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

Policy Number: CS024KY.03
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Instructions for Use

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Related Policy

- Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

See Benefit Considerations

Insulin Delivery

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 medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, CP: Durable Medical Equipment, Insulin Pump, Ambulatory.

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)

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

- Short-term use (3-14 days) by a healthcare provider for diagnostic purposes.
- Long-term use 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® 2020, Apr. 2020 Release, CP: Durable Medical Equipment, Continuous Glucose Monitors.
- Long-term use 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® 2021, Apr. 2021 Release, CP: Durable Medical Equipment, Continuous Glucose Monitors.

Click here to view the InterQual® criteria.

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

- CGM using an implantable glucose sensor (e.g., Eversense)
- CGM using a noninvasive device

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
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories

HCPCS Code	Description
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
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)
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit of Service
K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system
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
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

Diagnosis Code	Description
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
E11.3532	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye

Diagnosis Code	Description
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
E11.638	Type 2 diabetes mellitus with other oral complications

Diagnosis Code	Description
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, 2020):

- Type 1 diabetes (due to autoimmune beta-cell destruction, usually leading to absolute insulin deficiency).
- Type 2 diabetes (due to a progressive loss of beta-cell insulin secretion frequently on the background of insulin resistance).
- Gestational diabetes mellitus (GDM) (diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to pregnancy). GDM resembles type 2 diabetes and usually disappears after childbirth.
- Other subtypes of diabetes have been identified. The most common subtype is 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.

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. Self-monitoring of blood glucose (SMBG) and laboratory testing of glycosylated hemoglobin (HbA1C) to measure longer term glycemic control are standard methods for glucose testing (ADA, 2020).

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 SMBG. 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 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 fluid 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 SMBG obtained using fingerstick blood samples, but can alert individuals of the need to perform SMBG. 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.

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).

Hayes reported that an overall very-low-quality body of evidence does not allow for conclusions to be drawn regarding the safety and efficacy of the V-Go system. Although the evidence consistently suggests that V-Go therapy is associated with improved glycemic control in patients with type 1 or type 2 diabetes, the body of evidence comprised poor- to very-poor-quality studies of relatively small size. The quality of the body of evidence was also limited by the lack of comparative studies, lack of prospective study designs, limited data on outcomes associated with longer-term use, likely patient overlap between 2 of the 4 eligible studies and manufacturer support of all of the eligible studies. It is also unknown whether administering insulin with the V-Go device has a greater impact on sustained glycemic control than administration of insulin via MDIs. No systematic reviews or meta-analyses evaluating V-Go were identified (Hayes, 2018a; updated 2019).

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

Lane et al. (2019) evaluated whether real-time CGM improves glycemic control over intermittent SMBG in GDM. Patients with GDM were randomized to use either real-time (n=11) or blinded (n=12) CGM. The primary outcome was mean glucose values after four weeks. Secondary outcomes included glycemic control and a composite of obstetric and neonatal outcomes. The use of real-time CGM did not significantly decrease mean glucose values compared with intermittent SMBG after 4 weeks of CGM use. There were also no significant differences in the time spent in glycemic target, maternal or neonatal outcomes. This study may, however, have been too small to detect a clinically significant difference in outcomes.

Voormolen et al. (2018) investigated the effectiveness of retrospective CGM use in pregnant women with type 1 or type 2 diabetes who were undergoing insulin therapy at gestational age < 16 weeks, or women who were undergoing insulin treatment for GDM at gestational age < 30 weeks. The study randomized 300 pregnant women with type 1 (n=109), type 2 (n=82) or GDM (n=109) to either CGM (n=147) or standard treatment (n=153). Glycemic control was assessed by CGM for 5-7 days every 6 weeks in the CGM group, while SMBG and HbA1c measurements were applied in both groups. Primary outcome was macrosomia, defined as birth weight above the 90th percentile. Secondary outcomes were glycemic control and maternal and neonatal complications. HbA1c levels were similar between treatment groups. The incidence of macrosomia was 31.0% in the CGM group and 28.4% in the standard treatment group. The differences were not statistically significant. The study may, however, have been too small to detect clinically significant differences in important outcomes. For example, non-statistically significant benefits of CGM were observed on birth weight (mean difference 72 grams), failure to thrive (2.8 versus 4.8%), and, in the subgroup of women with GDM, on the risk of preeclampsia (1.9 versus 13.0%).

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 review by Ramen, et al. (2017), 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

There is insufficient clinical evidence assessing the safety or effectiveness of implantable glucose sensors on patient outcomes in comparison to other CGM devices or to other methods of blood glucose monitoring. While non-implantable CGMs have been shown to improve patient outcomes, similar data for implantable devices is lacking.

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.

A Hayes report evaluated the Eversense CGM in adults with type 1 or type 2 diabetes. The report concluded that a very-low-quality body of evidence suggests that the Eversense CGM is highly correlated with and moderately accurate in the measurement of 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. In addition, the body of evidence is limited by an evidence base of fair- to poor-quality studies, small number of patients, inconsistencies and variability in the clinical validity outcomes and insufficient evidence to evaluate the clinical utility of the Eversense CGM. Long-term use of Eversense sensors has not been evaluated (Hayes, 2018b; updated 2020).

