Dear Ms. Shaw,
On behalf of the American Association of Clinical Endocrinologists (AACE), I have attached a letter, for your review, dated April 22, 2004, regarding C-peptide testing in the National Coverage Decision (NDC) for Continuous Subcutaneous Insulin Infusion (CSII) (Section 60-14). Originally, AACE sent this letter to the attention of Dr. Polansky; however, we have learned that yourself and Dr. Schott are now handing this matter. We appreciate your consideration of this important request and if you have any further questions, please do not hesitate to contact me.

Jennifer Carlin
jcarlin@aace.com
American Association of Clinical Endocrinologists
Administrative Assistant of Legislation and Socioeconomics
Phone: 904-353-7878 ext. 23
Fax: 904-353-8185

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

April 22, 2004

Ms. Betty Shaw
Centers for Medicare & Medicaid Services
Coverage and Analysis Group
Office of Clinical Standards and Quality
7500 Security Blvd.
C1-09-06 Mail Slop
Baltimore, Maryland 21244

Dear Ms. Shaw:

On behalf of the American Association of Clinical Endocrinologists (AACE), and its over 4,600 members, I am writing to request that CMS reconsider the current inclusion of C-peptide testing in the National Coverage Decision (NCD) for Continuous Subcutaneous Insulin Infusion (CSII) (Section 60-14). AACE worked closely with CMS during the initial coverage decision for insulin pump therapy and was actively involved with the 2001 policy which revised an absolute value for C-peptide level to the current policy stating that the C-peptide values must be less than or equal to, the lower limit of normal of the laboratory method +10%.

Based on published literature and clinical practice, AACE is requesting that CMS remove the C-peptide criteria from their CSII coverage policy. Although C-peptide testing can measure endogenous insulin production, it is a laboratory value that has minimal use as a clinical indicator in determining appropriate candidates for CSII. There are no studies to support the notion that C-peptide levels can guide patient selection or predict the success of insulin pump therapy. In medical practice today, the C-peptide test is not routinely done. The decision to initiate insulin therapy or CSII is based upon presenting clinical criteria, namely inadequate glucose control in the face of concerted efforts by patient and physician to achieve acceptable glucose levels.

Outside of the C-peptide test, we agree the Medicare clinical criteria for insulin pump coverage is consistent with clinical practice, payor policies and professional society recommendations.

1. Patient is unable to maintain HbA1c below 6.5% (see ACE Consensus statement on guidelines for Glycemic control-enclosed)
2. Patient has failed oral agents and followed a regime of multiple daily injections
3. Patient is able to monitor blood sugars 4 x day
4. Patient has severe glycemic excursions, (i.e., hypoglycemia or dawn phenomenon)
5. Patient has completed comprehensive diabetes education

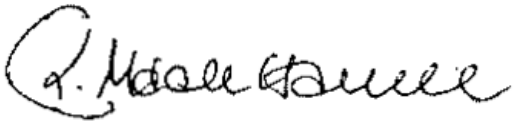
We are also acutely aware that C-peptide testing is not appropriate for people with renal insufficiency. In addition, we disagree with the current coverage policy which requires

existing pump patients to requalify for CSII with a C-peptide test once they become a Medicare beneficiary.

AACE requests that CMS remove the C-peptide criteria from the NCD for insulin pump therapy. Please feel free to contact me or Ms. Shelley Garrett at 904-353-7878 ext. 42 if you have any questions or need further information.

Thank you in advance for your time and consideration of this important request.

Sincerely,



Donald A. Bergman, MD. FACE
AACE President

R, Mack Harrell, MD, FACP, FACE
Chair, Managed Care/Third Party Relations Committee

cc: AACE Board of Directors
Managed Care and Third Party Relations Committee

Comment # 2:
Submitter: Erin Meyerhoff, FNP, CDE
Organization: University of Colorado Health Sciences Center
Date: Fri, April 23, 2004 7:03 PM

Comment:

With the review of criteria for using c-peptide for Medicare eligibility for an insulin pump, I would like the following factors considered:

1. c-peptide values reveal how much insulin a person is making. A person may be making enough insulin to be considered "normal". However, if this were truly normal and enough insulin for the person, their glucose levels would be normal and they wouldn't have diabetes. Many people with type 2 diabetes require insulin to control their blood glucose values because they may make insulin, but it is not enough for them to have normal glucose metabolism.
2. Adults that develop type 1 diabetes tend to loose their insulin secretion over a longer period of time than a child with type 1. They still may be making some insulin, but again, it is not enough to keep their glucose level normal. Because they are type 1, they require insulin and they are often very sensitive to insulin. They may only need 1 unit to cover a meal. Sometimes, one unit is too much and a pump is beneficial because it can deliver tenths of units of insulin for those that only need 0.2 or 0.3 units.
3. C-peptides are dependent on the glucose at the time of the blood draw. If the glucose is quite low, the c-peptide will also probably be low.

Comment #3:
Submitter: Antoinette Moran, MD
Organization: University of Minnesota
Date: Tue, April 27, 2004 10:04 AM

Comment:

I am a pediatric endocrinologist at the University of Minnesota with clinical and research expertise in the area of cystic fibrosis related diabetes (CFRD). Forty percent of adult CF patients and twenty-five percent of adolescents have diabetes. These patients are insulin deficient, but still make measurable amounts of insulin and c-peptide. Insulin sensitivity is normal except for when they are acutely ill. There is a well-established relationship between insulin deficiency and clinical deterioration in CFRD. BMI and pulmonary function deteriorate much more rapidly in CF patients with diabetes than in CF patients with normal glucose tolerance. Insulin deficiency leads to increased protein catabolism and fatty acid turnover. The resulting loss of weight and lean body mass contribue to pumonary disease and clinical decline. Protein catabolism and weight loss can be prevented if sufficient insulin is provided.

Traditional subcutaneous insulin injections are problematic for many CFRD patients. These people need to eat constantly, all day long, to consume the 3000-5000

kcal/day that many of them require to stay healthy. This requires multiple injections---often 6-8 per day. Not only does pump therapy reduce the number of injections, but it allows them to use dual, extended and combination waves in order to better match their "grazing" pattern of eating. In addition, the flexibility in basal rate helps prevent nighttime hypoglycemia, which is a common complication in CF patients treated with glargine.

There are other settings where I also believe it is appropriate to treat c-peptide positive patients with insulin pumps. In particular, I deal with adolescents with type 2 diabetes. About 80% of the adolescents with T2DM in our Pediatric Diabetes Clinic cannot be adequately treated with oral agents alone, and require insulin therapy. These patients are not so different from adolescents with type 1 diabetes---they require a flexible insulin regimen than can accommodate their varied schedules, sports activities, etc.

I believe that the requirement that pump patients be c-peptide positive is quite arbitrary. In particular, however, I wish to lobby for this requirement to be dropped for patients with cystic fibrosis, and for adolescents with type 2 diabetes. Thank you.

Comment #4:
Submitter: Ginny Prescott
Organization:
Date: Mon, May 31, 2004 2:44 PM

Comment:

In regards to the current insulin pump c-peptide requirement of Ü 110% of the lowest lab value for Medicare-covered diabetics, I would like to offer my feedback during this open public opinion period that this requirement should be waived, as it is not a valid or consistent measure of how individual persons may process their own body's insulin.

There are many type II diabetics that are eliminated from the consideration pool because of a c-peptide level that is failing based on the current criteria: i.e. it is "too high" to be considered for Medicare coverage of an insulin pump. Because of the significant benefits of tight diabetes control such as reduction of eye and kidney complications, which could ultimately lead to Medicare-covered disabilities of blindness and/or kidney failure (DCCT study proved this for type I diabetics, and The UK Prospective Diabetes Study (UKPDS) proved it for type II diabetics) , the choice of which therapy to use on an out-of-control diabetic patient seems obvious and has been no secret in Europe for many years, but is still a constant struggle for US type II diabetics in getting an insulin pump thru Medicare. The patients must wait with their insulin-resistance or poor control due to aversion to multiple daily injections until they are in renal failure before Medicare will qualify them for coverage of a potentially-life extending insulin pump. By this time, other complications and hospitalizations will have undoubtedly far exceeded the dollars spent by Medicare on the type II patient that has gone blind, required a kidney transplant, lost fingers or toes due to neuropathy, or had numerous hospitalizations from erratic glucose levels than the funds that would have been spent on a one-time purchase (not rental - diabetics do not cure of diabetes during the current 15-month rental period) of an insulin

pump in a four-year equipment warranted time period and ongoing maintenance of quarterly disposable supplies.

There is obvious faith in the efficiency of insulin pump therapy for both type I and type II diabetics (especially among the elderly or disabled patients with Medicare coverage that are prone to complications) as evidenced by the boom of competition in insulin pump manufacturers in the last five years that have obtained FDA approvals to begin dispensation in the US.

I strongly feel that the c-peptide requirement is obsolete, inefficient, and unfairly exclusionary of type II diabetic Medicare patients that deserve the same quality of life as their insulin-pumping type I counterparts.

HealthONE ROSE Medical Center

DIABETES CENTER

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop Cl-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

April 27, 2004

Dear Ms. Shaw and Dr. Schott:

I am writing to request that you revise the National Coverage Decision regarding insulin pumps to remove C-peptide levels as the only valid indicator for patients needing continuous subcutaneous insulin infusion (CSII). I am a certified insulin pump trainer for a number of insulin pump companies and a certified diabetes educator. I work with physicians to train the patients for whom they prescribe insulin pump therapy. This process takes many hours of training. I have been working exclusively with patients with diabetes for 15 years.

In the summer of 2003 I trained a patient in how to use an insulin pump. Her blood sugars and Hemoglobin A1c were improving and she was having fewer blood glucose excursions. Then in 2004 she became a new Medicare beneficiary and did not meet the C-peptide requirements. Her finances were such that she could not afford to pay, out of her own pocket, for the supplies to remain on her pump. She returned to insulin injections and her blood sugars have worsened over the past few months. This month she was hospitalized and studies of her heart indicate almost total blockage of her vessels. The cardiologist, who has been following her since a previous bypass surgery, feels that this recent increase in blood sugar level led to the heart vessels closing off. There are not many options for additional vessels to use in another bypass procedure. In essence, CMS's current policy and her need to go off her insulin pump has left this patient with a death sentence. When other clinical evidence including improved Hemoglobin A1c and fewer glucose excursions tell us that CSII is providing superior control than injection, these parameters should be enough to justify continuation of the therapy.

Please re-evaluate the current rules based on the latest evidence and consider the experience of this one patient, (I could relate others). Thank you for your attention.

Sincerely,

Rosanne G. Ainscough, RD, CDR
Registered Dietitian, Certified Diabetes Educator, Certified Insulin Pump Trainer

4545 EAST 9TH AVE. SUITE 020 • DENVER, COLORADO • 80220
PHONE: 303-320-2490 • FAX: 303-320-2585

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CLINTON
FAMILY MEDICINE
W. J. Patterson, MD
Jody Adams, CFNP
Molly Snuggs, CFNP

April 19, 2004

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

Dear Ms. Shaw and Dr. Schott:

Please consider removing the c-peptide requirement for Medicare patients to benefit from pump therapy. Although this decision will not affect many of my patients, there are a select few that could greatly benefit. I am asking, as a concerned practitioner, for you to please give us the ability to help the patients who could truly benefit from pump therapy by removing the c-peptide requirement.

Thank you for your consideration.

Sincerely,

jody adams, CFNP
Jody Adams, N.P.

Jody Adams, N.P.

106 Clinton Parkway Clinton, Mississippi 39056 1-601-924-9005 fax 601-925-9463

Palm Valley Medical Clinic, P.A.
Noel Lopez, M.D., F.A.A.F.P.
Charlotte Ballard, MSN, RN, ENP-BC
5140 N. 10th St.
McAllen, Texas 78504
Office 956-972-1600
Fax 956-972-0880

April 13, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:

I welcomed your recent decision to review the current C-Peptide requirement for the Insulin Infusion Pump.

For some time, I have questioned the ability of the C-Peptide test to identify who is or is not a good candidate for the Insulin Pump. I am a Family Practice physician and treat patients with diabetes on a daily basis. Over the past few years, I have been very successful in moving many of my patients to a more intensive level of control. This has involved a more intensive multiple daily injection regimen; and in some cases, this has been achieved by using an Insulin Infusion Pump. I consider pump therapy a valuable tool in my ability to treat and manage my patients with diabetes who are insulin requiring.

I have become aware of the C-Peptide requirement and consider it a limiting factor in my ability to move a Medicare patient into the best possible situation for long-term diabetes management and blood sugar control. The test is not one that I run for any of my patients to determine or classify their diabetes. A person either requires insulin to maintain blood sugars or they do not. I also consider the test to be very subjective and one that can be affected by several factors including current oral agents, blood sugars, or recent meals. The test result can often vary greatly from month to month or year to year.

Recently, I have been able to achieve very positive results with patients who are even on both orals agents and insulin. For these types of patients or those who are solely insulin requiring, the C-Peptide can effectively limit my ability to manage and achieve the best possible outcomes by moving these patients into Insulin Pump Therapy.

I would welcome a more subjective requirement that considers a patient's history and level of compliance as the sale standard for approval of an insulin pump. Please consider these issues when you are reviewing the current standards for approval of an Insulin Infusion Pump.

Thanks,

SUMMIT MEDICAL ASSOCIATES, P.C.

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STACY B. BROWN, RN, CS, FNP
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summitmedicalassociatespc

April 30, 2004
Mrs. Betty Shaw
Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop CI-09-06
Office of Clinical Standards and Quality
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Mrs. Shaw and Dr. Schott,

I am writing in support of the elimination of the c-peptide criteria as a means of determining whether or not a person with Medicare is eligible to implement Continuous Subcutaneous Insulin Infusion therapy.

On numerous occasions, I have encountered persons who are unable to maintain optimal blood glucose control despite implementation of exercise, nutritional therapy, and insulin therapy with multiple daily injections. For these persons, CSII therapy is recommended. I have found that different variables affect c-peptide results. Despite the understanding that a c-peptide monitors the amount of endogenous insulin, results tend to vary dependent upon the actual blood glucose level at the time in which the c-peptide is drawn. In one particular example, there is evidence that the c-peptide exhibited a direct correlation with the blood glucose level. The results were as follows:

Date	05/23/00	03/07/02	05/05/03	07/14/03
Blood Glucose	100	88	287	159
C-peptide	1.9	1.3	3.2	2.4
HbAlc	12.2	11.2	9.6	9.8

As you review the data, please note the correlation of the variations. This is why I feel that the c-peptide level less than or equal to 110% of the lower limit of normal, should not be considered as a criteria for persons who would benefit from CSII.

Thank you for your time and consideration in reviewing this information.

Sincerely,

Dara Botts, RNC, FNP, ADM-BC
Diabetes Clinical Specialist

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare& Medicaid Services
7500 Security BLVD
Baltimore, MD 21244

April 29, 2004

As the Coordinator of the Diabetes Education Program at Euclid Hospital In Euclid Ohio, I come in contact with many patients with diabetes. I do not think any diabetic whether type 1 or type 2, should be denied an insulin pump for treatment of their diabetes. Many patients have exhausted other modes of treatment and insulin pump therapy could at least be another option to achieve improved control.

I am aware that Medicare only approves pumps for type 1 diabetics. Patients with type 2 diabetes have the same challenges in obtaining good control and these individuals should not be denied the most physiologic manner of insulin administration.

I understand you are accepting comments on whether the C-peptide criteria should be removed. I believe the diagnosis of type type 1 or type 2 should be made by a physician for it is not necessary to confirm the diagnosis previously made by a physician. Therefore not only am I in agreement with the removal, but as indicated above I believe whole heartedly, that people with type 2 Diabetes should have every available technology ie: pump therapy to maintain optimal control and prevent the devastating complications of diabetes and the costly burden of treating these complications.

On behalf of the thousands of patients I have worked with and will continue to work with in the future, I request your consideration of the above request.

Sincerely,

Eva Bradley RN BSN CDE

Eva Bradley, BSN, CDE

Lowcountry
Medical Associates
Family Practice · Internal Medicine · Pediatrics
West Ashley Primary Care

Internal Medicine
John P. Davis, Jr., M.D.
Timothy J. Jones, M.D.
William P. Clare, Jr., M.D.
R. Levern Livingston, M. D.
Alexander W. Marshall, Jr., M. D.
Elizabeth S. Burns, A.N.P.
Pamela Bright-Chambers, A.N.P.

Pediatrics
Cynthia M. Heldrich, MD

April 26, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Re: C-peptide criteria for insulin pump therapy

Dear Ms. Shaw and Dr. Schott:

This letter is to request removal of the C-peptide criteria from the National Coverage Decision for patients with diabetes who require insulin pump therapy. As a Nurse Practitioner and Certified Diabetes Educator, I see many people who benefit from insulin pump therapy. In my experience Medicare is the only third party payer who requires a C-peptide prior to initiation of insulin pump therapy. In addition, C-peptide levels are increased in renal failure. As you know, a majority of patients who have diabetes also have renal disease. It is well established in the medical literature and in medical centers throughout the country the programmable insulin pump is extremely effective in maintaining control of insulin-requiring diabetes when other methods have failed.

I submit two patients from our practice. The first is a 43-year-old male liver transplant patient who had severe glucose excursions and recurrent seizures from hypoglycemia. He was taking *70/30* bid. The unpredictable absorption of insulin made his already brittle diabetes difficult to manage. His therapy was changed to long-acting insulin at bedtime with fasting acting before meals. His control improved, but his A1C remained above an acceptable range. We began testing C-peptide in May 2002 in preparation for initiating pump therapy. The initial results did not meet the Medicare requirements. Over the next 18 months we periodically repeated AIC levels. In November 2003 when the C-Peptide level returned at <0.5 he was placed on a MiniMed insulin pump. I am happy to report he has had no further severe hypoglycemic episodes and last A1C was 6.6.

2270 Ashley Crossing Road, Suite 170
Charleston, South Carolina 29414
phone (843) 763-3700 fax (843) 763-3714

The second patient is a 44-year old female who had insulin-requiring diabetes for 23 years. She managed her diabetes with an insulin pump prior to receiving Medicare benefits. On injections she experienced nocturnal hypoglycemia and hypoglycemia unawareness. She also has the complications of peripheral vascular disease, coronary artery disease and diabetic gastroparesis. She had coronary artery bypass surgery in December of 2000. Clearly she benefited from pump therapy and to have to resume multiple daily injections would have been disastrous.

With today's technology, treatment and tight glucose control we are able to prevent costly and life-threatening complications of diabetes. Please join us in our efforts to provide the quality of life and treatment options that our patients deserve and discontinue C-peptide requirements for insulin pump therapy.

Your attention to the matter is appreciated.

Sincerely,

Pamela Bright-Chambers, RN, MSN, ANP, CDE

Apri1 15, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:

I recently became aware of your intentions to review the C-Peptide requirement that is currently in place for approval of an Insulin Infusion Pump.

For some time, I have questioned the ability of the C-Peptide test to identify who is or is not a good candidate for the Insulin Infusion Pump. I am a Family Nurse Practitioner and treat patients with diabetes on a daily basis. My practice consists of patients from all demographics with a great deal being of Medicare age.

Over the past few years, I have been very successful in moving many of my patients to a more intensive level of control. This has involved a more intensive multiple daily injection regimen; and in some cases, this has been achieved by using an Insulin Infusion Pump. I consider pump therapy a valuable tool in my ability to treat and manage my patients with diabetes who are insulin requiring.

I consider the C-Peptide requirement a limiting factor in my ability to treat and care for a Medicare patient who has moved into insulin therapy. In some of these cases, I consider the use of the Insulin Pump to be the best possible situation for long-term diabetes management and blood sugar control. I realize that not everyone is a candidate for an insulin pump and that there are certain standards and requirements that are needed before this decision is made. I do feel, however, that in some cases the C-Peptide requirement prevents me from treating my patients to the best of my ability and negatively affects my patient's health in the long run.

I would welcome a more subjective requirement that considers my intentions, a patient's history and level of compliance as the sole standard for approval of an insulin pump. Please consider these issues when you are reviewing the current standards for approval of an Insulin Infusion Pump.

Thanks,

Jean Gisler, FNP-C

Jean Gisler, FNP-C

April 26, 2004

Ms. Betty Shaw and Dr. Lawrence Schott:

I am writing this letter as a concerned Diabetes Educator. I have been working with one gentleman in particular who had been on an insulin pump for approximately the last 5 years with excellent outcomes. His A1C's were within normal ranges while he was on the pump-he was able to live his lifestyle (which for him includes the ability to have varying computer work hours/meal times/dosing of insulin--on a schedule that varies from day to day).

However, when he changed over to Medicare being his primary insurer-despite-the facts that the insulin pump system which he had been using was meeting both quality of life and control of disease process issues-he was required to have the c-peptide test run. Based on the results that were received back-he was declined approval of having his supplies covered by Medicare.

While standards and criteria do have to be developed for re-imbursement, in his particular instance, and I would suppose that there are many others like him-I strongly feel that the successful track record/results from having used the pump with better control should have been taken into consideration at a much higher percentage of weighting-either in place of but at least in addition to any c-peptide levels.

Thank you for taking this situation into consideration along with all the other scenarios which you are reviewing related to the c-peptide level requirement/insulin pump therapy approval.

Sincerely,

Susan K Gilbert

Susan K. Gilbert, R.N., B.S.N.-Diabetes Educator
Northern Michigan Hospital's Diabetes Center

CC: NMH file
Steven P. Iskenderian
Ms. Betty Shaw
Dr. Lawrence Schott

Barnes-Jewish Hospital

4921 Parkview Place
St. Louis, Missouri 63110

BJC HealthCare℠

To whom it may concern,

In response to (#CPG-D0092N)

In response to the web memo on C-peptide criteria, I feel it is important to emphasize a few points that as a Nurse Practioner, I feel are important.

Most people familiar with diabetes would agree with the following to support withdrawal of utilizing C-peptide level as criteria for insulin pump candidates.
• C-peptide levels and assays are inconsistent.
• C-peptide is elevated in patients with kidney failure. Kidney failure is a complication of diabetes that requires insensitive management and glycemic control yet the Cpeptide criteria
• C-peptide levels are affected by Corticosteroids, oral contraceptives, deferoxamine, rifampin, terbutaline and propranolol (all common therapies used by patients with diabetes.)
• C-peptide levels do not change the medical management of the diabetes.

Sincerely,

Diane O'Reilly RN BC-ANP

Diane O'Reilly, RN BC-ANP.

April 23, 2004

To Whom It May Concern:

As an Advance Practice Nurse in a small rural community, I deal each day with elderly patients with diabetes, usually Type 2, who have been send to me for recommendation related to their current insulin dose. The HbAlc is usually elevated above 8.5% and the fasting blood glucose is averaging 150-170 mg/dl. A frequent finding is the patient has been adjusting the insulin dose to prevent hypoglycemia which occurs most often during the night. This finding corresponds to the results of research conducted by Furuyu and colleagues, as reported by Inzucchi & Sherman (2003). The results indicated, "The more frequent the [hypoglycemic] episodes, especially nocturnal hypoglycemia, the more patients decreased their dose of insulin, intentionally targeting a higher glucose so that further hypoglycemia couid be avoided" (p.6). The results of additional research presented at the 63rd Annual Session of the American Diabetes Association, and reported by Inzucchi & Sherwin indicate similar findings. "Forty-five percent of the people with Type 2 diabetes cited fear of hypoglycemia as a cause for their reluctance to use insulin" (p.20). Benjamin (2000) states, "The chief concern about tight control in elderly patients with diabetes is the risk of hypoglycemia. The elderly are in general less aware of signs of hypoglycemia and are particularly at risk for this complication" (p.118).

In an attempt to readjust insulin doses to improve glycemic control, and to lessen the occurrence of nocturnal hypoglycemia, I am often faced with informing the patient that the manufacturer pre-mixed insulin is the problem. And that to improve the problem, the patient will need to agree to take three, or more recently, four injections a day. Riddle (2000) supports this finding when he stated, "With the progression of Type 2 diabetes, many people will eventually need insulin and often not just one or two injections of long-acting insulin but a full-scale multiple injection regimen" (p.195).

