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Disposable Insulin Pumps Prior Authorization Drug List A

Disposable Infusion Pump(s) Applied:	**Omnipod 5, Omnipod Dash, Omnipod Pods, V-Go, Twiist Starter Pack**

Criteria:
Disposable Infusion Pump(s) Applied will be approved when the requested device is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria

A. Diagnosis of Type 1 Diabetes as indicated by chart notes within past 180 days

1. Request is for Omnipod
2. If request is for Twiist Starter Pack, there is documented failure of Omnipod products

Approval Duration: 12 months

B. Diagnosis of Type 2 Diabetes mellitus requiring insulin therapy as indicated by chart notes within past 180 days

1. If request is for V-Go or Twiist Starter Pack, there is a documented failure of Omnipod **and**
2. Patient is on an insulin regimen of 3 or more injections per day requiring frequent self-adjustments of insulin dosage, **and**
3. Patient performs 4 or more blood glucose tests per day or is using Continuous Glucose Monitoring (CGM), **and**
4. ONE of the following while compliant on an optimized multiple daily insulin injection regimen:
    a) Glycated hemoglobin level (HbA1C) greater than 7% **or**
    b) History of recurring hypoglycemia **or**
    c) Wide fluctuations in blood glucose before mealtime **or**
    d) Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL **or**
    e) History of severe glycemic excursions **and**
5. Prescriber is a specialist or patient has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology, diabetes educator)

Approval Duration: 12 months

II. Continued Therapy Criteria

A. Diabetes mellitus requiring insulin therapy as indicated by chart notes within past 180 days

1. Patient meets the initial therapy criteria above **and**
2. Chart notes do not indicate patient inability to manage the insulin pump successfully.

Approval Duration: 12 months

References:

1. Omnipod Insulin Management System — 510(k) Premarket Notification K122953 (Product Code LZG)
2. Omnipod DASH / Omnipod Insulin Management System — 510(k) K192659
3. Omnipod Insulin Management System / Omnipod DASH — 510(k) K211575
4. Omnipod 5 iAGC / SmartAdjust / Automated Insulin Delivery — 510(k) K203774
5. American Diabetes Association. Diabetes Technology: Standards of Care in Diabetes - 2024. Diabetes Care 2024; 47S126-S144.

Policy Owned by: Curative PBM team