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

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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 Administrative Code Title 23: Medicaid Part 209, Durable Medical Equipment and Medical Supplies: Rule 1.31: Insulin Pumps.

Mississippi CHIP (Children's Health Insurance Program)

External insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for managing individuals with type 1 or insulin-requiring type 2 diabetes.

Note: Programmable disposable external insulin pumps (e.g., OmniPod) are considered clinically equivalent to standard insulin pumps. For Omnipod 5, refer to the federal, state, or contractual requirements.

For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Durable Medical Equipment, Insulin Pump, Ambulatory (Custom) – UHG.

Click here to view the InterQual® criteria.

Due to insufficient evidence of efficacy, the following devices are unproven and not medically necessary for managing individuals with diabetes:

- Implantable insulin pumps
- Insulin infuser ports
- 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 Administrative Code Title 23: Medicaid Part 225, Telemedicine: Chapter 4: Continuous Glucose Monitoring Services.

Mississippi CHIP (Children's Health Insurance Program)

Short-Term CGM

Short-term CGM use (3-14 days) by a healthcare provider for diagnostic purposes is proven and medically necessary for managing individual with diabetes.

Long-Term CGM

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.

For initial use, CGM is proven and medically necessary for managing individuals with diabetes in the following circumstances:

- Long-term use (greater than 14 days) for personal use at home for managing individuals with diabetes during pregnancy when certain criteria are met. For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Durable Medical Equipment, Continuous Glucose Monitors (Custom) - UHG.
- Long-term use (greater than 14 days) for personal use at home for managing individuals with type 1 or type 2 diabetes when certain criteria are met. For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Durable Medical Equipment, Continuous Glucose Monitors (Custom) - UHG.

Click here to view the InterQual® criteria.

For continuous long-term use, CGM is proven and medically necessary for managing individuals with diabetes who meet all of the following criteria:

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

CGM using the Eversense implantable glucose sensor is proven and medically necessary for managing individuals with type 1 or insulin-requiring type 2 diabetes when all of the following criteria are met:

- When used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions
- Clinical criteria noted above for initial long-term (greater than 14 days) CGM use are met

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

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]).

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 (American Diabetes Association [ADA] website and ADA, 2023).

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).

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, 2023).

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 too high. Some systems require calibration by the user (ADA website and ADA, 2023).

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
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

Coding Clarification: E1399 is often misused when reporting the i-Port device; however, the i-Port device is not durable medical equipment (DME).

HCPCS Code	Description
A4211	Supplies for self-administered injections
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

HCPCS Code	Description
A4239	Supply allowance for non-adjunctive, 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
E1399	Durable medical equipment, miscellaneous (Note: The i-Port device is not durable medical equipment (DME), nor does it have a listed code.)
E2102	Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
E2103	Non-adjunctive, 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
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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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
O24.415	Gestational diabetes mellitus in pregnancy, controlled by oral hypoglycemic drugs
O24.419	Gestational diabetes mellitus in pregnancy, unspecified control
O24.430	Gestational diabetes mellitus in the puerperium, diet controlled
O24.435	Gestational diabetes mellitus in 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 (American Diabetes Association, 2023):

- Type 1 diabetes (due to autoimmune beta-cell destruction, usually leading to absolute insulin deficiency, including latent autoimmune diabetes of adulthood [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). 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/AIDS, 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 impotence. 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. Blood glucose monitoring (BGM) and laboratory testing of hemoglobin A1c (HbA1c) to measure longer term glycemic control are standard methods for glucose testing (ADA, 2023).

Insulin Delivery

Standard external insulin pumps connect to flexible plastic tubing that ends with a needle inserted through the skin into the fatty tissue. 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).

An insulin infuser port is a device used to reduce the number of needle injections for individuals with insulin-dependent diabetes. An insertion needle guides a soft cannula into the subcutaneous tissue. Once applied, the insertion needle is removed, leaving the soft cannula under the skin to act as a direct channel into the subcutaneous tissue. Insulin is then injected through the cannula using a standard needle and syringe or insulin pen. Devices remain in place for up to 72 hours to accommodate multiple drug injections without additional needle sticks.

