MASSACHUSETTS

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Medical Policy
Insulin Delivery Devices

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Policy Number: 332

BCBSA Reference Number: N/A

Related Policies

Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid, #107

Policy[1]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

We cover insulin pumps and insulin pump supplies, in accordance with the Massachusetts State Mandate, General Laws Part I Title XXII Chapter 175 Section 47N: Items medically necessary for Diagnosis and Treatment of Diabetes. In accordance with the Massachusetts State Mandate, we cover the proper use of insulin delivery devices. Insulin delivery devices are covered to the extent that devices are generally covered by each member's benefit design.

External insulin pumps (with or without wireless communication capability) are considered **MEDICALLY NECESSARY** for individuals with diabetes, when prescribed by a diabetologist familiar with insulin pump management, in any of the following groups:

1. Individuals with documented diabetes mellitus meeting *all* the following criteria (a-e):
   a. Completed a comprehensive diabetes education program within the past two years; **AND**
   b. Follows a program of multiple daily injections of insulin; **AND**
   c. Has frequent self-adjustments of insulin doses for the past 6 months; **AND**
   d. Has documented frequency of glucose self-testing an average of at least 4 times per day during the past month; and
   e. Has documentation of *any* of the following while on a multiple daily injection regimen:
      - Glycosylated hemoglobin level (HbAlc) greater than 7.0 percent; **OR**
      - "Brittle" diabetes mellitus with recurrent episodes of diabetic ketoacidosis, hypoglycemia or both, resulting in recurrent and/or prolonged hospitalization; **OR**
      - History of recurring hypoglycemia or severe glycemic excursions; **OR**
      - Wide fluctuations in blood glucose before mealtime; **OR**
      - "Dawn phenomenon" with fasting blood sugars frequently exceeding 200 mg/dl.
2. Individuals with diabetes mellitus successfully using a continuous insulin infusion pump prior to enrollment, and have documented frequency of glucose self-testing on average of at least 4 times per day during the month prior to enrollment

Use of a disposable external insulin pump with wireless communication capability to a hand-held control unit (e.g., OmniPod®) is an acceptable alternative to a standard insulin infusion pump and considered **MEDICALLY NECESSARY** when the criteria above have been met.

Note: Omnipod® DASH and Omnipod® 5 can only be obtained through the pharmacy benefit.

Refills for medically necessary disposable external insulin pumps are considered **MEDICALLY NECESSARY.**

Replacement pumps:
The medical necessity of replacement external insulin pumps for pediatric individuals who require a larger insulin reservoir will be considered on a case-by-case basis. The following information is required when submitting requests:
1. Current insulin pump reservoir volume; and
2. Current insulin needs; and
3. Current insulin change out frequency required to meet individual needs.

The replacement of external insulin pumps that are out of warranty, are malfunctioning, and cannot be refurbished is considered **MEDICALLY NECESSARY.**

Note: The purchase of one insulin pump is allowed every 4 years.

The use of external insulin pumps for any indication other than those listed above is considered **NOT MEDICALLY NECESSARY.**

Replacement of currently functional and warranted insulin pumps for the sole purpose of receiving the most recent insulin pump technology (commonly referred to as an "upgrade") is considered **NOT MEDICALLY NECESSARY** as such upgrades have not been shown to make a clinically significant difference.

Equipment upgrades or accessories whose sole purpose is to integrate (with wireless communication technology) an insulin pump and interstitial glucose monitor are considered **NOT MEDICALLY NECESSARY.**

Note: Intensive diabetic management in any form, including the use of external insulin infusion pumps, is *CONTRAINDICATED* for individuals (or for children, their caregivers) who ***for any reason*** are unwilling or unable to participate actively in intensive glucose management and to acquire the cognitive and technical skills required by their regimen.

Insulin injection pens are considered **MEDICALLY NECESSARY** as determined by a licensed health care professional, in accordance with the Massachusetts Mandate, Chapter 175.

Jet pressure Infusion devices are considered **NOT MEDICALLY NECESSARY**.

