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**
Committee Approval Date	**10/18/18, 08/15/19, 04/16/20, 5/20/21, 5/19/22, 5/18/23**
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Archived Date	**N/A**
Archive Review Date	**N/A**
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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

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

A. Based upon our criteria and assessment of the peer-reviewed literature, **basic external insulin pumps** are considered **medically appropriate** for individuals with diabetes requiring insulin:
1. 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
2. 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; and
3. 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 assessment of the peer-reviewed literature, **basic external insulin pumps** are **medically appropriate** for women with gestational diabetes:
1. who require three or more insulin injections per day; and
2. whose diabetes cannot be controlled by intermittent dosing.

C. Based upon our criteria and assessment 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.
770G 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 appropriate** 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 effective date of the member's coverage with the Health Plan; and
   2. The pump has exceeded the warranty time period (Warranty period for insulin pumps: four years); and
   3. The pump is malfunctioning.

E. Replacement of an external insulin pump due 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 system (CGMS) (HCPCS: A9276, A9277, A9278, E2102, E2103, A4238, A4239)**

A. Based upon our criteria and assessment of the peer-reviewed literature, the use of a **CGM devices** have been medically proven to be effective and, therefore, is considered **medically appropriate** for individuals with diabetes requiring insulin, who meet **BOTH** of the following criteria:
   1. The patient requires insulin; (e.g., receives daily injections of insulin or uses an external insulin pump); and
   2. The age of the patient is consistent with U.S. Food and Drug Administration (FDA) indications for the specific CGM device.

B. Based upon our criteria and assessment of the peer-reviewed literature, the use of 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 indications makes the use of a transcutaneous CGM 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
   3. Any significant condition or situation requiring vibration alerts (e.g., patients lives alone and requires additional alarms to increase awareness of highs or lows).

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

Brand Name	**Manufacturer**	**Approved for:**	**Sensor**	**Transmitter**	**Receiver**
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
DexComG7	DexCom, Inc.	Individuals two years and older (can be worn during pregnancy for all types of diabetes)	Combined Sensor and transmitter Three per 30 days	N/A	One per year (Optional)

Guardian Connect System	Medtronic plc	Individuals 14 years and older	Four per 30 days	One per year	NA
FreeStyle Libre system	Abbott Diabetes Care, Inc.	Individuals four years and older	Two per 28 days	NA	One per one year
FreeStyle Libre 2 system	Abbott Diabetes Care, Inc.	Individuals four years and older	Two per 28 days	NA	One per one year
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 year
Eversense	Senseonics Holdings, Inc.	Individuals 18 years and older	One per 90 days	One per year	NA
Eversense E3	Senseonics Holdings, Inc.	Individuals 18 years and older	One per 180 days	One per year	NA

REPLACEMENT of a CGM device:

Transmitter (HCPCS: A9277, E2021) and/or Sensor (HCPCS: A4238, A4239 A9276, E2103):

C. Replacement of a CGM transmitter and/or sensor is considered **medically appropriate** when:
1. The CGMdevice has been previously approved by the Health Plan, or the CGMS device was in use prior to the effective date of the member's coverage with the Health Plan; and
2. The transmitter/receiver is out of warranty (Warranty Period for CGM: One Year).

III. **INITIAL Requests for COMBINED external insulin pump/CGM device (Artificial Pancreas) (HCPCS: E0784 and A9276, A9277, A9278)**

A. Based upon our criteria and assessment of the peer-reviewed literature, the external insulin pump/CGM 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 CGM device have been met.

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

Brand Name	**Manufacturer**	**Approved for:**
Minimed 630G System	Medtronic	Individuals seven years and older
Minimed 770G System	Medtronic	Individuals two years and older
T-slim with Control-IQ technology/DexcomG6	Tandem Diabetes Care, Inc.	Individuals six years and older

REPLACEMENT of combined external insulin pump/CGMS device (Artificial Pancreas):

B. Replacement of an external insulin pump/CGM device is considered medically appropriate when:
1. The combined external insulin pump and CGM device has been previously approved by the Health Plan or the combined external insuling pump/CGM device was in use prior to the effective date of the member's coverage with the Health Plan; and

2. The combined external insulin pump/CGM device's transmitter/receiver are out of warranty and the insulin pump is 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 CGM devices, has been medically proven to be effective and therefore, is considered **medically appropriate** for the following:

1. 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); and
2. 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 four 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 CGM device.

