Long-term implantable CGM gets FDA approval

August 2018—The FDA has approved Senseonics Holdings' Eversense Continuous Glucose Monitoring System for adults age 18 and older with diabetes. The system features an implantable glucose sensor and provides long-term continuous monitoring for up to three months.

Eversense uses a small sensor implanted just under the skin by a physician during an outpatient procedure. The implanted sensor works with a novel light-based technology to measure glucose levels and send information to a mobile app to alert users if glucose levels are too high or too low. The sensor is coated with a fluorescent chemical which, when exposed to blood sugar, produces a small amount of light that is measured by the sensor. Every five minutes, measurements are sent to a compatible mobile device that is running a device-specific mobile app.

The FDA evaluated clinical study data from 125 adults with diabetes and reviewed the device's effectiveness by comparing readings obtained by Eversense with those obtained by a laboratory-based glucose analyzer. The safety of the system's 90-day implantable sensor and the procedure used to implant it were also evaluated. The FDA held an advisory committee meeting to provide an independent assessment of the safety and effectiveness of the system. In an eight-to-zero vote, the committee recommended that the benefits of the system outweigh the risks for patients with diabetes.

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