MEDICAL POLICY

Excellus

SUBJECT: CONTINUOUS GLUCOSE MONITORING SYSTEMS/ EXTERNAL INSULIN PUMP THERAPY FOR DIABETES	EFFECTIVE DATE: 08/17/17, 10/18/18
POLICY NUMBER: 1.01.30 CATEGORY: Technology Assessment	PAGE: 1 OF: 13

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

POLICY STATEMENT:

A. **INITIAL Requests for insulin pump therapy (HCPCS: E0784)**

I. Based upon our criteria and review of the peer-reviewed literature, basic external insulin pumps are **medically appropriate** for individuals with diabetes requiring insulin who are on a program of multiple daily injections of insulin (at least 3 per day), with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and performs self-testing of glucose an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, has completed a comprehensive diabetes education program, and whose diabetes is poorly controlled despite best practices (Please refer to Guideline II).

II. Based upon our criteria and review of the peer-reviewed literature, basic external insulin pumps are **medically appropriate** for women with gestational diabetes who require insulin injections greater than or equal to 3 times per day; and cannot be controlled by intermittent dosing.

III. Based upon our criteria and review of the peer-reviewed literature, nonprogrammable disposable insulin delivery systems (e.g., V-Go™ disposable insulin delivery device) are considered investigational.

Examples of insulin pumps include *but are not limited to*:

Brand Name	Manufacturer
630G with SmartGuard™ technology	Medtronic Minimed,Inc
Omnipod®	Insulet Corporation
T-slimX2™	Tandem Diabetes Care, Inc

REPLACEMENT of an insulin pump:

I. Replacement of an insulin pump is considered **medically necessary** when:
1. The external insulin pump has been previously approved by the Health Plan or the external insulin pump is in use prior to the user enrolling in the Health Plan; and
2. the pump has exceeded the warranty time period; AND
3. the pump is malfunctioning.

II. Replacement due to slight damage (e.g., scratched screen) to the pump without causing the pump to malfunction or replacement desired due to advanced technology is considered **not medically necessary**.

B. **INITIAL Requests for continuous glucose monitoring (HCPCS: A9276, A9277, A9278, K0553, K0554)**

I. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of **continuous** use of Continuous Glucose Monitoring System (CGMS) devices has been medically proven to be effective and therefore **medically appropriate** for individuals with diabetes requiring insulin who are either on a program of multiple daily injections of insulin (at least 3 per day) OR using an insulin pump, performs self-testing of glucose an average of at least 4 times per day, and whose diabetes is poorly controlled as evidenced by recurrent, unexplained severe hypoglycemic episodes defined as blood glucose levels less than 54 mg/dL that puts the patient or others at risk; or experience hypoglycemic unawareness and are compliant with their medical regimen.

II. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of **continuous** use of Continuous Glucose Monitoring System (CGMS) devices has been medically proven to be effective and therefore **medically appropriate** for women with Type I diabetes who are pregnant or about to become pregnant and who cannot meet recommended targets for control of diabetes in pregnancy and the patient is participating in or has completed a comprehensive diabetic education program, there is documented self-monitoring of blood glucose at least 4 times per day by the patient, and the patient is compliant with recommended medical regimens.

III. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of **continuous** use of Continuous Glucose Monitoring System (CGMS) devices has not been shown to provide a benefit to patients younger than 7 years except for the DexCom G5® or DexCom G6® and is considered **investigational**.(*Please refer to Examples of continuous glucose monitoring systems below*).

IV. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of continuous use of Continuous Glucose Monitoring System (CGMS) devices with implantable sensors (e.g., Eversense®, Senseonics) is considered **investigational**.

Examples of continuous glucose monitoring systems include but are not limited to:

Brand Name	Manufacturer	Approved for:
DexCom G5®	DexCom, Inc	Individuals 2 years and older
DexComG6®	DexCom, Inc	Individuals 2 years and older
Guardian® Connect System	Medtronic Minimed, Inc	Individuals 14 years and older
FreeStyle Libre Flash	Abbott Diabetes Care, Inc	Individuals 18 years and older (not for use in pregnant women)
Eversense®	Senseonics	Individuals 18 years and older

REPLACEMENT of a continuous glucose monitor:

Transmitter (HCPCS: A9277) and/or Sensor (HCPCS: A9276, K0553, K0554):

I. Replacement of a CGMS is considered **medically necessary** when:
1. The CGMS has been previously approved by the Health Plan or the CGMS is in use prior to the user enrolling in the Health Plan; and
2. The transmitter is out of warranty; and
3. The transmitter is malfunctioning; and
4. There is documented evidence the member is compliant with their current CGMS device. Compliance is defined as at least 70% use rate of the device (e.g., 5 out of 7 days during a consecutive 30 day period) based on the log data, and
5. There is documented evidence of improvement in control of the disease Please see Guideline III).

