

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

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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 Indiana.

Coverage Rationale

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 certain circumstances. For medical necessity clinical coverage criteria, refer to the [Indiana Durable and Home Medical Equipment and Supplies Provider Reference Module](#).

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

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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
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)

HCPCS Code	Description
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
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

Diagnosis Code	Description
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
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

Diagnosis Code	Description
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
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 the puerperium, controlled by oral hypoglycemic drugs

Diagnosis Code	Description
O24.439	Gestational diabetes mellitus in the puerperium, unspecified control

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 $\geq 7\%$) 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 A1c. 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 regimens. A1c 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.

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/pmnm.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/pmnm.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/pmnm.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/pmnm.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/pmnm.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
- Insulet Omnipod Horizon (not yet FDA approved)
- Sooil Dana Diabecare IIS
- Tandem T:slim X2 with Basal – IQ
- Tandem T:slim X2 with Control - IQ

References

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Policy History/Revision Information

Date	Summary of Changes
07/01/2021	Coverage Rationale <ul style="list-style-type: none">Replaced reference to “InterQual® 2020” with “InterQual® 2021” Supporting Information <ul style="list-style-type: none">Archived previous policy version CS024IN.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 may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.