



**Disposable Insulin Delivery Systems**  
**OmniPod**  
**OmniPod Dash**  
**V-Go**  
**Effective 05/01/2022**

<b>Plan</b>	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MH UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

**Overview**

OmniPod, OmniPod Dash and V-go are disposable insulin devices which supply continuous insulin delivery systems.

No PA	Products that require PA*
	Omnipod <sup>® PD</sup>
	Omnipod Dash <sup>® PD</sup>
	V-Go <sup>® PD</sup>

\*Other forms of CSII may be available through DME.

<sup>PD</sup> Preferred Drug. In general, a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

**Coverage Guidelines**

Authorization may be granted for members new to AllWays Health Partners who are currently receiving OmniPod, OmniPod Dash or V-go, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

**OR**

Authorization may be granted for members who meet all of the following criteria and documentation has been submitted:

1. Member has a diagnosis of diabetes mellitus
2. If the request is for V-Go<sup>®</sup>, the member is ≥18 years of age

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3. Member’s current treatment plan OR provider recommendation involves testing blood glucose at least 4 times per day
4. Member is currently receiving multiple daily insulin injections (at least three) or is on an insulin pump<sup>‡</sup>
5. Member has an A1c > 7.0% or provider documents that member does not meet documented target treatment
6. **ONE** of the following:
  - a. Frequent hypoglycemia
  - b. Fluctuations of more than 100 mg/dL in blood glucose before mealtime
  - c. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL.
  - d. History of severe glycemic excursions

<sup>‡</sup>Members not receiving multiple daily insulin injections due to physical disability, visual impairment, cognitive impairment, or age <18 years may bypass this requirement

**Continuation of Therapy**

Reauthorization requires physician documentation of improvement in diabetic control/relative stability (e.g., provider attestation or A1c improvement or improvement in hypoglycemia or hyperglycemia can be considered to meet this requirement).

**Limitations**

1. Initial approvals will be granted for 3 months
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply\* (see Appendix for Approvable Quantity for Omnipod and Omnipod Dash Pods):

Omnipod and Omnipod Dash	10 pods per 30 days
Omnipod Starter Kit	1 kit every 5 years
V-Go	30 pods per 30 days

Omnipod and Omnipod DASH are available as both a starter kit and pod refills. The starter kit includes the personal diabetes manager (PDM) and associated equipment (e.g., charger, carrying case) and 5 pods. The pod refills are available as a box containing five pods. Omnipod pods can be worn for up to 72 hours. Since PDMs are not a disposable part of the Omnipod system, a starter kit should only be required when first initiating therapy and if the manufacturer warranty has expired. Therefore, the limit for Omnipod starter kits is one kit per five years.

**Appendix**

**Appendix A: Approvable Quantity for Omnipod and Omnipod Dash Pods**

Some patients may require more frequent pod changes due to irritation at the site of application or due to adhesion issues with the pod. However, there are strategies to minimize irritation and reduce risk of pods falling off. For skin irritation, these recommendations include site rotation, use of adhesive remover during site changes, topical creams and ointments, and hydrocolloid dressings. For adhesion issues, recommendations include tapes designed for use with medical devices, and skin preparation and adhesive removal products.

- If provider documents need for more frequent pod changes due to irritation, requests should document severity of the irritation and strategies used to mitigate irritation. If a request documents this information and meets all other criteria, an increased quantity may be approved as requested up to no more than 30 pods per 30 days.



- If provider documents need for more frequent pod changes due to adhesion issues, requests should document strategies used to reduce the risk of pods falling off. Members should at least try use of a tape designed for medical devices. If a request documents this information and meets all other criteria, an increased quantity may be approved as requested up to no more than 30 pods per 30 days.

## References

1. Omnipod. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: [https://www.accessdata.fda.gov/cdrh\\_docs/pdf19/K192659.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192659.pdf). Accessed April 2020.
2. American Diabetes Association. Standards of Medical Care in Diabetes-2020: *Diabetes Care* January 2020;43(Supplement 1).
3. McAdams BH, Rizvi AA. An Overview of Insulin Pumps and Glucose Sensors for the Generalist. *J Clinical Medicine* 2016;5;1-17.
4. Peters AL, Ahmann AJ, Battelino T et al. Diabetes Technology – Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab* 2016; 101(11):3922-3937.
5. Grunberger G, Abelseth JM, Baily TS et al. Consensus statement by the American Association of Clinical Endocrinologist/American College of Endocrinology Insulin Pump Management Task Force. *Endocr Pract.* 204;20(No 5):463-489.

## Review History

05/19/2021 – Created and reviewed to match MH UPPL for 7/1/2021. Effective 07/01/2021.

03/16/2022 – Reviewed and Updated for March P&T to match MH UPPL; Appendix section on Approvable Quantity for Omnipod and Omnipod Dash Pods updated to provide guidance on requests for Omnipod or Omnipod Dash greater than one pod every three days due to skin irritation or adhesion issues. Effective 05/01/2022

## Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.