

Medical Coverage Policy



**Blue Cross
Blue Shield**
of Rhode Island

Insulin Infusion Pumps-PREAUTH

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	12/1/1996	Policy Last Updated:	2/21/2012
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description:

External insulin infusion pump:

An external insulin infusion pumps for the treatment of diabetes mellitus is a portable device 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

Omipod system comes in two parts; the insulin delivery with basal rate and bolus delivery options, and a Personal Diabetes Management (PDM) with glucose meter that communicates wirelessly, which eliminates tubing for delivery of insulin.

Implantable insulin pump:

Implantable insulin pumps 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 mellitus is described as a group of diseases characterized by high levels of blood glucose resulting from defects in insulin production, insulin action, or both.

Types of Diabetes

Type 1 Diabetes: previously called insulin-dependent diabetes mellitus (IDDM) or juvenile-onset diabetes. Type 1 diabetes develops when the body's immune system destroys pancreatic beta cells, the only cells in the body that make the hormone insulin that regulates blood glucose. This form of diabetes usually strikes children and young adults, although disease onset can occur at any age. Type 1 diabetes may account for 5% to 10% of all diagnosed cases of diabetes. Risk factors for Type 1 diabetes may include autoimmune, genetic, and environmental factors.

Type 2 Diabetes: previously called non-insulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes. It usually begins as insulin resistance, a disorder in which the cells do not use insulin properly. Type 2 diabetes is associated with older age, obesity, family history of diabetes, history of gestational diabetes, impaired glucose metabolism, physical inactivity, and race/ethnicity. Type 2 diabetes is increasingly being diagnosed in children and adolescents.

Gestational diabetes: a form of glucose intolerance that is diagnosed in some women during pregnancy. It is more common among obese women and women with a family history of diabetes. During pregnancy, gestational diabetes requires treatment to normalize maternal blood glucose levels to avoid complications in the infant.²

Medical Criteria:

External insulin infusion pump:

The external insulin infusion pump is considered **medically necessary** for the treatment of insulin-dependent Type 1 diabetes for those who meet the criteria in section one **or** two. In some patients with Type 2 diabetes, as the need for insulin rises, the pancreas gradually loses its ability to produce insulin thus resulting in Type 1 diabetes. **Clinical documentation to support this (i.e., documentation of islet cell antibodies or C-peptide levels) must be submitted.**

1. Clinical information documenting Type 1 diabetes must be submitted:

- The member has completed a comprehensive diabetes education program; **and**
- The member has the behavioral/functional/technical ability to operate the pump and perform frequent blood glucose monitoring; **and**
- The member has been on a regime of multiple daily injections of insulin (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**
- The member has documented frequency of glucose self-testing an average of 4 times per day during the 2 months prior to initiation of the insulin pump; **and**

The member meets **ONE OR MORE** of the following criteria while on multiple daily injections (>3 injections per day) of insulin:

- Elevated glycosylated hemoglobin level (HbA1c)>7.0%, where upper range of normal is less than 6.0%; for other assays, 1% over upper range of normal); **or**
- History of recurring hypoglycemia (<60mg/dl); **or**
- Wide fluctuations in blood glucose before mealtime (e.g., preprandial blood glucose levels commonly exceed 140 mg/dL; **or**
- Dawn phenomenon with fasting blood glucose frequently exceeding 200mg/dL; **or**
- History of severe glycemic excursions; **OR**

2. The member with Type 1 diabetes has been on a pump prior to enrollment with the health plan and has a documented frequency of glucose self-testing an average of 4 times per day during the month prior to current enrollment.

Implantable insulin pump:

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

Combined use of continuous glucose monitor AND external insulin pumps:

The combined use of a continuous glucose monitor AND an external insulin pump both **require preauthorization** (see policy "Glucose Monitors (Glucometers) Including Continuous Glucose Monitoring Systems" for medically specific criteria).

Not Medically Necessary:

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.

Pregnant members should not initiate treatment with insulin infusion pumps while pregnant due to the difficulty in maintaining constant blood sugar levels. Starting the pump while pregnant may result in an increased risk for miscarriage due to the small risk for increased diabetic ketoacidosis episodes with pump therapy. Those who are already on the pump and doing well should remain on the pump.

Policy:

Preauthorization is required for the external infusion pump (and not required for the supplies) for BlueCHIP for Medicare and recommended for all other BCBSRI products.

External insulin infusion pumps are considered **medically necessary** when the above noted criteria are met for the treatment of insulin-dependent diabetes mellitus (Type I diabetes).

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

Coverage:

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

Diabetic equipment and supplies are provided in accordance with Rhode Island General Law §27-20-30. The details of the law can be found in the "Diabetes Self-Management Education Mandate" policy.

For **BlueCHIP for Medicare** members, insulin is covered in full under medical coverage (Part B).

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.

Upgrade:

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 "Glucose Monitoring (Glucometer) Continuous Glucose Monitoring Systems" for the criteria.

Repair and Replacement:

For information regarding the repair and replacement of insulin pumps; (please refer to the "Durable Medical Equipment (DME): Includes Rent-to-Purchase, Repair and Replacement and Federal Medicare (CMS) Guidelines Related to All Other DME Equipment" Policy.

Coding and Reimbursement for external insulin pump and supplies:

The following HCPC is **covered** for the external insulin pump and **requires preauthorization**:
E0784 External ambulatory infusion pump, insulin (PDM is used in conjunction with The Pod)

The following HCPCS are **covered** for the external insulin pump supplies and **do not require preauthorization**:

***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 (wireless insulin pump Omnipod).

*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.

The following HCPCS codes for batteries are **non-covered**:

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 topics:

BCBSRI policy: Diabetes Self-Management Education Mandate

BCBSRI policy: Durable Medical Equipment Repair and Replacement

BCBSRI policy: Glucose Monitors/Continuous Glucose Monitoring System

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