C. **INITIAL Requests for combined external insulin pump/continuous glucose monitoring systems (HCPCS: E0784, and A9276, A9277, A9278)**

I. Based upon our criteria and review of the peer-reviewed literature, the external insulin pump/continuous glucose monitoring system, which consists of sensor-augmented insulin pump therapy with the low glucose threshold suspend feature and a continuous glucose monitor, is considered **medically necessary** when the criteria for both an external insulin pump **AND** a continuous glucose monitor have been met.

Examples of external insulin pump/continuous glucose monitoring systems include but are not limited to:

Brand Name	Manufacturer	Approved for:
530G with SmartGuard™ technology/ Enlite®	Medtronic, Inc	individuals 16 *years and older*
630G with SmartGuard™ technology / Enlite®	Medtronic, Inc	individuals 16 *years and older*
670G with SmartGuard™ technology/ Guardian® Sensor 3	Medtronic, Inc	individuals 7 *years and older*

REPLACEMENT of combined external insulin pump/continuous glucose monitoring systems:

I. Replacement of an external insulin pump/continuous glucose monitoring system is considered medically necessary when:
   1. The external insulin pump and continuous glucose monitoring system has been previously approved by the Health Plan or the CGMS is in use prior to the user enrolling in the Health Plan; and
   2. The insulin pump and continuous glucose monitor transmitter are out of warranty and malfunctioning; and
   3. There is documented evidence the member is compliant with their current CGMS device. Compliance is defined as at least 70% use rate of the device (e.g., 5 out of 7 days during a consecutive 30 day period) based on the log data, and
   4. There is documented evidence of improvement in control of the disease.

D. INTERMITTANT use of continuous glucose monitoring

I. Based upon our criteria and assessment of the peer reviewed literature, the effectiveness of **intermittent** use of Continuous Glucose Monitoring System (CGMS) devices, has been medically proven to be effective and therefore **medically appropriate** in patients whose diabetes is poorly controlled despite current evidence of best practices and compliance with recommended medical regimens (Please refer to Policy Guidelines I and II) or women with type I diabetes who are pregnant or about to become pregnant and who cannot meet recommended targets for control of diabetes in pregnancy.

POLICY GUIDELINES:

I. Documentation of best practices in diabetes control for patients with diabetes include compliance with a regimen of 4 or more fingersticks each day and use of an insulin pump. During pregnancy, 3 or more insulin injections daily could also be considered best practice for patients not on an insulin pump prior to the pregnancy. Prior use of an intermittent (72-hour) glucose monitor would be considered a part of best practices for those considering use of a continuous glucose monitor.

II. Evidence of poorly controlled diabetes may include the following:
   A. HbA_{1C} greater than 7% within the last four months; or
   B. History of recurring hypoglycemia (lower blood glucose levels which put the patient or others at risk; or
   C. Wide fluctuations in blood glucose before mealtime; or
   D. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; or
   E. History of severe glycemic excursions .

III. Improvement in control of the disease may include the following:
   A. HbA1c within therapeutic range; or
   B. Tighter glucose control as evidenced by BG log; or
   C. Lack of dawn phenomenon and severe glycemic excursions.

IV. Only basic insulin pump models are **medically necessary**. The patient is liable for any non-medical accessories or add-ons.

V. Replacement of purchased equipment which is damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

VI. The MiniMed 530G system and 630G system was approved by the FDA for use by people with diabetes ages 16 and older.

VII. The MiniMed 670G system was approved by the FDA in people 7 years of age and older with type 1 diabetes.

VIII. The Dexcom G5® Mobile was approved by the FDA for adults and pediatric patients 2 years of age and older.

IX. The Dexcom G6® CGM system was approved by the FDA for adults and pediatric patients 2 years of age and older.

X. The FreeStyle Libre Flash glucose monitoring system was approved by the FDA for individuals 18 years of age and older with diabetes.

XI. The Eversense® glucose long term monitoring system was approved by the FDA for individuals 18 years and older with diabetes.

XII. New York State Law mandates coverage for insulin pumps and continuous glucose monitoring systems under health care contracts that provide major medical or similar comprehensive-type coverage for the treatment of diabetes, if recommended or prescribed by a physician or other licensed health care provider legally authorized to prescribe such devices under the New York State Education Law.

