# Clinical Policy: Insulin Delivery Systems (V-Go, Omnipod, InPen)

Reference Number: SC.CP.MP.03 Coding Implications
Date of Last Revision: 02/26 Revision Log

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

## Description

This policy describes the clinical criteria requirements for insulin delivery systems. The following are insulin delivery systems requiring prior authorization:

- V-Go® Wearable Insulin Delivery Device
- Omnipod DASH® Insulin Management System
- Omnipod® 5 Automated Insulin Delivery System
- InPen™ System

*Note: If request is for an insulin delivery system that is also a continuous glucose monitor, additional approval criteria apply. Refer to SC.CP.MP.02 Continuous Glucose Monitors policy.*

## FDA Approved Indication(s)

V-Go Wearable Insulin Delivery Device

- Use: Subcutaneous delivery of insulin to provide basal-prandial control.
  - The V-Go 20 Disposable Insulin Delivery Device is indicated for continuous subcutaneous infusion of 20 Units of insulin in one 24-hour time period (0.83 U/hr) 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 V-Go 30 Disposable Insulin Delivery Device is indicated for continuous subcutaneous infusion of 30 Units of insulin in one 24-hour time period (1 .25 U/hr) 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 V-Go 40 Disposable Insulin Delivery Device is indicated for continuous subcutaneous infusion of 40 Units of insulin in one 24-hour time period (1 .67 U/hr) and on-demand bolus dosing in 2-Unit increments (up to 36 Units per one 24-hour time period) in adult patients requiring insulin.
- Populations: Adult patients requiring insulin.*

**Patients who have to make regular adjustments or modifications to their basal rate during a 24-hour period, or whose amount of insulin used at meals requires adjustments of less than 2-Unit increments, should not use V-Go as it may result in hypoglycemia. V-Go has not been studied in patients who are pregnant or in patients diagnosed with gestational diabetes.*

- Components: 1) V-Go device, 2) EZ Fill device
- User guide and related resources: https://www.go-vgo.com/instructions-for-patient-use

Omnipod DASH Insulin Management System

- Use: Subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.
- Populations: Appropriate for use in type 1 diabetes, insulin-requiring type 2 diabetes, gestational diabetes, and latent autoimmune diabetes. Omnipod DASH can be used by people of all ages. See https://www.myomnipod.com/healthcareproviders/about-omnipod/prescribe.

- Components: 1) Adhesive disposable pump (DASH Pod), 2) handheld DASH Personal Diabetes Manager (PDM) device, 3) compatible Contour® Next One blood glucose meter (BGM)
    - *Contour Next* test strips and control solution are used with the Contour Next One BGM for quantitative measurement of blood glucose (BG) in fresh capillary whole blood drawn from the fingertips or palm.*
- Connectivity: Wireless *Bluetooth communication* between the DASH Pod, DASH PDM, Contour Next BGM and, if desired, an iPhone (iPhone application does not include insulin management - view only).**
- User guide and related resources: https://www.omnipod.com/current-podders/resources/omnipod-dash

**The Contour Next One BGM is intended for single-patient use and should not be shared. The BGM should not be used for the diagnosis of or screening for diabetes or for neonatal use.*
***Data may be uploaded to Insulet provided Glooko® software allowing sharing with caregivers and providers and access from anywhere (Cloud capability data sharing available). See https://support.glooko.com/hc/en-us for more information.*

Omnipod 5 Automated Insulin Delivery System

- Use: Subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.
- Populations: The Omnipod 5 Alternate Controller Enabled (ACE) Pump is intended for the management of diabetes mellitus in persons requiring insulin. The SmartAdjust technology and Omnipod 5 SmartBolus Calculator are intended for use in patients aged 2 years and older with Type 1 and Type 2 diabetes.
- Components: 1) Omnipod 5 ACE Pump (an adhesive disposable pump, or Pod), 2) Omnipod 5 App (on a provided Controller or installed on a compatible smartphone), 3) Dexcom G6®, G7®, or FreeStyle Libre 2 Plus® continuous glucose monitoring (CGM) system (must be obtained separately)
- Connectivity: Wireless *Bluetooth communication* between the Pod, Dexcom G6, G7, or FreeStyle Libre 2 Plus® CGM, and provided Controller or compatible smartphone (https://omnipod.com/compatibility)
- User guide and related resources: https://www.omnipod.com/current-podders/resources

