Medical Policy
Insulin Delivery Devices

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Policy Number: 332
BCBSA Reference Number: N/A
NCD/LCD: National Coverage Determination (NCD) for Infusion Pumps (280.14)

Related Policies
Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid, #107

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

We cover insulin pumps and insulin pump supplies, in accordance with the Massachusetts Mandate, Chapter 175. In accordance with the Massachusetts State Mandate, we cover the proper use of insulin delivery devices. Insulin delivery devices are covered to the extent that devices are generally covered by each member’s benefit design.

External insulin pumps (with or without wireless communication capability) are considered MEDICALLY NECESSARY for individuals with diabetes, when prescribed by a diabetologist familiar with insulin pump management, in any of the following groups:

1. Individuals with documented diabetes mellitus meeting all the following criteria (a-e):
   a. Completed a comprehensive diabetes education program within the past two years; AND
   b. Follows a program of multiple daily injections of insulin; AND
   c. Has frequent self-adjustments of insulin doses for the past 6 months; AND
   d. Has documented frequency of glucose self-testing an average of at least 4 times per day during the past month; and
   e. Has documentation of any of the following while on a multiple daily injection regimen:
      • Glycosylated hemoglobin level (HbA1c) greater than 7.0 percent; OR
      • "Brittle" diabetes mellitus with recurrent episodes of diabetic ketoacidosis, hypoglycemia or both, resulting in recurrent and/or prolonged hospitalization; OR
      • History of recurring hypoglycemia or severe glycemic excursions; OR
      • Wide fluctuations in blood glucose before mealtime; OR
      • "Dawn phenomenon" with fasting blood sugars frequently exceeding 200 mg/dl.

2. Individuals with diabetes mellitus successfully using a continuous insulin infusion pump prior to enrollment, and have documented frequency of glucose self-testing on average of at least 4 times per day during the month prior to enrollment
Use of a disposable external insulin pump with wireless communication capability to a hand-held control unit (e.g., OmniPod®) is an acceptable alternative to a standard insulin infusion pump and considered MEDICALLY NECESSARY when the criteria above have been met.

Refills for medically necessary disposable external insulin pumps are considered MEDICALLY NECESSARY.

Replacement pumps:
The medical necessity of replacement external insulin pumps for pediatric individuals who require a larger insulin reservoir will be considered on a case-by-case basis. The following information is required when submitting requests:
1. Current insulin pump reservoir volume; and
2. Current insulin needs; and
3. Current insulin change out frequency required to meet individual needs.

The replacement of external insulin pumps that are out of warranty, are malfunctioning, and cannot be refurbished is considered MEDICALLY NECESSARY.

Note: The purchase of one insulin pump is allowed every 4 years.

The use of external insulin pumps for any indication other than those listed above is considered NOT MEDICALLY NECESSARY.

Replacement of currently functional and warranted insulin pumps for the sole purpose of receiving the most recent insulin pump technology (commonly referred to as an "upgrade") is considered NOT MEDICALLY NECESSARY as such upgrades have not been shown to make a clinically significant difference.

Equipment upgrades or accessories whose sole purpose is to integrate (with wireless communication technology) an insulin pump and interstitial glucose monitor are considered NOT MEDICALLY NECESSARY.

Note: Intensive diabetic management in any form, including the use of external insulin infusion pumps, is CONTRAINDIATED for individuals (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.

Insulin injection pens are considered MEDICALLY NECESSARY as determined by a licensed health care professional, in accordance with the Massachusetts Mandate, Chapter 175.

Jet pressure Infusion devices are considered NOT MEDICALLY NECESSARY.

Surgically implanted insulin infusion systems are considered INVESTIGATIONAL.

Chronic intermittent intravenous insulin therapy (CIIT) and pulsatile IV insulin therapy (PIVIT) are considered INVESTIGATIONAL.

Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

We cover external insulin pumps for Medicare members in accordance with the CMS NCD. 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: (1) either meet the updated fasting C-Peptide testing requirement, or, are beta cell autoantibody positive; and, (2) satisfy the remaining criteria for insulin pump therapy as described below. Patients must meet either Criterion A or B as follows:
**Criterion A:** The patient has completed a comprehensive diabetes education program, 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, and 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, and meets one or more of the following criteria while on the multiple daily injection regimen:

- Glycosylated hemoglobin level (HbA1c) > 7.0%;
- History of recurring hypoglycemia;
- Wide fluctuations in blood glucose before mealtime;
- Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl; or,
- History of severe glycemic excursions.

**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.

**General CSII Criteria**
In addition to meeting Criterion A or B above, the following general requirements must be met:

The patient with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, or, as an alternative, must be beta cell autoantibody positive.

**Updated fasting C-peptide testing requirement:**

- Insulinopenia is defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory’s measurement method.
- For patients with renal insufficiency and creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine) ≤ 50 ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory’s measurement method.
- Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose ≤ 225 mg/dL.
- Levels only need to be documented once in the medical records.

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 pump must be ordered by and follow-up care of the patient must be managed by a physician who manages multiple patients with CSII and who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in the use of CSII.

**Other Uses of CSII**
The Centers for Medicare & Medicaid Services will continue to allow coverage of all other uses of CSII in accordance with the Category B investigational device exemption clinical trials regulation (42 CFR 405.201) or as a routine cost under the clinical trials policy (Medicare National Coverage Determinations Manual 310.1).

An implanted infusion pump for the infusion of insulin to treat diabetes is not covered. The data does not demonstrate that the pump provides effective administration of insulin.