XIII. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

External insulin pumps are utilized by diabetic patients for continuous subcutaneous insulin infusion (CSII) and who are unable to control their diabetes with multiple daily insulin injections. The pump contains an insulin filled cartridge or syringe connected to a catheter that is inserted into the patient's subcutaneous tissue, usually in the abdomen. After programming, the pump continuously delivers a predetermined amount of insulin to meet the patient's insulin requirements. The devices allow programming of different basal and bolus infusion rates, as needed.

CSII provides superior glycemic control over manual daily injections of insulin, decreases the frequency and/or severity of hypoglycemic reactions, and increases lifestyle flexibility.

The MiniMed 530G or 630G System (Medtronic Minimed, Inc) consists of the following devices that can be used in combination or individually: MiniMed 530G Insulin Pump or Minimed 630G Insulin pump, Enlite™ Sensor, Guardian Link 3™ Sensor and Transmitter, Enlite™ Serter, the MiniLink Real-Time System, the Bayer Contour NextLink glucose meter, CareLink® Pro Therapy Management Software for Diabetes, and CareLink® Personal Therapy Management Software for Diabetes. The system requires a prescription. The MiniMed 530G or 630G System is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. The MiniMed 530G or 630G System is not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond to the Threshold Suspend alarm to take measures to prevent or treat hypoglycemia himself. Continued approval of this device is contingent upon the submission of periodic reports, in order to provide continued reasonable assurance of the safety and effectiveness of the device. The MiniMed 530G system and 630G system was approved by the FDA for use by people with diabetes ages 16 and older.

The Minimed 670G system (Medtronic Minimed, Inc) is a hybrid closed loop system which includes an insulin pump with SmartGuard technology that can be programmed to automatically adjust delivery of basal insulin based on continuous glucose monitor sensor glucose values and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values. The Guardian Sensor (3) is intended for use with the MiniMed 670G system to continuously monitor glucose levels. It is intended to be used for detecting trends and

tracking patterns in persons 7 years and older and to be used by the MiniMed 670G system to automatically adjust basal insulin levels. The Guardian Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a confirmatory finger stick may be required. The Guardian Sensor (3) is indicated for 7 days of continuous use. The Guardian Link (3) Transmitter is intended for use with MiniMed 670G system. The Transmitter powers the glucose sensor, collects and calculates sensor data, and wireless sends the data to the MiniMed 670G insulin pump. The Transmitter is intended for single-patient multi-use. Minimed issued a warning stating the MiniMed 670G system may not be safe for use in children under the age of 7 because of the way that the system is designed and the daily insulin requirements. The Minimed 670G system should not be used in patients who require less than a total daily insulin dose of 8 units per day because the device requires a minimum of 8 units per day to operate safely. The MiniMed 670G system was approved by the FDA in people 7 years of age and older with type 1 diabetes.

Current best practices for treatment of diabetes may include multiple (4 or more) daily checks of blood glucose and multiple (3 or more) insulin injections or use of an insulin pump. Sometimes despite use of best practices, diabetes may remain poorly controlled which may result in adverse events. Some patients are able to recognize symptoms of hypoglycemia, but many are unaware of their lowered blood sugar which can lead to a severe hypoglycemic episode.

CGMS devices are used by diabetic patients to supplement, not replace, blood glucose information obtained using standard fingerstick glucose meters and test strips. These devices automatically measure, track interstitial glucose, and produce trends in glucose measurements throughout the day which may allow for tighter glucose control and a subsequent decrease in complications from diabetes. The CGMS device consists of a sensor, transmitter and receiver. The sensors are usually changed every 3-7 days. The warranties for the transmitters range from 6 months to 1 year depending on the type of device. Examples of FDA approved CGMS devices include but are not limited to the MiniMed CGMS® System Gold™ device, MiniMed Guardian® Real-Time CGMS device, and the FreeStyle Libre Flash. The MiniMed Guardian® Real-Time CGMS device is recommended for adults, age 18 years and over and, children and adolescents with diabetes age 7 to 17 years. The Dexcom G5® Mobile and Dexcom G6® CGM system are the only CGM FDA approved for adults and pediatric patients two years of age and older. The FreeStyle Libre Flash approved by the FDA for individuals with diabetes 18 years and older. This CGMS device consists of a handheld reader and a sensor worn on the back of the upper arm which measures glucose interstitially every minute and records the measurement every 15 minutes for up to 10 days. A hand held reader is positioned over the sensor to provider glucose measurements without the need for a routine finger stick and blood glucose calibration. A blood glucose reading is needed via fingerstick only when the Check Blood Glucose symbol appears on the reader, when symptoms do not match system readings, when you suspect readings may be inaccurate, or when you experience symptoms that may be due to high or low blood glucose. The FreeStyle Libre flash differs from more traditional CGMS devices in that it does not have an alarm system when the glucose values are above or below a point set by the user. Both the DexComG5® Mobile, Dexcom G6® CGM system and FreeStyle Libre Flash have FDA approval without the need for fingerstick blood glucose testing for diabetes treatment decisions. CGMS devices that do not require calibration fingerstick blood glucose have been designated as therapeutic CGMS devices by the Centers for Medicare and Medicaid Services.

The Eversense® Continuous Glucose Monitoring (CGM) system is a CGM device consisting of a fully implantable glucose sensor, a removable smart transmitter, and a mobile medical application. The sensor is designed to be inserted, using a local anesthetic, in an in-office clinic setting by a trained physician and has a 90 day sensor life. After 90 days the sensor is removed by the trained physician and a new sensor is inserted. The transmitter is attached to the skin with an adhesive that must be changed every 24 hours. The transmitter will vibrate at a certain frequency if the glucse is low and at another frequency is the glucose is high. A mobile app (either from a smart phone or Apple watch, etc) will record and alarm when the glucose readings are high or low. A confirmatory fingerstick is necessary when the device alarms.

RATIONALE:

A 2008 study funded by the Juvenile Diabetes Research Foundation enrolled 322 children, teenagers, and adults with Type 1 diabetes, randomly assigned half the participants to use CGM devices. At the end of six months, the adults (ages 25 to 72 years old) who were assigned to use continuous glucose monitors had a reduction of about half a percentage

point in their HbA1c levels compared to the control group, which saw a slight increase in HbA1c levels. This improvement was achieved without a difference in hypoglycemia, or low blood glucose levels, between the two groups. Statistically significant reductions in HbA1c were not seen in the two groups of younger people (ages 8 to 14 years old and 15 to 24 years old) who participated in the study. However, the people in these age groups used their CGM devices only 50% of the time or less. The adult group, which did see a drop in HbA1c levels, used the device more than 85% of the time. In all age groups, people who used the CGM device at least six days a week lowered their HbA1c levels. The researchers concluded that continuous glucose monitoring improves HbA1c levels and may enhance the management of Type 1 diabetes in adults who have the motivation to use this technology and the capability to incorporate it into their own daily diabetes management.

Raccah et al. performed a randomized two arm open-label study of 115 patients who used an insulin pump with CGMS or without. The authors observed improvement in A1c, a decrease in mean glucose concentration, and less glycemic variation in both groups, especially in the insulin pump + sensor group when the sensor was worn at least 70% of the time. The authors support use of insulin pumps capable of incorporating CGMS for improvement in glycemic control in previously poorly-controlled diabetes. However the compliance rate of the CGMS must be at least 70% to realize the greatest improvement. Kamble et al., compared the cost-effectiveness of using either an insulin pump with CGMS (Sensor Augmented Pump therapy -SAPT) or multiple daily injections (MDI) and self-monitoring blood glucose (SMBG) in patients that were part of the Sensor-Augmented Pump therapy for A1c Reduction (STAR 3) trial. The costs were the same for both groups for glucose meters, test strips, lancets, insulin and provider time but the costs associated with the insulin pump and CGMS also included the insulin pumps, transmitters sensors, insertion devices and other pump supplies. The authors found that the HbA1c values decreased more (0.6 % points) in the SAPT group when used at least 65% of the time but hospital admission, hospital inpatient days, and ED visits were similar for both groups. The SAPT group utilized more provider time, possibly related to device use. The lifetime estimate of direct medical costs was $253,493 for the SAPT group and $167,170 for the MDI group. The SAPT group had an assigned QALY of 10.794 while the MDI group's QALY was 10.418. The fear of hypoglycemia was less for the SAPT group which had an effect on the ICERS and showed a reduction. The authors concluded SAPT reduces HbA1c but when considering cost associated with SAPT compared to MDI, SAPT is not economically attractive in a number of situations. Differences in fear of hypoglycemia impacts cost effective ratios. The authors note that participants in the trials are highly motivated and received a high level of care which may bias results.

