

Local Coverage Determinations for Implantable CGMs Announced by Three Medicare Administrative Contractors



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Positive Implantable CGM Coverage Policy Criteria Lessens Burdens to Patient Access

GERMANTOWN, Md.--(BUSINESS WIRE)-- Senseonics Holdings, Inc. (NYSE American: SENS), a medical technology company focused on the development and commercialization of long-term, implantable continuous glucose monitoring (CGM) systems for people with diabetes, today announced that three Medicare Administrative Contractors (MACs) have issued Local Coverage Determinations (LCDs) for the use of implantable CGM systems, such as the Eversense® CGM System. LCDs are policy decisions by MACs establishing services as reasonable, necessary and eligible for payment by Medicare.

The announced LCDs from Novitas Solutions, Inc., (Novitas), First Coast Service Options, Inc., (FCSO) and WPS Government Health Administrators (WPS GHSA) will all be effective as of October 19, 2020, ahead of the 2021 Medicare Physician Fee Schedule Proposed Rule that will provide national coverage for the three CPT codes representing sensor insertion, removal and combined removal and insertion. The stated coverage criteria will make Eversense available to a broader group of Medicare patients who may have used or considered other CGM devices.

“We applaud these three MACs for simplifying and streamlining the requirements for patients and healthcare providers to access the implantable CGM benefit,” said Francine Kaufman, MD, Chief Medical Officer of Senseonics. “Diabetes patients who use BGM or CGM readings to administer insulin, either through an insulin pump, syringe, pen or inhaled are eligible to start implantable CGM or switch from another CGM to implantable technology. The three MACs have lifted some previous restrictions, such as documenting four fingerstick measurements per day and requiring additional health care provider visits. We believe lifting these restrictions and broadening the inclusion criteria significantly increases the number of Medicare patients eligible to use Eversense.”

“We are very pleased access to Eversense has been expanded to a large number of Medicare patients by these LCDs. In addition, the elimination of some coverage criteria

for implantable technology, like Eversense, will make it easier for patients to enjoy the benefits of our CGM system,” said Tim Goodnow, PhD, President and CEO of Senseonics. “Through our collaboration with Ascensia Diabetes Care, we will begin our sales and marketing efforts with Ascensia to include Medicare patients covered under the announced LCDs. We look forward to partnering with Ascensia to initiate our commercial activities in the coming weeks.”

Together these three MACs provide coverage for more than 18 states, including areas of high Medicare coverage concentration and serve approximately 20 million beneficiaries.

About Eversense

The Eversense® brand of continuous glucose monitoring (CGM) systems are indicated for continually measuring glucose levels in persons age 18 and older with diabetes. The Eversense® CGM system, available in the U.S. is indicated for up to 90 days and as a replacement of fingerstick blood glucose (BG) measurements for diabetes treatment decisions. Fingerstick BG measurements are still required for calibration twice per day, and when symptoms do not match CGM information or when taking medications of the tetracycline class. The Eversense® XL CGM system, available outside of the U.S., is indicated for up to 180 days and is intended to complement, not replace, fingerstick blood glucose monitoring. The sensor insertion and removal procedures for both systems are performed by a health care provider. The Eversense and Eversense XL CGM systems are prescription devices; patients should talk to their health care provider to learn more. For important safety information, see <https://eversensediababetes.com/safety-info/>.

About Senseonics

Senseonics Holdings, Inc. is a medical technology company focused on the design, development and commercialization of transformational glucose monitoring products designed to help people with diabetes confidently live their lives with ease. Senseonics' CGM systems, Eversense® and Eversense® XL, include a small sensor inserted completely under the skin that communicates with a smart transmitter worn over the sensor. The glucose data are automatically sent every 5 minutes to a mobile app on the user's smartphone.

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