MASSACHUSETTS

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Medical Policy

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid and Artificial Pancreas Device Systems

Table of Contents

Policy Number: 107

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Related Policies

- Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid and Artificial Pancreas Device Systems Prior Authorization Request Form, #845
- Insulin Delivery Devices, #332
- Islet Transplantation, #324

Policy[1]

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

TYPE 1 DIABETES

Continuous glucose monitoring (CGM) of glucose levels in interstitial fluid as a technique of diabetic monitoring may be considered **MEDICALLY NECESSARY** when the following situations occur:

- Individuals with type 1 diabetes who have demonstrated an understanding of the technology, are motivated to use the device correctly and consistently, are expected to adhere to a comprehensive diabetes treatment plan supervised by a qualified provider, and are capable of using the device to recognize alerts and alarms; **OR**
- Individuals 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**
- Individuals 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.

Use of an **automated insulin delivery system (artificial pancreas device system) with a low-glucose suspend feature** may be considered **MEDICALLY NECESSARY** if Food and Drug Administration–approved, in individuals with type 1 diabetes who meet all of the following criteria:

- Age 6 and older, **AND**
- Individuals with recurrent, unexplained, severe, (generally blood glucose levels less than 50 mg/dl) hypoglycemia for whom hypoglycemia puts the patient or others at risk, **OR**

- Individuals who become pregnant whose diabetes is poorly controlled.

Use of an **automated insulin delivery system (artificial pancreas device system) designated as hybrid closed-loop insulin delivery system (with low glucose suspend and suspend before low features)** may be considered **MEDICALLY NECESSARY** if Food and Drug Administration–approved, in individuals with type 1 diabetes who meet all of the following criteria:

- Age 6 and older, **AND**
- Individuals with recurrent, unexplained, severe, (generally blood glucose levels less than 50 mg/dl) hypoglycemia for whom hypoglycemia puts the patient or others at risk, **OR**
- Individuals who become pregnant whose diabetes is poorly controlled.

All other uses of monitoring of glucose levels and automated insulin delivery systems in interstitial fluid as a technique of diabetic monitoring for type 1 diabetes are considered **INVESTIGATIONAL**.

TYPE 2 DIABETES

CGM monitoring (including implantable CGM devices) of glucose levels in interstitial fluid may be considered **MEDICALLY NECESSARY**:

- In individuals with type 2 diabetes who are willing and able to use the device, 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.

Significant hypoglycemia may include recurrent, unexplained, severe (generally blood glucose levels <50 mg/dL) hypoglycemia or impaired awareness of hypoglycemia that puts the patient or others at risk.

CGM monitoring (including implantable CGM devices) of glucose levels in interstitial fluid may be considered **MEDICALLY NECESSARY**:

- In individuals with type 2 diabetes who require multiple daily doses of insulin and whose diabetes is poorly controlled and are capable of using devices safely.

Poorly controlled type 2 diabetes includes the following clinical situations: unexplained hypoglycemic episodes, hypoglycemic unawareness, and persistent hyperglycemia and A1C levels above target.

Use of an **automated insulin delivery system (artificial pancreas device system) with a low-glucose suspend feature** may be considered **MEDICALLY NECESSARY** if Food and Drug Administration–approved, in individuals with type 2 diabetes who meet all of the following criteria:

- Age 6 and older, **AND**
- Meets criteria for external insulin pump (see medical policy #332 Insulin Delivery Devices), **AND**
- Meets above criteria for long-term CGM monitoring.

Use of an **automated insulin delivery system (artificial pancreas device system) designated as hybrid closed-loop insulin delivery system (with low glucose suspend and suspend before low features)** may be considered **MEDICALLY NECESSARY** if Food and Drug Administration–approved, in individuals with type 2 diabetes who meet all of the following criteria:

- Over age 6 **AND**
    - Meets criteria for external insulin pump (see medical policy #332 Insulin Delivery Devices), **AND**
    - Meets above criteria for long-term CGM monitoring **OR**
- Age 2 to 6 years **AND**
    - Clinical diagnosis of type 1 diabetes for 3 months or more
    - Used insulin pump therapy for more than 3 months
    - Glycated hemoglobin level <10.0%
    - Minimum daily insulin requirement (Total Daily Dose) of greater than or equal to 8 units.

All other uses of CGM monitoring of glucose levels and automated insulin delivery systems in interstitial fluid as a technique of diabetic monitoring for type 2 diabetes are considered **INVESTIGATIONAL**.

