

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

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[RevisionLog](#)

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

Description

The following are continuous insulin delivery systems requiring prior authorization:

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

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/hcp/wp-content/uploads/sites/2/2019/12/ART-1361-Rev-A-V-Go-IFU-2019-V4.pdf>

Omnipod 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 can be used by people of all ages. See <https://www.myomnipod.com/healthcareproviders/about-omnipod/prescribe>.
- Components: 1) Adhesive disposable pump (Pod), 2) handheld Personal Diabetes Manager (PDM) device with *built-in* Abbott Freestyle blood glucose meter (BGM)
 - *Abbott FreeStyle* test strips and control solution are used with the Abbott FreeStyleBGM for quantitative measurement of blood glucose (BG) in fresh whole capillary blood from the finger, upper arm and palm.*
- Connectivity: Wireless *radiofrequency communication* between the Pod and PDM-BGM device.**
- User guide and related resources: <https://www.myomnipod.com/podder-support/resources-troubleshooting>

**The Abbott FreeStyle 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 Glooko® software allowing sharing with caregivers and providers and access from anywhere (data sharing available from provider's office or personal computer - Apple Macintosh computers 2012 or older are not compatible). See <https://support.glooko.com/hc/en-us> for more information.*

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 PDM device, 3) compatible Contour® Next One BGM
 - Contour Next test strips and control solution are used with the Contour Next One BGM for quantitative measurement of 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.myomnipod.com/DASH_Resource_Troubleshooting

**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.*

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that V-Go, Omnipod, Omnipod DASH, 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. Prescribed by or in consultation with an endocrinologist;
3. If request is for V-Go, age \geq 21 years;
4. If request is for InPen, age \geq 7 years;
5. 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 (see *Appendix B for examples of basal [intermediate- or long-acting] and bolus [short- or rapid-acting] insulin*);
 - ii. History of suboptimal blood sugar control despite appropriate management - examples of suboptimal control include, but are not limited to, any of the following (a-f):
 - a) Repeated hypoglycemic events (BG < 70 mg/dL);
 - b) Repeated episodes of diabetic ketoacidosis;
 - c) Wide blood sugar excursions;
 - d) Hypoglycemia unawareness;
 - e) Glycosylated hemoglobin level (HbA1c) \geq 7.0;
 - f) "Dawn phenomenon" with fasting blood sugars repeatedly > 200 mg/dL;
6. Member has monitored BG \geq 4 times a day for at least the last 6 months;
7. Member or caregiver has completed a physician-directed comprehensive diabetes management program;
8. 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);
9. Request meets one of the following (a or b):
 - a. V-Go: member cannot use Omnipod/Omnipod DASH; number of devices does not exceed 30 per month;*
 - b. Omnipod/Omnipod DASH: number of Pods does not exceed 10 per month;*
**For requests exceeding 10 Pods per month, a clinical rationale with documentation supports the higher quantity.*
 - c. InPen: Request does not exceed 1 system per year.

Approval duration: V-Go (6 months), Omnipod/Omnipod DASH (Pods – 6 months, device – one every 4 years), InPen (12 months – one device per year)

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Diabetes Mellitus (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy and is adherent to provider follow-up visits and training;
3. Request meets one of the following (a or b):
 - a. V-Go: number of device does not exceed 30 per month; *
**For requests exceeding 30 devices per month, a clinical rationale with documentation supports the higher quantity.*
 - b. Omnipod/Omnipod DASH: Number of Pods does not exceed 10 per month;*
**For requests exceeding 10 Pods per month, a clinical rationale with documentation supports the higher quantity.*
 - c. InPen: Request does not exceed 1 system per year.

