

Congress of the United States

Washington, DC 20515

March 27, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W., Room 445-G
Washington, D.C., 20201

Dear Administrator Verma:

As the co-chairs of the Senate and House Diabetes Caucus, we applaud the decisions in January 2017 and January 2018 by the Centers for Medicare and Medicaid Services (CMS) to provide coverage for continuous glucose monitors (CGMs). These coverage decisions have the potential to improve the lives of millions of Americans who are living with diabetes, and who rely on a continuous glucose monitor to manage the disease successfully.

Certain Medicare coverage policies, however, remain that restrict Medicare beneficiaries' access to the full spectrum of use for innovative diabetes therapies, including CGMs when used in conjunction with smart technology. In particular, many innovative technologies work in tandem with smartphone applications, and current Medicare coverage policies do not support this usage. We urge CMS to revise its decision to support the full spectrum of use.

CGMs are FDA-approved, physician-prescribed devices that detect and display blood glucose levels, revealing real-time trends. While we applaud CMS for recently expanding Medicare coverage to therapeutic CGMs, we are concerned that the Local Coverage Article prohibits beneficiaries from using a smartphone app to share their CGM glucose data, alerts, and alarms with others, including their adult children, caretakers, and healthcare providers.¹ The ability to share glucose data provides an extra layer of defense, as individuals who receive the CGM user's data can intervene and help prevent potentially life-threatening complications. Allowing patients to share their health data with caretakers, providers and family members is a particularly beneficial tool for older Americans with diabetes, who are at a higher risk for hypoglycemia unawareness and other serious complications.²

In addition to the benefits of sharing data with caretakers, providers and family, the use of smart phone apps also expands accessibility. For example, blind and low-vision diabetics cannot independently and safely use traditional CGM devices. When a CGM device is paired with an

¹ In relevant part, the article states: "There is no Medicare benefit for supplies used with equipment that is not classified as DME. Coverage of CGM system supplies is limited to those therapeutic CGM systems where the beneficiary ONLY uses a receiver classified as DME to display glucose data. If a beneficiary uses a non-DME device (smart phone, tablet, etc.) as the display device, either separately or in combination with a receiver classified as DME, the supplies shall be denied as non-covered by Medicare."

² *Management of Type 1 Diabetes in Older Adults*, Diabetes Spectrum (Feb. 2014). Available at: <https://doi.org/10.2337/diaspect.27.1.9>.

accessible smart phone app, that device becomes accessible for all possible users, including blind and low-vision diabetics. Without such innovative approaches to CGM devices and other vital medical technologies, blind and low-vision diabetics will continue to lack critical access to disease management and life-saving tools.

For those reasons, we are concerned that while most private payers permit individuals to use a smartphone app to share their data, individuals entering the Medicare program lose access to this important safety feature and some lose access to the device entirely. This restriction does not make sense and we are concerned that it will lead to poorer patient outcomes and less accessibility.

We urge CMS to work expeditiously to revise its continuous glucose monitor Local Coverage Article, to clarify that beneficiaries may choose to use a smartphone app, in conjunction with their CGM receiver, without losing Medicare coverage for that device.

As innovators continue to rapidly develop technologies that help individuals with diabetes manage their condition, we urge CMS to ensure that its Medicare coverage policies encourage, rather than discourage, the highest quality care and maximum accessibility. Thank you for your consideration and attention to this request. We welcome the opportunity to discuss this issue with you further.

Sincerely,



Susan M. Collins
United States Senator



Tom Reed
Member of Congress



Jeanne Shaheen
United States Senator



Diana DeGette
Member of Congress