

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Omnipod Eros/Classic Insulin Pump

Initiation (new start) criteria: Non-formulary **Omnipod Eros/Classic** will be covered on the prescription drug benefit when the following criteria are met:

Member aged 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 at least 0.88 ng/mL with a concurrent glucose of 70-225 mg/dL
 - In those with renal insufficiency with a creatinine clearance 50 ml/minute or less, insulinopenia is defined as a C-peptide level of 1.6 ng/mL or less 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) more than 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

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Omnipod Eros/Classic Insulin Pump

Member younger than 11 years of age:

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 members already taking the medication who have not been reviewed previously (e.g., new members): Non-formulary **Omnipod Eros/Classic** will be covered on the prescription drug benefit for when the following criteria are met:

Member aged 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 ≤ 0.88 ng/mL with a concurrent glucose of 70-225 mg/dL
 - In those with renal insufficiency with a creatinine clearance 50 ml/minute or less, insulinopenia is defined as a C-peptide level of 1.6 ng/mL or less 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 of age:

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

kp.org

Revised: 10/13/22
Effective: 12/01/22

All plans offered and underwritten by
Kaiser Foundation Health Plan of the Northwest