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	May 22, 2025
Next Review Date	May 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. Basic 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;
4. Completed a comprehensive diabetes education program;
5. Diabetes is poorly controlled despite best practices (please refer to Policy Guideline II).

B. Basic 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.

II. Replacement External Insulin Pump

A. Replacement of an external insulin pump is **medically appropriate** when **ALL** of 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;
2. The pump has exceeded its warranty (warranty period for insulin pumps: four (4) years) and the pump is malfunctioning.

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

1. Pump slightly damage (e.g., scratched screen);

2. Damage does not cause the pump to malfunction; or
3. Replacement driven by advancement in technology.

III. Nonprogrammable Disposable Insulin Delivery Systems (e.g., the V-Go disposable insulin delivery device) are considered **investigational.**

IV. 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 diabetes requiring insulin, who meet **BOTH** of the following criteria:

1. Requires insulin (e.g., receives daily injections of insulin or uses an external insulin pump);
2. The age of the individual 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 criteria for CGM and **ONE** of the following indications:

1. Physical disability, such as an impairment in vision, hearing, or dexterity;
2. A severe sensitivity to adhesives or plastics used in transcutaneous CGM components;
3. Any significant condition or situation requiring vibration alerts (e.g., individual lives alone and requires additional alarms to increase awareness of highs or lows).

V. Short Term Use (three (3) to seven (7) days) of Continuous Glucose Monitoring Device (CPT 95249, 95250, 95251)

A. Short term (three to seven days) use of CGM device is **medically appropriate** for **EITHER** of the following indications (1a or 2a):

1. Insulin dependent diabetic individual whose diabetes is poorly controlled despite current evidence of best practices; and
   a. compliance with recommended medical regimens (please refer to Policy Guidelines I and II); **or**
2. In women with type I diabetes who are pregnant or about to become pregnant; and
   a. who cannot meet recommended targets for control of diabetes in pregnancy.

VI. Replacement of CGMS Device Transmitter (HCPCS: A9277, E2021)

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

1. The CGM device has been previously approved by the Health Plan; **or**

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

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

A. Replacement of CGM sensor is **medically appropriate** in **EITHER** scenario:

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.

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

A. External insulin pump and 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 an external insulin pump **AND** a CGM device have been met.

IX. Replacement of a Combined External Insulin Pump and CGMS Device (Artificial Pancreas):

A. Replacement of an external insulin pump and CGM device is **medically appropriate** when **BOTH** 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

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Documentation of best practices in diabetes control for individuals with diabetes include compliance with a regimen of three (3) or more fingerstick each day and use of an insulin pump.

II. During pregnancy, documentation of three (3) or more insulin injections daily for individuals not on an insulin pump prior to the pregnancy.

III. Prior use of a short term (three (3) to seven (7) days) glucose monitor would be considered a part of best practices for those considering use of a CGM device.

IV. 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.

V. 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).

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

VII. 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**.

VIII. The MiniMed 630G system (artificial pancreas device) was approved by the FDA for use by individuals with type I diabetes aged ≥ seven (7) years.

IX. The Minimed 770G System was approved by the FDA for use in individuals with type I diabetes aged ≥ two (2) years.

X. The Dexcom G6 CGM was approved by the FDA for non-pregnant diabetic adults and pediatric individuals aged ≥ two (2) years.

XI. The Dexcom G7 CGM was approved by the FDA for pregnant diabetic adults and pediatric individuals aged ≥ two (2) years.

XII. The FreeStyle Libre Flash CGM was approved by the FDA for non-pregnant diabetic individuals aged ≥ 18 years.

XIII. The FreeStyle Libre 2 System ≥ CGM was approved by the FDA for individuals aged ≥ four (4) years.

XIV. The Eversense glucose long term CGM was approved by the FDA for diabetic individuals aged ≥ 18 years.

XV. The T-slim X2 insulin pump with Control-IQ system was approved by the FDA for diabetic individuals aged ≥ six (6) years.

DESCRIPTION

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 individual or others. Some individuals 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

External insulin pumps are utilized for continuous subcutaneous insulin infusion (CSII) by diabetic individuals, 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 individual's subcutaneous tissue, usually in the abdomen. After programming, the pump continuously delivers a predetermined amount of insulin to meet the individual'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

CGMS devices are used by diabetic individuals 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 several CGM devices available for use.

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 individuals aged 14 years and older. The Dexcom G6 CGM is the only FDA-approved CGM device approved for diabetic individuals two years and older. The FreeStyle Libre 14 Day CGM device was approved by the FDA for diabetic individuals 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 individuals 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 DexCom G6 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.

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.

SUPPORTIVE LITERATURE

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 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 (aged 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.

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 trials. Participants aged 14 through 24 with type 1 diabetes were randomly assigned (2:1) CLC (tandem control-IQ) or sensor augmented pump (SAP). The mean age of the 63 participants was 17 years old, with a mean baseline HbA1c of 8.1%. All 63 participants completed the trial. CLC significantly increase 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.

