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.

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Summary

Diabetes mellitus (DM), 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 mellitus (T1DM): The pancreas produces little or no insulin.
- Type 2 diabetes mellitus (T2DM): 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

Medical Necessity Criteria for Clinical Review

General Medical Necessity 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[*] 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: [*]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:

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

External Insulin Pump Delivery Systems Criteria

Note: For members who have been on an external insulin pump delivery system prior to enrollment with the Plan, please see Medical Necessity Criteria for Subsequent Clinical Review *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 Medical Necessity Criteria for equipment and supplies above are met; *AND*
2. Prescribed by or in consultation with an endocrinologist or other provider experienced in diabetes technology and management*; 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. The member meets ONE of the following:
        i. Diagnosis of type-1 diabetes*; or*
        ii. A child, where multiple daily insulin injections would be impractical or inappropriate*; or*
        iii. Complications of inadequate glycemic control (e.g., neuropathy, nephropathy, retinopathy) indicative of more intensive insulin regimens*; or*
        iv. Dawn phenomenon unresponsive to management with long-acting insulin agents (e.g., insulin glargine or detemir)*; or*
        v. For initial requests, HbA1c greater than 7% or above individualized target, despite an adequate regimen of multiple daily injections*; or*
        vi. Hypoglycemic episodes requiring third-party assistance (e.g., seizure, loss of consciousness, glucagon administration, transport to an emergency room, hospitalization)*; or*
        vii. Recurrent hypoglycemia (<70 mg/dL on at least two occasions despite adherence to recommended diabetic treatment plan)*; or*
        viii. 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.]
        ix. Wide swings in blood glucose values before meal time (e.g., regular fluctuations of pre-prandial blood glucose to levels <70 mg/dL and/or >140 mg/dL); *and*
    c. Completion of a comprehensive diabetes education program*; and*
    d. Currently uses three (3) or more insulin injections daily*; and*
    e. History of frequent self-adjustments of insulin doses for at least 6 months prior*; and*
    f. 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*
    g. Member or designated caregiver can be adequately trained and is motivated to adhere to blood glucose monitoring, or the member qualifies for continuous glucose monitoring*; and*
    h. Provider team (e.g., physician, nurses, diabetes educators, and dietitians) is experienced in diabetes technology and management and can provide ongoing education, follow-up and support.

When BOTH the "General Medical Necessity 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 meet the "General Medical Necessity 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.

Professional Diagnostic, Short-Term, or Long-Term Continuous Glucose Monitoring (CGM) Systems Criteria

Note: *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, and implantable glucose monitoring systems, like Eversense 365 CGM System.*

For members who have been on a professional diagnostic,short-term, or long-term CGM prior to enrollment with the Plan, please see Medical Necessity Criteria for Subsequent Clinical Review *below.*

The Plan considers Professional Diagnostic or Short-Term Continuous Glucose Monitoring Systems and its components medically necessary when the member meets ALL of the following criteria:

1. The General Medical Necessity Criteria for equipment and supplies above are met; *AND*
2. The member has a documented diagnosis of diabetes mellitus; *AND*
3. Short-term CGM is necessary, as indicated by BOTH of the following:
    a. Additional information on blood glucose levels is needed, as indicated by at least ONE of the following:
        i. Dawn phenomenon, known or suspected; *or*
        ii. Hypoglycemic unawareness; *or*
        iii. Nocturnal hyperglycemia, known or suspected; *or*
        iv. Postprandial hyperglycemia, known or suspected; *or*
        v. Significant change to the treatment regimen, such as starting insulin or transitioning from multiple daily doses to an insulin pump; *or*
        vi. Unexplained hyperglycemia; *and*
    b. Monitoring is limited to a maximum of three (3) to 14 days and for no more than 2 episodes within a 12-month period.

The Plan considers Long-Term Continuous Glucose Monitoring Systems and its components medically necessary when ALL of the following criteria are met:

1. The General Medical Necessity Criteria for equipment and supplies above are met; *AND*
2. The member has a documented diagnosis of diabetes mellitus; *AND*
3. Long-term continuous glucose monitoring is needed for the member's diabetes management, as evidenced by clinical documentation in the past 6 months showing ALL of the following:
    a. The member has a documented diabetic treatment plan in place and can be trained to use a CGM; *and*
    b. The member requires blood glucose checks daily; *and*
    c. The member meets at least ONE of the following:

i. Type 1 diabetes; *or*
ii. Type 2 diabetes treated with insulin who have hemoglobin A1c above goal, despite appropriate changes in insulin therapy and compliance with the treatment plan; *or*
iii. Type 2 diabetes treated with insulin with hyperglycemic excursions, despite appropriate changes in insulin therapy and compliance with the treatment plan*; or*
iv. Pregnant; *or*
v. 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*

4. IF the request is for, or a component of, the Senseonics Eversense 365 system, ALL of the following are met:
    a. The member has inadequate glycemic control despite compliance, with trial and failure of ONE of the following:
        i. Standard blood glucose monitors with frequent self-monitoring finger sticks; *or*
        ii. Flash glucose monitoring; *or*
        iii. Continuous glucose monitoring (non-implantable); *or*
        iv. Allergy to adhesive or other materials in non-implantable CGM devices; *and*
    b. The insertion and removal of the glucose sensor in the upper arm will be conducted by a healthcare practitioner; *and*
    c. The member meets ALL of the following:
        i. No evidence of being critically ill or hospitalized*; or*
        ii. No evidence of expecting to undergo an MRI (magnetic resonance imaging) procedure[‡] within 365 days for Eversense 365*; or*
        [‡]*NOTE: The Eversense Smart Transmitter is MR Unsafe and MUST BE REMOVED before undergoing an MRI procedure. The Eversense Sensor is MR Conditional under specific conditions. MRI staff should be informed about implanted sensors before any MRI procedure.*
        iii. No evidence of another active implantable device, e.g., an implantable defibrillator (passive implants are allowed, e.g., cardiac stents)*; or*
        iv. No evidence of history of dexamethasone or dexamethasone acetate contraindication, or allergies to systemic glucocorticoids*; or*
        v. No evidence of needing mannitol or sorbitol intravenously, or as a component of an irrigation solution or peritoneal dialysis solution*; or*
        vi. No evidence of pregnancy or nursing, unless the potential benefits of CGM use outweigh the risks, as determined by the prescribing physician*; or*

vii. No evidence of receiving immunosuppressant therapy, chemotherapy, or anticoagulant therapy, unless specifically approved by the prescribing physician in consultation with the healthcare practitioner performing the sensor insertion.

When the "General Medical Necessity Criteria", along with the criteria for "Professional Diagnostic,Short-Term, or Long-Term Continuous Glucose Monitoring (CGM) Systems" is 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[#]: 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 reader device	10 days	2
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.*

Table 3[#]: Stand-alone Prescription Long-Term CGM Systems

CGM System	FDA-approved or cleared for	Components	Use Life[‡]
Dexcom G6	at least two years old	Receiver	1 year
		Sensor	10 days per sensor
		Transmitter	90 days
Dexcom G7	at least two years old	Receiver	about 3 years
		Sensor	10 days per sensor
Freestyle Libre 2	at least four years old	Sensor	14 days per sensor
		Reader	about 3 years
FreeStyle Libre 2 Plus	at least two years old	Sensor	15-days per sensor
Freestyle Libre 3	at least four years old	Sensor	14 days per sensor
		Reader	about 3 years
FreeStyle Libre 3 Plus	at least two years old	Sensor	15-days per sensor
Freestyle Libre 14-day	≥18 years old	Sensor	14 days per sensor
		Reader	about 3 years
Medtronic Guardian Connect	between the ages of 14 and 75 years old	Guardian Sensor 3	7 days per sensor
		Guardian Connect Transmitter	can be cleaned up to 122 times or one year, whichever comes first
Senseonics Eversense 365	≥18 years old	Eversense 365 Sensor[#]	365 days
		Transmitter	1 year
Simplera System	≥18 years old	Sensor	6-7 days per sensor

[*] *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.*

[#] *The sensor insertion and removal procedures must be performed by a healthcare provider.*

Requests to Switch Continuous Glucose Monitoring Systems

Note: For all other requests, please see Initial Clinical Review or Continued Care/Subsequent Clinical Review 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 3 above)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, ALL of 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; *AND*
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.

