Medical Coverage Policy | Insulin Infusion Pumps

EFFECTIVE DATE: 09/01/2004
POLICY LAST UPDATED: 08/06/2013

OVERVIEW

The policy addresses insulin infusion pumps that are worn externally and those that are surgically implanted.

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

External insulin infusion pumps are medically necessary for members with diabetes who meet the selection criteria.

Implantable insulin infusion pumps are considered not medically necessary because there is insufficient evidence in the published medical literature to demonstrate its efficacy.

The combined use of a continuous glucose monitor AND an external insulin pump both **require preauthorization** (see policy Glucose Monitor policy for medical criteria).

Diabetic equipment and supplies are provided in accordance with Rhode Island General Law §27-20-30 and do not require preauthorization. The details of the law can be found in the Diabetes Self-Management Education Mandate policy.

Special Features:

BCBSRI will reimburse the basic external insulin infusion pump only. If the customer chooses to purchase a model with special features, such as one which can be worn while swimming, the customer will be responsible for the cost of the additional features in full.

Repair and Replacement:

For information regarding the repair and replacement of insulin pumps; (please refer to the "Durable Medical Equipment (DME)" policy.

New improved diabetes infusion pumps are regularly developed and approved by the FDA and covered by BCBSRI. An upgrade to a new infusion pump will not be covered when requested before the warranty of the old infusion pump runs out. Only then, when appropriately ordered by the physician, will it be covered according to the member's coverage allowance.

When a new infusion pump is requested with the added feature of a continuous glucose monitoring system (i.e., Paradigm® REAL-Time Insulin Pump and CGMS) the medical criteria for continuous glucose monitoring must be met before the new pump will be covered. Refer to the medical policy on Glucose Monitoring Systems for the criteria.

Insulin infusion sets and syringe with needle for the insulin infusion are typically reimbursed according to the member's pharmacy benefit. If a member does not have a pharmacy benefit it will then be covered under the member's medical benefit for BlueCHiP for Medicare and Commercial products.

BlueCHiP for Medicare
Insulin pumps and insulin used with the pump are covered under Medicare Part B. The insulin used and supplies needed to inject are covered under the prescription drug benefit (Part D).

MEDICAL CRITERIA

External insulin infusion and related drugs/supplies are considered medically necessary in the home setting for the treatment of diabetic patients who:

- Either meet the updated *fasting C-Peptide testing requirement (see above), or, are beta cell autoantibody positive; and
- Meet the criteria in section A or in section B described below:
    1. Members must meet all of the following criteria:
        a. 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 dose for at least 6 months prior to initiation of the insulin pump; and
        b. Has completed a comprehensive diabetes education program; and
        c. 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
        d. Meets at least one of the following criteria while on multiple daily injections (more than 3 injections per day) of insulin:
            i. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; or
            ii. Elevated glycosylated hemoglobin level (HbA1c greater than 7.0%, where upper range of normal is less than 6.0%; for other HbA1c assays, 1% over upper range of normal); or
            iii. History of recurring hypoglycemia (less than 60 mg/dL); or
            iv. History of severe glycemic excursions; or
            v. Wide fluctuations in blood glucose before mealtime (e.g., pre-prandial blood glucose levels commonly exceed 140 mg/dL); or
    2. The member has been on a pump prior to enrollment in BlueCHiP for Medicare, and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to BlueCHiP Medicare enrollment.

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 be considered medically necessary for poorly controlled women with diabetes to sometimes get started on the pump pre-pregnancy or in the first trimester.

Insulin infusion pumps are not medically necessary for members with end stage renal disease as it is difficult to manage insulin levels with end stage organ failure due to varying insulin requirements.

Continued coverage of the insulin pump will require the patient be seen and evaluated by the treating physician at least every 3 months.

Documentation of continued medical necessity of the external insulin infusion pump requires that the member be seen and evaluated by the treating physician at least once every 6 months.

BACKGROUND

External insulin infusion pumps for the treatment of diabetes mellitus are portable devices intended to provide continuous insulin infusion therapy over an extended time period. The external insulin infusion

pump is also known as a continuous subcutaneous insulin infusion pump, ambulatory pump, or mini-infuser. The device is battery powered and drug reservoir refilling is non-invasive. A catheter from the pump is attached to the desired access route for drug delivery. The external infusion pump is portable and can be worn on a belt around the patient's waist or from a shoulder harness.[1]
An implantable insulin pump is surgically implanted under the skin of the abdomen. The pump delivers small amounts of insulin throughout the day and extra amounts before meals or snacks. A remote control unit that prompts the pump to give the specified amount of insulin is used to control doses. The pump is refilled with insulin every 2 to 3 months.

Diabetes may develop at any age. Type 1, type 2, and gestational diabetes are the three main kinds Type 1 diabetes, formerly called juvenile diabetes or insulin-dependent diabetes, is usually first diagnosed in children, teenagers, or young adults. With this form of diabetes, the beta cells of the pancreas no longer make insulin because the body's immune system has attacked and destroyed them.

Type 2 diabetes, formerly called adult-onset diabetes or noninsulin-dependent diabetes, is the most common form of diabetes. People can develop type 2 diabetes at any age-even during childhood. This form of diabetes usually begins with insulin resistance, a condition in which fat, muscle, and liver cells do not use insulin properly. At first, the pancreas keeps up with the added demand by producing more insulin. In time, however, it loses the ability to secrete enough insulin in response to meals.

Some women develop gestational diabetes during the late stages of pregnancy. Although this form of diabetes usually goes away after the baby is born, a woman who has had it is more likely to develop type 2 diabetes later in life. Gestational diabetes is caused by the hormones of pregnancy or a shortage of insulin.

C-peptide is measured to tell the difference between insulin produced by the body and insulin injected into the body. When the pancreas produces insulin, it starts off as a large molecule. This molecule splits into two pieces: insulin and C-peptide. The function of C-peptide is not known.

The C-peptide level may be measured in a patient with type 2 diabetes to see if any insulin is still being produced by the body. It may also be measured in cases of hypoglycemia (low blood sugar) to see if the person's body is producing too much insulin.

*Fasting C-peptide testing include the following:

- 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

COVERAGE

BlueCHiP for Medicare |
Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable Diabetic Equipment/Supplies coverage.

Commercial |

CODING

The following HCPCS is **covered** and **requires preauthorization** for BlueCHiP for Medicare and Commercial products.	**E0784** External ambulatory infusion pump, insulin (PDM [Personal Diabetes Manager]is used in conjunction with The Pod)
The following HCPCS are **covered** for the external insulin pump supplies for BlueCHiP for Medicare and Commercial products:	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 A9274 External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
The following HCPCS codes for batteries are **not covered** for BlueCHiP for Medicare and Commercial products.	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

RELATED POLICIES

Durable Medical Equipment
Glucose Monitors

PUBLISHED

Provider Update	Sep 2013
Provider Update	May 2012
Provider Update	May 2011
Provider Update	Jun 2010
Provider Update	May 2009
Provider Update	Jun 2008
Policy Update	Jul 2006
Policy Update	Sep 2004

REFERENCES

Centers for Medicare and Medicaid Services (CMS).Local Coverage Determination (LCD): External Infusion Pumps (L5044)

Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for INFUSION PUMPS (280.14)

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