Public Comments for
Draft Decision Memo on
Insulin Pump: C-Peptide Levels as a Criterion Use
CAG –00092R
September 30-October 30, 2004

Commenter: Dinwiddie, Lesley, MSN, RN, FNP, CNN
Organization: American Nephrology Nurses' Association
Date: October 26, 2004
Comment:

The American Nephrology Nurses' Association (ANNA) thanks you for the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments regarding the Coverage Decision Memorandum for C-Peptide levels as a Criterion for Use of Insulin Pumps. Anna is a professional organization representing over 11,000 nephrology nurses whose main patient population is the hemodialysis population.

ANNA recognizes that the number of US citizens with potential and actual kidney disease is rising annually. This is due to several factors including an aging population and an increase in chronic diseases such as diabetes, which can cause renal dysfunction. Preventive care for all aspects of kidney disease is proven to slow the progression to end stage renal disease (ESRD), which requires dialysis or transplantation. Prevention of renal failure and preservation of renal function include early diagnosis, patient education, drug therapy, and referrals to specialists.

Diabetes is the primary diagnosis for new onset kidney disease with most patients having Type 2 diabetes. In addition to nephropathy, complications of untreated or undertreated diabetes include cardiovascular disease, neuropathy, and retinopathy. Patients with compromised renal function are unable to take all of the available oral agents and may need to be treated with insulin. Medicare is the primary insurer for ESRD patients and the cost for care increases when patients are unstable or hospitalized. Preventing complications by optimizing glucose control will decrease these costs.

ANNA supports the CMS decision to expand the parameters for C-Peptide results in people with chronic kidney disease (CKD), (clearance<50ml/min) who are not beta cell autoantibody positive. We are concerned that patients who are already stable on CSII must re-qualify for this therapy after becoming Medicare eligible either through age or by reaching ESRD. We recognize that C-peptides may not be as useful in this population due to the decreased rates of insulin clearance. We recognize that Medicare resources must be used carefully and that only appropriate patients should be managed with CSII.

We would request that some reasonable recourse be available to patients and their providers if it is determined that a patient who meets all other CSII criteria except for the C-peptide measurement can best be managed with SCII. The goal for every person with diabetes is to prevent or delay costly and deadly complications for as long as possible.

ANNA also supports ongoing research to determine the best methods of managing diabetes and preventing complications in the patient with renal dysfunction.

American Association of Clinical Endocrinologists

1000 Riverside Avenue • Suite 205 • Jacksonville, Florida 32204 • Phone: (904) 353-7878 • Fax: (904) 353-8185 • http://www.aace.com

October 27, 2004

Dr. Lawrence Schott
Ms. Betty Shaw
Centers for Medicare & Medicaid Services
Coverage and Analysis Group
7500 Security Blvd.
C1-09-06 Mail Stop
Baltimore, Maryland 21244

Dear Dr. Schott and Ms. Shaw:

We have had a chance to review the recent draft decision on C-peptide criteria for consideration for insulin pump therapy. This issue is also relevant for potential pancreas transplant patients as well.

1. We applaud CMS for raising the C-peptide requirement to double the lower limit of normal for those with renal insufficiency. This certainly reflects the known effect of impaired renal function on C-peptide clearance.

2. The decision to allow beta-cell autoantibody positive individuals to be eligible for the insulin pump therapy is a thoughtful advance. It is becoming clear that type 1 diabetes can evolve over a period of several years and initially mimics type 2 diabetes. The presence of beta cell antibodies identifies the patient as likely type 1 diabetes. This decision allows the physician to implement intensive therapy sooner, if necessitated by the patient's clinical status.

3. The addition of the fasting blood glucose is more difficult to interpret. Clinically, most endocrinologists would interpret a low C-peptide in the presence of a glucose > 225 mg/dl as indicative of true beta-cell failure and not of glucose toxicity. We do not feel that the fasting glucose is a valid indicator of patient selection and in addition we disagree with an absolute glucose level. For example, if the fasting glucose level is 230 mg/dl, yet the patient's C-peptide is at the lower limit of normal, in AACE's opinion this should not disqualify a patient.

Glucose levels can fluctuate widely, especially in those candidates considering CSII therapy and a single fasting glucose value is unlikely to correlate with glucotoxicity.

In practice, glucotoxicity is typically not a problem with Type 1 diabetes. If a patient with Type 2 diabetes presents with glucotoxicity, (chronic hyperglycemia), this would not be the time to assess appropriateness of CSII. Of note, Dr. Boden's paper used to support this requirement for a fasting glucose, studied normal non-diabetic subjects.

AACE strongly recommends that this requirement of a fasting glucose threshold be removed.

Sincerely,

Carlos R. Hamilton, Jr., MD, FACE
President

cc: AACE Board of Directors
AACE Coding Committee
Donald C. Jones, CEO

Medtronic
MiniMed

Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325-1219
www.minimed.com

tel 800.933.3322

October 22, 2004

Dr. Lawrence Schott
Ms. Betty Shaw
Centers for Medicare & Medicaid Services
Coverage and Analysis Group
7500 Security Blvd.
C1-09-06 Mail Stop
Baltimore, Maryland 21244

Dear Dr. Schott and Ms. Shaw:

We are writing in response to the Draft Decision Memorandum regarding C-peptide criterion (CAG-00092R) posted to the CMS website on September 30, 2004. We appreciate CMS' due diligence and effort to research new information available on insulin pumps and the validity of C-peptide testing.

The draft decision memo proposes three primary changes to the insulin pump C-peptide coverage requirements:

1. It allows Medicare beneficiaries to meet a beta cell autoantibody test in place of the C-peptide requirement.
2. It allows a higher C-peptide level for patients with renal insufficiency.
3. It requires that a fasting glucose level be taken to confirm the validity of the C-peptide test.

Overall, while the draft decision memorandum does not remove the C-peptide test as we requested, we nevertheless believe the proposed changes to the policy are favorable and promote appropriate use of continuous subcutaneous insulin infusion (CSII) among Medicare beneficiaries. In particular, the acceptance of a positive beta cell autoantibody test and recognition of the need for higher C-peptide levels for renal insufficiency will provide critical access for patients with immune mediated diabetes who have been ineligible under the current C-peptide test requirements.

We would like to comment on four specific areas of the decision memorandum:

1) the additional requirement of a fasting glucose test concurrent with a C-peptide test;
2) references to the FDA status of Medtronic MiniMed insulin pumps;
3) clarification of commercial coverage policies on C-peptide and insulin pumps and;
4) specific updates to the language of the coverage policy.

Fasting Glucose Test Requirement

We are concerned about the inclusion of the fasting glucose test concurrent with C-peptide testing. This additional fasting glucose requirement will not only be a financial burden to CMS and patients, but will result in increased workload for physicians. Although limited clinical data may support that a prolonged hyperglycemic state can result in a suppressed C-peptide, we do not understand how this will further define patient selection for CSII. These episodes of "glucose toxicity" are typically seen at initial diagnosis or acute crisis of their disease. In clinical practice, the front line of treatment for those episodes is to gain glycemic control; this is not the time that a physician would be selecting a patient for a pump. We feel the current criteria of C-peptide level that is "less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement" is sufficient to determine eligibility for those patients without renal insufficiency or positive beta cell autobodies.

Comments on FDA Status

Medtronic is concerned with Section V of the draft decision memorandum, which covers "FDA Status." Section V describes the approval status and indications for Medtronic MiniMed insulin pumps. It also provides a description of Medtronic MiniMed's recent compliance history and recall actions.

We were very surprised by the inclusion of Medtronic MiniMed's compliance history in this draft memorandum. While we note recent coverage decisions have included FDA product approval status, to our knowledge this is the first coverage analysis (at least of a medical device) that attempts to interject FDA compliance issues into the coverage context.

We believe the focus on recalls and compliance issues in the draft coverage analysis is inappropriate and addresses issues most appropriately left to the FDA. We are also concerned that the inclusion of FDA compliance language could set a harmful coverage precedent, leading Medicare contractors to independently address FDA issues beyond approval status, potentially resulting in unnecessary geographic variation in coverage.

We also believe the actual description of the compliance actions is unbalanced. We note the following in response to the text of section V:

- All of the recall actions were initiated by and entirely voluntary on the part of Medtronic MiniMed. In fact, MiniMed made numerous communications with patients to ensure their pumps and pump therapy were being managed appropriately throughout the process.

- The true number of pumps and related items with problems were in fact quite limited. Nevertheless, the recalls were broad to provide an additional measure of assurance to all MiniMed pump users.

- Medtronic provided replacement products free of charges in all instances, so patients never had to go without therapy or change back to multiple daily injections. One of the recalls was actually for a peripheral item that did not directly relate to the operation of the pump.

- We believe that all concerns raised by the FDA were addressed fully and completely to the agency's satisfaction, and our products remained available to patients at all times.

Ultimately, the clinical benefit of CSII and the true safety of the device affirm the therapy we provide to people with diabetes. In no way should any of the issues related to MiniMed's compliance actions be construed to negate the benefits to patients or be a factor in deciding whether to grant coverage to patients for insulin pumps.

We urge CMS to delete the references to Medtronic MiniMed's compliance history in section V of the draft decision memorandum. At a minimum, it should provide a balanced perspective on MiniMed's compliance actions (as described above), as well as the compliance history of all other pump manufacturers affected by the coverage decision. We also ask that the wording in the memo suggesting that insulin pump coverage should be restricted as a result of "risks and problems with the device" be deleted.

Commercial Payer Policies on C-Peptide

Under the paragraph titled "Current Health Plan Policy" section, the draft memorandum says that the "requestor stated they were unaware of any commercial policy in the United States implementing C-peptide testing as a criterion for insulin pump use." The memo subsequently describes an insulin pump coverage policy issued by Aetna that incorporates a C-peptide requirement. Given that the text of the memo could be read by some to imply that Medtronic was either unaware or not forthcoming about commercial payer policies, we feel it is important to provide further clarification on the information provided by Medtronic on this topic.

