Policy Title: Insulin Pumps
Policy Number: A.03

Primary Department: Medical Management
Affiliated Department(s): N/A

NCQA Standard: N/A
URAC Standard: N/A

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Special Instructions Alert: N/A

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Definitions:

**Insulin pump** An external insulin infusion pump is a programmable, battery-powered mechanical syringe/reservoir device controlled by a micro-computer to deliver a continuous subcutaneous insulin infusion (CSII) into the body. Typical devices have a two to three day supply of insulin connected to an infusion set attached to a small needle or cannula programmed to deliver a steady basal amount of insulin and release a bolus dose at meals and at programmed intervals. The purpose of an insulin pump is to provide an accurate, continuous, controlled delivery of insulin which can be regulated by the user to achieve intensive glucose control and prevent the metabolic complications of hypoglycemia, hyperglycemia and diabetic ketoacidosis. An external insulin pump is also known as a continuous subcutaneous insulin infusion pump, ambulatory pump or a mini-infuser and can be worn on the patient’s waistband or in a shoulder harness.

Policy: To ensure that the selection criteria are consistently followed and documented.

Procedure: Continuous Subcutaneous Insulin Infusion (CSII) Pumps (Effective for Services Performed On or after December 17, 2004). Continuous subcutaneous insulin infusion (CSII) and related drugs/supplies are covered as medically reasonable and necessary in the home setting for the treatment of diabetic patients who satisfy the criteria for insulin pump therapy as described below. Continued coverage of the insulin pump would require that the patient be seen and evaluated by the treating physician at least every 3 months. The patient or caregiver must go through diabetic educational counseling and be knowledgeable about meal planning.
Patients must be insulin dependent and meet either Criterion A or B as follows:

**Criterion A:** For a newly prescribed insulin pump: The patient has completed a comprehensive diabetes education program within three months prior to receiving insulin pump, and 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 doses for at least 6 months prior to initiation of the insulin pump. The member has completed a comprehensive diabetes education program; and the patient also has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump.

The member must meet at least one of the following criteria while on the multiple daily injection regimens:

- Glycosylated hemoglobin level (HbA1c) > 7.0 percent with multiple daily injections (including using long-acting insulin analogues if appropriate) despite the person and/or their carer carefully trying to manage their diabetes; OR
- Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL OR
- History of recurring symptomatic hypoglycemia (less than 60 mg/dl); OR
- History of severe glycemic excursions commonly associated with brittle diabetes, such as hypoglycemic unawareness, nocturnal hypoglycemia, extreme insulin sensitivity and/or very low insulin requirements; Wide fluctuations in blood glucose before mealtime (eg: pre-prandial blood glucose commonly exceeding 140 mg/dl).

For replacement pumps: Member must meet with participating specialist or certified diabetes educator for diabetes self-management education if HbA1C>9, or patient has recurrent hypoglycemia, or diabetes related ER or IP admission in past 12 months prior to approval for replacement insulin pump. **Replacement or upgrade of existing, properly functioning equipment, even if warranty has expired, does not meet** MHP medical criteria for coverage. **Replacement of a non-functioning external insulin infusion pump with a subsequent pump meets** MHP medical criteria for coverage.

**Criterion B:** The patient with diabetes has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment or a lifestyle that requires flexibility (due to school, work or travel schedule).
Closed Loop Systems, also called Artificial Pancreas Device Systems (APDS) that combine continuous glucose monitoring (CGM) with a combination pump and display unit are considered currently experimental and investigational and are not a covered health service due to lack of clinical evidence of safety and or efficacy in published peer reviewed medical literature.

Implantable insulin pumps (IIP) for the treatment of diabetes are considered experimental and investigational and currently are not a covered health service due to lack of clinical evidence of safety and or efficacy in published peer reviewed medical literature. No IIPs have received FDA approval for marketing at this time.

Special Instructions: N/A

CPT/HCPCS Codes:
E0784, S9145, A4230, A4231, E0781, E0780, E0779, A9274, A4232, A4230, A4222

References: