United Healthcare Community Plan

Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for Mississippi Only)

Policy Number: CS024MS.AD
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➲ Instructions for Use

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Related Policy

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Mississippi Only)

Application

This Medical Policy only applies to the state of Mississippi.

Coverage Rationale

➲ See Benefit Considerations

Insulin Delivery

Mississippi CAN (Coordinated Access Network)

For medical necessity clinical coverage criteria for insulin delivery and continuous glucose monitoring (CGM), refer to the Mississippi Division of Medicaid Administrative Code, Title 23, Part 209, Rule 1.31: Insulin Pumps.

Mississippi CHIP (Children's Health Insurance Program)

When used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions, external continuous subcutaneous insulin infusion pumps are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Technology.

Note: For Omnipod 5, refer to the federal, state, or contractual requirements.

Click here to view the InterQual® criteria.

External continuous subcutaneous insulin infusion pumps are medically necessary for managing individuals with diabetes due to other causes that require intensive insulin therapy (insulin-treated at least three times a day). Examples include but are not limited to cystic fibrosis-related diabetes, post-transplantation diabetes, or diabetes following pancreatic surgery.

The following devices are unproven and not medically necessary for managing individuals with diabetes due to insufficient evidence of efficacy.

- Implantable insulin pumps

- Nonprogrammable transdermal insulin delivery systems (e.g., V-Go)

Continuous Glucose Monitoring (CGM)

Mississippi CAN (Coordinated Access Network)

For medical necessity clinical coverage criteria for and continuous glucose monitoring (CGM), refer to the Mississippi Division of Medicaid Administrative Code, Title 23, Part 225, Rule 4.3: Continuous Glucose Monitoring Services.

Mississippi CHIP (Children's Health Insurance Program)

Short-Term CGM (3-14 days)

Short-term CGM use by a healthcare provider for diagnostic purposes is proven and medically necessary for managing individuals with diabetes.

Long-Term CGM (Greater Than 14 days)

Note: Coverage criteria noted below must be met whether the request comes through the UnitedHealthcare prior authorization process (type 2 or gestational diabetes) or a contracted supplier (type 1 diabetes).

Duration of approved authorization:
- Initial CGM authorization will be for up to six months.
- Reauthorization will be for up to 12 months.

When used according to FDA labeled indications, contraindications, warnings, and precautions, initial long-term CGM use is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Technology.

Click here to view the InterQual® criteria.

For continued long-term use, CGM is proven and medically necessary when all of the following criteria are met:
- Device is used according to FDA labeled indications, contraindications, warnings, and precautions
- Medical necessity clinical coverage criteria are met; refer to the InterQual® CP: Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Technology
- Individual is assessed by a provider every six months for adherence to the prescribed CGM regimen and treatment plan

Initial long-term CGM using an implantable glucose sensor (e.g., Eversense) is medically necessary for managing individuals with diabetes when all of the following criteria are met:
- Device is used according to FDA labeled indications, contraindications, warnings, and precautions
- Age ≥ 18
- One of the following:
  - Individual requires intensive insulin therapy (insulin-treated at least three times a day or insulin pump); or
  - Individual has a history of a level 3 hypoglycemic event or recurrent (more than one) level 2 hypoglycemic events that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan

Continued long-term CGM using an implantable glucose sensor (e.g., Eversense) is medically necessary for managing individuals with diabetes when all of the following criteria are met:
- Individual continues to require intensive insulin therapy (insulin-treated at least three times a day or insulin pump) or clinical criteria for initial use noted above were met at initiation of CGM for Hypoglycemia
- Individual is assessed by a provider every six months for adherence to the prescribed CGM regimen and treatment plan

Initial long-term CGM is medically necessary for managing individuals with diabetes on a nonintensive insulin treatment plan (e.g., basal insulin and/or oral medications) who have a history of a level 3 hypoglycemic event or recurrent (more than one) level 2 hypoglycemic events that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan.

Continued long-term CGM is medically necessary for managing individuals with diabetes on a nonintensive insulin treatment plan (e.g., basal insulin and/or oral medications) when all of the following criteria are met:

- Clinical criteria for initial use noted above were met at initiation of CGM
- Individual is assessed by a provider every six months for adherence to the prescribed CGM regimen and treatment plan

Long-term CGM is unproven and not medically necessary for managing individuals with diabetes on a nonintensive insulin treatment plan (e.g., basal insulin and/or oral medications) for all other indications.

CGM using a noninvasive device is unproven and not medically necessary for managing individuals with diabetes due to insufficient evidence of efficacy.

Definitions

Adjunctive CGM: An Adjunctive CGM requires the user to verify their glucose levels or trends displayed on a CGM with a blood glucose monitor prior to making treatment decisions [Centers for Medicare and Medicaid Services (CMS); American Diabetes Association (ADA), 2024].

Hypoglycemia: (ADA, 2024; McCall et al., 2023; Blonde et al., 2022)
- Level 2 – Glucose < 4 mg/dL (3.0 mmol/L). This level of Hypoglycemia is associated with increased risk for cognitive dysfunction and mortality.
- Level 3 – A severe event characterized by altered mental and/or physical state requiring third-party assistance for treatment. This level of Hypoglycemia is life-threatening and requires emergent treatment.

Intermittently Scanned (Flash) CGM (isCGM): Devices with two components: a combined glucose sensor/transmitter and a separate reader. These devices measure glucose levels continuously but require scanning for visualization and storage of glucose values. They are available with and without alarms (ADA website and ADA, 2024).

Non-Adjunctive CGM: A Non-Adjunctive CGM can be used to make treatment decisions without the need for a stand-alone blood glucose monitor to confirm testing results (CMS; ADA, 2024).

Professional CGM: Devices that are placed in a healthcare professional's office (or with remote instruction) and worn for a discrete period of time (generally 7–14 days). Data may be blinded or visible to the person wearing the device. The data is used to assess glycemic patterns and trends. Unlike Real-Time CGM and isCGM devices, these devices are clinic-based and not owned by the user (ADA, 2024).

