Prior Authorization Review Panel

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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: 02/01/2020**
Policy Number: PA.CP.PHAR.420	**Effective Date: 01/15/2020** **Revision Date: 01/15/2020**
Policy Name: Insulin Infusion Pump (Omnipod, Omnipod DASH)	

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:

New Policy Created

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Insulin Infusion Pump (Omnipod, Omnipod DASH)

Reference Number: PA.CP.PHAR.420
Effective Date: 01/2020
Last Review Date: 01/2020

Coding Implications
Revision Log

Description

The following are continuous insulin delivery systems requiring prior authorization: Omnipod® Insulin Management System and Omnipod DASH™ Insulin Management System.

FDA Approved Indication(s)

Omnipod Insulin Management System and Omnipod DASH Insulin Management System:

- Intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

Omnipod Insulin Management System

- 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

Omnipod DASH Insulin Management System

- 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.**
- User guide and related resources: https://www.myomnipod.com/DASH

**The Abbott FreeStyle and Contour Next One BGMs are intended for single-patient use and should not be shared. The BGMs 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.*

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 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 *(including but not limited to type 1, type 2, and gestational diabetes)*;
2. Prescribed by or in consultation with an endocrinologist;
3. Member has utilized one of the following insulin administration methods for at least the last 6 months (a or b):
   a. Use of an insulin pump *(see Appendix B for examples of insulin pumps)*;
   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 g/dL;
4. Member has monitored blood glucose ≥ 4 times a day for at least the last 6 months;
5. Member or caregiver has completed a physician-directed comprehensive diabetes management program;
6. Request meets both of the following (a and b):
   a. Number of Pods does not exceed 10 per month;*
   b. Number of devices does not exceed one per warranty period (four years).

_____

**For requests exceeding 10 Pods per month, a clinical rationale with documentation supports the higher quantity.*

Approval duration: Pods (6 months); device (initial and then once 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.

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. Request is for continuing use of the same Omnipod device *(if switching between the Omnipod and Omnipod DASH devices, please refer to the initial criteria)*;
3. Member is responding positively to therapy and is adherent to provider follow-up visits and training;
4. Request meets both of the following (a and b):
   a. Number of Pods does not exceed 10 per month;*
   b. Number of devices does not exceed one per warranty period (four years).

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**For requests exceeding 10 Pods per month, a clinical rationale with documentation supports the higher quantity.*

Approval duration: Pods (12 months); device (initial and then once 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 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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

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
INSULIN PUMPS With tubing:	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• MiniMed™ System (530G, 630G, 670G) • MiniMed™ Paradigm Revel™ Without tubing: • V-Go® 20, 30, 40		
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]) 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®)	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 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
Omnipod Insulin Management System *See User Guides for more information - available at https://www.myomnipod.com/podder-support* Omnipod DASH Insulin Management System *See User Guides for more information - available at https://www.myomnipod.com/DASH*	• 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 (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 o The PDM device and Pod are placed next to each other so that the PDM may prime the Pod. • Pod placement o For site selection, see User Guides. • Pod activation o The Pod features an insulin-providing cannula that inserts automatically with the press of an "activate" button on the PDM device. • Pod replacement o The Pod may remain on the skin from 1 to 3 days after which a new Pod should be filled, primed, applied, and activated.	200 units per day (1 Pod)

**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
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

1. Omnipod Insulin Management System and Omnipod DASH Insulin Management System 510(k) summary, No. K182630. Acton, MA: Insulet Corporation; January 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182630.pdf. Accessed March 25, 2019.
2. Omnipod Insulin Management System User Guide PDM Model UST400. Rev B September 2017. Available at: https://www.myomnipod.com/podder-support. Accessed March 29, 2019.
3. Lexicomp Online, Insulin Lexi-Drugs Online, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2019; April 1, 2019.

Omnipod Literature

4. Omnipod Insulin Management System. Podder's Handbook User Guide. Available at https://www.myomnipod.com/sites/default/files/inline-files/17845-5A%20Guide%2C%20Eros%20US%20User%20Guide%20Rev%20B%20-%20View.pdf. Accessed April 22, 2019.
5. Omnipod DASH Insulin Management System. Podder Resource Guide. Available at https://www.myomnipod.com/sites/default/files/media/documents/18296-ENG-AW%20Rev%20B_USA%20DASH%20User%20Guide.pdf. Accessed April 22, 2019.
6. Layne JE, Parkin CG, Zisser H. Efficacy of the Omnipod Insulin Management System on
7. 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.
8. 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.
9. Ly TT, Layne JE, Huyett LM, et al. Novel Bluetooth-enabled tubeless insulin pump: innovating pump therapy for patients in the digital age. J Diabetes Sci Technol. 2019;13(1):20-26.

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10. Diabetes technology: Standards of medical care in diabetes. American Diabetes Association. Diabetes Care 2019 Jan; 42 (Supplement 1): S71-S80. https://doi.org/10.2337/dc19-S007.

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12. 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.

Diabetes and Pregnancy

13. 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.
14. 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)

**The codes apply to the Omnipod System only; they do not apply to the Omnipod DASH System.*

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	01/15/20	