MASSACHUSETTS

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Medical Policy

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

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Policy Number: 107

BCBSA Reference Number: 1.01.20
NCD/LCD: Local Coverage Determination (LCD): Glucose Monitors (L33822)

Related Policies

Artificial Pancreas Device Systems, #720

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Continuous monitoring (ie, long-term) monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique of diabetic monitoring, including devices with low glucose suspend (LGS features), may be considered **MEDICALLY NECESSARY** when the following situations occur, despite use of best practices:

- Patients with type 1 diabetes that is not adequately controlled (A1c >7.5) who have demonstrated an understanding of the technology, are motivated to use the device correctly and consistently, are expected to be adherent 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 I 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 I diabetes who are pregnant. Poorly controlled type 1 diabetes includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis.

Intermittent monitoring (ie, 72 hours)* of glucose levels in interstitial fluid may be considered **MEDICALLY NECESSARY** in patients with type I diabetes whose diabetes is poorly controlled, despite current use of best practices.* Poorly controlled type 1 diabetes includes the following clinical situations: unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis.

*Best practices in diabetes control include compliance with a regimen of 4 or more finger sticks each day and use of an insulin pump. During pregnancy, 3 or more insulin injections daily could also be considered

best practice for patients not on an insulin pump prior to the pregnancy. Prior use of an intermittent (72-hour) glucose monitor would be considered a part of best practices for those considering use of a continuous glucose monitor.

Intermittent monitoring* of glucose levels in interstitial fluid may also be considered **MEDICALLY NECESSARY** 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.

Other uses of continuous monitoring of glucose levels in interstitial fluid as a technique of diabetic monitoring are considered **INVESTIGATIONAL**.

Medicare HMO Blue^{SM} and Medicare PPO Blue^{SM} Members

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link below.

Local Coverage Determinations (LCDs) for National Government Services, Inc.

Local Coverage Determination (LCD): Glucose Monitors (L33822)

Note: To review the specific LCD, please remember to click "accept" on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for **Medicare Advantage members living outside of Massachusetts**, please see the Centers for Medicare and Medicaid Services website at https://www.cms.gov for information regarding your specific jurisdiction.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue^{SM}	Prior authorization is **not required**.
Medicare PPO Blue^{SM}	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

For members with a pharmacy benefit:
A9276: Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit=1 day supply

Note: If a member does not have a pharmacy benefit, the above noted item would be covered according to the member's benefit and certificate language.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, and Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
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; 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; interpretation and report

HCPCS Codes

HCPCS codes:	Code Description
E0784	External ambulatory infusion pump, insulin
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit=1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and HCPCS codes above if <u>medical necessity criteria</u> are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma
E10.21	Type 1 diabetes mellitus with diabetic nephropathy
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral

E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E10.3291	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E10.3292	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E10.3293	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3299	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E10.3312	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E10.3391	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E10.3392	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E10.3393	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3399	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E10.3491	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E10.3492	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E10.3493	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3499	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E10.3521	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E10.3522	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye

E10.3523	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E10.3529	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye
E10.3531	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E10.3532	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E10.3533	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E10.3539	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye
E10.3541	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E10.3542	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye
E10.3543	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
E10.3549	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye
E10.3551	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E10.3552	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E10.3553	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral
E10.3559	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye
E10.3591	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E10.3592	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E10.3593	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E10.3599	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye
E10.36	Type 1 diabetes mellitus with diabetic cataract
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E10.44	Type 1 diabetes mellitus with diabetic amyotrophy
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication
E10.51	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.59	Type 1 diabetes mellitus with other circulatory complications
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E10.618	Type 1 diabetes mellitus with other diabetic arthropathy
E10.620	Type 1 diabetes mellitus with diabetic dermatitis
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E10.628	Type 1 diabetes mellitus with other skin complications
E10.630	Type 1 diabetes mellitus with periodontal disease
E10.638	Type 1 diabetes mellitus with other oral complications
E10.641	Type 1 diabetes mellitus with hypoglycemia with coma