Real-Time CGM (rtCGM): Devices with three components: a sensor (small wire catheter that is inserted under the skin), a transmitter that attaches to the sensor and sends information, and a handheld receiver and/or smartphone that displays glucose readings in real time. These devices measure and display glucose levels continuously and have audible alerts when glucose levels are out of range. Some systems require calibration by the user (ADA website and ADA, 2024).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
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
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

CPT Code	Description
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

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HCPCS Code	Description
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week
A4238	Supply allowance for adjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply
A9277	Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
A9278	Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
E0784	External ambulatory infusion pump, insulin
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
E2102	Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
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

Diagnosis Code	Description
E11.00	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E11.01	Type 2 diabetes mellitus with hyperosmolarity with coma
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma
E11.11	Type 2 diabetes mellitus with ketoacidosis with coma
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
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema

Diagnosis Code	Description
E11.3211	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3291	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E11.3292	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E11.3293	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3299	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3391	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E11.3392	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E11.3393	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3399	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3491	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E11.3492	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E11.3493	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3499	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral

Diagnosis Code	Description
E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E11.3521	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E11.3522	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E11.3523	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E11.3529	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye
E11.3531	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E11.3532	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E11.3533	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E11.3539	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye
E11.3541	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E11.3542	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye
E11.3543	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
E11.3549	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye
E11.3551	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E11.3552	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E11.3553	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral
E11.3559	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye
E11.3591	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E11.3592	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E11.3593	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E11.3599	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye
E11.36	Type 2 diabetes mellitus with diabetic cataract
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication
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
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene

Diagnosis Code	Description
E11.59	Type 2 diabetes mellitus with other circulatory complications
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy
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
E11.630	Type 2 diabetes mellitus with periodontal disease
E11.638	Type 2 diabetes mellitus with other oral complications
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
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
O24.410	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
O24.420	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
O24.430	Gestational diabetes mellitus in the puerperium, diet controlled
O24.434	Gestational diabetes mellitus in the puerperium, insulin controlled
O24.435	Gestational diabetes mellitus in the puerperium, controlled by oral hypoglycemic drugs
O24.439	Gestational diabetes mellitus in the puerperium, unspecified control

Description of Services

Diabetes mellitus can be classified into the following general categories (ADA, 2024):

- Type 1 diabetes (due to autoimmune beta-cell destruction, usually leading to absolute insulin deficiency, including latent autoimmune diabetes in adults [LADA]). LADA can be classified as a more slowly progressing variation of type 1 diabetes, yet it is often misdiagnosed as type 2.
- Type 2 diabetes (due to a non-autoimmune progressive loss of adequate beta-cell insulin secretion, frequently on the background of insulin resistance and metabolic syndrome).
- Gestational diabetes mellitus (GDM) (diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation or other types of diabetes occurring throughout pregnancy, such as type 1 diabetes). GDM resembles type 2 diabetes and usually disappears after childbirth.
- Specific types of diabetes due to other causes, e.g., monogenic diabetes syndromes (such as neonatal diabetes and maturity-onset diabetes of the young), diseases of the exocrine pancreas (such as cystic fibrosis and pancreatitis),

and drug- or chemical-induced diabetes (such as with glucocorticoid use, in the treatment of HIV, or after organ transplantation).

If poorly controlled, diabetes can lead to complications such as heart disease, stroke, peripheral vascular disease, retinal damage, kidney disease, nerve damage, and erectile dysfunction. In GDM, fetal and maternal health can be compromised.

Improved glycemic control has been shown to slow the onset or progression of major complications. Management of diabetes involves efforts to maintain blood glucose levels near the normal range. Glycemic status can be assessed by blood glucose monitoring (BGM), continuous glucose monitoring (CGM), and laboratory testing of hemoglobin A1c (HbA1c) (ADA, 2024).

Insulin Delivery

Standard external insulin pumps connect to flexible plastic tubing that ends with a needle inserted just under the skin. Another type of insulin pump (OmniPod®) combines an insulin reservoir placed on the skin with a wireless device to manage dosing and perform BGM. Both types of devices can be programmed to release small doses of insulin continuously (basal), or a bolus dose close to mealtime to control the rise in blood glucose after a meal. Newer patch devices (e.g., V-Go®) deliver preset basal and on-demand bolus dosages of insulin transdermally and lack programmability. Implantable insulin pumps are placed inside the body to deliver insulin in response to remote-control commands from the user (ADA Common Terms website).

Continuous Glucose Monitors (CGM)

CGM devices continuously monitor and record interstitial glucose levels and have three components: a sensor, transmitter, and receiver. Some CGM systems are designed for short-term diagnostic or professional use. These devices store retrospective information for review at a later time. Other CGM systems, including Real-Time CGM (rtCGM) and Intermittently Scanned CGM (isCGM), are designed for long-term personal use and allow the individual to take action based on the data displayed (ADA, 2024; American Medical Association, 2009). Available sensors are either disposable or implantable. Implantable sensors include a smart transmitter and mobile application and are based on fluorescence sensing technology. The sensor is designed to be inserted subcutaneously and communicate with the smart transmitter to wirelessly transmit glucose levels to a mobile device. These long-term devices are available with or without an integrated external insulin pump. A review by Messer et al. (2019) highlights clinically relevant aspects of newer advanced diabetes devices. Refer to the Definitions section for more details on the different types of CGM devices.

Benefit Considerations

For details regarding repair and replacement coverage, refer to the Medical Policy titled Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Mississippi Only).

Clinical Evidence

Insulin Delivery

Insulin Pumps for Diabetes Due to Other Causes

Specific types of diabetes due to other causes may require intensive insulin management. Examples include cystic fibrosis-related diabetes, post-transplantation diabetes, or diabetes following pancreatic surgery. Although the evidence is limited, professional societies state that insulin pumps may be considered in these populations with insulin deficiency that require multiple daily injections (ADA, 2024; McCall et al., 2023).