Each patient, and with good reasons, can find barriers to a multi-dose insulin regimen. What may not seem like a significant barrier to the health care provider is, none the less, a barrier to the patient who has to perform the function. Kirchbaum, et al. (2003) state that "People with diabetes perform 95% of their [diabetes] care" (p.659). Therefore, if the patient is unwilling to change, there may be little that can be done to improve glycemic control. But what does the health care provider do for the patient who acknowledges that change is needed and has demonstrated willingness to follow dietary and activity recommendations as well a self-blood glucose monitoring multiple times a day, but sees carrying insulin and supplies as a barrier? Or the patient who experiences higher blood sugars 16 hours after a glargine dose? Or the patient whose eyesight is poor and is unable to draw up insulin safely but is limited by the glargine packaging insert that states the dose may not remain stable when syringes are pre-filled and stored? Or the patient who, when placed on multi-dose insulin analogs, continues to experience nocturnal hypoglycemia in an effort to lower fasting blood sugars?

Even in the presence of such barriers, Ousman & Sharma (2001) challenge providers of care by stating, "Unless contraindications exist, a near normal or normal level of glycemia, as manifested in a normal HbAlc, should be a goal of didactic therapy" (p.77). Benjamin (2002) indicates that the elderly should not be excluded from a goal of normal glycemia

when he states, "Studies have found that elderly patients with elevated fasting blood glucose levels have a 50% higher cardiovascular and all-cause mortality" (p.118).

So, are there gold standard exclusions to optimal glycemic control? And if there are, what are they? Should the range of a C-peptide level be one of Ousman & Sharma's "contraindications" when considering an insulin pump? Or should an insulin pump, which has helped people with Type 1 diabetes achieve the goal of glycemic control be withheld, based on the presence of endogenous insulin, from a person with Type 2 diabetes and insulin resistance? The insulin resistant patient may have diminished endogenous insulin production, but more common is a finding of adequate or increased endogenous insulin, but the lack of insulin recognition at the cellular level. Complicating insulin resistance is an increasing idea that oral insulin sensitizers, once thought to be the answer to the cellular recognition deficit, are now found to have more limited use based on impaired hepatic, kidney and ardiovascular function in the elderly.

Or should a person's age be a "contraindication"? Benjamin goes on to state that "Careful selection of elderly patients for aggressive glycemic control will result in lower rates of diabetic complications and hypoglycemia" (p.118). Benjamin does not list the C-peptide level as one of the selection criteria. Lewis, reporting in the April, 2004 issue of Endocrine today, suggests, not from research findings, but anecdotally from care providers that "pump therapy [when used correctly by a motivated patient], can "stabilize blood glucose within a narrow range of control". Lewis also reports that "not all patients are candidates for the insulin pump" and the patient's health care provider needs to consider patient history, motivation and willingness to self-manage, as well as cognitive and technical ability to manage insulin pump therapy. None of which is found on a C-peptide level.

Gail J. Schnieder, Geriatric Clinical Nurse Specialist, CDE, CWOCN
Diabetes Education Center,
1104 East College Drive,
Marshall, MN 56258

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Henry Ford Health System

DIVISION OF ENDOCRINOLOGY
& BONE AND MINERAL METABOLISM
Henry Ford Hospital

Dorothy M. Kahkonen, **MD**
Division Head

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April 27, 2004

To Whom It May Concern:

I urge you to reconsider your decision re: The need for C-peptide test in relationship to authorization of pump candidacy.

I am employed in a very large urban hospital and we teach many pump patients. In the past, we have had experience with individuals whom fit all pump candidacy criteria, except for C-peptide value. These patients are being denied the opportunity for improved quality of life and decreased risk for diabetes related complications, due to this lab test.

The C-peptide test can vary in relation to collection time, as well as fasting status, etc. Just recently, I heard from a patient whom one month ago did not make guidelines based upon C-peptide results. I suggested she repeat the test in the early a.m., in fasting state. She communicated to me that now, her C-peptide was low enough and she has been approved for a pump.

That illustrates the variability of this test which can undermine pump approval. The true markers for adequate candidacy should include: motivation, glucose testing, multiple daily injections, ability to follow up and follow through and ability to problem solve.

Thank you for your consideration.

Sincerely,

Kelly A. Mann, RN, BSN, CDE

KELLY A. MANN, RN, BSN, CDE
Endocrinology & Metabolism

KAM:sg

GRAND RAPIDS ASSOCIATED INTERNISTS, PC.

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Internal Medicine
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Robert S. Rood, M.D.
Daniel R. Drumm, M.D.
Michael T. Bodley, M.D.
Nancy Wolotira, MS, RNC, CDE
Adult Nurse Practitioner

Diabetes
Robert S. Rood, M.D.
Susan Owen, R.N., MSN, CDE

April 28, 2004

To Whom It May Concern:

I am an Advanced Practice Nurse with a Specialty in Diabetes. I have worked with a diabetologist for 13 years, and during that time initiated insulin pump therapy in well over 500 patients. The age range of those patients is from 13 to 80. It has been one of the highlights of my career, watching what people can do to improve their care, when given the appropriate tools. But yet, there were those that "weren't allowed" due to the Medicare stipulation of a C peptide level.

Some of the most dramatic improvements I have seen were in patients that, if under the Medicare system, would not have been eligible for the benefit of an Insulin pump. One such patient, Mr. M. He was on over 180 units of insulin per day, and two oral agents. He suffers profound insulin resistance. Such high doses of insulin, while safe, do not encourage weight loss, which is integral to the improvement of his glucose control. Despite the high doses, his control was suboptimal. He made the decision to start insulin pump therapy and the results have been gratifying. Mr. M's glucose control, as judged by daily self testing, and Ale, has shown steady improvement. He feels better, is more interested in exercise, and is starting to lose weight. He has less episodes of hypoglycemia, despite an active job. He would not have met the C-Peptide criteria under Medicare guidelines, and I would not have been able to report such a success story to you.

Conversely, Mr. B also suffers uncontrolled diabetes with profound insulin resistance. He was denied a pump on the criteria of the C peptide 3 years ago, and continued to struggle with his diabetes and depression. Professionally, I know what this gentlemen needs, but the criteria exclude him from having the tool he so desperately needs to gain control of his diabetes, his depression, and his life. You see, insulin pump therapy, for many people like Mr. B is a life changing experience. They have felt bad for so long due to suboptimal control they can hardly believe how well they feel when the glucose control evolves.

I have many more patients with similar issues, but in the interest of time and paper will close with a plea that you strongly consider dropping the requirement of C Peptide for the benefit of those persons with diabetes, who could greatly improve their health given the tool of an insulin pump.

Respectfully,

Susan Owen

Susan Owen RN MSN CDE

Dean
HEALTH SYSTEM

April 27, 2004

To Whom It May Concern:

It has come to my attention that criteria for Medicare reimbursement for an insulin pump are being reevaluated. Currently, one of the criteria for Medicare reimbursement includes an abnormal C Peptide result, which is indicative of type 1 diabetes.

In view of the fact that intensive management has been shown to benefit people with both type 1 and type 2 diabetes, insulin pump therapy is clearly an option of treatment. Considering patients with both type 1 and type 2 diabetes for insulin pump therapy would negate the need for a C Peptide test. Therefore, I would ask that the requirement of a C Peptide test be dropped as a requirement for Medicare reimbursement for an insulin pump.

Thank you for considering this recommendation.

Sincerely,

Jean E. Espenshade RN PhD

JEAN ESPENSHADE, R.N. , PhD
DIABETES NURSE SPECIALIST

Dean
HEALTH SYSTEM

April 27, 2004

To Whom It May Concern:

It has come to my attention that criteria for Medicare reimbursement for an insulin pump are being reevaluated. Currently, one of the criteria for Medicare reimbursement includes an abnormal C Peptide result, which is indicative of type 1 diabetes.

In view of the fact that intensive management has been shown to benefit people with both type 1 and type 2 diabetes, insulin pump therapy is clearly an option of treatment. Considering patients with both type 1 and type 2 diabetes for insulin pump therapy would negate the need for a C Peptide test. Therefore, I would ask that the requirement of a C Peptide test be dropped as a requirement for Medicare reimbursement for an insulin pump.

Thank you for considering this recommendation.

Sincerely,

(Paul Bekx, MD - Endocrinologist)

Dean
HEALTH SYSTEM

April 27, 2004

To Whom It May Concern:

It has come to fly attention that criteria for Medicare reimbursement for an insulin pump are being reevaluated. Currently, one of the criteria for Medicare reimbursement includes an abnormal C Peptide result, which is indicative of type 1 diabetes.

In view of the fact that intensive management has been shown to benefit people with both type 1 and type 2 diabetes, insulin pump therapy is clearly an option of treatment. Considering patients with both type 1 and type 2 diabetes for insulin pump therapy would negate the need for a C Peptide test. Therefore, I would ask that the requirement of a C Peptide test be dropped as a requirement for Medicare reimbursement for an insulin pump.

Thank you for considering this recommendation.

Sincerely,

Paul M Reber, DO
Endocrinologist

Paul M Reber, DO
Endocrinologist

Dean
HEALTH SYSTEM

Apri1 27, 2004

To Whom It May Concern:

It has come to my attention that criteria for Medicare reimbursement for an insulin pump are being reevaluated. Currently, one of the criteria for Medicare reimbursement includes an abnormal C Peptide result, which is indicative of type I diabetes.

In view of the fact that intensive management has been shown to benefit people with both type 1 and type 2 diabetes, insulin pump therapy is clearly an option of treatment. Considering patients with both type 1 and type 2 diabetes for insulin pump therapy would negate the need for a C Peptide test. Therefore, I would ask that the requirement of a C Peptide test be dropped as a requirement for Medicare reimbursement for an insulin pump.

Thank you for considering this recommendation.

Sincerely,

Susan Engeseth R.N., APNP

Susan Engeseth, R.N., M.S., C.S.

April 22, 2004

To Whom It May Concern:

I understand that the current criteria for a Medicare reimbursed insulin pump is being re-evaluated. Currently, one of the criteria for a pump includes a C Peptide test. While the C Peptide test can help differentiate diagnosis between type 1 and type 2 diabetes, the C Peptide test results are not related to being a candidate for insulin pump therapy or the benefits that they would receive from that treatment. This is not a valid criteria in assessing people with Type 1 or Type 2 diabetes mellitus for obtaining pump therapy. C Peptide levels are not obtained prior to pump therapy on patients not on Medicare. The test is actually an added expense in many circumstances. I am hopeful that in your review of the criteria that C Peptide testing is taken out of the requirements for Medicare.
Thank you for your consideration.

Sincerely,

April Eddy, RN. CNS, CDE

Meriter Hospital, Inc.
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Madison, WI 53715-1596

608 267-6000
www.meriter.com

Date: 4-27-04

To: Ms. Betty Shaw & Dr. Lawrence Schott
Coverage & Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards & Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

From: Michael Adler, MD
207 N. Main Street
Plains, PA 18705
570-270-4699

Subject: Request to remove C-Peptide Criteria for Medicare Insulin Pump Patients

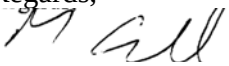
Dear Ms. Shaw & Dr. Schott,

I'd like to request the removal of the C-Peptide Criteria for Medicare Insulin Pump Patients. As a prescribing Endocrinologist of insulin pumps for well over 5 years I have numerous Medicare insulin pump patient and feel that C-Peptide levels are not valid as a determining factor for insulin pump therapy.

I have numerous pump patients with C-Peptide levels well out of Medicare's required ranges that have experience excellent clinical results with pump therapy for the management of their diabetes. (reduction of HAlc levels, greater control of glucose levels, reduction in the potential for secondary complications associated with diabetes, etc.)

I sincerely feel that the removal of Medicare's C-Peptide criteria is necessary and I appreciate your consideration.

Regards,



Michael Adler, MD

AbdulrahmanAlbustamy, M.D.
DIABETES - ENDOCRINOLOGY
5428 South Jackson Road • Edinburg, Texas 78539 • (956) 994-3627 • Fax (956) 618-5576 • Exchange 630-9290

April 14, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:

Thank you for the opportunity to comment on the current and future C-Peptide requirement in relation to the Insulin Infusion Pump.

I have become increasingly concerned over the past few years as to the effectiveness of this standard due to the fact that I am trying to move a limited number of my patients into pump therapy who are considered insulin requiring but still have a level of C-Peptide production that is above the current threshold. These are patients that I have moved through insulin/oral regimens and have not been able to obtain the control that they or myself desire for good diabetes management. In all of these cases, I consider these patients' excellent candidates for pump therapy. A move to the insulin pump would, in most of these cases, increase the level of overall control and allow these patients to reduce the risk of developing costly complications in the future.

I have seen a dramatic increase in the number of Type 2 patients who have moved into an intensive insulin regimen. These patients have been able to manage the insulin pump effectively and have been able to achieve a level of control that would not otherwise be achievable on the standard multiple daily injection regimen. The current C-Peptide requirement is different from any third party insurer or even Medicaid standards and currently limits my ability to move my patients into the Insulin Infusion Pump. As it stands now, my Medicare patients do not have this option due to the current standards/requirements. These patients will have to continue to try and manage their diabetes on their current injection regimens. I many of these cases, the risk of developing costly complications due to their diabetes will be increased.

I would welcome a move to abolish this arbitrary standard that prevents some of my patients achieving the best possible standard of care.

Thanks,

NADINE H. ALEX, M.D.
Board Certified in Internal Medicine
and Endocrinology

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PHONE: 724.347.1861
FAX: 724.347.2532

CATHERINE GUTOWSKI, CRNP, MSN,CDE
TAUNYA M. SKROK, PA-C, MPAS

4/25/04

Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security BLVD
Baltimore, MD 21244

Dear Ms. Shaw and Dr Schott:

I am writing in regards to using C-Peptide as criteria for approval of insulin pumps among Medicare and Medicaid eligible patients. I recommend dropping C-Peptide as criteria for the following reasons:

1) Often patients with Diabetes Type 1 have partial autoimmune destruction of the islet cells in the pancreas, hence still having detectable C-Peptides, but are DKA prone and labile, nevertheless. They have been denied a desperately needed insulin pump.

2). Often patients with Diabetes develop impaired renal function, which could art factually increase their C-Peptide.

3) I have had several patients that have had excellent control on an insulin pump, but were denied coverage by Medicare when they became Medicare eligible. To note is that many other insurance companies do not use C-Peptide as a criteria, but focus on other features, such as labile blood sugars with high incidences of hypoglycemia and DKA, end-organ complications, and chronically poor control despite compliance with an excellent 4-shot/day regimen.

Thank you for your attention in this matter.

Sincerely,

Nadine H. Alex, MD

ENDOCRINOLOGY NUCLEAR MEDICINE ASSOCIATES, P.A.
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April 16, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:

I recently became aware of your intentions to review the C-Peptide requirement that is currently in place for approval of an Insulin Infusion Pump.

For some time, I have questioned the ability of the C-Peptide test to identify who is or is not a good candidate for the Insulin Infusion Pump. I am an Endocrinologist with a large diabetic population. My practice consists of patients from all demographics with a large percentage being of Medicare age.

I realize why the C-Peptide has been in place and can assure you that a removal of this requirement would not result in an increase or flood of patients into the insulin pump. I consider the Insulin Pump to be a very useful tool for those patients who have moved into an intensive therapy regimen or are no longer successful on their current therapy. The Insulin Pump, however, is not for every patient and I am very cautious as to which of my patients are considered candidates for the Insulin Pump. In the case of some of my Medicare age patients who have been considered for the pump, the C-Peptide has prevented them from obtaining the best possible therapy. These individuals are considered highly motivated and qualified candidates.

In addition, I have several patients who are very successful on Insulin Pump Therapy who are now covered by Medicare. The c-peptide rule has caused considerable issues due to coverage. The respective patients c-peptide level is higher than the range allowed by Medicare. The patients cannot receive coverage for their supplies. In most cases, their secondary follows Medicare guidelines. One particular patient has a Whipple. His c-peptide will never be in the range allowed by Medicare. He (an MD) has been on pump therapy successfully for the past 6 years. Now, due to the current guideline, he cannot receive coverage for his insulin pump.

I would welcome a more subjective requirement that considers other factors such as a patient's history and my intentions as the sole standard for approval of an insulin pump. Please consider these issues when you are reviewing the current standards for approval of an Insulin Infusion Pump.

Thank you,

Richard M. Becker

ATLANTA
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R. DENNIS STEED, M.D.
DAVID G. ROBERTSON, M.D.
N. SPENCER WELCH, M.D.
CAROL GREENLEE, M.D.

April 26, 2004

Ms. Betty Shaw
Lawrence Schott, M.D.
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: C-Peptide Criteria for Insulin-Pump Patients

Dear Sir
I am writing this letter to request that you reconsider using C-peptide as one of the criteria for allowing patients on Medicare/Medicaid to obtain an insulin pump.

I am an expert in the field of insulin-pump therapy, as well as Type 1 diabetes. Our group has started over 2000 patients on insulin pumps, dating back to 1981, and we have a great deal of experience in the field of insulin-pump therapy in both Type I and Type 2 diabetes. In addition, I am the editor of the 2004 Fourth Edition of the *Medical Management of Type 1 Diabetes,* which is one of the American Diabetes Association's Clinical Education Series books. Further information on insulin-pump therapy and diagnosis, classification, and pathogenesis of Type 1 diabetes can be found in that book, as well as the value of C-Peptide in determining Type 1 diabetes.

The reason I believe that C-peptide should be removed from the list of criteria for institution of insulin pumps, is as follows:

1. C-peptide is a poor determinate of Type 1 diabetes within the first five years of diagnosis. All individuals with Type 1 diabetes, new onset (even presenting with ketoacidosis) usually have normal levels ofC-peptide. Over time, the C-peptide slowly diminishes in adults, with a more rapid disappearance in children. Thus, C-peptide to diagnosis Type 1 diabetes, within the first few years of onset, is of minimal benefit at best. The best criteria at that time would be islet cell antibody markers, which are currently only 75-90% sensitive. In addition, it is the goal of treatment of all Type 1 patients at onset, to do whatever you can for the individual to help maintain islet cell function, measured by C-peptide secretion. The best way to accomplish this is by placing the individual on either multiple daily injections or insulin-pump therapy. It was clearly shown in the Diabetes Control and Complications Trial that people entering the trial, that were within five years of the onset of diabetes, had greater retention of C-peptide and insulin secretion five years later, if intensive therapy was employed. There is one study in Italy by Paolo Pozzilli, which is entitled, "CSII vs. Intensive Insulin Therapy at Onset of Type 1 Diabetes: IMDIAB8, Two-year Randomized Trial", *(Diabetes,* Vol. 51, Supp. 2, June 10,

2002, Abstract 14-0R) showed that implementation of CSII at diagnosis of Type 1 diabetes is associated with protection of residual beta cells and an increase of endogenous insulin secretion. In addition to this study, many people who have Type 1 diabetes continue for years to maintain some C-peptide excretion, often above the lower limit of normal. Part of this is due to renal disease and their inability to excrete C-peptide in their kidneys, as well as other unknown factors.

2 Another reason to delete C-peptide as one of the criteria for institution of insulin pump therapy, is that certain Type 2 patients have been clearly shown to benefit from insulin-pump therapy. There are several articles on the benefit of insulin pump therapy in Type 2 diabetes. The most recent randomized, multi-centered, parallel group study of 127 Type 2 diabetes patients was published in *Diabetes Care* (Raskin P, Bode B, Marks J et al. Continuous subcutaneous insulin injection and multiple daily injection therapy are equally effective in type 2 diabetes. *Diabetes Care* 2003; 26:2598-2603) showing that both multiple daily injections and insulin-pump therapy are able to significantly improve glycemic control in Type 2 patients. The insulin-pump therapy group lowered AlC by 0.7 points, whereas the MDI group showed a 0.5 decrease in AlC. There was no significant difference in Al C between the two groups; however, the CSII group had better post-breakfast glucose control. The main benefit in the CSII group of patients was improvement in quality of life and greater acceptance of intensive insulin therapy, in this highly resistant group of Type 2 patients already failing conventional insulin therapy. This has also been published by Testa in *Diabetes*, June 2001

We have many patients who have positive C-peptide values in the 1-3 range, who currently fail multiple daily injections and even have episodes of ketoacidosis with hospitalization. Out of desperation, we have loaned them insulin pumps in order to keep them out of the hospital, improve their glycemic control and lessen future hospitalizations. We have several cases where this has dramatically improved the diabetes control in these Medicare patients, in spite of C-peptides being in the 1-3 range. I would be more than happy to give you those cases directly and have you examine the records (names protected via HIPPA regulations).

In summary, I would recommend removing C-peptide as one of the criteria for insulin pump therapy. I agree completely with your other criteria for insulin pump therapy which are: patient has been on an intensive regimen, including multiple daily injections, and is having inadequate glycemic control, marked variability in glucose levels, or a history of severe hypoglycemia or hypoglycemic unawareness. In addition to these criteria, the patient has to have shown the ability to monitor four times a day, inject insulin in a multi-daily injection format, follow up with physician on a consistent basis, and have some knowledge of carbohydrate counting, with visitation from a Diabetes Educator or Registered Dietitian.

If I can be of further help, please call me.

Sincerely yours,

Bruce W Bode

Bruce W Bode, M.D.
BWB/asm

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The Endocrine Group
Practice Limited to Endocrinology & Metabolism
Deaconess Medical Offices, Suite 310 • 5401 N. Portland • Oklahoma City, OK 73112
(405) 951-4160 • (405) 951-4162 fax

Cheryl S. Black, M.D.
Matthew T. Draelos, M.D.
James L. Males, M.D.
Ronald P. Painton, M.D.

April 27, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group Office of Clinical Standards and Quality
Mail Stop C1-09-06
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Ms. Shaw and Dr. Schott:

I am writing to you to request that you do away with the C-peptide requirement in order to prescribe insulin pumps to diabetics.

I am an endocrinologist who has a very active practice of Type 1 and Type 2 diabetes. Many of my Type 1 diabetics are on an insulin pump. On one hand, I feel that it is to some extent a waste of medical resources to retest patients who have by history been diagnosed with Type 1 diabetes and have been managed since the onset of diabetes with insulin. It is redundant to go back and try to document Type 1 diabetes.

Secondly and most importantly, I do not feel that the use of insulin pumps should be limited just to Type 1 diabetics. There are many diabetics who do not clearly fall into the category of either Type I or Type 2. In fact, I have several diabetic patients who have measurable C-peptide, but who are quite sensitive to insulin and are not at all responsive to oral agents. I have put many of these patients on pumps and they do quite well. To say that pump therapy is no longer an option to them because they have reached Medicare age and have a C-peptide is not seen in the best medical interest of these patients. I feel that as an endocrinologist who specializes in treating diabetes my clinical opinion is better than any test when it comes to making a determination as to how someone will do on an insulin pump. Certainly, I do not put all of my Type 2 diabetics on a pump, but a few of them are candidates for a pump and do quite well and I do not think that this option should be prohibited on the basis of a laboratory test. Therefore, on this basis I would urge you to revoke the requirement of low C-peptide before being able to prescribe an insulin pump and look at a more broader clinical picture and take into account of clinician judgement.

Sincerely,

Cheryl S Black

Cheryl S. Black, M.D.
CSB/sat

Ken M. Brantley, M.D., Ph.D., P.A.
INTERNAL MEDICINE
ENDOCRINOLOGY & DIABETES
1215 S. COULTER STREET, SUITE 405
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April 12, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:

Thank you for letting me address the current and future C-Peptide requirement in relation to the Insulin Infusion Pump. The C- Peptide criteria is one that has limited my ability to treat and care for my Medicare patients for some time and I urge you to reconsider the criteria.

Over the past several years, I have seen an increase in the amount of Type 2 patients who have moved into an intensive insulin regimen. My experience is that with the more intensive an insulin regimen - the better the level of control and outcomes I achieve with my patients. The current C-Peptide standard is different from any private payor or even Texas Medicaid standards and currently restricts my ability to move my patients into the Insulin Infusion Pump. I have worked with several patients who have been considered excellent candidates for the pump but have been denied because of the lack of a qualifying under the current criteria. This has made it much more of a challenge for these patients to achieve the best level of control possible and has contributed to an increased risk for diabetic complications.

