Insulin Delivery Systems and Continuous Glucose Monitoring

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Diabetes mellitus, commonly known as diabetes, is a chronic medical condition characterized by elevated blood glucose levels. This can occur due to insufficient insulin production by the pancreas, an organ located in the abdomen, or the body's inadequate response to insulin. Insulin is a hormone that enables glucose to enter cells, providing them with energy. In diabetes, blood sugar accumulates due to a lack of insulin or the body's improper response to it. Diabetes is classified into two main types:

- Type 1 diabetes: The pancreas produces little or no insulin.
- Type 2 diabetes: The body's cells do not respond effectively to insulin, and sometimes the pancreas does not produce enough insulin.

Managing diabetes necessitates regular monitoring and treatment, which often includes lifestyle adjustments, self-care, and medication to regulate blood glucose levels and reduce the risk of complications. Plan members diagnosed with Type 1 or Type 2 diabetes who meet specific medical necessity criteria and adhere to the American Diabetes Association (ADA) standards of care may be eligible for certain supplies and equipment covered by the plan, such as blood sugar monitoring tools

and insulin injection devices. Those with advanced disease or requiring more frequent insulin administration may qualify for continuous glucose monitoring and specialized insulin delivery systems.

- For details on the medical necessity criteria for medical nutrition counseling, refer to the Plan Clinical Guideline: Medical Nutrition Therapy (CG010).
- For information on the medical necessity criteria for diabetes equipment and supplies, consult the Plan Clinical Guideline: Diabetes Equipment and Supplies (CG028). A prescription or recommendation from a physician or licensed healthcare professional is required for diabetic supplies and equipment.
- The Plan also covers home glucose monitors and self-monitoring blood sugar products as an alternative to continuous glucose monitors (CGMs). To obtain a standard blood glucose meter from the preferred brand, please contact CVS/Caremark, the Plan's Prescription Benefit Manager.

Definitions

"Artificial Pancreas" devices are closed-loop, integrated continuous blood glucose monitor and insulin delivery system. Special built-in software measures the blood glucose similar to continuous glucose monitoring and automatically releases a specified amount of insulin in real-time and without patient interaction. The system may also have a glucagon administration component for episodes of hypoglycemia for which it is then referred to as a bihormonal, fully-automated artificial pancreas.

"Basal Rate" is the steady flow at which low levels of short-acting insulin are released to control blood glucose between meals and during sleep; this measurement ranges by time of day and is used in insulin pumps.

"Blood Glucose" is the main sugar found in the blood and the body's main source of energy. It is also called glucose or blood sugar. The blood level of glucose is noted in milligrams per deciliter (mg/dL). When blood sugar is too high for long periods of time, complications can occur as a result of blood vessel damage.

"Blood Glucose Monitors" are small, portable machines used to check blood glucose levels in the ambulatory setting. A member will prick his/her fingertip and place a small sample of blood into the device for a glucose reading. There are a number of different types of blood glucose monitors for specialized situations, such as those for members with visual impairments.

"Bolus" is an extra amount of insulin taken to cover an expected rise in blood glucose, often related to a meal or snack.

"Cartridge" (or a reservoir) holds the insulin and is locked into an external continuous subcutaneous insulin infusion pump device.

"Continuous Glucose Monitoring (CGM)" serves as an alternative to self-monitoring of blood glucose (SMBG) with a home glucose monitor for patients who have diabetes and require multiple daily measurements.

"Disposable Insulin Infusion Pumps" are insulin-delivery devices that consist of disposable components. Both the OmniPod and V-Go insulin delivery systems have disposable components, but they differ in that the OmniPod system is programmable, whereas the V-Go system is non-programmable.

"External Continuous Subcutaneous Insulin Infusion (CSII) Pumps" or **"Insulin Infusion Pumps"** are non-implantable insulin-delivery devices that can be worn on a belt, kept in a pocket, or attached directly to the skin. An insulin pump connects to narrow, flexible plastic tubing that ends with a needle inserted just under the skin. Users set the pump to give a basal amount of insulin continuously throughout the day. Pumps release bolus doses of insulin (several units at a time) at meals and at times when blood glucose is too high, based on programming done by the user. Insulin infusion pumps serve as an alternative to multiple daily injections of insulin. The infusion cannula should be changed every 2-3 days to avoid lipid hypertrophy at the infusion site. Insulin infusion pumps can be differentiated by programmable/non-programmable, disposable/reusable, and subcutaneous/transdermal/implantable.

"Flash Glucose Monitoring" refers to glucose monitoring that does not have an alarm, does not require self-monitoring of blood glucose (SMBG), and functions intermittently and on-demand rather than continuously (e.g., FreeStyle Libre System).

"Gestational Diabetes Mellitus (GDM)" is a type of diabetes mellitus that develops only during pregnancy and usually disappears upon delivery, but increases the risk that the mother will develop diabetes later. GDM is managed with meal planning, activity, oral agents, and, in some cases, insulin.

"Hemoglobin A1c (HbA1c)" is a test that measures a person's average blood glucose level over the past 2 to 3 months. It is also known as "A1C" or "glycosylated hemoglobin". A1C should be measured at least twice annually for stable glycemic control and at least quarterly for unstable glycemic control.

A1C test results may be affected by age, certain conditions, ethnicity, genetic traits, and pregnancy; the ADA recommends that treating providers review for discrepancies between A1c results and blood glucose results.

"Hyperglycemia" is excessive blood glucose. Fasting hyperglycemia is blood glucose above a desirable level after a person has fasted for at least 8 hours. Postprandial hyperglycemia is blood glucose above a desirable level 1 to 2 hours after a person has eaten.

"Hypoglycemia Unawareness" is a state in which a person does not feel or recognize the symptoms of hypoglycemia. People who have frequent episodes of hypoglycemia may no longer experience the warning signs of it.

"Hypoglycemia" is a condition that occurs when one's blood glucose is lower than normal, usually less than 70 mg/dL. Signs include hunger, nervousness, shakiness, perspiration, dizziness or lightheadedness, sleepiness, and confusion. If left untreated, hypoglycemia may lead to unconsciousness. Hypoglycemia is treated by consuming a carbohydrate-rich food such as a glucose tablet or juice. It may also be treated with an injection of glucagon if the person is unconscious or unable to swallow.

"Implantable Insulin Pump" is a device similar in function to an external insulin pump, however the components are implanted rather than worn or carried externally.

"Infusion Set" connects the insulin in an external continuous subcutaneous insulin infusion pump delivery device to a person's body. The set consists of narrow, flexible plastic tubing that ends with a needle inserted just under the skin.

"Insulin" is a hormone made by the beta cells of the pancreas. Insulin allows glucose to enter the cells in the body for use in energy production, and when it is inadequate, the sugar remains in the blood leading to diabetes. There are a variety of oral and parenteral medications that can increase insulin production, increase the body's sensitivity to existing insulin and reduce blood sugar. Insulin can also be injected or infused when lifestyle changes and non-insulin medications are inadequate.

"Remote Glucose Monitoring" refers to the transmission of blood glucose readings to an external device, such as the patient's phone, computer, or to a physician/healthcare provider. It can be a standalone device or integrated into the continuous glucose monitor system.

"Type 1 Diabetes" is an autoimmune condition that occurs when the beta cells of the pancreas are unable to produce enough insulin and therefore blood glucose cannot enter cells to be used for energy. Type 1 diabetes is often referred to as "insulin-dependent" because these patients require insulin daily to maintain their blood glucose at acceptable levels.

"Type 2 Diabetes" is a condition that occurs when either the pancreas doesn't produce enough insulin or the body cells become resistant to insulin. Type 2 diabetes is much more common than Type 1, and is often treated with combinations of lifestyle changes and non-insulin medications, although insulin can be required later in the disease course. Many individuals with Type 2 Diabetes are "insulin-requiring".

