



Subject: Insulin Pump*

Effective Date: March 23, 2004

Department(s): Utilization Management

Policy: Continuous infusion insulin pumps and supplies necessary for their effective use are reimbursable under Plans administered by QualCare, Inc.

Objective: To assure proper and consistent reimbursement and to delineate criteria for a medically necessary device.

Procedure:

1. Patients who are candidates for coverage of an insulin pump (**HCPCS E0784; A4230-A4232; A9274; J1817**) must have completed a diabetes self-management education program, a treatment program including at least 3 insulin injections a day for at least three months, with blood glucose self-testing an average of at least four times daily for two months prior to initiating insulin pump therapy, AND meet at least one of the following criteria:
 - a. Documented evidence of failure to achieve adequate glycemic control ($HbA1c \geq 7\%$)
 - b. Evidence of lifestyle patterns that do not permit the regulating of meals and injection schedules
 - c. Insulin-dependent diabetes complicated by pregnancy (**ICD-9 648.0; ICD-10 O24.011-3, O24.019, O24.111-3, O24.119**)[*Note this*

indication does NOT require prior intensive insulin treatment of at least 3 injections daily and four times daily blood glucose monitoring in 1 above]

- d. “Brittle” diabetes with documentation of repeated clinical episodes of symptomatic hypoglycemia or wide swings of glucose levels or dawn phenomenon (with fasting blood sugars frequently exceeding 200 mg/dL) (**ICD-9 250.1 – 250.3; 250.9; ICD-10 E10.10, E10.11, E10.641, E10.65, E10.69, E10.8, E11.00, E11.01, E11.641, E11.65, E11.69, E11.8, E13.00, E13.01, E13.10, E13.11, E13.641, E13.8**)
2. The requesting provider must document that the patient has the ability and commitment to comply with a regimen of pump care, frequent self-monitoring of blood glucose, and careful attention to diet and exercise.
3. For coverage criteria for continuous glucose monitoring, please refer to the separate policy “Glucose Monitoring (Continuous).”
4. All insulin pumps require pre-authorization.
5. Replacement of the external insulin pump- when the benefit design so allows- will be considered medically necessary only when the current pump is malfunctioning, is out of warranty and is not repairable. Replacement of a currently functioning insulin pump for the sole purpose of receiving the most recent insulin pump technology (i.e., “upgrading” for improved technology) is considered a convenience item and not medically necessary and is not reimbursable. Additional software or hardware required for downloading data to a device such as personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus is considered a convenience item and not medically necessary and is not reimbursable.

6. Disposable transdermal insulin delivery systems(e.g.V-Go) are considered self-use not requiring physician supervision and are not eligible for reimbursement under plans administered by QualCare, Inc. This type of delivery system may be coverable under a pharmacy benefit plan.

References

- American Diabetes Association (ADA). Standards of medical care in diabetes (previously called clinical practice recommendations) - 2018. Accessed at <http://care.diabetesjournals.org/content/by/year>
- Steineck I, Ranjan A, Nørgaard K, Schmidt S. Sensor-Augmented Insulin Pumps and Hypoglycemia Prevention in Type 1 Diabetes. *J Diabetes Sci Technol.* 2017;11(1):50-58(Jan)
- American Diabetes Association (ADA). Standards of medical care in diabetes (previously called clinical practice recommendations) - 2016. Accessed at <http://care.diabetesjournals.org/content/by/year>
- Grunberger G, Abelseth JM, Bailey TS, Bode BW, Handelsman Y, Hellman R, Jovanovič L, Lane WS, Raskin P, Tamborlane WV, Rothermel C. C. Consensus statement by the American Association Of Clinical Endocrinologists/American College Of Endocrinology Insulin Pump Management Task Force. *Endocr Pract.* 2014 May;20(5):463-89.
- Reznik Y, Cohen O, Aronson R, et al.; OpT2mise Study Group. Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (OpT2mise): a randomised open-label controlled trial. *Lancet* 2014;384:1265–1272
- Kmietowicz Z. Insulin pumps improve control and reduce complications in children with type 1 diabetes. *BMJ* 2013;347:f5154
- ACOG Practice Bulletin No. 60- Pre-gestational Diabetes Mellitus, reaffirmed 2014.(*Obstet Gynecol* 2005;105:675–85), at acog.org
- Bergenstal RM, Klonoff DC, Garg SK, Bode BW, Meredith M, et. Al. Threshold-based insulin-pump interruption for reduction of hypoglycemia. *The New Engl J Med.* June 22, 2013/DOI: 10.1056/NEJMoa130356[Epub ahead of print]
- Golden SH, Brown T, Yeh HC, Maruthur N, Ranasinghe P, et al. Methods for insulin delivery and glucose monitoring: Comparative Effectiveness[Internet] Rockville (MD): Agency for Healthcare Research and Quality (US); 2012 Jul. Report No.: 12-EHC036-EF.