Artificial Pancreas / Hybrid Closed-Loop Insulin Delivery Systems[5]

Note: For members who have been on this hybrid insulin system prior to enrollment with the Plan, please see Medical Necessity Criteria for Subsequent Clinical Review below.

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

1. The General Medical Necessity Criteria for equipment and supplies above are met; *AND*
2. The member meets the criteria for a new or replacement External Insulin Pump Delivery Systems Criteria (see above); *AND*
3. The member meets the criteria for a new or replacement Continuous Glucose Monitoring (see above); *AND*

4. The member has a documented diabetic treatment plan in place 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. Appropriate age recommendations or restrictions (see table 3); *or*
    b. No contraindications to requested system; *or*
    c. No interference by medications (e.g., Tylenol [acetaminophen], ascorbic acid, hydroxyurea depending on CGM integration); *or*
    d. No hearing or visual impairments prevent recognition of pump signals and/or alarms; *or*
    e. Daily insulin dosage (units) meets minimum dosage requirements for device functionality.

Table 4[*]: FDA-approved/cleared Artificial Pancreas/Hybrid Closed-Loop Insulin Delivery Systems

System	Manufacturer	Type	Age Indication	CGM[3] Integration	Insulin Dosing
iLet Bionic Pancreas	Beta Bionics	Closed -loop	≥6 years (T1DM)	Dexcom G6/7, Freestyle Libre 3 Plus	Fully automated insulin delivery based on qualitative meal announcements
MiniMed 630G	Medtronic	LGS[1]	≥14 years (T2DM)	Guardian Sensor 3	Suspends insulin delivery at preset low glucose threshold
MiniMed 780G	Medtronic	HCL[2]	≥7 years (T1DM)	Guardian Sensor 4	Auto-adjusts basal insulin; manual bolus; provides autocorrections as needed; meal detection
Omnipod 5	Insulet	HCL[2]	≥2 years (T1DM), ≥18 years (T2DM)	Dexcom G6/7, Freestyle Libre 2 Plus	Auto-adjusts basal insulin; manual bolus
t:slim X2 with Basal-IQ	Tandem	LGS[1]	≥6 years	Dexcom G6	Suspends insulin delivery based on predicted low glucose
t:slim X2 with Control-IQ	Tandem	HCL[2]	≥6 years (T1DM)	Dexcom G6/7, Freestyle Libre 2 Plus	Auto-adjusts basal insulin; manual bolus
Tandem Mobi	Tandem	HCL[2]	≥6 years	Dexcom G6/7	Auto-adjusts basal insulin; manual bolus

[1]LGS: Low Glucose Suspend

[2]HCL: Hybrid Closed-Loop

[3]CGM: Continuous Glucose Monitoring

[5]*NOTE: The information provided in this table is based on the current FDA approvals and indications for each device as of the reviewed date noted within* Clinical Guideline Revision/History Information*. The features, functionalities, and indications for these devices may change over time as manufacturers develop new technologies and receive updated regulatory approvals. Always refer to the manufacturer's official documentation and the most recent FDA approval status for the most accurate and up-to-date information on each device.*

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Medical Necessity Criteria

The Plan considers professional diagnostic, short-term, long-term continuous glucose monitoring, insulin delivery systems, and hybrid closed-loop insulin delivery systems (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 Medical Necessity 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 professional diagnostic or short-term continuous glucose monitoring system, insulin delivery system, or hybrid closed-loop insulin delivery 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)

Table 5	
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

Table 5	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
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]

Table 5	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each
K0602	Replacement battery for external infusion pump owned by patient, silver oxide, 3 volt, each
K0603	Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each
K0604	Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each
K0605	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