InPen System

- Use: Self-injection of a desired dose of insulin.
- Populations: Patients 7 years of age and older with diabetes.
- Components: 1) InPen smart insulin pen (reusable pen injector), 2) InPen App
    - The pen injector is compatible with Lilly Humalog® U-100 3.0 mL cartridges, Novo Nordisk Novolog® U-100 3.0 mL cartridges, and Novo Nordisk Fiasp® U-100 3.0 mL cartridges and single-use detachable and disposable pen needles (not included).
- Connectivity: Wireless *Bluetooth communication* between the InPen and a smart mobile device (iOS 10 or later; Android 6 or later) via the InPen App
    - The system may also be connected to a continuous glucose monitor (Medtronic, Dexcom, or Abbot) and Apple Health.
- User guide and related resources: https://www.companionmedical.com/guides/inpen-user-guide.pdf

**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 Absolute Total Care that V-Go, Omnipod DASH, Omnipod 5, Omnipod GO and InPen are **medically necessary** when the following criteria are met:

**I.** Initial Approval Criteria
A. Diabetes Mellitus (must meet all):
1. Diagnosis of diabetes mellitus;
2. Member must meet one of the following (a or b):
   a. Request is for a preferred Omnipod DASH Pods or Omnipod 5 NDC*;
   b. Request is for V-Go or InPen on the medical benefit**;
   **As noted on the SCDHHS sPDL*
   ***Requests for V-Go and InPen are a pharmacy benefit exclusion and must be submitted on medical benefit per single state PDL*
3. If request is for V-Go, Omnipod DASH, or InPen, diagnosis of Type 1 diabetes mellitus;
4. If request is for Omnipod 5, must meet one of the following (a or b):
   a. Diagnosis of Type 1 AND age ≥ 2 years
   b. Diagnosis of Type 2 diabetes AND ≥ 18 years;
5. Request is not for Omnipod DASH Intro Kit and Omnipod DASH PDM*;
   ** Omnipod DASH Intro Kit and Omnipod DASH PDM are not covered on the pharmacy benefit per single state PDL*
6. Prescribed by or in consultation with an endocrinologist;
7. If request is for V-Go, age ≥ 18 years;
8. If request is for InPen, age ≥ 7 years;
9. If request is for a non-preferred insulin delivery system, member has tried and failed TWO preferred insulin delivery systems (Omnipod DASH® Insulin Management System, Omnipod® 5 G6-G7 Automated Insulin Delivery System, Omnipod® 5 Libre2/Plus);
10. If request is for InPen, medical justification supports necessity of the digital component (i.e., rationale why insulin dose/usage cannot be calculated/tracked manually – for example, the member has an intellectual disability and no caregivers are available to assist with insulin dose calculation);
11. Request meets one of the following (a, b, or c):
    a. V-Go: Number of devices does not exceed 30 per month;*
    **For requests exceeding 30 devices per month, a clinical rationale with documentation to support the higher quantity is required.*
    b. Omnipod DASH/Omnipod 5: Both of the following (i and ii):
       i. Number of Pods does not exceed 10 per month;*
       **For requests exceeding 10 Pods per month, a clinical rationale with documentation to support the higher quantity is required.*
       ii. Number of devices does not exceed 1 per year;
    c. InPen: Request does not exceed 1 system per year.

**Approval duration:** V-Go (6 months), Omnipod DASH/Omnipod 5 (Pods – 6 months, device – 30 days), InPen (12 months – one device per year)

**A. 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 managed drugs on the formulary or ATC CDL (Medicaid), the no coverage criteria policy for the relevant line of business: SC.CP.PMN.255 for Medicaid; or
   b. For NON-managed drugs on the formulary or ATC CDL (Medicaid), the non-managed drug policy for the relevant line of business: SC.PHAR.106 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.

