

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)

REVIEW DATE: 09/21/2022

OVERVIEW

The Omnipod® Insulin Management System, Omnipod DASH® Insulin Management System, and Omnipod® 5 Automated Insulin Delivery System and intended for **subcutaneous delivery of insulin** at set and variable rates for the management of **diabetes mellitus** in persons requiring insulin.¹⁻³

It is noted that the Omnipod DASH is interoperable with a compatible blood glucose meter to receive and display blood glucose measurements.² 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.³

Dosing

Regardless of which system is being used, 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.

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

Availability

The Omnipod, Omnipod DASH, and Omnipod 5 systems are each made up 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.

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.

Automation: None.

Drug Quantity Limits

Product	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	5 pods/pack	15 pods	45 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.

CRITERIA

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.

REFERENCES

1. Omnipod® Insulin Management System [user guide]. Acton, MA: Insulet; May 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 2021. 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; January 2022. Available at: https://www.omnipod.com/sites/default/files/Omnipod-5_User-guide.pdf