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E08	Diabetes mellitus due to underlying condition
E08.0	Diabetes mellitus due to underlying condition with hyperosmolarity

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E08.00	Diabetes mellitus due to underlying condition with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E08.01	Diabetes mellitus due to underlying condition with hyperosmolarity with coma
E08.1	Diabetes mellitus due to underlying condition with ketoacidosis
E08.10	Diabetes mellitus due to underlying condition with ketoacidosis without coma
E08.11	Diabetes mellitus due to underlying condition with ketoacidosis with coma
E08.2	Diabetes mellitus due to underlying condition with kidney complications
E08.21	Diabetes mellitus due to underlying condition with diabetic nephropathy
E08.22	Diabetes mellitus due to underlying condition with diabetic chronic kidney disease
E08.29	Diabetes mellitus due to underlying condition with other diabetic kidney complication
E08.3	Diabetes mellitus due to underlying condition with ophthalmic complications
E08.31	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema
E08.319	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy without macular edema
E08.32	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy
E08.321	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema
E08.329	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema
E08.33	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E08.331	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema
E08.339	Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema
E08.34	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy
E08.341	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema
E08.349	Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema
E08.35	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy
E08.351	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema
E08.352	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula
E08.353	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula
E08.354	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment
E08.355	Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy
E08.359	Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema
E08.36	Diabetes mellitus due to underlying condition with diabetic cataract
E08.37	Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E08.39	Diabetes mellitus due to underlying condition with other diabetic ophthalmic complication
E08.4	Diabetes mellitus due to underlying condition with neurological complications
E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified
E08.41	Diabetes mellitus due to underlying condition with diabetic mononeuropathy
E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy
E08.44	Diabetes mellitus due to underlying condition with diabetic amyotrophy
E08.49	Diabetes mellitus due to underlying condition with other diabetic neurological complication
E08.5	Diabetes mellitus due to underlying condition with circulatory complications
E08.51	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy without gangrene
E08.52	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy with gangrene
E08.59	Diabetes mellitus due to underlying condition with other circulatory complications
E08.6	Diabetes mellitus due to underlying condition with other specified complications
E08.61	Diabetes mellitus due to underlying condition with diabetic arthropathy
E08.610	Diabetes mellitus due to underlying condition with diabetic neuropathic arthropathy
E08.618	Diabetes mellitus due to underlying condition with other diabetic arthropathy
E08.62	Diabetes mellitus due to underlying condition with skin complications
E08.620	Diabetes mellitus due to underlying condition with diabetic dermatitis

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E08.621	Diabetes mellitus due to underlying condition with foot ulcer
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer
E08.628	Diabetes mellitus due to underlying condition with other skin complications
E08.63	Diabetes mellitus due to underlying condition with oral complications
E08.630	Diabetes mellitus due to underlying condition with periodontal disease
E08.638	Diabetes mellitus due to underlying condition with other oral complications
E08.64	Diabetes mellitus due to underlying condition with hypoglycemia
E08.641	Diabetes mellitus due to underlying condition with hypoglycemia with coma
E08.649	Diabetes mellitus due to underlying condition with hypoglycemia without coma
E08.65	Diabetes mellitus due to underlying condition with hyperglycemia
E08.69	Diabetes mellitus due to underlying condition with other specified complication
E08.8	Diabetes mellitus due to underlying condition with unspecified complications
E08.9	Diabetes mellitus due to underlying condition without complications
E09	Drug or chemical induced diabetes mellitus
E09.0	Drug or chemical induced diabetes mellitus with hyperosmolarity
E09.00	Drug or chemical induced diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E09.01	Drug or chemical induced diabetes mellitus with hyperosmolarity with coma
E09.1	Drug or chemical induced diabetes mellitus with ketoacidosis
E09.10	Drug or chemical induced diabetes mellitus with ketoacidosis without coma
E09.11	Drug or chemical induced diabetes mellitus with ketoacidosis with coma
E09.2	Drug or chemical induced diabetes mellitus with kidney complications
E09.21	Drug or chemical induced diabetes mellitus with diabetic nephropathy

