



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

This Policy applies to the following Fallon Health products:

- Commercial
- Medicare Advantage
- MassHealth ACO
- NaviCare
- PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare Benefit Policy Manual, Chapter 20, Section 110 describes the durable medical equipment benefit and coverage of supplies and accessories that are necessary for the effective use of durable medical equipment for Medicare beneficiaries. Medicare does not have an NCD for insulin pumps. Noridian Healthcare Solutions, LLC is the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) with jurisdiction in our service area. Noridian Healthcare Solutions, LLC has an LCD for (MCD search 06-25-2021).

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

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

For Medicare Advantage, NaviCare and PACE plan members please refer to **Noridian HealthCare Solutions, LLC LCD for External Infusion Pumps (L33794)** for coverage criteria for insulin pumps.

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.

When coverage criteria are not met, the insulin pump and related accessories, supplies, and insulin will be denied as not reasonable and necessary.

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.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
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

References

1. Noridian Healthcare Solutions, LLC LCD for External Infusion Pumps (L33794). Original Effective Date 10/01/2015. Revision Effective Date 01/01/2021.
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3. American Diabetes Association. Standards of Medical Care in Diabetes – 2019. *Diabetes Care* Volume 42, Supplement 1, January 2019.
4. 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.
5. 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.
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7. 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.
8. 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.
9. 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.
10. 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.

11. 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.
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.

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)

06/25/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section.

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.