Continuous glucose monitors (CGMs) provide continuous "real-time" readings and data about trends in glucose levels. This can allow people with diabetes to understand the level of their glucose, maintain tighter control of their glucose levels which can lead to improved diabetes management and decrease risk of complications from diabetes.

The American Diabetes Association Standards in Medical Care in Diabetes (2018) states that "when used properly, continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens is a useful tool to lower A1C in adults with type 1diabetes who are not meeting glycemic targets. (Level of evidence: A). CGM may be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. (Level of evidence: C). Given the variable adherence to CGM, assess individual readiness for continuing CGM use prior to prescribing. (Level of evidence: E). When prescribing CGM, robust diabetes education, training, and support are required for optimal CGM implementation and ongoing use. (Level of evidence: E). People who have been successfully using CGM should have continued access after they turn 65 years of age. (Level of evidence: E).

The Endocrine Society Clinical Practice Guideline (2016) recommend continuous subcutaneous insulin infusion (CSII) over analog-based basal-bolus multiple daily injections (MDI) inpatients with type 1 diabetes mellitus (T1DM) who have not achieved their A1C goal, as long as the patient and caregivers are willing and able to use the device and in T1DM patients who have achieved their A1C goal but continue to experience severe hypoglycemia or high glucose variability, as long as the patient and caregivers are willing and able to use the device. For patients with type 2 diabetes mellitus (T2DM) who have poor glycemic control despite intensive insulin therapy, oral agents, other injectable therapy, and lifestyle modifications, CSII is suggested. Real-time continuous glucose monitoring (RT-CGM) devices is recommended for adult patients with T1DM who have A1C levels above target and who are willing and able to use these

devices on a nearly daily basis and in adult patient with well-controlled T1DM who are willing and able to use these devices on a nearly daily basis. Intermittent RT-CGM use in adult patients with T2DM (not on prandial insulin) who have A1C levels ≥ 7% and are willing and able to use the device is suggested. Education, training, and ongoing support to help achieve and maintain individualized glycemic goals is suggested in adults with T1DM and T2DM who use CSII and CGM.

The American Association of Clinical Endocrinologists and the American College of Endocrinology 2018 Position Statement on Integration of Insulin Pumps and Continuous Glucose Monitoring in Patients with Diabetes (Grunberger, et al., 2018) recommends Personal CGM should ideally be considered in all patients with Type I DM, especially those with a history of severe hypoglycemia, hypoglycemia unawareness, and to assist in the correction of hyperglycemia in patients not at goal. The benefits of CGM in patients with Type 2 DM have not been investigated to the same degree. CSII is appropriate in patients with Type I DM who are not at glyucemic goal, despite adherence to the maximum multi-dose injections, in special population of patients with type I DM (e.g., pregnancy, children, adolescents, and competitive athletes) and in patients with Type 1 DM who feel CSII would help achieve and maintain glycemic targets. Select patients with insulin dependent Type 2 DM and C-peptide positivity with suboptimal control on maximal basal/bolus injections, substantial "dawn phenomenon", or erratic lifestyle, or severe insulin resistance and in select patients with other DM types (e.g., postpancreatectomy).

The National Institute for Health and Care Excellence (NICE) guidelines on diagnosis and management of type 1 diabetes in adults (2015) state the following:
Do not offer real-time continuous glucose monitoring routinely to adults with type 1 diabetes. Consider real-time continuous glucose monitoring for adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring:

- Complete loss of awareness of hypoglycaemia.
- More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
- Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.
- Extreme fear of hypoglycaemia.
- Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.

The American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) Outpatient Glucose Monitoring Consensus Statement states that glucose monitoring is an essential component of care in all patients with diabetes. Blood glucose monitors (BGM) and CGMS are intended to empower patients to manage glucose levels and reduce the risk of hypoglycemia. Clinical practice guidelines from all major diabetes organizations recommend routine BGM for patients with Type 1 diabetes. Most of the guidelines recommend CGMS for patients with a history of severe hypoglycemia, or hypoglycemia unawareness as well as, for patients not at goal based on A1c. Many pediatric patients with diabetes are candidates for CGMS, especially if they or their family caregivers have the appropriate training to use the information effectively. There have been some studies of CGMS in Type 2 diabetes, but more studies are needed to identify the setting in which it can be more beneficial and cost-effective.

A Steering Committee made up of representatives from 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 formed a decision-making group for the Type 1 Diabetes Outcomes Program. Their goal was to develop a consensus on definitions for hypoglycemia, hyperglycemia, time in range, DKA, and patient reported outcomes and while their decisions were informed via input from researchers, industry, and people with diabetes they relied on published evidence, their own clinical expertise, and Advisory Committee feedback.