Implantable Insulin Pumps

At this time, implantable insulin pumps are only available in a clinical trial setting.

Nonprogrammable Transdermal Insulin Delivery

There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of nonprogrammable wearable disposable insulin delivery devices in the management of individuals with diabetes. Larger, well-designed studies with long-term follow-up and comparative effectiveness data are needed.

A prospective, observational, open-label, multicenter study evaluated glycemic control, insulin dosing, and hypoglycemia risk in patients using a V-Go device in a real-world setting. The primary objective was to compare change in mean HbA1c from baseline to the end of use. One hundred eighty-eight patients with type 2 diabetes and suboptimal glycemic control (HbA1c ≥ 7%) were enrolled in the study. At 12 months, 112 patients (60%) remained in the study, among whom 66 patients were on V-Go and 46 patients were using therapies other than V-Go. Use of V-Go resulted in significantly improved glycemic control across the patient population and did so with significantly less insulin among most patients with prior insulin use. Twenty-two patients (12%) reported hypoglycemic events (≤ 70 mg/dL), with an event rate of 1.51 events/patient/year. Study limitations include lack of a control group and high attrition rates (Grunberger et al., 2020).

Several retrospective chart reviews suggest that V-Go therapy is associated with improved glycemic control; however, these studies are limited by retrospective design, small sample size, and/or short-term follow-up. Further well-designed, prospective studies are needed to establish the safety and efficacy of this device in managing patients with diabetes (Hundal et al., 2020; Zeidan et al., 2020; Everitt et al., 2019; Raval et al., 2019; Sutton et al., 2018; Lajara et al., 2016; Lajara et al., 2015; Rosenfeld et al., 2012).

Continuous Glucose Monitoring

Implantable Glucose Sensor

A review of the clinical evidence concluded that the Eversense implantable glucose sensor is an acceptable alternative to standard CGMs. Comparative studies suggest that the Eversense clinical validity is comparable to other CGM devices.

Summary of Clinical Trials

- PROMISE – The prospective, multicenter, unblinded, nonrandomized study evaluated the accuracy and safety of the next-generation implantable Eversense CGM system for up to 180 days in 181 patients with type 1 or type 2 diabetes (Garg et al. 2022).
- PRECISION – The prospective, multicenter study evaluated the accuracy and safety of Eversense among 35 adults with type 1 or type 2 diabetes through 90 days (Christiansen et al., 2019).
- PRECISE II - The prospective, multicenter study evaluated the accuracy and safety of the Eversense CGM system in 90 adult participants with type 1 and type 2 diabetes (Christiansen et al., 2018).
- PRECISE trial – The prospective, multicenter pivotal trial evaluated the accuracy and longevity of the Eversense implantable CGM sensor in 71 participants, aged 18 years and older, with type 1 and type 2 diabetes (Kropff et al., 2017).

A Hayes Health Technology Assessment concluded that a low-quality body of evidence suggests that the Eversense CGM system is moderately accurate in measuring glucose levels compared with venous blood glucose or SMBG as reference standards. However, substantial uncertainty remains pertaining to the accuracy of the device across a range of glucose values. Additionally, the body of evidence is limited by an evidence base of fair- to very poor-quality studies, small numbers of patients, limited data assessing the accuracy of CGM across different glucose parameters, and inconsistencies in results between studies. Assessments of clinical utility were of low quality due to a small number of studies available evaluating health outcomes. One RCT reported no difference in HbA1c levels between a group of patients with an activated Eversense device compared with a group of patients with a blinded Eversense device (who used intermittent CGM or SMBG); however, patients with type 1 diabetes spent a significantly lower amount of time in hypoglycemia ranges compared with baseline use of SMBG. Overall, the evidence from the single-arm cohort studies suggests that the Eversense CGM System statistically significantly reduces HbA1c values by approximately 0.5%, which is of unclear clinical relevance. In addition, only a single study was available comparing health outcomes in patients who used the Eversense CGM System versus intermittent CGM or SMBG, which limits the conclusions that may be drawn regarding clinical utility (Hayes, 2022; updated 2023).

Renard et al. (2022) reported the results of two small RCTs of adults treated with insulin. The first trial (Cohort 1) included 149 adults with type 1 diabetes (T1DM) or type 2 diabetes (T2DM) and an HbA1c above 8%. Participants were implanted with the Eversense CGM then randomized to access or no access to the sensor readings. The study failed to demonstrate a benefit on the primary outcome, changes in HbA1c at six months after implantation. The second trial (Cohort 2) included 90 adults with T1DM who spent more than 90 minutes per day with glucose values below 70 mg/dL over the previous 28 days at baseline. This trial demonstrated a significant decrease after 3 to 4 months of Eversense use in time below 54 mg/dL (primary outcome, clinically significant hypoglycemia) with a group difference of about 23 minutes. The group differences further increased at 6 months post implantation (secondary outcome).

In a randomized crossover trial, Boscari et al. (2022) compared 12 weeks with a first-generation Eversense implantable sensor (n = 8) and 12 weeks with a Dexcom G5 transcutaneous sensor (n = 8). The primary outcome was sensor accuracy, expressed as mean absolute relative difference (MARD) versus capillary glucose values obtained by SMBG. Secondary outcomes were time of CGM use, efficacy (HbA1c; time in range, time above and below range) and safety. Psychological outcomes were also considered. Overall, Eversense performed better than Dexcom G5 with a MARD versus SMBG of 12.27% ±11.55% (mean ±SD) versus 13.14% ±14.76%; p-value < 0.001. Eversense was more accurate than Dexcom G5 in the normal range, but there were no differences in the hypo- and hyperglycemic ranges.

