

Local Coverage Determination Proposed for Implantable Continuous Glucose Monitors by Medicare Administrative Contractors



May 14, 2020

Long-term implantable CGM coverage for devices such as Eversense in line with current CGM criteria

GERMANTOWN, Md.--(BUSINESS WIRE)-- Senseonics Holdings, Inc. (NYSE American: SENS) a medical technology company focused on the development and commercialization of the first and only long-term, implantable continuous glucose monitoring system for people with diabetes, announced today that three Medicare Administrative Contractors (MACs), Palmetto, First Coast Service Options (FCSO) and Novitas have removed implantable continuous glucose monitors (CGM) such as Eversense from their non-coverage policy. In addition, FCSO and Novitas have each published proposed Local Coverage Determinations (LCD) for implantable CGMs. This now enables the MACs to adjudicate claims for the Eversense CGM system submitted by healthcare providers for their Medicare beneficiaries as a Part B physician service.

The proposed LCD includes coverage criteria specific to therapeutic implantable CGMs such as Eversense that is equivalent to the existing LCD for other therapeutic CGMs currently administered by the durable medical equipment (DME) MACs. This policy will make Eversense available to the same group of patients who may have considered other CGM devices. As a physician service, Medicare beneficiaries will receive Eversense in the clinician's office without having to coordinate a CGM delivery through a DME supplier.

"This is a step forward for patients in need of more CGM options. We commend FCSO and Novitas for making Eversense available to Medicare beneficiaries through the proposed LCD. The coverage policy for implantable CGM aligns very well with the published clinical evidence on Eversense. The MACs have stated in their analysis that objective criteria for implantable CGM is similar to transcutaneous CGMs and hence the coverage will be in line with current CGM criteria," said Tim Goodnow, PhD, President and Chief Executive Officer of Senseonics.

“We recognize that this is the first step in the LCD process. Open comments will be made available to the public and we are hopeful that these LCDs will become effective sometime during the summer. In the meantime, FCSO, Novitas, and Palmetto have removed the CPT Codes used for the Eversense procedure from the non-coverage LCDs. This will allow for the MACs to review and adjudicate claims submitted by healthcare providers while the LCD completes the formal development process,” stated Dr. Goodnow.

About Eversense

The Eversense[®] Continuous Glucose Monitoring (CGM) System is indicated for continually measuring glucose levels in persons age 18 and older with diabetes for up to 90 days. The system will be used to replace fingerstick blood glucose (BG) measurements for diabetes treatment decisions. Fingerstick BG measurements will still be required for calibration twice per day, and when symptoms do not match CGM information or when taking medications of the tetracycline class. The sensor insertion and removal procedures are performed by a health care provider. The Eversense CGM System is a prescription device; 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.

FORWARD LOOKING STATEMENTS

Any statements in this press release about future expectations, plans and prospects for Senseonics, including statements about potential coverage decisions, the potential impact or meaning of coverage decisions, including without limitation making Eversense available, claim adjudication, and the potential life-enhancing benefits Eversense offers people with diabetes, and other statements containing the words “believe,” “expect,” “intend,” “may,” “projects,” “will,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties in the development and regulatory approval processes, uncertainties inherent in the commercial launch and commercial expansion of the product,

uncertainties in insurer, regulatory and administrative processes and decisions, and such other factors as are set forth in the risk factors detailed in Senseonics' Annual Report on Form 10-K for the year ended December 31, 2019, and Senseonics' other filings with the SEC under the heading "Risk Factors." In addition, the forward-looking statements included in this press release represent Senseonics' views as of the date hereof. Senseonics anticipates that subsequent events and developments will cause Senseonics' views to change. However, while Senseonics may elect to update these forward-looking statements at some point in the future, Senseonics specifically disclaims any obligation to do so except as required by law. These forward-looking statements should not be relied upon as representing Senseonics' views as of any date subsequent to the date hereof.

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