Beck et al. (2023) conducted a meta-analysis of RCT outcomes on the effects of the hybrid closed loop Control-IQ technology (Control-IQ) and in subgroup 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 3 RCTs comparing Control-IQ to a Control group using CGM in 369 participants with type 1 diabetes (T1D) from age 2 to 72 years old. Time in range 70–180 mg/dL (TIR) 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 T1D 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 appears to have substantial impact. No subgroups were identified that did not benefit from Control-IQ, hybrid-closed loop technology. Investigator strongly suggest use for all youth and adults with T1D.

Uhl et al. (2024) conducted a systematic review and meta-analysis of randomized controlled trials (RCT) on continuous glucose monitor (CGM) for managing type 2 diabetes clinical outcomes and glucose control. Objective measures consisted of adults ≥18 years older with type 2 diabetes reporting on hemoglobin A1c (HbA1c), time in range, hyperglycemia, and hypoglycemia. Finding included 14 randomized trials with 825 individuals using real time CGM's and 822 using flash CGM (FGM). CGM's use showed a modest but statistically significantly HbA1c reduction levels of about 0.32%. Separate analysis for each device shows similar HbA1c reductions. Both real time continuous glucose monitoring and flash CGM's led to modest but significantly HbA1c declines in type 2 individuals. Researchers suggest longer studies are needed to assess if short-term glucose control improvement led to better outcomes.

Gupta et al. (2024) investigated the effect of short-term application of real-time and intermittently scanned CGMS (rt and is-CGMS) in Type 1 Diabetes Mellitus (T1D) individuals change in HbA1c over 3 months. T1D individuals were randomized into three groups in a ratio of 1:1:2, Group A (rt-CGMS for 2 weeks initially, followed by is-CGMS for 2 weeks at 3 months), Group B (is-CGMS for 2 weeks initially followed by rt CGMS for 2 weeks at 3 months) and Group C (only self-monitoring of blood glucose), respectively. HbA1c at baseline, 3, and 6 months were compared. Out of a total 68 T1D 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 is-CGMS to rt CGMS led to significant improvement in glycemic variability indices. In addition, intermittent application of CGMS for 2 weeks improves short- and long-term blood glucose control in T1D.

PROFESSIONAL GUIDELINE(S)

The American Diabetes Association Standards in Medical Care in Diabetes (2021) state:

- 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 individuals 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) in Diabetes, 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) in individuals with type 1 diabetes mellitus (T1DM) who have not achieved their A1C goal, and in T1DM individuals

who have achieved their A1C goal but continue to experience severe hypoglycemia or high glucose variability, as long as the individual and caregivers are willing and able to use the device. For individuals 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 individuals with T1DM who have A1C levels above target, and in adult individuals 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 individuals 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 Individuals with Diabetes (Grunberger, et al., 2018) recommended that personal CGM devices ideally be considered in all individuals with T1DM, especially those with a history of severe hypoglycemia or hypoglycemia unawareness, and to assist in the correction of hyperglycemia in individuals not at goal. The benefits of CGM in individuals with T2DM have not been investigated to the same degree. CSII is appropriate in individuals with T1DM who are not at glycemic goal, despite adherence to the maximum multi-dose injections, in special population of individuals with T1DM (e.g., pregnant women, children, adolescents, and competitive athletes), and in individuals with T1DM who feel that CSII would help them achieve and maintain glycemic targets. Select individuals with insulin-dependent T2DM and C-peptide positivity with suboptimal control on maximal basal/bolus injections, substantial "dawn phenomenon," erratic lifestyle, or severe insulin resistance may benefit from CSII, as well as select individuals with other DM types (e.g., post pancreatectomy).

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 individuals with diabetes. Blood glucose monitors (BGM) and CGM devices are intended to empower individuals to manage glucose levels and reduce the risk of hypoglycemia. Clinical practice guidelines from all major diabetes organizations recommend routine BGM for individuals with type 1 diabetes. Most of the guidelines recommend CGM devices for individuals with a history of severe hypoglycemia, or hypoglycemia unawareness as well as, for individuals not at goal based on A1c. Many pediatric individuals 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 committee feedback.

The above identified 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 a forementioned level 1 or 2 for hypoglycemia.

REGULATORY STATUS

I. Examples of FDA approved basic external insulin pumps including but 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.

II. Examples of FDA approved CGM devices including, but are not limited to the following:

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 plc	Individuals ≥14 years	Four per 30 days	One per year	NA
Freestyle Libre system	Abbott Diabetes Care, Inc.	Individuals ≥ four (4) years	Two per 28 days	N/A	One per one year
FreeStyle Libre 2 system	Abbott Diabetes Care, Inc.	Individuals ≥ four (4) years	Two per 28 days	N/A	One per one year
FreeStyle Libre 14 Day System	Abbott Diabetes Care, Inc.	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 Inc.	Children, adolescents, and adults ≥ two (2) 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
T-slim with Control-IQ technology/Dexcom G6	Tandem Diabetes Care, Inc.	Individuals ≥ six (6) years

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

Code	Description
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

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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
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)

Code	Description
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-	Unspecified pre-existing diabetes mellitus in pregnancy, childbirth and the

Code	Description
O24.33	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 Apr 22]

LCD - Glucose Monitors (L33822) [accessed 2025 Apr 22]

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

Date	Summary of Changes
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