**National Coverage Determination (NCD) for Infusion Pumps (280.14)**

**Prior Authorization Information**
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>No</th>
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<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>No</td>
</tr>
<tr>
<td>Medicare HMO Blue Sm</td>
<td>No</td>
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<tr>
<td>Medicare PPO Blue Sm</td>
<td>No</td>
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**CPT Codes / HCPCS Codes / ICD Codes**

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS) PPO and Indemnity:

**HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>A4210</td>
<td>Needle-free injection device, each</td>
</tr>
<tr>
<td>A4230</td>
<td>Infusion set for external insulin pump, non-needle, cannula type</td>
</tr>
<tr>
<td>A4231</td>
<td>Infusion set for external insulin pump, needle type</td>
</tr>
<tr>
<td>A4232</td>
<td>Syringe with needle for external insulin pump, sterile, 3cc</td>
</tr>
<tr>
<td>A9274</td>
<td>(Omnipod), External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories. (There is a limit of insulin pump reservoirs of 15 units per 30 days. Effective 2/1/2012)</td>
</tr>
<tr>
<td>E0784</td>
<td>External ambulatory infusion pump, insulin</td>
</tr>
<tr>
<td>S9145</td>
<td>Insulin pump initiation, instruction in initial use of pump (pump not included)</td>
</tr>
<tr>
<td>S5560</td>
<td>Insulin delivery device, reusable pen; 1.5 ml size</td>
</tr>
<tr>
<td>S5561</td>
<td>Insulin delivery device, reusable pen; 3 ml size</td>
</tr>
<tr>
<td>S5570</td>
<td>Insulin delivery, disposable pen (including insulin); 1.5 ml size</td>
</tr>
<tr>
<td>S5571</td>
<td>Insulin delivery device, disposable pen (including insulin); 3 ml size</td>
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</table>

*Note:* Insulin pumps and supplies are processed as described through each member’s subscriber certificate.

**Description**

An external insulin infusion pump is a programmable, battery-powered mechanical syringe/reservoir device controlled by a micro-computer to provide continuous subcutaneous insulin infusion (CSII) in individuals with diabetes mellitus. Typically, the syringe has a two to three day insulin capacity and is connected to an infusion set attached to a small needle or cannula which is inserted into the subcutaneous tissue. The syringe and pump devices are battery operated and controlled by a small computer that is programmed to deliver a steady “basal” amount of insulin. Pumps may also release a “bolus” dose at meals and at programmed intervals. The purpose of the insulin pump is to provide an accurate, continuous, controlled delivery of insulin which can be regulated by the user to achieve
intensive glucose control objectives and to prevent the metabolic complications of hypoglycemia, hyperglycemia and diabetic ketoacidosis. Other more recently developed devices are not battery powered and rely on mechanical instillation of programmed basal and bolus insulin. This document addresses the medically necessary uses of these devices.

**Summary**
The evidence supports the efficacy of the external insulin infusion pump for properly trained diabetics who are not well controlled on intensive, multi-dose insulin therapy. Benefits are seen in long-term control as shown by lowered glycosylated hemoglobin A1c levels. In addition, stability of blood glucose self-measurement values as well as surveyed functional status and quality of life outcomes have been shown to improve in individuals using continuous insulin pump therapy.

The use of external insulin infusion pumps requires careful selection of individuals, meticulous monitoring, and thorough education and long-term ongoing follow-up. This care is generally provided by a multidisciplinary team of health professionals with specific expertise and experience in the management of individuals on insulin pump treatment.

Definitive, agreed upon selection criteria for continuous insulin infusion have not been established. Intensive insulin therapy has been shown to reduce complications and improve outcome in pregnant women with type 1 diabetes, and external insulin pump therapy is considered an appropriate alternative to multiple daily injections for this group (Kitzmiller, 1991). There is also evidence to support the use of external insulin pump therapy for type 1 diabetics who have not achieved adequate glucose control despite multiple daily injections. There is evidence to suggest that insulin pumps may benefit individuals with various types of glycemic excursions such as the “dawn phenomenon” (early morning rise in blood glucose), nocturnal hypoglycemic episodes, hypoglycemic unawareness, and severe hypoglycemia (Hirsch, 1990; Pickup, 2002; Selam, 1990).

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>10/2017</td>
<td>Clarified coding information.</td>
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<tr>
<td>10/2016</td>
<td>Clarified coding information.</td>
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<tr>
<td>1/2016</td>
<td>Language clarified under the coding section to indicate that insulin pumps and supplies are processed as described through each member’s subscriber certificate. 1/2016.</td>
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<tr>
<td>12/2014</td>
<td>Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.</td>
</tr>
<tr>
<td>11/2011</td>
<td>Added limit of insulin pump reservoirs (HCPCS level II code A9274) of 15 units per 30 days. Effective 2/1/2012.</td>
</tr>
<tr>
<td>6/2010</td>
<td>Added Medicare language regarding non-coverage of services comprising an Outpatient Intravenous Insulin Therapy regimen when furnished pursuant to an OIVIT regimen.</td>
</tr>
<tr>
<td>3/2010</td>
<td>Policy updated to reflect decision to allow the purchase of one insulin pump once in 4 years. Effective 3/10/2010</td>
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<tr>
<td>7/2000</td>
<td>Policy updated to allow the purchase of one insulin pump once in 5 years.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References


Endnotes

1 Massachusetts State Mandate, Chapter 175.