Clinical Indications

General Criteria

The Plan considers **insulin pump delivery systems or continuous glucose monitoring systems (CGMS) and its components** medically necessary when **ALL** of the following general criteria are met **AND** the medical necessity criteria for the devices below are met:

1. The requested product has received U.S. Food and Drug Administration (FDA) approval/clearance **AND** is age-appropriate for the member; ***AND***
2. The member has a diagnosis of diabetes mellitus; ***AND***
3. Recent clinical documentation[ɳ] within the last six (6) months is provided showing **ALL** of the following:
    a. A prescription for the requested product with **ALL** of the following:
        i. Product to be dispensed; ***and***
        ii. Quantity to be dispensed (or frequency of testing); ***and***
        iii. Prescriber's signature and date; ***and***
    b. Hemoglobin A1c test results.

    NOTE: [ɳ]All of the above documentation must be updated every 6 months to show compliance with treatment options. If any of the required documentation is more than 6 months old, it must be updated as soon as possible before any renewal request for coverage.
4. Additional criteria, as outlined below, must also be met depending on the specific equipment and supplies requested:

External Insulin Pump Delivery Systems Criteria

- ➔ *For members who have been on an external insulin pump delivery system prior to enrollment with the Plan, please see* Continued Care Criteria *below.*
- ➔ *For a replacement, see* Replacement Insulin Pumps Criteria *below.*

The Plan considers **non-implantable insulin infusion pumps and supplies** medically necessary when **ALL** of the following criteria are met:

1. The "General Criteria" for equipment and supplies above are met; ***AND***
2. Prescribed by or in consultation with an endocrinologist***; AND***
3. Chart documentation is provided for the member showing **ALL** of the following:
    a. Diagnosis of type 1 or type 2 diabetes mellitus with uncontrolled hyperglycemia***; and***
    b. Is beta cell autoantibody positive **OR** insulinopenic, as confirmed by **BOTH** of the following:
        i. A fasting C-peptide level measured with a concurrently obtained fasting glucose less than or equal to (≤) 225 mg/dL; ***and***
        ii. The measured fasting C-peptide level meets **ONE** of the following:
            1. is undetectable (absolute insulin deficiency)***; or***
            2. is less than or equal to 110% of the lower limit of normal established by the laboratory***; or***
            3. is less than or equal to 200% of the lower limit of normal established by the laboratory AND the member has documentation of renal insufficiency and creatinine clearance less than or equal to (≤) 50 ml/minute; ***and***
    c. At least **ONE** of the following:
        i. A child, where multiple daily insulin injections would be impractical or inappropriate***; or***
        ii. Complications of inadequate glycemic control (e.g., neuropathy, nephropathy, retinopathy) indicative of more intensive insulin regimens***; or***
        iii. Dawn phenomenon unresponsive to management with long-acting insulin agents (e.g., insulin glargine or detemir)***; or***
        iv. For initial requests, HbA1c greater than 7% or above individualized target, despite an adequate regimen of multiple daily injections***; or***
        v. Hypoglycemic episodes requiring third-party assistance (e.g., seizure, loss of consciousness, glucagon administration, transport to an emergency room, hospitalization)***; or***
        vi. Recurrent hypoglycemia (<60 mg/dL on at least two occasions despite adherence to recommended diabetic treatment plan)***; or***

vii. Pregnancy or planning for pregnancy; ***or***
[NOTE: Earlier initiation of insulin infusion pumps may be indicated in women at high risk of fetal or maternal complications of diabetes and pregnancy.]

viii. Wide swings in blood glucose values before meal time (e.g., regular fluctuations of preprandial blood glucose to levels <60 mg/dL and/or >140 mg/dL); ***and***

d. Completion of a comprehensive diabetes education program***; and***
e. Currently uses three (3) or more insulin injections daily***; and***
f. History of frequent self-adjustments of insulin doses for at least 6 months prior***; and***
g. Self-monitors blood glucose at least three (3) times per day (e.g., before meals and at bedtime) for the immediate two (2) months prior***; and***
h. Member or designated caregiver can be adequately trained and is motivated to adhere to blood glucose monitoring at least 3 times per day, or the member qualifies for continuous glucose monitoring***; and***
i. Provider team (e.g., physician, nurses, diabetes educators, and dietitians) is experienced in the management and support of patients with insulin infusion pumps.

When **BOTH** the General Criteria and External Insulin Pump Delivery Systems Criteria above are met **OR** were previously met and the member has a continued documented need for an insulin pump delivery system, the Plan considers the following quantities medically necessary:

Table 1: External Insulin Pump Delivery Systems & Supplies Medically Necessary Quantities

Insulin Infusion Supply	Quantity‡ Per 3 Months	Quantity‡ Per 1 Year
Infusion set (A4230, A4231)	45	180
Supplies for maintenance of insulin infusion pump (A4226)	13	52
Needles or syringes (A4206, A4215, A4232)	60	240
External ambulatory infusion pump, insulin (E0784)	-	1 per 4 years (unless malfunctioning and/or out of warranty)
External ambulatory infusion pump, insulin, using therapeutic continuous glucose sensing (E0787)	-	1 per 4 years (unless malfunctioning and/or out of warranty)
Cartridges or syringe reservoirs (S5565-S5566, J1817)	30	120

Sterile insertion-site dressing (i.e., Tegaderm) (A6257)	45 / 3 boxes	180

[$]Quantities are suggested guidance and are subject to review of the medical record and prescription. Requests that exceed the suggested quantity must be submitted with clinical documentation of medical necessity.

Replacement Insulin Pump Delivery Systems Criteria

Replacement Insulin Pump Delivery Systems are considered **NOT** medically necessary for the purpose of adding convenience features or new technologies (e.g., adding a wireless communication system to the glucose monitor). Replacement insulin pumps are considered medically necessary when recent chart documentation (within last 6 months) indicates **ALL** of the following:

1. the member continues to meets the **General Criteria** above***; AND***
2. the member has demonstrated adherence to diabetes management and use of devices***; AND***
3. The request is for **ONE** of the following:
    a. A pediatric member requiring a replacement pump with larger insulin reservoir due to growth***; or***
    b. Replacement of a malfunctioning pump that is no longer under warranty OR cannot be refurbished and restored to fully functional order.

Continuous Glucose Monitoring (CGM) Systems[#] Criteria

[#]This includes Professional Diagnostic CGM (also known as Short-Term CGMS), as well as real-time CGM (rtCGM) and intermittently scanned CGM (isCGM) devices, which are occasionally called "flash" CGM systems. Implantable Glucose Monitoring systems, like Eversense and Eversense E3 CGM System, are not included (please see below for criteria specifically related to Implantable Glucose Monitoring systems, such as Eversense and Eversense E3 CGM System).

➔ *For members who have been on a CGM prior to enrollment with the Plan, please see* **Continued Care Criteria** *below.*

The Plan considers **Continuous Glucose Monitoring Systems and its components**[#] medically necessary when the member meets ALL of the following criteria:

1. The "**General Criteria**" for equipment and supplies above; ***AND***
2. Documented diagnosis of diabetes mellitus; ***AND***
3. At least **ONE** of the following:
    a. Long-term continuous glucose monitoring is needed for the member's diabetes management, as evidenced by clinical documentation in the past 6 months showing:

i. The member has documented adherence to diabetic treatment plan and can be trained to use a CGM; ***and***

ii. The member consistently checks blood glucose at least 3 times daily; ***and***

iii. The member meets at least ONE of the following:

1. Type 1 diabetes; ***or***
2. Type 2 diabetes treated with basal insulin who have hemoglobin A1c above goal, despite appropriate changes in insulin therapy and compliance with the treatment plan; ***or***
3. On intensive insulin therapy, defined as 3 or more injections of insulin per day or the use of an insulin pump; ***or***
4. Pregnant; ***or***
5. Problematic hypoglycemia, defined as having a history of:
    a. Frequent/severe hypoglycemia; ***or***
    b. Nocturnal hypoglycemia; ***or***
    c. Hypoglycemia unawareness; ***or***
    d. Severe hypoglycemia (≥2 episodes with blood glucose <54 mg/dL in the past 30 days); ***or***

b. Short-term CGM is necessary, as indicated by **BOTH** of the following:

i. Additional information on blood glucose levels is needed, as indicated by at least **ONE** of the following:

1. Dawn phenomenon, known or suspected; ***or***
2. Hypoglycemic unawareness; ***or***
3. Nocturnal hyperglycemia, known or suspected; ***or***
4. Postprandial hyperglycemia, known or suspected; ***or***
5. Significant change to the treatment regimen, such as starting insulin or transitioning from multiple daily doses to an insulin pump; ***or***
6. Unexplained hyperglycemia; ***and***

ii. Monitoring is limited to a maximum of three (3) to 14 days and for no more than 2 episodes within a 12-month period.

