

Continuous Subcutaneous Insulin Infusion Pump

Origination: 05/14/04	Revised: 03/21/08	Annual Review: 12/15/11
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Purpose:

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to Continuous Subcutaneous Insulin Infusion Pump in order to determine inclusion in the benefit plan.

Recommendation:

A recommendation was made by the MTAC following discussion by committee members based on current literature:

Eligibility Criteria

- Members must meet *all* of the following criteria:
 1. The Member or Member's representative must have completed a comprehensive diabetes education program **and**
 2. The Member has been on a program of multiple daily injections of insulin, at least three (3) injections per day, with frequent self-adjustments of insulin dose for at least six (6) months prior to initiation of the insulin pump **and**
 3. The Member has documented frequency of glucose self-testing an average of at least four (4) times per day during the two (2) months prior to initiation of the insulin pump **and**
 4. Diabetes needs to be documented by a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method; for Members with renal insufficiency and documented creatinine clearance ≤ 50 ml/minutes, fasting C-peptide level would have to be less than or equal to 200% of the lower limit of normal of the laboratory's measurement method; alternatively, a positive beta cell autoantibody test could be demonstrated;
 5. The Member meets *one (1) or more* of the following criteria while on multiple daily injections (>3 injections per day) of insulin:
 - a. Elevated glycosylated hemoglobin level (HbA1c > 7.0%, where upper range of normal is less than 6.0%; for other HbA1c assays, 1% over upper range of normal); or
 - b. History of recurring hypoglycemia (< 60 mg/dL); or
 - c. Wide fluctuation of blood glucose level(s) before mealtime (e.g., preprandial blood glucose levels commonly exceed 140 mg/dL); or
 - d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; or

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Recommendation, continued:

Eligibility Criteria, continued

- Members must meet *all* of the following criteria, continued:
 5. The Member meets *one (1) or more* of the following criteria while on multiple daily injections (>3 injections per day) of insulin, continued:
 - e. History of severe glycemic excursions; or
 - I. The Member with type 1 diabetes, documented by a C-peptide level < 0.5, has been on a pump prior to enrollment in AvMed Health Plans and has documented frequency of glucose self-testing an average of at least four (4) times per day during the month prior to AvMed enrollment;
 - II. Continued coverage of the insulin pump would require that the Member has been seen and evaluated by the treating physician at least every three (3) months. The pump must be ordered by and follow-up care of the Member must be managed by a physician who manages multiple patients with CSII and who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in the use of CSII.

References:

1. Saudek CD, Duckworth WC, Giobbie-Hurder A, et al. Implantable insulin pump vs multiple-dose insulin for non-insulin-dependent diabetes mellitus: a randomized clinical trial. Department of Veterans Affairs Implantable Insulin Pump Study Group. JAMA. 1996;276(16):1322-1327.
2. U.S. Department of Health and Human Services, Health Care Financing Administration. Infusion pumps. Medicare Coverage Issues Manual §60-14. HCFA Pub. 6. Baltimore, MD: HCFA, 2000.
3. TriCenturion, LLC. External infusion pumps. Medicare Local Medical Review Policy. DMERC Region A. Policy No. EIP20030901. Columbia, SC: TriCenturion; revised October 1, 2003.
4. American Diabetes Association. Standards of medical care for patients with diabetes mellitus. Diabetes Care. 1995;18(Supp 1):8-15.

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5. U.S. Department of Health and Human Services, Health Care Financing Administration. Decision Memorandum. Continuous Subcutaneous Insulin Infusion Pump Issue # CAG-00041. Baltimore, MD: HCFA, August 26, 1999. Accessed September 28, 1999.

References, continued:

6. Diabetes Control and Complications Trial Research Group. Implementation of Treatment Protocols in the Diabetes Control and Complications Trial. *Diabetes Care*. 1995;18(3):361-376.
7. Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New Engl J Med*. 1993;329:977-986.
8. Marcus AO, Fernandez MP. Insulin pump therapy. Acceptable alternative to injection therapy. *Postgraduate Med*. 1996;99(3):1-7 .
9. Agency for Health Care Policy and Research. Reassessment of external insulin infusion pumps. AHCPR Assessment No. 9. Rockville, MD: AHCPR, July 1991.
10. American Medical Association, Diagnostic and Therapeutic Technology Assessment. Continuous subcutaneous insulin infusion. Chicago, IL: AMA, 1989.

Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed Health Plan benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plan makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.