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 are designed for long-term personal use and display information in real-time allowing the individual to take action based on the data (American Medical Association, 2009). For most devices, glucose measurements provided during continuous monitoring are not intended to replace standard BGM obtained using fingerstick blood samples, but can alert individuals of the need to perform BGM. 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.

Implantable CGM includes a small sensor, smart transmitter and mobile application. 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.

Benefit Considerations

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

Clinical Evidence

Insulin Delivery

Nonprogrammable Transdermal Insulin Delivery

There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of transdermal insulin delivery in the management of individuals with diabetes.

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 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 (Everitt et al., 2019; Raval et al., 2019; Sutton et al., 2018; Lajara et al., 2016; Lajara et al., 2015; Rosenfeld et al., 2012).

Implantable Insulin Pumps

Implantable insulin pumps are a promising new technology for the treatment of insulin-dependent diabetes but at this time are only available in a clinical trial setting.

Insulin Infuser Ports

There is insufficient evidence in the clinical literature demonstrating that the use of insulin infuser ports results in improved glycemic control beyond what can be achieved by using standard insulin delivery methods. Further well-designed, large-scale randomized controlled trials are needed to establish the safety and efficacy of these devices.

Khan et al. (2019) conducted a prospective study evaluating the i-Port system in 55 insulin-treated patients. Of the 55 patients, 93% had type 1 diabetes and used an insulin pen. Patients were divided into two groups: regular users of the i-Port (n = 27), who used it for ≥ 3 months, and irregular users (n = 28), who used it for < 3 months. Irregular users had a longer duration of diabetes at baseline compared to regular users, were less likely to report noncompliance with insulin usage, were more likely to self-inject insulin and had a lower HbA1c. Although there were fewer hospitalizations and hypoglycemic episodes, and compliance improved with i-Port usage, there were no statistical differences between groups in treatment satisfaction or mean glycemic control scores.

Blevins et al. (2008) conducted a prospective, randomized controlled cross-over trial comparing the outcomes of insulin-dependent diabetics (n = 74) who used the i-Port compared to standard multi-injection insulin therapy. Type 1 (n = 56) and type 2 (n = 18) diabetics were randomly assigned to one of four cohort groups. Cohort 1 (n = 18) compared standard injections (SI) to single i-Port, cohort 2 (n = 20) compared single i-Port to SI, cohort 3 (n = 18) compared dual i-Ports to single i-Port and cohort 4 (n = 18) compared single i-Port to dual i-Ports. At the end of the first three weeks, each group switched to the alternative method for an additional three weeks. Ten participants were lost to follow-up, six of which were due to device related issues (adhesive failure, discomfort, hyperglycemia, cannula bends and adverse events). Participant's glycosylated albumin was not significantly different between SI, single i-Port and dual i-Port treatment regiments. HbA1c levels were similar among all cohorts at the initiation and completion of the study. Adverse events included erythema, suppuration, skin irritation, itching, and bruising at the i-Port insertion site. Three events of severe hyperglycemia were also reported.

Continuous Glucose Monitoring

Diabetes During Pregnancy

García-Moreno et al. (2022) conducted a systematic review and meta-analysis of studies evaluating the effect of CGM on maternal and neonatal outcomes compared to standard care with blood glucose monitoring in pregnant women with GDM. Six randomized controlled trials (RCTs) were included (n = 482). The use of CGM was associated with lower HbA1c levels at the end of pregnancy compared to blood glucose monitoring. Women using CGM also had less gestational weight gain, and their children had lower birth weights. (Lane et al. (2019) and Voormolen et al. (2018), previously cited in this policy, are included in this systematic review.)

