

November 6, 2019

VIA E-MAIL

Tamara Syrek Jensen
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850
Tamara.SyrekJensen@cms.hhs.gov

RE: Requested Removal of Medicare Coverage Restriction for Therapeutic Continuous Glucose Monitors (CGMs): Frequent (Four or More Times Per Day) Self-Testing with BGM

Dear Ms. Syrek Jensen:

On behalf of our members and the people we represent, the American Association of Clinical Endocrinologists (AACE), the American Association of Diabetes Educators (AADE), the American Diabetes Association (ADA), Endocrine Society, and JDRF request removal of the Medicare coverage restriction that limits access to therapeutic continuous glucose monitoring (CGM) systems to beneficiaries who have been performing frequent (four or more times a day) self-testing with a blood glucose monitor (BGM). Individually and collectively, our organizations include and represent thousands of patients and the leading clinical and scientific experts in the fields of endocrinology and diabetes care:

- **AACE** represents over 7,000 clinical endocrinologists in the U.S. and abroad who specialize in diagnosing and treating endocrine and metabolic disorders such as diabetes, thyroid disease, osteoporosis, growth hormone deficiency, cholesterol disorders, hypertension and obesity.
- **AADE** is an interdisciplinary association of healthcare professionals dedicated to integrated clinical and self-management as a key component in the care of people with diabetes and related chronic conditions. AADE represents over 14,000 diabetes care and education specialists including nurses, nurse practitioners, physician assistants, dietitians, pharmacists, exercise specialists, and others.
- Founded in 1940, the **ADA** is the nation's leading voluntary health organization whose mission is to prevent and cure diabetes, and to improve the lives of all people affected by diabetes. ADA membership includes more than 540,000 people with diabetes, their families and caregivers, as well as a professional society of nearly 20,000 health care professionals.
- Founded in 1916, the **Endocrine Society** represents more than 18,000 physicians and scientists in the field of endocrinology who are engaged in the treatment and

research of endocrine disorders, such as diabetes, hypertension, osteoporosis, infertility, obesity, and thyroid disease.

- **JDRF** is the leading global organization funding type 1 diabetes research—a patient organization with a mission of improving lives today and tomorrow by accelerating life-changing breakthroughs to cure, prevent and treat type 1 diabetes and its complications.

Our organizations support the adoption of appropriate Medicare coverage of therapeutic CGM systems for patients with diabetes, as indicated in our respective clinical practice guidelines and recommendations.¹ Each organization developed these guidelines and recommendations through analysis of published scientific and clinical evidence, as well as the input and advice of our members. This evidence has repeatedly demonstrated that CGM systems can help certain patients improve their glucose control by providing actionable data to adjust insulin to keep blood sugar in range.

Neither the recommendations of any organization represented here, nor the current standards of clinical practice, supports a restriction on CGM coverage that limits access to patients who have a demonstrated history of BGM self-testing at least four times per day. Removing a barrier to CGM coverage by eliminating this “four times per day” testing requirement will better align Medicare coverage criteria for therapeutic CGMs with peer-reviewed clinical evidence and standards of practice recommended by our organizations. This development would improve the health outcomes of beneficiaries with diabetes by improving glycemic control and reducing hypoglycemia.

Thank you for your consideration of our request. If you have any questions or need additional information, please contact Krista Maier, Vice President, Public Policy with the American Diabetes Association at KMaier@diabetes.org or 703-253-4365.

Sincerely,

American Association of Clinical Endocrinologists
American Association of Diabetes Educators
American Diabetes Association
Endocrine Society
JDRF

cc: Ing-Jye Cheng, CMS
Dr. Susan Miller, CMS
Dr. Joseph Chin, CMS

¹ See <https://professional.diabetes.org/content-page/practice-guidelines-resources>; <https://www.aace.com/disease-state-resources/diabetes/guidelines>; <https://www.endocrine.org/guidelines-and-clinical-practice/clinical-practice-guidelines>; <https://www.diabeteseducator.org/practice/practice-documents>; <https://www.jdrf.org/impact/advocacy/cgm-medicare-coverage/>.