

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 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

kp.org

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Omnipod 5 Insulin Pump

- 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
 - 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 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 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-

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Omnipod 5 Insulin Pump

- ii. Insulinopenia defined as (all 3 conditions must be met):
 - Fasting c-peptide $\leq 110\%$ of the lower limit of normal (≤ 0.88 ng/mL for KP lab) or $\leq 200\%$ of the lower limit of normal (≤ 1.6 ng/mL for KP lab) for patients with $\text{CrCl} \leq 50$ mL/min
 - Fasting glucose ≤ 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 (≤ 0.88 ng/mL for KP lab) or $\leq 200\%$ of the lower limit of normal (≤ 1.6 ng/mL for KP lab) for patients with $\text{CrCl} \leq 50$ mL/min
 - ii. Fasting glucose ≤ 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