Automated insulin delivery systems (artificial pancreas device system) with a low-glucose suspend feature are considered **INVESTIGATIONAL** in individuals with type 2 diabetes.

Automated insulin delivery systems (artificial pancreas device system) designated as hybrid closed-loop insulin delivery systems (with low glucose suspend and suspend before low features) are considered **INVESTIGATIONAL** in individuals with type 2 diabetes.

GESTATIONAL DIABETES

CGM device monitoring of glucose levels in interstitial fluid in individuals with gestational diabetes is considered **INVESTIGATIONAL**.

Automated insulin delivery systems (artificial pancreas device system) with a low-glucose suspend feature and Automated insulin delivery systems (artificial pancreas device system) designated as hybrid closed-loop insulin delivery systems (with low glucose suspend and suspend before low features) are considered **INVESTIGATIONAL** in individuals with gestational diabetes.

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 required**. *
Commercial PPO	Prior authorization is **required**. *

Annual re-authorization requests:
Prior authorization is required on an annual basis. If the patient met prior authorization requirements on initial approval, continued approval will be granted so long as the requesting provider deems the device clinically appropriate.

*Prior Authorization Request Form: Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid and Artificial Pancreas Device Systems

This form must be completed and faxed to: Medical and Surgical: 1-888-282-0780; Medicare Advantage: 1-800-447-2994.

Click here for Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid and Artificial Pancreas Device Systems Prior Authorization Request Form, #845.

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 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:

The following HCPCS codes **require prior authorization for Commercial HMO/POS/PPO/EPO and Medicare Advantage HMO/PPO Blue**.

HCPCS Codes:

HCPCS codes:	Code Description
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM) system, includes all supplies and accessories, 1-month supply = 1 unit of service
S1036	Transmitter; external, for use with artificial pancreas device system

The following CPT and HCPCS codes **do not require prior authorization**.

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
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training

HCPCS Codes:

HCPCS codes	Code Description
A4238	Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit=1-day supply
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
E0784	External ambulatory infusion pump, insulin
E2102	Adjunctive continuous glucose monitor or receiver
G0308	Creation of subcutaneous pocket with insertion of 180-day implantable interstitial glucose sensor, including system activation and patient training
K0554	Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system

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, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes:

HCPCS codes	Code Description
S1034	Artificial pancreas device system (eg, low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S1035	Sensor; invasive (eg, subcutaneous), disposable, for use with **artificial pancreas** device system, 1 unit = 1-day supply
S1037	Receiver (monitor); external, for use with **artificial pancreas** device system

The following ICD Diagnosis Codes are considered medically necessary when submitted with the HCPCS codes above if medical necessity criteria 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
E10.36	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

Description

ARTIFICIAL PANCREAS DEVICE SYSTEMS

Diabetes and Glycemic Control

Tight glucose control in patients with diabetes has been associated with improved health outcomes. The American Diabetes Association has recommended a glycated hemoglobin level below 7% for most patients. However, hypoglycemia may place a limit on the ability to achieve tighter glycemic control. Hypoglycemic events in adults range from mild to severe based on a number of factors including the glucose nadir, the presence of symptoms, and whether the episode can be self-treated or requires help for recovery. Children and adolescents represent a population of individuals with type 1 diabetes who have challenges in controlling hyperglycemia and avoiding hypoglycemia. Hypoglycemia is the most common acute complication of type 1 diabetes.

Table 1 is a summary of selected clinical outcomes in type 1 diabetes clinical management and research.

Table 1. Outcome Measures for Type 1 Diabetes

Measure	Definition	Guideline type	Organization	Date
Hypoglycemia		Stakeholder survey, expert opinion with evidence review	Type 1 Diabetes Outcome Program[a1]	2017
Level 1 Level 2 Level 3	Glucose <70mg/dl but ≥ 54 mg/dl Glucose <54 mg/dl Event characterized by altered mental/physical status requiring assistance			
Hypoglycemia	Same as Type 1 Diabetes Outcome Program[a]	Professional Practice Committee with systematic literature review	ADA[2]	2019
Hypoglycemia Clinical alert for evaluation and/or treatment Clinically important or serious Severe hypoglycemia	 Glucose <70mg/dl Glucose <54 mg/dl Severe cognitive impairment requiring external assistance by another person to take corrective action	Clinical Practice Consensus	ISPAD[3]	2018
Hyperglycemia Level 1 Level 2	 Glucose >180 mg/dL and ≤250 mg/dL Glucose >250 mg/dL		Type 1 Diabetes Outcome Program[a1]	2017

