Clinical Policy: Insulin Delivery Systems

Reference Number: IL.CP.MP.534
Effective Date: 09/25/2026
Last Review Date: 08/2026

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description / Definition

An insulin delivery system is any device or method used to administer insulin in a controlled manner to treat diabetes. For the purpose of this policy, we will restrict this to insulin pumps, which are small wearable devices which automatically administer insulin subcutaneously. The wearable devices administer rapid-acting insulin through a catheter which is inserted below the skin. This insulin is usually administered as a basal continuous infusion, supplemented by insulin administered as a bolus to correct elevated glucose readings, or before meals based upon the prescribed protocol.

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**If request is for an insulin delivery system that is also a continuous glucose monitor, additional approval criteria apply. Refer to the Continuous Glucose Monitor policy for the relevant line of business: CP.PMN.214 for Medicaid.*

FDA Approved Indication(s)

An insulin delivery system may only be utilized for a FDA approved indication

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Insulin Pumps are **medically necessary** when the following criteria are met:

I.

A. Initial Therapy

1. Member has utilized one of the following insulin administration methods for at least the last 6 months (a or b):*
   a. Continuous insulin delivery system *(see Appendix B for examples)*;
   b. Multiple daily insulin injections (meets i and ii):
      i. Administration of at least 3 daily injections of a basal and bolus insulin regimen
      ii. History of suboptimal blood sugar control despite appropriate management – examples of suboptimal control include, but are not limited to, any of the following (1-6):
         1) Repeated hypoglycemic events (BG < 70 mg/dL);
         2) Repeated episodes of diabetic ketoacidosis;
         3) Wide blood sugar excursions;
         4) Hypoglycemia unawareness;

5) Glycosylated hemoglobin level (HbA1c) ≥ 7.0;
6) "Dawn phenomenon" with fasting blood sugars repeatedly > 200 mg/dL;

2. Member has monitored BG ≥ 4 times a day for at least the last 6 months;

Approval duration: Medicaid: 6 months

II. Continued Therapy

A. Diabetes Mellitus (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Member is adherent to provider follow-up visits and training;

Approval duration:
Medicaid: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACE: alternate controller enabled
BG: blood glucose
BGM: blood glucose meter
CGM: continuous glucose monitoring
CSII: continuous subcutaneous insulin infusion
FDA: Food and Drug Administration
GLP-1: glucagon-like peptide-1
MDI: multiple daily doses of insulin

PDM: Personal Diabetes Manager
Pod: tubeless insulin pump
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

*Approved Pumps are listed in **MDN.CP.PHAR.534***

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
CONTINUOUS INSULIN DELIVERY SYSTEMS • **ILET INSULIN PUMP DEVI** • **ILET INSULIN INFUSION KIT – CONTACT DETACH 23" 6MM MISC** • **ILET INSULIN INFUSION KIT – INSET 23" 6MM MISC** • **ILET INSULIN INFUSION KIT – 32" 6MM MISC** • **ILET STARTER KIT – CONTACT DETACH 23 6MM MISC** • **OMNIPOD 5 LIBRE2 PLUS G6** • **OMNIPOD 5 DEXCON G7G6 PODS (GEN 5)** • **OMNIPOD 5 LIBRE2 PLUS G6PODS** • **OMNIPOD DASH PODS (GEN 4)**	Varies	Varies
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Appendix B: Contraindications/Boxed Warnings

- Contraindication(s):
  Insulin Pumps are not recommended for people who are:
  - Unable to monitor glucose as recommended by their healthcare provider
  - Unable to maintain contact with their healthcare provider
  - Unable to use the System according to instructions

  Omnipod 5 is additionally not recommended for people who:
  - Are taking hydroxyurea as it could lead to falsely elevated CGM values and result in over-delivery of insulin that can lead to severe hypoglycemia
  - Do not have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms, and reminders
- Boxed warning(s): none reported

V. References

Clinical trials and reviews

1. Grunberger G, Rosenfeld CR, Bode BW, Abbott SD, Nikkel C, Shi L, Strange P. Effectiveness of V-Go for patients with type 2 diabetes in a real-world setting: A prospective observational study. Drugs Real World Outcomes. 2020 Mar;7(1):31-40. 5.

2. Sutton D, Higdon C, Nikkel C, Hilsinger K. Clinical benefits over time associated with use of V-Go Wearable Insulin Delivery Device in adult patients with diabetes: a retrospective analysis. Advances in Therapy 2018 May; 35(5): 631-43.
3. Lajara R, Fetchick DA, Morris DA, Nikkel C. Use of V-Go insulin delivery device with sub-optimally controlled diabetes mellitus: a retrospective analysis from a large specialized diabetes system. Diabetes Ther. 2015;6(4):531-545.
4. Lajara R, Davidson JA, Nikkel C, Morris TL. Clinical and cost effectiveness of insulin delivery with V-Go disposable insulin delivery device versus multiple daily injections in patients with type 2 diabetes inadequately controlled on basal insulin. Endocrine Practice 2016 June;22(6):726-735.