Boscari et al. (2021) conducted a small study (n = 11) comparing the accuracy of the Dexcom G5 transcutaneous sensor and the first-generation Eversense implantable sensor in adults with insulin-treated type 1 diabetes. The two devices were worn simultaneously and compared to SMGB (over 7 days) or venous blood glucose during a one-day clinical visit when hypoglycemia was induced to test CGM performances during rapid glycemia changes. The Dexcom G5 and Eversense had similar accuracy, when compared with SMBG readings collected both at home and during the clinic visit. However, compared to venous glucose levels during the clinic visit, the Dexcom G5 was more accurate than the Eversense device (absolute relative difference, ARD: 7.9 versus 11.4%, p < 0.001). When blood glucose decreased, Dexcom also performed better than Eversense (7.3 versus 13.6%, p < 0.001).

Fokkert et al. (2020) compared the performance of two CGM devices between a week of normal daily activities and a week of intense physical activity (mountain biking) among 23 adults with type 1 diabetes. The investigators concluded that during "exercise compared with daily life activities, interstitial glucose readings with both the Eversense (fluorescence based) and the Free Style Libre (glucose oxidase based) were less accurate, often with clinically relevant differences, compared with capillary measurements." The performance of the two devices did not, however, seem to be clinically significantly different from one another, although the study did not test differences between devices. This study suggests challenges in accuracy during intense exercise, but no clinically significant difference in performance between the Eversense and Free Style Libre devices.

An ECRI clinical evidence assessment reported that evidence from five multicenter diagnostic accuracy cohort studies comparing Eversense's accuracy with that of plasma glucose readings or SMBG values indicates the device provides relatively accurate data. A European registry study of > 3,000 users found the system was safe over multiple cycles of use. Implantation was associated with infrequent, nonserious adverse events. However, findings from the three prospective cohort studies that compared sensor readings with plasma glucose levels recorded at predetermined time intervals may not generalize to the broader patient population for whom the device is intended. Also, most of the real-world experience data on the Eversense device is derived from its use in Europe and South Africa and may not be completely generalizable to other healthcare settings due to differences in healthcare practices and because the Eversense sensor initially approved in Europe had a different design (ECRI, 2020).

Tweden et al. (2020) assessed the performance of the Eversense CGM system in adult patients with diabetes who had gone through at least four sensor cycles. Sensors were replaced every 90 or 180 days depending on the product used. The Eversense Data Management System was used to evaluate the accuracy of sensor glucose (SG) values against SMBG. Mean SG and associated measures of variability, glucose management indicator (GMI), and percent and time in range were calculated for the 24-hour time period over each cycle. In addition, transmitter wear time was evaluated across each sensor wear cycle. Among the 945 users included in the analysis, the mean absolute relative difference (MARD) using 152,206, 174,645, 206,024, and 172,587 calibration matched pairs against SMBG was 11.9% (3.6%), 11.5% (4.0%), 11.8% (4.7%), and 11.5% (4.1%) during the first four sensor cycles, respectively. Mean values of the CGM metrics over the first sensor cycle were 156.5 mg/dL for SG, 54.7 mg/dL for SD, 0.35 for coefficient of variation, and 7.04% for GMI. Percent SG at different glycemic ranges was as follows: < 54 mg/dL was 1.1% (16 min), < 70 mg/dL was 4.6% (66 min), ≥ 70-180 mg/dL (time in range) was 64.5% (929 min), > 180 - 250 mg/dL was 22.8% (328 min), and > 250 mg/dL was 8.1% (117 min). The median transmitter wear time over the first cycle was 83.2%. CGM metrics and wear time were similar over the subsequent three cycles. This study is limited by its retrospective design.

In a prospective, multicenter, observational study, Irace et al. (2020) evaluated the changes in HbA1c and CGM metrics associated with use of the implantable 180-day Eversense CGM System in 100 adult patients with type 1 diabetes. HbA1c was measured at baseline and at 180 days. Changes in time in range (glucose 70-180 mg/dL), time above range (glucose > 180 mg/dL], time below range (glucose < 70 mg/dL) and glycemic variability were also assessed. Fifty-six percent of patients were insulin pump users and 45% were previous CGM users. HbA1c significantly decreased in patients after 180 days of sensor wear (-0.43% ±0.69%, 5 ±8 mmol/mol; p < 0.0001). Improvements were greater in subgroups of patients who were CGM naïve regardless of the insulin delivery method. Time in range significantly increased and time above range and mean daily sensor glucose significantly decreased, while time below range did not change after 180 days of sensor wear. Study limitations include lack of a comparator group, small patient population and short-term follow-up.

In a 6-week, home-use study, Jafri et al. (2020) evaluated the accuracy of the Dexcom G5, Abbott Freestyle Libre Pro, and Senseonics Eversense CGM devices in 23 individuals with type 1 diabetes who wore all three devices concurrently. The primary outcome was the MARD between CGM readings and plasma-glucose values obtained approximately twice daily by the subjects. All three CGM systems produced higher average MARDs than during in-clinic studies. However, since all three CGM systems were worn by the same individuals and used the same meter for comparator glucose measurements, direct comparisons were possible. In the three-way comparison, Eversense achieved the lowest nominal MARD (14.8%) followed by Dexcom G5 (16.3%) and Libre Pro (18.0%). Studies with longer follow-up and larger patient populations are needed to confirm these findings.

The Post-Market Clinical Follow-up (PMCF) registry evaluated the long-term safety and performance of the Eversense CGM system over multiple sensor insertion/removal cycles among adults with type 1 and type 2 diabetes. The primary safety endpoint was the rate of serious adverse events (SAEs) through four sensor insertion/removal cycles. Of 3,023 enrolled patients, 280 completed four cycles. No related SAEs were reported. The most frequently reported adverse events were sensor location site infection, inability to remove the sensor upon first attempt and adhesive patch location site irritation. One non-serious allergic reaction to lidocaine was reported, which resolved with administration of an antihistamine. The full intended sensor life was achieved by 91% of 90-day sensors and 75% of 180-day sensors. This study is limited by its observational nature. Further studies are needed to evaluate the clinical utility of the Eversense system and the impact on health outcomes (Deiss et al., 2020).

