Mass General Brigham
Health Plan

Disposable Insulin Delivery Systems
OmniPod
OmniPod Dash
V-Go
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

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

Coverage Guidelines
Authorization may be granted for members new to the plan 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. The member is managing their diabetes with multiple daily insulin injections (i.e., at least 3 injections per day) with frequent self-adjustments of the insulin dose for at least 6 months
2. The member has documented frequency of glucose self-testing an average of at least 4 times per day for the past two months OR the patient has been using a continuous glucose monitor (CGM) for the past two months
3. The member has completed a comprehensive diabetes education program
4. The member has experienced any of the following while on multiple daily injections of insulin (i.e., more than 3 injections per day):
    - Elevated glycosylated hemoglobin level (e.g., HbA1c greater than 7 percent)
    - History of recurrent hypoglycemia (e.g., blood glucose levels less than 70 mg/dL)
    - Wide fluctuations in blood glucose before mealtime
    - "Dawn" phenomenon with fasting blood sugars frequently exceeding 200 mg/dL, E) history of severe glycemic excursions

Continuation criteria:
Reauthorization requires physician attestation that member has positive clinical response to therapy.

Limitations
1. Initial approvals and reauthorizations will be granted for 12 months
2. The following quantity limits apply:

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.

References

1. Omnipod. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: 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(Supplement1).
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
01/20/2021 – Created and reviewed
3/17/2021 – Reviewed; added V-go to criteria. Effective 03/09/21.
11/15/2023 – Reviewed and Updated for Nov P&T; Updated reauthorization criteria to physician attestation that member has positive clinical response to therapy. Effective 1/1/24