



INSULIN PUMPS AND INSULIN PUMP SUPPLIES

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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 FCHP.

FCHP 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.

- For commercial plan members, insulin for insulin pumps is covered under the prescription drug benefit.
- For Fallon Senior Plan™ members, insulin for insulin pumps is covered under Part B (medical benefit).

Medical Criteria

FCHP 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

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.

- 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. 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 FCHP.

FCHP 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:

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.

- 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
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 FCHP.

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 (CIIT) 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

Codes	Number	Description
HCPCS	E0784	External ambulatory infusion pump, insulin
	A4221	Supplies for maintenance of drug infusion catheter, per week (includes infusion sets)
	K0552	Supplies for external drug infusion pump, syringe type cartridge (reservoir), sterile, each
	K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 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

Codes	Number	Description
	G0108	Diabetes outpatient self-management training services, individual, per 30 minutes.
	G0109	Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes.

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Related Policies

Diabetic Services and Supplies

Products to Which This Policy Applies

Commercial plans

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Commonwealth Care
- ⊕ Companion Care

Fallon Senior Plan™

- ⊕ Fallon Senior Plan™

References

1. Centers for Medicare & Medicaid Services. National Heritage Insurance Company LCD for External Infusion Pumps (L5044). Revision 04/01/2010. Available at: http://www.medicarenhic.com/dme/medical_review/mr_lcd_current.shtml.
2. Eugster EA, Francis G and the Lawson-Wilkins Drug and Therapeutics Committee. Position Statement: Continuous Subcutaneous Insulin Infusion in Very Young Children with Type 1 Diabetes. *Pediatrics* 2006 Oct;118(4):1244-49.
3. Weinzimer SA, Ahern JH, Doyle EA, Vincent MR, Dziura J, Steffen AT, Tamborlane WV. Persistence of Benefits of Continuous Subcutaneous Insulin Infusion in Very Young Children with Type 1 Diabetes: A Follow-up Report. *Pediatrics* 2004 Dec;114(6):1601-05.
4. Kaufman FR, Halvorson M, Carpenter S, Devoe D, Pitukcheewanont P. Insulin Pump Therapy in Young Children with Diabetes. *Diabetes Spectrum* 2001;14(2):84-89.
5. Mensing C, Boucher J, Cypress M et al. National Standards for Diabetes Self-Management Education. *Diabetes Care*. 2007;30(1):S96-S103.
6. Centers for Medicare & Medicaid Services. MLN Matters® Number: SE0905. Training Medicare Patients on Use of Home Glucose Monitors and Related Billing Information.
7. American Diabetes Association. 2009 Resource Guide: Insulin Pumps. *Diabetes Forecast*. January 2009. Available at: <http://forecast.diabetes.org/files/images/InsulinPumpChartREV.pdf>.

Committee Review Dates:

Utilization Management Committee: 08/2000, 06/2003

Benefit Committee: 02/1994, 10/1999, 07/2000

Technology Assessment Subcommittee: 03/27/2007, 05/22/07, 02/23/10, 03/23/10

Technology Assessment Committee: 04/08/08, 06/02/10

IMPORTANT NOTE

Not all services are covered for all commercial products or employer groups. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy & Criteria Statement.