MEDICAL POLICY

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Medical Policy Title	**Continuous Glucose Monitoring Systems/External Insulin Pump Therapy for Diabetes**
Policy Number	**1.01.30**
Current Effective Date	**January 1, 2026**
Next Review Date	**December 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Initial Request for External Insulin Pump Therapy (HCPCS: E0784)*

A. External insulin pumps are **medically appropriate** for individuals with diabetes requiring insulin when **ALL** the following criteria are met:

1. On a program of multiple daily injections of insulin (at least three (3) per day);
2. Require frequent self-adjustments of insulin dose for at least three (3) months prior to initiation of the insulin pump;
3. Performs self-testing of glucose an average of at least three (3) times per day one (1) month prior to initiation of the insulin pump or has been using a continuous glucose monitor (CGM);
4. Completed a comprehensive diabetes education program;
5. Diabetes is poorly controlled despite best practices (please refer to Policy Guideline II).

B. External insulin pumps are **medically appropriate** for women with gestational diabetes when **BOTH** of the following criteria are met:

1. Require three (3) or more insulin injections per day;
2. Diabetes cannot be controlled by intermittent dosing.

*Disposable external insulin infusion pumps (e.g., OmniPod Insulin Management System/Omnipod Dash, V-Go transdermal insulin delivery device) are considered acceptable alternatives to standard insulin infusion pumps.

II. Replacement External Insulin Pump

A. Replacement of an external insulin pump is **medically appropriate** when the following criteria are met:

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 its warranty (warranty period for insulin pumps: four (4) years) and the pump is malfunctioning; **or**

3. The request is for a child in need of a larger insulin reservoir.

B. Replacement of an external insulin pump is **not medically necessary** for the following indications including, but not limited to:

1. Slight damage to the pump (e.g., scratched screen);
2. Damage does not cause the pump to malfunction; **or**
3. Replacement request is driven by an advancement in technology.

III. Initial Request for Continuous Glucose Monitoring System (CGMS) (HCPCS: A9276, A9277, A9278, E2102, E2103, A4238, A4239)

A. Continuous glucose monitoring (CGM) devices are **medically appropriate** for individuals with a diagnosis of diabetes mellitus (i.e., Type 1, Type 2, other specific types of diabetes, gestational diabetes) whose age is consistent with U.S. Food and Drug Administration (FDA) indications for the specific CGM device.

B. Implantable sensors (e.g., Eversense, Senseonics) are **medically appropriate** for individuals with diabetes who meet the following criteria:

1. Age is consistent with U.S. Food and Drug Administration (FDA) indications for the specific CGM device; and have **ANY** of the following:
   a. Physical disability, such as an impairment in vision, hearing, or dexterity;
   b. A severe sensitivity to adhesives or plastics used in transcutaneous CGM components; **or**
   c. Any significant condition or situation requiring vibration alerts (e.g., individual lives alone and requires additional alarms to increase awareness of highs or lows).

IV. Professional Glucose Monitoring (three (3) to seven (7) days) (CPT: 95249, 95250, 95251)

A. Professional Glucose Monitoring is **medically appropriate** for **EITHER** of the following indications:

1. Diabetes is poorly controlled despite current evidence of best practices; **and**
   a. has demonstrated compliance with recommended medical regimens; **or**
2. For individuals with a diagnosis of diabetes mellitus (i.e., Type 1, Type 2, other specific types of diabetes, gestational diabetes) who
   a. are pregnant or about to become pregnant; **and**
   b. who cannot meet recommended targets for control of diabetes in pregnancy.

~~V.~~ Replacement of a CGM Device Transmitter (HCPCS: A9277, E2102)

A. Replacement of a CGM transmitter is **medically appropriate** when the following criteria are met:

1. The transmitter or receiver is out of warranty (Warranty Period for CGM: One Year); **and**
2. The CGM device has been previously approved by the Health Plan; **or**
3. The CGM device was in use prior to the effective date of the member's coverage with the Health Plan.

VI. Replacement of a CGM Sensor (HCPCS: A4238, A4239 A9276, E2103)

A. Replacement of a CGM sensor is **medically appropriate** when **EITHER** of the following criteria are met:

1. CGM device has been previously approved by the Health Plan; **or**
2. CGM device was in use prior to the effective date of the member's coverage with the Health Plan.