In the multicenter, randomized controlled CONCEPTT trial, Feig et al. (2017) evaluated the effectiveness of CGM on maternal glucose control and obstetric and neonatal health outcomes in women with type 1 diabetes. Investigators ran two trials in parallel for pregnant participants and for participants planning pregnancy. A total of 325 women (215 pregnant, 110 planning pregnancy) were randomly assigned to capillary glucose monitoring with CGM (108 pregnant, 53 planning pregnancy) or without (107 pregnant, 57 planning pregnancy). Randomization was stratified by insulin delivery (pump or injections) and baseline HbA1c. The primary outcome was change in HbA1c from randomization to 34 weeks' gestation in pregnant women and to 24 weeks or conception in women planning pregnancy. Secondary outcomes included obstetric and neonatal health outcomes. The CGM group had a small but significant reduction in HbA1c levels at 34 weeks' gestation compared to the control group. Pregnant CGM users also spent more time in target glycemic control range and less time in the hyperglycemic range than did pregnant control participants. Neonatal health outcomes were significantly improved in the CGM group, with a lower proportion of infants who were large for their gestational age, fewer neonatal intensive care admissions lasting more than 24 hours, less neonatal hypoglycemia and shorter length of hospital stay.

In a Cochrane review, Raman et al. (2017) compared the effects of different methods and settings for glucose monitoring for women with GDM on maternal and fetal, neonatal and child and adult outcomes. Evidence from 11 RCTs (n = 1272) suggested no clear differences for the primary outcomes, or many secondary outcomes assessed in the review. This review does not, however, integrate the more recent promising data from the Lane et al. (2019) and Voormolen et al. (2018) studies among women with GDM.

Wei et al. (2016), a study included in the systematic reviews by Ramen et al. (2017) and García-Moreno et al. (2022), investigated the effects of CGM on maternal and neonatal outcomes. Data from 106 women with GDM in gestational weeks 24-

28 were included in the analysis. Participants were randomized to the prenatal care plus CGM group (n = 51) or the SMBG group (n = 55). Those in the CGM group were further randomized to a second trimester/early (n = 24) or third trimester/late (n = 27) subgroup. There were no significant differences in most prenatal or obstetric outcomes (e.g., Caesarean delivery rate, Apgar score at 5 minutes, birth weight or neonatal hypoglycemia) between the CGM and SMBG groups. Although not statistically significant, the CGM group had lower HbA1c levels than the SMBG group. The proportion of GDM women with excessive gestational weight gain was lower in the CGM group than in the SMBG group (33.3% versus 56.4%; p = 0.039), and women who initiated CGM earlier gained less weight (62.8% versus 38.2%; p = 0.017). While not statistically significant, the incidence of large-for-gestational age was lower in the CGM group as compared to the SMBG group (35.3% versus 52.7%; p = 0.071). This study may have been too small to detect a clinically significant difference in outcomes, but it does suggest a likely benefit.

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.

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).

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 vs. 11.4%, p < 0.001). When blood glucose decreased, Dexcom also performed better than Eversense (7.3 vs. 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 5 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 > 3000 users found the system was safe over multiple cycles of use. Implantation was associated with infrequent, nonserious adverse events. However, findings from the 3 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%). 16.9%). 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 4 sensor insertion/removal cycles. Of 3,023 enrolled patients, 280 completed 4 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.

PROMISE Study

In the prospective, multicenter, unblinded, nonrandomized PROMISE study, Garg et al. (2022) evaluated the accuracy and safety of the next-generation implantable Eversense CGM system (n = 181) for up to 180 days in patients with type 1 or type 2 diabetes. All participants were inserted with a primary sensor. Ninety-six participants had a second sensor, either an identical sensor (n = 53) or a modified sacrificial boronic acid sensor (n = 43) inserted in their other arm. Participants underwent 10 clinic visits to measure accuracy by comparing the sensor glucose values with standard reference glucose values. The percent sensor readings within 20 mg/dL or 20% of reference values (20/20% agreement rate) were 92.9% for the primary sensor and 93.9% for the modified sensor. In the hypoglycemic ranges of 40-60 mg/dL and 61-80 mg/dL, the agreement rates were 89.4% and 92.2% for the primary sensor and 96.5% and 96.8% for the modified sensor, respectively. Confirmed hypoglycemic alert detection rate was 93% for primary sensor and 94% for the modified sensor. Sixty-five percent of the primary sensors survived to 180 days. Ninety percent of the modified sensors survived to 180 days. There were no device- or procedure-related serious adverse events. This study is limited by a lack of randomization and control and short-term follow-up.

