

External Infusion Insulin Pumps

Date of Origin: 05/2015

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Dates Reviewed: 05/2015, 07/2016, 10/2016, 02/2019, 01/2020, 02/2021, 02/2022, 02/2023, 01/2024

Developed By: Medical Necessity Criteria Committee

I. Description

An insulin pump is an external battery-operated device that delivers subcutaneous insulin into the body in a programmed and controlled manner. It is indicated for insulin-dependent diabetics whose blood glucose levels cannot be controlled by intermittent insulin dosing even with maximal patient compliance. The goal of an insulin pump is to achieve near-normal blood glucose levels, prevent acute metabolic complications, and delay the onset and progression of late-stage secondary macrovascular and microvascular complications of diabetes.

An artificial pancreas is a system made of three parts that work together to mimic how a healthy pancreas controls blood glucose in the body. An artificial pancreas system uses a continuous glucose monitor, an insulin pump, and a program stored on the pump or a smartphone(top). It's a system that closely mimics the glucose-regulating function of a healthy pancreas. Other terms used for artificial pancreas device systems include a 'closed-loop' system, an 'automated insulin delivery system' system, or an 'autonomous system for glycemic control'.

An Artificial Pancreas Device System not only monitors glucose levels in the body but also automatically adjusts the delivery of insulin to reduce high glucose levels (hyperglycemia) and minimize the incidence of low blood glucose (hypoglycemia) with little or no input from the patient.

II. Criteria: CWQI HCS-0039A

- A. **Continuous Subcutaneous Insulin Infusion (CSII) Pumps and related drugs/supplies** (FDA approved) are covered to plan limitations for adults or children with a diagnosis of Diabetes Type I or Type II when **1 or more** of the following criteria are met:
- a. **External insulin pumps** are considered medically necessary when **all** of the following are met:
 - i. The patient has **completed a comprehensive diabetes education program** and **all** of the following:
 1. The patient has been on a program of multiple daily injections of insulin (i.e., 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
 2. The patient 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, and meets **1 or more** of the following criteria while on the multiple injection regimen:
 - a. Glycosylated hemoglobin level (*HbA1C*) greater than 7 percent
 - b. History of recurring hypoglycemia <70 mg/dl
 - c. Wide fluctuations in blood glucose before mealtime

- d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
 - e. History of severe glycemic excursions
 - 3. The external insulin infusion pump must be ordered, and follow-up care rendered by a physician and **all** of the following:
 - a. The physician has experience managing patients on continuous subcutaneous insulin infusion therapy
 - b. The physician works closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy
- b. The member has been on a pump prior to enrollment with Moda Health and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Moda Health enrollment
- c. **The patient has an insulin pump, and a replacement pump is required.**
 - i. A replacement pump will be authorized if the pump is past warranty and is not functioning properly.
 - ii. A replacement pump is necessary for a child who requires a larger insulin reservoir
- d. **Pregnancy-related conditions** are considered medically necessary when **1 or more** of the following criteria are met:
 - i. The patient has the onset of gestational diabetes and experiences erratic blood sugars despite maximal patient compliance; or
 - ii. Pregnancy occurs in a previously diagnosed diabetic and the patient has erratic blood sugars despite maximal compliance; or
 - iii. When pregnancy is anticipated within 3 months in the diagnosed diabetic and the patient is experiencing **1 or more** of the following:
 - 1. The patient has erratic blood sugar
 - 2. The patient has ketoacidosis
 - 3. The patient has symptomatic hypoglycemia despite maximal patient compliance

- B. **Renewal and continuation of an external infusion pump and supplies** is considered medically necessary when **all** of the following are met:
 - a. The patient has been seen and evaluated by the treating physician at least every 6 months
 - b. The external insulin infusion pump must be ordered, and follow-up care rendered by a physician and **all** of the following:
 - i. The physician has experience managing patients on continuous subcutaneous insulin infusion therapy
 - ii. The physician works closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy

C. Limitations and Exclusions

- a. Moda Health considers any/all of the following **NOT** medically necessary:
 - i. An insulin pump upgrade (*Per manufacturer guidelines, pump upgrades are provided when the pump is still under warranty*)
 - ii. Replacement of a functioning insulin pump with an insulin pump with wireless communication to a glucose monitor as such wireless communication has not been shown to improve clinical outcomes