## II. Continued Therapy

**A. Diabetes Mellitus** (must meet all)**:**
1. Member is currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member is adherent to provider follow-up visits and training;
4. Request is not for Omnipod DASH Intro Kit and Omnipod DASH PDM*;
   ** Omnipod DASH Intro Kit and Omnipod DASH PDM are not covered on the pharmacy benefit per single state PDL*
5. Request meets one of the following (a, b, or c):
   a. V-Go: Number of devices does not exceed 30 per month;*
      **For requests exceeding 30 devices per month, a clinical rationale with documentation to support the higher quantity is required.*
   b. Omnipod DASH/Omnipod 5: Both of the following (i and ii):
      i. Number of Pods does not exceed 10 per month;*
         **For requests exceeding 10 Pods per month, a clinical rationale with documentation to support the higher quantity is required.*
      ii. Number of devices does not exceed 1 device per year;
   c. InPen: Request does not exceed 1 system per year.

**Approval duration:** V-Go (12 months), Omnipod DASH/Omnipod 5 (Pods – 12 months, device – 30 days), Omnipod GO (Pods – 12 months), InPen (12 months – one device per year)

**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 managed drugs on the formulary or ATC CDL (Medicaid), the no coverage criteria policy for the relevant line of business: SC.CP.PMN.255 for Medicaid; or
   b. For NON-managed drugs on the formulary or ATC CDL (Medicaid), the non-managed drug policy for the relevant line of business: SC.PHAR.106 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
sPDL: SCDHHS single preferred drug list
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **CONTINUOUS INSULIN DELIVERY SYSTEMS**<br>Insulin pumps (with tubing [automated options available])<br>• MiniMed™ System (530G, 630G, 670G)<br>• MiniMed™ Paradigm Revel™<br>• t:slim™ X2 Insulin Pump<br>Insulin pumps (without tubing)<br>• Omnipod DASH Insulin Management System<br>• Omnipod 5 Automated Insulin Delivery System<br>Insulin patches<br>• V-Go 20, 30, 40 Wearable Insulin Delivery Device (disposable) | Varies | Varies |
| **INSULIN**<br>**Human Insulin**<br>Short-acting:<br>• Regular insulin (HumuLIN® R U-500, HumuLIN® R U-500 KwikPen®, HumuLIN® R [OTC], NovoLIN® R ReliOn [OTC], NovoLIN® R [OTC]) | Varies | Varies |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Intermediate-acting:<br>• Insulin NPH (HumuLIN® N KwikPen® [OTC], HumuLIN® N [OTC], NovoLIN® N ReliOn [OTC], NovoLIN® N [OTC])<br>Intermediate-acting and short-acting combinations:<br>• Insulin NPH and regular insulin (HumuLIN® 70/30, HumuLIN® 70/30 KwikPen®, NovoLIN® 70/30)<br>**Insulin Analogs**<br>Rapid-acting<br>• Insulin glulisine (Apidra, Apidra SoloStar®)<br>• Insulin lispro (Admelog, Admelog SoloStar®, HumaLOG®, HumaLOG Junior KwikPen®, HumaLOG KwikPen®, Lyumjev®)<br>• Insulin aspart (Fiasp®, Fiasp FlexTouch®, NovoLOG®, NovoLOG FlexPen®, NovoLOG PenFill®)<br>Intermediate-acting and short-acting combinations:<br>• Insulin aspart protamine and insulin aspart (NovoLOG Mix® 70/30, NovoLOG Mix 70/30 FlexPen®)<br>• Insulin lispro protamine and insulin lispro (HumaLOG Mix®, HumaLOG Mix® 50/50, HumaLOG Mix 50/50 KwikPen®, HumaLOG Mix® 75/25, HumaLOG Mix 75/25 KwikPen®)<br>Long-acting<br>• Insulin glargine (Basaglar KwikPen®, Lantus®, Lantus SoloStar®, Toujeo Max SoloStar®, Toujeo SoloStar®)<br>• Insulin detemir (Levemir®, Levemir FlexTouch®)<br>• Insulin degludec (Tresiba®, Tresiba FlexTouch®) | | |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **ANTIDIABETIC AGENTS**<br>• **Biguanide**: metformin<br>• **Sulfonylureas**: glipizide, glimepiride, glyburide<br>• **Thiazolidinedione**: pioglitazone<br>• **GLP-1 receptor agonists**: dulaglutide (Trulicity®), exenatide ER (Bydureon®, Bydureon BCise®), exenatide IR (Byetta®), liraglutide (Victoza®), liraglutide/insulin degludec (Xultophy®), lixisenatide/insulin glargine (Soliqua®), semaglutide (Ozempic®, Rybelsus®), tirzepatide (Mounjaro™)<br>• **SGLT2 inhibitors**: bexagliflozin (Brenzavvy™), canagliflozin (Invokana®), canagliflozin/metformin (Invokamet®, Invokamet® XR), dapagliflozin (Farxiga®), dapagliflozin/metformin (Xigduo® XR), dapagliflozin/*saxagliptin (Qtern®),* empagliflozin (Jardiance®), empagliflozin/linagliptin (Glyxambi®), empagliflozin/linagliptin/metformin (Trijardy™ XR), empagliflozin/metformin (Synjardy®, Synjardy® XR), ertugliflozin/sitagliptin (Steglujan™), sotagliflozin (Inpefa™)<br>• **DPP-4 inhibitors**: *alogliptin (*Nesina®*)*, *alogliptin/metformin* (Kazano®*)*, *alogliptin/pioglitazone* (Oseni®*),* linagliptin (Tradjenta®), *linagliptin/metformin (Jentadueto®, Jentadueto® XR), saxagliptin (Onglyza®), saxagliptin/metformin (Kombiglyze® XR), sitagliptin (Januvia®, Zituvio™), sitagliptin/metformin (Janumet®, Janumet® XR, Zituvimet™)* | Varies | Varies |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  Omnipod DASH and Omnipod 5are not recommended for people who are:
  - Unable to monitor glucose as recommended by their healthcare provider (*at least 4 blood glucose tests per day for Omnipod DASH*)
  - 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