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E09.22	Drug or chemical induced diabetes mellitus with diabetic chronic kidney disease
E09.29	Drug or chemical induced diabetes mellitus with other diabetic kidney complication
E09.3	Drug or chemical induced diabetes mellitus with ophthalmic complications
E09.31	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy
E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.319	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy without macular edema
E09.32	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy
E09.321	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E09.329	Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E09.33	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy
E09.331	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E09.339	Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E09.34	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy
E09.341	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E09.349	Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E09.35	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy
E09.351	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema
E09.352	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula
E09.353	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula
E09.354	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment
E09.355	Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy
E09.359	Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema
E09.36	Drug or chemical induced diabetes mellitus with diabetic cataract
E09.37	Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment
E09.39	Drug or chemical induced diabetes mellitus with other diabetic ophthalmic complication
E09.4	Drug or chemical induced diabetes mellitus with neurological complications
E09.40	Drug or chemical induced diabetes mellitus with neurological complications with diabetic neuropathy, unspecified
E09.41	Drug or chemical induced diabetes mellitus with neurological complications with diabetic mononeuropathy
E09.42	Drug or chemical induced diabetes mellitus with neurological complications with diabetic polyneuropathy
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly)neuropathy

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E09.44	Drug or chemical induced diabetes mellitus with neurological complications with diabetic amyotrophy
E09.49	Drug or chemical induced diabetes mellitus with neurological complications with other diabetic neurological complication
E09.5	Drug or chemical induced diabetes mellitus with circulatory complications
E09.51	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy without gangrene
E09.52	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy with gangrene
E09.59	Drug or chemical induced diabetes mellitus with other circulatory complications
E09.6	Drug or chemical induced diabetes mellitus with other specified complications
E09.61	Drug or chemical induced diabetes mellitus with diabetic arthropathy
E09.610	Drug or chemical induced diabetes mellitus with diabetic neuropathic arthropathy
E09.618	Drug or chemical induced diabetes mellitus with other diabetic arthropathy
E09.62	Drug or chemical induced diabetes mellitus with skin complications
E09.620	Drug or chemical induced diabetes mellitus with diabetic dermatitis
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer
E09.628	Drug or chemical induced diabetes mellitus with other skin complications
E09.63	Drug or chemical induced diabetes mellitus with oral complications
E09.630	Drug or chemical induced diabetes mellitus with periodontal disease
E09.638	Drug or chemical induced diabetes mellitus with other oral complications
E09.64	Drug or chemical induced diabetes mellitus with hypoglycemia
E09.641	Drug or chemical induced diabetes mellitus with hypoglycemia with coma

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E09.649	Drug or chemical induced diabetes mellitus with hypoglycemia without coma
E09.65	Drug or chemical induced diabetes mellitus with hyperglycemia
E09.69	Drug or chemical induced diabetes mellitus with other specified complication
E09.8	Drug or chemical induced diabetes mellitus with unspecified complications
E09.9	Drug or chemical induced diabetes mellitus without complications
E10	Type 1 diabetes mellitus
E10.1	Type 1 diabetes mellitus with ketoacidosis
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma
E10.2	Type 1 diabetes mellitus with kidney complications
E10.21	Type 1 diabetes mellitus with diabetic nephropathy
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication
E10.3	Type 1 diabetes mellitus with ophthalmic complications
E10.31	Type 1 diabetes mellitus with unspecified diabetic retinopathy
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E10.32	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy
E10.321	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E10.329	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E10.33	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy
E10.331	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E10.339	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E10.34	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy
E10.341	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.349	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema
E10.35	Type 1 diabetes mellitus with proliferative diabetic retinopathy
E10.351	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E10.352	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula
E10.353	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula
E10.354	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment
E10.355	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy
E10.359	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E10.36	Type 1 diabetes mellitus with diabetic cataract
E10.37	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication
E10.4	Type 1 diabetes mellitus with neurological complications

