



DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Diabetes – Omnipod Pods Drug Quantity Management Policy – Per Days
- Omnipod® Classic Pods (Insulet)
 - Omnipod DASH® Pods (Insulet)
 - Omnipod® 5 G6 Pods (Insulet)
 - Omnipod® 5 G6-G7 Pods (Insulet)
 - Omnipod GO™ Pods (Insulet)

REVIEW DATE: 03/06/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

The Omnipod® Insulin Management System, Omnipod DASH® Insulin Management System, Omnipod® 5 Automated Insulin Delivery System, and the Omnipod GO™ Insulin Delivery Device are subcutaneous (SC) insulin delivery systems.¹⁻⁴

- The Omnipod Insulin Management System is intended for SC delivery of insulin at set and variable rates for the management of diabetes mellitus (DM) in persons requiring insulin and for the quantitative measurement of glucose in fresh capillary whole blood (in vitro) from the finger.¹
- Omnipod DASH Insulin Management System is intended for SC delivery of insulin at set and variable rates (basal and bolus) for the management of DM in persons requiring insulin.² Omnipod DASH is indicated for patients of all ages with either Type 1 or Type 2 DM. Omnipod DASH is interoperable with a compatible blood glucose meter to receive and display blood glucose measurements.

- Omnipod 5 Automated Insulin Delivery System is intended for the SC delivery of insulin, at set and variable rates (basal and bolus), for the management of DM in persons requiring insulin.³ It is indicated for patients with Type 1 DM \geq 2 years of age. The Omnipod 5 is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.
- Omnipod GO is intended for the SC infusion of insulin at a preset basal rate in one 24-hour time period for 3 days (72 hours) in adults with Type 2 DM.⁴

Dosing

For the Omnipod, Omnipod DASH, and Omnipod 5 systems, the pods should be replaced at least once every 72 hours or after delivering 200 units of U-100 insulin, whichever comes first.¹⁻³ Pods may also need to be replaced more frequently due to possible issues with the pod itself or the device. The type of insulin may also dictate how frequently the pod needs to be changed. Omnipod GO pods deliver insulin continuously for up to 72 hours at a fixed daily basal rate.⁴

The Omnipod and Omnipod DASH systems have been studied and found to be safe with the following U-100 rapid-acting insulins: NovoLog[®] (insulin aspart), Fiasp[®] (insulin aspart), Humalog[®] (insulin lispro), Lyumjev[™] (insulin lispro-aabc), Apidra[®] (insulin glulisine), or Admelog[®] (insulin lispro). NovoLog, Fiasp, Humalog, Lyumjev, and Admelog are compatible with for use up to 72 hours (3 days), while Apidra is compatible for use up to 48 hours (2 days).^{1,2}

The Omnipod 5 system is compatible with NovoLog, Humalog, and Admelog, which can all be used for up to 72 hours (3 days).³

The Omnipod GO system is compatible with NovoLog, Fiasp, Humalog, Admelog, and Lyumjev, which can all be used for up to 72 hours (3 days).⁴

Availability

The Omnipod, Omnipod DASH, and Omnipod 5 systems each consist of two parts: the pod, which delivers insulin to the patient, and the Personal Diabetes Manager (PDM), which allows the patient to control the pod.^{1,2} The pod itself is a lightweight, self-adhesive device that the patient fills with insulin and wear directly on their body. Each pod requires a minimum of 85 units of U-100 insulin to begin operation and can hold up to 200 units. The pod is applied to the patient's skin with an adhesive, similar to an adhesive bandage and delivers insulin into through a small flexible cannula, based on instructions from the PDM.

Unlike the other Omnipod systems, Omnipod GO does not require the use of a dedicated controller or mobile application.⁴ Omnipod GO pods deliver insulin at preprogrammed basal rates of 10, 15, 20, 25, 30, 35, or 40 units per day over 3 days (72 hours). Pods are available in packages of 5 pods each.

Of note, the pods from the different Omnipod systems are not interchangeable with one another. For example, Omnipod Pods will not be compatible with an Omnipod DASH system.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Omnipod Pods. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and/or Package Size	Retail Maximum Quantity per 30 Days	Home Delivery Maximum Quantity per 90 days
Omnipod® Classic Pods	5 pods/pack	15 pods*	45 pods*
Omnipod DASH® Pods	5 pods/pack	15 pods*	45 pods*
Omnipod® 5 Pods (G6 and G6-G7)	5 pods/pack	15 pods*	45 pods*
Omnipod GO™ Pods	10 units/day (5 pods/pack)	10 pods	30 pods
	15 units/day (5 pods/pack)	10 pods	30 pods
	20 units/day (5 pods/pack)	10 pods	30 pods
	25 units/day (5 pods/pack)	10 pods	30 pods
	30 units/day (5 pods/pack)	10 pods	30 pods
	35 units/day (5 pods/pack)	10 pods	30 pods
	40 units/day (5 pods/pack)	10 pods	30 pods

* This is enough drug to provide a patient with a new pod every 48 hours and allow for delivery approximately 200 units of a U-100 every 48 hours.

Diabetes – Omnipod Pods Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Omnipod Classic Pods, Omnipod DASH Pods, Omnipod 5 Pods (G6 and G6-G7)

1. If a patient requires the pod to be changed more frequently than every 48 hours, approve the requested quantity for a 30-day supply at retail and a 90-day supply at home delivery.

Omnipod GO Pods

No overrides recommended.

REFERENCES

1. Omnipod® Insulin Management System [user guide]. Acton, MA: Insulet; October 2021.
Available at: https://www.omnipod.com/sites/default/files/2021-04/Omnipod-System_User-Guide_English.pdf
2. Omnipod DASH® Insulin Management System [user guide]. Acton, MA: Insulet; October 2023.
Available at: https://www.omnipod.com/sites/default/files/2021-04/Omnipod-DASH_User-Guide_English.pdf
3. Omnipod® 5 Automated Insulin Delivery System [user guide]. Acton, MA: Insulet; October 2023.
Available at: https://www.omnipod.com/sites/default/files/Omnipod-5_User-guide.pdf.
4. Omnipod GO™ Insulin Management System [user guide]. Acton, MA: Insulet; October 2023.
Available at: https://www.omnipod.com/sites/default/files/Omnipod-GO_User_Guide_US_English.pdf.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/21/2022
Annual Revision	New quantity limits for Omnipod GO pods were added to policy. No clinical overrides apply.	07/26/2023
Early Annual Revision	Omnipod 5 G6-G7 Pods: New quantity limits of 15 pods per 30 days at retail and 45 pods per 90 days at home delivery were added to the policy. Clinical override criteria apply.	03/06/2024

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