Sanchez et al. (2019) analyzed real-world data from the first U.S. commercial users of the Eversense system. The first 205 patients who reached a 90-day wear period were included in the analysis. Of the 205 patients, 129 had type 1 diabetes, 18 had type 2 diabetes and 58 were unreported.

- Time in range (≥ 70-180 mg/dL) was 62.3%
- > 180-250 mg/dL was 21.9%
- > 250 mg/dL was 11.6%
- < 54 mg/dL was 1.2%
- < 70 mg/dL was 4.1%

Nighttime values were similar. The sensor reinsertion rate was 78.5%. The median transmitter wear time was 83.6%. There were no related serious adverse events. The data showed promising glycemic results, sensor accuracy and safety. Further long-term studies are needed to confirm these results and determine the impact on health outcomes.

In a prospective, single-center, single-arm study, Aronson et al. (2019) evaluated the safety and effectiveness of the Eversense XL implantable CGM system through 180 days in a primarily adolescent population with type 1 diabetes (n = 36). Overall, MARD was 9.4%. CGM system agreement through 60, 120 and 180 days was 82.9%, 83.6% and 83.4%, respectively. Surveillance error grid analysis showed 98.4% of paired values in clinically acceptable error zones A and B. No insertion/removal or device-related serious adverse events were reported. Study limitations include lack of randomization and control, small patient population and short-term follow-up.

Nonintensive Insulin Therapy

Jancev et al. (2024) conducted a systematic review and meta-analysis evaluating the effect of rtCGM or isCGM on glycemic control in adults with type 2 diabetes. Twelve RCTs (n = 1248) were included; eight investigating rtCGM and four isCGM. The sample size ranged from 25 to 224 participants. Change in HbA1c and time in range (TIR), time below range (TBR), time above range (TAR) and glycemic variability were assessed. The investigators also assessed the effects of CGM on severe hypoglycemia and micro- and macrovascular complications. Compared with BGM, CGM use (rtCGM or isCGM) led to an average 3.43 mmol/mol decrease in HbA1c. This effect was comparable in studies that included individuals using insulin with or without oral agents and individuals using oral agents only. Use of rtCGM showed a trend towards a larger effect than use of isCGM. CGM was also associated with a 6.36% increase in TIR, a 0.66% decrease in TBR, a 5.86% decrease in TAR, and a 1.47% decrease in glycemic variability. Three studies reported one or more events of severe hypoglycemia and macrovascular complications. In comparison with BGM, CGM use led to a non-statistically significant difference in the incidence of severe hypoglycemia and macrovascular complications. No studies reported data on microvascular complications. The authors concluded that CGM use compared with BGM is associated with improvements in glycemic control in adults with type 2 diabetes. Included study limitations were small sample sizes, short-term follow-up and open-label design. (Includes Moon et al., 2023; Martens et al., 2021; Wada et al., 2020; Vigersky et al., 2012.)

An ECRI report assessed the safety and efficacy of replacing BGM with CGM by individuals with type 2 diabetes on noninsulin therapies and found the evidence inconclusive. Larger RCTs with follow-up of at least 1 year that compare CGM and BGM are needed (ECRI, 2021).

Several retrospective, observational studies evaluated the use of CGM in individuals with poorly controlled type 2 diabetes on less intensive treatment regimens. While these studies showed reductions in HbA1C, further results from larger, randomized controlled trials are needed to determine the role of CGM in this patient population (Conti et al., 2024; Al Hayek and Al Dawish, 2023; Carlson et al., 2022; Wright et al., 2021).

Noninvasive Devices
There are no FDA approved noninvasive continuous glucose monitors on the market at this time.

Clinical Practice Guidelines
American Association of Clinical Endocrinology (AACE)
AACE clinical practice guidelines provide evidence-based recommendations for the comprehensive care of persons with diabetes mellitus (Blonde et al., 2022).

AACE clinical practice guidelines provide evidence-based recommendations for the use of advanced technology in the management of persons with diabetes mellitus (Grunberger et al., 2021).
- CGM is strongly recommended for all persons with diabetes treated with intensive insulin therapy, defined as three or more injections of insulin per day or the use of an insulin pump. Grade A; High Strength of Evidence; BEL 1
- CGM is recommended for all individuals with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness). Grade A; Intermediate-High Strength of Evidence; BEL 1
- CGM is recommended for children/adolescents with type 1 diabetes. Grade A; Intermediate-High Strength of Evidence; BEL 1
- CGM is recommended for pregnant women with type 1 and type 2 diabetes treated with intensive insulin therapy. Grade A; Intermediate-High Strength of Evidence; BEL 1
- CGM is recommended for women with gestational diabetes on insulin therapy. Grade A; Intermediate Strength of Evidence; BEL 1
- CGM may be recommended for women with gestational diabetes who are not on insulin therapy. Grade B; Intermediate Strength of Evidence; BEL 1
- CGM may be recommended for individuals with type 2 diabetes who are treated with less intensive insulin therapy. Grade B; Intermediate Strength of Evidence; BEL 1

American Diabetes Association (ADA)
Insulin Delivery
The 2024 *Standards of Medical Care in Diabetes* make the following recommendations:
- Automated insulin delivery systems should be offered for diabetes management to youth and adults with type 1 diabetes (Level of Evidence [LOE] A) and other types of insulin-deficient diabetes (LOE E) who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on an individual's circumstances, preferences, and needs.
- Insulin pump therapy alone with or without sensor-augmented low glucose suspend feature and/or automated insulin delivery systems should be offered for diabetes management to youth and adults on MDIs with type 1 diabetes (LOE A) or other types of insulin-deficient diabetes (LOE E) who are capable of using the device safely (either by themselves or with a caregiver) and are not able to use or do not choose an automated insulin delivery system. The choice of device should be made based on an individual's circumstances, preferences, and needs. (LOE A)
- Insulin pump therapy can be offered for diabetes management to youth and adults on MDIs with type 2 diabetes who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on an individual's circumstances, preferences, and needs. (LOE A)

