MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Continuous Glucose Monitoring Systems/ External Insulin Pump Therapy for Diabetes**
Policy Number	**1.01.30**
Category	**Technology Assessment**
Effective Date	**08/17/17**
Revised Date	**10/18/18, 08/15/19, 04/16/20**
Product Disclaimer	• *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

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

A. Based upon our criteria and review of the peer-reviewed literature, basic external insulin pumps are considered **medically appropriate** for patients with diabetes requiring insulin who are on a program of multiple daily injections of insulin (at least three per day), with frequent self-adjustments of insulin dose for at least three months prior to initiation of the insulin pump; and who perform self-testing of glucose an average of at least four times per day during the two months prior to initiation of the insulin pump; who have completed a comprehensive diabetes education program, and whose diabetes is poorly controlled despite best practices (Please refer to Policy Guideline II).

B. 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 three times per day; and whose diabetes cannot be controlled by intermittent dosing.

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

Examples of basic external insulin pumps include *but are not limited to the following*:

Brand Name	Manufacturer
630G with SmartGuard technology	Medtronic Minimed, Inc.
640G with SmartGuard technology	Medtronic Minimed, Inc.
Omnipod	Insulet Corporation
T-slimX2	Tandem Diabetes Care, Inc.

REPLACEMENT of an insulin pump:

D. Replacement of an external insulin pump is considered **medically approrpaite** when:
1. The external insulin pump has been previously approved by the Health Plan or the external insulin pump was 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.

E. Replacement of an external insulin pumpdue to slight damage (e.g., scratched screen) that does not cause the pump to malfunction or replacement desired due to advanced technology, is considered **not medically necessary**.

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

A. Based upon our criteria and review of the peer reviewed literature, the use of Continuous Glucose Monitoring System (CGMS) devices has been medically proven to be effective and therefore, is considered **medically appropriate** for those patients with diabetes when BOTH of the following criteria are met:
   1. The patient requires insulin; (e.g., receives multiple daily injections of insulin (at least three per day) or uses an external insulin pump); and
   2. The age of the patient is consistent with FDA indications for the specific CGMS device.

B. Based upon our criteria and review of the peer reviewed literature, with the exception of the DexCon G5 or DexCom G6 (*Please refer to Examples of continuous glucose monitoring systems below*), use of Continuous Glucose Monitoring System (CGMS) devices has not been shown to provide a benefit to patients younger than seven years and, therefore, is considered **investigational**..

C. Based upon our criteria and review of the peer reviewed literature, devices with implantable sensors (e.g., Eversense, Senseonics) is considered medically appropriate for individuals with diabetes who meet criteria for continueous glucose monitoring, where *one or more* of the following makes the use of a transcutaneous CGMS device not possible:
   1. Physical disability, such as an impairment in vision, hearing, or dexterity; or
   2. A severe sensitivity to adhesives or plastics used in transcutaneous CGM components; or
   1. Any significant condition or situation requiring vibration alerts (e.g., patients living alone who may require additional alarms to alert them to highs or lows).

Examples of CGMS devices include, but are not limited to, the following:

Brand Name	Manufacturer	Approved for:	Sensor	Transmitter	Receiver
DexCom G5	DexCom, Inc.	Individuals two years and older	Four per 28 days	Four per per 360 days	One per year
DexComG6	DexCom, Inc.	Individuals two years and older (not for use in pregnant women, people on dialysis, or critically ill patients)	Three per 30 days	Four per 360 days	One per year
Guardian Connect System	Medtronic plc	Individuals 14 years and older	Four per 30 days	One per year	NA
FreeStyle Libre 14 Day System	Abbott Diabetes Care, Inc.	Individuals 18 years and older (not for use in pregnant women)	Two per 28 days	NA	One per one years
Eversense	Senseonics Holdings, Inc.	Individuals 18 years and older	One per 90 days	One per year	NA

REPLACEMENT of a CGM device:

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

D. Replacement of a CGMS transmitter and/or sensor is considered **medically appropriate** when:

1. The CGMS device has been previously approved by the Health Plan, or the CGMS device was in use prior to the user enrolling in the Health Plan; and
2. The transmitter/receiver is out of warranty and malfunctioning.

