AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Disposable Insulin Pumps	Page:	1 of 8
Effective Date:	2/3/2025	Last Review Date:	4/2024; 1/2025

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

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.

Description:

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The Omnipod GO Insulin Delivery Device is intended for the subcutaneous infusion of insulin at a preset basal rate in one 24-hour time period for 3 days (72 hours) in adults with type 2 diabetes. Other Omnipod products (e.g., Omnipod DASH, Omnipod 5) are intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The V-Go series of Wearable Insulin Delivery Devices are indicated for continuous subcutaneous infusion of either 20 Units of Insulin (0.83 U/hr), 30 Units of insulin (1.25 U/hr), or 40 Units of insulin (1.67 U/hr) in one 24-hour time period and on-demand bolus dosing in 2 Unit increments (up to 36 Units per one 24-hour time period) in adults requiring insulin.[1-8]

All patients with type 1 diabetes mellitus (T1DM) and many patients with type 2 diabetes mellitus (T2DM) require insulin to maintain adequate glucose control.[11] Most individuals with T1DM should be treated with multiple daily injections of prandial and basal insulin, or continuous subcutaneous insulin infusion. There are multiple approaches to treatment, and the central precept in T1DM management is that some form of insulin be given in a planned regimen tailored to the individual to keep them safe and out of diabetic ketoacidosis and to avoid significant hypoglycemia, with every effort made to reach the individual's glycemic targets. T2DM therapy should be individualized based on the level of glycemia and the presence of comorbidities, complications, and access. Metformin is often the preferred initial therapy. Other agents may be appropriate as first line or in addition to metformin to reduce blood glucose and/or to address specific comorbidities (such as atherosclerotic cardiovascular disease [ASCVD], heart failure [HF], chronic kidney disease [CKD], obesity, nonalcoholic fatty liver disease [NAFLD]) independent of glucose-lowering effects.[10] The need for the greater potency of injectable medications is common, particularly in people with a longer duration of diabetes. In patients with T2DM, a glucagon-like peptide-1 (GLP-1) receptor agonist is preferred to insulin when possible. If insulin is used, combination therapy with a GLP-1 receptor agonist is recommended for greater efficacy and durability of treatment effect. Basal insulin alone is the most convenient initial insulin regimen and can be added to metformin and other oral agents. Many individuals with T2DM require doses of insulin before meals, in addition to basal insulin, to reach glycemic targets. When hemoglobin A1c (A1C) is greater than or equal to 1.5% above the glycemic target, many patients will require dual combination therapy to achieve their target A1C level. Insulin should be considered as part of any combination regimen when hyperglycemia is severe, especially if catabolic

features (weight loss, hypertriglyceridemia, ketosis) are present.[9] Patients on intensive insulin regimens have an increased risk of hypoglycemia, and continuous subcutaneous insulin infusion can help improve glucose control and minimize hypoglycemia.[12]

Successful diabetes care requires a systematic approach to supporting patients' behavior change efforts. High-quality diabetes self-management education and support (DSMES) has been shown to improve patient self-management, satisfaction, and glucose outcomes. National DSMES standards call for an integrated approach that includes clinical content and skills, behavioral strategies (goal setting, problem solving), and engagement with psychosocial concerns. All patients with diabetes should participate in diabetes self-management education and receive the support needed to facilitate the knowledge, decision-making, and skills mastery for diabetes self-care.[9] To reduce the risk of adverse events, it is recommended that patients receive extensive education regarding the technical aspects of insulin pump use.[13,14] Therefore, patients who have undergone a comprehensive diabetes education program will be considered for approval.

Omnipod GO:

The Omnipod GO Pod delivers continuous basal insulin.[7] The subject device is intended for the subcutaneous infusion of insulin at a preset basal rate (i.e., for a fixed volume in one 24-hour time period) for 3 days (72 hours) in adults with type 2
diabetes. The device does not offer the ability to deliver a bolus.[1] Because this device offers only one mode of insulin delivery, patients who do not require bolus or mealtime insulin will be considered for approval.

Blood glucose monitoring (BGM) is thus an integral component of effective therapy of individuals taking insulin.[9] The Omnipod GO Pod does not check glucose. Check glucose at least once a day, or as advised by a healthcare provider.[7] All persons who use insulin should use continuous glucose monitoring (CGM) or perform BGM a minimum of twice daily and ideally before any insulin injection.[10] The evidence is insufficient regarding when to prescribe BGM and how often monitoring is needed for insulin-treated people with diabetes who do not use intensive insulin therapy, such as those with type 2 diabetes taking basal insulin with or without oral agents and/or noninsulin injectables. However, for those taking basal insulin, assessing fasting glucose with BGM to inform dose adjustments to achieve blood glucose targets results in lower A1C.[9]

Coverage will be considered if a patient has a hypersensitivity to an ingredient in all available basal insulin (e.g., long-acting insulin, intermediate-acting insulin).

Omnipod GO is available as pods with seven different basal rates: 10, 15 20, 25, 30, 35, and 40 units per day. Each strength is available as a kit with 5 pods per kit. Omnipod GO should be changed once every 72 hours (3 days).[1,7] Therefore, the limit for the Omnipod GO will be 10 pods per 30 days.

Other Omnipod Products and V-Go:

Continuous subcutaneous insulin infusion (CSII), or insulin pumps, deliver rapid-acting insulin throughout the day to help manage blood glucose levels.[9] A pump delivers programmable basal insulin around the clock which is tailored to the patient's 24-hour glucose profile. Patients can also deliver bolus insulin which infuses over a few minutes to a few hours. Insulin boluses cover meals and correct for high blood glucose levels.[11] There is no consensus to guide choosing which form of insulin administration is best for a given individual. Thus, the choice of multiple daily injections (MDI) or an insulin pump is often based on the characteristics of the person with diabetes and which method is most likely to benefit them.[9] Consensus and position statements by the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) and practice guidelines by the Endocrine Society outline indications and patient characteristics for insulin pump treatment.[12-14] An ideal candidate for insulin pump therapy would be a patient who currently performs multiple insulin injections daily and at least 4 self-monitored blood glucose (SMBG) measurements daily, and should be motivated to achieve glucose control.[13,14] Most individuals on intensive insulin regimens (MDI or insulin pump therapy) should be encouraged to assess glucose levels using blood glucose monitoring (BGM) and/or continuous glucose monitoring (CGM) prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to and while performing critical tasks such as driving. For many patients using BGM this requires checking up to 6–10 times daily, although individual needs may vary. When testing blood glucose levels, the target for normal glucose control with pre-prandial levels is between 80 mg/dL and 130 mg/dL. Level 1 hypoglycemia is defined as a measurable glucose concentration less than 70 mg/dL but greater than or equal to 54 mg/dL. Level 2 hypoglycemia is defined as a blood glucose concentration less than 54 mg/dL. Lastly, level 3 hypoglycemia is defined as a severe event characterized by altered mental and/or physical functioning that requires assistance from another person for recovery.[9] Patients who are managing their diabetes with multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of the insulin dose for at least 6 months and who have performed an average of 4 or more SMBG measurements daily for the past 2 months or have been using a CGM for the past two months will be considered for approval.

In addition to being maintained on multiple daily injections of insulin and performing frequent SMBG measurements daily, there are multiple other factors to consider when selecting patients for insulin pump therapy. Suitable candidates for insulin pump therapy include patients currently using multiple daily injections of insulin who have an elevated glycosylated hemoglobin level (e.g., HbA1c greater than 7%) or patients with recurrent hypoglycemia (e.g., blood glucose levels less than 70 mg/dL), wide fluctuations in blood glucose levels, severe or wide glycemic excursions, or "dawn phenomenon" (defined as persistent severe early morning hyperglycemia) with fasting blood sugars frequently exceeding 200 mg/dL.[9,11-15] Therefore, patients with any of these characteristics will be considered for approval.

Patients should be reassessed periodically to determine success of their diabetes treatment regimen and ensure continued suitability for insulin pump therapy.[9,12-14] HbA1c levels in patients who are stable on therapy should be taken at least every six months.[8]

For patients currently established on insulin pump therapy, coverage will be approved if the patient has performed glucose self-testing an average of at least 4 times per day or is currently using a continuous glucose monitor (CGM).

Other Omnipod products (e.g., Omnipod DASH, Omnipod 5) 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 should be changed at least every 48 to 72 hours (2-3 days) or after delivering 200 units of insulin.[2,3,5,6] Therefore, the limit for Omnipod pods will be 10 pods per month for those requiring less than 200 units of insulin within a 72-hour period. If a patient requires more than 200 units of insulin per 72-hour period, the limit will be 15 pods per month. 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.

V-Go is available as three different basal rates: 20 units per day (V-Go 20), 30 units per day (V-Go 30), and 40 units per day (V-Go 40). All V-Go strengths are available as kits with 30 pumps per kit. V-Go is a disposable insulin pump that is applied once daily, being changed every 24 hours.[4,7] Therefore, the limit for V-Go will be 30 pumps per month.

Applicable Drug List:

- Preferred: Omnipod (all Rx products)
- Non-preferred: V-Go (all products)

Policy/Guideline:

For V-Go requests, the patient is unable to take the preferred Omnipod product, due to a trial and inadequate treatment response or intolerance, or a contraindication.

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) 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 additional quantities of Omnipod pods are being requested, then the patient requires more than 200 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 additional quantities of Omnipod pods are being requested, then the patient requires more than 200 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 Limit:

- Omnipod GO: 10 pods per 30 days
- Other Omnipod products (e.g., Omnipod 5, Omnipod Dash):
  - Omnipod starter kit: 1 kit per 365 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
- V-Go: 30 pumps per 30 days

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