



## MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an independent  
Licensee of the Blue Cross and Blue Shield Association

### Medical Policy

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

### Table of Contents

- [Policy: Commercial](#)
- [Description](#)
- [Information Pertaining to All Policies](#)
- [Authorization Information](#)
- [Policy History](#)
- [Endnotes](#)
- [Coding Information](#)
- [References](#)

### Policy Number: 107

BCBSA Reference Number: 1.01.20; 1.01.30 (For Plan internal use only)

### 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<sup>1</sup>

#### 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 is considered **MEDICALLY NECESSARY** for individuals with type 1 diabetes.

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 age 6 and older.

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 6 and older.

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 the following scenarios:**

- In individuals with type 2 diabetes who experience significant hypoglycemia\* and are on multiple daily doses (4 or more) of insulin or an insulin pump in the setting of insulin deficiency, **OR**
- In individuals with type 2 diabetes whose diabetes is poorly controlled\*\* and require multiple daily doses of insulin (4 or more).

\***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.

\*\***Poorly controlled type 2 diabetes** includes the following clinical situations: unexplained hypoglycemic episodes, hypoglycemic unawareness, and persistent hyperglycemia and A1C levels above target (7% for adults and children).

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 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 Meets above criteria for CGM monitoring.
  - 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 **MEDICALLY NECESSARY**.

**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 for A4238, A4239 and A9277 for type 2 diabetes
Commercial PPO	Prior authorization is required for A4238, A4239 and A9277 for type 2 diabetes

### 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 HCPCS 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
A4238	Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service

A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
-------	---

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

Level 2	Glucose >250 mg/dL			
Time in Range <sup>b</sup>	Percentage of glucose readings in the range of 70–180 mg/dL per unit of time		Type 1 Diabetes Outcome Program <sup>a</sup>	2017
Diabetic ketoacidosis (DKA)	Elevated serum or urine ketones > ULN Serum bicarbonate <15 mEq/L Blood pH <7.3		Type 1 Diabetes Outcome Program <sup>a3</sup>	2017

ADA: American Diabetes Association, ISPAD: International Society for Pediatric and Adolescent Diabetes; ULN: upper limit of normal.

<sup>a</sup>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.

<sup>b</sup>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<sub>1c</sub> (HbA<sub>1c</sub>) 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<sub>1c</sub> 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.<sup>1</sup>

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

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.<sup>3,4</sup> 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<sub>1c</sub> 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 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 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 ( $\leq 65$  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<sub>1c</sub> (HbA<sub>1c</sub>) 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<sub>1c</sub> 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<sub>1c</sub> 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 HbA<sub>1c</sub> 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 HbA1c levels from baseline to 24 weeks was -0.3% favoring CGM. The difference in the proportion of individuals with a relative reduction in HbA1c level 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 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 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 and a prospective. In one trial, HbA1c levels showed clinically significant reductions from 32-36 weeks gestation compared with women randomized to standard antenatal care. Relevant outcome are symptoms, improvement in maternal and neonatal outcomes in individuals with type 1 or 2 diabetes, QOL, and treatment-related morbidity. Trial reporting demonstrated CGM as a more preferable alternative than standards of care and diagnosis by way of oral glucose testing. The evidence is insufficient to determine the effects of the technology on health outcomes.

<b>Date</b>	<b>Action</b>
12/2023	Prior authorization for A4238, A4239 and A9277 removed for type 1 diabetes. Medically necessary statement added for coverage of Continuous glucose monitoring for gestational diabetes. Policy criteria reformatted and clarified. 12/2023.
3/2023	Clarified coding information.
1/2023	Clarified coding information. Removed K0553 as it was deleted and replaced with A4239. Effective 1/1/2023.
12/2022	Clarified coding information.
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. <b>Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid.</b> Effective 1/1/2020. <ul style="list-style-type: none"> <li>o Medically necessary indications added for use of short-term or long-term CGM in specific T2DM individuals with criteria.</li> <li>o Prior authorization is required.</li> </ul> <b>Artificial Pancreas.</b> Effective 1/1/2020. <ul style="list-style-type: none"> <li>o Age criterion changed in the first medically necessary statement.</li> <li>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.</li> <li>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.</li> <li>o Prior authorization is required</li> </ul> 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](#)