III. **INITIAL Requests for combined external insulin pump/CGMS device (HCPCS: E0784, and A9276, A9277, A9278)**

A. Based upon our criteria and review of the peer-reviewed literature, the external insulin pump/CGMS device, which consists of sensor-augmented insulin pump therapy with a low glucose threshold suspend feature and a continuous glucose monitor, is considered **medically appropriate** when the criteria for both an external insulin pump **AND** a CGMS device 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, plc	Individuals 16 *years and older*
630G with SmartGuard™ technology / Enlite	Medtronic, plc	Individuals 16 *years and older*
670G with SmartGuard™ technology/ Guardian® Sensor 3	Medtronic, plc	Individuals 7 *years and older*

REPLACEMENT of combined external insulin pump/CGMS device:

B. Replacement of an external insulin pump/CGMS device is considered medically approrpiate when:
1. The combined external insulin pump and CGMS device has been previously approved by the Health Plan or the combined external insuling pump/CGMS device was in use prior to the user enrolling in the Health Plan; and
2. The externalinsulin pump and CGMS device's transmitter/receiver are out of warranty and malfunctioning.

IV. SHORT TERM USE of continuous glucose monitoring

Based upon our criteria and review of the peer reviewed literature, the effectiveness of short term (three to seven days) use of CGMS devices, has been medically proven to be effective and therefore, is considered **medically appropriate** in insulin dependent diabetic 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 in 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.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

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, three 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 a short term (three to seven days) glucose monitor would be considered a part of best practices for those considering use of a CGMS device.

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 (blood glucose levels low enough to 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 any of the following:

A. HbA1c within therapeutic range; or
B. fewer episodes of hyperglycemia or hypoglycemia; or
C. more time spent in range.

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

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

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

VII. The MiniMed 670G system was approved by the FDA for use by patients with tpe I diabetes ages 7 years and older.

VIII. The Dexcom G5 Mobile was approved by the FDA for diabetic patients ages two years and older.

IX. The Dexcom G6 CGMS was approved by the FDA for non-pregnant diabetic adults and pediatric patients ages two years and older.

X. The FreeStyle Libre Flash CGMS was approved by the FDA for non-pregnant diabetic patients 18 years and older.

XI. The Eversense glucose long term CGMS was approved by the FDA for diabetic patients 18 years and older.

XII. New York State law mandates coverage of insulin pumps and CGMS devices under health care contracts and certificates 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 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 for continuous subcutaneous insulin infusion (CSII) by diabetic patients who are unable to control their diabetes with multiple daily insulin injections. An external insulin pump contains an insulin filled cartridge or syringe connected to a catheter which 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 amounts, 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 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, MiniLink Real-Time System, 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; rather, the system is intended 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 ; rather, it is intended to suspend insulin delivery when the user is unable to respond to the Threshold Suspend alarm to take measures to prevent or treat hypoglycemia. 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 diabetic patients ages 16 and older.

The Minimed 670G System is a hybrid closed loop system . It includes an external 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 Link 3 Sensor 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 diabetic patients ages seven years and older and to be used in conjunction with the MiniMed 670G System to automatically adjust basal insulin levels. The Guardian Link 3 Sensor 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 Link 3 Sensor is indicated for seven 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 wirelessly sends the data to the MiniMed 670G insulin pump. The transmitter is intended for single-patient multi-use. Medtronic issued a warning stating the MiniMed 670G System may not be safe for use in children under the age of seven because of the way that the system is designed and the lower daily insulin requirements. The Minimed 670G System should not be used in patients who require less than a total daily insulin dose of eight units per day because the device requires a minimum of eight units per day to operate safely. The MiniMed 670G System was approved by the FDA for use in patients with type I diabetes ages seven years and older.