- Inzucchi SE , Bergenstal RM, Buse JB, Diamant M, et. Al. Management of hyperglycemia in type 2 diabetes: a patient centered approach. *2012 Diabetes Care*;35:1364-79(Jun)
- Rubin RR, Peyrot M. Patient-reported outcomes and diabetes technology: a systematic review of the literature. *Pediatric Endocrinol Rev.* 2010. 7(suppl 3):S405-12 (Aug)
- Valla V, Therapeutics of diabetes mellitus: focus on insulin analogues and insulin pumps. *Exp Diabetes Res.*2010 May 26. doi 10.1155/2010/178372 (published online)
- Eisenbarth GS, Polonsky KS, Buse JB. Type 1 Diabetes Mellitus. Ch 31 in Kronenberg HM, Melmed S, Polonsky KS, *et al.* *Williams Textbook of Endocrinology.* 11th ed. Philadelphia. Saunders Elsevier. 2008
- Brunton S. Insulin Delivery Systems: Reducing Barriers to Insulin Therapy and Advancing Diabetes Mellitus Treatment. *Am J Med* 2008;121(6 suppl):S35-S41 (Jun)
- White RD. Insulin Pump Therapy (Continuous Subcutaneous Insulin Infusion). *Prim Care* 2007;34(4):845-871 (Dec)
- Lombardo F, Iafusco D, Salzano G, *et al.* The egg or the chicken ? Further data on whether good compliance to multi-injection insulin therapy should be a criterion for insulin pump therapy, or does insulin pump therapy improve compliance? *J Pediatr* 2007;151(6):e23-e24 (Dec)
- Mukhopadhyay A, Farrell T, Fraser RB, *et al.* Continuous subcutaneous insulin infusion vs intensive conventional insulin therapy in pregnant diabetic women : A systematic review and metaanalysis of randomized, controlled trials. *Am J Obstet Gynecol* 2007;197(5):447-456 (Nov)
- Eisenbarth GS. Update in Type 1 Diabetes. *J Clin Endocrinol Metab* 2007;92(7):2403-2047 (Jul)
- Yogev Y, Hod M. Use of new technologies for monitoring and treating diabetes in pregnancy. *Obstet Gynecol Clin North Am.* 2007;34(2):241-253 (Jun)
- Hoogma RP, Hammond PJ, Gomis R, *et al.* Comparison of the effects of continuous subcutaneous insulin infusion (CSII) and NPH-based multiple daily insulin injections (MDI) on glycaemic control and quality of life: results of the 5-nations trial. *Diabet Med* 2006;23(2):141-147 (Feb)
- Weinzimer SA, Sikes KA, Steffer AT, *et al.* Insulin Pump Treatment of Childhood Type 1 Diabetes. *Pediatr Clin N amer*2005;52(6):1677-1688 (Dec)
- Scuffham P, Carr L. The cost-effectiveness of continuous subcutaneous insulin infusion compared with multiple daily injections for the management of diabetes. *Diabet Med* 2003;20(7): 586-593 (Jul)
- Eisenbarth GS, Polonsky KS, Buse JB. Insulin Administration by an External Insulin Pump. In Type 1 Diabetes Mellitus. Ch 30 in Larsen PR, Kronenberg HM, Melmed S, *et al* *Williams Textbook of Endocrinology* 10th ed. Philadelphia. Saunders. 2003.

Pickup J, Mattock M, Kerry S. Glycaemic control with continuous subcutaneous insulin infusion compared with intensive insulin injections in patients with type 1 diabetes: meta-analysis of randomised controlled trials. *BMJ* 2002;324:1-6 (23 Mar)

U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. Medicare Coverage Database. NCD for Infusion Pumps (60-14). January 1, 2002. www.cms.hhs.gov/mcd (accessed 2/27/04)

Lenhard MJ, Reeves GD. Continuous Subcutaneous Insulin Infusion. A Comprehensive Review of Insulin Pump Therapy. *Arch Intern Med* 2001;161:2293-2300 (Oct 22)

Kyler JSS, Hirsch IB. Diabetes Mellitus. Ch 96 in Noble J. Textbook of Primary Care Medicine, 3rd ed. St. Louis. Mosby. 2001 pp 829-830

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*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail