External Insulin Infusion Pump

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<tr>
<th>Type:</th>
<th>Policy Specific Section:</th>
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<td>Medical Necessity and Investigational/Experimental</td>
<td>Durable Medical Equipment</td>
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<tr>
<th>Original Policy Date:</th>
<th>Effective Date:</th>
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<tr>
<td>November 1, 1981</td>
<td>September 25, 2009</td>
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Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

An external insulin infusion pump, also known as a continuous subcutaneous insulin infusion (CSII) pump, ambulatory pump, or mini-infuser, is a portable device used to deliver insulin to manage diabetic patients unable to control their diabetes with multiple daily insulin injections. The battery operated pump contains an insulin filled cartridge or syringe (worn at the waist) connected to a catheter that is inserted into the patient's subcutaneous tissue, usually in the
abdomen. The pump is programmed to deliver a predetermined amount of insulin to meet the patient's insulin requirements and allows programming of different basal and bolus infusion rates as needed. The purpose of the pump is to provide an accurate, continuous controlled delivery of insulin to achieve intensive glucose control.

Policy

An external insulin infusion pump is considered **medically necessary** for insulin-requiring diabetic patients when **both** of the following criteria are met:

- Documented clinical presentation of at least one of the following:
  - Glycohemoglobin level (HbA1c) greater than 7%
  - History of recurrent severe hypoglycemia/hypoglycemia unawareness (typically a blood glucose < 50 mg/dL) or severe glycemic excursions
  - History of recurrent diabetic ketoacidosis, hypoglycemia or both, resulting in recurrent and/or prolonged hospitalization
  - Wide fluctuations in blood glucose before mealtime
  - Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL
  - Beta cell antibody positive or documented fasting serum C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory’s measurement and a concurrently obtained fasting glucose less than 225mg/dL
  - Renal insufficiency with a creatinine clearance less than or equal to 50 ml/minute and a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory measurement

- Documented diabetes management demonstrated by all of the following:
  - Seen by medical provider three times within the last year
  - Completion of a comprehensive diabetes education program
  - Insulin injections >/= to three times a day with self adjusted dose changes for at least six months prior to the initiation of an insulin pump
  - Blood glucose testing >/= to three times a day during the past month

An external insulin infusion pump is considered **medically necessary** for preconception or pregnant diabetic women who meet **both** of the following:

- Insulin injections >/= to three times a day
- Failure to meet glycemic control goals

An external insulin infusion pump is considered **medically necessary** for patients who have been on an external insulin pump prior to enrollment and have documented frequency of glucose self-testing an average of three times a day during the past month.

The following are considered **not medically necessary**:

- Additional software or hardware for downloading data to a personal computer to aid in self-management of diabetes mellitus
• Equipment upgrades or accessories whose sole purpose is to integrate, through communication technology, an insulin pump and interstitial glucose monitor (e.g., patient has a functioning stand-alone insulin pump and a stand-alone continuous glucose monitoring system (CGMS) and requests integration)
• The replacement of an external insulin infusion pump for any of the following situations:
  o Device can be repaired or refurbished
  o Device is under warranty
  o Documentation of malfunction is not provided (e.g., repair logs, MD notes)

Policy Guideline

Examples of external insulin pumps discussed in this policy include, but are not limited to:

• Standard external insulin infusion pumps (stand-alone units e.g., Animus, Medtronic Minimed Paradigm 511)
• Integrated or combined external insulin infusion pumps (e.g., MiniMed Paradigm® REAL-Time System)*
• Disposable external insulin pump with wireless communication capability to a hand-held control unit and standard finger-stick blood glucose monitoring system (e.g., Omnipod®)

(Note: If a continuous glucose monitoring system (CGMS) is requested along with the external insulin pump; refer to the Blue Shield of California (BSC) Medical Policy-Continuous Glucose Monitoring System).

Disposable External Insulin Pump (e.g., Omnipod®) CPT codes include:

• E0784 (external insulin infusion pump)
• A9274 (disposable delivery system). The disposable system should be changed every three days.

Notes:

• Intensive diabetic management in any form, including the use of external insulin infusion pump, is contraindicated for patients (or for children, their caregivers) who for any reason are unwilling or unable to participate actively in intensive glucose management and to acquire the cognitive and technical skills required by their regimen
• Wide fluctuations in plasma blood glucose at mealtime: Preprandial target goals for non-pregnant patients with diabetes are 80-120 mg/dL; changes are suggested when average plasma glucose levels are less than 80 mg/dL or greater than 140 mg/dL (Williams and Larsen, 2003)
• Supplies required for the proper use of a medically necessary external insulin pump including custom-designed batteries and power supplies are considered medically necessary durable medical equipment (DME)
• If an insulin pump fails, a back up pump is not required because the patient can revert to multiple daily injections (MDI) until the pump is repaired or replaced
• External insulin infusion pump warranty is four years
## Documentation Required for Clinical Review

### Pre Service
- Age of current pump and medical necessity for replacement
- Date pump warranty expired
- Make and model of the current insulin pump
- Patients insulin to carbohydrate ration
- Patients target blood sugar
- Physicians office visit notes for the last 6 months
- Record of patients insulin dosing for carbohydrate consumption and blood sugars over target
- Repair log or documentation in MD progress notes of pump failure/description of pump problem

### Post Service
- Documentation of completion of a diabetic education program
- Glucose Diary: glucose self testing 3x a day for past month prior to initiation of pump
- Laboratory report including: HbA1c, glucose levels, C-peptide (if applicable)
- History and physical and/or consultation report(s) to include:
  - Documentation of at least three insulin injections per day requiring self adjustment of insulin dose for at least six months
  - Three diabetes management related chart notes within the last year

### For Patients on an external insulin pump prior to enrollment
- Glucose Diary: glucose self testing 3x a day for past month prior to initiation of pump

### For requests for External Insulin Pump Repair or Replacement, documentation of the following:
- MD notes that include description of pump failure or problem
- Pump warranty expiration date and/or repair history

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.