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UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER

INSULIN PUMPS (CONTINUOUS SUBCUTANEOUS INSULIN INFUSION THERAPY) AND CONTINUOUS GLUCOSE MONITORING SYSTEMS

**1. Purpose.** This Veterans Health Administration (VHA) Information Letter provides recommendations to VHA clinical staff regarding identification of Veterans who may be candidates for Continuous Glucose Monitoring Systems (CGMS). Such individuals should be candidates for intensive control of diabetes based upon criteria recommended by VHA-Department of Defense (DOD) Diabetes Guidelines for Primary Care. However, because the clinical trials upon which intensive control recommendations were made utilized conventional insulin delivery techniques, and because technology has evolved, a review of recent evidence was conducted to address the following questions:

*a. What are the safety, efficacy and cost-effectiveness of insulin pumps versus conventional multi-dose insulin regimens for managing patients with diabetes? What constitutes long-term use of these monitors and their discontinuance?*

Medical literature indicates that the efficacy of continuous subcutaneous delivery of insulin using pumps was comparable to intensive multidose subcutaneous insulin therapy (MDI) in the context of randomized clinical trials for individuals with type 1 diabetes and insulinopenic type 2 diabetes. Individuals with type 1 diabetes who complied with regimens may achieve improved glycemic control without an increase in hypoglycemia. Patient satisfaction on pump therapy was comparable to or superior to MDI. Safety, with respect to serious hypoglycemic reactions, was comparable. Infections, usually minor, were a risk with pumps. Discontinuation of the pump, due to malfunction or human factors, could result in diabetic ketoacidosis. Studies did not provide sufficient information to comment upon long-term continuance of pump therapy. Cost-effectiveness could not be evaluated in a rigorous fashion. The major benefit is quality of life.

*b. What are the safety, efficacy and cost-effectiveness of CGMS versus self-monitoring of blood glucose (SMBG) for managing patients with diabetes using insulin? What constitutes long-term use of these monitors and their discontinuance?*

There are insufficient data at this time to permit a systematic evaluation of CGMS in the context of insulin pump therapy for the Veteran population.

(1) A few small clinical trials showed that efficacy was variable with some studies showing no difference in hemoglobin A1c and others showing less than 1.0 percent difference between CGMS and SMBG. These studies did not demonstrate decreased severe hypoglycemia risk with CGMS; however, the overall reports of severe hypoglycemia were low. Large, long-term comparative trials beyond 6 months are needed.

(2) These studies did not necessarily include patients who may benefit from this technology (e.g. hypoglycemia unawareness, patients with severe or frequent hypoglycemia); therefore, it is difficult to conclude if such patients may benefit based upon the current evidence. However, if appropriately selected, such patients may be considered for a trial of these technologies.

## **2. Recommendations**

a. It is recommended that Insulin pumps be considered for patients with diabetes meeting the criteria adapted from Centers for Medicare and Medicaid Services (CMS) reimbursement criteria. At this time, CGMS cannot be recommended due to lack of outcome data. This conclusion will be re-reviewed based upon the emerging literature. Exceptional requests need to be reviewed by the health care provider on a case-by-case basis for severe and frequent hypoglycemia despite compliance with a pump and appropriate target values of A1c.

b. All field requests for CGMS devices need to be made by an endocrinologist or diabetes team with expertise in this technology, and with knowledge of the patient. Explicit documentation of the following criteria needs to be provided:

### **(1) Criterion A**

(a) The patient has completed a comprehensive diabetes education program, and has been on a MDI regimen (i.e., at least three injections per day), with frequent self-adjustments of insulin doses for at least 6 months prior to initiation of the insulin pump, and

(b) The patient has a documented frequency of glucose self-testing an average of at least four times per day during the 2 months prior to initiation of the insulin pump.

(2) **Criterion B.** The patient meets one or more of the following criteria while on the MDI regimen:

(a) Glycosylated hemoglobin level (HbA1c) more than 7.0 percent for patients in whom a less than 7.0 percent goal is appropriate consistent with VHA-DOD Guidelines;

(b) History of recurring severe or functionally disabling hypoglycemia;

(c) Wide fluctuations in blood glucose levels before mealtime; and

(d) Fasting blood glucose levels frequently exceeding 200 mg/dl.

c. C-peptide is not recommended as a criterion because of concerns that it could exclude some patients with pancreo-ptyvic diabetes (war injuries to pancreas, pancreatic resections, or insufficiencies for other reasons, etc.). These patients are usually more difficult to control (due to glucagon as well as insulin deficiency) yet may not meet strict C-peptide criteria. Antibody IL testing (GAD 65) may not be sensitive or specific, in part because they may be present only near the time of diagnosis.

### 3. References

a. VHA Patient Care Services Technology Assessment Panel Adams EJ, VATAP. VA Technology Assessment Program. (US Department of Veterans Affairs. Veterans Health Administration. Office of Patient Care Services): Boston. Appropriate Use of Insulin Pump—Real-Time Continuous Glucose Monitoring Systems in the Veteran Population, 17 Pgs. *VATAP Brief Overview*, July 2006. <http://www.va.gov/vatap/pubs/FinalreportInsulinCBGM9-08.pdf>

b. NICE Guidance. TA151 Diabetes-insulin pump therapy. July 23, 2008. <http://www.nice.org.uk/guidance/index.jsp?action=download&o=41301>.

c. Blue Cross Blue Shield Massachusetts. Diabetic Supplies. Document 202. Posted 5/29/08. [http://www.bluecrossma.com/common/en\\_US/medical\\_policies/202%20Diabetic%20Supplies%20prn.pdf](http://www.bluecrossma.com/common/en_US/medical_policies/202%20Diabetic%20Supplies%20prn.pdf)

d. 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=ncl](http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncl).

e. The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes. *N Engl J Med* 2008; 359: 1464-1476.

**4. Inquiries.** Questions regarding this information letter may be addressed to Leonard Pogach M.D., MBA, National Program Director, Endocrinology and Diabetes, VA Central Office, Office of Patient Care Services, Medical and Surgical Services at (973) 676-1000 Extension 1693 or by Fax at (973) 395-7091.

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