Surgically implanted insulin infusion systems are considered **INVESTIGATIONAL.**

Chronic intermittent intravenous insulin therapy (CIIIT) and pulsatile IV insulin therapy (PIVIT) are considered **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient
- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient
- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS) PPO and Indemnity:

HCPCS Codes

HCPCS codes:	Code Description
A4210	Needle-free injection device, each
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week
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	(Omnipod), External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories. (There is a limit of insulin pump reservoirs of 15 units per 30 days. Effective 2/1/2012)
E0784	External ambulatory infusion pump, insulin
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)
S5560	Insulin delivery device, reusable pen; 1.5 ml size
S5561	Insulin delivery device, reusable pen; 3 ml size
S5570	Insulin delivery, disposable pen (including insulin): 1.5 ml size
S5571	Insulin delivery device, disposable pen (including insulin); 3 ml size

The following CPT code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
0740T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; initial set-up and patient education
0741T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; provision of software, data collection, transmission, and storage, each 30 days

Note: Insulin pumps and supplies are processed as described through each member's subscriber certificate.

Description

An external insulin infusion pump is a programmable, battery-powered mechanical syringe/reservoir device controlled by a micro-computer to provide continuous subcutaneous insulin infusion (CSII) in individuals with diabetes mellitus. Typically, the syringe has a two-to-three-day insulin capacity and is connected to an infusion set attached to a small needle or cannula which is inserted into the subcutaneous tissue. The syringe and pump devices are battery operated and controlled by a small computer that is programmed to deliver a steady "basal" amount of insulin. Pumps may also release a "bolus" dose at meals and at programmed intervals. The purpose of the insulin pump is to provide an accurate, continuous, controlled delivery of insulin which can be regulated by the user to achieve intensive glucose control objectives and to prevent the metabolic complications of hypoglycemia, hyperglycemia and diabetic ketoacidosis. Other more recently developed devices are not battery powered and rely on mechanical instillation of programmed basal and bolus insulin. This document addresses the medically necessary uses of these devices.

Summary

The evidence supports the efficacy of the external insulin infusion pump for properly trained diabetics who are not well controlled on intensive, multi-dose insulin therapy. Benefits are seen in long-term control as shown by lowered glycosylated hemoglobin A1c levels. In addition, stability of blood glucose self-measurement values as well as surveyed functional status and quality of life outcomes have been shown to improve in individuals using continuous insulin pump therapy.

The use of external insulin infusion pumps requires careful selection of individuals, meticulous monitoring, and thorough education and long-term ongoing follow-up. This care is generally provided by a multidisciplinary team of health professionals with specific expertise and experience in the management of individuals on insulin pump treatment.

Definitive, agreed upon selection criteria for continuous insulin infusion have not been established. Intensive insulin therapy has been shown to reduce complications and improve outcome in pregnant women with type 1 diabetes, and external insulin pump therapy is considered an appropriate alternative to multiple daily injections for this group (Kitzmiller, 1991). There is also evidence to support the use of external insulin pump therapy for type 1 diabetics who have not achieved adequate glucose control despite multiple daily injections. There is evidence to suggest that insulin pumps may benefit individuals with various types of glycemic excursions such as the "dawn phenomenon" (early morning rise in blood glucose), nocturnal hypoglycemic episodes, hypoglycemic unawareness, and severe hypoglycemia (Hirsch, 1990; Pickup, 2002; Selam, 1990).

Policy History

Date	Action
1/2023	Clarified coding information.
7/2022	Annual policy review. Policy statements unchanged.
4/2022	Policy clarified to include a note that Omnipod® DASH and Omnipod® 5 can only be obtained through the pharmacy benefit.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
1/2020	Clarified coding information.
8/2018	Medically necessary statements regarding Massachusetts State Mandate, General Laws Part I Title XXII Chapter 175 Section 47N: Items medically necessary for Diagnosis and Treatment of Diabetes clarified. 8/10/2018
10/2017	Clarified coding information.
10/2016	Clarified coding information.
1/2016	Language clarified under the coding section to indicate that insulin pumps and supplies are processed as described through each member's subscriber certificate. 1/2016.
11/2014	New covered indications for type 2 diabetes described. Language on artificial pancreas transferred to medical policy 107, Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid. Coding information clarified. Effective 11/1/2014.