Approval duration: V-Go (12 months), Omnipod/Omnipod DASH (Pods – 12 months, device – one every 4 years), InPen (6 months or to the member’s renewal date, whichever is longer – one device per year)

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BG: blood glucose
 BGM: blood glucose meter
 CSII: continuous subcutaneous insulin infusion
 FDA: Food and Drug Administration

MDI: Multiple daily doses of insulin
 PDM: Person Diabetes Manager
 Pod: tubeless insulin pump
 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 <u>Insulin pumps (with tubing [automated options available])</u> <ul style="list-style-type: none"> • MiniMed™ System (530G, 630G, 670G) • MiniMed™ Paradigm Revel™ • t:slim™ X2 Insulin Pump <u>Insulin pumps (without tubing)</u> <ul style="list-style-type: none"> • Omnipod Insulin Management System • Omnipod DASH Insulin Management System <u>Insulin patches</u> <ul style="list-style-type: none"> • V-Go 20, 30, 40 Wearable Insulin Delivery Device (disposable) 	Varies	Varies
INSULIN Human Insulin <u>Short-acting:</u> <ul style="list-style-type: none"> • Regular insulin (HumuLIN® R U-500, HumuLIN® R U- 500 KwikPen®, HumuLIN® R [OTC], NovoLIN® R ReliOn [OTC], NovoLIN® R [OTC]) <u>Intermediate-acting:</u> <ul style="list-style-type: none"> • Insulin NPH (HumuLIN® N KwikPen® [OTC], HumuLIN® N [OTC], NovoLIN® N ReliOn [OTC], NovoLIN® N [OTC]) <u>Intermediate-acting and short-acting combinations:</u>	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<ul style="list-style-type: none"> Insulin NPH and regular insulin (HumuLIN[®] 70/30, HumuLIN[®] 70/30 KwikPen[®], NovoLIN[®] 70/30) <p>Insulin Analogs</p> <p><u>Rapid-acting</u></p> <ul style="list-style-type: none"> Insulin glulisine (Apidra, Apidra SoloStar[®]) Insulin lispro (Admelog, Admelog SoloStar[®], HumaLOG[®], HumaLOG Junior KwikPen[®], HumaLOG KwikPen[®], Insulin aspart (Fiasp[®], Fiasp FlexTouch[®], NovoLOG[®], NovoLOG FlexPen[®], NovoLOG PenFill[®]) <p><u>Intermediate-acting and short-acting combinations:</u></p> <ul style="list-style-type: none"> Insulin aspart protamine and insulin aspart (NovoLOG Mix[®] 70/30, NovoLOG Mix 70/30 FlexPen[®]) 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[®]) <p><u>Long-acting</u></p> <ul style="list-style-type: none"> Insulin glargine (Basaglar KwikPen[®], Lantus[®], Lantus SoloStar[®], Toujeo Max SoloStar[®], Toujeo SoloStar[®]) Insulin detemir (Levemir[®], Levemir FlexTouch[®]) Insulin degludec (Tresiba[®], Tresiba FlexTouch[®]) 		

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 and Omnipod DASH Insulin Management Systems are not recommended for people who are:
 - Unable to perform at least 4 blood glucose tests per day
 - Unable to maintain contact with their healthcare provider
 - Unable to use the System according to instructions
 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 See User Guide for more information: https://www.go-vgo.com/hcp/wp-content/uploads/sites/2/2019/12/ART-1361-Rev-A-V-Go-IFU-2019-V4.pdf	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. <ul style="list-style-type: none"> 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 	Varies by device

