



Insulin Pumps and Supplies

Clinical Coverage Criteria

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.

Policy

Fallon Health Requires Prior Authorization for Insulin Pumps. The request must be supported by the treating provider(s) medical records.

Fallon Health covers an external insulin pump for the management of type 1 and type 2 diabetes when the plan member meets criterion 1 or 2 below:

1. The member meets all of the following:
 - The member has completed a comprehensive diabetes education program.
 - 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.
 - 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.
 - While on a program of 3 or more insulin injections per day, the member has a history of one or more of the following:
 - Glycosylated hemoglobin (HbA1C) level > 7%
 - Recurrent hypoglycemia
 - Wide fluctuations in blood glucose before mealtime
 - Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
 - 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 Fallon Health.
 - 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 will be considered once every 4 years. Should there be a defect prior to this time the supplier is responsible for repair and a temporary replacement while the repair is ongoing.

- For replacement the failure of the current pump must be investigated and documented during an Endocrinologist or other prescribing physician office visit and it has been confirmed the supplier cannot refurbish the pump.
- Insulin for insulin pumps requires a prescription and must be obtained at via a plan provider.

Renewal of Supplies:

For continued approval of Insulin Pump related supplies, beyond the initial 12 month approval, the below criteria must be met and documented in the member’s medical records.

1. The member must be compliant with use of the Insulin Pump.
2. The member’s HbA1c remains stable or improves as result of usage of the Insulin Pump.

For a combined Insulin Pump and Continuous Glucose Monitor a member must meet criteria under this policy and Fallon Health’s Continuous Glucose Monitor policy. These devices are fairly new technology and as such specific documentation is needed from the prescribing Physician as to their necessity.

Effective June 1, 2019 Code A9274 (External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories) will be covered with approved prior authorization for disposable insulin pumps if it is specifically on the providers contract. Any other provider who utilizes this code will be denied.

Exclusions

- 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.
- Supplies or accessories not required for the functioning of the insulin pump, such as alcohol, alcohol wipes, adhesives, adhesive remover, carrying cases, clips, pouches, shower packs, etc. (Please note it is possible these are covered for certain Fallon products, consult the specific plan benefits)
- Implantable insulin pumps or other non-FDA approved devices.
- 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 when done as part of Diabetic Self-Management Training DSME/T performed by a registered professional.
- Artificial Pancreas systems unless otherwise specified.

Codes

| Code type | Code | Description |
|-----------|-------|--|
| HCPCS | E0784 | External ambulatory infusion pump, insulin |
| | A4221 | Supplies for maintenance of drug infusion catheter, per week (list drug separately) |
| | A9274 | External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories |

| | | |
|--|-------|---|
| | K0552 | Supplies for external drug infusion pump, syringe type cartridge, sterile, each |
| | 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 |

References

- Centers for Medicare & Medicaid Services. Nordion Healthcare Solutions LCD for External Infusion Pumps (L33794). Last Updated January 1, 2019.
- 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.
- American Diabetes Association. Standards of Medical Care in Diabetes – 2019. *Diabetes Care* Volume 42, Supplement 1, January 2019
- Carlsson BM, Attvall S, Clements M, et al. Insulin pump-long-term effects on glycemic control: an observational study at 10 diabetes clinics in Sweden. *Diabetes Technol Ther.* 2013; 15(4):302-307.
- Pańkowska E, Błazik M, Dziechciarz P, et al. Continuous subcutaneous insulin infusion vs. multiple daily injections in children with type 1 diabetes: a systematic review and meta-analysis of randomized control trials. *Pediatr Diabetes.* 2009; 10(1):52-58.
- Misso ML, Egberts KJ, Page M, et al. Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus. *Cochrane Database Syst Rev.* 2010;(1):CD005103.
- Roeder HA, Moore TR, Ramos GA. Insulin pump dosing across gestation in women with well-controlled type 1 diabetes mellitus. *Am J Obstet Gynecol.* 2012 Oct;207(4):324.e1-5. doi: 10.1016/j.ajog.2012.06.029.
- Brancato D, Fleres M, Aiello V, et al. The effectiveness and durability of an early insulin pump therapy in children and adolescents with type 1 diabetes mellitus. *Diabetes Technol Ther.* 2014 Nov;16(11):735-41. doi: 10.1089/dia.2014.0034.
- Matejko B, Skupien J, Mrozińska S, et al Factors associated with glycemic control in adult type 1 diabetes patients treated with insulin pump therapy. *Endocrine.* 2015 Feb;48(1):164-9. doi: 10.1007/s12020-014-0274-2. Epub 2014 May 6.
- Marchand L, Kawasaki-Ogita Y, et al. Long-Term Effects of Continuous Subcutaneous Insulin Infusion on Glucose Control and Microvascular Complications in Patients With Type 1 Diabetes. *J Diabetes Sci Technol.* 2017 Mar 1:1932296817700161. doi: 10.1177/1932296817700161.
- Easa N, Alany R, Carew M, Vangala A. A review of non-invasive insulin delivery systems for diabetes therapy in clinical trials over the past decade. *Drug Discov*

Today. 2018 Nov 19. pii: S1359-6446(18)30254-X. doi:
10.1016/j.drudis.2018.11.010.

12. Girardot S, Mousin F, Vezinet J, et. al. Kalman Filter-Based Novel Methodology to Assess Insulin Pump Accuracy. *Diabetes Technol Ther.* 2019 Oct;21(10):557-565. doi: 10.1089/dia.2019.0147.

Policy History

Origination date: 10/1999
Approval(s): Utilization Management Committee: 08/2000, 06/2003
Benefit Committee: 02/1994, 10/1999, 07/2000
Technology Assessment Subcommittee: 03/27/2007, 05/22/2007, 02/23/2010, 03/23/2010
Technology Assessment Committee: 04/08/2008, 06/02/2010, 08/28/2013, 12/03/2014 (updated template, references, and criteria for type 1 and 2 now the same) 01/27/2016 (updated references), 05/25/2016 (clarified language regarding repair/replacement) 05/24/2017 (updated language regarding combined insulin pumps/continuous glucose monitors, updated references), 12/06/2017 (added criteria for supply renewals), 12/05/2018 (updated references), 06/01/2019 (updated coverage of code A9274, policy not reviewed at TAC), 10/23/2019 (updated references)

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates 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. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.