II. Evidence of poorly controlled diabetes may include, but are not limited to, the following:
   A. HbA_{1C} greater than 7% within the last four months;
   B. history of recurring hypoglycemia (blood glucose levels low enough to put the patient or others at risk;
   C. wide fluctuations in blood glucose before mealtime;
   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 be evidence by, among other indications, any of the following:
   A. HbA1c within therapeutic range;
   B. fewer episodes of hyperglycemia or hypoglycemia; or
   C. more time spent in range (avoidance of either high or low glucose values).

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 630G system was approved by the FDA for use by patients with type I diabetes aged seven years and older.

VII. The Minimed 770G System was approved by the FDA for use in patients with type I diabetes aged two years and older.

VIII. The Dexcom G6 CGM was approved by the FDA for non-pregnant diabetic adults and pediatric patients aged two years and older.

IX. The Dexcom G7 CGM was approved by the FDA for pregnant diabetic adults and pediatric patients aged two years and older.

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

XI. The FreeStyle Libre 2 System CGM was approved by the FDA for patients aged four years and older.

XII. The Eversense glucose long term CGM was approved by the FDA for diabetic patients aged 18 years and older.

XIII. The T-slim X2 insulin pump with Control-IQ system was approved by the FDA for diabetic patients aged six years and older.

DESCRIPTION

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.

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 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 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.

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 CGM device consists of a sensor, transmitter and receiver. The sensor is usually changed every three to fourteen days. The warranties for the transmitters range from three months to one year, depending on the type of device. There are a number of CGM devices available for use.

The Minimed 630G or Minimed 770G system are hybrid, closed-loop systems that consists of both an insulin pump and a CGM. The system(s) include an external insulin pump with SmartGuard technology that can be programmed to automatically adjust delivery of basal insulin, based on the glucose monitor sensor glucose value. Insulin delivery can be suspended when the sensor glucose value falls below, or is predicted to fall below predefined threshold values. The Guardian Link 3 Sensor continuously monitors glucose levels, is intended to be used for detecting trends, and is able 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 sensor component of the Guardian Link 3 Sensor is indicated for seven days of continuous use. The Guardian Link 3 Sensor also contains a transmitter, which powers the glucose sensor, collects and calculates sensor data, and wirelessly sends the data to the MiniMed 630G or 770G insulin pump. The transmitter is intended for multiple uses by a single-patient. Medtronic issued a warning stating that the MiniMed 630G 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 of younger children. The Minimed 630G 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.

Examples of other FDA-approved CGM devices include, but are not limited to, the MiniMed Guardian Real-Time CGM device and the FreeStyle Libre 14 Day CGM device. The MiniMed Guardian Real-Time CGM device is recommended for diabetic patients aged 14 years and older. The Dexcom G6 CGM is the only FDA-approved CGM device approved for diabetic patients two years and older. The FreeStyle Libre 14 Day CGM device was approved by the FDA for diabetic patients aged 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 10 days. A handheld reader is positioned over the sensor to provider glucose measurements without the need for a routine

fingerstick 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 experienced do not match system readings, when there is a suspicion that the readings may be inaccurate, or when symptoms experienced may be due to high or low blood glucose. The FreeStyle Libre 14 Day CGM device differs from more traditional CGM 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 FreeStyle Libre 2 has optional, real-time glucose alarms that notify the patient, if glucose levels get too low or too high. The DexComG5 Mobile, Dexcom G6 CGM, and FreeStyle Libre 14 Day devices all have FDA approval without the need for fingerstick blood glucose testing for diabetes treatment decisions. CGM devices that do not require calibration fingerstick blood glucose have been designated as therapeutic CGM devices by the Centers for Medicare and Medicaid Services.

The DexComG6 and the Freestyle Libre CGM are considered therapeutic or nonadjunctive CGMs. A "therapeutic/nonadjunctive" CGM is a system approved by the FDA as a replacement for home blood glucose monitors. It performs the medically necessary function of the home glucose monitor to make diabetes treatment decisions.

The Eversense CGM device consists 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; it has a 90 or 180 day sensor life. After 90 or 180 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 if the glucose is high. A mobile application (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 (aged 25 to 72 years) who were assigned to use CGM devices, 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 (agesd eight to 14 years and 15 to 24 years) who participated in the study. However, the subjects 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 their devices more than 85% of the time. In all age groups, subjects who used the CGM 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.