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E10.44	Type 1 diabetes mellitus with diabetic amyotrophy
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication
E10.5	Type 1 diabetes mellitus with circulatory complications
E10.51	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.59	Type 1 diabetes mellitus with other circulatory complications
E10.6	Type 1 diabetes mellitus with other specified complications
E10.61	Type 1 diabetes mellitus with diabetic arthropathy
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E10.618	Type 1 diabetes mellitus with other diabetic arthropathy
E10.62	Type 1 diabetes mellitus with skin complications
E10.620	Type 1 diabetes mellitus with diabetic dermatitis
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E10.628	Type 1 diabetes mellitus with other skin complications
E10.63	Type 1 diabetes mellitus with oral complications
E10.630	Type 1 diabetes mellitus with periodontal disease
E10.638	Type 1 diabetes mellitus with other oral complications
E10.64	Type 1 diabetes mellitus with hypoglycemia

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E10.641	Type 1 diabetes mellitus with hypoglycemia with coma
E10.649	Type 1 diabetes mellitus with hypoglycemia without coma
E10.65	Type 1 diabetes mellitus with hyperglycemia
E10.69	Type 1 diabetes mellitus with other specified complication
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications
E10.A	Type 1 diabetes mellitus, presymptomatic
E10.A0	Type 1 diabetes mellitus, presymptomatic, unspecified
E10.A1	Type 1 diabetes mellitus, presymptomatic, Stage 1
E10.A2	Type 1 diabetes mellitus, presymptomatic, Stage 2
E11	Type 2 diabetes mellitus
E11.0	Type 2 diabetes mellitus with hyperosmolarity
E11.00	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E11.01	Type 2 diabetes mellitus with hyperosmolarity with coma
E11.1	Type 2 diabetes mellitus with ketoacidosis
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma
E11.11	Type 2 diabetes mellitus with ketoacidosis with coma
E11.2	Type 2 diabetes mellitus with kidney complications
E11.21	Type 2 diabetes mellitus with diabetic nephropathy
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication
E11.3	Type 2 diabetes mellitus with ophthalmic complications

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E11.31	Type 2 diabetes mellitus with unspecified diabetic retinopathy
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E11.32	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy
E11.321	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E11.329	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E11.33	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy
E11.331	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E11.339	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E11.34	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy
E11.341	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E11.349	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema
E11.35	Type 2 diabetes mellitus with proliferative diabetic retinopathy
E11.351	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E11.352	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula
E11.353	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E11.354	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment
E11.355	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy
E11.359	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E11.36	Type 2 diabetes mellitus with diabetic cataract
E11.37	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication
E11.4	Type 2 diabetes mellitus with neurological complications
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
E11.5	Type 2 diabetes mellitus with circulatory complications
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E11.59	Type 2 diabetes mellitus with other circulatory complications
E11.6	Type 2 diabetes mellitus with other specified complications
E11.61	Type 2 diabetes mellitus with diabetic arthropathy
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E11.62	Type 2 diabetes mellitus with skin complications
E11.620	Type 2 diabetes mellitus with diabetic dermatitis
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E11.628	Type 2 diabetes mellitus with other skin complications
E11.63	Type 2 diabetes mellitus with oral complications
E11.630	Type 2 diabetes mellitus with periodontal disease
E11.638	Type 2 diabetes mellitus with other oral complications
E11.64	Type 2 diabetes mellitus with hypoglycemia
E11.641	Type 2 diabetes mellitus with hypoglycemia with coma
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.69	Type 2 diabetes mellitus with other specified complication
E11.8	Type 2 diabetes mellitus with unspecified complications
E11.9	Type 2 diabetes mellitus without complications
E13	Other specified diabetes mellitus
E13.0	Other specified diabetes mellitus with hyperosmolarity
E13.00	Other specified diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E13.01	Other specified diabetes mellitus with hyperosmolarity with coma
E13.1	Other specified diabetes mellitus with ketoacidosis
E13.10	Other specified diabetes mellitus with ketoacidosis without coma
E13.11	Other specified diabetes mellitus with ketoacidosis with coma

