Insulin Delivery for Managing Diabetes (for Ohio Only)

Policy Number: CS0242OH.C
Effective Date: October 1, 2024

➲ 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, Durable medical equipment, prostheses, orthoses, and supplies (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 and Diabetes Due to Other Causes

When used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions, external continuous subcutaneous insulin infusion pumps are proven and medically necessary for gestational diabetes and diabetes due to other causes in certain circumstances. 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.

External continuous subcutaneous insulin infusion pumps are medically necessary for managing individuals with diabetes due to other causes that require intensive insulin therapy (insulin-treated at least 3 times a day). Examples include, but are not limited to cystic fibrosis-related diabetes, post-transplantation diabetes, or diabetes following pancreatic surgery.

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The following devices are unproven and not medically necessary for managing individuals with diabetes due to insufficient evidence of efficacy:

- Implantable insulin pumps
- 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 the 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.

HCPCS Code	Description
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
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 (ADA), 2023]:

- Type 1 diabetes [due to autoimmune beta-cell destruction, usually leading to absolute insulin deficiency, including 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.
- 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 or other types of diabetes occurring throughout pregnancy, such as type 1 diabetes). 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 erectile dysfunction. 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. Glycemic status can be assessed by blood glucose monitoring (BGM) and laboratory testing of hemoglobin A1c (HbA1C) (ADA, 2024).

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Insulin Delivery

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

Clinical Evidence

Insulin Delivery

Nonprogrammable Transdermal Insulin Delivery

There is insufficient evidence in the clinical literature demonstrating the safety and efficacy of nonprogrammable wearable disposable insulin delivery devices in the management of individuals with diabetes. Larger, well-designed studies with long-term follow-up and comparative effectiveness data are needed.

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 (Hundal et al., 2020; Zeidan et al., 2020; 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.

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).

AACE clinical practice guidelines provide evidence-based recommendations for the use of advanced technology in the management of persons with diabetes mellitus (Grunberger et al., 2021).

- CGM is strongly recommended for all persons with diabetes treated with intensive insulin therapy, defined as 3 or more injections of insulin per day or the use of an insulin pump. Grade A; High Strength of Evidence; BEL 1
- CGM is recommended for all individuals with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness). Grade A; Intermediate-High Strength of Evidence; BEL 1
- CGM is recommended for children/adolescents with type 1 diabetes. Grade A; Intermediate-High Strength of Evidence; BEL 1
- CGM is recommended for pregnant women with type 1 and type 2 diabetes treated with intensive insulin therapy. Grade A; Intermediate-High Strength of Evidence; BEL 1
- CGM is recommended for women with gestational diabetes on insulin therapy. Grade A; Intermediate Strength of Evidence; BEL 1
- CGM may be recommended for women with gestational diabetes who are not on insulin therapy. Grade B; Intermediate Strength of Evidence; BEL 1
- CGM may be recommended for individuals with type 2 diabetes who are treated with less intensive insulin therapy. Grade B; Intermediate Strength of Evidence; BEL 1

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American Diabetes Association (ADA)

Insulin Delivery

The 2024 *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
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 or QFG): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 14, 2023)

For information on automated insulin delivery systems or 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 March 13, 2024)

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

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

- Beta Bionics iLet
- Insulet Omnipod 5
- Insulet Omnipod DASH
- Medtronic MiniMed 630G

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- Medtronic MiniMed 770GMedtronic MiniMed 780G
- Sooil Dana Diabecare
- Tandem Mobi
- Tandem t:slim X2 with Basal – IQ
- Tandem t:slim X2 with Control – IQ

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Ohio Administrative Code/Rule 5160-10-01. Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-10-01. Accessed May 1, 2023.

Ohio Administrative Code/Rule 5160-10-29. Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): insulin pumps. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-10-29. Accessed May 1, 2023.

Ohio Administrative Code/Rule 5160-10-02. Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): repairs. Available at: https://codes.ohio.gov/ohio-administrative-code/rule-5160-10-02. Accessed May 1, 2023.

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Policy History/Revision Information

Date	Summary of Changes

10/01/2024	**Coverage Rationale**
	Insulin Delivery
	Gestational Diabetes and Diabetes Due to Other Causes
	• Added language to indicate:
	  ○ External continuous subcutaneous insulin infusion pumps are proven and medically necessary for gestational diabetes and diabetes due to other causes in certain circumstances when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions
	  ○ External continuous subcutaneous insulin infusion pumps are medically necessary for managing individuals with diabetes due to other causes that require intensive insulin therapy (insulin-treated at least 3 times a day); examples include, but are not limited to cystic fibrosis-related diabetes, post-transplantation diabetes, or diabetes following pancreatic surgery
	• Revised list of unproven and not medically necessary devices; removed “insulin infuser ports”
	Applicable Codes
	• Removed HCPCS codes A4211 and E1399
	• Removed coding clarification pertaining to HCPCS code E1399
	Supporting Information
	• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
	• Archived previous policy version CS0242OH.B

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.

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