PRECISION Study

In the prospective, multicenter PRECISION study, Christiansen et al. (2019) further evaluated the accuracy and safety of Eversense among adults with type 1 or type 2 diabetes (n = 35) through 90 days. An updated algorithm was also applied to sensor data from the PRECISE II study to evaluate consistency of accuracy results. The system was shown to be accurate overall with a MARD of 9.6%. Eighty-five percent of CGM values were within 15/15% of reference. All sensors were functional through day 90. No device- or procedure-related SAEs occurred. This study corroborated the favorable accuracy and safety profile observed in PRECISE II. The updated algorithm improved accuracy of measurements in PRECISE II. Study limitations include lack of randomization and control, small patient population and short-term follow-up.

PRECISE II Study

In the prospective, multicenter PRECISE II trial, Christiansen et al. (2018) evaluated the accuracy and safety of the Eversense CGM system in 90 adult participants with type 1 and type 2 diabetes. The updated system included a modified algorithm and a new sensor configuration. The primary efficacy endpoint was the mean absolute relative difference (MARD) between Eversense and reference measurements through 90 days postinsertion for reference glucose values from 40 to 400 mg/dL. The primary safety endpoint was the incidence of device-related or sensor insertion/removal procedure-related SAEs through 90 days

postinsertion. The system was accurate, with an overall MARD value of 8.8% across the clinically relevant glucose range, with 93% of CGM values within 20% of reference values. The system correctly identified hypoglycemia (< 70 mg/dL) 93% of the time and hyperglycemia (> 80 mg/dL) 96% of the time. A limited but statistically significant reduction of accuracy occurred in the last month of use. Ninety-one percent of sensors were functional through day 90. One related SAE (1.1%) occurred during the study for removal of a sensor. The authors concluded that the Eversense system provided accurate glucose readings through the intended 90-day sensor life with a favorable safety profile. Study limitations include lack of randomization, small patient population and short-term follow-up. Long-term surveillance studies are required to ensure that the safety profile remains favorable with multiple sensor placements and removals.

PRECISE Study

In the PRECISE trial, Kropff et al. (2017) evaluated the accuracy and longevity of the Eversense (Senseonics, Inc.) implantable CGM sensor. Seventy-one participants, aged 18 years and older with type 1 and type 2 diabetes, participated in the 180-day prospective, multicenter pivotal trial. CGM accuracy was assessed during eight in-clinic visits with the MARD for venous reference glucose values > 4.2 mmol/L as the primary end point. Secondary end points included Clarke Error Grid Analysis and alarm performance. The primary safety outcome was device-related serious adverse events. The MARD value against reference glucose values > 4.2 mmol/L was 11.1%. Clarke Error Grid Analysis showed 99.2% of samples in the clinically acceptable error zones. Eighty-one percent of hypoglycemic events were detected by the CGM system within 30 min. A limited but statistically significant reduction of CGM measurement accuracy occurred in the last month of use, possibly due to long-term degradation of the glucose indicating gel before end of sensor life was reached. No device-related serious adverse events occurred during the study. This study is limited by a lack of randomization and control, small patient population and short-term follow-up. Further studies are needed to assess the safety and efficacy of these devices.

