I. Description

An external insulin infusion pump is a programmable, battery-powered mechanical syringe/reservoir device that is controlled by a micro-computer to provide continuous subcutaneous insulin infusion (CSII) to patients with diabetes mellitus who are insulinopenic. The pump delivers a steady "basal" amount of insulin and releases a bolus dose at meals or smaller amounts at programmed times. Frequent monitoring of the blood glucose (e.g., four times per day) is essential to ensure appropriate delivery of insulin dosage.

II. Criteria/Guidelines

A. An external insulin pump (E0784) is covered (subject to Limitations/Exclusions and Administrative Guidelines) when all of the following criteria are met:

1. Patient clearly has a history of type 1 diabetes mellitus; or
2. Auto-antibody test, i.e., islet cell cytoplasmic auto-antibodies (ICA), glutamic acid decarboxylase auto-antibodies (GADA) or insulinoma-associated antigen 2 auto-antibodies (IA-2A) is positive; or
3. Fasting C-peptide level is
   a. Less than or equal to 110 percent of the lower limit of the reference range and a fasting blood glucose obtained at the same time is less than or equal to 225 mg/dl ; or
   b. For patients with renal insufficiency and a creatinine clearance (actual or calculated) is less than or equal to 50 ml/minute, fasting C-peptide level is less than or equal to 200 percent of the lower limit of the reference range and a fasting blood glucose obtained at the same time is less than or equal to 225 mg/dl.
   AND
4. The patient or caregiver has completed a comprehensive diabetes self-management education program, including instruction in carbohydrate counting.
5. The patient or caregiver has demonstrated compliance and competence with an intensive insulin regimen for at least three months prior to the request for the insulin pump, including the following:
a. Multiple daily injections of insulin i.e., at least three injections per day, with frequent self-adjustments of insulin dose based on glucose measurements and carbohydrate counting.
b. Glucose self-testing an average of at least four times per day.

6. The patient has one of the following despite treatment with an intensive insulin regimen:
   a. Glycosylated hemoglobin level (HbA1c) greater than seven percent
   b. Repeated and unpredictable hypoglycemia
   c. Wide fluctuations in preprandial blood glucose
   d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
   e. Severe glycemic excursions

7. The external insulin pump is ordered and follow-up care will be provided by a physician who manages multiple patients on CSII therapy and who works closely with a team of nurses, diabetic educators and dieticians who are knowledgeable in the use of CSII.

B. Replacement of an external insulin pump is covered (subject to Limitations/Exclusions and Administrative Guidelines) when the following criteria are met:

1. Documentation from the patient’s medical record supports that the pump is malfunctioning, out of warranty and cannot be repaired; or
2. Documentation from the patient’s medical record supports that a pump with newer technology or special feature is medically necessary.
   AND
3. The replacement is ordered by the treating physician.
4. The patient has type 1 diabetes, has continued to use the pump and has a documented frequency of glucose self-testing an average of at least four times per day during the month prior to the request for replacement.
5. HbA1c is less than or equal to 9.5 during the three months prior to request for replacement.

III. Limitations/Exclusions

A. Replacement of an insulin pump for the sole purpose of receiving an upgrade in technology is not covered.

B. Supplies used with an insulin pump are not covered when coverage criteria for the insulin pump are not met.

C. Transdermal insulin delivery system, e.g., V-Go Disposable Insulin Delivery Device, is not covered because it is not known to be effective in improving health outcomes.

IV. Administrative Guidelines

A. Precertification is required. Complete HMSA's Precertification request and mail or fax the form as indicated. The following documentation must be submitted:
   1. Auto-antibody or fasting C-peptide with blood glucose (in the absence of a clear history of type 1 diabetes mellitus).
   2. Notes documenting that the patient has completed a comprehensive diabetes self-management education program.
3. Record (log) supporting administration of multiple daily doses of insulin with frequent self-adjustment of dose based on glucose measurements and carbohydrate counting and supporting glucose self-testing an average of at least four times per day in the three months preceding the request.
4. Results of HbA1c obtained within three months of the request.

B. Precertification for replacement pumps is required and must be initiated by the treating physician. The following documentation must be submitted:
1. Documentation supporting that the patient has continued to use the external infusion pump and that the pump is malfunctioning or that new technology is medically necessary.
2. Record (log) supporting frequency of glucose self-testing an average at least four times per day during the month prior to the request for replacement.
3. Results of HbA1c obtained within three months of the request for replacement.

V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawai‘i’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References

4. Medicare Coverage Policy. LCD for External Infusion Pumps (L11570) 08/01/2012.