AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Disposable Insulin Pumps	Page:	1 of 4
Effective Date:	4/27/2026	Last Review Date:	4/2026

Applies to:	☐Illinois	☐Florida	☒Florida Kids
	☒New Jersey	☒Maryland	☒Michigan
	☒Pennsylvania Kids	☒Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for disposable insulin pumps under the patient's prescription drug benefit.

Applicable Drug List:

Preferred Agents:
Omnipod (all Rx products)
Twiist (all Rx products)

Non-preferred Agent:
V-Go (all products)

Policy/Guideline:

For V-Go requests, the patient is unable to take the preferred Omnipod and Twiist products, due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Authorization may be granted for the requested medical device when the following criteria are met:

- The request is for other Omnipod products (e.g., Omnipod DASH, Omnipod 5), Twiist or V-Go and ONE of the following criteria are met:
  - The patient is NOT currently established on therapy with an insulin pump and ALL of the following criteria are met:
    - The patient is managing their diabetes with multiple daily insulin injections.
    - The patient has completed a comprehensive diabetes education program.
    - 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).
    - If the patient does NOT have a diagnosis of type 1 diabetes, then the patient has experienced an elevated glycosylated hemoglobin level (e.g., HbA1c greater than 7 percent) while on multiple daily injections of insulin (i.e., at least 3 injections per day) for at least 6 months OR the patient has experienced ANY of the following while on multiple daily injections of insulin (i.e., at least 3 injections per day) for at least 3 months: 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, history of severe glycemic excursions.
    - If an Omnipod starter kit is being requested, then the patient has not received an Omnipod starter kit within the past 4 years.

- If a Twiist starter kit is being requested, then the patient has not received a Twiist starter kit within the past 3 years.
- If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period.
- If additional quantities of Twiist Refill Kits or Refill Kits with Infusion Sets are being requested, then the patient requires more than 300 units of insulin within a 72-hour period.

- The patient is currently established on therapy with an insulin pump and ALL of the following criteria are met:
  - 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).
  - If an Omnipod starter kit is being requested, then the patient has not received an Omnipod starter kit within the past 4 years.
  - If a Twiist starter kit is being requested, then the patient has not received a Twiist starter kit within the past 3 years.
  - If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period.
  - If additional quantities of Twiist Refill Kits or Refill Kits with Infusion Sets are being requested, then the patient requires more than 300 units of insulin within a 72-hour period

Type 2 Diabetes Mellitus

Authorization may be granted for the requested medical device when the patient has a diagnosis of type 2 diabetes mellitus when the following criteria is met:

- The request is for Omnipod GO and ALL of the following criteria are met:
  - The patient does NOT require bolus or mealtime insulin.
  - The patient has completed a comprehensive diabetes education program.
  - The patient meets ONE of the following:
    - The patient has documented frequency of glucose self-testing at least once daily.
    - The patient has been using a continuous glucose monitor (CGM).
  - The patient has a hypersensitivity to an ingredient in ALL available basal insulin (e.g., long-acting insulin, intermediate-acting insulin).

Approval Duration and Quantity Restrictions:

Approval: 12 months

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 4 years
- Omnipod pod refills: 10 pods per 30 days or 30 pods per 90 days for patients using 200 units of insulin or less per 72-hour period
- Omnipod pod refills: 15 pods per 30 days or 45 pods per 90 days for patients using more than 200 units of insulin per 72-hour period

Twiist products:
- Twiist Starter kit: 1 kit per 3 years
- Twiist Refill Kit: 1 Refill Kit (10 cassettes) per 30 days or 3 Refill Kits (30 cassettes) per 90 days for patients using 300 units of insulin or less per 72-hour period
- Twiist Refill Kit: 2 Refill Kits (20 cassettes) per 30 days or 6 Refill Kits (60 cassettes) per 90 days for patients using more than 300 units of insulin per 72-hour period
- Twiist Refill Kit with Infusion Sets: 1 Refill Kit with Infusion Sets (10 cassettes + 10 infusions sets) per 30 days or 3 Refill Kits with Infusion Sets (30 cassettes + 30 infusion sets) per 90 days for patients using 300 units of insulin or less per 72-hour period
- Twiist Refill Kit with Infusion Sets: 2 Refill Kits with Infusion Sets (20 cassettes + 20 infusions sets) per 30 days or 6 Refill Kits with Infusion Sets (60 cassettes + 60 infusion sets) per 90 days for patients using more than 300 units of insulin per 72-hour period

V-Go: 30 pumps per 30 days

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 March 17, 2026.
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 17, 2026.
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 17, 2026.
4. Twiist System. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K250930. Accessed March 17, 2026.
5. 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 17, 2026.
6. Omnipod DASH User Guide. Acton, MA: Insulet Corporation; November 2025. Available at: https://www.omnipod.com/sites/default/files/2021-04/Omnipod-DASH_User-Guide_English.pdf. Accessed February 20, 2026.
7. Omnipod 5 User Guide. Acton, MA: Insulet Corporation: October 2025. Available at: https://www.omnipod.com/sites/default/files/Omnipod-5_Quick-Start-Guide.pdf . Accessed February 20, 2026.
8. Omnipod 5 System Technical User Guide. October 2025. Available at: https://www.omnipod.com/sites/default/files/Omnipod-5_User-guide.pdf. Accessed March 17, 2025.

9. Omnipod GO User Guide. Acton, MA: Insulet Corporation: October 2023. Available at: https://www.omnipod.com/sites/default/files/Omnipod-GO_User_Guide_US_English.pdf. Accessed March 17, 2026.
10. Omnipod System User Guide. Acton, MA. Insulet Corporation: October 2021. Available at: https://www.omnipod.com/sites/default/files/2021-04/Omnipod-System_User-Guide_English.pdf. Accessed February 20, 2026.
11. Twiist User Guide. Manchester, NH. Sequel Med Tech, LLC. October 2025. Available at: https://cdn.prod.website-files.com/670639c6c25356587872bc22/691f1b0cea5e550a2db14271_twiist%20User%20Guide%20Rev%201.15%20English%20(Electronic).pdf. Accessed March 10, 2026.
12. V-Go Wearable Insulin Delivery Device Instructions for Patient Use. Mannkind Corporation; May 2024 Available at: https://www.go-vgo.com/wp-content/uploads/2024/07/ART-1361-Rev-E-V-Go-IFU.pdf. Accessed February 20, 2026.
13. American Diabetes Association, Standards of Care in Diabetes – 2026. Diabetes Care 2026;49(Suppl. 1):S1-S377.
14. 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.
15. McAdams BH, Rizvi AA. An Overview of Insulin Pumps and Glucose Sensors for the Generalist. J Clin Med 2016;5;1-17.
16. Samson SL, Vellanki P, Blonde L et. al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm – 2023 Update. Endocrine Pract. 2023; 29:305-340.
17. 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. Endocrine Pract. 2021. 27: 505-537.
18. 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.
19. National Coverage Determination (NCD) for Infusion Pumps (280.14); Revision Effective Date 12/17/2004. Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&NCAId=41&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=BC%7cSAD%7cRTC%7cReg&PolicyType=Both&s=47&KeyWord=INSULIN+PUMP&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=EAAAABAAIAAA&. Accessed March 11, 2026.