- iii. Additional software or hardware required for downloading data to a personal computer to aid in diabetes self-management as it is considered a convenience item
 - iv. Chronic intermittent intravenous insulin therapy (CIIT) or pulsatile IV insulin therapy (PIVIT)
 - v. A fully implantable infusion pump for the infusion of insulin to treat diabetes. Data does not demonstrate that the pump provides effective administration of insulin
- b. Moda Health considers non-programmable Disposable Insulin Delivery Systems (e. g. V-Go™ disposable insulin delivery device) experimental or investigational because their effectiveness has not been established

III. Information Submitted with the Prior Authorization Request:

1. Clinical records for the past 12 months
2. Patient diary of blood sugar/insulin dosing for the prior 2-month period
3. Laboratory Hgb A1c values

IV. CPT or HCPC codes covered:

Codes	Description
E0784	External ambulatory infusion pump, insulin <i>(Artificial Pancreas Device system)</i>
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units

V. CPT or HCPC codes NOT covered:

Codes	Description
E1399	non-programmable Disposable Insulin Delivery Systems

VI. Annual Review History

Review Date	Revisions	Effective Date
07/2013	Annual Review: Added table with a review date, revisions, and effective date.	07/2013
06/14	Annual Review: No changes	06/2014
05/2015	Annual Review: Added reference to Medicare Criteria; Added HCPC and ICD-9 codes, ICD-10 codes	06/24/2015
07/2016	Annual Review	07/27/2016
10/2016	Updated with new Medicare guidelines, deleted ICD-9 codes	10/26/2016
02/27/2019	Annual Review: Replaced Medicare guidelines with links to Medicare resources, updated HCPC codes	03/01/2019

01/2020	Annual Review: New code E0787 added to covered list	02/01/2020
02/2021	Annual Review: No content change	03/01/2021
02/2022	Annual Review: Indicated pumps and supplies are FDA approved	03/01/2022
02/2023	Annual Review: No content changes	03/01/2023
01/2024	Annual Review: No content changes	02/01/2024
05/2024	Update: Addition of Artificial Pancreas Device System for CGM	

VII. References

1. American Diabetes Association (ADA). Position statement. Standards of medical care in diabetes-2006. Jan, 2006: Accessed on July 1, 2011 at: http://care.diabetesjournals.org/cgi/reprint/29/suppl_1/s4
2. Bernasko J. Intensive insulin therapy in pregnancy: strategies for successful implementation in pregestational diabetes mellitus. J Matern Fetal Neonatal Med. 2007 Feb;20(2):125-32.
3. Cohen ND, Shaw JE. Diabetes: advances in treatment. Intern Med J. 2007 Jun;37(6):383-8.
4. Colquitt JL, Green C, Sidhu MK, et al. Clinical and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes. Health Technol Asses. October 2004; 8(43): iii, 1-171.
5. Continuous Subcutaneous Insulin Infusion Therapy for Children and Adolescents: An Option for Routine Diabetes Care. Pediatrics. February 2001; 107(2).
6. De Galan BE. Insulin pump therapy, should we consider it more often? J. of Neth Med. November 2004; 62(10):341-343.
7. 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. Accessed December 2019 <https://www.ncbi.nlm.nih.gov/pubmed/8366922>
8. Diabetes: Modern Insulin Therapy for Type 1 Diabetes Mellitus, Primary Care; Clinics in Office Practice. December 1999; 26(4)
9. Fox L, Buckloh L, Smith S, et al. A randomized controlled trial of insulin pump therapy in young children with type 1 diabetes. Diabetes Care. June 6, 2005; 28(5):1277-1281.
10. Medicare Coverage Issues Manual 60-14 September 26, 2001
11. National Institute for Clinical Excellence. Guidance on the use of continuous subcutaneous insulin infusion for diabetes #57, February 2003.
12. OMAP External Insulin Infusion Pump #410-122-0525
13. Revised Medicare Insulin Pump Coverage Criteria; Medtronic MiniMed; February 2005.
14. Physician Advisors
15. Centers for Medicare & Medicaid Services; Local Coverage Article: External Infusion Pumps- Policy Article (A52507); Noridian Healthcare Solutions, LLC; Original Article Effective Date 10/01/2015; Revision Effective Date 07/01/2016
16. Centers for Medicare & Medicaid Services; Local Coverage Determination (LCD): External Infusion Pumps (L33794); Noridian Healthcare Solutions, LLC; Original Effective Date 10/01/2015; Revision Effective Date 10/01/2016.
17. Centers for Medicare & Medicaid Services; National Coverage Determination (NCD) for Infusion Pumps (280.14); Effective date 12/17/2004; Implementation Date 2/18/2005.