Kamble et al. (2012) compared the cost-effectiveness of using either an insulin pump with CGM (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 CGM device included, not only the insulin pumps, but also the 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 admissions, 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. The authors noted that differences in fear of hypoglycemia impacts cost-effectiveness ratios. The authors also noted that participants in the trials were highly motivated and received a high level of care which can bias results.

CGM devices provide continuous, "real-time" readings and data about trends in glucose levels. This can allow people with diabetes to understand 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 (2021) stated:

- When used properly, continuous glucose monitoring (CGM) in conjunction with multiple daily injections and continuous subcutaneous insulin infusion (level of evidence: A) and other forms of insulin therapy (level of evidence: C) are a useful tool to lower and/or maintain A1C levels and/or reduce hypoglycemia in adults and youth with diabetes.
- When used properly, intermittently scanned continuous CGM in conjunction with multiple daily injections and continuous subcutaneous insulin infusion (level of evidence: A) and other forms of insulin therapy (level of evidence: C) can be a useful and may lower A1C levels and/or reduce hypoglycemia in adults and youth with diabetes to replace self-monitoring blood glucose.
- In patients on multiple daily injections and continuous subcutaneous insulin infusion, CGM devices should be used as close to daily as possible for maximal benefit. (level of evidence: A). Intermittently scanned CGM devices should be scanned frequently, at a minimum once every 8 h.
- When prescribing CGM, robust diabetes education, training, and support are required for optimal CGM implementation and ongoing use. People using CGM devices need to have the ability to perform self-monitoring of blood glucose in order to calibrate their monitor and/or verify readings if discordant from their symptoms (level of evidence: B).
- When used as an adjunct to pre- and postprandial self-monitoring of blood glucose, continuous glucose monitoring can help to achieve A1C targets in diabetes and pregnancy.

The American Diabetes Association (ADA) Standards of Care (2023) comment on the role of rtCGM and isCGM in management of diabetes.

- The use of real time CGM (rtCGM) (level of evidence A) or intermittently scanned CGM (isCGM) (level of evidence B) should be offered for diabetes management in adults with diabetes on multiple daily insulin injections or CSII.
- These devices also should be offered in youth with diabetes on multiple daily insulin injections or CSII (level of evidence B for rtCGM in youth with type 1 diabetes; level of evidence E for other scenarios).
- The use of rtCGM (level of evidence A) or isCGM (level of evidence C) should also be offered for diabetes management in adults with diabetes on basal insulin.
- In all cases, it is noted that the choice of device should be made based on the individual's circumstances, preferences, and needs.

The Endocrine Society Clinical Practice Guideline (2016) recommended 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, 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 are recommended for adult patients with T1DM who have A1C levels above target, 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% or greater and are willing and able to use the device. 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 CGM devices ideally be considered in all patients with T1DM, especially those with a history of severe hypoglycemia or 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 glycemic goal, despite adherence to the maximum multi-dose injections, in special population of patients with T1DM (e.g., pregnanct women, children, adolescents, and competitive athletes), and in patients with T1DM who feel that CSII would help them 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 from CSII, 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 **(**2022) made the following recommendation:

Offer adults with type I diabetes a choice of real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as "flash"), based on their individual preferences, needs, characteristics, and the functionality of the devices available.

The American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) Outpatient Glucose Monitoring Consensus Statement (2016) indicated that glucose monitoring is an essential component of care in all patients with diabetes. Blood glucose monitors (BGM) and CGM 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 CGM 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 CGM devices, especially if they or their family caregivers have the appropriate training to use the information effectively. There have been some studies of the use of CGM devices 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 dommittee feedback.

The steering committee defined three levels of hypoglycemia:

- Level 1hypoglucemia was 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. Blood glucose levels at less than 70 mg/dL (3.9 mmol/L) are relevant and "clinically important," despite a lack of severe symptoms.
- Level 2 hypoglycemia was 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 was defined as "a severe event characterized by altered mental and/or physical status requiring assistance." At this level, a person's 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.*

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

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
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
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 (*Effective 01/01/2023*)
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 (CGM)
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system (CGM)

Code	Description
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)
E2102	Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver (CGM) (*Effective 01/01/2023*)
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service *(Termed 12/31/2022)*
K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system *(Termed 12/31/2022)*
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)
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

Code	Description
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)

REFERENCES

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*Key Article

KEY WORDS

CGMS, Continuous glucose monitor, CGM, 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 Determination (LCD) for Glucose Monitors. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822&ver=55&ContrId=389&ContrVer=1&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAIAAACAAAAA&=+

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/view/article.aspx?articleid=52464&ver=49&