I would support a decision to abolish this arbitrary standard that prevents some of my patients achieving the best possible standard of care.

Thanks,

Kenny Brantley, MD

ENDOCRINOLOGY ASSOCIATES, INC.

CARL H. BIVENS, M.D., F.A.C.P., F.A.C.E.
MICHAEL H. KOCH, M.D., F.A.C.E.
D. JAMES BAILEY, III, M.D.

1030 SOUTH JEFFERSON ST., SUITE 200
ROANOKE, VIRGINIA 24016

PHONE (540) 344-3276
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April 26, 2004

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

Dear Ms. Shaw and Dr. Schott:

I'm happy to learn that Medicare is re-evaluating the requirement for C-peptide measurements to qualify Medicare recipients for coverage for insulin pump infusion therapy. In my experience, C-peptide measurement is not a valid indicator for patients who would benefit from insulin pump infusion therapy. There are also factors which influence C-peptide measurement including those patients with chronic renal insufficiency. Patients who are also currently on insulin pump infusion therapy run the risk of not being able to continue their therapy when their insurance changes to Medicare.

I would strongly urge you to reconsider the C-peptide requirement for the use of insulin pump infusion therapy. I strongly believe that this requirement poses a barrier to patients who would greatly benefit from this type of therapy. I thank you for your consideration of this matter and look forward to the results of your decision.

With kindest regards.

Sincerely,

D. James Bailey, III, M.D.
DJB/vs
C:Meditronic MiniMed Rep

April 20, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:

For some time, I have questioned the ability of the C-Peptide test to identify who is or is not a good candidate for the Insulin Pump. I am an Endocrinologist and treat patients with diabetes on a daily basis. Overall, I have been very successful in moving many of my patients to a more intensive level of control. This has been achieved by using an Insulin Infusion Pump. I consider pump therapy a valuable tool in my ability to treat and manage my insulin requiring patients.

I have become aware of the C-Peptide requirement and consider it a limiting factor in my ability to move a Medicare patient into the best possible situation for long-term diabetes management and blood sugar control. The test is not one that I run for any of my patients to determine or classify their diabetes. A person either requires insulin to maintain blood sugars or they do not. I also consider the test to be very subjective and one that can be affected by several factors including current oral agents, blood sugars, or recent meals. The test result can often vary greatly from month to month or year to year.

Recently, I have been able to achieve very positive results with patients who are even on both orals agents and insulin. For these types of patients and for those who are solely insulin requiring, the C-Peptide can effectively limit my ability to manage and achieve the best possible outcomes by moving these patients into Insulin Pump Therapy.

I would welcome a more subjective requirement that considers a patient's history and level of compliance as the sole standard for approval of an insulin pump. Please consider these issues when you are reviewing the current standards for approval of an Insulin Infusion Pump.

Thank you,

Jeannie, Baquero, MD

Southwest
Diagnostic
Clinic,L.L.P.

April 13, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:

I would welcome your recent decision to review the current C-Peptide criteria for the Insulin Infusion Pump.

For several years, I have questioned the ability of the C-Peptide test to identify who is or is not a good candidate for the Insulin Pump. I am an Endocrinologist and treat many patients with diabetes on a daily basis. Over the past few years, our program has been very successful in moving many of our patients to a more intensive level of therapy. This has involved a more intensive multiple daily injection regimen; and in many cases, this has been achieved by using an Insulin Infusion Pump. I consider CSII a valuable tool in our ability to manage my patients with diabetes who are insulin requiring.

I am aware of the C-Peptide requirement and consider it a limiting factor in our ability to move a Medicare patient into the best possible situation for long-term diabetes management and blood sugar control. This test is not one that we routinely run for any of our patients to determine or classify their diabetes. A person either requires insulin to maintain blood sugars or they do not.

I would welcome a more subjective requirement that considers a patient's history and level of compliance as the sole standard for approval of an insulin pump. Please consider these issues when you are revie .ng the current criteria for approval of an insulin infusion Pump.

Thanks,

anks,

Jose Beceiro, MD

Jose Beceiro, M.D., F.A.C.P
Endocrinology Metabolism
Lipid Clinic

3801 50th Street I Lubbock, Tx 79413/ 806.771.5505 i Fax 806.771.5522

Date: 4-27-04

To: Ms. Betty Shaw & Dr. Lawrence Schott
Coverage & Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards & Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

From: Recaredo Berbano, MD
207 N. Main Street
Plains, PA 18705
570-270-4699

Subject: Request to remove C-Peptide Criteria for Medicare Insulin Pump Patients

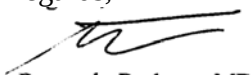
Dear Ms. Shaw & Dr. Schott,

I'd like to request the removal of the C-Peptide Criteria for Medicare Insulin Pump Patients. As a prescribing Endocrinologist of insulin pumps for well over 5 years I have numerous Medicare insulin pump patient and feel that C-Peptide levels are not valid as a determining factor for insulin pump therapy.

I have numerous pump patients with C-Peptide levels well out of Medicare's required ranges that have experience excellent clinical results with pump therapy for the management of their diabetes. (reduction of HA1c levels, greater control of glucose levels, reduction in the potential for secondary complications associated with diabetes, etc.)

I sincerely feel that the removal of Medicare's C-Peptide criteria is necessary and I appreciate your consideration.

Regards,



Recaredo Berbano, MD

MARK W BRADFORD, MD INC PS

400 LILLY ROAD NE, SUITE 7

OLYMPIA WA 98506

TELEPHONE (360)459-7713

April 23, 2004

Ms Betty Shaw and Dr Lawrence Schott
Coverage and Analyst Grp
Ms C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Svcs
7500 Security Blvd
Baltimore, Maryland 21244

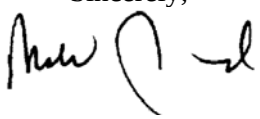
Re: Donna Begley
DOB: 3/31/37

Dear Ms Shaw and Dr Schott:

Please consider this to be a request that the C-peptide requirement for pump therapy be removed from your criteria. Many of our patients are transitioning from pump therapy from private insurance to pump therapy under Medicare. Why we are forced to order an expensive and inadequate test in a patient who has already demonstrated good care of diabetes on an existing medical program is beyond understanding. This would be comparable to asking a patient to go off all blood pressure medications just to prove that they have hypertension. Patients with good control of diabetes have been deemed appropriate candidates for insulin pump and should not be required to demonstrate they have no insulin secretion. Many patients who still have some insulin secretion benefit significantly from insulin pump therapy. There are many type 2 diabetics who also can benefit from pump therapy, and to deny them this therapy because they are not insulin deficient diabetics is also beyond understanding.

Let us try to make this a more rational process and not make the only litmus test for an insulin pump be the measurement of a C-peptide.

Sincerely,



Mark W Bradford, MD
Internal Medicine

MWBradford/rm
Fax copy: Paul Peloquin c/o Mini Med 253-265-3916

DIPLOMATE
AMERICAN BOARD OF INTERNAL MEDICINE
ENDOCRINOLOGY AND METABOLISM

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1421 JOHNSTON-WILLIS DRIVE
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JAMES P. WIGAND, M.D.
INTERNAL MEDICINE
ENDOCRINOLOGY, DIABETES & METABOLISM

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RANDALL M. ROBINSON, M.D.
INTERNAL MEDICINE/ENDROCRINOLOGY

BRIAN M. WASSERMAN, M.D.
INTERNAL MEDICINE

17 APRIL 2004

Ms. Shaw & Dr. Schott—

PLEASE remove the C-peptide criteria for Medicare recipients' National Coverage Decision regarding insulin infusion pump therapy. The C-peptide test is a waste of money in this setting. The predictive value of the test, both positive & negative, is poor. The C-peptide does not predict success with insulin pump therapy. I have cared for many patients who were insulin-deficient and would have benefited from pump therapy but could not qualify due to the (arbitrary) C-peptide requirement.

Please vote to remove this archaic regulation.

[illegible] MD FACE

The University of Kansas Medical Center

School of Medicine
Department of Pediatrics
Division of Endocrinology

James Lynn Casey, M.D., Section Chief
Genevieve DelRosario, M.H.S., PA-C
Barbara A. Pagacz, R.N., B.S., C.D.E.
Shawna K. Ware, R.N., B.S.N.
Martha V. Barnard, R.N., Ph.D.
Martha Berner, M.S., R.D.

April 27, 2004

Dr, Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid services
7500 Security Building
Baltimore, MD 21244

RE: Deleting C-Peptide criteria for use of insulin pump in Medicare patients.

Dear Sirs:

The use of the C-Peptide criteria for Medicare patients to determine whether or not a patient would be a candidate for an insulin pump is outdated and ridiculous. Please accept this as a vote to have this requirement resented.

In my practice of Endocrinology, I have had many Type II Diabetics who needed the type of control that an insulin pump provides. Having the C-Peptide level go low only means that insulin is not being secreted. When the C-Peptide level *is* elevated it usually means that there is insulin resistance, but that should not be a criteria for the use of an insulin pump.

I can think of one patient, age 65, who had very unstable diabetes uncontrolled by short acting insulin and many oral medications. Her C-Peptide level was elevated at a level of 12. In spite of that, she was started on an insulin pump and within 3 months her hemoglobin Al-C dropped from an unsafe level of 9.5 to a very acceptable level of 7.0. Her diabetes was markedly improved, her complications of hypertension and renal dysfunction were improving and he was continued on the insulin pump for several years since this period of time.

Again, it is my opinion that the C-Peptide is not a valid indication for a patient who needs to change their diabetic control to an insulin pump. 1hope that you will give consideration to having this changed as soon as possible.

Thank you for your attention in this matter,

James L. Casey, MD
Clinical Assistant Professor
Section Chief, Pediatric Endocrinology

Drs. Chadband and Rowland, P.C.

Robert B. Chadband, M.D.
Michael J. Rowland, M.D.

April 27, 2004

Dear Ms. Shaw and Dr. Schott;

I understand that Medicare will be reviewing the C-peptide criteria for patients who wish to initiate or continue insulin pump therapy. I have long opposed the inane C-peptide limitation. An arbitrary C-peptide number has no relationship to the potential benefits of continuous insulin pump therapy for persons with diabetes. I have found C-peptide results to be variable and inconsistent It has been difficult to explain to patients who had benefited from pump therapy at age 64 the reason they now do not qualify for therapy because they are now 65. This limitation, in my opinion, is medical age discrimination.

For motivated diabetics, either Type 1 or Type 2, insulin pump therapy has proven clinical benefits in reducing the morbidity associated with both forms of this condition. Please do not deny Medicare patients' access to an important clinical tool based on such an insignificant, arbitrary, and capricious measure.

Please consider my request to drop the C-peptide criteria so that anyone with insulin requiring diabetes who is motivated sufficiently to achieve optimal glycemic control may have equal access to optimal medical care.

Sincerely,

Robert B. Chadband, M.D.

48 Medical Park East Drive. Suite 452 • Birmingham, AL 35235 • Ofc.: (205) 838-3673 or Fax: (205) 833-3441

Ronald H. Chochinov, M.D., Inc.
168 North Brent Street, Suite 404
Ventura, CA 93003

(805) 641-6525
FAX (805) 641-6530

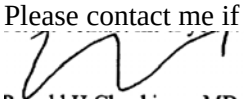
To Whom It May Concern:

I am sending to you this letter to share with you my thoughts regarding the C-peptide criteria your organization uses to determine whether or not a patient is appropriate for an Insulin Pump (also known as CSII). As a physician, I agree that the C-peptide test is a reasonable way to determine whether or not a patient is a Type 1 or a Type 2 diabetic. However, the C-peptide value is not an appropriate indicator as to who is a "good" insulin pump candidate. In the past, it was thought that insulin pump therapy was for Type 1 diabetics because the majority are using insulin for their treatment. However, both Type 1 and Type 2 diabetic patients use insulin for intensive management and in my experience; this type of management can best be achieved with the use of an insulin pump. There are studies both old and more recent that prove that insulin is the best choice for intensive diabetes management. Insulin pumps allow for precise delivery (as little as .025 unit increments), specialized delivery patterns (dual and square wave patterns), as well as the ability to fine-tune numerous basal rates for different needs throughout the day. All of this is necessary for both Type} and Type 2 patients.

While C-peptide was traditionally used to classify the type of diabetic patient, it is no longer a clinically relevant indicator in assessing pump candidacy. In addition, many of my Type 2 patients who received their insulin pump prior to becoming Medicare eligible will now be unable to receive their pumps supplies once they switch over to Medicare because of this test. Clearly there are other ways to assess as to whether or not a patient is a proper candidate for an insulin pump. The criteria I use to determine candidacy is the number of times a day a patient is testing blood sugars, hemoglobin AIC (HbA1c) values (which differ for Type I and Type 2), number of injections per day, erratic blood sugar data showing highs and lows, and the use of a CGMS monitor (Continuous Glucose Monitor) which measures blood glucose information every 5 minutes amounting in 288 times per day for 3 to 5 days. I review this data and look for trends and patterns, or lack thereof and use this to determine pump candidates. I also look for a history of severe hypoglycemia and the number of emergency room visits and or paramedic assistances needed per year.

I ask that you review this information and consider changing the criteria to some of these more valid determinants so that I can offer the best possible form of treatment for my patients. Diabetes is a very difficult disease to manage and patients often need advanced forms of therapy to achieve this difficult task.

Please contact me if you would like to discuss my views further.



Robert H. Chochinov, MD

SUFFOLK ENDOCRINOLOGY ASSOCIATES, L.L.P.
STONY BROOK MEDICAL PARK
2500 NESCONSET HIGHWAY, BLDG.
STONY BROOK, N.Y. 11790

PHONE (631) 751-7772
FAX (631) 751-7773

DIPLOMATES· AMERICAN BOARD OF INTERNAL MEDICINE·ENDOCRINOLOGY
HOWARD A. BRAND. M.D., F.A.C.E.
JUDITH CHOWN. M. D.
JUSTIN G. MATRISCIANO. M. D.
PHYLLIS MIGDAL. M. D.
MICHELLE C. JARDINE. M. D.

April 28, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1·09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Ms. Shaw and Dr. Schott,

It has recently come to my attention that Medicare is considering the deletion of the C·Peptide requirement for coverage of insulin pumps. This requirement has created distinct clinical difficulties and increased costs for patients with long standing type I diabetes, and barriers to patients with type 2 diabetes.

As a practicing endocrinologist, I have recommended insulin pumps for my patients with type 1diabetes. Approximately 90% of my patients, however, have type 2 diabetes, and I am frustrated by their inaccessibility to the most physiologic insulin therapy for treatment of their type 2 diabetes.

Over the last decade there have been a number of studies documenting the advantages of pump therapy to patients with type 2 diabetes (Jenning, *Diabetes Care,* 1991; Koval, *IJiabeles,* 1993; Davidson, *Diabeto{ogia,* 1999; Hanaire-Broutin, *Diabetes Care, 2000;* Testa, *Diabetes,* 2001; Wainstein, *DiabetolQgia,* 2001; and Pouwels, *Diabetic Medicine,* 2(03). The reasons for the success of pump therapy include:

- reduction in Hgb Alc by as much as 2.1 %,
- reduction in the amount of insulin required,
- reduction in cardiovascular risk factors,
- decreased weight,
- improved patient quality of life and
- definite patient preference

Thank you for your consideration of this critical issue.

Sincerely,

J. Chown MD mc.

Judith Chown, M.D.

DIABETES RESOURCE CENTER

PIEDMONT HOSPITAL

April 27, 2004

John G. Clarke
Diabetes Resource Center
Piedmont Hospital
1968 Peachtree Road
Atlanta, GA 30309

Ms. Betty Shaw; Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore Maryland 21244

Dear Ms. Shaw and Dr. Schott:

Please consider omitting the Medicare requirement for C-peptide testing as a criteria for reimbursement on insulin pumps and pump supplies. Once a person becomes insulin dependent, an insulin pump using rapid acting human insulin becomes a valid treatment option, not just a lifestyle choice. The benefits of pump therapy are there for persons with either type1 or type2 diabetes.

I am concerned also for the many people already using insulin pump therapy who will be denied coverage for their pump supplies as they age and join the Medicare ranks.

Sincerely,

John G. Clarke,

1968 Peachtree Road, N.W. ● Atlanta, Georgia 30309 ● Phone 404-605-3823 ● Fax 404-350-0380

BLANK CHILDREN'S HOSPITAL

Children's Hospital Physicians

Administrative Office
1200 Pleasant Street
Des Moines, Iowa 50309
(515)241-5926
Fax (515)241-5127
Billing Inquiries (515)471-9292

April 26, 2004

To Whom It May Concern:

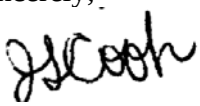
It has been brought to me attention that CMS is exploring the possibility of dropping the C-peptide criteria for obtaining an insulin pump. Since state Medicaid policy is often guided by what CMS does, I wanted to share my thoughts on how requiring a C-peptide result has negatively impacted my patients and practice.

As a pediatric endocrinologist I don't have any Medicare patients nor do I have any Type 2 patients that would require an insulin pump. Therefore having the state pay for a laboratory to perform a C-peptide level on a child with Type I diabetes mellitus in order to confirm this diagnosis seems to me like a waste of our taxpayer's resources. The clinic here at Blank Childrens has a defined protocol for children and families to adhere to before getting a prescription for an insulin pump including hours of diabetes education.

Last year in the summer of 2003 the C-peptide criteria took a cruel and unfortunate twist. For some reason the policy makers for Iowa Medicaid decided all of its patients on an insulin pump needed to submit a C-peptide each month to receive their ongoing supplies. This created undue stress and heartache for several of my patients and their families. There was an interruption in the delivery of supplies because of this issue. The mother of one of my patients was in tears calling my clinic, the pump manufacturer and Iowa Medicaid trying to get resolution because as a nurse, she knew that getting another C peptide was a waste of time, effort and money. It took several months to get an audience with Iowa Medicaid and explain what a C-peptide test reveals and get the policy changed. One of my teenage patients unfortunately ended up in diabetic ketoacidosis because she ran out of pump supplies and was confused by the interruption in their delivery.

Please consider removing the C-peptide criteria because as I've chronicled it is a test: rarely order in my practice. I also can't believe that it is of much clinical use for my colleagues who see adult Medicare patients with insulin dependent diabetes mellitus. Insulin pump therapy is a wonderful tool for the individuals who are motivated and willing to work with their health care providers. The choice of an insulin pump can empower a patient to achieve better glycemic control and improve their quality of life. This treatment option really should be in the hands of the patients and their physicians, not a lab value of little clinical merit. Thanks for your interest on this timely issue.

Sincerely,



Jennifer Cook, MD

Dale Davies, M.D., P.A.

300 N. Highland, Ste 530
Shennan, Texas 75092
(903) 957-7200

April 19, 2004

Dr. Lawrence Schott and Ms. Betty Shaw

This letter is written to request the removal of the C peptide criteria for pump therapy. My practice is 75% Medicare and my patients suffer because of this decision. This test is inappropriate for several reasons.

To begin, I would like to refer you to the attached copy that comes directly from my laboratory book. I have circled the information that I believe to be relevant. The newest oral medications are compatible, and frequently, taken in combination with insulin therapy. Without holding medications, it is very difficult to collect an accurate reading.

However, if I were able to obtain an accurate reading, I still do not believe that it is indicative of need for pump therapy. For example:

68 year old male patient with type II for 26 years. He takes Avandia 4mg with Humulin 70/30. He has Humulin R per sliding scale pm. This patient is known to be alert, oriented, and compliant. He keeps a log of his glucometer readings and his meals. He participates in an exercise program with his girlfriend a minimum of 4 days a week. He does not meet the criteria for Medicare for pump therapy because of the C peptide. With a pump, this patient could continue his active lifestyle without multiple daily injections. The benefit of the bolus wizard would help to deter from his hypoglycemic episodes (he had a car wreck earlier this year with a glucose of32). The stability, that we already know comes with pump therapy, might prevent or delay all of the complications that accompany this disease.

The same technology available to other patients should also be available for Medicare patients. Although I understand it is necessary to have guidelines, I do not feel the C peptide appropriate. Please reconsider your criteria.

Thank you

Dale Davies M.D

Dale Davies, MD

Note: Conversion to Text for this page didn't fully complete.

Type of test: Blood

Normal findings 0.78 to 1.89 ng/mL or
0.26 to 0.62 nmol/L (51 units)

Test explanation and related physiology

C peptide is formed in the islet of Langerhans of th
during the conversion of proinsulin to insulin and
C peptide is released into the portal vein in a 1: 1 ratio
Because it has a longer half-life than ,insulin, more C p
ists in the peripheral circulation. C peptide levels corr
insulin levels in the blood, except in islet-cell tumors
in obese patients.

The capacity of the pancreatic beta cells to secrete
be evaluated by measuring insulin or C peptide. Thus
is a by-product of *endogenous* insulin synthesis and a
endogenous insulin production with or without ex
sulin injections.

C peptide is not affected by the presence or absenc
antibodies. Therefore, residual beta-cell function c
ated in the patient with diabetes who is treated with i
who may have insulin antibodies. This most often 0
tients treated with bovine or pork insulin.

C-peptide values are high in patients with insulino
patients, C-peptide concentrations parallel the plasma
ues. This test is also useful in evaluating patients -glycemia
and in identifYing those patients with ficti
glycemia caused by surrepitious injection of insulin
tients have high circulating levels of insulin and (I'
C-peptide value. because *exogenous* insulin suppresses
insulin release. This suppression does not occur in '.
Normal C-peptide levels occur in diabetics who are˜
This blood test also can be used to detect the prese
ual tissue in patients who have had a pancreatectomy:

Interfering factors

• Because the majority of C peptide is degraded in
renal failure can cause increased levels.

that may cause *imreased* levels ofC peptide include
poglycemic agents (e.g., sulfonylureas).

re and patient care

. the procedure to the patient.
ct the patient to fast for 8 to 10 hours before the test.
ater is permitted.
t venous blood in one red-top tube of blood.
ressure or a pressure dressing to the venipuncture site.
the venipuncture site for bleeding.

I findings

ased **levels *'Iff* Decreased levels**
Fictituous hypoglycemiaRadical
pancreatectomy
Diabetes mellitus

Maine Medical Center

MAINE CENTER FOR DIABETES

April 16, 2004

Re: C-peptide Criteria for Insulin Pump Therapy

To Whom It May Concern:

1 am writing to strongly encourage Medicare to drop the requirement for C-peptide deficiency as an indication for insulin pump therapy. Many of my patients were either excluded from the benefits of insulin pump therapy, or had to payout of pocket for this important modality in their management. In some cases, patients have had renal insufficiency, which falsely elevated their C-peptide level. One patient in particular has benefited tremendously from his insulin pump in his diabetes management through all the complications of diabetes, including his coronary revascularization and end stage kidney disease requiring dialysis. He is extremely grateful for the benefit of being on the insulin pump to get him through all these difficult periods during the course of his diabetes. He was unable to afford the pump and we were fortunately able to obtain one from another patient. Although this helped this one individual, there are many others who have suffered because of their lack of access to this state-of-art modality of therapy.

Although the majority of my pump-treated patients have Type 1 Diabetes, there are some Type 2 patients who would benefit from insulin pump therapy, in terms of more consistent and physiologic delivery of insulin, and ease of multiple bolusing. This may be especially helpful for patients with gastroparesis and delayed gastric emptying, severe hypoglycemia with recurrent episodes of impaired consciousness, or patients with a vigorous "dawn phenomenon". To exclude ail these patients that would benefit from pump therapy based on an arbitrary cutoff for C-Peptide concentration does not seem appropriate and in the best interest of my patients.

I am writing to strongly recommend that Medicare reconsider and change their policy requiring plasma C-peptide deficiency for insulin pump coverage.

