Reference number(s)
3762-C

Initial Prior Authorization with Quantity Limit Disposable Insulin Pumps

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name
Omnipod (all prescription products)
V-Go (all products)

Coverage Criteria

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)

Quantity Limits Apply

Omnipod GO: 10 pods (2 kits) per 25 days or 30 pods (6 kits) per 75 days

Other Omnipod products (e.g., Omnipod 5, Omnipod Dash):

Omnipod starter kit: 1 kit per 999 days

Omnipod pod refills: 10 pods per 25 days or 30 pods per 75 days for patients using less than 200 units of insulin per 72-hour period

Omnipod pod refills: 15 pods per 25 days or 45 pods per 75 days for patients using greater than 200 units of insulin per 72-hour period

V-Go: 30 pumps per 25 days or 90 pumps per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 3762-C: DOA: 12 months

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