Continuous Insulin Delivery Systems

5. Section 7, diabetes technology: Standards of medical care in diabetes – 2025. American Diabetes Association. Diabetes Care. 2025; 48 (Supplement 1): S146-S166. https://doi.org/10.2337/dc25-S007.
6. Section 9, pharmacologic approaches to glycemic treatment: Standards of medical care in diabetes – 2025. American Diabetes Association. Diabetes Care. 2025; 48 (Supplement 1): S181-S206. https://doi.org/10.2337/dc25-S009.
7. Grunberger G, Handelsman Y, Bloomgarden ZT, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2018 position statement on integration of insulin pumps and continuous glucose monitoring in patients with diabetes mellitus. Endocrine Practice; March 2018: 24(3): 302-308.
8. Peters AL, Ahmann AJ, Hirsch IB, et al. Advances in glucose monitoring and automated insulin delivery: supplement to Endocrine Society clinical practice guidelines. J Endocr Soc; October 5 2018; 2(11): 1214-1225.
9. Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology clinical practice guideline: The use of advanced technology in the management of persons with diabetes mellitus. Endocrine Practice. 2021; 27: 505-537.

Diabetes and Pregnancy

10. Blumer I, Hadar E, Hadden DR, et al. Diabetes and pregnancy: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. November 2013; 98(11): 4227-49.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description*
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories (Suggest NDC level or Invoice pricing) (Pod)
E0784	External ambulatory infusion pump, insulin (PDM device)
A4211	Supplies for self-administered injection

**A9274 and E0784: Omnipod System (note: these codes do not apply to Omnipod DASH or Omnipod 5, which are available only through pharmacy distribution); A9274: V-Go; A4211: not specific but can be applied to InPen. Note: S5561 (Insulin delivery device, reusable pen) does NOT apply to InPen.*

NDCs	Description

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Original Approval Date		09/25/2026

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical

policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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SENATE BILL 3414

Illinois Medicaid Preferred Drug List; Effective January 1, 2026.
https://hfs.illinois.gov/medicalproviders/pharmacy/preferred.html

GLUCOSE MONITORING SUPPLIES : INSULIN INFUSION DISPOSABLE PUMP	ILET INSULIN PUMP	DEVI	PREFERRED_WITH_PA	
	ILET INSULIN INFUSION KIT - CONTACT DETACH 23" 6MM	MISC	PREFERRED_WITH_PA	
	ILET INSULIN INFUSION KIT - INSET 23" 6MM	MISC	PREFERRED_WITH_PA	
	ILET INSULIN INFUSION KIT - INSET 32" 6MM	MISC	PREFERRED_WITH_PA	
	ILET INSULIN INFUSION KIT- INSET 32" 6MM	MISC	PREFERRED_WITH_PA	
	ILET STARTER KIT - CONTACT DETACH 23" 6MM	MISC	PREFERRED_WITH_PA	
	ILET STARTER KIT - INSET23" 6MM	MISC	PREFERRED_WITH_PA	
	ILET STARTER KIT - INSET32" 6MM	MISC	PREFERRED_WITH_PA	
	OMNIPOD 5 DEXCOM G7G6 INTRO KIT (GEN 5)	KIT	PREFERRED_WITH_PA	
	OMNIPOD 5 G7 INTRO KIT (GEN 5)	KIT		NON_PREFERRED
	OMNIPOD 5 LIBRE2 PLUS G6INTRO GEN 5	KIT	PREFERRED_WITH_PA	
	OMNIPOD DASH INTRO KIT (GEN 4)	KIT		NON_PREFERRED
	OMNIPOD DASH PDM KIT (GEN 4)	KIT		NON_PREFERRED
	OMNIPOD GO 10 UNITS/DAY	KIT		NON_PREFERRED
	OMNIPOD GO 15 UNITS/DAY	KIT		NON_PREFERRED
	OMNIPOD GO 20 UNITS/DAY	KIT		NON_PREFERRED
	OMNIPOD GO 25 UNITS/DAY	KIT		NON_PREFERRED
	OMNIPOD GO 30 UNITS/DAY	KIT		NON_PREFERRED
	OMNIPOD GO 35 UNITS/DAY	KIT		NON_PREFERRED
	OMNIPOD GO 40 UNITS/DAY	KIT		NON_PREFERRED
	TWIIST REFILL KIT	KIT		NON_PREFERRED
	TWIIST REFILL KIT/INFUSION SET	KIT		NON_PREFERRED
	TWIIST STARTER KIT	KIT		NON_PREFERRED
	V-GO 20	KIT		NON_PREFERRED
	V-GO 30	KIT		NON_PREFERRED

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	V-GO 40	KIT		NON_PREFERRED
	OMNIPOD 5 DEXCOM G7G6 PODS (GEN 5)	MISC	PREFERRED_WITH_PA	
	OMNIPOD 5 G7 PODS (GEN 5)	MISC		NON_PREFERRED
	OMNIPOD 5 LIBRE2 PLUS G6PODS	MISC	PREFERRED_WITH_PA	
	OMNIPOD CLASSIC PODS (GEN 3)	MISC		NON_PREFERRED
	OMNIPOD DASH PODS (GEN 4)	MISC	PREFERRED_WITH_PA	