



August 10, 2016

Dr. Patrick Conway, MD, MSc
Acting Principal Deputy Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Room C5-25-25
Baltimore, MD 21244

Dear Dr. Conway,

On behalf of the Endocrine Society, I am writing you regarding the need to provide Medicare coverage for OmniPod wireless continuous insulin pumps, an issue of great concern to our members and the patients that they treat. With more than 18,000 members, the Endocrine Society is the world's oldest, largest, and most active organization devoted to research and treatment of the full range of endocrine disorders, including diabetes.

Currently, Medicare does not cover the tubing-free, wireless continuous insulin pump although this insulin delivery system was approved by the FDA over ten years ago. For years, the Endocrine Society has joined with many in the diabetes community to advocate for DME coverage for OmniPod. CMS continuously has rejected these requests without justification. Recently, however, we became aware of legislative history and congressional intent concerning the creation of the Part D Drug Benefit that speaks to providing coverage through this mechanism. In anticipating new technologies and the possibility of new ways to deliver insulin, Congress stated that it was its intention for Part D to cover any insulin delivery device **not** covered under Part B as durable medical equipment (DME). In addition, CMS has even published policies stating that all products directly associated with the delivery of insulin into the body, including future potential delivery mechanisms, are to be covered under the Part D Drug Benefit, if not covered as DME under Part B.

Further, it should be noted that the lack of Medicare access to OmniPod is not in the best health interest of its beneficiaries. The Society believes that it is critical for patients to be able to manage their diabetes easily and that patient-centered approaches should be used when determining treatments for patients with diabetes. The OmniPod offers some distinct advantages to elderly diabetes patients who experience dexterity issues, neuropathy, retinopathy and other diabetes-related complications. Many of these patients have found it easier to manage pumps that do not require handling of insertion needles, insulin reservoirs, and tubing sets. In addition, many patients have successfully managed their diabetes with the Omnipod for many years. However, these beneficiaries are forced to discontinue the use of these devices as they age into Medicare and are forced to revert to shots or use other delivery systems that are more difficult for them to use.

The Society urges you to reconsider your previous decision and provide coverage of the OmniPod through the Part D Drug Benefit. We would like to meet with you to discuss further or, should you have any questions or need additional information on this important issue, please contact Meredith Dyer, Associate Director, Health Policy at mdyer@endocrine.org or (202) 971-3637.

Sincerely,

A handwritten signature in cursive script that reads "Henry Kronenberg".

Henry Kronenberg, MD
President, Endocrine Society