Appendix 1 – Applicable Diagnosis Codes:

Codes	Description
E08.01	Diabetes mellitus due to underlying condition with hyperosmolarity with coma
E08.10	Diabetes mellitus due to underlying condition with ketoacidosis without coma
E08.11	Diabetes mellitus due to underlying condition with ketoacidosis with coma
E08.21	Diabetes mellitus due to underlying condition with diabetic nephropathy
E08.311	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema
E08.319	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy without macular edema
E08.36	Diabetes mellitus due to underlying condition with diabetic cataract
E08.39	Diabetes mellitus due to underlying condition with other diabetic ophthalmic complication
E08.40	Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified
E08.41	Diabetes mellitus due to underlying condition with diabetic mononeuropathy
E08.42	Diabetes mellitus due to underlying condition with diabetic polyneuropathy
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy
E08.44	Diabetes mellitus due to underlying condition with diabetic amyotrophy
E08.49	Diabetes mellitus due to underlying condition with other diabetic neurological complication
E08.51	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy without gangrene
E08.610	Diabetes mellitus due to underlying condition with diabetic neuropathic arthropathy
E08.618	Diabetes mellitus due to underlying condition with other diabetic arthropathy
E08.620	Diabetes mellitus due to underlying condition with foot ulcer
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer
E08.628	Diabetes mellitus due to underlying condition with other skin complications
E08.630	Diabetes mellitus due to underlying condition with periodontal disease
E08.638	Diabetes mellitus due to underlying condition with other oral complications
E08.641	Diabetes mellitus due to underlying condition with hypoglycemia with coma
E08.65	Diabetes mellitus due to underlying condition with hyperglycemia
E08.69	Diabetes mellitus due to underlying condition with other specified complication
E08.8	Diabetes mellitus due to underlying condition with unspecified complications
E08.9	Diabetes mellitus due to underlying condition without complications
E09.01	Drug or chemical induced diabetes mellitus with hyperosmolarity with coma
E09.10	Drug or chemical induced diabetes mellitus with ketoacidosis without coma
E09.11	Drug or chemical induced diabetes mellitus with ketoacidosis with coma
E09.21	Drug or chemical induced diabetes mellitus with diabetic nephropathy
E09.311	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema
E09.319	Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy without macular edema
E09.39	Drug or chemical induced diabetes mellitus with other diabetic ophthalmic complication
E09.40	Drug or chemical induced diabetes mellitus with neurological complications with diabetic neuropathy, unspecified

