April 20, 2024

Medicare Evidence Development and Coverage Advisory Committee
Coverage and Analysis Group (CAG)
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Attention: CMS-3458-N
Submitted via www.regulations.gov

RE: Devices for Self-management of Type 1 and Insulin-Dependent Type 2 Diabetes; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee-May 21, 2024

Senseonics, Incorporated (Senseonics) is pleased to submit this statement to the Centers for Medicare and Medicaid Services (CMS) Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). As an interested stakeholder and manufacturer of the first of its kind implanted CGM (iCGM) system, Senseonics welcomes this opportunity to respond to the solicitation from CMS.

Senseonics is the manufacturer of Eversense® E3, the current FDA-approved implanted CGM (iCGM) system to include a fully implantable, long-term sensor to detect glucose. The Eversense® E3 CGM system received FDA- approval for its therapeutic indications in February 2022. The sensor is implanted under the skin by a physician, nurse practitioner or physician's assistant and lasts for 180-days and uses an optical fluorescent measurement system to measure interstitial glucose concentrations. To date, there have been two categories of CGM systems that measure glucose in the interstitial fluid, transcutaneous and fully-implantable. There are commercial products in the U.S. in both categories for patients with diabetes, three that are transcutaneous CGM systems replaced by the patient every 7-14 days and the one fully implantable 180-day CGM system. Having multiple CGM products available to patients with type 1 and type 2 diabetes is important since there is a diversity of preference that patients have when they manage their diabetes.

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The use of continuous glucose monitoring systems (CGM) has been shown to improve diabetes management in numerous randomized control trials, as well as real-world evidence studies. These studies have included older adults and have irrefutably shown benefit and safety to the older adult population.

In response to the summary posted in the solicitation for responses, please consider our feedback below. It is clear to Senseonics that studies done to date in type 1 and type 2 diabetes, including in older adults, have employed clinically meaningful endpoints that suggest that CGM has immense benefit to patients with diabetes.

First, we believe that the studies included in the search and reported in the CER allow for a thorough interpretation of the literature supporting CGM. Most searches of this nature do not extend beyond 5 years since technologies, particularly in CGM and automated insulin delivery devices, are so rapidly advancing. Going back further would not add useful information.

We agree that the CER focuses on Clinical, Qualitative, Resource Use and Safety domains, which we feel are completely appropriate. Of course, this takes into account that the approved products have already demonstrated appropriate efficacy and safety. It is important to ensure that the mean absolute relative differences (MARDs) between the sensor glucose values and the gold-standard reference values and additional efficacy measurements of CGM products across the duration of sensor wear and glucose ranges (including hypoglycemia) are adequate to allow for continuous efficacy and particularly low range accuracy. While Time in Range (TIR, 70-180 mg/dL) is of great importance in clinical trials, there is a movement towards Time in Tight Range (TITR, 70-140 mg/dL) as being an additional valid glucose goal. This of course does not diminish the importance of Time Below Range for older adults, who are at heightened risk of hypoglycemia, and perhaps more susceptible to false compression lows if sedentary. Assessing different glucometrics (TIR, Time Below and Time Above) by time of day is also of interest, to assess the impact of nocturnal hypoglycemia and hyperglycemia. These metrics have been shown to be significantly improved in patients with type 1 and type 2 diabetes when using CGM, including in studies with older adults.

Senseonics agrees that A1C, hyperglycemia, assessed as level 2 (>250 mg/dL), and levels 1 (<70 mg/dL), 2 (<54 mg/dL) and 3 (meets the definition of severe hypoglycemia) hypoglycemia remain as key outcome measures, particularly for older adults. This is in concert with guidelines from ADA and the International Consensus. In older adults, particularly those with long-

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standing diabetes (with an emphasis on type 1 older adults and those with type 2 on intensive insulin regimens or sulfonylurea medications) hypoglycemia is of greatest concern. We do believe that the threshold of <70 mg/dL for hypoglycemia is appropriate and that both time in hypoglycemic ranges and episodes of hypoglycemia are important. Again, the susceptibility of older adults to hypoglycemia, and reduction in hypoglycemia in older adults when using CGM is supported by the clinical literature cited in the CER.

It appears that the studies done to date have been adequate and informative of safety and efficacy for older adults with type 1 and type 2 diabetes.

Senseonics appreciates the ability to respond to the MEDCAC inquiry.

Sincerely yours,

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