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E13.2	Other specified diabetes mellitus with kidney complications
E13.21	Other specified diabetes mellitus with diabetic nephropathy
E13.22	Other specified diabetes mellitus with diabetic chronic kidney disease
E13.29	Other specified diabetes mellitus with other diabetic kidney complication
E13.3	Other specified diabetes mellitus with ophthalmic complications
E13.31	Other specified diabetes mellitus with unspecified diabetic retinopathy
E13.311	Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema
E13.319	Other specified diabetes mellitus with unspecified diabetic retinopathy without macular edema
E13.32	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy
E13.321	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E13.329	Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E13.33	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy
E13.331	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema
E13.339	Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E13.34	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy
E13.341	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E13.349	Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E13.35	Other specified diabetes mellitus with proliferative diabetic retinopathy
E13.351	Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema
E13.352	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula
E13.353	Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula
E13.354	Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment
E13.355	Other specified diabetes mellitus with stable proliferative diabetic retinopathy
E13.359	Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema
E13.36	Other specified diabetes mellitus with diabetic cataract
E13.37	Other specified diabetes mellitus with diabetic macular edema, resolved following treatment
E13.39	Other specified diabetes mellitus with other diabetic ophthalmic complication
E13.4	Other specified diabetes mellitus with neurological complications
E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy
E13.42	Other specified diabetes mellitus with diabetic polyneuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.44	Other specified diabetes mellitus with diabetic amyotrophy
E13.49	Other specified diabetes mellitus with other diabetic neurological complication
E13.5	Other specified diabetes mellitus with circulatory complications
E13.51	Other specified diabetes mellitus with diabetic peripheral angiopathy without gangrene

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
E13.52	Other specified diabetes mellitus with diabetic peripheral angiopathy with gangrene
E13.59	Other specified diabetes mellitus with other circulatory complications
E13.6	Other specified diabetes mellitus with other specified complications
E13.61	Other specified diabetes mellitus with diabetic arthropathy
E13.610	Other specified diabetes mellitus with diabetic neuropathic arthropathy
E13.618	Other specified diabetes mellitus with other diabetic arthropathy
E13.62	Other specified diabetes mellitus with skin complications
E13.620	Other specified diabetes mellitus with diabetic dermatitis
E13.621	Other specified diabetes mellitus with foot ulcer
E13.622	Other specified diabetes mellitus with other skin ulcer
E13.628	Other specified diabetes mellitus with other skin complications
E13.63	Other specified diabetes mellitus with oral complications
E13.630	Other specified diabetes mellitus with periodontal disease
E13.638	Other specified diabetes mellitus with other oral complications
E13.64	Other specified diabetes mellitus with hypoglycemia
E13.641	Other specified diabetes mellitus with hypoglycemia with coma
E13.649	Other specified diabetes mellitus with hypoglycemia without coma
E13.65	Other specified diabetes mellitus with hyperglycemia
E13.69	Other specified diabetes mellitus with other specified complication
E13.8	Other specified diabetes mellitus with unspecified complications
E13.9	Other specified diabetes mellitus without complications
O24	Diabetes mellitus in pregnancy, childbirth, and the puerperium