  InPen is not intended for anyone unable or unwilling to:
  - Test blood glucose levels as recommended by a healthcare provider

- Maintain sufficient diabetes self-care skills
- Visit a healthcare provider regularly

- Boxed warning(s): none reported

## V. Dosage and Administration

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| V-Go Wearable (disposable) Insulin Delivery Device<br>*See User Guide for more information: https://www.go-vgo.com/instructions-for-patient-use* | V-Go is designed for 24-hour wear and requires one insulin type – U-100 fast-acting insulin. Humalog (insulin lispro, rDNA origin) and NovoLog (insulin aspart, rDNA origin) have been tested and found to be safe for use in V-Go.<br>• Stability and storage: Humalog has been tested in V-Go and has been demonstrated to be stable for up to 24 hours refrigerated or at room temperature followed by 24 hours wear. NovoLog has been demonstrated to be stable for up to 5 days refrigerated or 3 days at room temperature followed by 24 hours wear. The EZ Fill has been demonstrated to be acceptable for filling Humalog and NovoLog for up to 30 days.<br>• Description: 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. It is designed for the subcutaneous infusion of insulin. After filling V-Go with insulin using the EZ Fill, V-Go is secured to the patient's skin over the infusion site with an adhesive backed foam pad. Once activated, V-Go delivers a continuous infusion of insulin at a fixed rate. V-Go also allows the user to initiate bolus injections to supplement their daily basal insulin requirements. A window in the top of the device allows the user to see into the reservoir to check the drug and to monitor the progress of the infusion. | Varies by device |
| Omnipod DASH Insulin Management System<br>*See User Guide for more information: https://www.omnipod.com/current-podders/resources/omnipod-dash* | • Initial Omnipod DASH System use<br>  ○ Provider recommends initial program settings and meets with patient and Omnipod System Trainer to program the PDM device and first Pod.<br>• Filling the Pod<br>  ○ The Pod is filled with insulin FDA approved for insulin pumps (i.e., the following rapid-acting U100 insulin analogs: insulin glulisine | 200 units per day (1 Pod) |

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| | (Apidra), insulin lispro (Admelog, HumaLOG, Lyumjev), insulin aspart (Fiasp, NovoLOG)).<br>○ Pod capacity accommodates 85 to 200 units of insulin depending on patient need *(for initial programming, each Pod must be filled with at least 85 units of insulin)*.<br>• Pod priming<br>○ The PDM device and Pod are placed next to each other so that the PDM may prime the Pod.<br>• Pod placement<br>○ For site selection, see User Guides.<br>• Pod activation<br>○ The Pod features an insulin-providing cannula that inserts automatically with the press of an "activate" button on the PDM device.<br>• Pod replacement<br>○ The Pod may remain on the skin from 1 to 3 days after which a new Pod should be filled, primed, applied, and activated. | |
| InPen System<br>*See User Guide for more information: https://www.companionmedical.com/guides/inpen-user-guide.pdf* | • Determining the dose<br>○ The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments. For doses greater than 30 units the dose must be split into multiple doses.<br>○ The InPen dose calculator is a component of the InPen App. It can calculate an insulin dose or carbohydrate intake based on user entered data.<br>○ For an insulin dose based on amount of carbohydrates, a healthcare professional must provide patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software prior to use.<br>○ For an insulin dose based on fixed/variable meal sizes, a healthcare professional must provide patient-specific fixed doses/meal sizes to be programmed into the software prior to use.<br>• Injecting the dose | Not applicable |

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| | ○ Insert the insulin cartridge into the cartridge holder of the InPen.<br>○ Attach the needle and prime the pen. The pen must be primed before every injection.<br>○ Select the dose by turning the dose knob.<br>○ Insert the needle into the upper arms, stomach, or thighs.<br>○ Place thumb on the injection button, then slowly and firmly push the button until it stops moving. Continue to hold the button for 8 seconds and then remove the needle from the skin. Check to make sure there is a 0 in the dose window to confirm the complete dose has been received.<br>○ Remove and discard the needle into a sharps container.<br>• Handling and storage<br>○ When an insulin cartridge is installed in the InPen, store the InPen at room temperature. Refer to the insulin manufacturer or literature that came with the insulin for information on how to store the cartridges and how long to keep them.<br>○ Remove the needle after every use. Do not store the InPen with the needle attached.<br>○ Do not store the InPen in a refrigerator.<br>• Cleaning the device<br>○ The InPen should be cleaned whenever it is visibly dirty. Clean the InPen as needed only with a soft cloth moistened with water, being careful not to get water inside. Never submerge the InPen. If insulin gets on the InPen, clean it off right away.<br>• Replacements<br>○ The InPen has a 1-year life. It contains a lithium battery which is not replaceable.<br>○ A low battery icon will appear on the InPen App when the InPen is reaching the end of its life and needs to be replaced. | |
| Omnipod 5 Automated Insulin Delivery Systems | • There is no tubing with the Pod allowing placement almost anywhere an injection would be given. The Pod may be worn for up to 3 days and can be filled with up to 200 units of U-100 rapid-acting insulin (minimum 85 units). | 200 units per day (1 Pod) |

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| | ○ The Pod, SmartAdjust technology, and SmartBolus Calculator are compatible with the following U-100 insulins: NovoLOG, HumaLOG, and AdmeLOG.<br>• The Omnipod 5 App allows the patient to select a basal profile, target glucose and bolus settings, activate and deactivate the Pod, connect with the Dexcom G6/G7 CGM, Freestyle Libre 2 Plus, and select insulin delivery mode<br>• The Omnipod 5 System communicates with the Dexcom G6/G7 and Freestyle Libre 2 Plus CGM Systems. CGM values and trends from the Dexcom G6/G7 and Freestyle Libre 2 Plus are used for automated insulin delivery in Automated Mode, as well as bolus calculations in both Automated and Manual Mode. The Dexcom G6/G7 sensor must be started in the Dexcom app in order to use CGM values and trends in the Omnipod 5 System.<br>• There are 2 modes of operation: Automated and Manual.<br>○ In Automated mode, SmartAdjust technology adjusts insulin every 5 minutes to bring the glucose value to the customized glucose target, or Target Glucose. The adjustment is based on a prediction of where your glucose will be 60 minutes in the future and considers your CGM value and trend, adaptive basal rate, and insulin that is still working in your body.<br>○ In Manual mode, the Omnipod 5 System delivers insulin based on user-defined Basal Programs. During Manual Mode, there is no automated adjustment of insulin delivery. | |

