

## Evidence Based Guideline

### External Insulin Pumps

<b>File Name:</b>	external_insulin_pumps
<b>Origination:</b>	2/1994
<b>Last CAP Review:</b>	7/2011
<b>Next CAP Review:</b>	7/2012
<b>Last Review:</b>	7/2011

#### Description of Procedure or Service

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An external insulin infusion pump is a programmable, battery-powered mechanical syringe/reservoir device controlled by a micro-computer to deliver a continuous subcutaneous insulin infusion (CSII) into the body. Typical devices have a two to three day supply of insulin connected to an infusion set attached to a small needle or cannula programmed to deliver a steady basal amount of insulin and release a bolus dose at meals and at programmed intervals. The purpose of an insulin pump is to provide an accurate, continuous, controlled delivery of insulin which can be regulated by the user to achieve intensive glucose control and prevent the metabolic complications of hypoglycemia, hyperglycemia and diabetic ketoacidosis. An insulin pump is considered Durable Medical Equipment.

In many people, CSII or multiple insulin injections can provide equivalent improvements in control. Some clinicians recommend CSII only when 3 or 4 daily injections fail to provide adequate control. CSII may also be appropriate for those motivated patients whose daily schedule makes conventional therapy less effective. Use of CSII requires care by skilled professionals, careful selection of patients, meticulous patient monitoring and thorough patient education and training.

**\*\*\*Note: This Evidence Based Guideline is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### Evidence Based Guideline for External Insulin Pumps

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External insulin pumps may be appropriate for the treatment of diabetic patients who: (1) meet the updated fasting C-Peptide testing requirement or are beta cell autoantibody positive; **and** (2) satisfy the remaining criteria for insulin pump therapy as described below.

- 1) The patient with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, or must be beta cell autoantibody positive.

Updated fasting C-peptide testing requirement:

- Insulinopenia (defined as fasting C-peptide level less than or equal to 110% of the lower limit of normal of the laboratory's measurement method)
  - For patients with renal insufficiency and creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine) less than 50 ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory's measurement method
- Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose less than 225 mg/dL
- Levels only need to be documented once in the medical records.
- Fasting C-peptide levels are not required for patients diagnosed at younger than 12

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years of age

AND

- 2) Patients must meet one of the following criteria (A, B, or C):
  - A. Patient requires multiple insulin doses, usually more than three per day and usually with mixed long-acting/short acting insulin. These multiple and mixed doses have been required for a period of:
    1. at least 6 months and all of the following criteria are met:
      - a. Erratic blood sugar, ketoacidosis, or symptomatic hypoglycemia in spite of maximal patient compliance and intermittent dosing; **and**
      - b. Hgb A-1C is greater than 7.0% unless there is documented frequent hypoglycemia that contributes to a low or normal Hgb A-1C.**and**
      - c. The patient is involved in a comprehensive diabetes care program (e.g., the BCBSNC or other diabetes disease management program) **and**
      - d. An endocrinologist or physician with similar skill and training in the management of external insulin pumps prescribes the pump or is involved with the care of the patient. (This may include initial consult visit and phone or written follow-up)
    2. less than 6 months but more than 3 months and the patient has documented extenuating circumstances. These cases may be reviewed on an individual consideration basis.
  - B. Patient with gestational diabetes or when pregnancy occurs or is anticipated within 3 months in a previously diagnosed diabetic with **ANY** of the following indications:
    1. Erratic blood sugars in spite of maximal patient compliance and split dosing; **or**
    2. Other evidence that adequate control is not being achieved.
  - C. A member with chronic renal failure and brittle diabetes could benefit from tight control with an insulin pump as long as he/she is not having renal dialysis.

Note: The recommended goal is for a patient's Hgb A-1C to be less than 7.

### **Medical Evidence regarding External Insulin Pumps indicates it is not recommended in the following situations**

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External insulin pumps are not recommended when the medical guidelines shown above are not met.

### **Benefits Application**

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

An external insulin pump is considered Durable Medical Equipment (DME).

Syringes and infusion sets associated with External Insulin Pumps would be processed as medical supplies.

### **Billing/Coding/Physician Documentation Information**

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This guideline may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: A4230, A4231, A4232, A9274, E0784, S9145*

# External Insulin Pumps

## Scientific Background and Reference Sources

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Senior Director, Medical Affairs - 2/94

Physician Advisory Group - 10/95

Consultant Review 12/97

Resources provided by vendors

American Association of Diabetes Educators - "How to succeed with insulin pump patients", Bruce W. Bode, MD, FACE; Linda Frederickson, MA, RN, CDE; Volume 1, Number 2, 1999.

