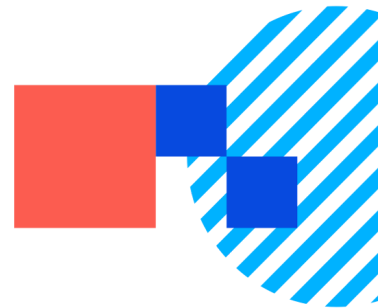




Disposable Insulin Pumps Prior Authorization Drug List A

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

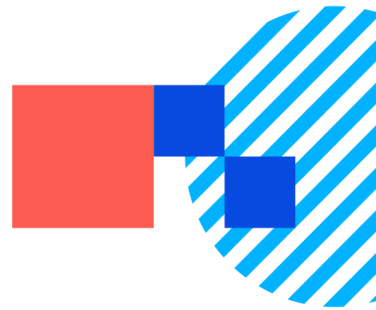
1. Request is for Omnipod
2. If request is for Twiist Starter Pack, there is documented failure of Omnipod products

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