Implantable Glucose Monitoring (e.g., Eversense, Eversense E3 CGM System)

➔ *For members who have been on this implantable glucose monitor prior to enrollment with the Plan, please see* Continued Care Criteria *below.*

The Plan considers the initial request for long term (90-180 days) FDA approved or cleared **implantable glucose monitoring** medical necessary when **ALL** of the following criteria are met:

1. The "General Criteria" for equipment and supplies above are met; ***AND***

2. Diagnosis of Type 1 or 2 diabetes mellitus; ***AND***
3. The member is age 18 years or older; ***AND***
4. The member has inadequate glycemic control despite compliance, with trial and failure of **ONE** of the below:
    a. Standard blood glucose monitors with frequent self-monitoring finger sticks; ***or***
    b. Flash glucose monitoring; ***or***
    c. Continuous glucose monitoring (non-implantable); ***or***
    d. Allergy to adhesive or other materials in non-implantable CGM devices; ***AND***
5. The insertion of the glucose sensor in the upper arm will be conducted by a healthcare practitioner; ***AND***
6. Long-term continuous glucose monitoring is needed for the member's diabetes management, as evidenced by clinical documentation in the past 6 months showing:
    a. The member has documented adherence to diabetic treatment plan and can be trained to use a CGM; ***and***
    b. The member consistently checks blood glucose at least 3 times daily; ***and***
    c. The member meets at least ONE of the following:
        i. Type 1 diabetes; ***or***
        ii. Type 2 diabetes treated with basal insulin who have hemoglobin A1c above goal, despite appropriate changes in insulin therapy and compliance with the treatment plan; ***or***
        iii. On intensive insulin therapy, defined as 3 or more injections of insulin per day or the use of an insulin pump; ***or***
        iv. Problematic hypoglycemia, defined as having a history of:
            1. Frequent/severe hypoglycemia; ***or***
            2. Nocturnal hypoglycemia; ***or***
            3. Hypoglycemia unawareness; ***or***
            4. Severe hypoglycemia (≥2 episodes with blood glucose <54 mg/dL in the past 30 days); ***AND***
7. The member does not have any of the following contraindications:
    a. Critically ill or hospitalized***; or***
    b. Expecting to undergo an MRI (magnetic resonance imaging) procedure within 90-days for Eversense or 180-days for Eversense E3 (Eversense sensor and transmitter are incompatible and must be removed before MRI procedure)***; or***
    c. Has another active implantable device, e.g., an implantable defibrillator (passive implants are allowed, e.g., cardiac stents)***; or***

d. History of dexamethasone or dexamethasone acetate contraindication, or allergies to systemic glucocorticoids***; or***
e. Need mannitol or sorbitol intravenously, or as a component of an irrigation solution or peritoneal dialysis solution***; or***
f. Pregnant or nursing***; or***
g. Receiving immunosuppressant therapy, chemotherapy, or anticoagulant therapy.

When the **General Criteria**, along with the criteria for **Continuous Glucose Monitoring (CGM) Systems OR Implantable Glucose Monitoring**, are satisfied, or have been satisfied in the past, and the member demonstrates an ongoing documented need for a CGM, the Plan deems the following quantities to be medically necessary:

Table 2[#]: Personal/Long-term CGMS Medically Necessary Quantities

CGM System	FDA-approved or cleared for	Components	Use Life	Quantity[‡] Per	
				3-months	1-year
Dexcom G6	at least two years old	Receiver	1 year	1 per year (unless malfunctioning and/or out of warranty)	
		Sensor	10 days per sensor	9	37
		Transmitter	90 days	1	5
Dexcom G7	at least two years old	Receiver	about 3 years	1 per 3 years (unless malfunctioning and/or out of warranty)	
		Sensor	10 days per sensor	9	37
Freestyle Libre 2	at least four years old	Sensor	14 days per sensor	7	27
		Reader	about 3 years	1 per 3 years (unless malfunctioning and/or out of warranty)	
Freestyle Libre 3	at least four years old	Sensor	14 days per sensor	7	27
Freestyle Libre 14-day	≥18 years old	Sensor	14 days per sensor	7	27

		Reader	about 3 years	1 per 3 years (unless malfunctioning and/or out of warranty)	
Medtronic Guardian Connect	between the ages of 14 and 75 years old	Guardian Sensor 3	7 days per sensor	13	53
		Guardian Connect Transmitter	can be cleaned up to 122 times or one year, whichever comes first	1 per year (unless malfunctioning and/or out of warranty)	
Senseonics Eversense & Eversense E3	≥18 years old	Eversense Sensor *	90 days	1	5
		Eversense E3 Sensor *	up to 180 days	1 per 6 months	2
		Transmitter	1 year	1 per year (unless malfunctioning and/or out of warranty)	

[#]*This is not an exhaustive list. When medical necessity criteria is met for products not listed, quantities for supplies will reflect FDA-approved or cleared indications for use.*

Table 3[#]: Professional Diagnostic/Short-Term CGMS Medically Necessary Quantities

CGM System	FDA-approved or cleared for	Components	Wear Time	Quantity[‡] per 12-month period
Abbott Freestyle Libre Pro	≥18 years old	disposable combined wired glucose sensor/transmitter and a separate touchscreen reader device	14 days	2
Dexcom G6 Pro	2 years and older	disposable wired glucose sensor/transmitter and a separate touchscreen	10 days	2

		reader device		
Medtronic iPro 2	Not specified	disposable wired sensor and a data transmitter, which is attached to the sensor	6 days	2

[#]*This is not an exhaustive list. When medical necessity criteria is met for products not listed, quantities for supplies will reflect FDA-approved or cleared indications for use.*

[‡]*Quantities are suggested guidance and are subject to review of the medical record and prescription. Requests that exceed the suggested quantity must be submitted with clinical documentation of medical necessity.*

Medical Necessity Criteria for Requests to Switch Continuous Glucose Monitoring Systems

➔ *For all other requests, please see* Initial Requests *or* Continued Care Criteria *below*

The Plan considers requests to switch **Continuous Glucose Monitoring Systems** medically necessary if the member meets **ONE** of the following:

1. The member has an allergy or reaction to their current CGM system adhesive or components that is unable to be managed or resolved; ***OR***
2. The member requires a switch to a CGM system compatible with their insulin pump or automated insulin delivery system; ***OR***
3. For members enrolled in an Oscar-designated disease management program - the member requires a switch to a CGMS meeting designated program requirements (i.e., switch their non-Dexcom Glucose Monitor to a Dexcom branded CGM device).

Exception Criteria for Additional Receivers/Readers (*see Table 2: Personal/Long-term CGMS Medically Necessary Quantities*)

The Plan recognizes that there may be situations where an additional receiver/reader for a covered stand-alone Continuous Glucose Monitoring (CGM) system is needed prior to the 3-year replacement period for select products. In such cases, the following criteria must be met:

1. The currently owned receiver/reader must be non-functional and unable to be repaired or replaced by the manufacturer. Documentation should clearly indicate that the receiver/reader is no longer operational and cannot be fixed or replaced.
2. The member or healthcare provider must have made reasonable attempts to troubleshoot and resolve the issue with the non-functional receiver/reader. Documentation should demonstrate the efforts made to troubleshoot the device and the inability to repair or replace it.

NOTE: Replacement is limited to one receiver/reader per 3-year. Exceptions may be considered for special populations, such as children who may accidentally damage the device within the 3-year period. In such cases, documentation should clearly demonstrate that the monitoring needs of the individual cannot be adequately met with the approved replacement limit.

