

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 \(for Indiana Only\)](#)

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® CP: Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Technology.

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 Health Coverage Programs Provider Reference Module: Durable and Home Medical Equipment and Supplies](#).

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

CPT® is a registered trademark of the American Medical Association

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
*A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply
A9277	Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
A9278	Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
E0784	External ambulatory infusion pump, insulin
*E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
*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	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
S1030	Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)
*S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)
*S1034	Artificial pancreas device system (e.g., low glucose suspend [lgs] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
*S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
*S1036	Transmitter; external, for use with artificial pancreas device system
*S1037	Receiver (monitor); external, for use with artificial pancreas device system

Note: Codes labeled with an asterisk (*) are not managed for medical necessity review for the state of Indiana at the time this policy became effective. Refer to the most up to date prior authorization list for Indiana at [Prior Authorization and Notification: UnitedHealthcare Community Plan of Indiana](#).

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

Diagnosis Code	Description
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
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye
E11.3491	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye
E11.3492	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye
E11.3493	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E11.3499	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral

Diagnosis Code	Description
E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye
E11.3521	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E11.3522	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E11.3523	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E11.3529	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye
E11.3531	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E11.3532	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E11.3533	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E11.3539	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye
E11.3541	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E11.3542	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye
E11.3543	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
E11.3549	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye
E11.3551	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E11.3552	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E11.3553	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral
E11.3559	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye
E11.3591	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E11.3592	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E11.3593	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E11.3599	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye
E11.36	Type 2 diabetes mellitus with diabetic cataract
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication

Diagnosis Code	Description
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
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.

Benefit Considerations

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

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 $\geq 7\%$) 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).

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 regimens. A1c levels were similar among all cohorts at the initiation and completion of the study. Adverse events included erythema, suppurative, skin irritation, itching, and bruising at the i-Port insertion site. Three events of severe hyperglycemia were also reported.

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)

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/pmnm.cfm>. (Accessed February 14, 2023)

For information on hybrid closed-loop insulin pumps (e.g., MiniMed 670G), 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 iPort® 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 iPort 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
- Insulet OmniPod DASH
- Medtronic MiniMed 630G
- Medtronic MiniMed 770G
- Sooil Dana Diabecare IIS
- Tandem t:slim X2 with Basal - IQ
- Tandem t:slim X2 with Control – IQ

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Policy History/Revision Information

Date	Summary of Changes
08/01/2023	<p>Coverage Rationale</p> <p><i>Insulin Delivery</i></p> <ul style="list-style-type: none"> Removed instruction to refer to the federal, state, or contractual requirements for [more information on] Omnipod 5 <p>Definitions</p> <ul style="list-style-type: none"> Added definition of: <ul style="list-style-type: none"> Adjunctive CGM Intermittently Scanned (Flash) CGM (isCGM) Non-Adjunctive CGM Professional CGM Real-Time CGM (rtCGM) <p>Supporting Information</p> <ul style="list-style-type: none"> Added <i>Benefit Considerations</i> section Updated <i>Description of Services, Clinical Evidence, FDA, and References</i> sections to reflect the most current information Archived previous policy version CS024IN.08

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.