Continuous Glucose Monitoring (CGM)
The 2024 Standards of Medical Care in Diabetes make the following recommendations:
- Real-time CGM (LOE A) or intermittently scanned CGM (LOE B) should be offered for diabetes management in adults with diabetes on MDIs or continuous subcutaneous insulin infusion who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on an individual's circumstances, preferences, and needs.
- Real-time CGM (LOE A) or intermittently scanned CGM (LOE C) should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on an individual's circumstances, preferences, and needs.
- Real-time CGM (LOE B) or intermittently scanned CGM (LOE E) should be offered for diabetes management in youth with type 1 diabetes on MDIs or continuous subcutaneous insulin infusion who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on an individual's circumstances, preferences, and needs.
- Real-time CGM or intermittently scanned CGM should be offered for diabetes management in youth with type 2 diabetes on MDIs or continuous subcutaneous insulin infusion who are capable of using devices safely (either by

themselves or with a caregiver). The choice of device should be made based on an individual's circumstances, preferences, and needs. (LOE E)
- In people with diabetes on MDIs or continuous subcutaneous insulin infusion, real-time CGM devices should be used as close to daily as possible for maximal benefit. (LOE A) Intermittently scanned CGM devices should be scanned frequently, at a minimum once every 8 hours to avoid gaps in data. (LOE A)
- When used as an adjunct to pre- and post-prandial blood glucose monitoring, CGM can help to achieve HbA1c targets in diabetes and pregnancy. (LOE B)
- Periodic use of real-time or intermittently scanned CGM or use of professional CGM can be helpful for diabetes management in circumstances where consistent use of CGM is not desired or available. (LOE C)
- Skin reactions, either due to irritation or allergy, should be assessed and addressed to aid in successful use of devices. (LOE E)
- People who wear CGM devices should be educated on potential interfering substances and other factors that may affect accuracy. (LOE C)

ADA Level of Evidence	Description

A	• Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including:
	  ○ Evidence from a well-conducted multicenter trial
	  ○ Evidence from a meta-analysis that incorporated quality ratings in the analysis
	• Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:
	  ○ Evidence from a well-conducted trial at one or more institutions
	  ○ Evidence from a meta-analysis that incorporated quality ratings in the analysis

B	• Supportive evidence from well-conducted cohort studies
	  ○ Evidence from a well-conducted prospective cohort study or registry
	  ○ Evidence from a well-conducted meta-analysis of cohort studies
	• Supportive evidence from a well-conducted case-control study

C	• Supportive evidence from poorly controlled or uncontrolled studies
	  ○ Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
	  ○ Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
	  ○ Evidence from case series or case reports
	• Conflicting evidence with the weight of evidence supporting the recommendation

E	• Expert consensus or clinical experience

Endocrine Society

An Endocrine Society clinical practice guideline presents several recommendations for managing individuals at high risk for hypoglycemia. Most of the studies reviewed in developing the recommendations included individuals with type 1 or type 2 diabetes at risk for hypoglycemia. Although these populations make up the majority of people living with diabetes and are the target population for this guideline, others with diabetes are at risk for hypoglycemia and would benefit from these recommendations. These include those with monogenic forms of diabetes, diabetes in pregnancy, diseases involving the exocrine pancreas (e.g., cystic fibrosis and hemochromatosis), those with drug-related hyperglycemia (including those taking glucocorticoids), and those with diabetes following pancreatic surgery (McCall et al., 2023).

An Endocrine Society clinical practice guideline on the treatment of diabetes in older adults recommends that patients aged 65 and older, who are treated with insulin, perform frequent fingerstick glucose monitoring and/or CGM (to assess glycemia) in addition to HbA1c (LeRoith et al., 2019).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Insulin Delivery

For information on external insulin pumps, refer to the following website (use product codes LZG or QFG): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed March 13, 2024)

For information on automated insulin delivery systems or hybrid closed-loop insulin pumps, refer to the following website (use product code OZP): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed March 13, 2024)

No implantable insulin pumps have received FDA approval at this time.

Insulin Pump Models with or without a CGM component (this is not an exhaustive list):
- Beta Bionics iLet
- Insulet Omnipod 5
- Insulet Omnipod DASH
- Medtronic MiniMed 630G
- Medtronic MiniMed 770G
- Medtronic MiniMed 780G
- Sooil Dana Diabecare
- Tandem Mobi
- Tandem t:slim X2 with Basal - IQ
- Tandem t:slim X2 with Control - IQ

Continuous Glucose Monitors (CGM)

For information on CGMs, refer to the following website (use product code MDS): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed March 13, 2024)

CGM Models (this is not an exhaustive list):
- Abbott FreeStyle Libre 2
- Abbott FreeStyle Libre 3
- Abbott FreeStyle Libre 14-Day
- Dexcom G6
- Dexcom G7
- Medtronic Guardian Connect
- Ascensia Eversense E3

The Eversense CGM system received FDA premarket approval (P160048) on June 21, 2018. The original device was indicated for continually measuring glucose levels in adults (18 years or older) with diabetes for up to 90 days and did not replace information obtained from standard home blood glucose monitoring devices. On June 6, 2019, the device was approved for non-adjunctive use (P160048/S006). On February 10, 2022, the Eversense E3 device received FDA premarket approval (P160048/S016) expanding the indicated use up to 180 days in adults (18 years or older). Eversense is classified under product codes QCD and QHJ. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160048. (Accessed March 13, 2024)

References

Al Hayek AA and Al Dawish MA. Use of flash glucose monitoring and glycemic control in patients with type 2 diabetes mellitus not treated with an intensive insulin regimen: 1-year real-life retrospective cohort study. Adv Ther. 2023 Jun;40(6):2855-2868.

American Diabetes Association. Standards of medical care in diabetes - 2024. Available at: https://diabetesjournals.org/care/issue/47/Supplement_1. Accessed March 29, 2024.

American Diabetes Association website. Common terms. Implantable insulin pump. Available at: https://www.diabetes.org/resources/students/common-terms. Accessed March 29, 2024.