E09.41	Drug or chemical induced diabetes mellitus with neurological complications with diabetic mononeuropathy
E09.42	Drug or chemical induced diabetes mellitus with neurological complications with diabetic polyneuropathy
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly)neuropathy
E09.44	Drug or chemical induced diabetes mellitus with neurological complications with diabetic amyotrophy
E09.49	Drug or chemical induced diabetes mellitus with neurological complications with other diabetic neurological complication
E09.51	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy without gangrene
E09.610	Drug or chemical induced diabetes mellitus with diabetic neuropathic arthropathy
E09.618	Drug or chemical induced diabetes mellitus with other diabetic arthropathy
E09.620	Drug or chemical induced diabetes mellitus with diabetic dermatitis
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer
E09.628	Drug or chemical induced diabetes mellitus with other skin complications
E09.630	Drug or chemical induced diabetes mellitus with periodontal disease
E09.638	Drug or chemical induced diabetes mellitus with other oral complications
E09.641	Drug or chemical induced diabetes mellitus with hypoglycemia with coma
E09.649	Drug or chemical induced diabetes mellitus with hypoglycemia without coma
E09.65	Drug or chemical induced diabetes mellitus with hyperglycemia
E09.69	Drug or chemical induced diabetes mellitus with other specified complication
E09.8	Drug or chemical induced diabetes mellitus with unspecified complications
E09.9	Drug or chemical induced diabetes mellitus without complications
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma
E10.21	Type 1 diabetes mellitus with other diabetic kidney complication
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E10.36	Type 1 diabetes mellitus with diabetic cataract
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.51	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E10.618	Type 1 diabetes mellitus with other diabetic arthropathy
E10.620	Type 1 diabetes mellitus with diabetic dermatitis
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E10.628	Type 1 diabetes mellitus with other skin complications
E10.630	Type 1 diabetes mellitus with periodontal disease
E10.638	Type 1 diabetes mellitus with periodontal disease
E10.641	Type 1 diabetes mellitus with hypoglycemia with coma
E10.649	Type 1 diabetes mellitus with hypoglycemia without coma

E10.65	Type 1 diabetes mellitus with hyperglycemia
E10.69	Type 1 diabetes mellitus with other specified complication
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications
E11.00	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E11.01	Type 2 diabetes mellitus with hyperosmolarity with coma
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E11.36	Type 2 diabetes mellitus with diabetic cataract
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy
E11.620	Type 2 diabetes mellitus with diabetic dermatitis
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E11.628	Type 2 diabetes mellitus with other skin complications
E11.630	Type 2 diabetes mellitus with periodontal disease
E11.638	Type 2 diabetes mellitus with other oral complications
E11.641	Type 2 diabetes mellitus with hypoglycemia with coma
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.69	Type 2 diabetes mellitus with other specified complication
E11.8	Type 2 diabetes mellitus with unspecified complications
E11.9	Type 2 diabetes mellitus without complications
E13.00	Other specified diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
E13.10	Other specified diabetes mellitus with ketoacidosis without coma
E13.11	Other specified diabetes mellitus with ketoacidosis with coma
E13.39	Other specified diabetes mellitus with other diabetic ophthalmic complication
E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy
E13.42	Other specified diabetes mellitus with diabetic polyneuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
E43.44	Other specified diabetes mellitus with diabetic amyotrophy
E13.49	Other specified diabetes mellitus with other diabetic neurological complication
E13.59	Other specified diabetes mellitus with other circulatory complications
E13.620	Other specified diabetes mellitus with diabetic dermatitis
E13.621	Other specified diabetes mellitus with foot ulcer
E13.622	Other specified diabetes mellitus with other skin ulcer
E13.628	Other specified diabetes mellitus with other skin complications
E13.638	Other specified diabetes mellitus with other oral complications

E13.641	Other specified diabetes mellitus with hypoglycemia with coma
E13.649	Other specified diabetes mellitus with hypoglycemia without coma
E13.65	Other specified diabetes mellitus with hyperglycemia
E13.69	Other specified diabetes mellitus with other specified complication.
E13.8	Other specified diabetes mellitus with unspecified complications
E13.9	Other specified diabetes mellitus without complications
O24.319	Unspecified pre-existing diabetes mellitus in pregnancy, unspecified trimester
O24.32	Unspecified pre-existing diabetes mellitus in childbirth
O24.911	Unspecified diabetes mellitus in pregnancy, first trimester
O24.912	Unspecified diabetes mellitus in pregnancy, second trimester
O24.913	Unspecified diabetes mellitus in pregnancy, third trimester
O24.92	Unspecified diabetes mellitus in childbirth
O24.93	Unspecified diabetes mellitus in the puerperium

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s): L33794, 280.14
LCA (A52507) https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52507&ver=41&Date=&DocID=A52507&SearchType=Advanced&bc=JAAAABAAAA&	

NCD/LCD Document (s):
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794&ver=77&Date=&DocID=L33794&SearchType=Advanced&bc=KAAAABAAAA&
https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R27NCD.pdf

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC