



# Insulin Pumps Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

Target agents for MN Medicaid are Omnipod, Omnipod DASH, and Omnipod GO products.

## POLICY REVIEW CYCLE

**Effective Date**  
04-01-2024

**Date of Origin**  
01-01-2021

## 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®  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 subcutaneous insulin infusion. In addition, many patients with type 2 diabetes eventually require insulin therapy for both prandial and basal blood glucose control.(4)
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	<p>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)</p> <p>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)</p> <p>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)</p> <p>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)</p> <p>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)</p> <p>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)</p>
Safety	<p>The Omnipod 5 System is NOT recommended for people who are:(1,2)</p> <ul style="list-style-type: none"> <li>• Unable to monitor glucose as recommended by their healthcare provider are</li> <li>• Unable to maintain contact with their healthcare provider are</li> <li>• Unable to use the Omnipod 5 System according to instructions are</li> <li>• Taking hydroxyurea as it could lead to falsely elevated CGM values and result in over-delivery of insulin that can lead to severe hypoglycemia</li> <li>• Do NOT have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms, and reminders</li> <li>• 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</li> </ul>

	<p>and smartphone should be placed outside of the procedure room. Exposure to MRI, CT, or diathermy treatment can damage the components.</p> <p>Insulin pump therapy is NOT recommended for people who are:(1,2)</p> <ul style="list-style-type: none"> <li>• Unable to perform at least four (4) blood glucose tests per day</li> <li>• Unable to maintain contact with their healthcare provider</li> <li>• Unable to use the any system according to instructions</li> </ul>
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**REFERENCES**

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

**POLICY AGENT SUMMARY PRIOR AUTHORIZATION**

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Omnipod go 10 units/day	*insulin infusion disposable pump kit	10 UNIT/24HR	M ; N ; O ; Y	N		
Omnipod go 15 units/day	*insulin infusion disposable pump kit	15 UNIT/24HR	M ; N ; O ; Y	N		
Omnipod go 25 units/day	*insulin infusion disposable pump kit	25 UNIT/24HR	M ; N ; O ; Y	N		

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Omnipod go 35 units/day	*insulin infusion disposable pump kit	35 UNIT/24HR	M ; N ; O ; Y	N		
Omnipod 5 g6 pods (gen 5) ; Omnipod classic pods (gen ; Omnipod dash pods (gen 4)	*Insulin Infusion Disposable Pump Supplies***		M ; N ; O ; Y	N		
Omnipod 5 g6 intro kit (g	*insulin infusion disposable pump kit***		M ; N ; O ; Y	N		
Omnipod classic pdm start	*insulin infusion disposable pump kit***		M ; N ; O ; Y	N		
Omnipod dash intro kit (g	*insulin infusion disposable pump kit***		M ; N ; O ; Y	N		
Omnipod dash pdm kit (gen	*insulin infusion disposable pump kit***		M ; N ; O ; Y	N		
Omnipod go 20 units/day	*insulin infusion disposable pump kit	20 UNIT/24HR	M ; N ; O ; Y	N		
Omnipod go 30 units/day	*insulin infusion disposable pump kit	30 UNIT/24HR	M ; N ; O ; Y	N		
Omnipod go 40 units/day	*insulin infusion disposable pump kit	40 UNIT/24HR	M ; N ; O ; Y	N		

## 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
Omnipod 5 g6 intro kit (g	*insulin infusion disposable pump kit***		1	Kit	720	DAYS			085083 00001
Omnipod 5 g6 pods (gen 5) ; Omnipod classic pods (gen ; Omnipod dash pods (gen 4)	*Insulin Infusion Disposable Pump Supplies***		30	Pods	30	DAYS			
Omnipod classic pdm start	*insulin infusion disposable pump kit***		1	Kit	720	DAYS			085081 14002
Omnipod dash intro kit (g	*insulin infusion disposable pump kit***		1	Kit	720	DAYS			085082 00032
Omnipod dash pdm kit (gen	*insulin infusion disposable pump kit***		1	Kit	720	DAYS			085082 00000
Omnipod go 10 units/day	*insulin infusion disposable pump kit	10 UNIT/24 HR	10	Kits	30	DAYS			
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			085084 00020
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			085084 00030
Omnipod go 35 units/day	*insulin infusion disposable pump kit	35 UNIT/24 HR	10	Kits	30	DAYS			

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 go 40 units/day	*insulin infusion disposable pump kit	40 UNIT/24 HR	10	Kits	30	DAYS			085084 00040

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Omnipod 5 g6 intro kit (g	*insulin infusion disposable pump kit***		Medicaid
Omnipod 5 g6 pods (gen 5) ; Omnipod classic pods (gen ; Omnipod dash pods (gen 4)	*Insulin Infusion Disposable Pump Supplies***		Medicaid
Omnipod classic pdm start	*insulin infusion disposable pump kit***		Medicaid
Omnipod dash intro kit (g	*insulin infusion disposable pump kit***		Medicaid
Omnipod dash pdm kit (gen	*insulin infusion disposable pump kit***		Medicaid
Omnipod go 10 units/day	*insulin infusion disposable pump kit	10 UNIT/24HR	Medicaid
Omnipod go 15 units/day	*insulin infusion disposable pump kit	15 UNIT/24HR	Medicaid
Omnipod go 20 units/day	*insulin infusion disposable pump kit	20 UNIT/24HR	Medicaid
Omnipod go 25 units/day	*insulin infusion disposable pump kit	25 UNIT/24HR	Medicaid
Omnipod go 30 units/day	*insulin infusion disposable pump kit	30 UNIT/24HR	Medicaid
Omnipod go 35 units/day	*insulin infusion disposable pump kit	35 UNIT/24HR	Medicaid
Omnipod go 40 units/day	*insulin infusion disposable pump kit	40 UNIT/24HR	Medicaid