American Diabetes Association website. Devices and Technology: Choosing a CGM. Available at: https://diabetes.org/tools-support/devices-technology/choosing-cgm. Accessed March 29, 2024.

American Medical Association (AMA). CPT Assistant. December 2009;19(12):6-8. Updated February 2010; 20(2):13.

Aronson R, Abitbol A, Tweden KS. First assessment of the performance of an implantable continuous glucose monitoring system through 180 days in a primarily adolescent population with type 1 diabetes. Diabetes Obes Metab. 2019 Jul;21(7):1689-1694.

Blevins T, Shwartz SL, Bode B et al. A study assessing an injection port for administration of insulin. Diabetes Spectrum. 2008;21(3):197–202.

Blonde L, Umpierrez GE, Reddy SS, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a diabetes mellitus comprehensive care plan - 2022 update. Endocr Pract. 2022 Oct;28(10):923-1049.

Boscari F, Vettoretti M, Amato AML, et al. Comparing the accuracy of transcutaneous sensor and 90-day implantable glucose sensor. Nutr Metab Cardiovasc Dis. 2021 Feb 8;31(2):650-657.

Boscari F, Vettoretti M, Cavallin F, et al. Implantable and transcutaneous continuous glucose monitoring system: a randomized cross over trial comparing accuracy, efficacy and acceptance. J Endocrinol Invest. 2022 Jan;45(1):115-124.

Carlson AL, Daniel TD, DeSantis A, et al. Flash glucose monitoring in type 2 diabetes managed with basal insulin in the USA: a retrospective real-world chart review study and meta-analysis. BMJ Open Diabetes Res Care. 2022 Jan;10(1):e002590.

Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) L33822. Glucose monitors. Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822&ver=64&bc=0. Accessed March 29, 2024.

Christiansen MP, Klaff LJ, Bailey TS, et al. 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.

Christiansen MP, Klaff LJ, Brazg R, et al. 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.

Conti M, Massari G, Meneghini E, et al. Effectiveness and safety of the intermittently scanned continuous glucose monitoring system FreeStyle Libre 2 in patients with type 2 diabetes treated with basal insulin or oral antidiabetic drugs: an observational, retrospective real-world study. J Clin Med. 2024 Jan 23;13(3):642.

Deiss D, Irace C, Carlson G, et al. Real-world safety of an implantable continuous glucose sensor over multiple cycles of use: a post-market registry study. Diabetes Technol Ther. 2020 Jan;22(1):48-52.

ECRI Institute. Continuous versus self-monitored blood glucose for patients with type 2 diabetes mellitus on noninsulin therapies. Plymouth Meeting (PA): ECRI; 2021 May. (Clinical Evidence Assessment).

ECRI Institute. Eversense continuous glucose monitor (Senseonics Holdings, Inc.) for measuring glucose levels. Plymouth Meeting (PA): ECRI Institute; 2020 Jan 28. (Custom Product Brief).

Everitt B, Harrison HC Jr, Nikkel C, et al. Clinical and economic considerations based on persistency with a novel insulin delivery device versus conventional insulin delivery in patients with type 2 diabetes: A retrospective analysis. Res Social Adm Pharm. 2019 Sep;15(9):1126-1132.

Feig DS, Donovan LE, Corcoy R, et al.; CONCEPTT Collaborative Group. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicenter international randomized controlled trial. Lancet. 2017 Nov 25;390(10110):2347-2359. Erratum in: Lancet. 2017 Nov 25;390(10110):2346.

Fokkert M, van Dijk PR, Edens MA, et al. Performance of the Eversense versus the Free Style Libre Flash glucose monitor during exercise and normal daily activities in subjects with type 1 diabetes mellitus. BMJ Open Diabetes Res Care. 2020 Aug;8(1):e001193.

García-Moreno RM, Benítez-Valderrama P, Barquiel B, et al. Efficacy of continuous glucose monitoring on maternal and neonatal outcomes in gestational diabetes mellitus: a systematic review and meta-analysis of randomized clinical trials. Diabet Med. 2022 Jan;39(1):e14703.

Garg SK, Liljenquist D, Bode B, et al. Evaluation of accuracy and safety of the next-generation up to 180-day long-term implantable Eversense continuous glucose monitoring system: the PROMISE study. Diabetes Technol Ther. 2022 Feb;24(2):84-92.

Grunberger G, Rosenfeld CR, Bode BW, et al. Effectiveness of V-Go® for patients with type 2 diabetes in a real-world setting: a prospective observational study. Drugs Real World Outcomes. 2020 Mar;7(1):31-40.

Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The use of advanced technology in the management of persons with diabetes mellitus. Endocr Pract. 2021 Jun;27(6):505-537.

Hayes, Inc. Health Technology Assessment. Eversense continuous glucose monitoring system for maintaining glycemic control in adults with diabetes mellitus. Lansdale, PA: Hayes, Inc; March 2022. Updated March 2023.

Hundal R, Kowalyk S, Wakim A, et al. Multicenter real-world assessment of the effectiveness of V-Go wearable insulin delivery device in adult patients with type 2 diabetes (ENABLE study): a retrospective analysis. Med Devices (Auckl). 2020 Sep 22;13:283-291.

Irace C, Cutruzzolà A, Nuzzi A, et al. Clinical use of a 180-day implantable glucose sensor improves glycated hemoglobin and time in range in patients with type 1 diabetes. Diabetes Obes Metab. 2020 Jul;22(7):1056-1061.

Jafri RZ, Balliro CA, El-Khatib F, et al. 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.

Jancev M, Vissers TACM, Visseren FLJ, et al. Continuous glucose monitoring in adults with type 2 diabetes: a systematic review and meta-analysis. Diabetologia. 2024 May;67(5):798-810.

Khan AM, Alswat KA. Benefits of using the i-Port system on insulin-treated patients. Diabetes Spectr. 2019 Feb;32(1):30-35.

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 Jan;40(1):63-68.