VII. Initial Request for a Combined External Insulin Pump and CGM Device (Artificial Pancreas) (HCPCS: E0784 and A9276, A9277, A9278)

A. External insulin pumps and CGM devices consisting of sensor-augmented insulin pump therapy with a low glucose threshold suspend feature and a continuous glucose monitor, are considered **medically appropriate** when criteria for an external insulin pump **AND** a CGM device have been met.

VIII. Replacement of a Combined External Insulin Pump and CGM~~S~~ Device (Artificial Pancreas):

A. Replacement of an external insulin pump and CGM device is **medically appropriate** when **BOTH** of the following criteria are met:

1. The combined external insulin pump and CGM device has been previously approved by the Health Plan or the combined external insulin pump and 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 and CGM device's transmitter or receiver are out of warranty and the insulin pump is malfunctioning.

RELATED POLICIES

Not Applicable

POLICY GUIDELINE(S)

I. Evidence of poorly controlled diabetes may include, but are not limited to, the following:

A. Hemoglobin A1c (HbA1c) greater than 7% within the last four (4) months;

B. History of recurring hypoglycemia (blood glucose levels low enough to put the individual 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.

IX. Improvement in control of the disease may be evidenced 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).

X. The individual is liable for any non-medical accessories or add-ons of basic external insulin pump models.

XI. Replacement of purchased equipment that is damaged due to individual 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**.

DESCRIPTION

Continuous Glucose Monitoring (CGM) Devices

CGM devices are used by diabetic individuals to supplement, not replace, blood glucose information obtained using standard fingerstick glucose meters and test strips. These devices are placed subcutaneously and 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. Most of today's CGM systems are built with active alarms to alert the user of hypoglycemia, which they may not have been aware of otherwise. Additionally, as an added safety mechanism, many CGM systems have the capability to share data between the individual, clinicians, and caregivers.

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 two forms of CGM systems available for personal use. Real-time CGM (rtCGM) devices automatically transmit data to a receiver and/or smartphone of a person with diabetes, and isCGM, also historically known as "flash" CGM, which requires a person to "swipe" the receiver and/or smartphone close to the sensor to obtain current and historical glucose data.

External Insulin Pumps/Continuous Subcutaneous Insulin Infusion (CSII) Systems

CSIIs are the traditional insulin pumps, using tubing to deliver insulin from the machine through a cannula. They can be used by Type 1 (T1) and Type 2 (T2) patients who require precise dosing through flexible basal-bolus therapy. Injection sites are rotated every 24-72 hours. The primary benefit of the CSII is reduced injection burden, but additionally, they are discreet and are compatible with CGMs.

Sensor Augmented Pumps (SAPs)

Sensor-augmented pumps (SAPs), also known as hybrid closed-loop systems, include an insulin pump, a continuous glucose monitor (CGM), and an algorithm that automatically pauses insulin delivery when the user's glucose level is low or predicted to drop within the next 30 minutes. These devices have been shown to significantly reduce hypoglycemia, particularly overnight. SAPs have been replaced by automated insulin delivery (AID) systems, which demonstrate even better outcomes. However, AID systems can still operate in low-glucose or predictive low-glucose suspension modes, similar to SAPs.

Automated Insulin Delivery (AID) Systems

Like SAPs, AID systems consist of an insulin pump, a CGM, and an algorithm. These devices are now preferred over non-automated pumps and multi-dose injections for T1 diabetics. Examples include the iLet Bionic Pancreas System, the MiniMed 780G System, and the Omnipod 5, which was recently approved for use in T2 diabetes who are 18 years of age and older (SmartAdjust AID software, with the Omnipod 5 tubeless pump and Dexcom CGM).The algorithm uses CGM data to adjust insulin dosing by modifying preprogrammed basal rates or delivering microdoses of insulin every five minutes based on CGM readings. These systems require manual entry of carbohydrate amounts to assist with prandial dose calculations but also allow adjustments for physical activity.

Patch Pumps

Newer to the market, these are tubeless CSII, with automation, meant for T1 and T2 diabetics that can be treated with bolus only dosing because they are non-programmable. They reduce the injection burden in that they can be worn up to 3 days, and are simple to operate, but they do not have compatibility with CGMs.

The V-Go (Zealand Pharma) and Omnipod DASH (Insulet) are both disposable, tubeless insulin delivery systems that are indicated for T1 or T2 diabetics who require insulin. These systems deliver a pre-set basal rate and on demand boluses via a mechanical button or touchscreen controller (that is not disposable). Each is worn for 24 -72 hours, after which, is removed and a new device is needed to be attached. It does not work with a CGM.