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
O24.0	Pre-existing type 1 diabetes mellitus, in pregnancy, childbirth and the puerperium
O24.01	Pre-existing type 1 diabetes mellitus, in pregnancy
O24.011	Pre-existing type 1 diabetes mellitus, in pregnancy, first trimester
O24.012	Pre-existing type 1 diabetes mellitus, in pregnancy, second trimester
O24.013	Pre-existing type 1 diabetes mellitus, in pregnancy, third trimester
O24.019	Pre-existing type 1 diabetes mellitus, in pregnancy, unspecified trimester
O24.02	Pre-existing type 1 diabetes mellitus, in childbirth
O24.03	Pre-existing type 1 diabetes mellitus, in the puerperium
O24.1	Pre-existing type 2 diabetes mellitus, in pregnancy, childbirth and the puerperium
O24.11	Pre-existing type 2 diabetes mellitus, in pregnancy
O24.111	Pre-existing type 2 diabetes mellitus, in pregnancy, first trimester
O24.112	Pre-existing type 2 diabetes mellitus, in pregnancy, second trimester
O24.113	Pre-existing type 2 diabetes mellitus, in pregnancy, third trimester
O24.119	Pre-existing type 2 diabetes mellitus, in pregnancy, unspecified trimester
O24.12	Pre-existing type 2 diabetes mellitus, in childbirth
O24.13	Pre-existing type 2 diabetes mellitus, in the puerperium
O24.3	Unspecified pre-existing diabetes mellitus in pregnancy, childbirth and the puerperium
O24.31	Unspecified pre-existing diabetes mellitus in pregnancy
O24.311	Unspecified pre-existing diabetes mellitus in pregnancy, first trimester
O24.312	Unspecified pre-existing diabetes mellitus in pregnancy, second trimester
O24.313	Unspecified pre-existing diabetes mellitus in pregnancy, third trimester

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
O24.319	Unspecified pre-existing diabetes mellitus in pregnancy, unspecified trimester
O24.32	Unspecified pre-existing diabetes mellitus in childbirth
O24.33	Unspecified pre-existing diabetes mellitus in the puerperium
O24.4	Gestational diabetes mellitus
O24.41	Gestational diabetes mellitus in pregnancy
O24.410	Gestational diabetes mellitus in pregnancy, diet controlled
O24.414	Gestational diabetes mellitus in pregnancy, insulin controlled
O24.415	Gestational diabetes mellitus in pregnancy, controlled by oral hypoglycemic drugs
O24.419	Gestational diabetes mellitus in pregnancy, unspecified control
O24.42	Gestational diabetes mellitus in childbirth
O24.420	Gestational diabetes mellitus in childbirth, diet controlled
O24.424	Gestational diabetes mellitus in childbirth, insulin controlled
O24.425	Gestational diabetes mellitus in childbirth, controlled by oral hypoglycemic drugs
O24.429	Gestational diabetes mellitus in childbirth, unspecified control
O24.43	Gestational diabetes mellitus in the puerperium
O24.430	Gestational diabetes mellitus in the puerperium, diet controlled
O24.434	Gestational diabetes mellitus in the puerperium, insulin controlled
O24.435	Gestational diabetes mellitus in puerperium, controlled by oral hypoglycemic drugs
O24.439	Gestational diabetes mellitus in the puerperium, unspecified control
O24.8	Other pre-existing diabetes mellitus in pregnancy, childbirth, and the puerperium

Table 6	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
O24.81	Other pre-existing diabetes mellitus in pregnancy
O24.811	Other pre-existing diabetes mellitus in pregnancy, first trimester
O24.812	Other pre-existing diabetes mellitus in pregnancy, second trimester
O24.813	Other pre-existing diabetes mellitus in pregnancy, third trimester
O24.819	Other pre-existing diabetes mellitus in pregnancy, unspecified trimester
O24.82	Other pre-existing diabetes mellitus in childbirth
O24.83	Other pre-existing diabetes mellitus in the puerperium
O24.9	Unspecified diabetes mellitus in pregnancy, childbirth and the puerperium
O24.91	Unspecified diabetes mellitus in pregnancy
O24.911	Unspecified diabetes mellitus in pregnancy, first trimester
O24.912	Unspecified diabetes mellitus in pregnancy, second trimester
O24.913	Unspecified diabetes mellitus in pregnancy, third trimester
O24.919	Unspecified diabetes mellitus in pregnancy, unspecified trimester
O24.92	Unspecified diabetes mellitus in childbirth
O24.93	Unspecified diabetes mellitus in the puerperium
P70.2	Neonatal diabetes mellitus

Table 7: 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

Table 8: CPT/HCPCS codes *not* covered under the Medical Benefit Plan:	
Code	*Description*
These transdermal insulin delivery systems (e.g., V-Go) are considered self-use and may be covered under the Pharmacy Benefit Plan	
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)]

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