Time in Range[b]	Percentage of glucose readings in the range of 70–180 mg/dL per unit of time		Type 1 Diabetes Outcome Program[a]	2017
Diabetic ketoacidosis (DKA)	Elevated serum or urine ketones > ULN Serum bicarbonate <15 mEq/L Blood pH <7.3		Type 1 Diabetes Outcome Program[a3]	2017

ADA: American Diabetes Association, ISPAD: International Society for Pediatric and Adolescent Diabetes; ULN: upper limit of normal.
[a]Steering Committee: representatives from American Association of Clinical Endocrinologists (AACE), American Association Diabetes Educators, the American Diabetes Association (ADA), the Endocrine Society, JDRF International. The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, type 1 diabetes Exchange.

[b]Time in range: has also been adopted by researchers evaluating the precision and effectiveness of emerging glucose monitoring and automated insulin delivery technologies.

Type 1 diabetes is caused by the destruction of the pancreatic beta cells which produce insulin, and the necessary mainstay of treatment is insulin injections. Multiple studies have shown that intensive insulin treatment, aimed at tightly controlling blood glucose, reduces the risk of long-term complications of diabetes, such as retinopathy and renal disease. Optimal glycemic control, as assessed by glycated hemoglobin, and avoidance of hyper- and hypoglycemic excursions have been shown to prevent diabetes-related complications. Currently, insulin treatment strategies include either multiple daily insulin injections or continuous subcutaneous insulin infusion with an insulin pump.

Restoration of pancreatic function is potentially available through islet cell or allogeneic pancreas transplantation. Evidence reviews of these interventions are in policy #324 and policy #328 respectively.

CONTINUOUS OR INTERMITTENT MONITORING OF GLUCOSE IN INTERSTITIAL FLUID

Blood Glucose Control

The advent of blood glucose monitors for use by individuals in the home revolutionized the management of diabetes. Using fingersticks, individuals can monitor their blood glucose levels both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. Tight glucose control, defined as a strategy involving frequent glucose checks and a target hemoglobin A_{1c} (HbA_{1c}) level in the range of 7%, is now considered the standard of care for diabetic individuals. Randomized controlled trials assessing tight control have demonstrated benefits for individuals 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} level 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 individuals 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 individuals with type 1 diabetes. While individuals with insulin-treated type 2 diabetes may also

experience severe hypoglycemic episodes, there is a lower relative likelihood of severe hypoglycemia compared with individuals 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
Measurements of glucose in the interstitial fluid have been developed as a technique to measure glucose values automatically throughout the day, producing data that show the trends in glucose levels. Although devices measure glucose in the interstitial fluid on a periodic rather than a continuous basis, this type of monitoring is referred to as continuous glucose monitoring (CGM).

Currently, CGM devices are of 2 designs; real-time CGM (rtCGM) provides real-time data on glucose level, glucose trends, direction, and rate of change and, intermittently 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 individuals. While CGM potentially eliminates or decreases the number of required daily fingersticks, it should be noted that, according to the U.S. Food and Drug Administration (FDA) labeling, some marketed monitors are not intended as an alternative to traditional self-monitoring of blood glucose levels but rather as adjuncts to monitoring, supplying additional information on glucose trends not available from self-monitoring. 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).

