



December 11, 2009

Elizabeth Koller, MD, FACE  
Medical Officer  
Coverage and Analysis Group  
Centers for Medicare and Medicaid Services  
7500 Security Blvd  
Baltimore, MD 21244

Dear Dr. Koller:

Thank you for the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on its proposed coverage decision regarding outpatient intravenous insulin therapy (OIVIT). The Endocrine Society represents more than 14,000 physicians and scientists in the field of endocrinology who focus on complex medical conditions such as diabetes, thyroid conditions, and osteoporosis, among others.

CMS's decision memo includes a very thorough analysis of the background on OIVIT, and the Society supports the agency's proposed decision to release a non-coverage determination for OIVIT. However, the Society believes that the wording of CMS's major conclusion, "the evidence is adequate to conclude that outpatient intravenous insulin therapy does not improve health outcomes in Medicare beneficiaries", is somewhat overstated.

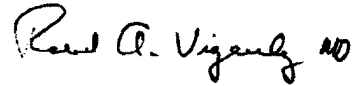
At this point in time, the Society does not believe that there is adequate evidence to conclude that OIVIT does not improve health outcomes, nor does it believe that there is adequate evidence to conclude that OIVIT does improve health outcomes. Rather, the Society believes that current evidence is inadequate to provide any definitive conclusion about health outcomes related to OIVIT in the Medicare population.

A key reason for the Society's conclusion is a lack of relevant data: the published human studies are very small, not properly controlled, and lacking appropriate statistical treatment. Perhaps most importantly, patients participating in published human studies of OIVIT seem to include almost exclusively patients with Type 1 diabetes, while the overwhelming majority of Medicare beneficiaries being offered OIVIT have Type 2 diabetes. The results of studies of OIVIT in Type 1 diabetes may have little relevance to the use of this procedure in patients with type 2 diabetes due to differences in pathogenesis and in the nature of the associated diabetic complications.

The Endocrine Society would suggest that CMS consider an alternate wording for its major conclusion: "the evidence is inadequate to conclude that outpatient intravenous insulin therapy improves health outcomes in Medicare beneficiaries." Such a conclusion would still justify a non-coverage determination for OIVIT at this time, but this phrasing leaves open the possibility that future, properly-done studies might show a health benefit of OIVIT in some subgroups of Medicare beneficiaries with Type 2 diabetes; at that point CMS could re-evaluate its non-coverage determination for OIVIT. However, until such additional evidence becomes available, The Endocrine Society fully supports the CMS proposal not to cover OIVIT for Medicare beneficiaries.

Thank you again for the opportunity to comment on this important issue. Please don't hesitate to contact Holly Whelan, Associate Director of Health Policy, with any additional questions.

Sincerely,

A handwritten signature in black ink that reads "Robert A. Vigersky MD". The signature is written in a cursive style with a large initial 'R' and 'V'.

Robert A. Vigersky, MD  
President  
The Endocrine Society