

NOV 28 2017

Administrator
Washington, DC 20201

The Honorable Susan Collins United States Senate Washington, DC 20510

Dear Senator Collins:

Thank you for your letter regarding coverage of the OmniPod insulin infusion pump used by Medicare beneficiaries with diabetes. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

The issues surrounding Medicare's ability to cover OmniPod under current statutory authority are complex. Medicare covers numerous items and services critical to beneficiaries with diabetes, but due to the requirements of Title XVIII of the Social Security Act, it does not provide coverage for every item.

We are working to consider how OmniPod fits into existing statutory benefit categories.

- In order for equipment to be covered under the Medicare Part B benefit category for durable medical equipment (DME), the equipment must satisfy the definition of DME. Under Medicare regulations, DME is defined as equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, generally is not useful in the absence of illness or injury, is appropriate for use in the home, and with respect to items classified as DME after January 1, 2012, has an expected life of at least three years.
- In order to be covered under Medicare Part D, items must meet the definition of a "covered part D drug". As defined in statute, this term includes "medical supplies associated with the injection of insulin".

We are continuing to examine this issue closely to determine if a path to coverage under the Medicare program is available. The analysis required as we review options related to OmniPod is complicated by the need to look across multiple Parts of Medicare.

We understand how important this issue is to patients using this equipment, and we will keep you informed of any developments. I will also provide this response to Senator Jeanne Shaheen.

Sincerely.

Seema Verma