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

Reference Number: PA.CP.PHAR.534
Effective Date: 10/2020
Last Review Date: 01/2023

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
- Omnipod® 5 Automated Insulin Delivery 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/instructions-for-patient-use.

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.
- 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.omnipod.com/current-podders/resources/omnipod-system

**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.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 6 years and older with Type 1 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® continuous glucose monitoring (CGM) system (must be obtained separately)

- Connectivity: Wireless *Bluetooth communication* between the Pod, Dexcom G6 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 health plans affiliated with PA Health & Wellness® that V-Go, Omnipod, Omnipod DASH, Omnipod 5, 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 ≥ 21 years;
4. If request is for InPen, age ≥ 7 years;
5. If request is for Omnipod 5, age ≥ 2 years;
6. 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;

7. Member has monitored BG ≥ 4 times a day for at least the last 6 months;
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. Member or caregiver has completed a physician-directed comprehensive diabetes management program;
10. 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. Omniod/Omnipod DASH/Omnipod 5: number of Pods does not exceed 10 per month;*
    ** For requests exceeding 30 devices per month, a clinical rationale with documentation to support the higher quantity is required.* InPen: Request does not exceed 1 system per year.

Approval duration: V-Go (6 months), Omnipod/Omnipod DASH/Omnipod 5 (Pods - 6 months, device - one every 4 years), InPen (12 months – one device per year)

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, 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. Omniod/Omnipod DASH/Omnipod 5: number of Pods does not exceed 10 per month;*
    ** For requests exceeding 30 devices per month, a clinical rationale with documentation to support the higher quantity is required.*
    c. InPen: Request does not exceed 1 system per year.

Approval duration: V-Go (12 months), Omnipod/Omnipod DASH/Omnipod 5 (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

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
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]) Intermediate-acting:	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• 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, Omnipod DASH, and Omnipod 5 are 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 and 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 *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. • 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.	Varies by device
Omnipod Insulin Management System *See User Guide for more information:* *https://www.omnipod.com/current-podders/resources/omnipod-system*	*The below dosing regimen applies to the Omnipod and Omnipod DASH systems; however, each system's Pods and devices are not interchangeable.* • 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	200 units per day (1 Pod)

Drug Name	Dosing Regimen*	Maximum Dose
Omnipod DASH Insulin Management System *See User Guide for more information:* *https://www.omnipod.com/current-podders/resources/omnipod-dash*	○ 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. • 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.	
InPen System *See User Guide for more information:* *https://www.companionmedical.com/guides/inpen-user-guide.pdf*	• Determining the dose ○ 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 ○ 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	Not applicable

Drug Name	Dosing Regimen*	Maximum Dose

	sizes to be programmed into the software prior to use.
	• Injecting the dose
	  ○ 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
	  ○ 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
	  ○ 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
	  ○ 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.	

Drug Name	Dosing Regimen*	Maximum Dose

Omnipod 5 Automated Insulin Delivery System	• 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).
	  ○ The Pod, SmartAdjust technology, and SmartBolus Calculator are compatible with the following U-100 insulins: NovoLOG, HumaLOG, and AdmeLOG.
	• 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 CGM, and select insulin delivery mode
	• The Omnipod 5 System communicates with the Dexcom G6 CGM System. CGM values and trends from the Dexcom G6 are used for automated insulin delivery in Automated Mode, as well as bolus calculations in both Automated and Manual Mode. The Dexcom G6 sensor must be started in the Dexcom app in order to use CGM values and trends in the Omnipod 5 System.
	• There are 2 modes of operation: Automated and Manual.
	  ○ 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.
	• 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.
		200 units per day (1 Pod)

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.

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.*
Omnipod 5 Automated Insulin Delivery System	• Omnipod 5 Intro Kit (Omnipod 5 Controller and Pods plus a separate but compatible Dexcom G6 CGM) • Omnipod 5 Refill 5 Pack Pods

VII. References

V-Go

FDA 510(k) device summary

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Omnipod, Omnipod DASH, Omnipod 5

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InPen

FDA 510(k) device summary

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Continuous Insulin Delivery Systems

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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, 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 latter codes does 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.*

NDCs	Description
62088000031	InPen Humalog, blue
62088000032	InPen Humalog, grey
62088000033	InPen Humalog, pink
62088000034	InPen Novolog/Fiasp, blue
62088000035	InPen Novolog/Fiasp, grey
62088000036	InPen Novolog/Fiasp, pink
08508200005	Omnipod DASH 5 Pack Pods
08508200032	Omnipod DASH Intro Kit

NDCs	Description
08508300021	Omnipod 5 Refill 5 Pack Pods
08508300001	Omnipod 5 Intro Kit

Reviews, Revisions, and Approvals	Date
Policy created: adapted from PA.CP.PHAR.505 Continuous Insulin Delivery Systems (now retired); added InPen;	07/2021
2Q 2022 annual review: added Omnipod 5; references reviewed and updated.	05/2022
For Omnipod 5, revised minimum age requirement from 6 years to 2 years per updated user guide.	01/2023