E10.649	Type 1 diabetes mellitus with hypoglycemia without coma
E10.65	Type 1 diabetes mellitus with hyperglycemia
E10.69	Type 1 diabetes mellitus with other specified complication
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications
O024.112	Pre-existing type 2 diabetes mellitus, in pregnancy, second trimester
O024.113	Pre-existing type 2 diabetes mellitus, in pregnancy, third trimester
O24.011	Pre-existing type 1 diabetes mellitus, in pregnancy, first trimester
O24.012	Pre-existing type 1 diabetes mellitus, in pregnancy, second trimester
O24.013	Pre-existing type 2 diabetes mellitus, in pregnancy, third trimester
O24.111	Pre-existing type 2 diabetes mellitus, in pregnancy, first trimester
O24.311	Unspecified pre-existing diabetes mellitus in pregnancy, first trimester
O24.312	Unspecified pre-existing diabetes mellitus in pregnancy, second trimester
O24.313	Unspecified pre-existing diabetes mellitus in pregnancy, third trimester
O24.811	Other pre-existing diabetes mellitus in pregnancy, first trimester
O24.812	Other pre-existing diabetes mellitus in pregnancy, second trimester
O24.813	Other pre-existing diabetes mellitus in pregnancy, third trimester
O24.911	Unspecified diabetes mellitus in pregnancy, first trimester
O24.912	Unspecified diabetes mellitus in pregnancy, second trimester
O24.913	Unspecified diabetes mellitus in pregnancy, third trimester

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, and Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM) system, includes all supplies and accessories, 1 month supply = 1 unit of service
K0554	Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system

See link below for further Medicare HMO Blue and Medicare PPO Blue coding guidance:
Local Coverage Determinations (LCDs) for National Government Services, Inc.

Local Coverage Determination (LCD): Glucose Monitors (L33822)

Description

BLOOD GLUCOSE CONTROL

The advent of blood glucose monitors for use by patients in the home revolutionized the management of diabetes. Using fingersticks, patients can monitor their blood glucose levels both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. Tight glucose control, defined as a strategy involving frequent glucose checks and a target hemoglobin A_{1c} (HbA_{1c}) level in the range of 7%, is now considered 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 HbA_{1c} level reduction of 10% is clinically meaningful and corresponds to approximately a 40% decrease in risk for progression of diabetic retinopathy and 25% decrease in risk for progression of renal disease.[1]

Due to an increase in turnover of red blood cells during pregnancy, HbA_{1c} levels are slightly lower in women with a normal pregnancy compared with nonpregnant women. The target A_{1c} in women with diabetes is also lower in pregnancy. The American Diabetes Association recommends that, if achievable without significant hypoglycemia, the A_{1c} levels should range between 6.0% to 6.5%; an A_{1c} levels less than 6% may be optimal as the pregnancy progresses.[2]

Tight glucose control requires multiple daily measurements of blood glucose (ie, before meals and at bedtime), a commitment that some patients may be unwilling or unable to meet. Also, 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.[3,4] An additional limitation of periodic self-measurements of blood glucose is that glucose levels are seen in isolation, and trends in glucose levels are undetected. For example, while a diabetic patient's fasting blood glucose level might be within normal values, hyperglycemia might be undetected postprandially, leading to elevated HbA_{1c} levels.

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).

Several devices have received approval from the U.S. Food and Drug Administration (FDA). The first approved devices were the Continuous Glucose Monitoring System (MiniMed), which uses an implanted temporary sensor in the subcutaneous tissues, and the GlucoWatch G2 Biographer, an external device worn like a wristwatch that measures glucose in interstitial fluid extracted through the skin by electric current (referred to as reverse iontophoresis).

Devices subsequently approved include those for pediatric use and those with more advanced software, more frequent measurements of glucose levels, or more sophisticated alarm systems. Devices initially measured interstitial glucose every 5 to 10 minutes and stored data for download and retrospective evaluation by a clinician. With currently available devices, the intervals at which interstitial glucose is measured ranges from every 1 to 2 minutes to 5 minutes, and most provide measurements in real-time directly to patients. While CGM potentially eliminates or decreases the number of required daily fingersticks, it should be noted that, according to the FDA labeling, 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 (ie, for periods of 72 hours) or continuously (ie, on a long-term basis).

In addition to stand-alone continuous glucose monitors, several insulin pump systems have built-in CGM. This evidence review addresses CGM devices, not the insulin pump portion of these systems.

Summary

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 (eg, 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.

Type 1 Diabetes
For individuals who have 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, 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 2 RCTs pre-specified 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 compares 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 length of hospital stay all favoring CGM. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome

Clinical input obtained in 2008 strongly supported use of long-term CGM in patients with poorly controlled type 1 diabetes who are pregnant.

For individuals who have type 1 diabetes who receive short-term (intermittent) glucose monitoring, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. The evidence for intermittent short-term monitoring on glycemic control is mixed, and there was no definite improvement in HbA1c levels. 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 evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2008 supported short-term (intermittent) glucose monitoring in patients with poorly controlled type 1 diabetes.