Artificial Pancreas / Hybrid Closed-Loop Insulin Delivery Systems (e.g., MiniMed 630G, 670G, 770G)

➔ *For members who have been on this hybrid insulin system prior to enrollment with the Plan, please see* Continued Care Criteria *below.*

The Plan considers **hybrid, closed-loop insulin delivery systems** medically necessary when **ALL** of the following criteria are met:

1. The "General Criteria" for equipment and supplies above are met; ***AND***
2. The member meets the criteria for a new or replacement "external insulin infusion pump"; ***AND***
3. The member meets the criteria for a new or replacement "continuous glucose monitoring"; ***AND***
4. The member has documented adherence to a diabetic treatment plan and can be trained (or member's guardian) to use the device; ***AND***
5. The requested system is FDA approved or cleared **AND** is being prescribed for use in accordance to the device-specific FDA limitations (when applicable), such as:
    a. Age recommendations or restrictions (e.g., the member must be ≥2 years old diagnosed with type 1 diabetes for MiniMed 770G); ***or***
    b. Contraindication to or interference by medications (e.g., Tylenol [acetaminophen]); ***or***
    c. Hearing or visual impairments prevent recognition of pump signals and/or alarms; ***or***
    d. Daily insulin dosage (units) does not meet minimum dosage requirements for device functionality.

Continued Care Criteria for Continuing Treatment After Initial Trial

The Plan considers **continuous glucose monitoring, insulin delivery systems, hybrid closed-loop insulin delivery systems, removal and replacement of glucose sensor for Eversense** (**including members who have been on the device/monitor prior to enrollment with the Plan**) medically necessary when **ALL** of the following criteria are met:

1. The member continues to meet the **"General Criteria"** above.
2. There is documented provider evaluation within the last 6 months that demonstrates the member's adherence to their diabetic treatment plan and devices. This evaluation should assess the member's compliance with the prescribed treatment regimen and use of the continuous glucose monitoring system, insulin delivery system, hybrid closed-loop insulin delivery system, or Eversense glucose monitoring system.

Experimental or Investigational / Not Medically Necessary

The Plan does not consider medically necessary the replacement or repair of units or associated equipment when lost or damaged due to neglect or improper care.

The following products, supplies, or indications are considered experimental, investigational, or convenience features:

1. Fully-Automated Bihormonal Artificial Pancreas Devices
    a. *Rationale:* At this time, there are no commercially available or FDA approved bihormonal artificial pancreas systems. Several small cross-over studies looking at this device demonstrated a lower mean glucose in the intervention group and fewer episodes of hypoglycemia. However, there have been no long-term safety or efficacy studies, and some of the existing studies have found similar results between single hormone (insulin) and bi-hormonal (insulin and glucagon) systems.
2. GlucoWatch Biographer Monitor (Cygnus Inc.) or any other hypoglycemic wristband alarm (A9280)
    a. *Rationale:* The clinical utility of these devices has not yet been demonstrated in any randomized clinical trials. The MITRE (Minimally Invasive Technology Role and Evaluation) study was a large clinical trial on 400 patients with diabetes on insulin. The study concluded that there was a small, short-term clinical benefit that subsided over time. Furthermore, the Biographer monitor had less impact on HbA1C than both standard treatment and continuous blood glucose monitoring.[20-21, 32, 92, 114]
3. Implantable Insulin Pumps
    a. *Rationale:* There have been studies demonstrating potential clinical benefit of implantable insulin pumps, however they do not currently have U.S. Food and Drug Administration (FDA) approval at this time, and the ADA 2023 guidelines do not mention implantable insulin pumps as a recommended treatment for diabetes.
4. Lasette™ Laser Blood Glucose Monitoring Device or other similar laser lancets
    a. *Rationale*: Evidence for the clinical benefit of laser blood glucose monitoring over standard blood glucose monitoring is limited in the medical literature; therefore, these devices are considered experimental or investigational.
5. Remote Glucose Monitoring (e.g., mySentry, MiniMed Connect, Dexcom Share) is not covered as a separately reimbursable or standalone device or service. Integrated remote glucose monitoring, such as when a CGM device has the ability to share data to a smart phone or through an app, may be considered medically necessary when the clinical criteria for CGM are met.

a. *Rationale:* There is limited evidence that telemonitoring or otherwise sharing glucose values results in an improvement in outcomes. A 2017 study by Lee et al conducted on 107 patients, 54 of which were frequent users of self-telemonitoring and 53 who were not, showed a small but significant difference in A1c values at 6 months. This study was limited by its non-randomized nature, small population, and potential confounding factors. Other studies have shown no benefit of telemonitoring of diabetes patients in terms of glycemic control. The use of standalone devices or telemonitoring services for remote glucose monitoring has yet to be fully explored, and further data is needed to determine if there is any potential benefit to this technology.[123, 124, 126]

6. Subcutaneous insulin infusers, including but not limited to, i-Port
    a. *Rationale:* There is a lack of clinical evidence supporting the use of insulin infusers and diabetes outcomes. Blevins et al (2008) conducted a randomized controlled crossover trial comparing outcomes of i-Port vs. standard insulin injection in 74 patients. A1c levels were similar among all subjects at the initiation and completion of the study, demonstrating no observable clinical benefit. Patients did report that it was more difficult to control their blood sugar levels with standard insulin injections; however the differences were non-significant (p=0.16).[14]

Applicable Billing Codes (CPT/HCPCS/ICD-10 Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
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 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
A4224	Supplies for maintenance of insulin infusion catheter, per week
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
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, nonneedle 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, non-implanted 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
A6257	Transparent film, sterile, 16 sq in or less, each dressing
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories [medically necessary when programmable] *[NOTE: Omnipod Dash has been available only under the pharmacy benefit as of April 2021. All other external insulin delivery systems will remain under medical benefit.]*
A9275	Home glucose disposable monitor, includes test strips
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial continuous glucose monitoring system, one unit = 1 day supply

A9277	Transmitter; external, for use with non-durable medical equipment interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with non-durable medical equipment interstitial continuous glucose monitoring system
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified
E2102	Adjunctive, non-implanted continuous glucose monitor or receiver
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver
E0784	External ambulatory infusion pump, insulin
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
G0308	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180 day implantable sensor, including system activation
G0309	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service [that is, a device that does not require a finger stick, e.g., Dexcom G5]
K0601 - K0605	Replacement battery for Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each
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
ICD-10 codes considered medically necessary if criteria are met:	
E08.00 - E13.9	Diabetes mellitus
O24.011-O24.93	Diabetes mellitus in pregnancy, childbirth and the puerperium
P70.2	Neonatal diabetes mellitus

CPT/HCPCS codes *not* considered medically necessary:	
Code	*Description*
A4257	Replacement lens shield cartridge for use with laser skin piercing device, each
A9280	Alert or alarm device, not otherwise classified [when billed as hypoglycemic wristband alarm (e.g., Sleep Sentry)]
E0620	Skin piercing device for collection of capillary blood, laser, each

CPT/HCPCS codes not covered under the Medical Benefit Plan: (*these transdermal insulin delivery systems (e.g., V-Go) are considered self-use and may be covered under the Pharmacy Benefit Plan*)	
Code	*Description*
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories [when billed as Non-Programmable Transdermal Insulin Delivery Systems (e.g., V-Go disposable insulin delivery device)]

References

1. Abbott Freestyle Libre Pro For Healthcare Professionals. Available from: https://www.freestyle.abbott/in-en/products/freestyle-libre-pro.html. Accessed August 2022.

