March 1, 2018

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Administrator Verma,

On behalf of the Endocrine Society, we write today to ask for reconsideration of the current coverage policy for therapeutic Continuous Glucose Monitors (CGM). The coverage determination as written does not allow patients to use smart phone technology to share glucose data with family, caregivers, and healthcare providers. This functionality is a key safety feature, particularly for patients who have severe or recurring hypoglycemia or hypoglycemia unawareness. It is unclear why this functionality is currently banned by the coverage policy. Consequently, we ask CMS to reevaluate this aspect of the decision.

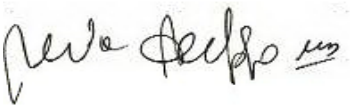
Hypoglycemia is a dangerous, potentially life-threatening complication of diabetes that resulted in more than 300,000 emergency room visits in 2009[1]. From 1999 to 2010, hospital admissions for hypoglycemia increased by 22.3% while rates of hyperglycemia decreased significantly[2]. As many hypoglycemic events are treated at home. These data likely underestimate the magnitude of the problem. The Department of Health and Human Services recognized this problem and included hypoglycemia as one of the top three preventable adverse drug events in its National Action Plan.

Patients with diabetes may experience seizure, coma, or death if hypoglycemia is not recognized. CGM allows for notification of decreasing blood glucose and hypoglycemia. Its mobile application enables caregivers to be notified. This is extremely important for hypoglycemic unaware patients or those who experience nocturnal hypoglycemia, which may become more frequent in the Medicare population as disease progresses. Caregivers can then act to prevent hypoglycemia and any associated adverse events.

Hypoglycemia diminishes quality of life for patients and drives preventable costs to the healthcare system. The Society is concerned that the current coverage determination prohibiting the use of the mobile application is a barrier to patient safety and preventable hypoglycemic events. As patients and caregivers use their own smart phone devices to enable this feature, reimbursement is not an issue.

We hope that CMS will reevaluate and reconsider the current CGM coverage determination to allow use of this important technology. Thank you for your consideration. We would be happy to provide further information to your staff, including having clinical diabetes experts available for discussion; please contact Meredith Dyer, Director of Health Policy, at mdyer@endocrine.org if we can help.

Sincerely,



Grazia Aleppo, MD
Chair, Clinical Affairs Core Committee
Endocrine Society

[1] https://www.cdc.gov/diabetes/statistics/hypoglycemia/fig1.htm
[2] https://health.gov/hcq/pdfs/ADE-Action-Plan-Diabetes-Agents.pdf