SUPPORTIVE LITERATURE

Wada et al (2020) conducted a 24-week, multicenter, open-label, randomized (1:1) parallel-group study to evaluate the effects of flash glucose monitoring (FGM) versus conventional self-monitoring of blood glucose (SMBG) on glycemic control in patients with non–insulin-treated T2 diabetes. Participants (FGM: n = 49; SMBG: n = 51) used their assigned device for 12 weeks (FGM group received a FreeStyle Libre from Abbott Diabetes Care; SMBG group received a FreeStyle Precision Neo, also from Abbott Diabetes Care). The primary outcome was the change in HbA1c between groups, analyzed using an analysis of covariance model that included baseline values and group as covariates. All participants and investigators were blinded to sensor glucose measurements during the baseline period. Additionally, the SMBG group was blinded again for the final two weeks of the 12-week intervention. At baseline, mean HbA1c levels were 7.83% in the FGM group and 7.84% in

the SMBG group. At 12 weeks, both groups showed reductions (FGM: –0.43%; SMBG: –0.30%; P ≤ 0.001). However, at 24 weeks, a significant decrease from baseline persisted in the FGM group but not in the SMBG group (FGM: –0.46%, P < 0.001; SMBG: –0.17%, P = 0.124). HbA1c reductions were significant using both ANCOVA and linear mixed model methods. The authors concluded that FGM use in non–insulin-treated patients may help maintain good glycemic control even after discontinuation of glucose measurement.

Isganaitis et al (2021) assessed the effectiveness and safety of closed loop control (CLC) insulin delivery systems in adolescents and young adults with type 1 diabetes. A sub analysis was conducted on data from a six-month multi center randomized trial. Participants aged 14 through 24 with type 1 diabetes were randomly assigned (2:1) to CLC (tandem control-IQ) or sensor augmented pump (SAP). The mean age of the 63 participants was 17 years, with a mean baseline HbA1c of 8.1%. All 63 participants completed the trial. CLC significantly increased the time in range (TIR) compared to SAP (13% increase with CLC versus 1% decrease with SAP). CLC reduced time >180mg/dl and time <70 mg/dl. There were no significant differences in HbA1c levels between the groups. The closed-loop system was active 89% of the time. There was one case of diabetic ketoacidosis that occurred in the CLC group. Researchers concluded that CLC used for six months was substantial and improve TIR and reduce hypoglycemia in adolescents and young adults with type 1 diabetes.

Grace and Salyer (2022) investigated the relevance of commonly used criteria for rtCGM in patients with T2 diabetes who were receiving less intensive therapy, specifically, fewer than three insulin injections per day and a history of blood glucose testing four times daily. This prospective, interventional, single-arm study included 38 patients and analyzed changes in HbA1c, average glucose, glycemic variability (percent coefficient of variation), and the percentage of TIR (70–180 mg/dL), below range (TBR; <70 mg/dL, <54 mg/dL), and above range (TAR; >180 mg/dL). Secondary outcomes included changes in body weight and body mass index (BMI). Participants included in the analysis had T2 diabetes, HbA1c >7.5%, and were treated with basal insulin, non-insulin injectable antidiabetic medications, oral antidiabetic medications, and/or diet and exercise. Screening occurred at baseline, with follow-up clinic visits at three and six months. A significant reduction in mean HbA1c was observed from baseline to three months (10.1% ± 1.8% to 7.3% ± 1.3%, P < 0.001) and at six months (10.1% ± 1.8% to 7.1% ± 1.2%, P < 0.001). Increases in TIR and reductions in TAR were noted across all groups, although no significant changes in glycemic variability were identified. All participants maintained TBR targets throughout the study period. Additional reductions were observed in weight (103.5 ± 18.2 kg to 100.3 ± 18.6 kg, P = 0.002) and BMI (35.6 ± 7.4 to 34.5 ± 6.3, P = 0.002). The authors concluded that, despite the study's single-arm design and short duration, intensive insulin therapy requirements and frequent monitoring criteria for CGM coverage are not relevant. They recommend expanding access to CGM for patients with type 2 diabetes who are treated with less intensive therapies.