Medical Policy Advisory Group - 12/99

Specialty Matched Consultant Advisory Panel - 10/2000

Medical Policy Advisory Group - 12/00

Specialty Matched Consultant Advisory Panel - 7/2002

Specialty Matched Consultant Advisory Panel - 6/2004

Specialty Matched Consultant Advisory Panel - 5/2006

Specialty Matched Consultant Advisory Panel - 5/2008

Bergenstal RM, Taborlane WV, Ahman A, et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes. N Engl J Med. 2010 Jun 29. Retrieved on July 24, 2010 from <http://www.ncbi.nlm.nih.gov/pubmed/20587585>

Specialty Matched Consultant Advisory Panel 8/2010

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Infusion Pumps (280.14). Baltimore, MD: CMS; February 2005. Accessed 6/9/2011 from: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&DocID=280.14&bc=gAAAAAgAAAA&>

Centers for Medicare & Medicaid Services (CMS). Decision memo for insulin pump: C-peptide levels as a criterion for use (CAG-00092R). Baltimore, MD: CMS; Accessed 6/9/2011 from: <http://www.cms.gov/mcd/viewdecisionmemo.asp?id=109>.

## Policy Implementation/Update Information

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2/94	Original policy issued
10/95	Revised: Added Hgb A-1C greater than 9.5
10/96	Reaffirmed
11/97	Reaffirmed
3/98	Revised: Changed Hgb A-1C to a level greater than 7.0. Added requirement of 6 months for evaluation of patient compliance and intermittent dosage. Added indication of Chronic Renal Failure. File name changed from (L)E0784.MED to (L)E0784.ALL.

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- 8/99 Reformatted, Description of Procedure changed, Medical Term Definitions added.
- 12/99 Medical Policy Advisory Group
- 2/00 Combined 1.a. and b. under "When an External Insulin Pump is covered". Also changed the term "all" to "both" and changed criteria to include "a. "and " b".
- 12/00 Specialty Matched Consultant Advisory Panel review. Change criteria under when External Insulin Pump is covered based on consultant feedback to include more specific information regarding the Hgb A-1C, the involvement of an endocrinologist, and the patient's involvement in a comprehensive diabetic care program. System coding changes. Medical Policy Advisory Group review. No further changes to criteria. Approve.
- 3/01 Revised statement in "When External Insulin Pumps are Covered" changed from "An endocrinologist prescribes or is involved in the care of the patient." to "A physician with documented skill and training managing external insulin pumps prescribes the pump or is involved with the care of the patient. (This may include initial consult visit and phone or written follow-up)"
- 3/01 Revised statement in "When External Insulin Pumps are Covered" changed from "A physician with documented skill and training managing external insulin pumps prescribes the pump or is involved with the care of the patient. (This may include initial consult visit and phone or written follow-up)" to "An endocrinologist or physician with similar skill and training in the management of external insulin pumps prescribes the pump or is involved with the care of the patient. (This may include initial consult visit and phone or written follow-up)"
- 4/02 When an External Insulin Pumps is covered section reformatted for clarity. No change to Billing/Coding Section.
- 8/02 Specialty Matched Consultant Advisory Panel review 7/1/2002. No changes.
- 4/04 Benefits Application and Billing/Coding sections updated for consistency.
- 6/24/04 Specialty Matched Consultant Advisory review. Added statement, "Syringes and infusion sets associated with External Insulin Pumps would be processed as medical supplies." under Benefits Application Section. No change to criteria. References added.
- 09/09/04 Description of Procedure or Service updated.
- 6/19/06 Specialty Matched Consultant Advisory Panel review 5/18/2006. No changes to policy statement. References added.
- 8/21/06 Medical Policy changed to Evidence Based Guideline.
- 12/31/07 Added new 2008 HCPCS code "A9274" to the "Billing/Coding" section.
- 7/28/08 Specialty Matched Consultant Advisory Panel review 5/29/08. No change to policy statement. References added. (btw)
- 6/22/10 Policy Guideline Number(s) removed (amw)
- 9/28/10 Specialty Matched Consultant Advisory Panel review 8/2010. References updated. (mco)
- 9/13/11 Description section updated. The following statement added to the medical criteria: "the patient with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, or must be beta cell autoantibody positive." Also added information regarding the fasting C-peptide testing requirements. References updated. Added codes A4230, A4231, A4232 and S9145 to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 7/27/11. (adn)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and

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is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.