Criteria Based Consultation Prescribing Program

CRITERIA FOR COVERAGE

Omnipod Insulin Pump

Non-formulary Omnipod will be covered when the following criteria are met:

CRITERIA FOR OMNIPOD COVERAGE

Must meet criteria A or B in both sections I and II:

I. A. C-peptide testing requirement: C-peptide documenting insulinopenia
   1) Insulinopenia defined as a fasting C-peptide level of ≤0.88 ng/mL with a concurrent glucose of 70-225 mg/dL
   2) In those with renal insufficiency with a creatinine clearance ≤50 ml/minute, insulinopenia is defined as a C-peptide level of ≤1.6 ng/mL with a concurrent glucose of 70-225 mg/dL
-OR-

   B. Beta cell autoantibody test is positive or clearly documented unequivocal history of type 1 DM

-AND-

   I. A. Meets 1 through 4 below:
      1. Completed a comprehensive diabetes education program which included a visit with a Nutritionist.
      2. Has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, under the guidance of an diabetologist and has had in-office or virtual visits with a diabetologist at least every 3 months during this period.
      3. Has documented frequency of glucose self-testing an average of at least 4 times per day or regular use of calibrated CGMS during the 2 months prior to initiation of the insulin pump.
      4. Meets one or more of the following criteria (a - e) while on the multiple injection regimen:
         a. Glycosylated hemoglobin level (HbA1C) greater than 7 percent.
         b. History of recurring hypoglycemia.
         c. Wide fluctuations in blood glucose before mealtime.
         d. Dawn phenomenon with fasting blood glucose frequently exceeding 200 mg/dL.
         e. History of severe glycemic excursions.

-OR-

   B. Patient has been on an external insulin infusion pump prior to enrollment at Kaiser Permanente and has documented frequency of glucose self-testing an average of at least 4 times per day or regular use of calibrated CGMS during the month prior to enrollment

Notes:

1. Members who are currently on pump therapy and new to Kaiser coverage are only required to meet criteria II B. New members will receive coverage of ongoing pump supplies, as long as they meet continued coverage requirements
2. Initial insulin pumps, supplies and replacement pumps and supplies must be ordered by Kaiser Permanente Endocrinology.
3. Continued coverage of an external insulin pump and supplies requires:
   a. The patient be seen and evaluated by the Diabetologist at least every 4 months – the follow up visit may be in-person or completed virtually through video or telephone conferencing, however at least one annual in-person office visit is required.
   b. HbA1c testing is required at least every 4 months.
   c. Documented check of glucose at least 4 times daily OR regular use of calibrated CGMS

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