August 24, 2015

Patrick Conway, MD
Acting Principal Deputy Administrator & Chief Medical Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Dr. Conway:

Our organizations represent people with diabetes, their caregivers and health professionals, and diabetes experts in the United States. We request a meeting with you to discuss ways in which we can work together to address four concerns we have with current Medicare coverage policy for the approval of continuous subcutaneous insulin infusion systems (CSII), i.e. insulin pumps, for people with diabetes. These concerns are:

1. Treatment interruption to those individuals currently using CSII as they age into the Medicare coverage group.

2. The current c-peptide and islet antibody requirements that qualify patients for CSII use.

3. The requirements of quarterly visits and testing for A1C for patients to remain eligible for CSII supplies.

4. The need to anticipate future technologic advancements in diabetes care in the development of coverage determinations.

Improved diabetes management has resulted in a significant reduction in life-threatening complications of diabetes and an increase in the life expectancy of those with diabetes. As a result, there has been a marked increase in the number of individuals with diabetes who age into Medicare. Unfortunately, the current criteria for coverage of CSII result in taking away effective and proven care from people who are well managed on CSII when they enter into Medicare.

The current requirements to prove islet autoimmunity and absolute beta cell failure need to be changed to reflect our current knowledge of the science of diabetes. Antibody titers in type 1 diabetes diminish rapidly with duration of diabetes, and the required ICA 512 antibody is no longer considered to be appropriate due to lack of standardization and sensitivity. Another problem is the current c-peptide requirement that fails to take into account the science demonstrating the benefits of CSII in c-peptide positive individuals, while erroneously suggesting this test discriminates between type 1 and type 2 diabetes. We now know that many people with type 1 diabetes remain c-peptide positive, while many with type 2 diabetes lose basal c-peptide response. The fact that c-peptide is excreted through a renal mechanism makes it an even less reliable indicator of beta cell capacity in the many people with diabetes who have renal impairment. In addition, definitions of type 1 and type 2 diabetes are clinically difficult to apply and are frequently wrong. Accordingly, our organizations strongly recommend that existing basal-bolus insulin requirement and/or demonstrated ability to utilize the CSII systems should be the criteria for CSII approval.

Current requirements for quarterly office visits and A1C determinations are onerous for the patient, expensive for the Medicare system, and unnecessary. What was first a general practice recommendation has become a Medicare requirement, but without an evidence base. In addition to the wasted resources, this requirement frequently leads vendors to delay the shipment of supplies. This can lead to pump therapy disruption and/or the patient's extended use of their dwindling supplies which is improper, off-label and potentially dangerous. We believe that stable patients may be seen and evaluated at less frequent intervals and that their CSII supplies should not be contingent upon person-to-person contact with the prescriber.

Finally, we would like to discuss the rapid development of emerging technologies such as closed loop systems which have been shown to be superior to CSII by virtue of a significant reduction in hypoglycemia. It is essential CMS develop an evidence-based coverage determination process before these devices are commercially available.

All of these recommendations are to further the goal of enabling those who have successfully managed their diabetes before aging into Medicare to continue that success, avoiding horrific and costly complications including blindness, amputation, kidney failure, heart attack and stroke.

We look forward to working with CMS to insure continued high quality care to our patients who are becoming Medicare beneficiaries, as well as those already in Medicare program and whose disease has progressed to requiring basal bolus insulin regimens. We wish to meet with you to discuss this further and look forward to finding a mutual time to do so. Please contact Dr. George Grunberger, President of the American Association of Clinical Endocrinologists (grunberger@gdi-pc.com, (313) 407-1926) so that we can collaborate on these important issues for our seniors with diabetes.

We appreciate your consideration of this issue.

Yours very truly,

George Grunberger, MD
President, American Association of Clinical Endocrinologists

Samuel Dagogo-Jack, MD
President of Medicine and Science, American Diabetes Association

Lisa H. Fish, MD
President, Endocrine Society

cc: Andy Slavitt, Acting Administrator
Tamara Syrek Jensen, Director, Coverage and Analysis Group