

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Smart insulin pen (InPen)

Initiation (new start) criteria: Non-formulary **InPen** will be covered on the prescription drug benefit for 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 ≤ 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, insulinopenia is defined as a C-peptide level of ≤ 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 and documentation that member/caregiver has demonstrated proficiency in use of carbohydrate counting and insulin to carbohydrate ratio dosing
 - b. Has been on a program of multiple daily injections (MDI) 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 InPen, 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.
 - This includes insulin to carbohydrate ratio and correction factor dosing for bolus insulin
 - 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 InPen
 - d. Meets one or more of the following criteria (i - vi) 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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- vi. Diagnosis of cognitive impairment or requires caregiver assistance with managing insulin

Member younger than 11 years

1. Prescribed by an endocrinologist or diabetologist
2. Diagnosis of diabetes mellitus requiring MDI insulin therapy (basal/bolus insulin regimen)
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 including insulin to carbohydrate ratio dosing and carbohydrate counting

Criteria for members already taking the medication who have not been reviewed previously (e.g., new members): Non-formulary InPen 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 ≤ 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, insulinopenia is defined as a C-peptide level of ≤ 1.6 ng/mL with a concurrent glucose of 70-225 mg/dL
3. On multiple daily injections of insulin (i.e. at least 3 injections per day) with insulin to carb ratio and correction factor dosing for bolus insulin.
4. 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. Prescribed by an endocrinologist or diabetologist

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2. Diagnosis of diabetes mellitus requiring MDI insulin therapy (basal/bolus insulin regimen)
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 month prior to enrollment