Current best practices for treatment of diabetes may include multiple (four or more) daily checks of blood glucose and either multiple (three or more) daily insulin injections or use of an external insulin pump. Sometimes despite use of best practices, diabetes may remain poorly controlled, resulting in adverse events for the patient or others. 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 and 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 sensor is usually changed every three to seven days. The warranties for the transmitters range from three months to one 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 14 Day CGMS device. The MiniMed Guardian Real-Time CGMS device is recommended for diabetic patients age ages seven years and older. The Dexcom G5 Mobile and Dexcom G6 CGMS are the only FDA CGMS devices approved for diabetic patients two years and older. The FreeStyle Libre 14 Day CGMS device was approved by the FDA for diabetic patients 18 years and older. This 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 ten 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 there is a suspiction that the readings may be inaccurate, or when symptoms experienced that may be due to high or low blood glucose. The FreeStyle Libre 14 Day CGMS device 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. The DexComG5 Mobile, Dexcom G6 CGMS and FreeStyle Libre 14 Day devices all 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 CGMS device is a CGMS 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 clinical 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 glucose is low and at another frequency is the glucose is high. A mobile app (either from a smart phone, smart watch, etc.) will record and will sound an alarm when the glucose readings are high or low. A confirmatory fingerstick is necessary when the alarm sounds.

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) 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 eight to 14 years and 15 to 24 years) who participated in the study. However, the subjects in these age groups used their CGMS 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, subjects who used the CGMS device at least six days per 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 external insulin pump with a CGMS device or without. The authors observed improvement in A1c, a decrease in mean glucose concentration, and less glycemic variation in both groups, especially in the combined insulin pump/CGMS device group when the sensor was worn at least 70% of the time. The authors support the use of insulin pumps capable of incorporating CGMS for improvement in glycemic control in previously poorly-controlled diabetes patients. However the compliance rate of the CGMS device 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 who were part of the SAPT 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 emergency department 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 that SAPT reduces HbA1c but given the comparative costs associated with SAPT and MDI, SAPT is not economically attractive in a number of situations. Differences in fear of hypoglycemia impacts cost effective ratios. The authors also 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 and maintain tighter control of their glucose levels which can lead to improved diabetes management and decreased risk of complications from diabetes.

The American Diabetes Association Standards in Medical Care in Diabetes (2018) states "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 is recommended 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 are 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) recommended that personal CGMS devices should ideally be considered in all patients with T1DM, 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 T2DM have not been investigated to the same degree. CSII is appropriate in patients with T1DM who are not at glyucemic goal, despite adherence to the maximum multi-dose injections, in special population of patients with T1DM (e.g., pregnancy, children, adolescents, and competitive athletes) and in patients with T1DM who feel that CSII would help achieve and maintain glycemic targets. Select patients with insulin dependent T2DM and C-peptide positivity with suboptimal control on maximal basal/bolus injections, substantial "dawn phenomenon", erratic lifestyle, or severe insulin resistancemay benefit, as well as, 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 optimized use of insulin therapy and conventional blood glucose monitoring:

- Complete loss of awareness of hypoglycaemia.
- More than one episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
- Frequent (more than two 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 ten 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 devices 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 devices 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 devices, 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 diabetics, 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, diabetic ketoacidosis, and patient reported

outcomes. 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 1hypoglucemia is defined as a measurable glucose concentration of less than 70 mg/dL (3.9 mmol/L) but greater than or equal to 54 mg/dL (3.0 mmol/L) which "can alert a person to take action". 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 less than 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 less than 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 less than 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

- *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.*

CPT Codes

Code	Description
95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0447T	Removal of implantable interstitial glucose sensor from subcutaneous glucse sensor from subcutaneous pocket via incision
0448T	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 Codes

Code	Description
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week (effective 1/1/2020)
A4230	Infusion set for external insulin pump, non needle 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
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing (e.g., Dexcom Continuous Glucose Monitoring System and the Tandem T:Slim) (effective 1/1/2020)
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 (for physician interpretation of data, use cpt code)
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use cpt code)
S1034	Artificial pancreas device system (e.g., 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 Codes

Code	Description
E10.10-E10.9	Type 1 diabetes mellitus (code range)

Code	Description
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 in pregnancy (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 (LCA) for Glucose Monitors. Please refer to the following LCA website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52464&ver=26&Cntrctr=389&ContrVer=1&CntrctrSelected=389*1&DocStatus=Active&s=41&bc=AhAAAAIAQAAA&

There is currently a Local Coverage Determination (LCD) for Category III CPT® Codes. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33392&ver=98&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=1&bc=AAgAAAQBAAAA&

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