

Abbott's FreeStyle® Libre 2 ICGM System Now Available To Medicare Beneficiaries

- U.S. Centers for Medicare & Medicaid Services (CMS) reimbursement expands access of the FreeStyle Libre 2 system to Medicare patients[1] to better manage their diabetes

- The FreeStyle Libre 2 technology is the only integrated continuous glucose monitoring (iCGM) system available that continuously measures glucose data every minute without the need for painful fingersticks[2]

- Widely available in the U.S., the FreeStyle Libre 2 system is priced 70% lower than other available continuous glucose monitoring devices[3]

ABBOTT PARK, Ill., Sept. 1, 2020 /PRNewswire/ -- Abbott (NYSE: ABT), the worldwide leader in continuous glucose monitoring (CGM),⁴ announced today its next-generation FreeStyle® Libre 2 integrated continuous glucose monitoring (iCGM) system is now available to Medicare patients. Having met the codes for therapeutic CGM systems used for coverage by the U.S. Centers for Medicare & Medicaid Services (CMS), the FreeStyle Libre 2 system is now accessible to all Medicare patients with diabetes who meet the eligibility criteria.

"Abbott designed the FreeStyle Libre portfolio for performance, access and affordability to make it broadly available to people with diabetes who need it," said Jared Watkin, senior vice president, Diabetes Care, Abbott. "By securing reimbursement, Abbott is making sure our latest life-changing technology can get to everyone who needs it, whether they're children, adults or seniors eligible for Medicare."

The FreeStyle Libre 2 system includes a sensor that is the easiest to apply^{5,6} and is worn on the back of the upper arm for up to 14 days, measuring glucose every minute. With a one-second scan using a handheld reader over the sensor, the system provides users with a real-time glucose reading, trend arrow and eight-hour history to help them and their healthcare providers make more informed treatment decisions.

The FreeStyle Libre 2 system includes optional real-time alarms and measures glucose levels every minute, meeting the highest level of accuracy standards⁷ over 14 days, including superior day one⁶ accuracy compared to the other iCGM and excellent accuracy and alarm performance at low end glucose levels.⁸ With a 14-day wear time, the FreeStyle Libre 2 system is the longest-lasting, self-applied iCGM sensor currently available, eliminating the need for fingersticks² – and priced at a third of the cost of other CGM systems.³

The pandemic is changing the way healthcare is delivered with greater acceptance of telehealth and medical technologies with remote monitoring capabilities such as CGMs. For instance, during the public health emergency, CMS is giving healthcare professionals [more flexibility](#) to prescribe CGMs⁹ to those who qualify. Additionally, the U.S. Food and Drug Administration (FDA) is allowing the FreeStyle Libre system to be used in [hospital settings](#)¹⁰ during the pandemic, making Abbott's diabetes technology more easily accessible.

As the #1 sensor-based glucose monitoring system used in the U.S. and worldwide,⁴ Abbott's FreeStyle Libre portfolio has changed the lives of more than 2 million people across more than 50 countries⁶ by providing breakthrough technology that is accessible and affordable.³ Abbott has secured partial or full reimbursement for the FreeStyle Libre portfolio in 37 countries, including Canada, France, Germany, Japan, the United Kingdom and the U.S. For more information, visit www.freestylelibre.us.

Indications and Important Safety Information

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older.*

WARNINGS/LIMITATIONS:

The System must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems. Remove the sensor before MRI, CT scan, X-ray, or diathermy treatment. Do not take high doses of vitamin C (more than 500 mg per day), as this may falsely raise your Sensor readings. Failure to use the System according to the instructions for use may result in missing a severe low blood glucose or high blood glucose event and/or making a treatment decision that may result in injury. If glucose alarms and readings from the System do not match symptoms or expectations, use a fingerstick blood glucose value to make diabetes treatment decisions. Seek medical attention when appropriate and contact Abbott Toll Free (855-632-8658) or visit * www.freestylelibre.us for detailed indications for use and safety information.

*Please refer to www.freestylelibre.us for the indications and important safety information.

About Abbott

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritional and branded generic medicines. Our 107,000 colleagues serve people in more than 160 countries.

Connect with us at www.abbott.com, on LinkedIn at www.linkedin.com/company/abbott/, on Facebook at www.facebook.com/Abbott and on Twitter @AbbottNews and @AbbottGlobal.

¹ Patients must meet Medicare eligibility coverage criteria. Local Coverage Determination: Glucose Monitors (L33822), January 2020.

² Fingersticks are required if your glucose alarms and readings do not match symptoms or when you see Check Blood Glucose symbol during the first 12 hours.

³ Based on a comparison of list prices of the FreeStyle Libre 14 day system versus competitors' CGM systems. FreeStyle Libre 2 system list price is the same rate as FreeStyle Libre 14 day system. The actual cost to patients may or may not be lower than other CGM systems, depending on the amount covered by insurance, if any.

⁴ Data on file, Abbott Diabetes Care. Data based on the number of users worldwide for the FreeStyle Libre portfolio compared to the number of users for other leading personal-use, sensor-based glucose monitoring systems.

⁵ Based on comparison to Dexcom G6.

⁶ Data on file, Abbott Diabetes Care.

⁷ Based on FDA iCGM special controls.

⁸ Based on comparison between FreeStyle Libre 2 and Dexcom G6 User Manuals and low glucose alarms set at 70 mg/dL.

⁹ CMS Interim Final Rule, CMS-5531-IFC, RIN 0938-AU32. Published in the Federal Register on May 8, 2020 and is available at <https://www.govinfo.gov/content/pkg/FR-2020-05-08/pdf/2020-09608.pdf>. CMS Issues Interim Final Rules with Comment (CMS-1744-IFC & CMS-5531-IFC) – COVID-19 Public Health Emergency – Revised May 21, 2020 <https://www.cgsmedicare.com/jc/pubs/news/2020/05/cope17333.html>.

¹⁰ Patients must be able to scan their FreeStyle Libre 14 day sensor by themselves.

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