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Omnipod 5 g6 intro kit (g	*insulin infusion disposable pump kit***		Medicaid
Omnipod 5 g6 pods (gen 5) ; Omnipod classic pods (gen ; Omnipod dash pods (gen 4)	*Insulin Infusion Disposable Pump Supplies***		Medicaid
Omnipod classic pdm start	*insulin infusion disposable pump kit***		Medicaid
Omnipod dash intro kit (g	*insulin infusion disposable pump kit***		Medicaid
Omnipod dash pdm kit (gen	*insulin infusion disposable pump kit***		Medicaid
Omnipod go 10 units/day	*insulin infusion disposable pump kit	10 UNIT/24HR	Medicaid
Omnipod go 15 units/day	*insulin infusion disposable pump kit	15 UNIT/24HR	Medicaid
Omnipod go 20 units/day	*insulin infusion disposable pump kit	20 UNIT/24HR	Medicaid
Omnipod go 25 units/day	*insulin infusion disposable pump kit	25 UNIT/24HR	Medicaid
Omnipod go 30 units/day	*insulin infusion disposable pump kit	30 UNIT/24HR	Medicaid
Omnipod go 35 units/day	*insulin infusion disposable pump kit	35 UNIT/24HR	Medicaid
Omnipod go 40 units/day	*insulin infusion disposable pump kit	40 UNIT/24HR	Medicaid

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Omnipod GO	<p><b>Omnipod GO</b> will be approved when BOTH of the following are met:</p> <ol style="list-style-type: none"> <li>1. ONE of the following: <ol style="list-style-type: none"> <li>A. Information has been provided that indicates the patient has been using the requested product within the past 90 days <b>OR</b></li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<p>B. The prescriber states the patient has been using the requested product within the past 90 days AND is at risk if therapy is changed <b>OR</b></p> <p>C. ALL of the following:</p> <ol style="list-style-type: none"> <li>1. The patient has diabetes mellitus type 2 AND requires insulin therapy <b>AND</b></li> <li>2. The patient has completed a comprehensive diabetes education program <b>AND</b></li> <li>3. The patient has demonstrated willingness and ability to play an active role in diabetes self-management <b>AND</b></li> </ol> <p>2. ONE of the following:</p> <ol style="list-style-type: none"> <li>1. The patient's age is within the manufacturer recommendations for the requested indication for the requested product <b>OR</b></li> <li>2. The prescriber has provided information in support of using the requested product for the patient's age</li> </ol> <p><b>Length of Approval: 12 months</b></p>
<p>Omnipod , Omnipod 5 G6, Omnipod DASH</p>	<p><b>Omnipod, Omnipod 5 G6, and Omnipod Dash</b> will be approved when BOTH of the following are met:</p> <ol style="list-style-type: none"> <li>1. ONE of the following: <ol style="list-style-type: none"> <li>A. Information has been provided that indicates the patient has been using the requested product within the past 90 days <b>OR</b></li> <li>B. The prescriber states the patient has been using the requested product within the past 90 days AND is at risk if therapy is changed <b>OR</b></li> <li>C. ALL of the following: <ol style="list-style-type: none"> <li>1. The patient has diabetes mellitus AND requires insulin therapy <b>AND</b></li> <li>2. The patient is on an insulin regimen of 3 or more injections per day <b>AND</b></li> <li>3. The patient performs 4 or more blood glucose tests per day or is using Continuous Glucose Monitoring (CGM) <b>AND</b></li> <li>4. The patient has completed a comprehensive diabetes education program <b>AND</b></li> <li>5. The patient has demonstrated willingness and ability to play an active role in diabetes self-management <b>AND</b></li> <li>6. The patient has had ONE of the following while compliant on an optimized multiple daily insulin injection regimen: <ol style="list-style-type: none"> <li>A. Glycosylated hemoglobin level (HbA1C) greater than 7% <b>OR</b></li> <li>B. History of recurring hypoglycemia <b>OR</b></li> <li>C. Wide fluctuations in blood glucose before mealtime <b>OR</b></li> <li>D. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL <b>OR</b></li> <li>E. History of severe glycemic excursions <b>AND</b></li> </ol> </li> </ol> </li> </ol> </li> <li>2. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient's age is within the manufacturer recommendations for the requested indication for the requested product <b>OR</b></li> <li>B. The prescriber has provided information in support of using the requested product for the patient's age</li> </ol> </li> </ol> <p><b>Length of Approval: 12 months</b></p>

### QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
<p>QL with PA</p>	<p><b>Quantity Limit for the Target agent(s)</b> will be approved for prescribed quantities when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>2. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) exceeds the program quantity limit <b>AND</b></li> <li>2. Information has been provided in support of therapy with a higher dose for the requested indication</li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<b>Length of Approval:</b> 12 months