Sincerely,

John T. Devlin, MD

Cc: Chris Robb, sent via facsimile

102 Campus Drive, Unit 116, Scarborough, Maine 04074-9308
(207) 885-7710 1-800-248-1043 Fax (207) 885-7528

Dr. Eric Dyess
1151 North State Street
Jackson ,MS 39202
601-948-5158

April 25, 2004

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

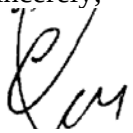
Dear Dr. Schott and Ms Shaw:

I am an endocrinologist who has many insulin pump patients. I have seen over time these patients qualify for Medicare and have a c-peptide that does not qualify. This causes a problem for the patient who has done well on this therapy. Because of the elevated c-peptide, they are forced to make a decision that may not be the best decision for their health, but the only decision they can make financially.

Please do what you can to have this requirement removed. It is one that can greatly impact patients and hinder my ability to give my patients the best care possible.

Thank you for your consideration.

Sincerely,



Dr. Eric Dyess

Scripps Whittier Diabetes Program
Diabetes Resource Center LJB28
The Whittier Institute
9894 Genesee Avenue
La Jolla, CA 92037
Tel 858-626-5672
Fax 858-626-7111

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

April 10, 2004

Dear Ms. Shaw and Dr. Schott:

Thank you for your reconsideration of the C-peptide test as an indicator for CSII (insulin pump therapy). The C-peptide is simply not a reliable predictive test, regardless of whether one is looking for a high or a low value. You will accomplish an important act of public health if you decide to eliminate the C-peptide as a criterion for CSII.

By way of personal introduction, I am a practicing clinical endocrinologist with a focus on diabetes, and I have supervised CSII for almost 25 years. I have also trained other endocrinologists in the use of CSII and intensive insulin management through many forums, including Meet the Professor sessions for the Endocrine Society Annual Scientific Meetings. Most importantly, I recently Chaired the national Taskforce on the Insulin Resistance Syndrome of the American College of Endocrinology (ACE) and the American Association of Clinical Endocrinologists (AACE) wherein, among other things, the lack of predictive value of C-peptide was examined. My CV is attached.

The decision to use CSII is a complex one clinically, based on a great deal of objective data demonstrating the patient's requirement for tight glucose control using around the clock insulin therapy, the patient's demonstrated technical capacity and motivation for CSII, and the relative failure of other therapeutic strategies. If a patient requires continuous insulin therapy, the level of measured C-peptide is not even noted as a guideline for clinical decision making.

Conversely, in patients failing oral anti-diabetic agents, a high level of C-peptide does not imply that insulin therapy can be avoided. A high C-peptide cannot even be used to diagnose insulin resistance (wherein there is usually insulin over-production), and C-peptide is found

nowhere in any validated clinical diagnostic algorithm of what therapy to choose for patients with diabetes.

As a clinician, this issue of C-peptide and CSII is not an abstract one. It has been tragic to tell patients that they cannot go on CSII for want of adequate insurance coverage due to the result of a blood test that I know is not valid. When some of our CSII patients become Medicare eligible, and have to abandon CSII if they cannot afford to personally pick up the costs, the disruption is especially painful.

I wish the C-peptide was a more useful test and I wish there were simple criteria for deciding who should use CSII. The reality today, however, is that there is no substitute for clinical judgment. I would support efforts to define, perhaps, a series of criteria that may weed out those for whom CSII is not appropriate, but the C-peptide is definitely not that answer.

Thank you again for your consideration of this. If any other information would be helpful, please don't hesitate to contact me. A hard copy of this letter on my stationary will be mailed to your office.

Sincerely,

Daniel Einhorn, MD, FACP, FACE
Medical Director and Director of Clinical Research
Scripps Whittier Institute for Diabetes
Associate Clinical Professor of Medicine, UCSD
Diabetes and Endocrine Associates
La Jolla, CA 92037
Office: 858-622-7200 Fax: 858-622-7211

Dr. Robert Evans
1151 North State Street
Suite 601
Jackson, MS 39202

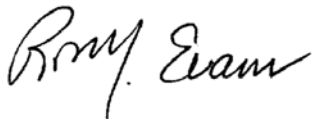
April 19, 2004

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

Dear Ms Shaw and Dr. Schott:

I am an endocrinologist who has prescribed many insulin pumps. I have seen the benefits of pump therapy in my practice and feel that it is a therapy that can benefit not only my patients with type 1 diabetes, but a select group of my patients with type 2 diabetes. Because of the c-peptide requirement, these patients with type 2 diabetes have been unable to benefit from this therapy. I am asking that you remove this c-peptide requirement so my patients with type 2 diabetes who I determine are good candidates for pump therapy, can benefit from this therapy and live a more normal life.

Regards,



Dr. Robert Evans

Steven Fehrenkamp, M.D.
4007 James Casey Street
Austin, TX 78745
512-445-2833

April 18, 2004

Dr. Lawrence Schott & Ms. Betty Shaw
Coverage and Analyst Group
Centers for Medicare & Medicaid Services
Baltimore, Maryland

Dear Dr. Schott and Ms. Shaw,

I am an Endocrinologist who treats patients with diabetes every day in my practice. It has come to my attention that there is a review taking place that is focusing on the C-Peptide requirement for Insulin Pumps. I welcome the opportunity to add my comments.

It is my opinion that an insulin infusion pump is medically necessary to achieve acceptable blood glucose control for many patients with diabetes. The current C-Peptide requirement that is in place as part of the approval process for an insulin pump is a limiting factor for many Medicare patients. The C-Peptide test is not a test that is routinely run during diagnosis or on-going care of a diabetic patient in my clinic or in any Endocrinology clinic that I know of. It is simply not a valid indicator of a patient's clinical situation or treatment needs. To insist on a "passing" C-Peptide for an Insulin Pump is often times equal to directly limiting the level of blood glucose control that a patient can experience.

Again, I am writing to request that the C-Peptide criteria be eliminated from the approval process for an Insulin Pump for Medicare patients. Thank you for your attention to this matter and for reviewing this outdated test requirement.

Sincerely,

Steven Fehrenkamp, M.D.

Diabetes & Endocrinology Specialists, Inc.
Norman Fishman, M.D.

222 S. Woodsmill Rd.
Suite 410 North
Chesterfield, MO 63017
Office: (314) 469-6224
Exchange: (314) 533-5858
Fax: (314)469-0744

Board Certified in Internal Medicine
Board Certified in Endocrinology

April 21, 2004

MEDICARE CRITERIA MEMO

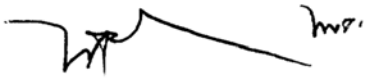
To whom it may concern,

It is important to amend the current Medicare guidelines to 'exclude C-peptide values as exclusion criteria for patients whom insulin pump therapy is medically necessary. As a board certified endocrinologist, I have several patients for whom insulin pump therapy has been denied based on C-peptide levels not their overall medical necessity.

One patient who comes to mind is a patient who has received a kidney transplant. The treatment needed to prevent rejection complicates his diabetes management. Excellent glycemic control is essential to preserve his kidney function. Pump therapy is medically necessary to treat his diabetes and prevent further complications. In addition, the steroids needed to prevent transplant rejection can falsely elevate C-peptide values. I find it difficult to understand that Medicare will pay for transplants, but will not cover an insulin pump in order to control blood glucoses to preserve the donated organ. Unfortunately this patient is currently on a less than optimal therapy simply because his C- peptide was too high.

I strongly encourage you to discontinue the C peptide criteria and to allow physicians to prescribe the pump for patients that meet all other basic guidelines such as multiple dose insulin and blood glucose monitoring.. Thank you for your consideration and I do look forward to a change in current Medicare criteria for insulin pump therapy.

Sincerely,



Norman Fishman MD

PENNSTATE
Milton S. Hershey Medical Center
College of Medicine

Department of Medicine
Division of Endocrinology,
Diabetes & Metabolism

Penn State Milton S. Hershey Medical Center
Penn State College of Medicine
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500 University Drive, P.O. Box 850
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Fellows:
Rehan Ahmad, D.O.
Svetlana Douglas, M.D.
Deborah A. Hackett, M.D.
Irina Lendel, M.D.

April 12, 2004

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

RE: C-Peptide Criteria for Medicare Patients

Dear Ms. Shaw and Dr. Schott:

As Co-Director of the Penn State Diabetes Center, I would like to bring to your attention my views on the use of C-peptide criteria for national coverage decision for insulin pump use.

Part of the problem is that C-peptide measurements are not uniformly performed and their accuracy is often suspect. Therefore, denying patient coverage for an insulin pump because their C-peptide is not acceptable does not appear to be logical.

We have had several patients where C-peptide levels were detected, in one case even after having had a complete pancreatectomy as a result of a Whipple procedure done. As you know, this is physiologically impossible and really speaks to the inadequacy of the C-peptide assay. We have had patients denied insulin pump therapy who otherwise would have benefited from this therapy, because their C-peptide levels were not acceptable. In particular,

it should be noted that C-peptide levels are unreliable in the setting of renal disease and again this would be another area where these would not be useful.

Based on my extensive experience with insulin pump patients and the care of those with diabetes, we at the Penn State Diabetes Center do not feel that C-peptide criteria are appropriate for judging whether patients can have coverage for insulin pump therapy. As you know, this therapy is extremely valuable for the appropriate patients. Clearly, it is necessary to have some criteria to determine who is appropriate; however, C-peptide really is not a valuable measure. Our usual criteria are that a patient is monitoring blood glucose four times per day and has learned carbohydrate-counting skills. These are our criteria for patients who are sub-optimally controlled under current therapy.

I would be glad to discuss this further with you at your convenience.

Respectfully,

Robert Gabbay, M.D., Ph.D.
Associate Professor of Medicine
Co-Director, Penn State Diabetes Center

James D. Geddes, M.D.
Internal Medicine
1311 E. General Cavazos, #F
Kingsville, Texas 78363

April 13, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:

I welcomed your recent decision to review the current C-Peptide requirement for the Insulin Infusion Pump.

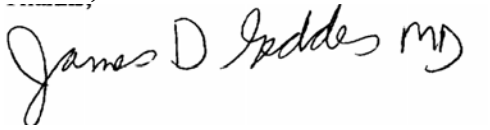
For some time, I have questioned the ability of the C-Peptide test to identify who is or is not a good candidate for the Insulin Pump. I am an Internal Medicine physician and treat patients with diabetes on a daily basis. Over the past few years, I have been very successful in moving many of my patients to a more intensive level of control. This has involved a more intensive multiple daily injection regimen; and in some cases, this has been achieved by using an Insulin Infusion Pump. I consider pump therapy a valuable tool in my ability to treat and manage my patients with diabetes who are insulin requiring.

I have become aware of the C-Peptide requirement and consider it a limiting factor in my ability to move a Medicare patient into the best possible situation for long-term diabetes management and blood sugar control. The test is not one that I run for any of my patients to determine or classify their diabetes. A person either requires insulin to maintain blood sugars or they do not. I also consider the test to be very subjective and one that can be affected by several factors including current oral agents, blood sugars, or recent meals. The test result can often vary greatly from month to month or year to year.

Recently, I have been able to achieve very positive results with patients who are even on both orals agents and insulin. For these types of patients or those who are solely insulin requiring, the C-Peptide can effectively limit my ability to manage and achieve the best possible outcomes by moving these patients into Insulin Pump Therapy.

I would welcome a more subjective requirement that considers a patient's history and level of compliance as the sole standard for approval of an insulin pump. Please consider these issues when you are reviewing the current standards for approval of an Insulin Infusion Pump.

Thanks,



NEIL J. GOLDBERG, M.D., INC.
INTERNAL MEDICINE
ENDOCRINOLOGY AND DIABETES
9808 VENICE BIND, CULVER CITY, CALIFORNIA 90232 SUITE 603
(310) 558-1836 (310) 838-6959 FAX

April 23, 2004

To whom it may concern:

Control of diabetes is the major goal of therapy in Type 1 and 2 diabetes. The absolute level of C peptide does not predict ability to control patients easily or by what means that control may be achieved. In Type 2 diabetes the relative deficiency of insulin varies inversely with insulin resistance, therefore the absolute level of c peptide does not absolutely reflect the tools necessary for control.

Due to progressive beta cell "failure", insulin may be necessary for type 2 diabetes. Usage of an insulin pump provides a meaningful intervention to achieve the goal of A1c<6.5% Recognition of the utility of the pump as the gold standard of care is well accepted in the literature and by national societies.

To use a pump properly, multiple blood sugar tests are required. The requirement of multiple injections prior to pump use only reflects the patients ability to use insulin, usage of the "poor man's pump", but has no direct bearing on pump use. If acquiring the best control of diabetes is an alternative for Medicare patients, then pump accessibility with reasonable prerequisites, is necessary.

Sincerely,

Neil Goldberg MD
Associate Professor of Medicine
UCLA

ATLANTA
DIABETES
ASSOCIATES

Endocrinology & Diabetes

PAUL C. DAVIDSON, M.D.
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R. DENNIS STEED, M.D.
DAVID G. ROBERTSON, M.D.
N. SPENCER WELCH, M.D.
CAROL GREENLEE, M.D.

April 29, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop: C1-01-06
Office of Medical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Shaw and Dr. Schott:

This letter is to ask that you consider medicare coverage without the C-peptide requirement. Many of our patients with type 2 diabetes who have measurable insulin production, do not meet the C-peptide criteria, and require insulin. In many cases the amount of insulin required can be safely and effectively provided by an insulin pumps. Insulin injections are one option but in brittle diabetics with complications such as severe hypoglycemia or persistent elevations in overnight blood sugars an insulin pump is an excellent solution. In other cases, patients have limited ability to monitor their blood sugar or administer insulin injections while they are fully capable of using an insulin pump due to its simple design. With a pump these patients who would have to be put in a nursing facility or have family members available around the clock, can adjust their own blood sugars on a continual basis. Furthermore, many patients already on a pump will have to discontinue using it when they reach Medicare age, as they will be unable to receive insurance benefits that will allow them to obtain their pump supplies on formulary. They must either pay full price for the supplies or return to four shot therapy after being off it for many, many years.

For many patients an insulin pump is the only option for optimal glycemic control. Many type 2 diabetics also have cardiovascular problems and neuropathy. Only with an insulin pump can a patient avoid the type of hyperglycemia that places them at risk for cardiac event for complications related to cardiac surgeries. In patients with neuropathy the insulin pump provides a much safer mechanism for administering insulin. Furthermore in many patients the C-peptide appears elevated due to renal insufficiency.

This issue is of great importance to the patients I see daily in my office. Please consider removing the C-peptide requirement or allowing the physician more ability to obtain and insulin pump for type 2 patients when appropriate. I would appreciate your consideration and support in these matters.

Sincerely,

M. Carol Greenlee, MD
MCG/ecm

Dr. Raymond Grenfell, Jr.
1151 North State Street
Jackson, MS 39202
601-948-5158

April 27, 2004

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

Dear Dr. Schott and Ms Shaw:

This letter is to ask for your sincere consideration is removing the c-peptide requirement for Medicare patients. I see no reason for the c-peptide to be a criteria, especially since it can often be falsely elevated in patients with certain situations, (i.e. obesity), which is common in my patients with type 2 diabetes. My biggest concern is that my patients who have been on insulin pump therapy for quite some time will become old enough to qualify for Medicare and without a c-peptide that qualifies, they will no longer be able to get their supplies. It does not make sense for these patients to have to come off of pump therapy for this reason.

Please take a serious look at this criteria and consider how many patients it can affect negatively if the c-peptide requirement is kept in place.

I thank you for your time and consideration and look forward to hearing the outcome.

Sincerely,

Dr. Raymond Grenfell

Galichia
MEDICAL GROUP

April 27, 2004

Ms. Betty Shaw
Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, Maryland 21244

To Whom It May Concern:

The current Medicare guidelines specify that the patient should have a C-peptide which is 110% of the lowest reference lab value. This guideline is unnecessary and unreliable since many patients are treated with insulin previously and it is impossible to obtain an accurate value since patients cannot discontinue their insulin without risking life threatening complications. Patients that reach the Medicare age and are on an insulin infusion pump cannot discontinue the pump to obtain a C-peptide level since this could result in death (the same risk as malfunction of the pump). In addition, many patients with longstanding diabetes may have been treated with animal insulin and may have antibodies which interfere with the test results and make the results unreliable.

Removal of this criterion would not result in adverse utilization of the insulin infusion pumps. It would result in a decreased expense to Medicare since the level of the C-peptide does not facilitate other changes in patient management and therefore is an unnecessary expense I the care of patients.

Sincerely,

Lillian R Harstine MD

Lillian R. Harstine, MD

Galichia Medical Group, PA • 2600 North Woodlawn • Wichita, Kansas 67220
316-684-3838 • 1-800-657-7250

Betty Shaw C-Peptide

From: "Mike Heile"

Date: *04/30/04* (Fri) 0618PM

Subject: C-peptide

Hi Betty,

My name is Mike Heile. I am a family practice physician who has taken a very special interest in the care of diabetic patients in Cincinnati, Ohio. I have a pretty even distribution of type 1 and type 2 patients. Very few of my type 2 patients have failed diet, exercise, oral medications, and different insulin regimens. Fortunately, for these people who continue to fail to make standards of care for A1C levels there is one more option- the insulin pump. Obviously, there are not as many of these type 2 patients who require an insulin pump compared to the type 1 insulin dependent patients, but thank heavens for this option. If it were not for this option many of these patients would continue to have sub-standard control and surely develop complications. C-peptide standards/requirements obviously limit the use of this resource to properly control diabetes in the medicare population. I have no question that if studied properly the few number of type 2 patients who truly require insulin pumps to properly control their disease would save the system money with less short term and long term complications. Please reconsider these C-peptide requirements and allow medicare patients to also have a fair share at properly controlling their disease.

Thanks for your time and please feel free to call or email me anytime if you should have any questions.

Sincerely,
Dr. Mike Heile
513-661-9217

INTERNAL MEDICINE AND ENDOCRINE ASSOCIATES OF AUGUSTA, P.C.
820 St. Sebastian Way, Suite 7A
Augusta, Georgia 30901
Phone (706) 722-0463
Fax (706) 722-3590

Internal Medicine - Board Certified
Robert E. Rychly, M.D.
Jimmy V. Lemke, M.D.

Endocrinology & Metabolism - Board Certified
Michael L. Graybeal, M.D., C.D.E.
Ian C. Herskowitz, M.D., C.D.E., F.A.C.E.
Leyla El-Choufi, M.D., F.A.C.E.

April 29, 2004

Ms. Betty Shaw, MS
Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality Centers
For Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

To Whom it May Concern:

This letter is in regards to Medicare's recent review on the necessity for C-peptide testing to determine eligibility for initiation of insulin pump therapy in the management of diabetes mellitus.

In my clinical experience as an Endocrinologist and in private practice for nearly 13 years, one of the problems that I have encountered in the use of the C-peptide test is that a number of patients who would be considered having measurable levels of insulin by the C-peptide criteria that are set up by Medicare, these patients despite using multiple insulin injections, on the order of four or more injections per day, are not achieving adequate level of glycemic control with these standardized regimens. I have encountered a number of instances in the past two to three years utilizing the C-peptide criteria where patients were denied eligibility for receiving an insulin pump because their C-peptide level was too high by the cut off that had been set under Medicare guidelines. These patients were highly motivated individuals with significant co-morbid complications associated with their diabetes condition who would have benefited greatly with the use of an insulin pump regimen to help stabilize their blood glucose and prevent progression of their diabetes related complications. Unfortunately, due to the excessive cost associated with the insulin pump therapy they could not afford out-of-pocket expenses to obtain the pump without the assistance with Medicare coverage. As a result, the C-peptide criteria that were set up under the Medicare guidelines denied these individuals from being able to receive the insulin pump for their treatment and care despite the fact that this was felt, based on their assessment by myself and diabetes educators who had worked with the patient, that it would greatly benefit and enhance the level of care that could be given to these individuals.

Other problems that have been encountered include patients who were on insulin pump therapy and then subsequently obtained Medicare health coverage and when their insulin pump fell out of warranty or could not be repaired and a replacement insulin pump needed to be obtained, these individuals were unable to receive the insulin pump because their C-peptide levels did not meet the guidelines set by Medicare even though their previous private health insurance coverage approved the insulin pump for the management of the patient with diabetes.

The significant disparity between the Medicare guidelines and the guidelines that are being used by private health insurance is creating additional confusion regarding the guidelines that being used to determine appropriate use of an insulin pump in the management of diabetes for these patients. Clearly, a standardization is needed with regards to these guidelines and I strongly feel the C-peptide test should be eliminated as an indicator to determine eligibility for insulin pump use and determination of treatment for patients with diabetes as an option in their care. I would strongly urge the Medicare Office to review these guidelines and consider changing the use of the C-peptide as one of the key markers to determine the eligibility and use other factors in the patient's condition as important indicators in the need for the patient to proceed insulin pump treatment.

If you have any questions regarding the contents of this letter or the importance of this issue, please feel free to contact me at my office.

Sincerely,

Ian C. Herskowitz, M.D., C.D.E., F.A.C.E.
Endocrinology and Metabolism

ICH:dp

HILLMAN CLINIC
Joseph C. Hillman, M.D.
2401 5th Street North
Columbus, Mississippi 39705
Telephone: (662-327-0016)
Fax: (662-327-7707)

Founded 1969

April 7, 2004

To Whom It May Concern:

This letter is to show my support for removing the c-peptide requirement for Medicare patients to qualify for insulin pump therapy. I have seen tremendous results with my insulin pump patients and feel very strongly that many of my Medicare patients could have those same benefits if their c-peptide qualified. My fear is that these Medicare patients are being denied of the best treatment available to them and that they are going to suffer the consequences later. I am very concerned about each and every one of my patients and want to help them achieve the best health possible. I feel that for some of those, insulin pump therapy is the way to achieve that and with a high c-peptide, our hands are tied.

Please help us by removing this c-peptide requirement. Patients on insulin pump therapy can live more normal, healthier lives and be more productive citizens. I want that for all of my patients.

Regards,

Dr. Joseph Hillman

Please remove
the C-peptide requirement!!

ENDOCRINE RESOURCE NETWORK www.endocrine-network.yourmd.com

JOHN W. INTERLANDI, M.D., F.A.C.E., C.C.D.
LEE MILLER, R.N., OFFICE MANAGER

5651 FRIST BLVD. # 208
HERMITAGE, TN. 37076
PHONE # 615-871-7258
FAX # 615-871-4982

4/29/2004

Ms. Betty Shaw / Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Center for Medicare and Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

Dear Ms. Shaw / Dr. Schott,

This is in regards to the Medicare requirement for a C-peptide level to be drawn before an insulin pump will be approved for patients with diabetes.

I agree that a C-peptide level is necessary for a firm diagnosis of Type 1 Diabetes.

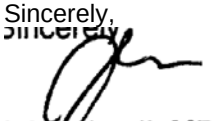
I do not agree, however, that patients with Type 1 Diabetes are the only ones who benefit from insulin pumps. Here are a few examples:

(1) Some patients with Type 2 Diabetes are insulin resistant AND insulin deficient. In these patients the C-peptide level is not a good indicator of how the patient will respond to exogenously administered insulin. I have plenty of patients in my practice with C-peptide levels of 2-3 who "act" just like a patient with Type 1 diabetes, e.g. brittle, wide fluctuations in glucose, dawn phenomenon, or poor response to 3-4 injections per day. Again, I'd like to emphasize that the C-peptide level only indicates how much insulin a patient produces from their own pancreas - but it is NOT a measurement of how well (or how poorly) a patient will respond to injected insulin. For this reason I think your criterion of requiring documentation that the patient is not doing well on at least 3 injections per day is a good one. It is more clinically appropriate than anything you could measure in the bloodstream.

(2) Patients with impairment of dexterity, such as tremor, osteoarthritis, diabetic neuropathy, strokes, etc. are often unable to manipulate syringes, but can manage to bolus themselves with an insulin pump, especially if a spouse can be trained to insert the pump every three days. There should be exceptions for patients who have conditions that prevent them from using insulin syringes, regardless of their C-peptide level.

(3) Finally, there are many patients who just want an insulin pump for lifestyle reasons such as erratic work hours, travel, etc. Many Medicare-age patients are still working, and a pump facilitates their ability to work because of it's flexibility. Flexibility is not just an issue for Type 1 patients.

Sincerely,



Thomas Jefferson University | Jefferson Medical College | Jefferson University Physicians

Department of Medicine
Division of Endocrinology and Metabolic Diseases

211 South 9th Street, Suite 600
Philadelphia, PA 19107
215-955-1925
Fax: 215-928-3160

April 27, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-C9-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

Dear Ms. Shaw and Dr. Schott,

I am writing to ask you to consider removing the C-Peptide requirement for candidates for CSII (Continuous Subcutaneous Insulin Infusion) from your National Coverage Decision.

The benefits of CSII are well documented in numerous published articles. In my practice, I prescribe and manage a large volume of insulin pump patients, including a number of T2DM patients. These patients would not have qualified for insulin pumps under current CMS guidelines. I have personally seen significant clinical benefits for these patients including weight loss, reduced insulin requirement and improved glycemic control. CSII provides the most flexibility for insulin dependent patients as well as the best delivery method due to the predictability of short-acting insulin.

Furthermore, renal insufficiency has been shown to alter C-Peptide levels, artificially raising C-Peptide in these patients.

I strive to provide the most appropriate therapy for my patients regardless of their insurance. I view CSII as the "gold standard" for insulin delivery, and don't like the idea that this therapy is not an option for a good T2DM candidate simply because they are covered by CMS. Because of the C-Peptide requirement, there is also a delay in the process of the pump for T1OM patients as well as an increase in cost to perform the test.

For these reasons, please consider removing the C-Peptide requirement for insulin pump eligibility.

Sincerely,

Serge Jabbour, MD
Associate Professor of Medicine
Division of Endocrinology, Diabetes & Metabolism
Thomas Jefferson Hospital, Philadelphia

SUFFOLK ENDOCRINOLOGY ASSOCIATES, L.L.P.
STONY BROOK MEDICAL PARK
2500 NESCONSET HIGHWAY, BLDG. #3
STONY BROOK, N.Y. 11790

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DIPLOMATES- AMERICAN BOARD OF INTERNAL MEDICINE-ENDOCRINOLOGY
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JUDITH CHOWN, M.D.
JUSTIN G. MATRISCIANO, M.D.
PHYLLIS MIGDAL, M.D.
MICHELLE C. JARDINE, M.D.

April 28, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop Cl-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Ms. Shaw and Dr. Schott,

It has recently come to my attention that Medicare is considering the deletion of the C-Peptide requirement for coverage of insulin pumps. This requirement has created distinct clinical difficulties and increased costs for patients with long standing type 1 diabetes, and barriers to patients with type 2 diabetes.

As a practicing endocrinologist, I have recommended insulin pumps for my patients with type 1 diabetes. Approximately 90% of my patients, however, have type 2 diabetes, and I am frustrated by their inaccessibility to the most physiologic insulin therapy for treatment of their type 2 diabetes.

Over the last decade there have been a number of studies documenting the advantages of pump therapy to patients with type 2 diabetes (Jenning, *Diabetes Care,* 1991; Koval, *Diabetes.* 1993; Davidson, *Diabetologia,* 1999; Hanaire-Broutin, *Diabetes Care, 2000;* Testa, *Diabetes,* 2001; Wainstein. *DiabetoJogia,* 2001; and Pouwels, *Diabetic MediCine,* 2003). The reasons for the success of pump therapy include:

- reduction in Hgb Alc by as much as 2.1%,
- reduction in the amount of insulin required,
- reduction in cardiovascular risk factors,
- decreased weight,
- improved patient quality of life and
- definite patient preference

Thank you for your consideration of this critical issue.

Sincerely,

Michelle Jardine, M.D.

HO-CHUNK NATION

Wanaisguni Hocira
House of Wellness Clinic

Kansas Dubray, MD – Internal Medicine, Pediatrics
LT. Ted Hall, Pharm D - Doctor of Pharmacy, Registered Pharmacist
David L. Jarvis, MD - Family Medicine, Board Certified
Thomas Walker, MD - Internal Medicine, Board Certified
Thomas Zirkel, DPM – Doctor of Podiatric Medicine

Date: *4/25/2004*

To: Ms Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Subj: C-peptide requirement for insulin pump authorization

I understand public comment is being sought on this. I work with a pre-dominantly Native American population, with about 150 diabetics, 2 of whom are Type l' s, the others all being Type 2's. For the occasional person I need to start on a pump, it is usually because they are requiring in excess of 100 units of insulin a day, ie, strongly insulin resistant. Therefore, the requirement to get a C-peptide level before CMMS will cover it is obviously ridiculous, as well as wasteful to our budget. It adds nothing to the patient care.

Even in a Type I, if they are so uncontrolled with usual care despite good efforts, the presence of a miniscule amount of C-peptide (ie some endogenous production) is clinically irrelevant.

I therefore support removing this requirement. The only real requirement that should be needed to justify the pump is documentation of good effort by the clinician, patient, and if needed, the patient's family, to control the diabetes with usual care.

I do think that at least in primary care practices such as my own, insulin pumps should not merely be used for convenience and appeal, as the clear majority of patients can manage their disease without one, and the expense to taxpayers is significant.

Opinions expressed here are my own only, and do not represent the Ho-Chunk Nation.

David L. Jarvis, MD
Diplomate, American Board of Family Practice
Wanaisguni Hocira
S-2845 White Eagle Rd.
Baraboo, WI 53913

THOMAS CUNNINGHAM JONES, M.D., P.C., F.A.C.E.
MIDDLE GEORGIA DIABETES and ENDOCRINE CLINIC
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April 27, 2004

Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop cl-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Dr. Schott:

I have been informed that your agency is in the process of reviewing the need and/or utility of the C-peptide criteria for insulin pump eligibility for Medicare recipients.

The C-peptide is valuable diagnostic tool. However, the C-peptide should not be the exclusive criterion for insulin pump eligibility. Many patients fail the C-peptide component for Medicare coverage for the insulin pump and related supplies. Further, many patients are not afforded the opportunity to achieve optimal glycemic control as a result of the denial of coverage for continuous subcutaneous insulin infusion.

As an endocrinologist, I would prefer to have more input into treatment modalities available to my patients. Removing the C-peptide criteria for insulin pump coverage would be beneficial to many patients that need the enhanced control offered via insulin pump therapy.

Sincerely,

Thomas C. Jones, M.D.

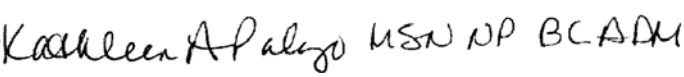
FORT WAYNE ENDOCRINOLOGY, PC
Ashok Kadambi, M.D., F.A.C.E.
4646 W. Jefferson Blvd., Suite 100 • Fort Wayne, IN, 46804
Phone: (260) 436-1248 • Fax: (260) 436-7968

To whom it may concern,

We are writing this letter in support of removing the c-peptide criteria for Medicare patients requiring an insulin pump in order to reach glycemic control. We do not feel that the c-peptide measurement is a valid indicator to determine the need for insulin delivery via a pump. The most important indicator for pump use is the patient's desire and ability to reach glycemic control in order to prevent both micro and macrovascular complications. As you know, many patients who have c-peptides above 0.8 have difficulty controlling their blood sugars despite multiple oral medil,;ations, multiple insulin injections, carbohydrate counting, exercise, and frequent blood sugar monitoring. Several of our patients who have not met this c-peptide requirement have not had the opportunity to experience glycemic control and continue with wide glucose excursions. Many of our patients are required to take large doses of insulin via injection due to insulin resistance; these large doses have at least a 50% variance of tissue absorption. This leads to wide swings in blood sugars and elevated risk for hypoglycemia. Insulin delivered via a pump has a 2% variance in absorption, therefore resulting in more efficacious delivery at lower doses with less variability in blood sugars and lower risk for hypoglycemia. We have experienced many privately insured patients with c-peptide levels above 0.8 start on insulin pumps and not only greatly reduce their insulin requirements along with their HbAIc measurements but also reduce their long term risks for complications. We have also witnessed the decline of glycemic control with patients on insulin pumps who are eligible for Medicare and must return to insulin injections due to this c-peptide requirement. In addition, insulin delivery via insulin pump is the optimal delivery system for renal patients, especially those on dialysis, due to their erratic utilization of insulin. The c-peptide levels should not be a gauge of need for this population. We feel that a thorough evaluation by experienced, qualified health care professionals is more important than a c-peptide requirement when determining need for pump therapy. Please consider our comments during your evaluation of this situation.

Sincerely,

Ashok Kadambi MD, FACE



Kathleen A. Palyo MSN NP BC-ADM

DIVISION OF ENDOCRINOLOGY
& BONE AND MINERAL METABOLISM
Henry Ford Hospital

Dorothy M. Kahkonen. MD
Division Head
2799 West Grand Boulevard
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April 27, 2004

TO: Betty Shaw and Dr. Lawrence Schott
Office of Clinical Standards and Quality Centers for
Medicare & Medicaid Services

RE: Medicare C-Peptide Requirement for Pump Coverage

C-peptide measurement is most helpful in defining residual insulin function. It doesn't necessarily identify those patients whose glycemic control is "helterskelter" with wide blood glucose swings and an increased likelihood of hypoglycemia. Insulin deficiency is a spectrum and using C-peptide levels to define therapy risks withholding treatment modalities that would be of benefit.

Insulin pump therapy smooths basal insulin delivery and permits more precise interaction between insulin delivery and food intake. Likewise, basal insulin delivery can be more precisely adjusted during periods of physical activity and exercise or when post-absorptive states exist or are prolonged. Use of an insulin pump helps concentrate the patient's attention to details of personal care while at the same time eases the personal disease management by the patient.

I favor removal of the C-peptide requirement as a criterion for insulin pump use. Every patient with insulin-requiring diabetes is an individual with a unique set of problems. Use of the C-peptide test may help us in final recommendations to the patient, but it is incorrect that the C-peptide level is used as a hurdle to be cleared.

Thanks for your consideration.

Sincerely yours,

Dorothy M. Kahkonen

DOROTHY M. KAHKONEN, M.D.
Division Head
Division of Endocrinology and Metabolism
DMK:cj

CONTRA COSTA MEDICAL GROUP
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Carherine Owen, M.D.
Hugh Wang, M.D.
Anrhony Lecours. N.D., FN.P.

Pediatrics
Paul Cortez, M.D.

Endocrinology
Roy Kaplan, M.D.

April 22, 2004

To Whom It May Concern:
I am pleased to hear you are reconsidering use of the C-peptide as a criterion for medical necessity for an insulin pump. In my extensive clinical experience with persons with diabetes mellitus, I have seen multiple instances when the C-peptide measured within the reference range for normal, and yet adequate control was not obtainable with multiple daily injections of insulin. A deficiency of insulin can occur which is significant enough to severely hamper glycemic control, and yet it does not fall below 110% of the low end of normal.

Additionally, I have had patients who are doing well on insulin pumps forced to switch to injections when they convert to Medicare benefits because they failed the C-peptide test. I find that particularly disturbing, as I have watched these patients' glycemic control worsen, and their psychological state suffer as well.

Insulin pumps have a role in some patients with Type 2 diabetes. I strongly believe the decision of candidacy for an insulin pump should be exclusively in the hands of the endocrinologist and his or her supporting team of clinicians.

Please feel free to call me if you care to discuss.

Sincerely,

Roy Kaplan, M.D.
2700 Grant Street Suite 200 Concord. CA 94520 Tel: (925) 677-0500 Fax: (925) 677-0519

PALM BEACH DIABETES & ENDOCRINE SPECIALISTS, P. A.

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8200 Jog Road, Suite 204, Boynton Beach, Florida 33437 (561) 659-6336 Fax 740-7148
550 Heritage Drive, Suite 150, Jupiter, Florida 33458 (561) 659-6336 Fax 745-4411

William A. Kaye, M.D., F.A.C.P.
Barry S. Horowitz, M.D., F.A.C.P
Gary M. Pepper, M.D., F.A.C.P.

Andrea Gatchair-Rose, M.D.
Shital Patel, M.D.
Edna Tokayer, M.D.
Erik A. Cohen, M.D.

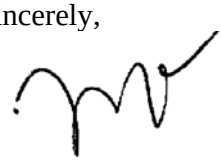
April 15, 2004

Dear Medicare representative:

I have been asked to add my thoughts about the meaning of a good or normal C-peptide level in diabetic individuals thought to otherwise be candidates for the insulin pump. I have been in the practice of diabetes management for 20 years. I can say without a doubt that often type 2 diabetic individuals are easier to manage than the type 1 diabetic individuals. Typically, as you know the distinction between type 2 and type 1 is often made with a C-peptide level. I appreciate Medicare's position that a good C-peptide level means that you have type 2 diabetes and therefore it means that you will probably be able to be better managed. However, there are frequent exceptions to this assumption and I can tell you with a clear conscience that there are individuals with type 2 diabetes, elevated C-peptide levels that who have diabetes that cannot be controlled using conventional insulin shots despite multiple doses. A good endocrinologist will only recommend an insulin pump when he absolutely believes it is needed and he does not use the C-peptide to make this determination. I hope that he will allow diabetics who have poor diabetic management yet good or high C-peptide levels to receive the insulin pump. This is a devastating disease and a simple lab value should not stand in the way to appropriate management.

Submitted with respect.

Sincerely,



William A. Kaye, M.D., F.A.C.P.

West County
Internal Medicine, Inc.

Charles Kilo, M.D., F.A.C.P. — Internal Medicine, Diabetes Endocrinology
Charles John Kilo, M.D. — Internal Medicine
Christine Wilmsen, M.D. — Internal Medicine

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April 20, 2004

CPEPTIDE CRITERIA MEMO

To whom it may concern,

I am in favor of excluding C-peptide from the current criteria to deny request for CSII based on medical necessity.

I see several patients with nephropathy who would benefit and possibly delay or prevent complications by intensive management with insulin pump therapy, yet they are denied on the basis of the C-peptide. This is despite the fact that they meet all other Medicare criteria, and that kidney failure can elevate the C-peptide levels. I realize that criteria are important when authorizing expensive DME; however, most of the costs related to diabetes are to treat complications. Patients with nephropathy and even early" microabinuria require tight glycemic control in order to delay dialysis and even the need for transplantation.

On an average, the 1st year cost following a kidney transplant is $116,100. Medications are approximately *$20,000/year.* Medicare covers all reasonable expenses except Part A deductible and Part B 20% co-insurance. This is a significant amount of money especially if early intensive management can delay and even reverse kidney complications. As a board certified endocrinologist and member of the ADA board of directors, my staff and I spend a significant amount of time educating patients and implementing intensive management to prevent and delay complications.

Thank you in advance and I am looking forward to moving in the right direction to eliminate a barrier to my medical decision regarding diabetes management.

Sincerely,

Charles Kilo, MD

Charles Kilo M.D.

Presbyterian

ENDOCRINOLOGY & OSTEOPOROSIS CONSULTANTS

Remarkable People. Remarkable Medicine.

Roberta S. Bracken, MD
Richard E. Kleinmann, MD
Adam F. Spirz, MD
E. Shannon Story; MD
Victoria Morimoto, PA-C

April 27, 2004

Lawrence Schott, M.D.
Coverage and Analyst Group, Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Dr. Schott:

I am writing to endorse elimination of the C-peptide requirement for approval of insulin pump therapy in Medicare and Medicaid patients. I would make the following two points:

1. With appreciation of the importance of tight blood sugar control and improved methods to achieve it, many people who develop type 1 diabetes early in life are now living into the Medicare age bracket. Insulin pump patients who clearly have type 1 diabetes and come under Medicare coverage are currently required to have a C-peptide test in order to continue to receive their insulin pump supplies. From a medical standpoint, this test is totally unnecessary. These are patients who have obvious type 1 diabetes, and may have been on insulin pump therapy for years.

2. Many patients with longstanding type 2 diabetes lose their responsiveness to oral agents and end up requiring intensive insulin regimens similar to those used by type 1 diabetics. In some of these patients, insulin pump therapy is the best way to achieve good blood sugar control. C-peptide levels are not a factor in this decision. Some patients with this stage of type 2 diabetes may still have measurable C-peptide levels that do not meet Medicare criteria for insulin pump therapy. This may lead the physician, in the interest of good patient care, to measure C-peptide multiple times, until an acceptable level happens to be obtained. Sometimes in type 2 diabetes, we may use C-peptide as one factor in deciding whether to persist in non insulin therapy or to start insulin. However, insulin pump therapy is a consideration later in the course when the patient is already on a multiple dose insulin regimen. At this point, C-peptide is not a factor in deciding whether insulin pump therapy is appropriate. In my opinion, insulin pump therapy is appropriate for any diabetic patient, type 1 or type 2, that requires and is compliant with an intensive insulin regimen and in whom insulin pump therapy would offer the potential for improved diabetes control and/or a more normal life-style. Clinically, the C-peptide level is not a factor in determining whether an individual patient is a good insulin pump candidate, and I do not feel that

it should be a Medicare or Medicaid criterion either. The current policy is leading to the expense and inconvenience of many unnecessary C-peptide tests.

I very much appreciate the opportunity to express an opinion on this matter.

Sincerely,

Richard E. Kleinmann, M.D., FACP, FACE
Endocrinology and Metabolism

REK:pc

1918 Randolph Road, Suite 220, Charlotte. NC 28207 Phone 704.338.6300 Fax 704.384.8287

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2521 GLENN HENDREN DRIVE, SUITE 306
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ENDOCRINOLOGY
MICHELLE L. ORR, M.D.
LAWRENCE E. KOPPERS, M.D.
F.A.C. P., F.A.C. E.

GASTROENTEROLOGY
GARY D. COOPER, M.D.

INTERNAL MEDICINE
JAMES H. OLSON, M.D.
HEATHER L. RICHIE, M.D.

April 19, 2004

Ms. Betty Shawn
Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06 Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Ms. Shawn and Dr. Schott:

As a practicing Board Certified Endocrinologist and Diabetologist with over 30 years experience. I believe it is imperative that we remove the C-Peptide criteria for Medicare patients. C-Peptide in my experience has had it greatest utility in diagnosing islet cell tumor of the pancreas producing insulin which are exceedingly rare. Many patients are not able to get insulin pump' therapy or to continue existing pump therapies because of problems in interpreting C-Peptide assays. Many of our patients have chronic renal disease and it is difficult to evaluate C-Peptide assays in the face of renal insufficiency.

Sincerely,

Lawrence E. Koppers, M.D.
LEK:sms

cc: Vesta Gimmarro, R.N.

SOUTH GEORGIA
MEDICAL CENTER
P.O. Box 1727, VALDOSTA, GEORGIA 31603-1727

May 05, 2004

Jennifer Lawrence, M.D.
3018 N. Patterson St.
Valdosta, Georgia 31602

Ms. Betty Shaw and Dr. Lawrence Schott.
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Ms. Shaw and Dr. Lawrence Schott:

This letter is in regard to C-peptide requirements for institution of continuous insulin infusion systems. I am an endocrinologist practicing in South Georgia, chief of endocrinology at South Georgia Medical Center and director of the Diabetes Management Center at South Georgia Medical Center. We have many patients who have benefited from being on insulin pumps. These are patients who may actually have demonstration of some insulin reserve by C-peptide analysis; however, they are patients we have chosen to institute on insulin pumps due to significant hypoglycemia and sensitivity to small adjustments in insulin. These are patients who benefit from having an insulin pump who can use a low basal rate for example in the evening and a higher basal rate during the day and who benefit from very small adjustments in insulin coverage at mealtime.

These issues have nothing to do with C-peptide levels or insulin reserve. They are, in fact, related more to insulin sensitivity or resistance. Therefore, I implore that you consider patients health issues over C-peptide levels in allowing patients with Medicare and Medicaid to have insulin pumps.

I also implore that you consider pregnant patients in whom blood sugar control is very important for our Medicaid patients.

I will be happy to answer any questions if needed.
Sincerely,

Jennifer Lawrence, M.D.
JL/adw

LAMPTON MEDICAL, PC

BRETT C. *LAMPTON, MD.*
INTERNAL MEDICINE
140 N 5th Street, Suite A
McComb, MS 39648
Phone (601) 684-2883 *Fax (601) 684-2866*

April 19, 2004

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

Dear Sirs:

I am writing this letter to ask your consideration in removing the c-peptide requirement for medicare patients to qualify for insulin pump therapy. Although the majority of my patients with type 2 diabetes are not insulin pump candidates, I would like the opportunity to help good pump candidates live a healthier life by placing them on this therapy. My intent is to help my patients manage their disease in the most effective manner possible. By removing the c-peptide qualification, I will be able to do that. Thank you for your time and consideration.

Sincerely,

Dr. Brett Lampton

The
DIABETES CENTER
at Mercy

April 19, 2004

Ms. Betty Shaw & Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

To Whom It May Concern:

I am writing to explain our experience with the difficulties of using C-peptide determinations as an indicator for which patients should be candidates for CSII, insulin pump therapy. While C-peptide determinations can often give an assessment of insulin reserve, this data in no way determines which patients will benefit from insulin pump therapy. Our clear experience is that other issues affecting a patients control, such as hypoglycemia frequency, dawn phenomena tendency, erratic schedules and advancing complications are far more relevant that C-peptide in determining appropriateness of pump therapy in a given patient. Patients with C-peptide over the limit are often in poor control, and as good or better pump candidates as those with lower C-peptide. An example of this situation is a Type 2 diabetic patient who despite moderate C-peptide production has a high degree of insulin resistance so that the circulating endogenous insulin is ineffective in achieving control. C-peptide determinations also have several technical issues that my add difficulty to interpreting the validity of a C-peptide level. Renal failure can give an inadequate picture of the true C-peptide level (l,2). A recent abstract at the 2003 National American Association of Clinical Endocrinologist meeting noted that "errors are likely when a single measure of C-peptide is used to distinguish between Type 1 and type 2 diabetes." (3) The effect of high glucose leading to glucose toxicity on the beta may transiently alter C peptide production; further blurring what is the true C-peptide level for an individual.

Finally, we have several personal experiences where C-peptide determinations created difficulties in making appropriate medical decisions for our patients. One of our patients had been on an insulin pump for 6 years before reaching Medicare eligibility and faced possible loss of her pump support if her C-peptide was high. She barely made the cut off, but this created major stress and anxiety in a patient who had done very well on pump therapy with A1c levels in the low 6's for many years. Another patient who had been clinically started on pump therapy and who was improved and satisfied was the required to get C peptide which was .2ng over the limit, she could lose support for her current pump. This situation has been highly traumatic for the patient and difficult for the medical staff.

The overall problem with C peptide is that there is a severe disconnect between' the C peptide number and any clinical relevance of this number in predicting who will successfully benefit

from initiation of pump therapy. Our evaluation of other well established clinical factors to determine eligibility is already sufficient to screen for appropriate pump use and proper resource allocation in the patient population.

Sincerely,

Philip A. Levin, MD
Medical Director, Diabetes Center at Mercy Medical Center
Associate Professor, University of MD School of Medicine

Reference:

1. Serum C-peptide concentrations poorly phenotype type 2 diabetic end-stage renal disease patients. Covic AM, Schelling JR, Constantier M, Iyengar SK, Sedor, Jr.
2. C-peptide kinetics following an intravenous glucose load in children undergoing Regular hemodialysis. Bulla M, Ronda-Vildosoka T, Hubinger D.
3. AACE 2003 - Zangeneh, The Natural History of Insulin Secretion in Patients with Type 2 Diabetes. Abstract 65

301 St. Paul Place Baltimore, Maryland 21202 Phone: 410-332-9800 Fax: 410-545-4514

Philip A. Levin, M.D.
Medical Director
Errol Rushovich, M.D.
Endocrinologist
Paula S. Yutzy, RN, BSPA, CDE, D
Director of Diabetes Education

ALICE K. LEE, M.D., F.A.C.P., F.A.C.E.
Endocrinology & Metabolism / Internal Medicine

April 28, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Ms. Shaw and Dr. Schott,

It has recently come to my attention that Medicare is considering the deletion of the C-Peptide requirement for coverage of insulin pumps. This requirement has created distinct clinical difficulties and increased costs for patients with long standing type 1 diabetes, and barriers to patients with type 2 diabetes.

