Aetna Better Health®

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
    AND
    - If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period

  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)
    AND
    - If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period

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 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
- Omnipod GO: 10 pods per 30 days

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