Clinical Policy: Continuous Insulin Delivery Systems (Omnipod, Omnipod DASH)

Reference Number: IL.ERX.PHAR.534
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Line of Business: Illinois Medicaid

Revision Log

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

Description

Omnipod® Insulin Management System and Omnipod DASH™ Insulin Management System are continuous insulin delivery systems.

FDA Approved Indication(s)

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.

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 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. 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;
4. Member has monitored BG ≥ 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. 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: Pods - 6 months, device - one every 4 years

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. 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: Pods - 12 months, device - one every 4 years

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: 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 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]) 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®)	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• 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): people who are unable to perform at least 4 blood glucose tests per day, unable to maintain contact with their healthcare provider, or unable to use the System according to instructions
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen*	Maximum Dose
Diabetes mellitus	● Initial Omnipod and Omnipod DASH System use ○ Provider recommends initial program settings and meets with patient and Omnipod System Trainer to program the PDM device and first Pod. ● Filling the Pod ○ 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 *(for initial programming, each Pod must be filled with at least 85 units of insulin)*. ● Pod priming ○ 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: ▪ Omnipod Insulin Management System: https://www.myomnipod.com/sites/default/files/media/documents/17845-5A-AW_003_02.pdf ▪ Omnipod DASH Insulin Management System: https://www.myomnipod.com/sites/default/files/media/documents/18296-ENG-AW_006_02-DASH-User-Guide-English.pdf ● 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.	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

FDA 510(k) Device Summary

1. Omnipod Insulin Management System and Omnipod DASH Insulin Management System 510(k) summary, No. K192659. Acton, MA: Insulet Corporation; October 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192659.pdf. Accessed February 10, 2020.

User Guides

2. Omnipod Insulin Management System. Podder's Handbook User Guide. Available at https://www.myomnipod.com/sites/default/files/media/documents/17845-5A-AW_003_02.pdf. Accessed August 14, 2020.
3. Omnipod DASH Insulin Management System. Podder's Handbook User Guide. Available at https://www.myomnipod.com/sites/default/files/media/documents/18296-ENG-AW_006_02-DASH-User-Guide-English.pdf. Accessed August 14, 2020.

Clinical Trials and Reviews

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11. 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.
12. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.08.21	11.21

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.