Lajara R, Davidson JA, Nikkel CC, Morris TL. Clinical and cost effectiveness of insulin delivery with V-Go disposable insulin delivery device versus multiple daily injections in patients with type 2 diabetes inadequately controlled on basal insulin. Endocr Pract. 2016 Jun;22(6):726-35.

Lajara R, Fetchick DA, Morris TL, Nikkel C. Use of V-Go® insulin delivery device in patients with sub-optimally controlled diabetes mellitus: a retrospective analysis from a large, specialized diabetes system. Diabetes Ther. 2015 Dec;6(4):531-545.

Lane AS, Mlynarczyk MA, de Veciana M, et al. Real-time continuous glucose monitoring in gestational diabetes: a randomized controlled trial. Am J Perinatol. 2019 Jul;36(9):891-897.

LeRoith D, Biessels GJ, Braithwaite SS, et al. Treatment of diabetes in older adults: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2019 May 1;104(5):1520-1574.

Mannkind website. https://www.go-vgo.com/. Accessed March 29, 2024.

Martens T, Beck RW, Bailey R, et al.; MOBILE Study Group. Effect of continuous glucose monitoring on glycemic control in patients with type 2 diabetes treated with basal insulin: a randomized clinical trial. JAMA. 2021 Jun 8;325(22):2262-2272.

McCall AL, Lieb DC, Gianchandani R, et al. Management of individuals with diabetes at high risk for hypoglycemia: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2023 Feb 15;108(3):529-562.

Messer LH, Berget C, Forlenza GP. A clinical guide to advanced diabetes devices and closed-loop systems using the CARES paradigm. Diabetes Technol Ther. 2019 Aug;21(8):462-469.

Mississippi Division of Medicaid Administrative Code, Title 23, Part 209: Durable Medical Equipment and Medical Supplies. https://medicaid.ms.gov/wp-content/uploads/2020/10/Title-23-Part-209-DME-and-Medical-Supplies-eff-10.1.20.pdf. Accessed April 19, 2024.

Mississippi Division of Medicaid Administrative Code, Title 23, Part 225: Telemedicine. https://medicaid.ms.gov/wp-content/uploads/2021/07/Title-23-Part-225-Telemedicine-eff-07.01.21.pdf. Accessed April 19, 2024.

Moon SJ, Kim KS, Lee WJ, et al. Efficacy of intermittent short-term use of a real-time continuous glucose monitoring system in non-insulin-treated patients with type 2 diabetes: A randomized controlled trial. Diabetes Obes Metab. 2023 Jan;25(1):110-120.

Raman P, Shepherd E, Dowswell T, et al. Different methods and settings for glucose monitoring for gestational diabetes during pregnancy. Cochrane Database Syst Rev. 2017 Oct 29;10:CD011069.

Raval AD, Nguyen MH, Zhou S, et al. Effect of V-Go versus multiple daily injections on glycemic control, insulin use, and diabetes medication costs among individuals with type 2 diabetes mellitus. J Manag Care Spec Pharm. 2019 Oct;25(10):1111-1123.

Renard E, Riveline JP, Hanaire H, Guerci B; on behalf of the investigators of France Adoption Clinical Trial. Reduction of clinically important low glucose excursions with a long-term implantable continuous glucose monitoring system in adults with type 1 diabetes prone to hypoglycaemia: the France Adoption Randomized Clinical Trial. Diabetes Obes Metab. 2022 May;24(5):859-867.

Rosenfeld CR, Bohannon NJ, Bode B, et al. The V-Go insulin delivery device used in clinical practice: patient perception and retrospective analysis of glycemic control. Endocr Pract. 2012 Sep-Oct;18(5):660-7.

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.

Sutton D, Higdon CD, Nikkel C, Hilsinger KA. Clinical benefits over time associated with use of V-Go wearable insulin delivery device in adult patients with diabetes: a retrospective analysis. Adv Ther. 2018 May;35(5):631-643.

Tweden KS, Deiss D, Rastogi R, et al. Longitudinal analysis of real-world performance of an implantable continuous glucose sensor over multiple sensor insertion and removal cycles. Diabetes Technol Ther. 2020 May;22(5):422-427.

Vigersky RA, Fonda SJ, Chellappa M, et al. Short- and long-term effects of real-time continuous glucose monitoring in patients with type 2 diabetes. Diabetes Care. 2012 Jan;35(1):32-8.

Voormolen DN, DeVries JH, Sanson RME, et al. Continuous glucose monitoring during diabetic pregnancy (GlucoMOMS): A multicenter randomized controlled trial. Diabetes Obes Metab. 2018 Aug;20(8):1894-1902.

Wada E, Onoue T, Kobayashi T, et al. Flash glucose monitoring helps achieve better glycemic control than conventional self-monitoring of blood glucose in non-insulin-treated type 2 diabetes: a randomized controlled trial. BMJ Open Diabetes Res Care. 2020 Jun;8(1):e001115.

Wei Q, Sun Z, Yang Y, et al. Effect of a CGMS and SMBG on maternal and neonatal outcomes in gestational diabetes mellitus: a randomized controlled trial. Sci Rep. 2016 Jan 27;6:19920.

Wright EE Jr, Kerr MSD, Reyes IJ, et al. Use of flash continuous glucose monitoring is associated with A1C reduction in people with type 2 diabetes treated with basal insulin or noninsulin therapy. Diabetes Spectr. 2021 May;34(2):184-189.

Zeidan T, Nikkel C, Dziengelewski B, et al. Clinical evaluation of basal-bolus therapy delivered by the V-Go® wearable insulin delivery device in patients with type 2 diabetes: a retrospective analysis. Pharmacy (Basel). 2020 Nov 14;8(4):215.

Policy History/Revision Information

Date	Summary of Changes
04/01/2025	**Applicable Codes** • Updated list of applicable HCPCS codes to reflect quarterly edits; removed G0564 and G0565 **Supporting Information** • Archived previous policy version CS024MS.AC

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.