12/2014	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
2/2014	Clarified non-coverage of 530G artificial pancreas system. Effective 2/10/2014.
1/2014	Clarified non-coverage of artificial pancreas system. Effective 1/1/2014.
11/2011	Added limit of insulin pump reservoirs (HCPCS level II code A9274) of 15 units per 30 days. Effective 2/1/2012.
5/2011	Reviewed - Medical Policy Group - Pediatrics and Endocrinology, no change in coverage statement.
2/2010	Reviewed - Medical Policy Group - Psychiatry, Ophthalmology, and Endocrinology, no change in coverage statement.
3/2010	Policy updated to reflect decision to allow the purchase of one insulin pump once in 4 years. Effective 3/10/2010.
7/2000	Policy updated to allow the purchase of one insulin pump once in 5 years.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

1. Berghaeuser MA, Kapellen T, Heidtmann B, et al. Continuous subcutaneous insulin infusion in toddlers starting at diagnosis of type 1 diabetes mellitus. A multicenter analysis of 104 patients from 63 centres in Germany and Austria. Pediatric Diabetes. 2008; 9(6):590–595.
2. Berthe E, Lireux B, Coffin C, et al. Effectiveness of intensive insulin therapy by multiple daily injections and continuous subcutaneous infusion: a comparison study in type 2 diabetes with conventional insulin regimen failure. Horm Metab Res. 2007; 39(3):224-229.
3. Bode BW, Steed RD, Davidson PC. Reduction in severe hypoglycemia with long-term continuous subcutaneous insulin infusion in type I diabetes. Diabetes Care. 1996; 19(4):324-327.
4. Bruttomesso D, Pianta A, Crassolara D, et al. Continuous subcutaneous insulin infusion (CSII) in the Veneto region: efficacy, acceptability, and quality of life. Diabet Med. 2002; 19(8):628-634.
5. 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.
6. Danne T, Battelino T, Jarosz-Chobot P, et al.; PedPump Study Group. Establishing glycaemic control with continuous subcutaneous insulin infusion in children and adolescents with type 1 diabetes: experience of the PedPump Study in 17 countries. Diabetologia. 2008; 51(9):1594-1601.
7. DeVries JH, Snoek FJ, Kostense PJ, et al. A randomized trial of continuous subcutaneous insulin infusion and intensive injection therapy in type 1 diabetes for patients with long-standing poor glycemic control. DiabetesCare. 2002; 25(11):2074-2080.
8. Diabetes Control and Complications Trial (DCCT) Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med. 1993; 329(14):977-986.
9. Fatourechi MM, Kudva YC, Murad MH, et al. Clinical review: Hypoglycemia with intensive insulin therapy: a systematic review and meta-analyses of randomized trials of continuous subcutaneous insulin infusion versus multiple daily injections. J Clin Endocrinol Metab. 2009; 94(3):729-740.
10. Halvorson M, Carpenter S, Kaiserman K, Kaufman FR. A pilot trial in pediatrics with the sensor-augmented pump: combining real-time continuous glucose monitoring with the insulin pump. J Pediatr. 2007; 150(1):103-105. e1.
11. Hanaire-Broutin H, Melki V, Bessieres-Lacombe S, Tauber JP. Comparison of continuous subcutaneous insulin infusion and multiple daily injection regimens using insulin lispro in type 1 diabetic patients on intensified treatment: a randomized study. The Study Group for the Development of Pump Therapy in Diabetes. Diabetes Care. 2000; 23(9):1232-1235.