Summary

ARTIFICIAL PANCREAS

For individuals who have type 1 diabetes who receive an artificial pancreas device system with a low-glucose suspend feature, the evidence includes 3 randomized controlled trials (RCTs) conducted in home settings. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. Primary eligibility criteria of the key RCT, the Automation to Simulate Pancreatic Insulin Response (ASPIRE) trial, were ages 16-to-70 years old, type 1 diabetes, glycated hemoglobin levels between 5.8% and 10.0%, and at least 2 nocturnal hypoglycemic events (≤65 mg/dL) lasting more than 20 minutes during a 2-week run-in phase. Both trials required at least 6 months of insulin pump use. Both RCTs reported significantly less hypoglycemia in the treatment group than in the control group. In both trials, primary outcomes were favorable for the group using an artificial pancreas system; however, findings from 1 trial were limited by nonstandard reporting of hypoglycemic episodes, and findings from the other trial were no longer statistically significant when 2 outliers (children) were excluded from analysis. The RCT limited to adults showed an improvement in the primary outcome (area under the curve for nocturnal hypoglycemic events). The area under the curve is not used for assessment in clinical practice but the current technology does allow user and provider review of similar trend data with continuous glucose monitoring. Results from the ASPIRE study suggested that there were increased risks of hyperglycemia and potential diabetic ketoacidosis in subjects using the threshold suspend feature. This finding may be related to whether or not actions are taken by the user to assess glycemic status, etiology of the low glucose (activity, diet or medication), and to resume insulin infusion. Both retrospective and prospective observational studies have reported reductions in rates and severity of hypoglycemic episodes in automated insulin delivery system users. The evidence suggests that the magnitude of reduction for hypoglycemic events in the type 1 diabetes population is likely to be clinically significant. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have type 1 diabetes who receive an artificial pancreas device system with a hybrid closed-loop insulin delivery system, the evidence includes multicenter pivotal trials using devices cleared by the U.S. Food and Drug Administration, supplemental data and analysis for expanded indications, and more recent studies focused on children and adolescents. Three crossover RCTs using a similar first-generation device approved outside the United States have been reported. Relevant outcomes are symptoms, change in disease status, morbid events, resource utilization, and treatment-related morbidity. Of the 3 crossover RCTs assessing a related device conducted outside the United States, 2 found significantly better outcomes (ie, time spent in nocturnal hypoglycemia and time spent in preferred glycemic range) with the device than with standard care and the other had mixed findings (significant difference in time spent in nocturnal hypoglycemia and no significant difference in time spent in preferred glycemic range).. Additional evidence from device performance studies and clinical studies all demonstrate reductions in time spent in various levels of hypoglycemia, improved time in range (70-180 mg/ dL), rare diabetic ketoacidosis, and few device-related adverse events. The evidence suggests that the magnitude of reduction for hypoglycemic events in the type 1 diabetes population is likely to be clinically significant. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

CONTINUOUS OR INTERMITTENT MONITORING OF GLUCOSE IN INTERSTITIAL FLUID

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

Type 1 Diabetes

For individuals with type 1 diabetes who are willing and able to use the device, and have adequate medical supervision, who receive long-term (continuous) glucose monitoring (CGM), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life (QOL), and treatment-related morbidity. Systematic reviews have generally found that at least in the short-term, long-term CGM resulted in significantly improved glycemic control for adults and children with type 1 diabetes, particularly highly compliant individuals. A 2017 individual patient data analysis, pooling data from 11 RCTs, found that reductions in hemoglobin A_{1c} (HbA_{1c}) levels were significantly greater with real-time CGM than with a control intervention. Two RCTs in individuals 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 HbA_{1c} 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 HbA_{1c}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 that the long-term use of CGM provides an improvement in net health outcomes for persons with type 1 diabetes mellitus.

For individuals with type 1 diabetes who have poor control of diabetes despite the use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation who receive short-term glucose monitoring, the evidence includes RCTs and systematic reviews. 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 consistent in HbA1c levels. Some trials have reported improvements in glucose control for the intermittent monitoring group but limitations in this body of evidence preclude conclusions. The definitions of control with short-term CGM use, duration of use and the specific monitoring protocols varied. In some studies, short-term monitoring was part of a larger strategy aimed at optimizing glucose control, and the impact of monitoring cannot be separated from the impact of other interventions. Studies have not shown

an advantage for intermittent glucose monitoring in reducing severe hypoglycemia events, but the number of events reported is generally small and effect estimates imprecise. The limited duration of use may preclude an assessment of any therapeutic effect. Two RCTs of short-term CGM use for monitoring in pregnancy included women with both type 1 and 2 diabetes, with most having type 1 diabetes. One trial reported a difference in HbA1c levels at 36 weeks; the proportion of infants that were large for gestational age (>90th percentile) favored CGM while the second trial did not. The differences in the proportions of infants born via cesarean section, gestational age at delivery, and infants with severe hypoglycemia were not statistically significant in either study. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice when used in specific situations such as poor control of diabetes despite the use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Type 2 Diabetes

For individuals with type 2 diabetes who receive long-term CGM, the evidence includes RCTs. The relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. Most RCTs of CGM in individuals 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 individuals were highly compliant during a run-in phase. The difference in change in HbA1clevels from baseline to 24 weeks was -0.3% favoring CGM. The difference in the proportion of individuals with a relative reduction in HbA1clevel by 10% or more was 22% favoring CGM. There were no differences in the proportions of individuals with an HbA1c level of less than 7% at week 24. There were no events of severe hypoglycemia or diabetic ketoacidosis in either group. The treatment groups did not differ in any of the QOL measures. RCTs using flash glucose-sensing technology as a replacement for self-monitoring of blood glucose for the management of insulin-dependent treated type 2diabetes found no difference in HbA1c change at 6 and 12 months between groups. However, time in severe hypoglycemia (<45mg/dL) was reduced for intervention participants. Two trials of CGM have enrolled pregnant women with type 2 diabetes, but the total number of women with type 2 diabetes included in both trials is only 58. One study reported a difference in HbA1c levels at 36 weeks, and the proportion of infants that were large for gestational age (>90th percentile) favored CGM while the second study did not. Neither trial reported analyses stratified by diabetes type. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input for long-term (continuous) CGM in individuals with type 2 diabetes who do not require insulin did not provide strong support of a safety benefit and clinically meaningful improvement in net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

and are consistent with generally accepted medical practice: selected individuals with type 2 diabetes who are (1) willing and able to use the CGM device and have adequate medical supervision and (2) experiencing significant hypoglycemia on multiple daily doses of insulin or an insulin pump in the setting of insulin deficiency. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with type 2 diabetes who require multiple daily doses of insulin and have poor control of diabetes despite the use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation who receive short-term CGM monitoring, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. Systematic reviews of three to four RCTs have found statistically significant benefits from CGM regarding glycemic control. However, the degree of HbA1c reduction and the difference in HbA1c reductions between groups may not be clinically significant. Also, the limited number of RCTs and variability among interventions make it difficult to identify an optimal approach to CGM or a subgroup of type 2 diabetes individuals who might benefit. Moreover, studies of CGM in individuals with type 2 diabetes have generally not addressed the clinically important issues of severe hypoglycemia and diabetic complications. Very few pregnant women with type 2 diabetes have been included in RCTs. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input for use of short-term CGM in individuals with type 2 diabetes who require multiple daily doses of insulin supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice when used in specific situations such as poor control of diabetes despite use of best practices or when basal insulin levels need to be determined prior to insulin pump initiation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Gestational Diabetes
For individuals who are pregnant with gestational diabetes who receive long-term CGM or short-term (intermittent) glucose monitoring, the evidence includes an RCT. Relevant outcome are symptoms, morbid events, QOL, and treatment-related morbidity. In the RCT, the type of glucose monitoring was unclear. Trial reporting was incomplete; however, there was no difference between the groups for most reported outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

Policy History

Date	Action
10/2022	Policy clarified to include medically necessary policy statements for individuals with type 2 diabetes who require multiple daily doses of insulin and whose diabetes is poorly controlled.
9/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
7/2022	Clarified coding information.
6/2022	Prior authorization information clarified for PPO plans. Effective 6/1/2022.
4/2022	Clarified coding information.
9/2021	Annual policy review. Artificial Pancreas: Medically necessary policy statement added for use of an FDA-approved hybrid closed loop system in children ages 2 to 6 years. Effective 9/1/2021.
2/2021	Annual policy review. Description, summary, and references updated. Policy statement(s) unchanged.

1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
8/2020	Annual policy review. Artificial Pancreas: Policy statements clarified to lower age cutoff to 6 years.
6/2020	Annual policy review. Artificial Pancreas: Description, summary and references updated. Policy statements unchanged. Policy statements unchanged.
5/2020	Clarified prior authorization information regarding continuation use for CGM devices. Removed best practices statement. Short term and long term CGM criteria combined. 5/1/2020.
1/2020	Annual policy review. **Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid.** Effective 1/1/2020. o Medically necessary indications added for use of short-term or long-term CGM in specific T2DM individuals with criteria. o Prior authorization is required. **Artificial Pancreas.** Effective 1/1/2020. o Age criterion changed in the first medically necessary statement. o Medically necessary statement added on FDA-approved automated insulin delivery system (artificial pancreas device system) designated as hybrid closed loop insulin delivery system in individuals with type 1 diabetes who meet specified criteria. o New investigational statement added on use of an automated insulin delivery system (artificial pancreas device system) for individuals who have not met specified criteria. o Prior authorization is required Medically necessary criteria for artificial pancreas were transferred to this policy from policy #720.
1/2019	Annual policy review. Description, summary and references updated. Policy statements unchanged.
7/2018	Clarified coding information.
4/2018	Annual 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 Annual policy review.
5/2015	Annual 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 monitors with low glucose suspend described. Clarified coding information. Effective 11/1/2014.
5/2014	New references added from Annual policy review. Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
9/2013	Annual 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	Annual 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

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Artificial Pancreas

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Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid

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Endnotes

[1] Based on expert opinion