus Statement on Comprehensive Type 2 Diabetes Management. It is recommended that therapy be evaluated regularly including the results of A1C, SMBG records (fasting and postprandial) or continuous glucose monitoring tracings. 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 1diabetes 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 optimized use of insulin therapy and conventional blood glucose monitoring:

- More than 1 episode a year of severe hypoglycemia with no obviously preventable precipitating cause.
- Complete loss of awareness of hypoglycemia.
- Frequent (more than 2 episodes a week) asymptomatic hypoglycemia that is causing problems with daily activities.
- Extreme fear of hypoglycemia.

Hyperglycemia (HbA1c [hemoglobin A1c] level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10times 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 (2020) “Standards of Medical Care in Diabetes: Diabetes Technology," included the following statement in the chapter on glycemic targets:

"Continuous glucose monitoring (CGM) also has an important role in assessing the effectiveness and safety of treatment in many patients with type 1 diabetes, and limited data suggest it may also be helpful in selected patients with type 2 diabetes, such as those on intensive insulin regimens."

The Standards also state that the technology has evolved rapidly in both accuracy and affordability and that data provided by CGM "will allow the provider to determine time in range (TIR) and to assess hypoglycemia, hyperglycemia, and glycemic variability", noting that there is a strong correlation between TIR and an A1C.

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."

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.

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

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 and do not have continuous or real-time alerts.

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	MiniMed (now Medtronic)	2006	Integrates CGM with a Paradigm insulin pump

Device	Manufacturer	Approval	Indications
called Paradigm Revel System)			
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,
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

Device	Manufacturer	Approval	Indications
Freestyle Libre 2® Flash Glucose Monitoring System	Abbott	6/2020	Children ≥ 4 years of age
Guardian Connect	Medtronic MiniMed	2018	Adolescents and adults (14-75 years) Continuous or periodic monitoring of interstitial glucose levels. Provides real-time glucose values, trends, and alerts through a Guardian Connect app installed on a compatible consumer electronic mobile device
Eversense Continuous Glucose Monitoring System	Senseonics	2018 2019	Adults ≥18 y. Continually measuring glucose levels up to 90 days. Use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. Adults ≥18 y. Continually measuring glucose levels up to 90 days. Indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions. Historical data from the system can be interpreted to aid in providing therapy adjustments.

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

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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
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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

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.