12. Hirsch IB, Farkas-Hirsch R, Skyler JS. Intensive insulin therapy for treatment of Type 1 diabetes. Diabetes Care. 1990; 13(12):1265-1283.
13. Jakisch BI, Wagner VM, Heidtmann B, et al. Comparison of continuous subcutaneous insulin infusion (CSII) and multiple daily injections (MDI) in paediatric Type 1 diabetes: a multicentre matched-pair cohort analysis over 3 years. Diabet Med. 2008; 25(1):80-85.
14. Jeitler K, Horvath K, Berghold A, et al. Continuous subcutaneous insulin infusion versus multiple daily insulin injections in patients with diabetes mellitus: systematic review and meta-analysis. Diabetologia. 2008; 51(6):941-951.
15. Kitzmiller JL, Gavin LA, Gin GD, et al. Preconception care of diabetes. Glycemic control prevents congenital anomalies. JAMA. 1991; 265(6):731-736.
16. Mastrototaro JJ, Cooper KW, Soundararajan G, et al. Clinical experience with an integrated continuous glucose sensor/insulin pump platform: a feasibility study. Adv Ther. 2006; 23(5):725-732.
17. Nathan DM, Zinman B, Cleary PA, et al.; Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Research Group. Modern-day clinical course of type 1 diabetes mellitus after 30 years' duration: the diabetes control and complications trial/epidemiology of diabetes interventions and complications and Pittsburgh epidemiology of diabetes complications experience (1983-2005). Arch Intern Med. 2009; 169(14):1307-1316.
18. Nuboer R, Borsboom GJ, Zoethout JA, et al. Effects of insulin pump vs. injection treatment on quality of life and impact of disease in children with type 1 diabetes mellitus in a randomized, prospective comparison. Pediatr Diabetes. 2008; 9(4 Pt 1):291-296.
19. 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.
20. Pickup J, Keen H. Continuous subcutaneous insulin infusion at 25 years: evidence base for expanding use of insulin pump therapy in type 1 diabetes. Diabetes Care. 2002; 25(3):593-598.
21. Pohar SL. Subcutaneous open-loop insulin delivery for type 1 diabetes: Paradigm Real-Time System. Issues Emerg Health Technol. 2007; (105):1-6.
22. Raskin P, Bode BW, Marks JB, et al. Continuous subcutaneous insulin infusion and multiple daily injection therapy are equally effective in type 2 diabetes: a randomized, parallel-group, 24-week study. Diabetes Care. 2003; 26(9):2598-2603.
23. Sanfield, JA, Hegstad M, Hanna RS. Protocol for outpatient screening and initiation of continuous subcutaneous insulin infusion therapy: impact on cost and quality. Diabetes Educ. 2002; 28(4):599-607.
24. Selam JL, Charles MA, Devices for insulin administration. Diabetes Care. 1990; 13(9):955-979.
25. American Association of Clinical Endocrinologists (AACE). American Association of Clinical Endocrinologists medical guidelines for clinical practice for developing a diabetes mellitus comprehensive care plan. Endocr Pract. 2011; 17(2):287-302.
26. American Diabetes Association. Standards of medical care in diabetes—2014. Diabetes Care. 2014; 37(Suppl 1):S14-S80.
27. Centers for Medicare and Medicaid Services. National Coverage Determination for Infusion Pumps. NCD #280.14. Effective February 4, 2005. Available at: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd. Accessed on March 03, 2014.
28. 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.
29. National Institute for Health and Clinical Excellence. NICE technology appraisal guidance 151: Continuous subcutaneous insulin infusion for the treatment of diabetes (review). July 2008. Available at: http://www.nice.org.uk/Guidance/TA151. Accessed on March 03, 2014.
30. Silverstein J, Klingensmith G, Copeland K, et al. Care of children and adolescents with type 1 diabetes: a statement of the American Diabetes Association. Diabetes Care. 2005; 28(1):186-212.

Endnotes

[1] Massachusetts State Mandate, General Laws Part I Title XXII Chapter 175 Section 47N: Items medically necessary for diagnosis and Treatment of Diabetes.