Dehennis et al. (2015) performed a multisite study to assess the accuracy of glucose measurement by the Senseonics CGM system using matched paired measurements to those obtained by laboratory reference analyzer values from venous blood samples. The Senseonics CGM, composed of an implantable sensor, external smart transmitter, and smartphone app, uses a single sensor for continuous display of accurate glucose values for 3 months. Adults ≥ 18 and ≤ 65 years of age who had a clinically confirmed diagnosis of type 1 diabetes mellitus or type 2 diabetes and who were receiving insulin injection therapy were eligible to participant in this study. Ten men and 14 women with type 1 diabetes mellitus underwent subcutaneous implantation of sensors in the upper arm. Eight-hour clinic sessions were performed every 14 days (days 1, 15, 30, 45, 60, 75, and 90), during which sensor glucose values were compared against venous blood lab reference measurements using MARDs. The subjects-maintained calibration of their CGM system twice daily by entering their SMBG measurement through the smartphone app. Twenty two of the twenty-four (92%) sensors reported glucose continuously for 90 days, and the MARD for all 24 sensors was 11.4 ±2.7% against venous reference glucose values. There was no significant difference in MARD throughout the 90-day study and no serious adverse events were noted. The authors concluded that the study showed successful in-clinic and home use of the Senseonics CGM system over 90 days in subjects with diabetes mellitus. Limitations of this study include non-randomization and small sample size.

Noninvasive Devices

There are no U.S. Food and Drug Administration (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).

American Diabetes Association (ADA)

Insulin Delivery

The 2023 *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 2023 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. (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 continuous use of CGM is not appropriate, 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)
- Continuous glucose monitoring device users 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

ADA Level of Evidence	Description

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 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).

National Institute for Health and Care Excellence (NICE)

NICE guidelines on diabetes in pregnancy (NICE, 2015; updated 2020) make the following recommendations:

- Offer CGM to all pregnant women with type 1 diabetes to help meet pregnancy blood glucose targets and improve neonatal outcomes.
- Offer intermittently scanned CGM (commonly referred to as flash) to pregnant women with type 1 diabetes who are unable to use CGM monitoring or express a clear preference for it.
- Consider CGM for pregnant women who are on insulin therapy but do not have type 1 diabetes, if:
  - They have problematic severe hypoglycemia (with or without impaired awareness of hypoglycemia);or
  - They have unstable blood glucose levels that are causing concern despite efforts to optimize glycemic control.

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 code LZG): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 14, 2023)

For information on 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 February 14, 2023)

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

The i-Port® Injection Port was approved by the FDA on September 9, 2005 (K052389). The injection port is indicated for use by people requiring multiple daily subcutaneous injections of physician prescribed medications, including insulin. The device is designed for use on adults and children for up to 72 hours. Additional information available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K052389. (Accessed February 14, 2023)

The i-Port Advance® Injection Port was approved by the FDA on February 16, 2012 (K120337). This model has the same indications as the original device but includes an automatic insertion component. Additional information available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K120337. (Accessed February 14, 2023)

Insulin Pump Models with or without a CGM component (this is not an exhaustive list):

- Insulet Omnipod 5
- Insulet Omnipod DASH
- Medtronic MiniMed 630G
- Medtronic MiniMed 770G

- Sooil Dana Diabecare
- 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 February 14, 2023)

CGM Models (this is not an exhaustive list):

- Abbott FreeStyle Libre 2 and Libre 14
- 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 February 14, 2023)

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Policy History/Revision Information

Date	Summary of Changes

08/01/2023	**Coverage Rationale**
	Continuous Glucose Monitoring (CGM)
	Mississippi Children's Health Insurance Program (CHIP)
	Long-Term CGM
	• Updated language pertaining to prior authorization to clarify the *duration of approved authorization* for initial CGM authorization will be for up to six months and reauthorization will be for up to 12 months
	• Added language to indicate CGM using the Eversense implantable glucose sensor is proven and medically necessary for managing individuals with type 1 or insulin-requiring type 2 diabetes when **all** of the following criteria are met:
	  ○ When used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions
	  ○ Clinical criteria noted [as proven and medically necessary in the policy] for initial long-term (greater than 14 days) CGM use are met
	• Removed language indicating CGM using an implantable glucose sensor (e.g., Eversense) is unproven and not medically necessary for managing individuals with diabetes
	Definitions
	• Added definition of:
	  ○ Adjunctive CGM

Date	Summary of Changes
	○ Intermittently Scanned (Flash) CGM (isCGM) ○ Non-Adjunctive CGM ○ Professional CGM ○ Real-Time CGM (rtCGM) **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version CS024MS.Z

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