Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2020**
Policy Number: PA.CP.PHAR.505	**Effective Date: 10/2020** **Revision Date: 10/2020**
Policy Name: Continuous Insulin Delivery Systems (V-Go, Omnipod)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Policy created. PA.CP.PHAR.420 Insulin Infusion Pump (Omniopd, Omnipod DASH) policy is retired and integrated into the present policy; V-Go wearable insulin delivery device added to the policy; Dawn phenomenon fasting blood sugar corrected - from 200 g/dL to 200 mg/dL; rapid-acting insulin analog Fiasp added to Omnipod / Omnipod DASH approved insulins; t:slim pump added to Appendix B; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

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

Reference Number: PA.CP.PHAR.505
Effective Date: 10/2020
Last Review Date: 10/2020

Coding Implications
Revision Log

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

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 FreeStyle BGM 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.*

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 PA Health & Wellness® that V-Go, Omnipod, and Omnipod DASH 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 ≥ 21 years;
4. 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) ≥ 7.0;
        f) "Dawn phenomenon" with fasting blood sugars repeatedly > 200 mg/dL;

5. Member has monitored BG ≥ 4 times a day for at least the last 6 months;
6. Member or caregiver has completed a physician-directed comprehensive diabetes management program;
7. Request meets one of the following (a or b):
    a. V-Go: number of devices does not exceed 30 per month;*
    **For requests exceeding 30 devices per month, a clinical rationale with documentation supports the higher quantity.*
    b. Omniod/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.*

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

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 devices does not exceed 30 per month;*
    **For requests exceeding 30 devices per month, a clinical rationale with documentation supports the higher quantity.*
    b. Omniod/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.*

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

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.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 – PA.CP.PMN.53

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: Personal 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 Insulin pumps (with tubing [automated options available]) • MiniMed™ System (530G, 630G, 670G) • MiniMed™ Paradigm Revel™ • t:slim™ X2 Insulin Pump Insulin pumps (without tubing) • Omnipod Insulin Management System • Omnipod DASH Insulin Management System Insulin patches • V-Go 20, 30, 40 Wearable Insulin Delivery Device (disposable)	Varies	Varies
INSULIN **Human Insulin** Short-acting: • 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: • Insulin NPH (HumuLIN® N KwikPen® [OTC], HumuLIN® N [OTC], NovoLIN® N ReliOn [OTC], NovoLIN® N [OTC]) Intermediate-acting and short-acting combinations: • Insulin NPH and regular insulin (HumuLIN® 70/30, HumuLIN® 70/30 KwikPen®, NovoLIN® 70/30) **Insulin Analogs** Rapid-acting • 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®) Intermediate-acting and short-acting combinations: • 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®) Long-acting • 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
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen*	Maximum Dose
V-Go Wearable (disposable) Insulin Delivery Device	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	Varies by device

Drug Name	Dosing Regimen*	Maximum Dose
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	aspart, rDNA origin) have been tested and found to be safe for use in V-Go. • 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. • 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.	
Omnipod Insulin Management System *See User Guide for more information: https://www.myomnipod.com/sites/default/files/media/documents/17845-5A-AW_003_02.pdf* Omnipod DASH Insulin Management System *See User Guide for more information: https://www.myomnipod.com/sites/default/files/media/documents/18296-ENG-AW_006_02-DASH-User-Guide-English.pdf*	• Initial Omnipod and Omnipod DASH System use o Provider recommends initial program settings and meets with patient and Omnipod System Trainer to program the PDM device and first Pod. • Filling the Pod o 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)). o 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).* • Pod priming	200 units per day (1 Pod)

Drug Name	Dosing Regimen*	Maximum Dose
	○ The PDM device and Pod are placed next to each other so that the PDM may prime the Pod. • Pod placement ○ For site selection, see User Guides. • Pod activation ○ The Pod features an insulin-providing cannula that inserts automatically with the press of an "activate" button on the PDM device. • Pod replacement ○ The Pod may remain on the skin from 1 to 3 days after which a new Pod should be filled, primed, applied, and activated.	

**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	• 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.*	• Omnipod Pack 5, 10 (packs of 5 or 10 Pods) • Starter Kit (PDM device with built-in FreeStyle BGM)* **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.*
Omnipod DASH Insulin Management System *All Omnipod DASH components (Pod, PDM, compatible BGM) have Bluetooth connectivity that is compatible with the iPhone.*	• Omnipod Pack 5 (packs of 5 Pods) • Starter Kit (PDM DASH device plus a separate but compatible Contour® Next One BGM)* **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.*

VII. References

V-Go

FDA 510(k) device summary

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 August 14, 2020.

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2. Instructions for Patient Use. P/N 2614-00 Rev. A 05/2019. Available at https://www.go-vgo.com/hcp/wp-content/uploads/sites/2/2019/12/ART-1361-Rev-A-V-Go-IFU-2019-V4.pdf. Accessed August 14, 2020.

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3. 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.
4. 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.
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10. 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.
11. Layne JE, Parkin CG, Zisser H, et al. Efficacy of a tubeless patch pump in patients with type 2 diabetes previously treated with multiple daily injections. J Diabetes Sci Technol. 2017;11(1):178-179.
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13. Lexicomp Online, Insulin Lexi-Drugs Online, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2020. Accessed February 10, 2020.

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14. Diabetes technology: Standards of medical care in diabetes. American Diabetes Association. Diabetes Care 2020 Jan; 43 (Supplement 1): S77-S88. https://doi.org/10.2337/dc20-S007.
15. 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.
16. 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.

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17. 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.
18. Guideline for detection and management of diabetes in pregnancy. Joslin Diabetes Center and Joslin Clinic. November 10, 2016, January 11, 2107. Available at https://www.joslin.org/Pregnancy-Guidelines_11-13-2016_corrected_1-11-2017.pdf. Accessed April 22, 2019.

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 (Pod)
E0784	External ambulatory infusion pump, insulin (PDM device)

**A9274 and E0784: Omnipod System (the codes do not apply to Omnipod DASH); A9274: V-Go..*

Reviews, Revisions, and Approvals	Date
Policy created. CP.PHAR.420 Insulin Infusion Pump (Omniopd, Omnipod DASH) policy is retired and integrated into the present policy; V-Go wearable insulin delivery device added to the policy; Dawn phenomenon fasting blood sugar corrected - from 200 g/dL to 200 mg/dL; rapid-acting insulin analog Fiasp added to Omnipod / Omnipod DASH approved insulins; t:slim pump added to Appendix B; references reviewed and updated.	10/2020