2. Ahmet A, Dagenais S, Barrowman NJ, et al. Prevalence of nocturnal hypoglycemia in pediatric type 1 diabetes: a pilot study using continuous glucose monitoring. J Pediatr. 2011 Aug; 159(2):297-302.e1.
3. American Diabetes Association Professional Practice Committee et al: 15. Management of diabetes in pregnancy: standards of medical care in diabetes-2022. Diabetes Care. 45(Supplement_1):S232-43, 2022
4. American Diabetes Association. Addendum. 7. Diabetes Technology: Standards of Medical Care in Diabetes—2020. Diabetes Care 2020 Aug;43(Suppl. 1):S77–S88. https://doi.org/10.2337/dc20-ad08c
5. American Diabetes Association. Diabetes Technology: Standards of Medical Care in Diabetes—2020. Diabetes Care. 2020 Jan; 43(Supplement 1): S77-S88. https://doi.org/10.2337/dc20-S007
6. American Diabetes Association. Gestational diabetes mellitus. Diabetes Care. 2004b Jan; 27 Suppl 1:S88-90.
7. American Diabetes Association. Introduction: Standards of Medical Care in Diabetes—2021. Diabetes Care. 2021 Jan; 44(Supplement 1): S1-S2. https://doi.org/10.2337/dc21-Sint
8. American Diabetes Association. Position Statement. Continuous subcutaneous insulin infusion. Diabetes Care 2004a; 27 (suppl 1):S110.
9. American Diabetes Association. Standards of medical care in diabetes - 2017. Available at: http://professional.diabetes.org/ResourcesForProfessionals.aspx?cid=84160. Accessed March 15, 2017.
10. American Diabetes Association. Standards of medical care in diabetes - 2018. Available at: http://care.diabetesjournals.org/content/diacare/suppl/2017/12/08/41.Supplement_1.DC1/DC_41_S1_Combined.pdf. Accessed October 10, 2018.
11. American Diabetes Association. Standards of medical care in diabetes - 2019. Available at: https://professional.diabetes.org/content-page/practice-guidelines-resources. Accessed July 23, 2019.
12. American Diabetes Association. Standards of Medical Care in Diabetes—2020 Abridged for Primary Care Providers. Clinical Diabetes. 2020; 38(1):10-38. doi:https://doi.org/10.2337/cd20-as01
13. American Medical Association (AMA). CPT Assistant. December 2009; 19(12):6-8. Updated February 2010; 20(2):13.
14. Amin R, Ross K, Acerini CL, et al. Hypoglycemia prevalence in prepubertal children with type 1 diabetes on standard insulin regimen: Use of continuous glucose monitoring system. Diabetes Care. 2003;26(3):662-667.

15. Arguello, Vanessa, Continuous Glucose Monitoring in Patients with Type 2 Diabetes Receiving Insulin Injections: Does this Mean Continuous Monitoring for Everyone, Ann Int Med; 2017, 167:436-437.
16. Atkinson MA, Eisenbarth GS, Michels AW. Type 1 diabetes. Lancet 2014;383(9911):69-82.
17. Bergenstal RM, Klonoff DC, Garg SK, et al.; ASPIRE In-Home Study Group. Threshold-based insulin-pump interruption for reduction of hypoglycemia. N Engl J Med. 2013 Jul 18; 369(3):224-32.
18. Bergenstal RM, Tamborlane WV, Ahmann A, et al.; STAR 3 Study Group. Effectiveness of sensor-augmented insulinpump therapy in type 1 diabetes. N Engl J Med. 2010 Jul 22; 363(4):311-20. Erratum in: N Engl J Med. 2010 Sep 9; 363(11):1092.
19. Blevins T, Schwartz SL, Bode B, et al. A Study assessing an injection port for administration of insulin. Diabetes Spectr. 2008;21:197-202.
20. Blue Cross Blue Shield Association (BCBSA), Technology Evaluation Center (TEC). Artificial pancreas device systems. TEC Assessment Program. Chicago, IL: BCBSA; May 2014;28(14).
21. Bode B, Steed RD, Davidson PC. Reduction in severe hypoglycemia with long-term continuous subcutaneous insulin infusion in type I diabetes. Diabetes Care. 1996;19(4):324-327.
22. Boland E, Monsod T, Delucia M, et al. Limitations of conventional methods of self-monitoring of blood glucose: Lessons learned from 3 days of continuous glucose sensing in pediatric patients with type 1 diabetes. Diabetes Care. 2001;24(11):1858-1862.
23. Boonin A, Balinski B, Sauter J, Martinez J, Abbott S. A Retrospective Chart Review of Two Different Insulin Administration Systems on Glycemic Control in Older Adults in Long-Term Care. J Gerontol Nurs. 2017;43(1):10-16.
24. Castle JR, El youssef J, Wilson LM, et al. Randomized Outpatient Trial of Single- and Dual-Hormone Closed-Loop Systems That Adapt to Exercise Using Wearable Sensors. Diabetes Care. 2018;41(7):1471-1477.
25. Chase HP, Beck R, Tamborlane W, et al. A randomized multicenter trial comparing the GlucoWatch Biographer with standard glucose monitoring in children with type 1 diabetes. Diabetes Care. 2005;28(5):1101-1106.
26. Chase HP, Beck RW, Xing D, et al. Continuous glucose monitoring in youth with type 1 diabetes: 12-month follow-up of the Juvenile Diabetes Research Foundation continuous glucose monitoring randomized trial. Diabetes Technol Ther. 2010 Jul;12(7):507-15.
27. Chase HP, Roberts MD, Wightman C, et al. Use of the GlucoWatch biographer in children with type 1 diabetes. Pediatrics. 2003;111(4 Pt 1):790-794.
28. Cheyne EH, Cavan DA, Kerr D. Performance of a continuous glucose monitoring system during controlled hypoglycaemia in healthy volunteers. Diabetes Technol Ther. 2002;4(5):607-613.

29. Chico A, Vidal-Rios P, Subira M, et al. The continuous glucose monitoring system is useful for detecting unrecognized hypoglycemias in patients with type 1 and type 2 diabetes but is not better than frequent capillary glucose measurements for improving metabolic control. Diabetes Care. 2003;26(4):1153-1157.
30. Christiansen MP, Klaff LJ, Bailey TS, Brazg R, Carlson G, Tweden KS. A Prospective Multicenter Evaluation of the Accuracy and Safety of an Implanted Continuous Glucose Sensor: The PRECISION Study. Diabetes Technol Ther. 2019 May;21(5):231-237. doi: 10.1089/dia.2019.0020. Epub 2019 Mar 29. PMID: 30925083; PMCID: PMC6532543.
31. Christiansen MP, Klaff LJ, Brazg R, Chang AR, Levy CJ, Lam D, Denham DS, Atiee G, Bode BW, Walters SJ, Kelley L, Bailey TS. A Prospective Multicenter Evaluation of the Accuracy of a Novel Implanted Continuous Glucose Sensor: PRECISE II. Diabetes Technol Ther. 2018 Mar;20(3):197-206. doi: 10.1089/dia.2017.0142. Epub 2018 Jan 30. PMID: 29381090; PMCID: PMC5867508.
32. ClinicalTrials.gov. Safety Evaluation of the Hybrid Closed Loop (HCL) system in pediatric subjects with Type 1 Diabetes. NCT NCT02660827. https://clinicaltrials.gov/ProvidedDocs/27/NCT02660827/Prot_000.pdf
33. Cooke D, Hurel SJ, Casbard A, et al. Randomized controlled trial to assess the impact of continuous glucose monitoring on HbA1c in insulin-treated diabetes (MITRE Study). Diabet Med. 2009 May;26(5):540-7.
34. de Bock, M, et al., Exploration of the Performance of a Hybrid Closed Loop Insulin Delivery Algorithm That Includes Insulin Delivery Limits Designed to Protect Against Hypoglycemia. J Diabetes Sci Technol, 2017. 11(1): p. 68-73.
35. de Bock, M., et al., Exploration of the Performance of a Hybrid Closed Loop Insulin Delivery Algorithm That Includes Insulin Delivery Limits Designed to Protect Against Hypoglycemia. J Diabetes Sci Technol, 2017. 11(1): p. 68-73.
36. Dehennis A, Mortellaro MA, Ioacara S. Multisite study of an implanted continuous glucose sensor over 90 days in patients with diabetes mellitus. J Diabetes Sci Technol. 2015;9(5):951-956.
37. Deiss D, Szadkowska A, Gordon D, Mallipedhi A, Schütz-Fuhrmann I, Aguilera E, Ringsell C, De Block C, Irace C. Clinical Practice Recommendations on the Routine Use of Eversense, the First Long-Term Implantable Continuous Glucose Monitoring System. Diabetes Technol Ther. 2019 May;21(5):254-264. doi: 10.1089/dia.2018.0397. Epub 2019 Apr 25. PMID: 31021180; PMCID: PMC6532544.
38. Desouza C, Salazar H, Cheong B, et al. Association of hypoglycemia and cardiac ischemia: A study based on continuous monitoring. Diabetes Care. 2003;26(5):1485-1489.
39. Dexcom G6 Guide. Available from: https://provider.dexcom.com/education-research/cgm-education-use/product-information/using-your-dexcom-g6-guide. Accessed August 2022.

