Insulin Delivery for Managing Diabetes (for Ohio Only)

Policy Number: CS0242OH.B
Effective Date: October 1, 2023

Instructions for Use

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Related Policy

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

Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

Note: For general coverage and payment policies for durable medical equipment (DME), prosthesis, orthotic devices, medical/surgical supplies, and supplier services, refer to the Ohio Administrative Code, Rule 5160-10-01 DMEPOS: general provisions.

Insulin Delivery

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

Type 1 and Type 2 Diabetes

For medical necessity clinical coverage criteria, refer to the Ohio Administrative Code, Rule 5160-10-29 | DMEPOS: insulin pumps.

Gestational Diabetes

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)

Coverage Limitations and Exclusions

For coverage limitations and exclusions, refer to the Ohio Administrative Code, Rule 5160-10-01 DMEPOS: general provisions and Ohio Administrative Code, Rule 5160-10-02 DMEPOS: repair.

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.

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
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.)
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

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.

Clinical Evidence

Insulin Delivery

Nonprogrammable Transdermal Insulin Delivery

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

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

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

Implantable Insulin Pumps

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

Insulin Infuser Ports

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

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

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

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)

ADA Level of Evidence	Description
A	• Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including: ○ Evidence from a well-conducted multicenter trial ○ Evidence from a meta-analysis that incorporated quality ratings in the analysis • Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including: ○ Evidence from a well-conducted trial at one or more institutions ○ Evidence from a meta-analysis that incorporated quality ratings in the analysis
B	• Supportive evidence from well-conducted cohort studies ○ Evidence from a well-conducted prospective cohort study or registry ○ Evidence from a well-conducted meta-analysis of cohort studies • Supportive evidence from a well-conducted case-control study

ADA Level of Evidence	Description

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

E	• Expert consensus or clinical experience

U.S. Food and Drug Administration (FDA)

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

Insulin Delivery

For information on external insulin pumps, refer to the following website (use product code LZG): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 14, 2023)

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

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

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

- Insulet Omnipod 5
- Insulet Omnipod DASH
- Medtronic MiniMed 630G
- Medtronic MiniMed 770G
- Sooil Dana Diabecare
- Tandem t:slim X2 with Basal – IQ
- Tandem t:slim X2 with Control – IQ

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Policy History/Revision Information

Date	Summary of Changes
10/01/2023	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version CS0242OH.A – P

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]) or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC) 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 Ohio 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.