Type 2 Diabetes
For individuals who have type 2 diabetes who receive long-term, real-time CGM, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Only the DIAMOND RCT (N=158) has used continuous, 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 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 quality of life measures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have type 2 diabetes who receive short-term, intermittent CGM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Systematic reviews of 3 to 4 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 small 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

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. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
1/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
7/2018	Clarified coding information.
4/2018	BCBSA National medical policy review. New medically necessary indications on long-term CGM described; background and summary clarified. Clarified coding information. Effective 4/1/2018.
1/2018	Clarified coding information.
11/2017	Clarified coding information.
7/2017	Local Coverage Determination (LCD): Glucose Monitors (L33822) added for Medicare Advantage members. Clarified coding information. Effective 7/1/2017.
10/2016	Clarified coding information.
7/2016	New references added from BCBSA National medical policy.
5/2015	BCBSA National medical policy review. Clarified coding information. Clarified continuous monitoring information. Statement on artificial pancreas system transferred to medical policy #720, Artificial Pancreas Device Systems. Effective 5/1/2015.
11/2014	New coverage for continuous glucose monitor with low glucose suspend described. Clarified coding information. Effective 11/1/2014.
5/2014	New references added from BCBSA National medical policy. Updated Coding section with ICD10 procedure and diagnosis codes.Effective 10/2015.
9/2013	BCBSA National medical policy review.New investigational indications described. Effective 9/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
5/2011	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
7/2010	BCBS Association National Policy Review. Coverage statement revised.
2/2010	Reviewed - Medical Policy Group - Psychiatry, Ophthalmology, and Endocrinology. No changes to policy statements.
6/2009	Medical Policy #107 effective 6/2/2009 describing covered and non-covered indications.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

1. Effect of intensive therapy on the microvascular complications of type 1 diabetes mellitus. *Jama.* May 15 2002;287(19):2563-2569. PMID 12020338
2. Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes-2018. *Diabetes Care.* Jan 2018;41(Suppl 1):S137-s143. PMID 29222384
3. 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. PMID 26254702
4. 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. PMID 25917335

5. Food and Drug Administration (FDA). Summary of Safety and Effectiveness (SSED): Dexcom G5 Mobile Continuous Glucose Monitoring System. 2016; https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120005S041b.pdf. Accessed February 26, 2018.
6. Blue Cross and Blue Shield Technology Evaluation Center (TEC). Use of intermittent or continuous interstitial fluid glucose monitoring in patients with diabetes mellitus. *TEC Assessments.* 2003;Volume 18:Tab 16.
7. Floyd B, Chandra P, Hall S, et al. Comparative analysis of the efficacy of continuous glucose monitoring and self-monitoring of blood glucose in type 1 diabetes mellitus. *J Diabetes Sci Technol.* Sep 2012;6(5):1094-1102. PMID 23063035
8. Gandhi GY, Kovalaske M, Kudva Y, et al. Efficacy of continuous glucose monitoring in improving glycemic control and reducing hypoglycemia: a systematic review and meta-analysis of randomized trials. *J Diabetes Sci Technol.* Jul 2011;5(4):952-965. PMID 21880239
9. Langendam M, Luijf YM, Hooft L, et al. Continuous glucose monitoring systems for type 1 diabetes mellitus. *Cochrane Database Syst Rev.* Jan 18 2012;1:CD008101. PMID 22258980
10. 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.* Jul 23 2013;5(1):39. PMID 23876067
11. Wojciechowski 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: systematic review and meta-analysis. *Pol Arch Med Wewn.* Oct 2011;121(10):333-343. PMID 22045094
12. 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. PMID 26207053
13. Benkhadra K, Alahdab F, Tamhane S, et al. Real-time continuous glucose monitoring in type 1 diabetes: a systematic review and individual patient data meta-analysis. *Clin Endocrinol (Oxf).* Mar 2017;86(3):354-360. PMID 27978595
14. van Beers CA, DeVries JH, Kleijer SJ, et al. Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycaemia (IN CONTROL): a randomised, open-label, crossover trial. *Lancet Diabetes Endocrinol.* Nov 2016;4(11):893-902. PMID 27641781
15. Gold AE, MacLeod KM, Frier BM. Frequency of severe hypoglycemia in patients with type I diabetes with impaired awareness of hypoglycemia. *Diabetes Care.* Jul 1994;17(7):697-703. PMID 7924780
16. Lind M, Polonsky W, Hirsch IB, et al. Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: The GOLD randomized clinical trial. *Jama.* Jan 24 2017;317(4):379-387. PMID 28118454
17. Beck RW, Riddlesworth T, Ruedy K, et al. Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: The DIAMOND randomized clinical trial. *Jama.* Jan 24 2017;317(4):371-378. PMID 28118453
18. Riddlesworth T, Price D, Cohen N, et al. Hypoglycemic event frequency and the effect of continuous glucose monitoring in adults with type 1 diabetes using multiple daily insulin injections. *Diabetes Ther.* Aug 2017;8(4):947-951. PMID 28616804
19. Polonsky WH, Hessler D, Ruedy KJ, et al. The impact of continuous glucose monitoring on markers of quality of life in adults with type 1 diabetes: further findings from the DIAMOND randomized clinical trial. *Diabetes Care.* Jun 2017;40(6):736-741. PMID 28389582
20. Feig DS, Donovan LE, Corcoy R, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. *Lancet.* Nov 25 2017;390(10110):2347-2359. PMID 28923465
21. Newman SP, Cooke D, Casbard A, et al. A randomised controlled trial to compare minimally invasive glucose monitoring devices with conventional monitoring in the management of insulin-treated diabetes mellitus (MITRE). *Health Technol Assess.* May 2009;13(28):iii-iv, ix-xi, 1-194. PMID 19476724
22. Voormolen DN, Devries JH, Evers IM, et al. The efficacy and effectiveness of continuous glucose monitoring during pregnancy: a systematic review. *Obstet Gynecol Surv.* Nov 2013;68(11):753-763. PMID 24193194
23. 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.* Jul 2013;36(7):1877-1883. PMID 23349548