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.

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 (>180 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 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 Diabetes Association (ADA)

Insulin Delivery

The 2021 *Standards of Medical Care in Diabetes* make the following recommendations:

- Insulin pump therapy may be considered as an option for all adults and youth with type 1 diabetes who are able to safely manage the device.
- Insulin pump therapy may be considered as an option for adults and youth with type 2 diabetes, and other forms of diabetes resulting in insulin deficiency, who are on MDIs and are able to safely manage the device.
- Sensor-augmented pump therapy with automatic low glucose suspend may be considered for adults and youth with diabetes to prevent/mitigate episodes of hypoglycemia.
- Automated insulin delivery systems may be considered in youth and adults with type 1 diabetes to improve glycemic control.

Continuous Glucose Monitoring (CGM)

The 2021 *Standards of Medical Care in Diabetes* make the following recommendations:

- When prescribing CGM devices, robust diabetes education, training and support are required for optimal CGM device implementation and ongoing use. Individuals using CGM devices need to have the ability to perform SMBG in order to calibrate the monitor and/or verify readings if discordant from symptoms.
- When used properly, real-time CGM in conjunction with insulin therapy is a useful tool to lower and/or maintain HbA1c levels and/or reduce hypoglycemia in adults and youth with diabetes.
- When used properly, intermittently scanned CGM in conjunction with insulin therapy can beuseful and may lower HbA1c levels and/or reduce hypoglycemia in adults and youth with diabetes to replace SMBG.
- Real-time CGM devices should be used as close to daily as possible for maximal benefit. Intermittently scanned CGM devices should be scanned frequently, at a minimum once every eight hours.
- When used as an adjunct to pre- and postprandial SMBG, CGM can help to achieve HbA1c targets in diabetes and pregnancy.
- Use of professional CGM and/or intermittent real-time or intermittently scanned CGM can be helpful in identifying and correcting patterns of hyper- and hypoglycemia and improving HbA1c levels in people with diabetes on noninsulin as well as basal insulin regimens.

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).

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, see the following website (use product code LZG): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 7, 2021)

For information on hybrid closed-loop insulin pumps (e.g., MiniMed 670G), see the following website (use product code OZP): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed January 7, 2021)

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 January 7, 2021)

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 January 7, 2021)

The V-Go device received FDA approval (K100504) on December 1, 2010. V-Go is a mechanical (no electronics), self-contained, sterile, patient fillable, single-use disposable insulin infusion device with an integrated stainless steel subcutaneous needle. The device is indicated for continuous subcutaneous infusion of insulin in one 24-hour time period and on-demand bolus dosing in 2-unit increments (up to 36 units per one 24-hour time period) in adult patients requiring insulin. The device is intended for use in patients with type 2 diabetes. Additional information available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K100504. (Accessed January 7, 2021)

A second FDA approval (K103825) came through on February 23, 2011. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K103825. (Accessed January 7, 2021)

Insulin Pump Models (this is not an exhaustive list):
- Insulet OmniPod
- Insulet OmniPod DASH
- Medtronic MiniMed 630G
- Medtronic MiniMed 670G
- Medtronic MiniMed 770G
- Sooil Dana Diabecare IIS
- Tandem T:slim X2 with Basal – IQ
- Tandem T:slim X2 with Control – IQ

Continuous Glucose Monitors (CGM)

For information on CGMs, see the following websites:
- Product code LZG: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- Product code MDS: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm

(Accessed January 7, 2021)

CGM Models (this is not an exhaustive list):
- Abbott FreeStyle Libre
- Dexcom G5
- Dexcom G6
- Medtronic MiniMed 530G
- Medtronic MiniMed 630G
- Medtronic MiniMed 670G
- Medtronic MiniMed 770G
- Medtronic Guardian Connect
- Medtronic MiniMed Paradigm Revel
- Sensionics Eversense
- sugarBEAT® (not yet FDA approved)
- Tandem T:slim X2 with Basal – IQ
- Tandem T:slim X2 with Control – IQ

The Eversense CGM system received FDA premarket approval (P160048) on June 21, 2018. The device is classified as an implanted CGM for adjunctive use, under product code QCD. The device is indicated for continually measuring glucose levels in adults (18 years or older) with diabetes for up to 90 days. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160048. (Accessed January 7, 2021)

FreeStyle Libre Pro – Stand-alone CGM approved for short-term professional diagnostic use only: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150021. (Accessed January 7, 2021)

iPro®2 Professional CGM: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150029. (Accessed January 7, 2021)

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Policy History/Revision Information

Date	Summary of Changes
07/01/2021	Coverage Rationale • Replaced references to “InterQual® 2020” with “InterQual® 2021” Supporting Information • Archived previous policy version CS024KY.02

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 uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Kentucky Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines 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.