



INSULIN PUMP, EXTERNAL AND SUBCUTANEOUS INSULIN DELIVERY HS-001



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

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Insulin Pump, External and Subcutaneous Insulin Delivery

Policy Number: HS-001

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8/20/2010; 8/12/2011

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Continuous subcutaneous insulin infusion (CSII) with an infusion pump is an alternative to conventional injection therapy for normalized levels of blood glucose. The external insulin pump is comprised of an insulin reservoir (syringe), a battery operated infusion rate selector, and a plastic catheter that is attached to a needle. The external insulin pump is worn externally and delivers insulin through the needle placed subcutaneously into the abdominal wall. Members must be willing and able to test their own blood glucose at least four (4) times a day. NOTE: External ambulatory insulin infusion pump therapy is also known as continuous subcutaneous insulin infusion (CSII).

Some external insulin infusion pumps are able to take results of the blood glucose reading, wirelessly transmit the results from the blood glucose monitor to the pump, and automatically adjust the insulin infusion rate, saving the member some extra steps. Wireless transmission from the blood glucose monitor to the pump and automated insulin infusion rate adjustment are considered integral features of the external insulin infusion pump and glucose monitor.

The external insulin pump is considered to be medically necessary durable medical equipment. However, due to legislative requirements regarding diabetes treatment, coverage of the pump is not subject to any DME limitations. Coverage for the pump is based on coverage guidelines and medical necessity. The insulin pump delivers insulin continuously in micro-doses of one-tenth of a unit. Basal rates are preprogrammed to deliver subcutaneously at a constant, low level similar to the delivery of insulin from the pancreas in the non-diabetic population. Basal rates can be set to meet the changing background insulin need that differs by individual metabolic rate. Boluses are programmed for actual food consumed and are usually delivered just prior to eating. Because diabetic patients frequently have gastromotility problems, better blood glucose control can be spread out over a period of up to eight hours. Furthermore, the pump delivers only short acting insulin in a more physiological way allowing a patient to be under better control despite active daily demands. Meals and snacks can be missed with no adverse effects. With multiple injections and the use of longer-acting insulins, the diabetic member needs to know significantly in advance what is going to occur during the course of a given day.

POSITION STATEMENT

External insulin infusion pumps **are considered medically necessary** DME for persons with diabetes who are beta cell autoantibody positive or have a 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 method, and who meet the criteria listed in paragraph A or B below. The Continuous subcutaneous insulin infusion (CSII) requires prior authorization.

A. Members must meet ALL of the following criteria:

1. The member has completed a comprehensive diabetes education program; **AND**
2. The member has been on a program of multiple injections of insulin, i.e., at least three injections per day, etc., with frequent self-adjustments of insulin dose for at least six months prior to initiation of the insulin pump; **AND**
3. The member has documented frequency of glucose self-testing an average of at least four times per day during the two months prior to initiation of the insulin pump; **AND**
4. Members must meet at least **ONE** of the following criteria while on multiple daily injections (more than three injections per day) of insulin:
 - a. Glycate hemoglobin level (HbA1c) > 7.0% OR
 - b. History of recurrent hypoglycemia (less than 60 mg/dL) OR

- c. Wide fluctuations in blood glucose before mealtime, e.g. pre-prandial blood glucose
- b. levels commonly exceed 140 mg/DL, etc. OR
- a. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL OR
- b. History of severe glycemic excursions.

OR;

- B. A new member with an already existing pump must have documented frequency of glucose self-testing an average of at least four times per day during the month prior to enrollment.

Enhanced Features

WellCare covers external pumps with certain relevant enhanced features as DME for members with Type 1 Diabetes Mellitus when both of the following medical necessity criteria are met:

- A. The criteria met for a stand insulin pump; **AND,**
- B. Members must meet at least **ONE** of the following conditions:
 - 1. The member has special need, i.e., hearing impairment requiring an additional or enhanced feature, etc.; **OR,**
 - 2. The member has not achieved adequate control to prevent acute metabolic complications such as hyperglycemia, hypoglycemia, or ketoacidosis with a standard external insulin pump; **OR,**
 - 3. The member is a child age <18 or who is managing his/her own insulin, where the child strongly prefers an integrated bolus wizard function.

Other Requirements

1. The pump must be ordered by and follow-up care of the member must be managed by a physician with experience managing members with insulin infusion pumps and who work closely with a team including nurses, diabetes educators, and dieticians who are knowledgeable in the use of insulin infusion pumps.
2. Continued coverage of the pump requires that the member be seen and evaluated by the treating physician at least every six months.
3. A member who is at least ten (10) years old and has experienced suboptimal glycemic control at least twice daily insulin therapy is eligible for CSII.
4. For members between the ages of 10-18 years old, the endocrinologist must document his or her opinion that a supportive and responsible adult will also be educated and involved in the pump therapy.
5. It may be considered medically necessary to initiate the use of insulin infusion pumps during pregnancy earlier than the criteria stated above to avoid fetal and maternal complications of diabetes and pregnancy. It may also be appropriate for poorly controlled women with diabetes to sometimes get started on the pump pre-pregnancy or in the first trimester.
6. The endocrinologist must express confidence that the member will learn and execute the procedures necessary for successful operation and interruption of the insulin pump and will diligently monitor outcomes.

CODING

CPT® Codes - No applicable codes

ICD-9-CM Procedure Codes - No applicable codes

Covered HCPCS Codes

A4230	Infusion set for external insulin pump, non-needle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3cc
E0784	External ambulatory infusion pump, insulin
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each
K0602	Replacement battery for external infusion pump owned by patient, silver oxide, 3 volt, each
K0603	Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each
K0604	Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each
K0605	Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)

Covered ICD-9-CM Diagnosis Codes

250.00 - 250.93 Diabetes mellitus

***Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.®©**

REFERENCES

Peer Reviewed

1. Hayes Medical Technology Directory: Continuous Glucose Monitoring Systems. Retrieved January 25, 2006.

Government Agencies, Professional and Medical Organizations

1. American Diabetes Association (ADA). Question and Answer. GlucoWatch Biographer. March 2001. http://www.diabetes.org/main/community/info_news/news/glu-watch.isp. Retrieved January 25, 2006.
2. Complete Guide to Medicare Coverage. November 2004. NDC 280.14. Infusion Pumps, January 1, 2002.

HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
8/12/2011	<ul style="list-style-type: none">• Approved by MPC. No changes.