Drug Name	Dosing Regimen	Maximum Dose
	<p>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.</p> <ul style="list-style-type: none"> • <u>Description:</u> 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. 	
<p>Omnipod Insulin Management System See <i>User Guide</i> for more information: https://www.myomnipod.com/sites/default/files/media/documents/18296-ENG-AW_006_02-DASH-User-Guide-English.pdf</p> <p>Omnipod DASH Insulin Management System See <i>User Guide</i> for more information: https://www.myomnipod.com/sites/default/files/media/documents/18296-ENG-AW_006_02-DASH-User-Guide-English.pdf</p>	<ul style="list-style-type: none"> • Initial Omnipod and Omnipod DASH System use <ul style="list-style-type: none"> ○ Provider recommends initial program settings and meets with patient and Omnipod System Trainer to program the PDM device and first Pod. • Filling the Pod <ul style="list-style-type: none"> ○ The Pod is filled with insulin FDA approved for insulin pumps (i.e., the following rapid-acting U100 insulin analogs: insulin glulisine (Apidra), insulin lispro (Admelog, HumaLOG), insulin aspart (Fiasp, NovoLOG)). ○ Pod capacity accommodates 85 to 200 units of insulin depending on patient need (<i>for initial programming, each Pod must be filled with at least 85 units of insulin</i>). • Pod priming <ul style="list-style-type: none"> ○ The PDM device and Pod are placed next to each other so that the PDM may prime the Pod. • Pod placement <ul style="list-style-type: none"> ○ For site selection, see User Guides. • Pod activation <ul style="list-style-type: none"> ○ The Pod features an insulin-providing cannula that inserts automatically with the press of an “activate” button on the PDM device. • Pod replacement <ul style="list-style-type: none"> ○ The Pod may remain on the skin from 1 to 3 days after which a new Pod should be filled, primed, applied, and activated. 	<p>200 units per day (1 Pod)</p>
<p>InPen System See <i>User Guide</i> for more information: https://www.companionmedical.com/guides/inpen-user-guide.pdf</p>	<ul style="list-style-type: none"> • Determining the dose <ul style="list-style-type: none"> ○ 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 	<p>Not applicable</p>

Drug Name	Dosing Regimen	Maximum Dose
	<ul style="list-style-type: none"> ○ 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. ○ 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. ○ 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. ● Injecting the dose <ul style="list-style-type: none"> ○ Insert the insulin cartridge into the cartridge holder of the InPen. ○ Attach the needle and prime the pen. The pen must be primed before every injection. ○ Select the dose by turning the dose knob. ○ Insert the needle into the upper arms, stomach, or thighs. ○ 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. ○ Remove and discard the needle into a sharps container. ● Handling and storage <ul style="list-style-type: none"> ○ 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. ○ Remove the needle after every use. Do not store the InPen with the needle attached. ○ Do not store the InPen in a refrigerator. ● Cleaning the device <ul style="list-style-type: none"> ○ 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. ● Replacements <ul style="list-style-type: none"> ○ The InPen has a 1-year life. It contains a lithium battery which is not replaceable. ■ 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. 	

**The dosing regimen applies to the Omnipod and Omnipod DASH systems; however, each system's Pods and devices are not interchangeable.*

VI. Product Availability

Drug Name	Availability
V-Go 20, 30, 40	<ul style="list-style-type: none"> V-Go is available as a 30-day supply in 3 options – V-Go 20, V-Go 30, and V-Go 40.
Omnipod Insulin Management System All Omnipod components (Pod, PDM, built-in BGM) have wireless radiofrequency connectivity that is not compatible with smartphones.	<ul style="list-style-type: none"> Omnipod Pack 5, 10 (packs of 5 or 10 Pods) Starter Kit (PDM device with built-in FreeStyle BGM)* <p><i>*The built-in FreeStyle BGM must be used with Abbott FreeStyle test strips and control solution; however, patients may choose to use other blood glucose testing methods with manual entry into the PDM device.</i></p>
Omnipod DASH Insulin Management System All Omnipod DASH components (Pod, PDM, compatible BGM) have Bluetooth connectivity that is compatible with the iPhone.	<ul style="list-style-type: none"> Omnipod Pack 5 (packs of 5 Pods) Starter Kit (PDM DASH device plus a separate but compatible Contour® Next One BGM)* <p><i>*The compatible Contour Next One BGM must be used with Ascensia Contour® Next test strips and control solution; however, patients may choose to use other blood glucose testing methods with manual entry into the PDM device.</i></p>
InPen System	<ul style="list-style-type: none"> InPen smart insulin pen for use with Humalog: blue, grey, pink InPen smart insulin pen for use with Novolog/Fiasp: blue, grey, pink

VII. References

V-Go

FDA 510(k) device summary

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Omnipod, Omnipod DASH

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InPen

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Continuous Insulin Delivery Systems

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.15.21	05.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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