## VI. Product Availability

| Drug Name | Availability |
|---|---|
| V-Go 20, 30, 40 | • V-Go is available as a 30-day supply in 3 options – V-Go 20, V-Go 30, and V-Go 40. |
| Omnipod DASH Insulin Management System<br>*All Omnipod DASH components (Pod, PDM, compatible BGM) have* | • Omnipod Pack 5 (packs of 5 Pods)<br>• Starter Kit (PDM DASH device plus a separate but compatible Contour® Next One BGM)*<br>**The compatible Contour Next One BGM must be used with Ascensia Contour® Next test strips and control solution; however, patients may* |

| Drug Name | Availability |
|---|---|
| *Bluetooth connectivity that is compatible with the iPhone.* | *choose to use other blood glucose testing methods with manual entry into the PDM device.* |
| InPen System | • InPen smart insulin pen for use with Humalog: blue, grey, pink<br>• InPen smart insulin pen for use with Novolog/Fiasp: blue, grey, pink |
| Omnipod 5 Dexcom G7G6 | • Omnipod 5 Intro Kit (Omnipod 5 Controller and Pods plus a separate but compatible Dexcom G6 or G7 CGM)<br>• Omnipod 5 Refill 5 Pack Pods |
| Omnipod 5 with Freestyle Libre 2 Plus G6 | • Omnipod 5 Intro Kit (Omnipod 5 Controller and Pods plus a separate but compatible CGM [Dexcom G6, Dexcom G7, or Freestyle Libre 2 Plus])<br>• Omnipod 5 Refill 5 Pack Pods |

**Coding Implications**

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2025, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. 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.*

| Reviews, Revisions, and Approvals | Revision Date | Approval Date |
|---|---|---|
| Policy created. | 11/25 | |
| Reviewed. References updated. No criteria changes. | 02/26 | 03/26 |

**References**

1. V-Go Insulin Delivery System 510(k) summary, No. K103825. Shrewsbury, MA: Valeritas, Inc.; February 2011. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103825.pdf. Accessed February 27, 2026.
2. Grunberger G, Rosenfeld CR, Bode BW, et al. Effectiveness of V-Go® for Patients with Type 2 Diabetes in a Real-World Setting: A Prospective Observational Study. *Drugs Real World Outcomes*. 2020;7(1):31-40. doi:10.1007/s40801-019-00173-8
3. Sutton D, Higdon CD, Nikkel C, Hilsinger KA. Clinical Benefits Over Time Associated with Use of V-Go Wearable Insulin Delivery Device in Adult Patients with Diabetes: A Retrospective Analysis. *Adv Ther*. 2018;35(5):631-643. doi:10.1007/s12325-018-0703-3
4. Lajara R, Fetchick DA, Morris TL, Nikkel C. Use of V-Go® Insulin Delivery Device in Patients with Sub-optimally Controlled Diabetes Mellitus: A Retrospective Analysis from a Large Specialized Diabetes System. *Diabetes Ther*. 2015;6(4):531-545. doi:10.1007/s13300-015-0138-7
5. Lajara R, Davidson JA, Nikkel CC, 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. *Endocr Pract*. 2016;22(6):726-735. doi:10.4158/EP151182.OR
6. Layne JE, Parkin CG, Zisser H. Efficacy of the Omnipod Insulin Management System on Glycemic Control in Patients With Type 1 Diabetes Previously Treated With Multiple Daily Injections or Continuous Subcutaneous Insulin Infusion. *J Diabetes Sci Technol*. 2016;10(5):1130-1135. Published 2016 Aug 22. doi:10.1177/1932296816638674
7. Ly TT, Layne JE, Huyett LM, Nazzaro D, O'Connor JB. Novel Bluetooth-Enabled Tubeless Insulin Pump: Innovating Pump Therapy for Patients in the Digital Age. *J Diabetes Sci Technol*. 2019;13(1):20-26. doi:10.1177/1932296818798836
8. 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. *Endocr Pract*. 2018;24(3):302-308. doi:10.4158/PS-2017-0155
9. Peters AL, Ahmann AJ, Hirsch IB, Raymond JK. Advances in Glucose Monitoring and Automated Insulin Delivery: Supplement to Endocrine Society Clinical Practice Guidelines. *J Endocr Soc*. 2018;2(11):1214-1225. Published 2018 Oct 5. doi:10.1210/js.2018-00262
10. 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. *Endocr Pract*. 2021;27(6):505-537. doi:10.1016/j.eprac.2021.04.008
11. Blumer I, Hadar E, Hadden DR, et al. Diabetes and pregnancy: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2013;98(11):4227-4249. doi:10.1210/jc.2013-2465

**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.

**Note: For Medicare members/enrollees,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.