As a practicing endocrinologist, I have recommended insulin pumps for my patients with type 1 diabetes. Approximately 90% of my patients, however, have type 2 diabetes, and I am frustrated by their inaccessibility to the most physiologic insulin therapy for treatment of their type 2 diabetes.

Over the last decade there have been a number of studies documenting the advantages of pump therapy to patients with type 2 diabetes (Jenning, *Diabetes Care*, 1991; Koval, *Diabetes.* 1993; Davidson, *Diabetologia*, 1999; Hanaire-Broutin, *Diabetes Care, 2000;*Testa, *Diabetes*, 2001; Wainstein, Diabetologia, 2001; and Pouwels, *Diabetic Medicine*, 2003). The reasons for the success of pump therapy include:

- reduction in Hgb A1c by as much as 2.1 %,
- reduction in the amount of insulin required,
- reduction in cardiovascular risk factors,
- decreased weight,
- improved patient quality of life and
- definite patient preference

Thank you for your consideration of this critical issue.

Sincerely,

Alice Lee, M.D.

41-61 Kissena Blvd., Concourse level, Suite 25A, Flushing NY 11355
Tel: (718) 321-2122 Fax: (718) 321-0148

LOMA LINDA UNIVERSITY MEDICAL CENTER

Diabetes Treatment Center

11285 Mountain View Avenue, Suite 40
Loma Linda, California 92354
(909) 558-3022

To Medicare,

This is a letter in regards to continuous subcutaneous insulin infusion (CSII aka insulin pump) and the utilization of C-peptide in determining candidate eligibility.

C-peptide is a useful test in determining pancreatic function. It is a much more specific test (because of its low inter-individual variability) for determining whether or not the beta cells of the pancreas are producing insulin than measuring insulin itself. Therefore, the primary use of this is to help distinguish between type 1 and type 2 diabetes.

Traditionally, insulin pumps were only selected for patients with type 1 diabetes. However, more recently, they have been used in type 2 diabetes with solid positive outcomes. C-peptides were used to classify if patient had type 1 diabetes and therefore a candidate for the insulin pump, however, since many patients with type 2 diabetes are now candidates, C-peptides is no longer clinically relevant in assessing pump candidacy.

Many patients with type 2 diabetes have congestive heart failure, renal insufficiency or liver dysfunction and therefore can not take certain diabetic oral agents. Because of these co-morbidities they need multiple daily injections to control their glycemia. In this way, they are "insulin" requiring diabetics irregardless of whether their C-peptide is present or not.

Possible candidacy criteria for insulin pump would be to:

I) Type 1 diabetes uncontrolled
2) Type 2 diabetes failed oral agents and on multiple daily injections and uncontrolled
3) HbAlc >6.5%
4) Severe hypoglycemia

Please do not hesitate to contact me should you have any questions.

Scott W. Lee, MD
Assistant Professor of Medicine

Southern California Thyroid, Diabetes &Endocrine Center
50 Bellefontaine St., Ste 308, Pasadena, CA 91105-3132
316 E. Las Tunas Dr., Ste 102, San Gabriel, CA 91776

Tel: (626) 585-8911 **Fax: (626) 585-8914**

Michael W. Lin, MD

Dear Medicare:

Date: Apr. 29, 2004

I am writing regarding the use of C-peptide for determining candidates suitable for insulin pump.

I have known that for insulin requiring diabetic patient to be approved for the insulin pump under Medicare, the C-peptide level has to be in the lower range of normal.

This may be a useful tool in some type 2 patients, but I have come across may insulin requiring type 2 patients with mid to high range C-peptide who have erratic control. These are the patients whom I believe will benefit from using insulin pump. Therefore. I am recommending the clinical assessment such as erratic glycemic control, frequent hypoglycemia, and etc. be used as criteria. The presence of C-peptide should not be a relevant factor.

Sincerely Yours.
Michael W. Lin, MD
Endocrinology, Diabetes &Metabolism

UNIVERSITY OF
SOUTH CAROLINA

SCHOOL OF MEDICINE
DEPARTMENT OF INTERNAL MEDICINE
TU LIN, M.D., PROFESSOR AND DIRECTOR, ENDOCRINOLOGY - 803/733-3124
JURAJ OSTERMAN, M.D., PH.D., PROFESSOR - 803/733-3126
H.V. MURDAUGH, JR., M.D., PROFESSOR - 803/733-3125
G.N. OLSEN, M.D., PROFESSOR AND DIRECTOR, PULMONARY - 803/733-3161

April 28, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Service
7500 Security BLVD
Baltimore, Maryland 21244

Dear Ms. Betty Shaw and Dr. Schott:

I do not agree current Medicare criteria for using C-peptide level for CSII. I have patient who has diabetes since age 3 and had kidney and pancreas transplant. Unfortunately her pancreas transplant failed and she is back on insulin. Her diabetes is brittle and poorly controlled. She also developed mild renal insufficiency. Insulin pump is the best way to get her diabetes under better control to prevent further deterioration of renal function. Unfortunately her C-peptide level was slightly above the cut off point, and request for insulin pump was denied. C-peptide level is a helpful guideline for insulin pump but need to take other factors into consideration. Furthermore, in patients with renal insufficiency, C-peptide level will not be valid.

I strongly support that Medicare changes current criteria using C-peptide test.

Sincerely,

Tu Lin, M.D.
Professor and Director
Division of Endocrinology

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Southwest
Diagnostic
Clinic, L.L.P.

April 20, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:

Thank you for letting me comment on the current and future C-Peptide requirement for the Insulin Infusion Pump. This requirement is one that has diminished my ability to treat and care for my patients with Medicare. Please reconsider the current requirements.

I have managed patients on Insulin Infusion Pumps for many years. Over the last several years, I have seen an increase in the number of Type 2 patients who have moved into an intensive insulin management. I know from my experience that the more intensive an insulin regimen - the better the level of control for the patient. The current C-Peptide criteria, is different from any private insurer or even Medicaid standards and limits my ability to move my patients into the Insulin Infusion Pump. I have several patients who are extremely motivated and are considered excellent candidates for the pump but have been denied because of the C-Peptide lab test. This criteria has made it much more difficult for these patients to achieve the best level of control possible and has led to an increased risk for diabetic complications within this patient population.

I would support a move to abolish this arbitrary standard that prevents some of my patients achieving the best possible standard of care.

Thanks,

Nelson Lum MD

Nelson W. Lum, M.D.
Board Certified Endocrinology & Metabolism
3801 50th Street Lubbock, Tx 79413 / (806) 771-5560 / Fax (806) 771-5522

Daniel Macias, M.D.
Endocrinology
Diplomate American Board of Endocrinology, Diabetes and Metabolism
Diplomate American Board of Internal Medicine

April 27, 2004

CMS
Ms. Betty Schott
Dr. Lawrence Schott
Coverage & Analyst Group
Mail Stub C1-0906 Office of Clinical Standards & Quality Centers for Medicare & Medicaid Svc
7500 Security Blvd.
Baltimore, MD 21244

Dear Madam/Sir:

I am writing to you regarding the CMS criteria regarding C-peptide for insulin pump candidates. Frankly, it has been my personal experience at the C-peptide testing is not an accurate and predictable test for classifying patients for insulin pumps. The testing is frankly insensitive and affected by many other medical conditions including renal failure in blood sugar levels. I believe consideration should be given for removal of the C-peptide as part of the criteria for insulin pump patients. I have had several patients in the past who had C-peptide which exceeded the CMS criteria who benefited from an insulin pump and who did quite well with it who were obvious excellent candidates. On the other hand, other patients I have known about including some from my colleagues, have not been able to obtain insulin pump despite obvious medical necessity.

As part of the 30-day comment period that has been made available by you, I am asking you to consider the exclusion of C-peptide levels as a sine qua none for meeting criteria for insulin pump. I sincerely hope that these rules art changed, since I am certain that it will be of great benefit to many patients who should benefit from an insulin pump, but who are presently disqualified from obtaining it.

Sincerely,

Daniel Macias, MD

122 High Street • Marshall, MI 49068 • (269) 781-3461

SAMUEL A. MALAYAN, M.D., Ph.D.
DIABETES • ENDOCRINOLOGY • METABOLISM
INTERNAL MEDICINE

Medicare

April 26, 2004

To Whom It May Concern:

I am an endocrinologist who practices in Glendale, California. The majority of my patients are type 2 diabetics. I am writing this letter to request that you reconsider the condition that patients must have a C-peptide level below the maximum reference range for a given laboratory qualify for in order to receive insulin pump therapy. The reason for this request is that there are many patients who have C-peptide levels higher than the minimum reference range, who would still benefit greatly from insulin pump therapy. For example, I have a patient who is a lean man who requires more than five-hundred units of insulin presently. His hemoglobin A1C is still at 9.0%. His C-peptide level is *1.6mg/ml;* the minimum of the reference range is 1.1 *mg/ml.* I have had patients who required similarly large doses of insulin; some of them benefited greatly from insulin pump therapy, even though their C-peptide level was above the minimum of the reference range. If Medicare authorized the use of insulin pump in such appropriate patients, in spite of C-peptide level above the reference range, I could treat them more effectively, and thereby reduce complications of Diabetes.

There are many other situations in Clinical Endocrinology in which patients have done C-peptides which are not below the reference range, yet they are clearly insulin requiring. There is particularly the case in those patients who require large doses of insulin. I hope that you will take the benefit of my twenty years of clinical practice, and take my request of changing the particular criterion for enabling patients to be treated with insulin pump therapy. If such a change were made, it would certainly be cost effective, patients who are well controlled are able to avoid blindness, and stage renal disease, and amputations. Furthermore, the occurrence of Coronary Hearth Disease can be decreased.

I hope that this letter will aid you when you reconsider the criteria for conesage of insulin pump by Medicare.

Yours truly,

Samuel A. Malayan, M.D., Ph.D.

610 N. Central Ave. Suite 301, Glendale, CA 91203 Tel.: (818) 550-0702 Fax: (818) 550-0705

Deo Martinez, M.D., P.C.
DIPLOMATE AMERICAN BOARD OF INTERNAL MEDICINE
DIABETES SPECIALIST
MEDICAL DIRECTOR, DIABETES TREATMENT CENTER, PARKVIEW COMMUNITY HOSPITAL
13050 HEACOCK STREET
MORENO VALLEY, CALIFORNIA 92553

(909) 656-1660

April 26, 2004

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Attention: Ms. Betty Shaw
Dr. Lawrence Schott

RE: C-PEPTIDE CRITERIA FOR CSII

Dear Ms. Shaw and Dr. Schott:

This letter is to express my views on the use of C-peptide criteria in determining eligibility of Medicare patients for insulin pump therapy.

In my practice, I have patients up to the age of 73 years on insulin pump therapy. It is a valuable tool in obtaining and maintaining glucose control, regardless of age or type of diabetes. Many patients who have been unsuccessful in obtaining control through the use of MDI, have found the insulin pump to be highly effective in achieving euglycemia. Patients experiencing frequent hypoglycemia events due to attempting to achieve tight control on MDI, find a decrease in those events with the use of insulin pump therapy.

In January 2002, the criteria that a Medicare patient have type 1 diabetes in order to use CSII was removed. This was a step in the right direction, as we all know that pump therapy also benefits those with type 2 diabetes. People with type 2 diabetes frequently require intensive insulin therapy to manage the complex and multiple co-morbidities involved in this disease process. Euglycemia is not always able to be achieved with multiple injections. The use of the insulin pump, however, provides us with that opportunity. Removing the C-peptide criteria completely at this point, would continue to improve the lives of more people, and I would encourage CMS to do so.

Sincerely,

Deo Martinez, MD

IMA

INDIANA MEDICAL ASSOCIATES LLC

April 21, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards & Quality
Centers for Medicare & Medical Services
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Ms. Shaw and Dr. Schott,

It has been brought to my attention that Medicare is using a normal C-Peptide lab result as criteria to deny authorization for insulin pumps for diabetic type II patients. I hope the following information will helpful in shedding some new light on this policy.

The C-peptide is a useful tool when used along with other factors in determining what is necessary for a patient's treatment plan. There are many variables that work together in controlling individual blood sugars to use just one criterion. Even though a C-peptide level falls in normal range, the individual may be insulin deficient in ability to control blood sugars. The C-peptide only means that the patient can produce some insulin.

I see many patients in this office whose C-peptide is within normal range but their blood sugars are erratic and cause them many episodes of highs and lows. It is these highs and lows that are dangerous and an insulin pump has been proven to be very effective in controlling the blood sugar.

As research shows, blood sugar control prevents many complications normally seen in uncontrolled diabetes. This not only benefits the individuals involved but, in turn, would save the program further expense in the future. The complications from uncontrolled diabetes are tremendously ravaging and expensive.

I have many years of experience in treating diabetes and have numerous patient case histories where their C-peptide was in normal range but their erratic blood sugars caused numerous problems. Once they began using the insulin pump, their blood sugars leveled out and they achieved remarkable control.

I believe a physician's recommendation based on the individual's condition and blood sugar history should be used to determine the use of an insulin pump. A normal C-peptide should not be the criteria considered in the denial of an insulin pump and supplies. The pump is necessary for patients whose blood sugars are difficult to control and is beneficial for all concerned. I can provide many case histories if you need more information or documentation.

Sincerely,

L Mastbaum MD

Leonard I. Mastbaum., MD, FACE
Endocrinology

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April 28, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Ms. Shaw and Dr. Schott,

It has recently come to my attention that Medicare is considering the deletion of the C-Peptide requirement for coverage of insulin pumps. This requirement has created distinct clinical difficulties and increased costs for patients with long standing type 1 diabetes, and barriers to patients with type 2 diabetes. As a practicing endocrinologist, I have recommended insulin pumps for my patients with type 1 diabetes. Approximately 90% of my patients, however, have type 2 diabetes, and 1 am frustrated by their inaccessibility to the most physiologic insulin therapy for treatment of their type 2 diabetes. Over the last decade there have been a number of studies documenting the advantages of pump therapy to patients with type 2 diabetes (Jenning, *Diabetes Care,1991* Koval, *Diabetes,* 1993; Davidson, *Diabelologia,* 1999; Hanaire-Broutin, *Diabetes Care, 2000;* Testa, *Diabetes,* 2001; Wainstein, *Diabetologia,* 2001; and Pouwels, *Diabetic Medicine,* 2003). The reasons for the success of pump therapy include:

- reduction in Hgb A1c by as much as 2.1%,
- reduction in the amount of insulin required,
- reduction in cardiovascular risk factors,
- decreased weight,
- improved patient quality of life and
- definite patient preference

Thank you for your consideration of this critical issue.

Sincerely,

J. Matrisciano M.D. M.L.

Justin Matrisciano, M.D.

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J.H. Warvel, Jr., M.D.
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April 29, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Dr. Schott and Ms. Shaw:

I am writing this letter to make you aware of my concern about continued C peptide testing being used as a criteria for any coverage decision pertaining to insulin infusion pumps.

I am an endocrinologist in Indianapolis, Indiana and have been in practice for 18 years. I was trained at the Joslin Diabetes Center in Boston, Massachusetts and have a large diabetes practice in Central Indiana.

I believe that we have one of the larger insulin pump practices in the country based on the number of patients involved and the ongoing care that we provide for those patients.

Several years ago when C peptide testing became mandatory for coverage decisions regarding insulin pump therapy, I thought that it was an absurd use of that test.

Insulin pump therapy benefits patients with Type 1diabetes and also in certain circumstances patients with Type 2 diabetes.

Clearly the absence of C peptide is an indicator that an individual has Type 1 diabetes, however, it really should have no bearing on the clinical decision to offer insulin pump therapy to a patient with diabetes mellitus.

I can think of no instances where drawing a C peptide has been of any clinical benefit, or have any relevance in my decision to advise a patient to use an insulin pump to manage their disease.

I have many examples in my own practice where patients who have had Type 1 diabetes for longer than 30 years who have been forced, even after they have been on an insulin pump, to come to the office only to determine that they, in fact, are C peptide negative. C peptide testing should be at the discretion of the prescribing physician, and not mandated in a general sense with some notion that it might help in the decision to use an insulin pump for treatment.

Furthermore, there are patients who have long standing Type 2 diabetes who are insulin deficient but not C peptide negative, who benefit from insulin pump therapy and are denied coverage because of the presence of measurable C peptide.

In my opinion, mandatory C peptide testing has no bearing on the decision-making process that leads to a recommendation for insulin pump therapy.

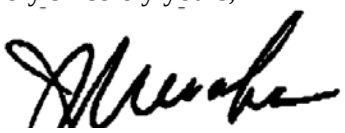
Those of us who are involved in large insulin pump programs might better be able to advise you on selection criteria that would lead to successful treatment with insulin pumps, and better serve as a screen for appropriate use of the device. Laboratory testing of any sort would not necessarily be needed to develop effective screening guidelines.

In conclusion, I would recommend very strongly that C peptide testing be eliminated as a test that influences the decision for coverage on insulin pump therapy in any way.

I would be more than happy to speak with you directly on this matter. My private line at the office here in Indianapolis is 317-573-4061. I am in the office Tuesday through Friday, usually from early in the morning until mid afternoon,

Thank you very kindly for taking a moment to read this letter.

Very sincerely yours,



James E. Meacham, M.D., F.A.C.E.
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April 07, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

Dear Ms. Shaw and Dr. Schott:

I am writing to submit a recommendation that C-peptide levels not be used to determine eligibility status for insulin pump coverage. I am strongly in support of this recommendation for several reasons. Firstly, C-peptide is not a useful marker of a patient's clinical status, nor is it ever used to make changes in therapeutic recommendations for patients that have diabetes. It has limited diagnostic utility and is most often used within the setting of research protocols and academic studies. What often determine the need for intensification of insulin therapy are the patient's blood glucose fluctuations, current anti-glycemic therapies and education/problem solving skills. The decision to use CSII or MDI for implementation of intensive insulin therapy is based on the best possible assessment of the health status and diabetes control by patient and health care provider team. The goal of insulin management is to achieve the lowest possible (and appropriate) A1C without unacceptable hypoglycemia. To this end it should be the informed-patient's and the informed treating physician's decision whether insulin therapy is best implemented through CSII or MDI.

We have a considerable experience with using CSII for diabetes management, having instituted educational programs for patients starting CSII therapy for many years. Over the past 6 years we have averaged about 60-80 pump starts yearly, and often have the

opportunity of "re-educating" patients that were started on insulin pump therapy elsewhere. What we often observe is that patients are started on CSII without proper education on the issues of basal/bolus insulin replacement and are thus not making full use of some of the most important aspects of insulin pump therapy. These patients are familiar with some of the basic button pushing features, but have not been trained to properly evaluate adequacy of basal insulin replacement, carbohydrate ratios, correction ratios, etc. Nor have their problem solving skills for diabetes management through CSII been enhanced. A more effective method to ensure that CSII is implemented appropriately would be to require that patients starting CSII be referred to a diabetes education center with appropriate experience in insulin pump therapy. The additional self-management education that these patients will receive from attending such a program would significantly enhance their ability to use insulin pump therapy efficiently and effectively.

If I can provide any additional information or feedback regarding insulin management through either pump or MDI, please do not hesitate to contact me.

Sincerely,

Luigi Meneghini, MD, MBA
Associate Professor of Clinical Medicine
Director, Eleanor & Joseph Kosow Diabetes Treatment Center
Diabetes Research Institute of the University of Miami School of Medicine

LM/sc

LARRY N. MERKLE, MD, FACP
DONALD E. BARILLA, MD, FACP
ENDOCRINOLOGY

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Telephone - 610-820-9557
Fax - 610-820-8529

April 26, 2004

Larry N. Merkle, M.D.

Dear Ms. Betty Shaw and Dr. Lawrence Schott,

It has come to my attention that CMS is reconsidering the c-peptide requirement for insulin pump therapy. I am of the opinion that the c-peptide should be removed completely. The decision for the appropriateness of an insulin pump is a clinical decision and therefore should be made by the physician assessing and treating his or her patient.

I am currently treating both type1 and type 2 patients who are experiencing better control and healthier lives because they are successfully using an insulin pump. As these type 2 patients become Medicare eligible, I am concerned that if these patients don't meet the c-peptide criteria, they will have to discontinue the therapy that has improved their control and successfully managed their diabetes.

In addition, I currently have a type 1 patient with renal disease, who was on an insulin pump for several years. When she became Medicare eligible she was no longer able to continue pump therapy because of the inadequacy of the c-peptide with renal patients. This has been very unfortunate as her control has been less than adequate since stopping pump therapy.

Thank you for your reconsideration regarding this issue.

Sincerely,

Larry N. Merkle, M.D.
Endocrinologist

Children's Mercy HOSPITALS & CLINICS

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Kansas City, Missouri 64108
Phone (816) 234-3000 Fax (816) 842-7420

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April 26, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, Maryland 21244

Dear Ms. Shaw and Dr. Schott,

I am writing this letter to discuss the CMS use of C-peptide levels as criteria for approval of Continuous Subcutaneous Insulin Infusion Pumps (CSII). I am a pediatric endocrinologist in Kansas City, Missouri. We manage over 1300 diabetic patients. We have found CSII pumps to be an outstanding way to help patients manage their diabetes. Within our patient population we have a significant number of patients on Medicaid. The diagnosis of Type 1 vs. type 2 diabetes is largely based on the clinical presentation of the patient. While use of C-peptide levels can be used as a guide, there are many instances when these levels are not accurate. For example, a patient with Type 1 diabetes may be identified very early in the course of their disease and still produce a small amount a insulin leading to a falsely reassuring C-peptide level. I am finding that the C-peptide requirement adds one more unnecessary hurdle to getting our patients on insulin pumps. The goal of any physician working with patients with diabetes should be to find the best possible way to help them achieve a Hemoglobin Al c at or below 7.0%. Achieving this goal, regardless of the type and method of insulin delivery, is best for the individual patient and our healthcare system in general. Continuing the C-peptide requirement will, in my opinion, limit this opportunity. Thank you very much for your consideration.

Sincerely,

L. Kurt Midyett, MD

L. Kurt Midyett, MD

SUFFOLK ENDOCRINOLOGY ASSOCIATES, L.L.P.
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PHYLLIS MIGDAL, M.D.
MICHELLE C. JARDINE, M.D.

April 28, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Dear Ms. Shaw and Dr. Schott,

It has recently come to my attention that Medicare is considering the deletion of the C-Peptide requirement for coverage of insulin pumps. This requirement has created distinct clinical difficulties and increased costs for patients with long standing type 1 diabetes, and barriers to patients with type 2 diabetes. As a practicing endocrinologist, I have recommended insulin pumps for my patients with type 1 diabetes. Approximately 90% of my patients, however, have type 2 diabetes, and I am frustrated by their inaccessibility to the most physiologic insulin therapy for treatment of their type 2 diabetes.
Over the last decade there have been a number of studies documenting the advantages of pump therapy to patients with type 2 diabetes (Jenning, *Diabetes Care*, 1991; Koval, *Diabetes*, 1993; Davidson, *Diabetologia*, 1999; Hanaire-Broutin, *Diabetes Care, 2000;* Testa, *Diabetes*, 2001; Wainstein, *Diabetologia*, 2001; and Pouwels, *Diabetic Medicine*, 2003). The reasons for the success of pump therapy include:

- reduction in Hgb Alc by as much as 2.1%,
- reduction in the amount of insulin required,
- reduction in cardiovascular risk factors,
- decreased weight,
- improved patient quality of life and
- definite patient preference

Thank you for your consideration of this critical issue.

Sincerely,

Phyllis Migdal, M.D.

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare& Medicaid Services
7500 Security BLVD
Baltimore, MD 21244

April 26, 2004
As a board certified endocrinologist, I am submitting this letter in opposition of the current criteria set forth by Medicare in determining which patients are candidates for insulin pump therapy.

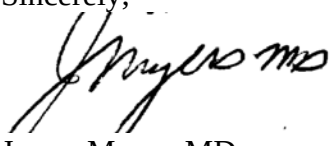
I have over 250 patients on insulin pumps both type 1and type 2 patients. I prescribe insulin pumps for my patients for whom their glucose control is not optimal with injections despite many changes in amounts of insulin, types of insulin and the number of injections they are taking.