40. Dexcom G6 Pro Training & Resources. Available from: https://provider.dexcom.com/products/dexcom-g6-pro/training-resources. Accessed August 2022.
41. Diabetes Control and Complications Trial (DCCT) Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin dependent diabetes mellitus. N Engl J Med. 1993;329:977-86.
42. Diabetes Research in Children Network (DirecNet) Study Group, Buckingham B, Beck RW, Tamborlane WV, Xing D, Kollman C, Fiallo-Scharer R, Mauras N, Ruedy KJ, Tansey M, Weinzimer SA, Wysocki T. Continuous glucose monitoring in children with type 1 diabetes. J Pediatr. 2007 Oct;151(4):388-93, 393.e1-2.
43. Diabetes Research in Children Network (DirecNet) Study Group. Psychological aspects of continuous glucose monitoring in pediatric type 1 diabetes. Pediatr Diabetes. 2006;7(1):32-38.
44. Diabetes Research in Children Network (DirecNet) Study Group. Use of the DirecNet Applied Treatment Algorithm (DATA) for diabetes management with a real-time continuous glucose monitor (the FreeStyle Navigator). Pediatr Diabetes. 2008 Apr;9(2):142-7.
45. Edelman SV. Watching your glucose with the GlucoWatch. Diabetes Technol Ther. 2001;3(2):283-284.
46. El-Khatib FH, Balliro C, Hillard MA, et al. Home use of a bihormonal bionic pancreas versus insulin pump therapy in adults with type 1 diabetes: a multicentre randomised crossover trial. Lancet 2017; 389:369.
47. El-Khatib FH, Russell SJ, Nathan DM, et al. A bihormonal closed-loop artificial pancreas for type 1 diabetes. Sci Transl Med 2010; 2:27ra27.
48. Farrar D, Tuffnell DJ, West J. Continuous subcutaneous insulin infusion versus multiple daily injections of insulin for pregnant women with diabetes. Cochrane Database Syst Rev. 2007;(3):CD005542.
49. Fatourechi MM, Kudva YC, Murad MH, Elamin MB, et al. Clinical review: Hypoglycemia with intensive insulin therapy: a systematic review and meta-analyses of randomized trials of continuous subcutaneous insulin infusion versus multiple daily injections. J Clin Endocrinol Metab. 2009 Mar;94(3):729-40.
50. Feig DS, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. Lancet 2017;390(10110):2347-2359. DOI: 10.1016/S0140-6736(17)32400-5.
51. Fischer U. Continuous in vivo monitoring in diabetes: The subcutaneous glucose concentration. Acta Anaesthesiol Scand Suppl. 1995;104:21-29.

52. Floyd B, Chandra P, Hall S, et al. Comparative analysis of the efficacy of continuous glucose monitoring and selfmonitoring of blood glucose in type 1 diabetes mellitus. J Diabetes Sci Technol. 2012 Sep 1;6(5):1094-102.
53. FreeStyle Libre: Healthcare Professionals. Available from: https://provider.freestyle.abbott/ca-en/home.html. Accessed August 2022.
54. Garg, SK, et al. Glucose Outcomes with the In-Home Use of a Hybrid Closed-Loop Insulin Delivery System in Adolescents and Adults with Type 1 Diabetes. Diabetes Technol Ther, 2017. 19(3): p. 155-163.
55. Garg, SK, et al. Glucose Outcomes with the In-Home Use of a Hybrid Closed-Loop Insulin Delivery System in Adolescents and Adults with Type 1 Diabetes. Diabetes Technol Ther, 2017. 19(3): p. 155-163.
56. Golden SH, Brown T, Yeh HC, et al. Methods for Insulin Delivery and Glucose Monitoring: Comparative Effectiveness. Comparative Effectiveness Review No. 57. (Prepared by Johns Hopkins University Evidence-based Practice Center under Contract No. 290-2007-10061-I.) AHRQ Publication No. 12-EHC036-EF. Rockville, MD: Agency for Healthcare Research and Quality. July 2012.
57. Guerci B, Floriot M, Bohme P, et al. Clinical performance of CGMS in type 1 diabetic patients treated by continuous subcutaneous insulin infusion using insulin analogs. Diabetes Care. 2003;26(3):582-589.
58. Haidar A, Legault L, Messier V, et al. Comparison of dual-hormone artificial pancreas, single-hormone artificial pancreas, and conventional insulin pump therapy for glycaemic control in patients with type 1 diabetes: an open-label randomised controlled crossover trial. Lancet Diabetes Endocrinol. 2015;3(1):17-26.
59. Hammond P. Continuous subcutaneous insulin infusion: Short-term benefits apparent, long-term benefits speculative. Br J Diabetes Vasc Dis. 2004;4(2):104-108.
60. Handelsman Y, Bloomgarden ZT, Grunberger G, et al.; American Association of Clinical Endocrinologists and American College of Endocrinology. Clinical practice guidelines for developing a diabetes mellitus comprehensive care plan - 2015. Endocr Pract. 2015 Apr;21 Suppl 1:1-87.
61. Hay LC, Wilmshurst EG, Fulcher G. Unrecognized hypo- and hyperglycemia in well-controlled patients with type 2 diabetes mellitus: The results of continuous glucose monitoring. Diabetes Technol Ther. 2003;5(1):19-26.
62. Hayes, Inc. Health Technology Assessment. Artificial Pancreas with the MiniMed 670G for the Management of Diabetes Mellitus. Lansdale, PA: Hayes, Inc.; Nov 2020. https://evidence.hayesinc.com/report/htb.medtronic3863

63. Hayes, Inc. Health Technology Assessment. Eversense Continuous Glucose Monitor For Maintaining Glycemic Control In Adults With Diabetes Mellitus. Lansdale, PA: Hayes, Inc.; July 2020.
64. Hayes, Inc. Health Technology Brief. Eversense Continuous Glucose Monitor for Maintaining Glycemic Control in Adults with Diabetes Mellitus. http://www.hayesinc.com. Published September 14, 2018. Accessed July 23, 2019.
65. Hayes, Inc. Search & Summary. OmniPod insulin management system (Insulet Corporation). http://www.hayesinc.com. Published October 25, 2018. Accessed July 22, 2019
66. Hovorka R, et al. Overnight closed loop insulin delivery (artificial pancreas) in adults with type 1 diabetes: crossover randomised controlled studies. British Medical Journal 2011;342:d1855.
67. Institute for Clinical and Economic Review (ICER). Comparative Effectiveness Public Advisory Council (CEPAC). Controversies in the management of patients with type 2 diabetes. December 2014. Available at: http://www.icerreview.org/wp-content/uploads/2015/03/CEPAC-T2D-Final-Report-December-22.pdf. Accessed March 23, 2017.
68. International Consensus on Use of Continuous Glucose Monitoring, Diabetes Care, 2017, Dec; 40(12); 1631-1640. Available at http://care.diabetesjournals.org/content/40/12/1631.
69. Jafri RZ, Balliro CA, El-Khatib F, Maheno MM, Hillard MA, O'Donovan A, Selagamsetty R, Zheng H, Damiano ER, Russell SJ. A Three-Way Accuracy Comparison of the Dexcom G5, Abbott Freestyle Libre Pro, and Senseonics Eversense Continuous Glucose Monitoring Devices in a Home-Use Study of Subjects with Type 1 Diabetes. Diabetes Technol Ther. 2020 Nov;22(11):846-852. doi: 10.1089/dia.2019.0449. PMID: 32453604.
70. Jahn LG, Capurro JJ, Levy BL. Comparative dose accuracy of durable and patch insulin infusion pumps. J Diabetes Sci Technol. 2013;7(4):1011-1020.
71. Jeitler K, Horvath K, Berghold A, et al. Continuous subcutaneous insulin infusion versus multiple daily insulin injections in patients with diabetes mellitus: systematic review and meta-analysis. Diabetologia. 2008 Jun;51(6):941-51.
72. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Beck RW, Buckingham B, et al. Factors predictive of use and of benefit from continuous glucose monitoring in type 1 diabetes. Diabetes Care. 2009a Nov;32(11):1947-53.
73. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, et al. Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med. 2008 Oct 2;359(14):1464-76.
74. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. The effect of continuous glucose monitoring in well-controlled type 1 diabetes. Diabetes Care. 2009b Aug;32(8):1378-83.

75. Juvenile Diabetes Research Foundation. Continuous Glucose Monitoring Study Group, Bode B, Beck RW, et al. Sustained benefit of continuous glucose monitoring on A1C, glucose profiles, and hypoglycemia in adults with type 1 diabetes. Diabetes Care. 2009c Nov;32(11):2047-9.
76. Karhula T, Vuorinen AL, Rääpysjärvi K, et al. Telemonitoring and Mobile Phone-Based Health Coaching Among Finnish Diabetic and Heart Disease Patients: Randomized Controlled Trial. J Med Internet Res. 2015;17(6):e153.
77. Katalenich B, Shi L, Liu S, et al. Evaluation of a Remote Monitoring System for Diabetes Control. Clin Ther. 2015;37(6):1216-25.
78. Kaufman FR, Austin J, Neinstein A, et al. Nocturnal hypoglycemia detected with the Continuous Glucose Monitoring System in pediatric patients with type 1 diabetes. J Pediatr. 2002;141(5):625-630.
79. Kaufman FR, Gibson LC, Halvorson M, et al. A pilot study of the continuous glucose monitoring system: Clinical decisions and glycemic control after its use in pediatric type 1 diabetic subjects. Diabetes Care. 2001;24(12):2030-2034.
80. Klonoff DC, et al. Continuous glucose monitoring: an Endocrine Society Clinical Practice Guideline. Journal of Clinical Endocrinology and Metabolism 2011;96(10):2968-79. (Reaffirmed November 2015)
81. Klonoff DC, Parkes JL, Kovatchev BP, et al. Investigation of the Accuracy of 18 Marketed Blood Glucose Monitors. Diabetes Care 2018 Aug; 41(8): 1681-1688.
82. Koivisto VA, Yki-Järvinen H, Helve E, et al. Pathogenesis and prevention of the dawn phenomenon in diabetic patients treated with CSII. Diabetes. 1986;35:78-82.
83. Kovatchev BP, et al. Safety of outpatient closed-loop control: first randomized crossover trials of a wearable artificial pancreas. Diabetes Care 2014;37(7):1789-96.
84. Kropff J, Choudhary P, Neupane S, Barnard K, Bain SC, Kapitza C, Forst T, Link M, Dehennis A, DeVries JH. Accuracy and Longevity of an Implantable Continuous Glucose Sensor in the PRECISE Study: A 180-Day, Prospective, Multicenter, Pivotal Trial. Diabetes Care. 2017 Jan;40(1):63-68. doi: 10.2337/dc16-1525. Epub 2016 Nov 4. PMID: 27815290.
85. Kropff J, Choudhary P, Neupane S, et al. Accuracy and longevity of an implantable continuous glucose sensor in the PRECISE Study: A 180-day, prospective, multicenter, pivotal trial. Diabetes Care. 2017;40(1):63-68.
86. Kudva YC, Carter RE, Cobelli C, Basu R, Basu A. Closed-loop artificial pancreas systems: physiological input to enhance next-generation devices. Diabetes Care 2014;37(5): 1184-90.
87. Kumareswaran K, et al. Feasibility of closed-loop insulin delivery in type 2 diabetes: a randomized controlled study. Diabetes Care 2014;37(5):1198-203.
88. Langendam M, Luijf YM, Hooft L, et al. Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochrane Database Syst Rev. 2012 Jan 18;1:CD008101.

89. Lee MK, Lee KH, Yoo SH, Park CY. Impact of initial active engagement in self-monitoring with a telemonitoring device on glycemic control among patients with type 2 diabetes. Sci Rep. 2017;7(1):3866.
90. Leelarathna L, et al. Day and night home closed-loop insulin delivery in adults with type 1 diabetes: three-center randomized crossover study. Diabetes Care 2014;37(7):1931-7.
91. Lorenz C, Sandoval W, Mortellaro M. Interference Assessment of Various Endogenous and Exogenous Substances on the Performance of the Eversense Long-Term Implantable Continuous Glucose Monitoring System. Diabetes Technol Ther. 2018 May;20(5):344-352. doi: 10.1089/dia.2018.0028. Epub 2018 Mar 30. PMID: 29600877; PMCID: PMC5963543.
92. Luijf YM, et al. Day and Night Closed-Loop Control in Adults With Type 1 Diabetes Mellitus: A comparison of two closed-loop algorithms driving continuous subcutaneous insulin infusion versus patient sel-f-management. Diabetes Care 2013;36(12):3882-7.
93. Maran A, Crepaldi C, Tiengo A, et al. Continuous subcutaneous glucose monitoring in diabetic patients: A multicenter analysis. Diabetes Care. 2002;25(2):347-352.
94. Marcus AO, Fernandez MP. Insulin pump therapy. Acceptable alternative to injection therapy. Postgrad Med. 1996;99(3):1-7.
95. Mastrototaro JJ, Gross TM. Reproducibility of the continuous glucose monitoring system matches previous reports and the intended use of the product. Diabetes Care. 2003;26(1):256.
96. Mauras N, et al. A randomized clinical trial to assess the efficacy and safety of real-time continuous glucose monitoring in the management of type 1 diabetes in young children aged 4 to <10 years. Diabetes Care 2012;35(2):204-10.
97. McAdams BH, Rizvi AA. An Overview of Insulin Pumps and Glucose Sensors for the Generalist. J Clin Med. 2016;5(1):5. Published 2016 Jan 4. doi:10.3390/jcm5010005.
98. McCulloch DK. Blood glucose self-monitoring in management of adults with diabetes mellitus. UpToDate Inc., Waltham, MA. Last reviewed February 2017.
99. McCulloch DK. Management of blood glucose in adults with type 1 diabetes mellitus. UpToDate Inc., Waltham, MA. Last reviewed February 2017.
100. McCulloch DK. Patient Education: Diabetes Mellitus type 1: Overview (Beyond the Basics). UpToDate Inc., Waltham, MA. Last reviewed February 2017.
101. McCulloch DK. Patient Education: Diabetes Mellitus type 2: Overview (Beyond the Basics). UpToDate Inc., Waltham, MA. Last reviewed February 2017.
102. Meade LT. The use of continuous glucose monitoring in patients with type 2 diabetes. Diabetes Technology & Therapeutics 2012;14(2):190-5.
103. Medtronic Guardian Connect System User Guide. Available from: https://www.medtronicdiabetes.com/sites/default/files/library/download-library/user-guides/GuardianT%20Connect%20CGM%20System%20User%20Guide.PDF

