Insulin Pumps Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
04-01-2024

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Omnipod DASH® System Infusion disposable pump kit	For subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.		8
Omnipod GO® Infusion disposable pump kit	For the subcutaneous infusion of insulin at a preset basal rate in one 24-hour time period for 3 days (72 hours) in adults with type 2 diabetes.		12
Omnipod® 5 G6* Infusion disposable pump supplies	For subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.	*The Omnipod 5 System is designed to work with the Dexcom G6 Continuous Glucose Monitor (CGM)	11
Omnipod® 5 G7 Infusion disposable pump supplies			11
Omnipod® Infusion disposable pump kit	For subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.		7
V-Go® Infusion disposable pump kit	For continuous subcutaneous infusion of either 20 Units of insulin (0.83 U/hr), 30 Units of insulin (1.25 U/hr) or 40 Units of insulin (1.67 U/hr) in one 24-hour time period and on-demand bolus dosing in 2 Unit increments (up to 36 Units per one 24-hour time period) in adults requiring insulin.		10

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Diabetes	The American Diabetes Association recommends that most people with type 1 diabetes should be treated with multiple daily injections of prandial and basal insulin, or

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	subcutaneous insulin infusion. In addition, many patients with type 2 diabetes eventually require insulin therapy for both prandial and basal blood glucose control.(4) The purpose of insulin pumps is to mimic the pancreas' normal release of insulin.(5) Since insulin pumps only use short-acting insulin, frequent blood glucose checks for safety are required. Most diabetes providers will require a patient to check their blood glucose at least four times daily before using an insulin pump. There are technical aspects to using a pump; using a pump can be more complicated than injections in some ways.(6) Insulin pump therapy is not recommended for people who are unable to perform at least four blood glucose checks per day, are unable to maintain contact with their healthcare provider, or are unable to use the system according to instructions.(1) The Omnipod is a small device that is filled with insulin by the patient and worn on the body. Up to 200 units of insulin can be injected into the Pod. Omnipod is designed for use with U-100 rapid-acting insulin. NovoRapid, Humalog, and Apidra are safe to use in the Omnipod, but only Humalog and Apidra are compatible for up to 72 hours. The Pod should be changed when either 200 Units of insulin has been delivered or 72 hours has elapsed. Once applied, the patient uses a Personal Diabetes Manager (PDM) wireless device to control the rate and amount of insulin delivered by the pod. Insulin can be delivered at a basal rate as well as a bolus (such as would be used at mealtime). The PDM also contains a FreeStyle blood glucose meter. Information from the PDM can be uploaded to data management software for review.(7) The Omnipod DASH system uses the DASH PDM with a smart-phone like device with a touchscreen and connected to the Pod via Bluetooth. The Omnipod system and the Omnipod DASH system are not compatible; Pods from one system cannot be used with the other.(8) The manufacturer warranties the PDM for a period of 4 years from initial purchase.(2) Omnipods are packaged in boxes of 10. Omnipod DASH pods are packaged in boxes of 5.(9) The Omnipod 5 system is integrated with the Dexcom G6 Continuous Glucose Monitor. The Pod can be adjusted by using the Omnipod 5 App on a compatible smartphone, or with an included wireless controller.(11) The Omnipod GO insulin delivery device is intended for the subcutaneous infusion of insulin at a preset basal rate in one 24-hour time period for 3 days (72 hours) in adults with type 2 diabetes. It comes in 7 different models: 10, 15, 20, 25, 30, 35, and 40 units per day. There is no ability to deliver a bolus dose of insulin using the Omnipod GO.(12) The V-Go system is a device that is applied to the skin like a patch that delivers insulin to the patient. Three types of V-Go devices are available, delivering 20, 30, or 40 units of insulin over 24 hours. A U-100 fast acting insulin should be used with V-Go. Humalog, and NovoLog have been found to be safe for use in V-Go. The device delivers insulin at the basal rate over 24 hours specified by which device is selected. The device can also deliver a bolus of 2 units to the patient by clicking a button on the device. Up to 36 units (18 clicks) of insulin can be delivered via bolus per device. V-Go devices are packaged as a kit containing 30 V-Go devices and a filling accessory. They are to be dispensed as a full kit; kits are not to be broken apart.(10)
Safety	The Omnipod 5 System is NOT recommended for people who are:(1,2) • Unable to monitor glucose as recommended by their healthcare provider are • Unable to maintain contact with their healthcare provider are • Unable to use the Omnipod 5 System according to instructions 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

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	• Device components including the Pod, CGM transmitter, and CGM sensor must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. In addition, the Controller and smartphone should be placed outside of the procedure room. Exposure to MRI, CT, or diathermy treatment can damage the components. Insulin pump therapy is NOT recommended for people who are:(1,2) • Unable to perform at least four (4) blood glucose tests per day • Unable to maintain contact with their healthcare provider • Unable to use the any system according to instructions

REFERENCES

Number	Reference
1	Omnipod System User Guide. Insulet Corporation. 2018-2023. Available at: https://www.omnipod.com/safety.
2	Omnipod DASH System User Guide. Insulet Corporation. 2018-2023. Available at: https://www.omnipod.com/safety.
3	V-Go Health Care Provider website. Mankind Corporation. July 2023. Available at: https://www.go-vgo.com/hcp/.
4	American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: *Standards of Medical Care in Diabetes-2023*. Available at: https://diabetesjournals.org/care/article/46/Supplement_1/S140/148057/9-Pharmacologic-Approaches-to-Glycemic-Treatment.
5	Device Technology. American Diabetes Association. Available at: https://www.diabetes.org/diabetes/device-technology
6	Who Should Use a Pump? American Diabetes Association. Available at: https://www.diabetes.org/diabetes/device-technology/who-should-use-a-pump.
7	Podder's Handbook Omnipod User's Guide. Available at: https://www.myomnipod.com/en-gb/eros-user-guide.
8	Omnipod Dash Insulin Management System Frequently Asked Questions. Available at: https://www.myomnipod.com/en-gb/faq-dash.
9	Diabetic Warehouse e-commerce site. Available at: https://www.diabeticwarehouse.org/pages/search-results-page?q=omnipod.
10	V-Go Product Website. Available at: https://www.go-vgo.com/.
11	Omnipod 5 Information. Available at: https://www.omnipod.com/what-is-omnipod/omnipod-5.
12	Omnipod GO marketing approval letter and Form 3881 https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223372.pdf.

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Omnipod 5 g6 intro kit (g ; Omnipod 5 g7 intro kit (g ; Omnipod classic pdm start ; Omnipod dash intro kit (g ; Omnipod dash pdm kit (gen	*insulin infusion disposable pump kit***		1	Kit	720	DAYS			
Omnipod 5 g6 pods (gen 5) ; Omnipod 5 g7 pods (gen 5) ; Omnipod classic pods (gen ; Omnipod dash pods (gen 4)	*insulin infusion disposable pump reservoir***		30	Pods	30	DAYS			
Omnipod go 10 units/day	*insulin infusion disposable pump kit	10 UNIT/24 HR	10	Kits	30	DAY			
Omnipod go 15 units/day	*insulin infusion disposable pump kit	15 UNIT/24 HR	10	Kits	30	DAYS			
Omnipod go 20 units/day	*insulin infusion disposable pump kit	20 UNIT/24 HR	10	Kits	30	DAYS			08508400020
Omnipod go 25 units/day	*insulin infusion disposable pump kit	25 UNIT/24 HR	10	Kits	30	DAYS			
Omnipod go 30 units/day	*insulin infusion disposable pump kit	30 UNIT/24 HR	10	Kits	30	DAYS			08508400030
Omnipod go 35 units/day	*insulin infusion disposable pump kit	35 UNIT/24 HR	10	Kits	30	DAYS			
Omnipod go 40 units/day	*insulin infusion disposable pump kit	40 UNIT/24 HR	10	Kits	30	DAYS			08508400040
V-go 20	*insulin infusion disposable pump kit	20 UNIT/24 HR	30	Systems	30	DAYS			08560940003
V-go 30	*insulin infusion disposable pump kit	30 UNIT/24 HR	30	Systems	30	DAYS			08560940002
V-go 40	*insulin infusion disposable pump kit	40 UNIT/24 HR	30	Systems	30	DAYS			08560940001

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Omnipod 5 g6 intro kit (g ; Omnipod 5 g7 intro kit (g ; Omnipod classic pdm start ; Omnipod dash intro kit (g ; Omnipod dash pdm kit (gen	*insulin infusion disposable pump kit***		Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Omnipod 5 g6 pods (gen 5) ; Omnipod 5 g7 pods (gen 5) ; Omnipod classic pods (gen ; Omnipod dash pods (gen 4)	*insulin infusion disposable pump reservoir***		Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Omnipod go 10 units/day	*insulin infusion disposable pump kit	10 UNIT/24HR	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Omnipod go 15 units/day	*insulin infusion disposable pump kit	15 UNIT/24HR	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Omnipod go 20 units/day	*insulin infusion disposable pump kit	20 UNIT/24HR	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Omnipod go 25 units/day	*insulin infusion disposable pump kit	25 UNIT/24HR	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Omnipod go 30 units/day	*insulin infusion disposable pump kit	30 UNIT/24HR	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Omnipod go 35 units/day	*insulin infusion disposable pump kit	35 UNIT/24HR	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Omnipod go 40 units/day	*insulin infusion disposable pump kit	40 UNIT/24HR	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
V-go 20	*insulin infusion disposable pump kit	20 UNIT/24HR	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
V-go 30	*insulin infusion disposable pump kit	30 UNIT/24HR	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
V-go 40	*insulin infusion disposable pump kit	40 UNIT/24HR	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: 1. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** 2. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

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