My type 2 patients who have gone on pump therapy have seen the same health benefits as my type 1patients on pumps and I do not understand why the coverage for pump therapy should be limited to those patients within the Medicare system who have type 1 diabetes.

I have instances where I had younger patients on Medicare who were on the pump through private insurance and upon going on Medicare for disability had to go off pump therapy because their C-peptide result came back too high. I was quite surprised to see some patient's c-peptide levels come back high as I had determined or diagnosed those patients as type 1 due to their younger age and no other typical characteristics of type 2 diabetes ie: overweight status, insulin resistance and being prone to ketoacidosis.

As a physician who takes care of thousands of patients with diabetes, I am voicing my support to discontinue the current c-peptide criteria for determining insulin pump candidate selection. I would support an initiative to have Medicare approve insulin pumps for type 2 individuals as well. The health related costs from diabetes complications f far outweighs the initial cost for pump therapy and if more type 2 diabetic patients used pumps these costs would decrease.

Sincerely,



James Myers, MD
Board Certified Endocrinologist, Internist

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April 28, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
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- decreased weight,
- improved patient quality of life and
- definite patient preference

Thank you for your consideration of this critical issue.

H. Narula M.D. MC.

Harmeet Narula, M.D.

PETER T. NGO, M.D., F.A.C.E.
Diplomate, Subspecialty of Endocrinology, Diabetes and Metabolism

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Laredo, TX 78041
Telephone: (956) 712-9171
Fax: (956) 712-9402

April 12, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

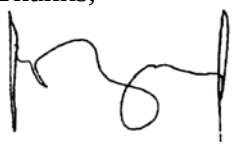
To Whom It May Concern:

Thank you for the opportunity to comment on the current and future C-Peptide requirement in relation to the Insulin Infusion Pump. This requirement is one that has limited my ability to treat and care for my Medicare patients for some time and I am encouraged that you are reconsidering the criteria.

Over the past two years, I have seen a dramatic increase in the number of Type 2 patients- who have moved into an intensive insulin regimen. I know from experience that with the more intensive an insulin regimen - the better the level of control for the patient. The current C-Peptide requirement is different from any third party insurer or even Medicaid standards and currently limits my ability to move my patients into the Insulin Infusion Pump. I have several patients who have been considered excellent candidates for the pump but have been denied because of the lack of a qualifying C-Peptide lab test. This has made it much more difficult for these patients to achieve the best level of control possible and has contributed to an increased risk for diabetic complications within this population.

I would welcome a move to abolish this arbitrary standard that prevents some of my patients achieving the best possible standard of care.

Thanks,



NEW YORK MEDICAL COLLEGE
A Medical University

DEPARTMENT OF PEDIATRICS
DIVISION OF ENDOCRINE AND METABOLIC MEDICINE

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Richard A. Noto, M.D., Chief
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Alicia Romano, M.D.
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Michael Frey, Ph.D.
Jessica Glynn, M.S., R.N., C.F.N.P.
Ann Sangalli, R.N.

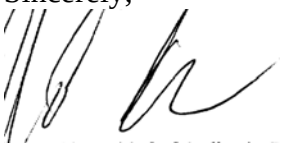
Julieann Waclawski, R.N., C.S., P.N.P.
Rebecca H. Crespi, R.N., M.S.N., C.P.N.P.
Simone Wilker, B.S., M.B.A.
Veronica Belen, Off. Mgr.
Dipali Gajjar, B.S.

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

Dear Ms. Shaw, and Doctor Schott,

My name is Richard Noto, MD; I am a Pediatric Endocrinologist in practice for 20 years. I treated and started the first patients in New York State with a portable insulin infusion pump in 1980. The insulin pump is a dramatic improvement in the care of patients and children with diabetes. It provides not only better control but improved lifestyle benefits. C-Peptide criteria for deciding if someone should be treated with the insulin pump makes absolutely no sense. Patient selection should be based on the individual needs of the patient, as determined by the prescribing physician. The insulin pump is a better way of treating diabetes and should be looked at that way, and not as a last ditch effort to deal with someone who is in poor control. In the long run, treating patients with insulin pump therapy is also cost effective. I hope you support the idea of having unlimited criteria for the utilization an insulin pump, and not strict criteria based on Alc values or C-Peptide results. Thank you for your attention to this matter.

Sincerely,



Richard Noto, MD – Chief of Pediatric Endocrinology New York Medical College

WILLIE TEO ONG, M.D., F.A.C.E.

Board Certified In Internal Medicine & Endocrinology, Diabetes and Metabolism

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Phone (956) 548-0077
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April 12, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
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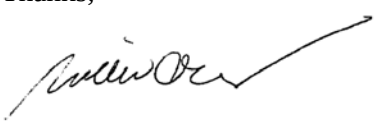
To Whom It May Concern:

Thank you for the opportunity to comment on the current and future C-Peptide requirement in relation to the Insulin Infusion Pump. This requirement is one that has limited my ability to treat and care for my Medicare patients for some time and I am encouraged that you are reconsidering the criteria.

Over the past two years, I have seen a dramatic increase in the number of Type 2 patients who have moved into an intensive insulin regimen. I know from experience that with the more intensive an insulin regimen - the better the level of control for the patient. The current C-Peptide requirement is different from any third party insurer or even Medicaid standards and currently limits my ability to move my patients into the Insulin Infusion Purnp. I have several patients who have been considered excellent candidates for the pump but have been denied because of the lack of a qualifying C-Peptide lab test. This has made it much more difficult for these patients to achieve the best level of control possible and has contributed to an increased risk for diabetic complications within this population.

I would welcome a move to abolish this arbitrary standard that prevents some of my patients achieving the best possible standard of care.

Thanks,



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GARY D. COOPER, M.D.

INTERNAL MEDICINE
JAMES H. OLSON, M.D.
HEATHER L. RICHIE, M.D.
JANICE K. McGOVNEY, M.D.

April 14, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Ms. Shaw and Dr. Schott:

I am writing regarding the use of C-peptide tests as an indicator for patients under concern for continuous subcutaneous insulin infusion devices/insulin pumps. An insulin pump is an insulin delivery device. We all know that patients with both type 1 and type 2 diabetes require insulin. An insulin pump is a safe effective means of achieving improved control with less hypoglycemia in many patients whether they are a type I or a type 2. I have had many type 2 patients successfully use insulin pumps with excellent control for years who find that, when they reach the age of Medicare, no longer can use their pump because they still have some endogenous production of insulin. Whether you are a type 1 or a type 2, improved diabetic control and avoidance of hypoglycemia are important goals and an insulin pump is beneficial in this.

I do not understand the requirement regarding C-peptide. C-peptide values can still be present in patients with type 1 diabetes, particularly early in the course of their disease, and can be low or high in patients with type 2 diabetes. As an endocrinologist, we do not have a standardized way of doing C-peptide levels and using them for interpretation and I am unsure as to why Medicare has chosen this test to determine whether a patient should use an insulin pump or not.

Thank you very much for considering dropping the use of C-peptide to determine the need for an insulin pump in a type 2 diabetic patient on Medicare.

Sincerely,

Michelle L. Orr, M.D.

UAB SCHOOL OF MEDICINE
Department of Medicine

April 28, 2004

Dear Ms. Shaw and Dr. Schott,

It has come to my attention that your agency is currently reviewing the C-peptide criteria that is required for patients to be approved for insulin pump therapy. As an endocrinologist, I have considerable experience with this device and have witnessed the difference it can make in glycemic control and quality of life. Unfortunately, several patients whom I regarded as good candidates have been denied access to insulin pumps because of their C-peptide results.

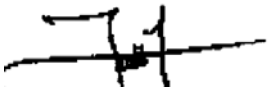
In my professional opinion, the criteria for approval of insulin pumps should be revised so that all patients with type 1 diabetes mellitus (T1DM) might have access to the most advanced form of insulin therapy when prescribed by a board certified endocrinologist. Also, please keep in mind that up to 10% of patients who have been diagnosed with type 2 diabetes by their primary care physicians have actually been misdiagnosed and may have latent autoimmune diabetes of the adult (LADA). Additionally, patients with T1DM and chronic renal failure may have an elevated C-peptide which may overestimate their beta cell function.

As it stands now, patients with T1DM who are currently being treated with the help of and insulin pump risk losing their supply benefits when they reach Medicare age. Forcing these people to give up their pumps and go back to injections would be most unfortunate.

On the other hand, I do not support the wide spread use of insulin pumps for the treatment of type 2 diabetes mellitus (T2DM). I consider it to be an unnecessarily expensive form of treatment which should be reserved for only patients with T2DM with special needs or circumstances. Here again I believe that criteria should include approval only when prescribed by a board certified endocrinologist. However, in the case of T2DM, since there are a few unscrupulous endocrinologist in this country who prescribe insulin pumps even when there is no need only to profit from personal deals with the pump manufacturing companies, I believe that strict but well designed and fair criteria should be in place to allow for the justified use in the few situations where there is a real need while making it difficult for those few dishonest physicians that are
looking to profit form the unjustified widespread use of insulin pumps for patients with true insulin resistant T2DM.. In these cases I believe that using only C-peptide criteria would be too simplistic and unrealistic. I would be happy to assist you in designing such guidelines if you desire.

I ask that you consider these points as you perform your review.

Sincerely,



Fernando Ovalle, MD
Assistant Professor of Medicine
Director, Clinical Research Unit
Director, Fellowship Training Program
Division of Endocrinology, Diabetes & Metabolism
University of Alabama at Birmingham School of Medicine

THE ENDOCRINE GROUP

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Cheryl S. Black, M.D.
Matthew T. Draelos, M.D.
James L. Males, M.D.
Ronald P. Painton, M.D.

April 21, 2004

TO WHOM IT MAY CONCERN

Dear Sir or Madam:

The purpose of this letter is to state my feelings as an endocrinologist relating to the utility of C-peptide levels for determination of insulin pump therapy in people with diabetes.

Patients who have had longstanding type 1 diabetes mellitus generally demonstrate undetectable C-peptide levels and have been insulin requiring for many years in a great number of clinical situations. Measuring C-peptide levels in these patients for pump therapy eligibility (as well as those with more recently diagnosed type 1 diabetes mellitus, particularly if complicated by episodes of diabetic ketoacidosis) is useless from a clinical standpoint in that these patients often require complicated insulin regimens including the use of insulin pump therapy. Even if C-peptides are measurable (although low), insulin pump therapy can frequently be very helpful to these patients since they often have very labile blood sugars and other regimens are frequently quite ineffective when compared to pump therapy.

We see many patients with type 2 diabetes who require insulin therapy, and even though their C-peptide levels may be measurable, they often exhibit very labile blood sugars and frequently require sophisticated insulin regimens. In these patients, insulin pump therapy can be extremely helpful in stabilizing their blood sugars and preventing diabetic complications.

In view of the above, I would recommend consideration be given to discontinuing the requirement for C-peptide levels in diabetic patients who are candidates for insulin pump therapy (both type 1 and type 2). Insulin pump therapy can be extremely helpful in the prevention of diabetic complications (as well as in improving one's lifestyle) in both groups of patients regardless of their underlying C-peptide production, assuming they are truly insulin requiring.

I hope this note will be hopeful. Please let me know if there are any questions.

Sincerely,

Sincerely,

Ronald P. Painton, M.D.
RPP:wdb
CC: Ms. Betty Shaw/Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Allied Institute of Medicine

David Pak, D.O.
Robert Ching, D.O.
Kristen Pak, D.O.

April 20, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:

I welcomed your recent decision to review the current C-Peptide requirement for the Insulin Infusion Pump.

For some time, I have questioned the ability of the C-Peptide test to identify who is or is not a good candidate for the Insulin Pump. I am an Internal Medicine physician and treat patients with diabetes on a daily basis. Over the past few years, I have been very successful in moving many of my patients to a more intensive level of control. This has involved a more intensive multiple daily injection regimen; and in some cases, this has been achieved by using an Insulin Infusion Pump. I consider pump therapy a valuable tool in my ability to treat and manage my patients with diabetes who are insulin requiring.

I have become aware of the C-Peptide requirement and consider it a limiting factor in my ability to move a Medicare patient into the best possible situation for long-term diabetes management and blood sugar control. The test is not one that I run for any of my patients to determine or classify their diabetes. A person either requires insulin to maintain blood sugars or they do not. I also consider the test to be very subjective and one that can be affected by several factors including current oral agents, blood sugars, or recent meals. The test result can often vary greatly from month to month or year to year.

Recently, I have been able to achieve very positive results with patients who are even on both orals agents and insulin. For these types of patients or those who are solely insulin requiring, the C-Peptide can effectively limit my ability to manage and achieve the best possible outcomes by moving these patients into Insulin Pump Therapy.

I would welcome a more subjective requirement that considers a patient's history and level of compliance as the sole standard for approval of an insulin pump. Please consider these issues when you are reviewing the current standards for approval of an Insulin Infusion Pump.

Thanks,

David Pak, D.O.

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DIPLOMATE AMERICAN BOARD OF ENDOCRINOLOGY AND METABOLISM

April 28, 2004

Jesse Polansky, M.D., MPH
Centers for Medicare & Medicaid Services
Coverage and Analysis Group
7500 Security Blvd.
C1-09-06 Mail Stop
Baltimore, Maryland 21244

Dear Mr. Polansky,

This letter is in regards to continuous subcutaneous insulin infusion(CSII) and the utilization of the C-peptide in determining candidate eligibility.

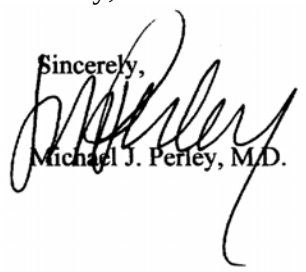
Traditionally, insulin pumps were only for patients with type 1 diabetes. The C-peptides were used to classify if the patient had type 1 diabetes and would then be a candidate for the insulin pump. However, since many patients with type 2 diabetes are now candidates for the insulin pump the C-peptides are no longer clinically relevant to assessing pump candidacy.

Many patients with type 2 diabetes have renal insufficiency, congestive heart failure and liver dysfunction and cannot take certain oral diabetic medications, and therefore need multiple daily insulin injections to control their glycemia. Because of this criteria they are candidates for insulin pump therapy, irregardless of whether their C-peptide is present or not.

Possible candidacy criteria for insulin pump would be to:

1) Type 1 diabetes uncontrolled
2) Type 2 diabetes failed oral medications and on multiple daily injections and uncontrolled
3) HbAlc>6.5%
4) Severe hypoglycemia

Sincerely,



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Meridian, Mississippi 39301

Janet L. Price, D.O.
Family Practice
Appointment Desk: 601/703-9265
Office: 601/703-4487

April 27, 04

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

Dear Sirs:

I am writing this letter to support the decision to have the c-peptide stipulation removed in determining approvals for Medicare patients to qualify for insulin pumps. Insulin pump therapy is one that can significantly improve a patient's state of health and reduce their risk of secondary complications. Patients with type 2 diabetes are at the same risk of developing complications such as neuropathy, retinopathy and nephropathy and with poor glycemic control, their risk of suffering from these complications are far greater than if they had better control. I feel that with insulin pump therapy in the type 2 population, better health can be achieved and in the long run, reduce the amount of dollars spent treating these secondary complications.

Please do what you can to remove the c-peptide stipulation so our Medicare patients who are good candidates for pump therapy can benefit long-term.

Sincerely,

Diabetic Care Associates

R.A. Ramanujan, MD
Nancy Fehrenbach, FNP-C
Kathryn Scott-Hlavac, FNP
Darlene Keller, RD, CDN, CDE

Phone: 607.723.1676
Fax: 607.772.6304

20-24 S. Washington Street
Binghamton, NY 13903

April 29, 2004

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

Dear Ms. Shaw and Dr Schott,

I would like to request that the C-Peptide criteria be removed as a qualifying factor for my Medicare patients that I choose for insulin pump therapy.

Through my personal experience and professional opinion as a practicing Endocrinologist, I feel that the C-Peptide test is not a valid indicator for potential Medicare insulin pump users.

Thank you for your consideration. If you have any questions, please do not hesitate to contact me at my office.

Sincerely,

R.A. Ramanujan, M.D.

THE CLEVELAND CLINIC FOUNDATION
S. Sethu K. Reddy, M.D., MBA, FRCPC, FACP, FACE
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April 26, 2004

Dr. Lawrence Schott
Coverage & Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards & Quality
Centers for Medicare & Medicaid Services
7600 Security Blvd.
Baltimore, MD 21244

Dear Dr. Schott:

I appreciate the 2001 policy which revised an absolute value for C-peptide level to be less than or equal to, the lower limit of normal of the laboratory method +10%.

On further investigation, I am requesting that CMS remove the C-peptide criteria from their CSII coverage policy. Although C-peptide testing can measure endogenous insulin production, it is a laboratory value that has minimal use as a clinical indicator in determine appropriate candidates for CSII.

The DCCT study showed that intensive therapy protected C-peptide levels, in Type I DM patients. This might make the C-peptide levels confusing. In the situation of renal impairment, C-peptide levels may be higher than expected and are not informative. The decision to initiate insulin therapy or CSII is based upon presenting clinical criteria, namely inadequate glucose control in the face of concerted efforts by patient and physician to achieve acceptable glucose levels.

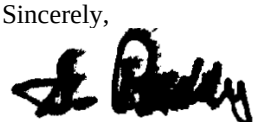
Outside of the C-peptide test, the other clinical criteria for insulin pump coverage are consistent with clinical practice, payor pollicies and professional society recommendations.

1. Patient is unable to maintain HbAlc below 6.5%
2. Patient has failed oral agents and followed a regime of multiple daily injections.
3. Patient is able to monitor blood sugars 4x day.
4. Patient has severe glycemic excursion, (i.e., and hypoglycemia or dawn phenomenon).
5. Patient has completed comprehensive diabetes education.

In addition, the current coverage policy which requires existing pump patients to requalify for CSII with a C-peptide test once they become a Medicare beneficiary is unnecessary.

Based on this information, CMS should remove the C-peptide criteria as an absolute contraindication from the NCD for insulin pump therapy. Please feel free to contact me if you have any questions or need further information.

Sincerely,



Sethu K. Reddy, MD
Chairman

ATLANTA
DIABETES
ASSOCIATES
Endocrinology & Diabetes

PAUL C. DAVIDSON, M.D.
BRUCE W. BODE, M.D.
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DAVID G. ROBERTSON, M.D.
N. SPENCER WELCH, M.D.
CAROL GREENLEE, M.D.

April 29, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop: Cl-01-06
Office of Medical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Shaw and Dr. Schott:

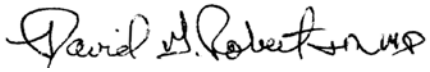
This letter is to ask that you consider Medicare coverage without requirement for C-peptide criteria or allow physician input for situations that involve C-peptides above the current Medicare standard. Many of our patients with type 2 diabetes have measurable insulin production and C-peptide levels that are not clinically significant in terms of their overall care. These patients require insulin. In many cases the amount of insulin these patients require is well within the amount that can be safely and effectively provided by an insulin pump. In patients who take multiple injections of insulin per day, but have repeated problems with hypoglycemia or persistent elevations in overnight blood sugars, an insulin pump provides an excellent solution. In some situations, I have been able to obtain approval for my patients with kidney transplants to receive insulin pumps despite the elevations in C-peptides. However, outside of the transplant situation, many of my patients with severe neuropathy or cardiovascular complications of diabetes do not have insulin pump therapy available to them. I have patients for whom the ability to monitor blood sugar is limited, and the ability to obtain insulin from the refrigerator is limited, but their vision is not impaired and they are fully able to manipulate an insulin pump. This allows them to adjust their blood sugars by adjustments in their insulin in pump rates on an ongoing basis, and not require that they be put in a nursing facility or have family members available twenty four hours a day, seven days a week to help them with their diabetes care.

In short, only through the availability of insulin pump therapy can many patients with type 2 diabetes safely approach the glycemic control goals necessary to prevent complications. Only with an insulin pump, can some of my patients with cardiovascular complications avoid the type of hyperglycemia that placed them at risk for either cardiac events or complications related to cardiac surgeries. In patients with neuropathy insulin pump therapy provides a much safer mechanism for providing insulin. Insulin pumps can be shut down when blood sugars are falling and neither NPH nor Lantus have this option.

The solution to this situation is either to remove the C-peptide criteria for selection of patients to receive continuous insulin infusions, or to allow for physician input in a meaningful way that produces an opportunity for patients with type 2 diabetes to receive pump therapy where appropriate. The obvious situation where renal disease causes artificial elevations of C-peptide also must be addressed.

Please consider a reasonable solution to this dilemma that prevents patients who would best be served by insulin pump therapy from receiving this very valuable form of treatment.

Sincerely,



David G. Robertson, M.D.
DGR/kcc

77 COLLIER ROAD, N.W., SUITE 2080, ATLANTA, GEORGIA 30309 (404) 355-4393 FAX (404) 609-7648

Annaville Family Medicine
Roger G. Ramon M.D.
10635 Leopard Road
Corpus Christi, TX 78410

April 13, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:
I welcomed your recent decision to review the current C-Peptide requirement for the Insulin Infusion Pump.

For some time, I have questioned the ability of the C-Peptide test to identify who is or is not a good candidate for the Insulin Pump. I am a Family Practice physician and treat patients with diabetes on a daily basis. Over the past few years, I have been very successful in moving many of my patients to a more intensive level of control. This has involved a more intensive multiple daily injection regimen; and in some cases, this has been achieved by using an insulin Infusion Pump. I consider pump therapy a valuable tool in my ability to treat and manage my patients with diabetes who are insulin requiring.

I have become aware of the C-Peptide requirement and consider it a limiting factor in my ability to move a Medicare patient into the best possible situation for long-term diabetes management and blood sugar control. The test is not one that I run for any of my patients to determine or classify their diabetes. A person either requires insulin to maintain blood sugars or they do not. I also consider the test to be very subjective and one that can be affected by several factors including current oral agents, blood sugars, or recent meals. The test result can often vary greatly from month to month or year to year.

Recently, I have been able to achieve very positive results with patients who are even on both orals agents and insulin. For these types of patients or those who are solely insulin requiring, the C-Peptide can effectively limit my ability to manage and achieve the best possible outcomes by moving these patients into Insulin Pump Therapy.

I would welcome a more subjective requirement that considers a patient's history and level of compliance as the sole standard for approval of an insulin pump. Please consider these issues when you are reviewing the current standards for approval of an Insulin Infusion Pump.

Thanks,
s,

Michigan
Endocrine
Consultants

Solomon I. Rosenblatt, M.D.
Sander J. Paul, M.D.
Robert C. Igwe, M.D.
Suchitra Bhakta, M.D.
Lavinia Boboc, M.D.

Ms. Betty Shaw
Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards
And Quality Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

April 28, 2004

Dear Ms. Shaw:

Thank you for the opportunity to provide support for removal of the C-peptide criteria from your National Coverage decision. First, patients with documented type 1 diabetes mellitus who are covered by Medicare are wasting money on the C-peptide testing. Second, the C-peptide assay is variable to the point that C-peptide acceptable levels may be regional. This allows the regional administration in some areas to be more restrictive than others. That is nonsense when it applies to national coverage. I encourage the use of the same criteria that are applied to non Medicare patients.

Please feel free to call or write if I can provide additional assistance.

With kindest regards,

Solomon I. Rosenblatt, M.D.
SIR/cem

1695 West Twelve Mile Road· Suite 220· Berkley, MI48072· (248) 543-3700· Fax: (248) 543-4180

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ANTHONY J. ROSS, M.D. PAUL N. GOBBO, M.D. D. SUE SHADE, P.A.-C

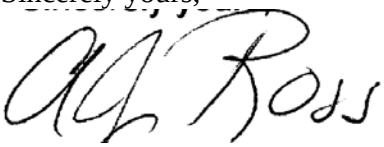
April 26, 2004

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

Dear Ms. Shaw and Dr. Lawrence Schott:

I have been alerted that the medical advisory board is looking at conditions or criteria for the use of insulin infusions pumps in diabetics. I have also been informed that the use of C-peptide is considered as part of the standard. It is my medical opinion that the C-peptide is of no consequence or use when deciding whether the patient needs to be on an insulin infusion pump. The only thing of any clinical significance is if the patient is uncontrolled on maximum medical management with oral and insulin medication for type II and insulin, and in some cases additional oral medication for resistance in type I. If the patients who are on maximum medical therapy still are uncontrolled, they are candidates for an insulin infusion pump regardless of the level of C-peptide. C-peptide should not play a role in determining the patient's need for insulin infusion pump.