The Steering Committee defined three levels of hypoglycemia:
Level 1 is defined as a measurable glucose concentration of <70 mg/dL (3.9 mmol/L) but ≥54 mg/dL (3.0 mmol/L) which "can alert a person to take action", they wrote.
In those without diabetes, a blood sugar of 70 mg/dL (3.9 mmol/L) is known as low blood sugar. So blood glucose at <70 mg/dL (3.9 mmol/L) are relevant and "clinically important" despite a lack of severe symptoms

Level 2 hypoglycemia is defined as a measurable glucose concentration of <54 mg/dL (3.0 mmol/L) which requires immediate action. At this stage, "neurogenic and neuroglycopenic hypoglycemic symptoms begin to occur, ultimately leading to brain dysfunction at levels <50 mg/dL (2.8 mmol/L),"
At this level, symptoms like behavioral changes, visual changes, seizure, and loss of consciousness occur due to "central nervous system neuronal glucose deprivation,"

Level 3 hypoglycemia is defined as a severe event characterized by altered mental and/or physical status requiring assistance."
At this level, a persons symptoms are such that they require help from others. For some, this level may occur during the aforementioned level 1 or 2 for hypoglycemia.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	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 (*effective 1/1/2018*)
	95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
	95251	physician interpretation and report
	0446T **(E/I)**	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
	0447T **(E/I)**	Removal of implantable interstitial glucose sensor from subcutaneous glucse sensor from subcutaneous pocket via incision
	0448T **(E/I)**	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation

HCPCS:	A4230	Infusion set for external insulin pump, nonneedle cannula type
	A4231	Infusion set for external insulin pump, needle type
	A4232	Syringe with needle for external insulin pump, sterile, 3 cc
	A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
	A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply

	A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
	A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
	E0784	External ambulatory infusion pump, insulin
	K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit Of Service
	K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system
	S1030	Continuous noninvasive glucose monitoring device, purchase
	S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor
	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
	S1036	Transmitter; external, for use with artificial pancreas device system
	S1037	Receiver (monitor); external, for use with artificial pancreas device system
	S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)
ICD10:	E10.10-E10.9	Type 1 diabetes mellitus (code range)
	E11.00-E11.9	Type 2 diabetes mellitus (code range)
	E13.00-E13.9	Other specified diabetes mellitus (code range)
	E79.0	Hyperuricemia without signs of inflammatory arthritis and tophaceous disease
	O24.011-O24.019	Pre-existing diabetes mellitus, type 1, in pregnancy (code range)
	O24.03	Pre-existing diabetes mellitus, type 1, in the puerperium
	O24.111-O24.119	Pre-existing diabetes mellitus, type 2, in pregnancy (code range)
	O24.13	Pre-existing diabetes mellitus, type 2, in the puerperium
	O24.311-O24.33	Unspecified pre-existing diabetes mellitus in pregnancy, childbirth and the puerperium (code range)
	O24.410-O24.439	Gestational diabetes mellitus (code range)
	O24.811-O24.819	Other pre-existing diabetes mellitus in pregnancy (code range)

O24.83	Other pre-existing diabetes mellitus in the puerperium
O24.911-O24.93	Unspecified diabetes mellitus in pregnancy, childbirth and the puerperium (code range)
O99.810-O99.815	Abnormal glucose complicating pregnancy, childbirth and the puerperium **(code range)**
P70.2	Neonatal diabetes mellitus
R73.01-R73.9	Elevated blood glucose level (code range)

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* key article

KEY WORDS: CGMS, Continuous glucose monitor, DexCom STS, Freestyle Navigator, Interstitial glucose monitoring, MiniMed CGMS® System Gold™, MiniMed Guardian® Real-Time, MiniMed Paradigm Revel® Real-Time system, DexCom G5®,Wrist glucose monitor, Continuous subcutaneous insulin infusion, CSII, Insulin pump therapy

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Infusion Pumps. Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&bc=AgAAgAAAAAAA&

There is currently a Local Coverage Article for Glucose Monitors (A52464). Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52464&ver=21&Cntrctr=389&ContrVer=1&CntrctrSelected=389*1&DocStatus=Active&s=41&bc=AhAAAAIAgAAA&

There is currently a Local Coverage Determination (LCD) for Glucose Monitors. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33822&ver=17&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=Active&bc=AggAAAQBAAAA&