Beck et al (2023) conducted a meta-analysis of randomized controlled trial (RCT) outcomes on the effects of the hybrid closed loop Control-IQ technology (Control-IQ) in subgroups based on baseline characteristics such as race and ethnicity, social economic status (SES), pre-study insulin delivery modalities (pump or multiple daily injections) and baseline glycemic control. Data were pooled and analyzed from three RCTs comparing Control-IQ to a Control group using CGM in 369 participants

with T1 diabetes from age 2 to 72 years old. TIR 70–180 mg/dL in the Control-IQ group (n = 256) increased from 57% – 17% at baseline to 70% – 11% during follow-up, and in the Control group (n = 113) was 56% – 15% and 57% – 14%, respectively (adjusted treatment group difference = 11.5%, 95% confidence interval +9.7% to +13.2%, P < 0.001), an increase of 2.8 h/day on average. Significant reductions in mean glucose, hyperglycemia metrics, hypoglycemic metrics, and HbA1c were also observed. A statistically similar beneficial treatment effect on time in range 70–180 mg/dL was observed across the full age range regardless of race-ethnicity, household income, pre-study continuous glucose monitor use, or pre-study insulin delivery method. Participants with the highest baseline HbA1c levels showed the greatest improvements in TIR and HbA1c. The pooled analysis of Control-IQ RCTs demonstrated the beneficial effect of Control-IQ in T1 diabetes across a broad spectrum of participant characteristics (e.g., racial-ethnic minority, lower SES, lack of pre-study insulin pump experience, and high HbA1c levels). The most benefit was observed in participants with the worst baseline glycemic control in whom the auto-bolus feature of the Control-IQ algorithm has substantial impact. No subgroups were identified that did not benefit from Control-IQ, hybrid-closed loop technology. The investigators strongly suggested its use for all youth and adults with T1 diabetes.

Uhl et al (2024) conducted a systematic review and meta-analysis of RCTs on CGM for the management of T2 diabetes in adults ≥18 years older. Objective measures consisted of HbA1c, TIR, hyperglycemia, and hypoglycemia. Findings included 14 randomized trials with 825 individuals using real time CGMs (rtCGM) and 822 using flash CGM. The use of CGM showed modest but statistically significant HbA1c reduction levels of about 0.32%. Separate analysis for each device showed similar HbA1c reductions. Both rtCGM and flash CGMs led to a modest but significant decline in HbA1c for T2 individuals.

Gupta et al (2024) investigated the effect of short-term application of rt and isCGMS in individuals with T1D. They measured HbA1c levels over a period of 3 months. T1 diabetic individuals were randomized into three groups in a ratio of 1:1:2, Group A (rtCGMS for 2 weeks initially, followed by isCGMS for 2 weeks at 3 months), Group B (isCGMS for 2 weeks initially followed by rtCGMS for 2 weeks at 3 months) and Group C (only self-monitoring of blood glucose), respectively. The HbA1c was measured at baseline, 3, and 6 months. Out of a total 68 T1 diabetic individuals, HbA1c decreased significantly in groups A and B at 6 months compared to the baseline, but not in group C. HbA1c was significantly lower in Group A compared to Group C at 3 and 6 months. Fructosamine levels significantly decreased in Group B before and after cross-over. Switching from isCGMS to rtCGMS led to significant improvement in glycemic variability indices. Authors concluded that intermittent application of CGMS for 2 weeks improves short- and long-term blood glucose control in T1 diabetes.

PROFESSIONAL GUIDELINE(S)

The American Diabetes Association (ADA) Professional Practice Committee published an updated Standards in Medical Care in Diabetes 2025, with a chapter dedicated to diabetes in technology, acknowledging the rapid evolution and complexity of new devices that can improve the lives and health of people with diabetes, but can be barriers to implementation for not just people with

diabetes, but for their care partners and their dedicated health care team.

The ADA published 32 recommendations in the report, which consistently stated throughout that device selection should be made based on the individual's circumstances, preferences, skill level, and needs. The recommendations include, but are not limited to the following:

1. "Diabetes devices should be offered to people with diabetes (A);
2. Initiation of continuous glucose monitoring (CGM) should be offered to people with type 1 diabetes early in the disease, even at time of diagnosis (A);
3. When prescribing a device, ensure that people with diabetes and caregivers receive initial and ongoing education and training, either in person, or remotely, and ongoing evaluation of technique, results, and the ability to utilize data, including uploading or sharing data (if applicable) to monitor and adjust therapy (C);
4. People with diabetes who have been using CGM, continuous subcutaneous insulin infusion and/or automated insulin delivery (AID) for diabetes management should have continued access across third-party payors regardless of age or A1C levels (E);
5. Recommend early initiation, including at diagnosis, of CGM, CSII, and AID depending on a person's or caregiver's preferences (C);
6. People who are taking insulin and using BGM should be encouraged to check their blood glucose levels when appropriate based on their insulin therapy. This may include checking when fasting, prior to meals and snacks, after meals, at bedtime, in the middle of the night, prior to, during, and after exercise when hypoglycemia is suspected, after treating low blood glucose levels until they are normoglycemic, when hyperglycemia is suspected, and prior to and while performing critical tasks such as driving (B);
7. Although BGM in people on noninsulin therapies has not consistently shown clinically significant reductions in A1C levels, it may be helpful when modifying meal plans, physical activity plans, and/or medications (particularly medications that can cause hypoglycemia) in conjunction with a treatment adjustment program (E);
8. Recommend real-time CGM (rtCGM) (A) or intermittently scanned CGM (isCGM) (B) for diabetes management to youth (C) and adults (B) with diabetes on any type of insulin therapy.
9. Consider using rtCGM or isCGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals (B).
10. CGM can help achieve glycemic goals (e.g., time in range and time above range) (A) and A1C goal (B) in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy;
11. In circumstances when consistent use of CGM is not feasible, consider periodic use of personal or professional CGM to adjust medication and/or lifestyle (C);

12. Skin reactions, either due to irritation or allergy, should be assessed and addressed to aid in successful use of devices (E);
13. AID systems should be the preferred insulin delivery method to improve glycemic outcomes and reduce hypoglycemia and disparities in youth and adults with type 1 diabetes and other types of insulin-deficient diabetes who are capable of using the device (either by themselves or with a caregiver) (A);
14. Insulin pump therapy, preferably with CGM, should be offered for diabetes management to youth and adults on multi-dose insulin with type 2 diabetes who can use the device safely (either by themselves or with a caregiver) (A)."

The ADA addresses insulin delivery systems in Chapter 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes- 2025, and includes insulin patches as a proper administration technique, stating that selection of method of administration will depend on a variety of individual-specific factors and needs, cost and coverage, and individual preferences.

In 2025, the Endocrine Society and European Society of Endocrinology published a joint clinical practice guideline regarding preexisting diabetes and pregnancy, which includes, but is not limited to the following:

- Despite being limited direct evidence of superiority of CGM use, it may offer a potential advantage over SBMG in certain subgroups of preexisting T2 diabetes, and therefore pregnant individuals with T2 diabetes should be considered for either CGM or SMBG.
- The standard of care pregnancy glucose targets of fasting <95mg/dl (5.3mmol/L), one-hour post prandial <140mg/dl (7.8 mmol/L), two-hour post prandial <120 md/dl (6.7mmoL)should be used rather than a single CGM target in individuals with pre-existing diabetes mellitus.

The Management of Individuals with Diabetes at High Risk for Hypoglycemia Endocrine Society Clinical Practice Guideline was published by McCall and colleagues in 2022. The recommendations include:

- CGM is preferred over SMBG for patients with T1 diabetes receiving multiple daily injections;
- rtCGM and algorithm-driven insulin pumps should be utilized for adults and children with T1 diabetes, instead of multiple daily injections and SMBG;
- rtCGM is suggested for outpatients with T2 diabetes who take insulin and/or sulfonylureas and are at risk for hypoglycemia.

The American Association of Clinical Endocrinology (AACE) Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons with Diabetes Mellitus was published by Grunberger G et al in 2021. AACE addresses the following:

- The glucose metrics to be utilized in clinical practice to assess glycemic status;
- Identification of those who would benefit from diabetes technologies, including but not limited to CGM use for all individuals with problematic hypoglycemia, CGM may be recommended for

women with gestational diabetes mellitus who are not on insulin therapy and also that CGM may be recommended for individuals with T2 diabetes who are treated with less intensive insulin therapy (Grade B);

- The most efficient approach to interpreting continuous glucose monitoring data;
- Diagnostic/professional CGM considerations;
- Insulin delivery techniques;
- Safety considerations for the use of diabetes technology including CGMs, insulin delivery devices, integrated devices, open-source automatic insulin-dosing systems not approved by the U.S. Food and Drug Administration;
- The implementation of diabetes technologies to clinical practice.

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."

A 2017 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 (Agiostratidou et al). 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 above identified steering committee defined three levels of hypoglycemia:

- Level 1 hypoglycemia 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 a forementioned level 1 or 2 for hypoglycemia.

REGULATORY STATUS

The New York State Insurance Laws require a medical expense indemnity corporation or a health service corporation which provides medical coverage that includes coverage for physician services in a physician's office and every policy which provides major medical or similar comprehensive type coverage to include coverage of certain equipment and supplies for the treatment of diabetes when recommended or prescribed by a physician or other licensed health care provider. Additionally, coverage must include diabetes self-management education, limited to visits medically necessary upon the diagnosis of diabetes, where a physician diagnoses a significant change in the patient's symptoms or conditions which necessitate changes in a patient's self-management, or where reeducation or refresher education is necessary.