Sincerely yours,



Anthony J. Ross, M.D.
AARF

Drs. Chadband and Rowland, P.C.

Robert B. Chadband, M.D.
Michael J. Rowland, M.D.

April 27, 2004

Dear Ms. Shaw and Dr. Schott:

It has come to my attention that Medicare will be reviewing the C-peptide criteria for patients going on insulin pump therapy. I am in full support of eliminating C-peptide as a criterion as it has kept some of my patients from receiving the most advanced form of insulin therapy. Insulin pump therapy provides patients with better glycemic control than daily injections. Revising the criteria would allow Type 2 diabetic patients who require insulin to utilize insulin pump therapy.

Additionally, patients are put at risk of losing supply benefits when they reach Medicare age. Going back on injections would adversely affect their glycemic control as well as their quality of life.

Please consider these points as you perform your review.

Sincerely,

Michael J. Rowland, M.D.

48 Medical Park East Drive • Suite 452 • Birmingham, AL 35235 • Office: (205) 838-3673 or Fax: (205) 833-3441

RAGHDA SAHLOUL, M.D.
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Diabetes and Metabolism
3100 MacCorkle Avenue, S.E. Suite 606
Charleston, WV 25304
Telephone: (304) 345-8665

April 26, 2004

Mrs. Debbie Shaw
Dr. Lawrence Schott
Coverage & Analyst Group Mail Stop C1-09-06
Office of Clinical Standards & Quality
Centers for Medicare & Medicare Services
7500 Security Boulevard
Baltimore, MD 21244

To Whom It May Concern:

To this is to kindly ask you to reconsider approving the continued- insulin pump for Type II diabetic patients. As you know, Type II diabetics have decreased pancreatic function at some stage of their disease process. At that point, oral medications do not work and they have to use insulin. At that time, they act just like Type I diabetics and continuous glucose infusion, in. a compliant patient, definitely provides a more physiological way of providing insulin and enables the patient to reach better control with less hypoglycemia.

I propose that you consider approving insulin pumps for patients who are compliant, following up with an endocrinologist and have proof that they follow up, as asked, every three to six months. Also, special consideration for patients with kidney transplants and patients who are on three injections or more with poor control. I believe in such population the insulin pump will be something that is needed and it will be harder to be abused.

Thank you very much for your consideration.

Sincerely,

Raghda Sahloul, M.D.
RS/cts:tmw

TALLAHASSEE ENDOCRINE ASSOCIATES
2406 East Plaza Drive Phone: 850-877-7387
Tallahassee, FL 32308 Fax: 850-656-3376

Terry W. Sherraden, M.D., F.A.C.E.
Diplomate American Board of Internal Medicine
Diplomate American Board of Endocrinology
Fellow of the American College of Endocrinology

April 27, 2004

Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Dr. Schott:

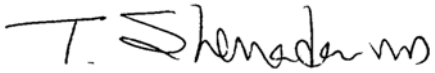
I am writing to you concerning the CMS C-Peptide criteria for insulin pump therapy consideration for patients. I have extensive experience utilizing insulin pumps for improving diabetes control. These pumps have been useful in a wide range of patient types. Over the past few years since Medicare coverage began for insulin pumps, many of my older patients have benefited having excellent glycemic control that was unattainable with multiple daily injections. As my patient population ages however many more of my patients will be attaining Medicare age. I am concerned about their ability to continue the insulin pump therapy already started that has given them good glucose control.

In my practice insulin pumps have been useful for improving glucose control in a wide variety of patients. Many of these patients have type 1 diabetes and are C-Peptide negative, however there is a growing group of type 2 patients who have equally benefited by improved glucose control with insulin pump therapy. Many of these patients, who have benefited significantly by their insulin pump therapy, may have some remaining endogenous insulin function and may not be C-Peptide negative.

In my opinion, the C-Peptide level is not an accurate indicator of endogenous insulin production in all patients. Certainly renal disease can falsely elevate C-Peptide. Fasting or postprandial states may also give widely differing C-Peptide levels. Even more importantly, many of my patients who have benefited the most from insulin pump therapy have type 2 diabetes and would not even be expected to be C-Peptide negative.

In summary, it is not clear to me that C-Peptide is always an accurate indication of endogenous insulin production, and there are many people who have already benefited from insulin pump therapy who have type 2 diabetes mellitus. I would expect criteria for insulin pump approval to evaluate patients for the ability to benefit from insulin pump therapy more than just be able to show low C-Peptide levels. Removal of the C-Peptide level criteria will allow us to use insulin pump treatment in patients that are more appropriate for this therapy.

Sincerely,



Terry W. Sherraden, M. D.
TWS/kh

cc: Ms. Betty Shaw

TALLA P. SHANKAR, M.D., F.A.C.E
Internal Medicine, Endocrinology, Diabetes & Metabolism
Office: 678-289-5054 • Fax: 678-565-0473

April 26, 2004

Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD

Dear Dr. Schott:

It has come to my attention that your agency will be evaluating the necessity and/or applicability of the C-peptide test as it relates to qualification for insulin pump therapy.

The C-peptide test is not a valid indicator of need for insulin pump therapy. For example, there are many patients that may not qualify under the C-peptide criteria for pump therapy that would achieve significant overall improvement in glycemic control following initiation of insulin pump therapy.

Further, it becomes increasingly complex for patients that have not yet reached Medicare age eligibility. Many patients begin insulin pump therapy prior to reaching age 65. However, many of these patients would not be able to access the necessary supplies under the current program guidelines.

It is my sincere hope that your agency removes the C-peptide test as the determinant for insulin pump therapy. Insulin pump therapy can provide a very valuable tool to improve overall glycemic control which has been proven to reduce complications associated with diabetes.

Sincerely,

T. Shankar, M.D., F.A.C.E.

1000 Hospital Drive, Building B• Stockbridge, Georgia 30281

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NORTH GEORGIA ENDOSCOPY CENTER

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April 19, 2004

Ms. Betty Shaw
Lawrence Schott, M.D.
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

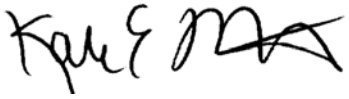
Dear Ms. Shaw and Dr. Scott:

Many patients with Type-1 Diabetes Mellitus, prior to having Medicare, have had abnormal C-peptide levels, meeting the criteria for Medicare to receive insulin pump therapy and supplies. Once patients are eligible for Medicare, however, repeat levels may be above the normal cut-off criteria, which make the patient ineligible to have their insulin supplies covered. It would seem to be more patient-friendly that once diagnosis of Type-1 Diabetes Mellitus has been made that patients would be grandfathered in and have their insulin pump supplies covered by Medicare.

Insulin pump therapy is not only useful to improve glycemic control for Type1 diabetics, but also Type-2 diabetic patients who are failing intensive insulin therapy. Patients who use insulin therapy with Type-2 Diabetes Mellitus have a reduced insulin quantity and lower blood glucose excursions and hypoglycemic events, as well.

Thank you for the consideration of removing C-peptide as a criterion for Type-1 diabetic patients who have already been on insulin pump therapy and are continuing their therapy with Medicare coverage.

Sincerely,



Karen E. Smith, M.D.
Endocrinology, Diabetes, and Metabolism

KS/dm

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A Division of Etowah Regional Medical Services, P. C.

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security BLVD
Baltimore, MD 21244

Dear Ms. Betty Shaw and Dr. Lawrence Schott:

I write in support of the planned discontinuation of Medicare's C-peptide criteria for insulin pump therapy funding.

Insulin pump therapy is the best means of providing intensive insulin therapy in Type 1 and Type 2 diabetics. Many Type 2 diabetics, especially those with advanced disease, are grossly insulin deficient relative to their insulin resistance and benefit greatly from pump therapy. And, while there are new drugs available to the Type 2 diabetics, many patients can not benefit from these therapies, either because of contraindications secondary to comorbidities or because their diabetes has progressed to the point that oral therapies are ineffective. For such patients, insulin pump therapy is a great means of achieving glycemic control with less risk of hypoglycemia than conventional insulin therapy and the current C-peptide criteria is a disservice to these patients. The current C-peptide criteria is also a disservice patients with latent autoimmune diabetes of adulthood (LADA). Patients with this form of Type 1 diabetes can manifest in older age with progressive insulin requiring diabetes but often have low but detectable C-peptides at onset Patients with LADA are not uncommon and require intensive insulin therapy to achieve good control, as demonstrated by the UKPDS cohort (1). Injection insulin therapy is also a great problem for patients with visual impairment, but these patients can dose sound prompted boluses of insulin with a pump. I recently started a blind patient who cares for herself on an insulin pump with sound bolusing. In conjunction with a talking meter, this patient improved her glycemic control and now avoids the severe hypoglycemia that frequently requires EMS response.

Thank for your time and consideration in this issue.

Sincerely, 

Jeremy Soule, MD

(1) UKPDS 25: autoantibodies to islet-cell cytoplasm and glutamic acid decarboxylase for prediction ofinsulin requirement in type 2 diabetes. UK Prospective Diabetes Study Group. Turner R; Stratton I; Horton V; Manley S; Zimmet P; Mackay IR; Shattock M; Bottazzo GF; Holman R - *Lancet* - I-Nov-1997; 350(9087): 1288-93.

Endocrinology, Diabetes & Metabolism Consultants, P. **C.**

To whom it may concern,

C-Peptide Medicare

I am in favor of discontinuing the C-peptide as criteria for authorization of insulin pumps and insulin pump supplies. Listed are several reasons the C-peptide should not be part of the criteria.

- C-peptide values do not influence the way I empower my patients to manage their diabetes. Many patients with type 2 diabetes have difficulty with glycemic control and need intensive management given their level of insulin resistance.

- I prescribe insulin pump therapy on the basis of medical need. There are some patients that are insulin resistant and require large doses. The way a pump delivers insulin can prevent large depots of insulin that occur and effect absorption when given by syringe.

- Patients who have elevated C-peptide levels and obtained their insulin pump prior to Medicare are no longer able to receive their supplies. I find it hard to believe that I have patients that have an insulin pump yet no means to utilize the therapy.

Thank you in advance for considering a change in current policy.

Sincerely yours,

K. George Thampy, M.D., PhD.

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http://www.drthampy.yourmd.com

R. JOE TEAGUE MD[PC]
Endocrinology · Diabetes· Metabolism· Nutrition

April 26, 2004

Dear Ms. Shaw and Dr. Schott,

I am a practicing endocrinologist who has prescribed and managed insulin pump therapy for more than one hundred patients. Because your agency is currently performing a review of the C-peptide criteria that is used to qualify patients for this therapy, I am taking this opportunity to communicate the problem that I have with using this particular test as the sole basis for approving or denying the therapy. As people age, renal function tends to decline, as measured by creatinine clearance, and C-peptide results will be less reliable as an accurate measure of insulin sufficiency. In a younger group, this would have little impact, but the Medicare population is heavily comprised of older Americans. A better option might be to also consider other factors such as the number of injections per day or the rate of hypoglycemic episodes.

I would appreciate your review and consideration so that everyone who may benefit from insulin pump therapy might have access to the highest standard of care.

Sincerely,

R. Joe Teague, MD

1600 Carraway Blvd
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Birmingham, AL 35234
Phone: 205.502.6600
Fax: 205.502.6604

Jerry Thurman, M.D.
Endocrinology, Diabetes & Metabolism

April 17, 2004

RE: Medicare C- peptide Criteria

To whom it may concern,

I am in support of changing the current Medicare criteria of utilizing the C-peptide as criteria to deny coverage of insulin pump therapy to a person with diabetes, whom it is medically necessary.

As a board certified endocrinologist, I take care of Medicare patients everyday that cost our Medicare system a substantial financial burden due to complications that could be prevented by utilizing insulin pump therapy.

I only prescribe or recommend CSII for Medicare patients for whom an insulin pump is medically necessary to prevent complications and control their diabetes. In cases where a patient's C- peptide is elevated, I must prescribe less than optimal diabetes management. Suboptimal glycemic control increases the risk of costly complications and hospitalizations as stated in the DCCT results and ADA standards of care. I realize there are significant cost factors and criteria that are an important part of the authorization process; however a C-peptide result is not an appropriate measurement of medical necessity, since it does not influence or predict the need for specific diabetes management.

Thank you in advance for your consideration to change the current guidelines.

Sincerely,

Jerry Thurman MD

Gateway Endocrinology Associates
400 First Capitol Dr., Suite 409
St. Charles, MO 63301
Office: (636) 916-4842
Fax: (636) 916-0812

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After Hours (956) 632-5435

April 13, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:

I welcomed your recent decision to review the current C-Peptide requirement for the Insulin Infusion Pump.

For some time, I have questioned the ability of the C-Peptide test to identify who is or is not a good candidate for the Insulin Pump. I am an Internal Medicine physician and treat patients with diabetes on a daily basis. Over the past few years, I have been very successful in moving many of my patients to a more intensive level of control. This has involved a more intensive multiple daily injection regimen; and in some cases, this has been achieved by using an Insulin Infusion Pump. I consider pump therapy a valuable tool in my ability to treat and manage my patients with diabetes who are insulin requiring.

I have become aware of the C-Peptide requirement and consider it a limiting factor in my ability to move a Medicare patient into the best possible situation for long-term diabetes management and blood sugar control. The test is not one that I run for any of my patients to determine or classify their diabetes. A person either requires insulin to maintain blood sugars or they do not. I also consider the test to be very subjective and one that can be affected by several factors including current oral agents, blood sugars, or recent meals. The test result can often vary greatly from month to month or year to year.

Recently, I have been able to achieve very positive results with patients who are even on both orals agents and insulin. For these types of patients or those who are solely insulin requiring, the C-Peptide can effectively limit my ability to manage and achieve the best possible outcomes by moving these patients into Insulin Pump Therapy.

I would welcome a more subjective requirement that considers a patient's history and level of compliance as the sole standard for approval of an insulin pump. Please consider these issues when you are reviewing the current standards for approval of an Insulin Infusion Pump.

Thanks,

Chino Medical Group, Inc.

Betty Shaw and Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

April 10, 2004

Dear Ms. Shaw and Dr. Schott:

I am a family physician managing over 200 patients on insulin pumps. Over 70% of these patients have type 2 diabetes with severe insulin resistance and require over 150 units of insulin per day. In fact, several of my patients use over 500 units of insulin daily. I currently have 25 patients using U500 insulin in their insulin pumps. These patients feel that the U500 insulin has significantly improved their quality of life. Prior to their initiation of pump therapy they were injecting over 100 units of insulin before each meal and taking over 100 units of basal insulin at bedtime. Still, their fasting blood sugars were in the range of 300 mg/dL and their AlC levels were over 10%. Using U500 with their insulin pumps we have been very successful at lowering their AIC to the recommended target of7% in the vast majority of these patients. In turn, we hope to reduce their risk of microvascular and macrovascular complications while significantly reducing the cost of hospitalization for these patients.

As these individuals become older, they will be forced to undergo a lab test for C-peptide analysis so that their insulin pumps and supplies will be covered by medicare. Unfortunately, these patients with severe insulin resistance will have no chance to pass such a test because they are producing very high levels of their own insulin. The problem is that their own insulin simply does not work to lower their own blood glucose levels. Some of these patients will have C-peptide levels 10-15 times higher than normal. Thus, they will be informed that they will not be eligible for pump supplies nor will they be considered as pump candidates. However, if any patient is more deserving of a pump or easier to manage on an insulin pump, it would be a patient with type 2 diabetes. These patients rarely become hypoglycemic and respond very well to basal-bolus insulin replacement therapy. In addition, they become very motivated to participate in their intensive diabetes management as they notice their targeted blood glucose values and A1C levels being reached more easily and safely than with multiple daily injections.

Many studies have demonstrated that reducing AIC levels by 3% can, in turn, reduce medical costs by 75%. Patients with severe insulin resistance can incur huge expenses due to their higher risk of developing microvascular and macrovascular disease. Therefore, if we can provide these individuals with a simpler path towards obtaining an insulin pump, we can reduce long term costs and improve these patients quality of life. The C-peptide level has absolutely no clinical value in assessing whether or not these patients would be good pump candidates.

Thank you for your time and consideration.

Sincerely,

Jeff Unger, MD
Director, Chino Medical Group
Diabetes Intervention Center
Assistant Professor of Family Medicine
Loma Linda University School of Medicine

Rocky Mountain Diabetes and Osteoporosis Center

JOHN E. LILJENQUIST, MD. PA • CARL D. VANCE, MD

April 12, 2004

Lawrence Schott, M.D
Coverage and Analysis Group'
Mailstop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: The use of C-peptide in conjunction with continuous subcutaneous insulin infusion pump.

Dear Dr. Schott:

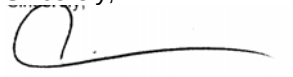
This letter is in regard to the current requirement by Medicare that a patient have a C-peptide of less than 0.5 in order to qualify for a CSII. As you know, the data continues to support the idea of tight glycemic control as an excellent method of reducing long-term complications associated with diabetes.

In my practice as a diabetologist, I see significant benefits in those patients who are on intensive insulin regimens such the use of a CSII compared to those who are in less aggressive therapy. Oftentimes, it is difficult for the patients, especially the elderly, to obtain such tight control using insulin delivered through a syringe. There are multiple reasons for this, but in the elderly, one of the major benefits of an insulin infusion pump is the ability to deliver accurate dosing down to a fraction of a unit of insulin. With the syringe, almost none of our patients were able to do this accurately.

Many of our patients have not been able to benefit from this improved glycemic control because, although they were making insufficient amounts of their own insulin, they still had some endogenous production, which would disqualify them from this program.

I appreciate your help in this regard. If there is additional information that I can provide, do not hesitate to contact me.

Sincerely,



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DIABETES
ASSOCIATES

Endocrinology & Diabetes

PAUL C. DAVIDSON, M.D.
BRUCE W. BODE, M.D.
R. DENNIS STEED, M.D.
DAVID G. ROBERTSON, M.D.
N. SPENCER WELCH, M.D.
CAROL GREENLEE, M.D.

April 29, 2004

Dr. Lawrence Schctt
Coverage Analysis Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

I have been practicing endocrinology for 17 years In the Atlanta, Georgia area and my practice is made up predominately of diabetics.

I would like to express my support for relaxing the c-peptide criteria in allowing patients to start on insulin pump therapy. I have a great number of Type 2 patients whose c-peptides, although not below 1 ng/mL, definitely need an insulin pump if they are to achieve appropriate levels of glycemic control. I have several patients in my practice that are Type 2 that have excellent control
with the insulin pump, but once they reach Medicare age, they will be unable to receive insurance benefits that will allow them to get their pump supplies on formulary. I have also had patients that we have gone back to four shot therapy because they did not meet criteria for coverage of their insulin pump supplies.

Another argument that I think is important to consider, which I thought was valid when Medicare first started covering the insulin pumps, certain patients with renal impairment, c-peptide levels may be falsely elevated due to improper renal clearance of c-peptide.

This issue is of vital importance to my patients that have Type 2 diabetes approaching Medicare age and I feel that relaxing these c-peptide requirements would allow them to continue on this most appropriate mode of insulin therapy. I appreciate your consideration and support in these matters.

Sincerely,

N. Spencer Welch, M.D.

NSW/amg

77 COLLIER ROAD, N.W., SUITE 2080, ATLANTA, GEORGIA 30309 (404) 355·4393 FAX (404) 609-7648

BRUCE E. WHEELER. M.D., P.A.
INTERNAL MEDICINE
2710 HOSPITAL DRIVE, SUITE 114
VICTORIA, TEXAS 77901

TELEPHONE (512) 578-0231

April 15, 2004

Ms. Betty Shaw and Dr. Lawrence Schott
Coverage And Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security BLVD
Baltimore, Maryland 21244

To Whom It May Concern:

I recently became aware of your intentions to review the C-Peptide requirement that is currently in place for approval of an Insulin Infusion Pump.

For some time, I have questioned the ability of the C-Peptide test to identify who is or is not a good candidate for the Insulin Infusion Pump. I am an Internal Medicine Physician with a rural population. My practice consists of patients from all demographics with a large percentage being of Medicare age.

I realize why the C-Peptide has been in place and can assure you that a removal of this requirement would not result in an increase or flood of patients into the insulin pump. I consider the Insulin Pump to be a very useful tool for those patients who have moved into an intensive therapy regimen or are no longer successful on their current therapy. The Insulin Pump, however, is not for every patient and I am very cautious as to which of my patients are considered candidates for the Insulin Pump. In the case of some of my Medicare age patients who have been considered for the pump, the C-Peptide has prevented them from obtaining the best possible therapy. These individuals are considered highly motivated and qualified candidates.

I would welcome a more subjective requirement that considers other factors such as a patient's history and my intentions as the sole standard for approval of an insulin pump. Please consider these issues when you are reviewing the current standards for approval of an Insulin Infusion Pump.

Thanks,

DIVISION OF ENDOCRINOLOGY
& BONE AND MINERAL METABOLISM
Henry Ford Hospital

Dorothy M. Kahkonen, MD
Division Head
2799 West Grand Boulevard
Detroit, MI 48202-2689
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(313) 916-2132
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(313) 916-8343

April 27, 2004

To Whom It May Concern:

C-peptide measurement is most helpful in defining residual insulin function. It doesn't necessarily identify those patients whose glycemic control is "helter-skelter" with wide blood glucose swings and an increased likelihood of hypoglycemia.

Insulin pump therapy smooths basal insulin delivery and permits more precise interaction between insulin delivery and food intake. Likewise, basal insulin delivery can be more precisely adjusted during periods of physical activity and exercise or when post-absorptive states exist or are prolonged. Use of an insulin pump helps concentrate the patient's attention to details of personal care while at the same time eases the personal disease management by the patient.

I favor removal of the C-peptide requirement as a criterion for insulin pump use. Every patient with insulin-requiring diabetes is an individual with a unique set of problems. Use of the C-peptide test may help us in final recommendations to the patient, but it is incorrect that the C-peptide level is used as a hurdle to be cleared.

Thanks for your consideration.

Sincerely yours,

FRED W. WHITEHOUSE, M.D.
Division Head Emeritus
Division of Endocrinology and Metabolism

FWW:cj

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4/27/04

To: Ms. Betty Shaw & Dr. Lawrence Schott
Coverage and Analyst Group
Mail Stop C1-09-06
Office of Clinical Standards and Quality
7500 Security Blvd.
Baltimore, MD 21244

Dear Ms. Shaw and Dr. Schott,

My name is Tracy Allen. I am a physician assistant who works at the Diabetes & Endocrine Center in Bangor Maine. I am writing in hopes that you will reconsider requiring a C-Peptide $\leq$ .05 as a qualifying factor for Type II diabetics to go on/ or remain on the insulin pump.

We have multiple patients that are well controlled using the pump. I know of two that are in jeopardy of losing the pump due to the fact that their C-Peptide was > .05. In one case, the patient had severe fluctuations in blood sugars while on intensive insulin therapy using lantus and humalog. These lows were related to varying levels of physical activity and can be very dangerous; especially in the elderly.

The pump allows Type I and Type II diabetics to manage their blood sugar more effectively. It also allows them to adjust basal rates to reflect differing levels of activity. In most of our Type II diabetics, we are very focused on helping them lose or maintain their current weight. The pump allows the patient to decrease the basal rate for exercise versus forcing them to increase carbohydrate intake to prevent or treat low blood sugars.

I feel that in the long term, pump patients benefit from having more control over their diabetes. In most of our pump patients the HbAlc comes down. As important in our elderly patients is the fact that they are less likely to have low blood sugars as their activity levels fluctuate day-to-day.

Thank you for your time and consideration.

Tracy L Allen, PA-C