24. Murphy HR, Rayman G, Lewis K, et al. Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomised clinical trial. *BMJ.* Sep 25 2008;337:a1680. PMID 18818254
25. Ehrhardt NM, Chellappa M, Walker MS, et al. The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. *J Diabetes Sci Technol.* May 2011;5(3):668-675. PMID 21722581
26. Cosson E, Hamo-Tchatchouang E, Dufaitre-Patouraux L, et al. Multicentre, randomised, controlled study of the impact of continuous sub-cutaneous glucose monitoring (GlucoDay) on glycaemic control in type 1 and type 2 diabetes patients. *Diabetes Metab.* Sep 2009;35(4):312-318. PMID 19560388
27. Allen NA, Fain JA, Braun B, et al. Continuous glucose monitoring counseling improves physical activity behaviors of individuals with type 2 diabetes: A randomized clinical trial. *Diabetes Res Clin Pract.* Jun 2008;80(3):371-379. PMID 18304674
28. Yoo HJ, An HG, Park SY, et al. Use of a real time continuous glucose monitoring system as a motivational device for poorly controlled type 2 diabetes. *Diabetes Res Clin Pract.* Oct 2008;82(1):73-79. PMID 18701183
29. Beck RW, Riddlesworth TD, Ruedy K, et al. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections: a randomized trial. *Ann Intern Med.* Sep 19 2017;167(6):365-374. PMID 28828487
30. 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. PMID 26647072
31. Vigersky RA, Fonda SJ, Chellappa M, et al. Short- and long-term effects of real-time continuous glucose monitoring in patients with type 2 diabetes. *Diabetes Care.* Jan 2012;35(1):32-38. PMID 22100963
32. Wei Q, Sun Z, Yang Y, et al. Effect of a CGMS and SMBG on maternal and neonatal outcomes in gestational diabetes mellitus: a randomized controlled trial. *Sci Rep.* Jan 27 2016;6:19920. PMID 26814139
33. Bailey TS, Grunberger G, Bode BW, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2016 outpatient glucose monitoring consensus statement. *Endocr Pract.* Feb 2016;22(2):231-261. PMID 26848630
34. National Institute for Health and Care Excellence (NICE). Type 1 diabetes in adults: diagnosis and management [NG17]. 2016; https://www.nice.org.uk/guidance/ng17?unlid=382286372016220232952. Accessed February 26, 2018.
35. American Diabetes Association. 6. Glycemic Targets: Standards of Medical Care in Diabetes-2018. *Diabetes Care.* Jan 2018;41(Suppl 1):S55-S64. PMID 29222377
36. Peters AL, Ahmann AJ, Battelino T, et al. Diabetes technology-continuous subcutaneous insulin infusion therapy and continuous glucose monitoring in adults: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* Nov 2016;101(11):3922-3937. PMID 27588440
37. Centers for Medicare & Medicare Services. Durable Medical Equipment, Prosthetics/Orthotics & Supplies Fee Schedule 2017; https://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposfeesched/index.html. Accessed February 26, 2018.