

# Criteria Based Consultation Prescribing Program

## CRITERIA FOR COVERAGE

### Omnipod DASH Insulin Pump

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

**Member age 11 years or older must meet all of the following criteria:**

1. Prescribed by an endocrinologist or diabetologist
  2. Has one of the following diagnoses:
    - a. Type 1 diabetes mellitus with one of the following lab results:
      - i. Presence of any of the following 3 antibodies: glutamic acid decarboxylase-65 (GAD-65) antibody, islet cell antibody (ICA), or zinc transporter 8 (ZnT8) antibody (but NOT anti-insulin antibody in insulin-treated individuals)

-OR-

    - ii. Insulinopenia defined as (all 3 conditions must be met):
      - Fasting c-peptide  $\leq$  110% of the lower limit of normal ( $\leq$  0.88 ng/mL for KP lab) or  $\leq$  200% of the lower limit of normal ( $\leq$  1.6 ng/mL for KP lab) for patients with CrCl  $\leq$  50 mL/min
      - Fasting glucose  $\leq$  225 mg/dL obtained at the same time as c-peptide lab
      - A1c is 8% or less at the time of the c-peptide measurement

-OR-

  - b. Type 2 or other diabetes mellitus with insulinopenia defined as (all 3 conditions must be met):
    - i. Fasting c-peptide  $\leq$  110% of the lower limit of normal ( $\leq$  0.88 ng/mL for KP lab) or  $\leq$  200% of the lower limit of normal ( $\leq$  1.6 ng/mL for KP lab) for patients with CrCl  $\leq$  50 mL/min
    - ii. Fasting glucose  $\leq$  225 mg/dL obtained at the same time as c-peptide lab
    - iii. A1c is 8% or less at the time of the c-peptide measurement
3. Takes multiple daily insulin injections (MDI) defined as 3 or more injections per day
4. Has failed MDI therapy as determined by the treating clinician:
  - a. over a 3-month period for members 11-17 years of age
  - b. over a 6-month period for members 18 years and older
  - c. Any period for pregnant members with type 1 diabetes
5. Has been working with an Endocrinologist, Diabetic Specialist or Diabetes Care Team for:
  - a. At least 3 months for members 11-17 years of age

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## CRITERIA FOR COVERAGE

### Omnipod DASH Insulin Pump

- b. At least 6 months for members 18 and older
- c. No time requirement for pregnant members with type 1 diabetes
- 6. Has necessary carbohydrate counting skills as determined by the treating clinician
- 7. Performs frequent blood glucose monitoring (at least 4 times daily) or uses a continuous glucose monitor

#### **Member younger than 11 years old and meets all of the following criteria:**

- 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 continuous glucose monitor
- 4. Documentation that family/member has demonstrated proficiency in use of MDI insulin
- 5. Documentation that family/member has or will have completed pump training in pediatric diabetes clinic

**Criteria for members already taking the medication who have not been reviewed previously (e.g., new members):** Formulary **Omnipod DASH** will be covered on the prescription drug benefit for when the following criteria are met:

#### **Member age 11 years or older must meet all of the following criteria:**

- 1. Has one of the following diagnoses:
  - a. Type 1 diabetes mellitus with one of the following lab results:
    - i. Presence of any of the following 3 antibodies: glutamic acid decarboxylase-65 (GAD-65) antibody, islet cell antibody (ICA), or zinc transporter 8 (ZnT8) antibody (but NOT anti-insulin antibody in insulin-treated individuals)
  - OR-
  - ii. Insulinopenia defined as (all 3 conditions must be met):
    - Fasting c-peptide  $\leq$  110% of the lower limit of normal ( $\leq$  0.88 ng/mL for KP lab) or  $\leq$  200% of the lower limit of normal ( $\leq$  1.6 ng/mL for KP lab) for patients with CrCl  $\leq$  50 mL/min
    - Fasting glucose  $\leq$  225 mg/dL obtained at the same time as c-peptide lab
    - A1c is 8% or less at the time of the c-peptide measurement

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## CRITERIA FOR COVERAGE

### Omnipod DASH Insulin Pump

-OR-

- b. Type 2 or other diabetes mellitus with insulinopenia defined as (all 3 conditions must be met):
  - i. Fasting c-peptide  $\leq$  110% of the lower limit of normal ( $\leq$  0.88 ng/mL for KP lab) or  $\leq$  200% of the lower limit of normal ( $\leq$  1.6 ng/mL for KP lab) for patients with CrCl  $\leq$  50 mL/min
  - ii. Fasting glucose  $\leq$  225 mg/dL obtained at the same time as c-peptide lab
  - iii. A1c is 8% or less at the time of the c-peptide measurement

#### **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 continuous glucose monitor