We stated in presentations and follow-up letters with CMS that commercial payors "do not routinely use C-peptide as a coverage criterion," which is accurate. However, Medtronic did in fact call the Aetna policy to CMS's attention at the initial February 2003 meeting to discuss reopening the C-peptide coverage requirement. While we discussed the existence of the Aetna policy at that meeting, we stated that "in our experience, Aetna has not limited pump coverage based on C-peptide testing. In addition, their policy has not been updated to the revised 2002 CMS guidelines of a C-peptide level less than or equal to 110% of the lower norm of lab values."

Given that information about Aetna's coverage policy was communicated to CMS, we ask that the text under "Current Health Plan Policy" be clarified to remove any potential misunderstanding about the information provided by Medtronic to CMS.

Specific Coverage Manual Updates

The draft decision memorandum provides a summary of the changes CMS is proposing to the national coverage policy on insulin pumps. The memo, however, does not provide draft text of the actual proposed coverage policy. Medicare NCD Manual 280.14 (formerly 60-14) Section A.5 will need to be updated to reflect these changes.

We have attached some suggested wording to update the existing implementation guidelines that reflect our understanding of the draft decision memorandum. Revisions are shown using the "Track Changes" feature of Word.

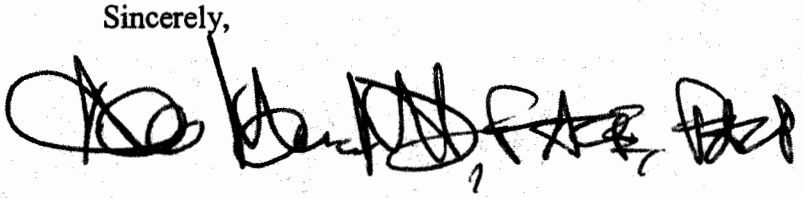
It is not our intent to preempt the work of your staff. Rather, it is our intent to share with you our understanding of the proposed changes in a format that lends itself to easy review and revision. We ask that you contact us if our draft revision of the current instruction is not consistent with your intent.

Conclusion

Once again we appreciate the positive changes recommended by CMS in the draft decision memorandum on the C-peptide coverage requirement. The draft policy would improve care by ensuring appropriate diabetes patients have access to insulin pump therapy. We also appreciate CMS taking into consideration the concerns raised in this letter.

We are looking forward to our discussion on Thursday, October 28th. Due to potential operational challenges when implementing this revised coverage decision, we would like to offer participation in the development of the implementation guidelines for operationalizing this revised coverage decision.

Sincerely,



Alan Marcus, MD, FACE, FACP
Director of Medical Affairs
Medtronic MiniMed

cc: Steve Phurrough, MD
Marcel Salive, MD

Attachment: Proposed Revisions to Medicare NCD Manual 280.14 (formerly CIM 60-14) Section A.5

5. Continuous subcutaneous insulin infusion pumps (CSII) (Effective for Services Performed On or After 4/1/2000).—

An external infusion pump and related drugs/supplies are covered as medically necessary in the home setting in the ~~following situation:~~

~~T~~treatment of diabetes.

In order to be covered, patients must meet criterion A or B and diabetes must be documented in accordance with criterion C:

Criterion A

The patient has completed a comprehensive diabetes education program, and 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, and 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 one or more of the following criteria while on the multiple daily injection regimen:

(1) Glycosylated hemoglobin level (HbAlc) > 7.0 percent
(2) History of recurring hypoglycemia
(3) Wide fluctuations in blood glucose before mealtime
(4) Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
(5) History of severe glycemic excursions

Criterion B

The patient with diabetes has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.

Criterion C

Effective for Services Performed on or after January 1, 2002, and before XXX, 2004, Diabetes needs to be documented by a fasting C-peptide level that is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method.

Effective for Services Performed on or after XXX, 2004, diabetes needs to be documented (once) by positive beta cell autoantibodies or by one of the following

fasting C-peptide testing requirements:~~(Effective for Services Performed on or after January 1, 2002.)~~

- A fasting C-peptide level must be less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method. Under this requirement, fasting C-peptide levels are considered valid only with a documented, concurrently obtained fasting glucose ≤225 mg/dL ±15%.
- For patients with renal insufficiency and documented creatinine clearance (actual or calculated from age, weight and serum creatinine) ≤50 ml/minute, diabetes may be documented by a fasting C-peptide level that is less than or equal to 200 percent of the lower limit of normal of the laboratory's measurement method.

Continued coverage of the insulin pump would require that the patient has been seen and evaluated by the treating physician at least every 3 months.

The pump must be ordered by and follow-up care of the patient 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.

Coverage of all other uses of CSII in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201) or as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1) is allowed.