

# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Omnipod 5 Insulin Pump

**Initiation (new start) criteria:** Formulary **Omnipod 5** will be covered on the prescription drug benefit when the following criteria are met:

**Member age 11 years or older**

1. Prescribed by an endocrinologist or diabetologist
2. Member has one of the following conditions:
  - a. Type 1 diabetes mellitus (as indicated by positive Beta cell autoantibody test or clearly documented unequivocal history of type 1 DM)
  - b. Type 2 diabetes mellitus AND insulinopenia;
    - Insulinopenia is defined as a fasting C-peptide level of  $\leq 0.88$  ng/mL with a concurrent glucose of 70-225 mg/dL
    - In those with renal insufficiency with a creatinine clearance  $\leq 50$  ml/minute, insulinopenia is defined as a C-peptide level of  $\leq 1.6$  ng/mL with a concurrent glucose of 70-225 mg/dL
3. Member meets all of the following criteria (a-d) below:
  - a. Completed a comprehensive diabetes education program which included a visit with a nutritionist
  - b. 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 a diabetologist and has had in-office or virtual visits with a diabetologist at least every 3 months during this period
  - c. 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
  - d. Meets one or more of the following criteria (i - v) while on a regimen of multiple daily injections of insulin:
    - i. Glycosylated hemoglobin level (HbA1c)  $> 7\%$
    - ii. History of recurring hypoglycemia
    - iii. Wide fluctuations in blood glucose before mealtime
    - iv. Dawn phenomenon with fasting blood glucose frequently exceeding 200 mg/dL
    - v. History of severe glycemic excursions

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## CRITERIA FOR DRUG COVERAGE

### Omnipod 5 Insulin Pump

#### **Member younger than 11 years**

1. Prescribed by an endocrinologist or diabetologist
2. Diagnosis of diabetes mellitus requiring insulin therapy
3. Documentation that family/member have demonstrated proficiency in blood glucose monitoring by blood glucose meter or CGMS
4. Documentation that family/member have demonstrated proficiency in use of MDI insulin
5. Documentation that family/member have or will have completed pump training in pediatric diabetes clinic

**Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:** Formulary **Omnipod 5** will be covered on the prescription drug benefit when the following criteria are met:

#### **Member age 11 years or older**

1. Member has one of the following conditions:
  - Type 1 diabetes mellitus (as indicated by positive Beta cell autoantibody test or clearly documented unequivocal history of type 1 DM)
  - Type 2 diabetes mellitus AND insulinopenia;
    - Insulinopenia is defined as a fasting C-peptide level of  $\leq 0.88$  ng/mL with a concurrent glucose of 70-225 mg/dL
    - In those with renal insufficiency with a creatinine clearance  $\leq 50$  ml/minute, insulinopenia is defined as a C-peptide level of  $\leq 1.6$  ng/mL with a concurrent glucose of 70-225 mg/dL
2. Member 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

#### **Member younger than 11 years**

1. Diagnosis of diabetes mellitus requiring insulin therapy
2. Member 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