## References

### Artificial Pancreas

1. American Diabetes Association. 6. Glycemic Targets. Diabetes Care. Jan 2017; 40(Suppl 1): S48-S56. PMID 27979893
2. American Diabetes Association. 6. Glycemic Targets: Standards of Medical Care in Diabetes-2019. Diabetes Care. Jan 2019; 42(Suppl 1): S61-S70. PMID 30559232
3. Abraham MB, Jones TW, Naranjo D, et al. ISPAD Clinical Practice Consensus Guidelines 2018: Assessment and management of hypoglycemia in children and adolescents with diabetes. Pediatr Diabetes. Oct 2018; 19 Suppl 27: 178-192. PMID 29869358
4. Agiostratidou G, Anhalt H, Ball D, et al. Standardizing Clinically Meaningful Outcome Measures Beyond HbA 1c for Type 1 Diabetes: A Consensus Report of the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange. Diabetes Care. Dec 2017; 40(12): 1622-1630. PMID 29162582
5. Food and Drug Administration (FDA). Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems [draft]. 2012; <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259305.pdf>. Accessed July 3, 2022
6. Food & Drug Administration. MiniMed 770G System. Summary of Safety and Effectiveness Data. 2020. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf16/P160017S076B.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160017S076B.pdf). July 3, 2022.
7. Forlenza GP, Li Z, Buckingham BA, et al. Predictive Low-Glucose Suspend Reduces Hypoglycemia in Adults, Adolescents, and Children With Type 1 Diabetes in an At-Home Randomized Crossover Study: Results of the PROLOG Trial. Diabetes Care. Oct 2018; 41(10): 2155-2161. PMID 30089663
8. Food and Drug Administration (FDA). Premarket Approval (PMA): MiniMed 530G System. 2013; <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120010>. Accessed July 3, 2022
9. Food and Drug Administration (FDA). Premarket Approval (PMA): MiniMed 630G System with Smartguard. 2016; <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=320606>. Accessed July 3, 2022
10. Food and Drug Administration (FDA). Premarket Approval (PMA): MiniMed 670G System. 2016; <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160017>. Accessed July 3, 2022.
11. Food and Drug Administration (FDA). t:slim X2 Insulin Pump with Basal-IQ Technology Premarket Approval (2018). [https://www.accessdata.fda.gov/cdrh\\_docs/pdf18/P180008A.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180008A.pdf). Accessed July 3, 2022.
12. Faulds ER, Zappe J, Dungan KM. REAL-WORLD IMPLICATIONS OF HYBRID CLOSE LOOP (HCL) INSULIN DELIVERY SYSTEM. Endocr Pract. May 2019; 25(5): 477-484. PMID 30865545

13. Blue Cross and Blue Shield Technology Evaluation Center (TEC). Artificial Pancreas Device Systems. TEC Assessments. 2013;Volume 28:Tab 14
14. Bergenstal RM, Garg S, Weinzimer SA, et al. Safety of a Hybrid Closed-Loop Insulin Delivery System in Patients With Type 1 Diabetes. *JAMA*. Oct 04 2016; 316(13): 1407-1408. PMID 27629148
15. Ly TT, Nicholas JA, Retterath A, et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycemia in patients with type 1 diabetes: a randomized clinical trial. *JAMA*. Sep 25 2013; 310(12): 1240-7. PMID 24065010
16. Forlenza GP, Ekhlaspour L, Breton M, et al. Successful At-Home Use of the Tandem Control-IQ Artificial Pancreas System in Young Children During a Randomized Controlled Trial. *Diabetes Technol Ther*. Apr 2019; 21(4): 159-169. PMID 30888835
17. American Diabetes Association. 7. Diabetes Technology: Standards of Medical Care in Diabetes-2021. *Diabetes Care*. Jan 2021; 44(Suppl 1): S85-S99. PMID 33298418
18. Garg SK, Weinzimer SA, Tamborlane WV, et al. Glucose Outcomes with the In-Home Use of a Hybrid Closed-Loop Insulin Delivery System in Adolescents and Adults with Type 1 Diabetes. *Diabetes Technol Ther*. Mar 2017; 19(3): 155-163. PMID 28134564
19. Beato-Vibora PI, Gallego-Gamero F, Lazaro-Martin L, et al. Prospective Analysis of the Impact of Commercialized Hybrid Closed-Loop System on Glycemic Control, Glycemic Variability, and Patient-Related Outcomes in Children and Adults: A Focus on Superiority Over Predictive Low-Glucose Suspend Technology. *Diabetes Technol Ther*. Dec 2020; 22(12): 912-919. PMID 31855446
20. Garg S, Brazg RL, Bailey TS, et al. Reduction in duration of hypoglycemia by automatic suspension of insulin delivery: the in-clinic ASPIRE study. *Diabetes Technol Ther*. Mar 2012; 14(3): 205-9. PMID 22316089
21. Forlenza GP, Deshpande S, Ly TT, et al. Application of Zone Model Predictive Control Artificial Pancreas During Extended Use of Infusion Set and Sensor: A Randomized Crossover-Controlled Home-Use Trial. *Diabetes Care*. Aug 2017; 40(8): 1096-1102. PMID 28584075
22. Tauschmann M, Thabit H, Bally L, et al. Closed-loop insulin delivery in suboptimally controlled type 1 diabetes: a multicentre, 12-week randomised trial. *Lancet*. Oct 13 2018; 392(10155): 1321-1329. PMID 30292578
23. Abraham MB, Nicholas JA, Smith GJ, et al. Reduction in Hypoglycemia With the Predictive Low-Glucose Management System: A Long-term Randomized Controlled Trial in Adolescents With Type 1 Diabetes. *Diabetes Care*. Feb 2018; 41(2): 303-310. PMID 29191844
24. Wood MA, Shulman DI, Forlenza GP, et al. In-Clinic Evaluation of the MiniMed 670G System "Suspend Before Low" Feature in Children with Type 1 Diabetes. *Diabetes Technol Ther*. Nov 2018; 20(11): 731-737. PMID 30299976
25. Breton MD, Kanapka LG, Beck RW, et al. A Randomized Trial of Closed-Loop Control in Children with Type 1 Diabetes. *N Engl J Med*. Aug 27 2020; 383(9): 836-845. PMID 32846062
26. Kanapka LG, Wadwa RP, Breton MD, et al. Extended Use of the Control-IQ Closed-Loop Control System in Children With Type 1 Diabetes. *Diabetes Care*. Feb 2021; 44(2): 473-478. PMID 33355258
27. Cobry EC, Kanapka LG, Cengiz E, et al. Health-Related Quality of Life and Treatment Satisfaction in Parents and Children with Type 1 Diabetes Using Closed-Loop Control. *Diabetes Technol Ther*. Jun 2021; 23(6): 401-409. PMID 33404325
28. Forlenza GP, Pinhas-Hamiel O, Liljenquist DR, et al. Safety Evaluation of the MiniMed 670G System in Children 7-13 Years of Age with Type 1 Diabetes. *Diabetes Technol Ther*. Jan 2019; 21(1): 11-19. PMID 30585770
29. Messer LH, Forlenza GP, Sherr JL, et al. Optimizing Hybrid Closed-Loop Therapy in Adolescents and Emerging Adults Using the MiniMed 670G System. *Diabetes Care*. Apr 2018; 41(4): 789-796. PMID 29444895
30. Brown SA, Forlenza GP, Bode BW, et al. Multicenter Trial of a Tubeless, On-Body Automated Insulin Delivery System With Customizable Glycemic Targets in Pediatric and Adult Participants With Type 1 Diabetes. *Diabetes Care*. Jul 2021; 44(7): 1630-1640. PMID 34099518
31. Gomez AM, Marin Carrillo LF, Munoz Velandia OM, et al. Long-Term Efficacy and Safety of Sensor Augmented Insulin Pump Therapy with Low-Glucose Suspend Feature in Patients with Type 1 Diabetes. *Diabetes Technol Ther*. Feb 2017; 19(2): 109-114. PMID 28001445
32. Brown SA, Kovatchev BP, Raghinaru D, et al. Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes. *N Engl J Med*. Oct 31 2019; 381(18): 1707-1717. PMID 31618560

### **Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid**

1. Writing Team for the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Research Group. Effect of intensive therapy on the microvascular complications of type 1 diabetes mellitus. *JAMA*. May 15 2002; 287(19): 2563-9. PMID 12020338
2. American Diabetes Association. 13. 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): 428-33. PMID 26254702
4. Gehlert 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*. Apr 27 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](https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120005S041b.pdf). Accessed November 1, 2020.
6. 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 01 2012; 6(5): 1094-102. PMID 23063035
7. Scott EM, Bilous RW, Kautzky-Willer A. Accuracy, User Acceptability, and Safety Evaluation for the FreeStyle Libre Flash Glucose Monitoring System When Used by Pregnant Women with Diabetes. *Diabetes Technol Ther*. 2018 Mar;20(3):180-188. doi: 10.1089/dia.2017.0386. Epub 2018 Feb 22. PMID: 29470094; PMCID: PMC5867506.
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 01 2011; 5(4): 952-65. PMID 21880239
9. Langendam M, Luijck 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*. 2013; 5: 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): 333-43. 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): 1592-609. 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. 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
15. 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
16. 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
17. 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
18. Laffel LM, Kanapka LG, Beck RW, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adolescents and Young Adults With Type 1 Diabetes: A Randomized Clinical Trial. *JAMA*. Jun 16 2020; 323(23): 2388-2396. PMID 32543683

19. Pratley RE, Kanapka LG, Rickels MR, et al. Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults With Type 1 Diabetes: A Randomized Clinical Trial. *JAMA*. Jun 16 2020; 323(23): 2397-2406. PMID 32543682
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. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data: Eversense Continuous Glucose Monitoring System (2019). [https://www.accessdata.fda.gov/cdrh\\_docs/pdf16/P160048B.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048B.pdf). Accessed October November 2, 2020.
22. Kropff J, Choudhary P, Neupane S, et al. Accuracy and Longevity of an Implantable Continuous Glucose Sensor in the PRECISE Study: A 180-Day, Prospective, Multicenter, Pivotal Trial. *Diabetes Care*. Jan 2017; 40(1): 63-68. PMID 27815290
23. Christiansen MP, Klaff LJ, Brazg R, et al. A Prospective Multicenter Evaluation of the Accuracy of a Novel Implanted Continuous Glucose Sensor: PRECISE II. *Diabetes Technol Ther*. Mar 2018; 20(3): 197-206. PMID 29381090
24. Sanchez P, Ghosh-Dastidar S, Tweden KS, et al. Real-World Data from the First U.S. Commercial Users of an Implantable Continuous Glucose Sensor. *Diabetes Technol Ther*. Dec 2019; 21(12): 677-681. PMID 31385732
25. Deiss D, Irace C, Carlson G, et al. Real-World Safety of an Implantable Continuous Glucose Sensor Over Multiple Cycles of Use: A Post-Market Registry Study. *Diabetes Technol Ther*. Jan 2020; 22(1): 48-52. PMID 31418587
26. Tweden KS, Deiss D, Rastogi R, et al. Longitudinal Analysis of Real-World Performance of an Implantable Continuous Glucose Sensor over Multiple Sensor Insertion and Removal Cycles. *Diabetes Technol Ther*. May 2020; 22(5): 422-427. PMID 31697182
27. 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
28. 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): 753-63. PMID 24193194
29. 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): 1877-83. PMID 23349548
30. 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
31. Ida S, Kaneko R, Murata K. Utility of Real-Time and Retrospective Continuous Glucose Monitoring in Patients with Type 2 Diabetes Mellitus: A Meta-Analysis of Randomized Controlled Trials. *J Diabetes Res*. 2019; 2019: 4684815. PMID 30775385
32. 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 01 2011; 5(3): 668-75. PMID 21722581
33. 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): 312-8. PMID 19560388
34. 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): 371-9. PMID 18304674
35. 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): 73-9. PMID 18701183
36. Ajjan RA, Abougila K, Bellary S, et al. Sensor and software use for the glycaemic management of insulin-treated type 1 and type 2 diabetes patients. *Diab Vasc Dis Res*. May 2016; 13(3): 211-9. PMID 27000105

37. Haak T, Hanaire H, Ajjan R, et al. Flash Glucose-Sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-Treated Type 2 Diabetes: a Multicenter, Open-Label Randomized Controlled Trial. *Diabetes Ther.* Feb 2017; 8(1): 55-73. PMID 28000140
38. 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
39. 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): 32-8. PMID 22100963
40. Haak T, Hanaire H, Ajjan R, et al. Use of Flash Glucose-Sensing Technology for 12 months as a Replacement for Blood Glucose Monitoring in Insulin-treated Type 2 Diabetes. *Diabetes Ther.* Jun 2017; 8(3): 573-586. PMID 28401454
41. Furler J, O'Neal D, Speight J, et al. Use of professional-mode flash glucose monitoring, at 3-month intervals, in adults with type 2 diabetes in general practice (GP-OSMOTIC): a pragmatic, open-label, 12-month, randomised controlled trial. *Lancet Diabetes Endocrinol.* Jan 2020; 8(1): 17-26. PMID 31862147
42. 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
43. American Association of Clinical Endocrinology and American College of Endocrinology. Comprehensive Type 2 Diabetes Management Algorithm. 2020. <https://pro.aace.com/disease-state-resources/diabetes/clinical-practice-guidelines-treatment-algorithms/comprehensive>. Accessed November 2, 2020.
44. 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 November 2, 2020.
45. American Diabetes Association. Standards of Medical Care in Diabetes. 2020. <https://professional.diabetes.org/content-page/practice-guidelines-resources>. Accessed November 2, 2020.
46. 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
47. Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. *Diabetes Care.* Aug 2019; 42(8): 1593-1603. PMID 31177185
48. 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 November 2, 2020.
49. Centers for Medicare & Medicare Services. Durable Medical Equipment (DME) Center; <https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center>. Accessed November 3, 2020.

## Endnotes

---

<sup>1</sup> Based on expert opinion