INSULIN PUMPS AND INSULIN PUMP SUPPLIES

Number: 200401-0005
Effective Date: 8/1/2013
Revision Date: N/A

Overview
An external insulin pump is a device that delivers insulin subcutaneously. The insulin is delivered in a programmed and controlled manner and eliminates the need for the patient to self-inject insulin. The main goal in using an insulin pump is to achieve near-normal blood glucose levels in order to prevent both acute and chronic complications of diabetes.

An implantable insulin pump is designed to deliver insulin directly into the peritoneal cavity where it can be more rapidly and predictably absorbed, versus in the subcutaneous tissue. Implantable insulin pumps have received approval for distribution in some countries in Europe, but implantable insulin pumps are not FDA-approved for distribution in the U.S.

Covered Services
Insulin pumps require prior authorization by FTC.

FTC covers external insulin pumps for diabetics who meet the medical criteria listed below. When an insulin pump is covered, the supplies that are necessary for the functioning of the insulin pump are also covered. Insulin pump supplies include insulin reservoirs, infusion sets and batteries.

Note: Insulin for insulin pumps requires a prescription and must be obtained at a plan pharmacy.

Medical Criteria
FTC covers an external insulin pump for the management of type 1 diabetes when the plan member meets criterion 1 (a-d) or 2 below:
1. The member meets all of the following:
   a. The member has completed a comprehensive diabetes education program.¹
   b. The member has been on a program of 3 or more insulin injections per day with frequent self-adjustments of insulin dose for at least 6 months prior to the initiation of the insulin pump.
   c. The member 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.

¹ When considering the use of insulin pump therapy in very young children, the burden of day-to-day management rests entirely on the child’s parents and every effort must be made to ensure that they have realistic expectations of what insulin pump therapy can and cannot do. Baseline criteria for very young children should include having motivated parents who are clearly committed to insulin pump therapy.
d. While on a program of 3 or more insulin injections per day, the member has a history of one or more of the following:
   i. Glycosylated hemoglobin (HbA1C) level > 7%
   ii. Recurrent hypoglycemia
   iii. Wide fluctuations in blood glucose before mealtime
   iv. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
   v. Severe glycemic excursions

2. The member has been on an external insulin pump prior to enrollment and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to enrolling in FTC.

FTC covers an external insulin pump for the management of type 2 diabetes when the plan member meets criterion 1 or 2 and 3 (a-d) or 4 below:

1. C-peptide testing requirement – must meet criterion a or b and must meet criterion c below:
   a. C-peptide level is less than or equal to 110% of the lower limit of normal of the laboratory’s measurement method.
   b. For members with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200% of the lower limit of normal of the laboratory’s measurement method.
   c. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dL.

2. Beta cell autoantibody test is positive.

3. The member meets all (a-d) of the following:
   a. The member has completed a comprehensive diabetes education program.\(^2\)
   b. The member has been on a program of 3 or more insulin injections per day with frequent self-adjustments of insulin dose for at least 6 months prior to the initiation of the insulin pump.
   c. The member 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.
   d. While on a program of 3 or more insulin injections per day, the member has a history of one or more of the following:
      i. Glycosylated hemoglobin (HbA1C) level > 7%
      ii. Recurrent hypoglycemia
      iii. Wide fluctuations in blood glucose before mealtime
      iv. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
      v. Severe glycemic excursions

\(^2\) When considering the use of insulin pump therapy in very young children, the burden of day-to-day management rests entirely on the child’s parents and every effort must be made to ensure that they have realistic expectations of what insulin pump therapy can and cannot do. Baseline criteria for very young children should include having motivated parents who are clearly committed to insulin pump therapy.
4. The member has been on an external insulin pump prior to enrollment and has documented frequency of glucose self testing an average of at least 4 times per day during the month prior to enrolling in FTC.

These medical criteria were adapted from the Centers for Medicare & Medicaid (CMS) local coverage determination (National Heritage Insurance Company L5044) for External Infusion Pumps.

Continued coverage of an external insulin pump requires that the member be seen and evaluated by his/her treating physician at least every 3 months.

Replacement of an insulin pump is covered once in 4 years.

**Exclusions**

1. Chronic intermittent intravenous insulin therapy (CIIIT) also referred to as metabolic activation therapy (MAT), or pulsatile intravenous insulin therapy (PIIT) is not covered because it is considered experimental/investigational or unproven.

2. Combined continuous subcutaneous insulin infusion and blood glucose monitoring systems, such as the MiniMed Paradigm Real-Time System, manufactured by Medtronic, because they are considered experimental/investigational or unproven.

3. Supplies or accessories not required for the functioning of the insulin pump, such as alcohol, alcohol wipes (e.g., IV Prep), adhesives (e.g., Mastisol®), adhesive remover (e.g., Detachol®), carrying cases, clips, pouches, shower packs, etc.

4. Implantable insulin pumps or other non-FDA approved devices.

5. HCPCS code S9145 (Insulin pump initiation, instruction in initial use of pump) is not covered/reimbursed. The appropriate code to bill for the insulin pump initiation is G0108 or G0109.

**Codes**

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS</td>
<td>E0784</td>
<td>External ambulatory infusion pump, insulin</td>
</tr>
<tr>
<td></td>
<td>A4221</td>
<td>Supplies for maintenance of drug infusion catheter, per week (includes infusion sets)</td>
</tr>
<tr>
<td></td>
<td>K0552</td>
<td>Supplies for external drug infusion pump, syringe type cartridge (reservoir), sterile, each</td>
</tr>
<tr>
<td></td>
<td>K0601</td>
<td>Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each</td>
</tr>
<tr>
<td></td>
<td>K0603</td>
<td>Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each</td>
</tr>
<tr>
<td></td>
<td>K0604</td>
<td>Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each</td>
</tr>
<tr>
<td></td>
<td>G0108</td>
<td>Diabetes outpatient self-management training services, individual, per 30 minutes.</td>
</tr>
<tr>
<td></td>
<td>G0109</td>
<td>Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes.</td>
</tr>
</tbody>
</table>
References