

Protocol for Omnipod (All Rx Products)

I. Criteria for Approval:

The requested medical device will be covered with prior authorization when the following criteria are met:

- The request is for Omnipod GO

AND

- The patient has a diagnosis of type 2 diabetes mellitus

AND

- The patient does NOT require bolus or mealtime insulin

AND

- The patient has completed a comprehensive diabetes education program

AND

- The patient has documented frequency of glucose self-testing at least once daily OR the patient has been using a continuous glucose monitor (CGM)

AND

- The patient has a hypersensitivity to an ingredient in ALL available basal insulin (e.g., long-acting insulin, intermediate-acting insulin)

OR

- The request is for other Omnipod products (e.g., Omnipod DASH, Omnipod 5)

AND

- The request is NOT for continuation of therapy

AND

- The patient is managing their diabetes with multiple daily insulin injections (i.e., at least 3 injections per day) with frequent self-adjustments of the insulin dose for at least 6 months

AND

- The patient has documented frequency of glucose self-testing an average of at least 4 times per day for the past two months OR the patient has been using a continuous glucose monitor (CGM) for the past two months

AND

- The patient has completed a comprehensive diabetes education program

AND

- The patient has experienced any of the following while on multiple daily injections of insulin (i.e., more than 3 injections per day): A) elevated glycosylated hemoglobin level (e.g., HbA1c greater than 7 percent), B) history of recurrent hypoglycemia (e.g., blood glucose levels less than 70 mg/dL), C) wide fluctuations in blood glucose before mealtime, D) "dawn" phenomenon with fasting blood sugars frequently exceeding 200 mg/dL, E) history of severe glycemic excursions

OR

- The patient is currently established on therapy with an insulin pump

AND

- 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)

II. Duration of Approval if Requirements Are Met:

A. Approval Duration:

- 12 month

B. Quantity Level Limit:

- Omnipod starter kit: 1 kit/365 days
- Omnipod pod refills: 10 pods/30 days
- Omnipod GO: 10 pods per 30 days

References

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