The U.S. Food and Drug Administration (FDA) regulates CGMS and external insulin pumps as medical devices. All CGMS and external insulin pumps including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Nov 11]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Nov 11]

I. Examples of FDA approved external insulin pumps include, but are not limited to the following:

Brand Name	Manufacturer
MiniMed 770G with SmartGuard technology	Medtronic
MiniMed 780G System	Medtronic
Omnipod	Insulet Corp.
CeQur Simplicity	CeQur
iLet Bionic Pancreas System	Beta Bionics
Omnipod 5	Insulet Corp.
Omnipod Dash	Insulet Corp.
t:slim X2 Insulin Pump with Control-	Tandem Diabetes Care

IQ	
twist	Sequel
V-Go	Zealand Pharma

II. Examples of FDA approved CGM devices include, but are not limited to:

Brand Name	Manufacturer	Approved for:	Sensor	Transmitter	Receiver
DexCom G6	DexCom, Inc.	Individuals ≥ two (2) years (not for use in pregnant women, people on dialysis, or critically ill patients)	Three per 30 days	Four per 360 days	One per year
DexCom G7	DexCom, Inc.	Individuals ≥ two (2) years (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 Diabetes	Individuals ≥14 years	Four per 30 days	One per year	NA
Guardian Sensor 3 with Guardian Link 3 transmitter	Medtronic Diabetes	Individuals > 2 with Medtronic 770G system, 7+ with Medtronic 670G system	7 days	Rechargeable	N/A
FreeStyle Libre 2 system	Abbott Diabetes Care	Individuals ≥ four (4) years	Two per 28 days	N/A	One per one year
FreeStyle Libre 14 Day System	Abbott Diabetes Care	Individuals ≥18 years (not for use in pregnant women)	Two per 28 days	N/A	One per one year

FreeStyle Libre 3	Abbott Diabetes Care	Children, adolescents, and adults ≥ two (2) years	Two per 28 days	N/A	One per year
FreeStyle Libre 3 Plus	Abbott Diabetes Care	Individuals ≥ 4 years	Two per 28 days	N/A	One per year
Eversense	Senseonics Holdings, Inc.	Individuals ≥18 years	One per 90 days	One per year	NA
Eversense E3	Senseonics Holdings, Inc.	Individuals ≥18 years	One per 180 days	One per year	NA

III. Examples of FDA approved external insulin pump/continuous glucose monitoring systems include, but are not limited to:

Brand Name	Manufacturer	Approved for:
Minimed 630G System	Medtronic	Individuals ≥ seven (7) years
Minimed 770G System	Medtronic	Individuals ≥ two (2) years
Minimed 780G System	Medtronic	Children and adults with type 1 diabetes Type 2 insulin treated diabetics ≥ 18 years
T-slim with Control-IQ technology/Dexcom G6	Tandem Diabetes Care, Inc.	Individuals ≥ six (6) years
iLet Bionic Pancreas	Beta Bionics	Individuals ≥6 years of age with type 1 diabetes

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational

- (NMN)=Not medically necessary/appropriate

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 glucose 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

Code	Description
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
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)
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)
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 (e.g., 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
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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SEARCH TERMS

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.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Infusion Pumps (280.14) [accessed 2025 Nov 18]

LCD - Glucose Monitors (L33822) [accessed 2025 Nov 18]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do

not apply.

- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION	
Committee Approval Dates	
10/18/18, 08/15/19, 04/16/20, 05/20/21, 05/19/22, 05/18/23, 05/16/24, 05/22/25, 12/18/25	
Date	**Summary of Changes**
12/18/25	• Annual Review. Expanded criteria for insulin pump requests to include members who use continuous glucose monitoring rather than finger sticks. Policy criteria updated to remove insulin dependency requirements; disposable external insulin pumps are no longer investigational.
05/22/25	• Annual policy updated. Policy statement I.A.3 initial request for external insulin pump medically necessary indication for self-testing of glucose changed from four times a day to three times per day and prior initiation requirement from two months to one month for the initiation of the insulin pump. Updated policy statement VI replacement of CGMS device. Added a new policy statement for replacements of CGM sensors.
01/01/25	• Summary of changes tracking implemented.
08/17/17	• Original effective date