



OmniPod Guideline OMNIPOD (ALL RX PRODUCTS)

The requested medical device will be covered with prior authorization when the following criteria are met:

- The request is for Omnipod GO
 - AND**
 - The patient has a diagnosis of type 2 diabetes mellitus
 - AND**
 - The patient does NOT require bolus or mealtime insulin
 - AND**
 - The patient has completed a comprehensive diabetes education program
 - AND**
 - The patient has documented frequency of glucose self-testing at least once daily OR the patient has been using a continuous glucose monitor (CGM)
 - AND**
 - The patient has a hypersensitivity to an ingredient in ALL available basal insulin (e.g., long-acting insulin, intermediate-acting insulin)
- OR**
- The request is for other Omnipod products (e.g., Omnipod DASH, Omnipod 5)
 - AND**
 - The request is NOT for continuation of therapy
 - AND**
 - The patient 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
 - AND**
 - The patient 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
 - AND**
 - The patient has completed a comprehensive diabetes education program
 - AND**
 - The patient has experienced any of the following while on multiple daily injections of insulin (i.e., more than 3 injections per day): A) elevated glycosylated hemoglobin level (e.g., HbA1c greater than 7 percent), B) history of recurrent hypoglycemia (e.g., blood glucose levels less than 70 mg/dL), C) wide fluctuations in blood glucose before mealtime, D) “dawn” phenomenon with fasting blood sugars frequently exceeding 200 mg/dL, E) history of severe glycemic excursions
 - AND**
 - If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period
 - OR**
 - The patient is currently established on therapy with an insulin pump
 - AND**
 - The patient has documented frequency of glucose self-testing an average of at least 4 times per day OR the patient is using a continuous glucose monitor (CGM)
 - AND**
 - If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period

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**Quantity Level Limits:**

- Omnipod GO: 10 pods per 30 days
- Other Omnipod products (e.g., Omnipod 5, Omnipod Dash): Omnipod starter kit: 1 kit per 999 days
- Omnipod pod refills: 10 pods per 30 days for patients using less than 200 units of insulin per 72-hour period
- Omnipod pod refills: 15 pods per 30 days for patients using greater than 200 units of insulin per 72-hour period

Approval Duration: 12 month**OmniPod References:**

1. Omnipod GO. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/reviews/K223372.pdf. Accessed October 16, 2023.
2. Omnipod, Omnipod DASH Insulin Management System. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192659.pdf. Accessed March 21, 2023.
3. Omnipod 5 ACE Pump (Pod). 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203768.pdf. Accessed March 21, 2023.
4. V-Go. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf10/K100504.pdf. Accessed March 21, 2023.
5. Omnipod DASH User Guide. Acton, MA: Insulet Corporation; October 2021. Available at: https://www.omnipod.com/sites/default/files/2021-04/Omnipod-DASH_User-Guide_English.pdf. Accessed March 21, 2023.
6. Omnipod 5 User Guide. Acton, MA: Insulet Corporation: August 2022. Available at: https://www.omnipod.com/sites/default/files/Omnipod-5_User-guide.pdf. Accessed March 21, 2023.
7. Omnipod GO User Guide. Acton, MA: Insulet Corporation: May 2023. Available at: https://www.omnipod.com/sites/default/files/Omnipod-GO_User_Guide_US_English.pdf. Accessed August 21, 2023.
8. V-Go Wearable Insulin Delivery Device Instructions for Patient Use. Mannkind Corporation; June 2022. Available at: <https://www.go-vgo.com/instructions-for-patient-use/>. Accessed March 21, 2023.
9. El Sayed NA, Aleppo G, Aroda VR et. al. American Diabetes Association, Standards of Care in Diabetes – 2023. Diabetes Care 2023;46(Suppl. 1):S1-S291.
10. Blonde L, Umpierrez GE, Reddy SS et. al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan – 2022 Update. Endocr Pract. 2022; 28(10):923-1049.
11. McAdams BH, Rizvi AA. An Overview of Insulin Pumps and Glucose Sensors for the Generalist. J Clin Med 2016;5;1-17.
12. 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.
13. 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. 2014;20(5):463-489.
14. Grunberger G, Handelsman Y, Bloomgarden ZT, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2018 Position Statement on Integration of Insulin Pumps and Continuous Glucose Monitoring in Patients with Diabetes Mellitus. Endocr Pract. 2018;24(3):302-308.
15. National Coverage Determination (NCD) for Infusion Pumps (280.14); Revision Effective Date 12/17/2004. Available at:

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