104. Medtronic iPro 2 Professional CGM. Available from: https://www.medtronicdiabetes.com/download-library/ipro-2. Accessed August 2022.
105. Minimed 670G: a hybrid closed-loop insulin delivery system. Med Lett Drugs Ther, 2016. 58(1508): p. 147-148.
106. Minimed 670G: a hybrid closed-loop insulin delivery system. Med Lett Drugs Ther, 2016. 58(1508): p. 147-148.
107. Mukhopadhyay A, Farrell T, Fraser RB, Ola B. Continuous subcutaneous insulin infusion vs intensive conventional insulin therapy in pregnant diabetic women: A systematic review and metaanalysis of randomized, controlled trials. Am J Obstet Gynecol. 2007;197(5):447-456.
108. National Institute for Health and Care Excellence (NICE). CG17. Type 1 diabetes in adults: diagnosis and management. August 2015. Updated July 2016. Available at: https://www.nice.org.uk/guidance/ng17. Accessed March 15, 2017.
109. National Institute for Health and Care Excellence (NICE). CG18. Diabetes (type 1 and type 2) in children and young people: diagnosis and management. August 2015. Updated November 2016. Available at: https://www.nice.org.uk/guidance/ng18. Accessed March 15, 2017.
110. Newman SP, Hurel SJ, Cooke D, et al. A randomized control trial of continuous glucose monitoring devices on Hb A1c -- The MITRE study. American Diabetes Association 67th Scientific Sessions: Abstract 0115-OR. Presented June 23, 2007. Alexandria, VA: American Diabetes Association; 2007.
111. Nimri R, et al. The "Glucositter" overnight automated closed loop system for type 1 diabetes: a randomized crossover trial. Pediatric Diabetes 2013;14(3):15967. DOI: 10.1111/pedi.120-25.
112. Oppel E, Kamann S, Heinemann L, Reichl FX, Högg C. The implanted glucose monitoring system Eversense: An alternative for diabetes patients with isobornyl acrylate allergy. Contact Dermatitis. 2020 Feb;82(2):101-104. doi: 10.1111/cod.13392. Epub 2019 Sep 17. PMID: 31463958.
113. Petrovski G, Dimitrovski C, Bogoev M, Milenkovic T, Ahmeti I, Bitovska I. Is there a difference in pregnancy and glycemic outcome in patients with type 1 diabetes on insulin pump with constant or intermittent glucose monitoring? A pilot study. Diabetes Technology and Therapeutics 2011;13(11):1109-13.
114. Phillip M, et al. Nocturnal glucose control with an artificial pancreas at a diabetes camp. New England Journal of Medicine 2013;368(9):824-33.
115. Pickup JC, Sutton AJ. Severe hypoglycaemia and glycaemic control in Type 1 diabetes: meta-analysis of multiple daily insulin injections compared with continuous subcutaneous insulin infusion. Diabet Med. 2008 Jul;25(7):765-74.

116. Poomalar GK. Changing trends in management of gestational diabetes mellitus. World Journal of Diabetes 2015;6(2):284-95.
117. Potts RO, Tamada JA, Tierney MJ. Glucose monitoring by reverse iontophoresis. Diabetes Metab Res Rev. 2002;18 Suppl 1:S49-S53.
118. Reznik Y, Cohen O, Aronson R, et al.; OpT2mise Study Group. Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (OpT2mise): a randomized open-label controlled trial. Lancet. 2014 Oct 4;384(9950):1265-72.
119. Robert JJ. Continuous monitoring of blood glucose. Horm Res. 2002;57 Suppl 1:81-84.
120. Rosenfeld CR, Bohannon NJ, Bode B, et al. TheV-Go insulin delivery device used in clinical practice: Patient perception and retrospective analysis of glycemic control. Endocr Pract. 2012;18(5):660-667.
121. Russell SJ, El-Khatib FH, Sinha M, et al. Outpatient glycemic control with a bionic pancreas in type 1 diabetes. N Engl J Med 2014; 371:313.
122. Russell SJ, et al. Outpatient glycemic control with a bionic pancreas in type 1 diabetes. New England Journal of Medicine 2014;371(4):3132-5.
123. Sanchez P, Ghosh-Dastidar S, Tweden KS, Kaufman FR. Real-World Data from the First U.S. Commercial Users of an Implantable Continuous Glucose Sensor. Diabetes Technol Ther. 2019 Dec;21(12):677-681. doi: 10.1089/dia.2019.0234. Epub 2019 Aug 28. PMID: 31385732.
124. Saudek CD, Duckworth WC, Giobbie-Hurder A, et al. Implantable insulin pump vs multiple-dose insulin for non-insulin-dependent diabetes mellitus: A randomized clinical trial. Department of Veterans Affairs Implantable Insulin Pump Study Group. JAMA. 1996;276(16):1322-1327.
125. Senseonics Eversense Health Care Provider Resources Library. Available from: https://www.ascensiadiabetes.com/eversense/health-care-professionals/eversense-system/. Accessed August 2022.
126. Sutton D, Higdon C, Carmon M, Abbott S. Regular Insulin Administered With the V-Go Disposable Insulin Delivery Device in a Clinical Diabetes Setting: A Retrospective Analysis of Efficacy and Cost. Clin Diabetes. 2016;34(4):201-205.
127. Szypowska A, Ramotowska A, Dzygalo K, Golicki D. Beneficial effect of real-time continuous glucose monitoring system on glycemic control in type 1 diabetic patients: systematic review and meta-analysis of randomized trials. Eur J Endocrinol. 2012 Apr;166(4):567-74.
128. Tanenberg R, Bode B, Lane W, et al. Use of the Continuous Glucose Monitoring System to guide therapy in patients with insulin-treated diabetes: A randomized controlled trial. Mayo Clin Proc. 2004;79(12):1521-1526.

129. Thabit H, et al. Home use of closed-loop insulin delivery for overnight glucose control in adults with type 1 diabetes: a 4-week, multicentre, randomised crossover study. Lancet. Diabetes & Endocrinology 2014;2(9):7019. DOI: 10.1016/S22138587(14)70114-7.
130. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med. 1993;329(14):977-986.
131. Tierney MJ, Tamada JA, Potts RO, et al. Clinical evaluation of the GlucoWatch biographer: A continual, non-invasive glucose monitor for patients with diabetes. Biosens Bioelectron. 2001;16(9-12):621-629.
132. Trajanoski Z, Wach P, Gfrerer R, et al. Portable device for continuous fractionated blood sampling and continuous ex vivo blood glucose monitoring. Biosens Bioelectron. 1996;11(5):479-487.
133. U.S. Food and Drug Administration (FDA). MiniMed 770G System. (Medtronic MiniMed, Inc. Northridge, CA). Summary of Safety and Effectiveness PMA Number: P160017/S076. Notice of Approval 8/31/2020. https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160017S076B.pdf
134. US Food and Drug Administration (FDA). Eversense continuous glucose monitoring system. (Senseonics, Incorporated, Germantown, MD) PMA Number: P160048. Jun 21, 2018. Accessed August 19, 2021. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160048
135. Vague P, Lassmann-Vague V, Belicar P, Alessis C. The implantable insulin pump in the treatment of diabetes. Hopes and reality? Bull Acad Natl Med. 1996 ;180(4):831-841; discussion 841-843.
136. Vigersky RA, Fonda SJ, Chellappa M, Walker MS, Ehrhardt NM. Short and long-term effects of real-time continuous glucose monitoring in patients with type 2 diabetes. Diabetes Care 2012;35(1):32-8.
137. Wolpert HA. Continuous glucose monitoring--coming of age. N Engl J Med. 2010;363(4):383-384.
138. Zick R, Petersen B, Richter M, Haug C; SAFIR Study Group. Comparison of continuous blood glucose measurement with conventional documentation of hypoglycemia in patients with Type 2 diabetes on multiple daily insulin injection therapy. Diabetes Technol Ther. 2007;9(6):483-492.
139. American Diabetes Association Professional Practice Committee et al: 15. Management of diabetes in pregnancy: standards of medical care in diabetes-2022. Diabetes Care. 45(Supplement_1):S232-43, 2022
140. Nuha A. ElSayed, Grazia Aleppo, Vanita R. Aroda, Raveendhara R. Bannuru, Florence M. Brown, Dennis Bruemmer, Billy S. Collins, Marisa E. Hilliard, Diana Isaacs, Eric L. Johnson, Scott

Kahan, Kamlesh Khunti, Jose Leon, Sarah K. Lyons, Mary Lou Perry, Priya Prahalad, Richard E. Pratley, Jane Jeffrie Seley, Robert C. Stanton, Robert A. Gabbay; on behalf of the American Diabetes Association, 7. Diabetes Technology: Standards of Care in Diabetes—2023. Diabetes Care 1 January 2023; 46 (Supplement_1): S111–S127. https://doi.org/10.2337/dc23-S007

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