Applicable Devices: Omnipod 5, Omnipod DASH, Omnipod Go, Twiist, V-GO

Preferred: Omnipod 5, Omnipod DASH

Non-preferred: Omnipod Go, Twiist, V-GO

Date of Origin: 9/2/2022

Date Last Reviewed / Revised: 12/9/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to IV are met)

I. Documented diagnosis of one of the following A or B AND must meet criteria listed under applicable diagnosis:

A. Diagnosis of type 1 diabetes mellitus

B. Diagnosis of type 2 diabetes mellitus and the following criteria 1 or 2 is met:

1. Documentation of adherence to multiple daily injections of insulin (ie, basal and bolus insulin) for at least 6 months and treatment requires both a and b:

a) Frequent self-adjustments of insulin dose based on glucose measurements and carbohydrate counting

b) At least 4 self-monitoring of blood glucose (SMBG) tests per day or is using a continuous glucose monitor (CGM)

2. Documentation of suboptimal glycemic control while adherent to multiple daily injections of insulin with at least 1 of the following symptoms or conditions:

a) Glycosylated hemoglobin level (HbA1c) > 7%

b) Recurrent hypoglycemia, recurrent nocturnal hypoglycemia, and/or hypoglycemia unawareness

c) Dawn phenomenon with fasting glucose levels exceeding 200 mg/dL

d) History of severe glycemic excursions

II. Request is for a device with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines. Refer to Table 1 for FDA-approved indications.

III. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Patients not using a CGM who are unable to perform at least 4 SMBG tests per day.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Omnipod 5

- 1 Intro Kit or 1 controller device per 4 years
- 15 pods per 30 days

- Omnipod DASH
  - 1 Intro Kit or 1 Personal Diabetes Manager device per 4 years
  - 15 pods per 30 days
- Omnipod Go
  - 10 per 30 days
- Twiist
  - 1 Starter kit per 2 years
  - 1 Refill Kit per 30 days
  - 1 Refill Kit/Infusion Set per 30 days
- V-GO
  - 30 per 30 days

Approval Length

- **Authorization:** 1 year
- **Re-Authorization:** 1 year, with updated progress notes documenting adherence to prescriber follow-up visits, proper and adherent device use, and a positive response to therapy compared to baseline (eg, decrease in HbA1c, reduced frequency of severe hypoglycemia episodes, increased time in range and/or decreased time below range, decrease in ER visits, etc.)

Appendix

Table 1. FDA indications for disposable insulin delivery systems.

	Type 1 Diabetes Mellitus	Type 2 Diabetes Mellitus	Minimum Age
Omnipod 5	✓	✓ (18 years minimum)	2 years
Omnipod DASH	✓	✓	N/A
Omnipod Go		✓	18 years
Twiist	✓		6 years
V-GO	✓	✓	21 years

References

1. American Diabetes Association Professional Practice Committee; 7. Diabetes Technology: Standards of Care in Diabetes—2025. *Diabetes Care* 1 January 2025; 48 (Supplement_1): S146–S166. https://doi.org/10.2337/dc25-S007
2. Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology Clinical practice guideline: The use of advanced technology in the management of persons with diabetes mellitus. *Endocr Pract*. 2021;27(6):505-537. doi:10.1016/j.eprac.2021.04.008

3. Omnipod 5 Automated Insulin Delivery System. User Guide. Insulet; 2025. Accessed December 9, 2025 https://www.omnipod.com/sites/default/files/Omnipod-5_User-guide.pdf
4. Omnipod Dash Insulin Management System. User Guide. Insulet; 2025. Accessed December 9, 2025. https://www.omnipod.com/sites/default/files/2021-04/Omnipod-DASH_User-Guide_English.pdf
5. Omnipod Go. User Guide. Insulet; 2023. Accessed December 9, 2025. https://www.omnipod.com/sites/default/files/Omnipod-GO_User_Guide_US_English.pdf
6. Twiist. Quick Brochure. Sequel Med Tech; 2025. Accessed December 9, 2025 https://cdn.prod.websitefiles.com/670639c6c25356587872bc22/691f1b0cea5e550a2db14271_twiist%20User%20Guide%20Rev%201.15%20English%20(Electronic).pdf
7. V-GO. User Guide. Mannkind Corp; 2024. Accessed December 9, 2025 . https://www.go-vgo.com/wp-content/uploads/2024/07/ART-1361-Rev-E-V-Go-IFU.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.