Abbott's Revolutionary Continuous Glucose Monitoring System, FreeStyle® Libre, Now Available To Medicare Patients

- CMS reimbursement provides opportunity for Medicare patients who meet eligibility criteria to access FreeStyle Libre System

- FreeStyle Libre System can replace traditional blood glucose monitoring, eliminating the need for routine fingersticks(1) or any user calibration

ABBOTT PARK, Ill., Jan. 4, 2018 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the FreeStyle® Libre System, the company's revolutionary new continuous glucose monitoring (CGM) 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). Coverage includes all Medicare patients with diabetes who use insulin and who meet the eligibility criteria[2].

The factory-calibrated FreeStyle Libre system is the only CGM system recognized by Medicare that requires no user calibration whatsoever (either by fingerstick or manual data entry). The system also does not require the need for routine fingersticks[1]. The high accuracy of the FreeStyle Libre system allows for patients to dose insulin based on the results[1].

"At Abbott, we are continuously challenging ourselves to ensure our innovative technology is accessible to the majority of people who need it," said Jared Watkin, senior vice president, Diabetes Care, Abbott. "CMS's recognition of this revolutionary health technology, which removes the need for any user calibration, is ultimately going to empower Medicare beneficiaries with diabetes to live better, healthier lives."

Designed to be approachable, accessible and affordable for the 30 million people with diabetes in the United States[3], the FreeStyle Libre system reads glucose levels through a sensor that is worn on the back of the upper arm for up to 10 days, making it the longest lasting personal glucose sensor available in the U.S.

FREESTYLE LIBRE AND OTHER CGM TECHNOLOGY

Key differences between the FreeStyle Libre system and other CGM technology include:

- FreeStyle Libre system is factory calibrated so it requires no user calibrations for accuracy, including any manual data entry or the need for routine fingersticks[1] –therefore removing the additional costs and burden of blood glucose monitoring to the patient
- FreeStyle Libre system includes only two pieces (sensor, reader) vs. three for alternative systems (sensor, reader, transmitter), making it much less cumbersome to use
- For non-Medicare patients, FreeStyle Libre system is available at major U.S. retail pharmacies, removing the barrier of complicated paperwork necessary for commercial insurance coverage and making it more readily accessible to patients

"The accessibility and affordability of this CGM technology is unprecedented, and this is a huge step forward for the diabetes community—both Type 1 and Type 2," said George Grunberger, M.D., chairman, Grunberger Diabetes Institute. "More importantly, the evidence of FreeStyle Libre being used in the real-world shows how people are getting better insights into their glucose levels with this product and achieving better glycemic control – that's something that you can't put a price to."

Last year, CMS announced coverage for therapeutic CGM[4] for certain beneficiaries who have either Type 1 or Type 2 diabetes and intensively manage their insulin. To be included in this category, the device must be approved by the U.S. Food & Drug Administration (FDA) for use in place of a blood glucose monitor (BGM), enabling patients to make treatment decisions based on the information provided. With the recent approval by the FDA, the FreeStyle Libre system can be used as a replacement for BGM[1].

HOW THE FREESTYLE LIBRE SYSTEM WORKS

With the FreeStyle Libre system, people with diabetes can:

- **Self-apply** the sensor, which is approximately the size of two stacked quarters, to the back of the upper arm.
- Capture real-time **glucose readings** with one-second painless scans of a small hand-held reader over the sensor.
- **Identify glucose level trends** (high, low, stable) with a directional arrow and review eight hours of glucose history.
- Receive glucose readings through clothing,[5] making testing **more convenient and discreet**[6]. The FreeStyle Libre sensor is also water-resistant[7], and can be worn in the shower and during swimming.
- **Avoid interference with acetaminophen**, an active ingredient in more than 500 common over-the-counter medications, which can falsely raise reported glucose levels in certain CGMs to appear as if they are at dangerously high levels[8].

WHERE YOU CAN FIND THE FREESTYLE LIBRE SYSTEM

- Medicare patients can access the FreeStyle Libre system by prescription through Edgepark Medical Supplies, Byram Healthcare, Solara Medical Supplies, Edwards Health Care Services, Better Living Now and Mini Pharmacy in the U.S.

- For non-Medicare patients, the FreeStyle Libre system is also available at five major retail pharmacies in the country (CVS, Walgreens, RiteAid, Walmart and Kroger).

The FreeStyle Libre system is now being used by more than 400,000 people across more than 40 countries[9]. Abbott has secured partial or full reimbursement for the FreeStyle Libre system in 21 countries, including France, Japan, the United Kingdom and now the U.S. For more information, please visit: www.freestylelibre.us.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

The FreeStyle Libre Flash Glucose Monitoring system is a continuous glucose monitoring (CGM) device indicated for replacing blood glucose testing and detecting trends and tracking patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments in persons (age 18 and older) with diabetes. The system is intended for single patient use and requires a prescription.

CONTRAINDICATIONS: Remove the sensor before MRI, CT scan, X-ray, or diathermy treatment.

WARNINGS/LIMITATIONS: Do not ignore symptoms that may be due to low or high blood glucose, hypoglycemic unawareness, or dehydration. Check sensor glucose readings with a blood glucose meter when Check Blood Glucose symbol appears, when symptoms do not match system readings, or when readings are suspected to be inaccurate. The FreeStyle Libre system does not have alarms unless the sensor is scanned, and the system contains small parts that may be dangerous if swallowed. The FreeStyle Libre system is not approved for pregnant women, persons on dialysis, or critically-ill population. Sensor placement is not approved for sites other than the back of the arm and standard precautions for transmission of blood borne pathogens should be taken. The built-in blood glucose meter is not for use on dehydrated, hypotensive, in shock, hyperglycemic-hyperosmolar state, with or without ketosis, neonates, critically-ill patients, or for diagnosis or screening of diabetes. Review all product information before use or contact Abbott Toll Free (855-632-8658) or visit www.freestylelibre.us for detailed indications for use and safety information.

About Abbott
At Abbott, we're committed to helping people live their best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 94,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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[1] Fingersticks are required for treatment decisions when you see Check Blood Glucose symbol, when symptoms do not match system readings, when you suspect readings may be inaccurate, or when you experience symptoms that may be due to high or low blood glucose

[2] Local Coverage Article: Glucose Monitor Policy Article (A52464),May 2017

[3] Center for Disease Control, https://www.cdc.gov/media/releases/2017/p0718-diabetes-report.html

[4] Centers for Medicare & Medicaid Services Ruling CMS-1682-R: "Classification of Therapeutic Continuous Glucose Monitors as 'Durable Medical Equipment' under Medicare Part B," January 12, 2017

[5] The reader can capture data from the sensor when it is within 1cm to 4cm of the sensor.

[6] Data on file. Abbott Diabetes Care

[7] Sensor is water-resistant in up to 1 meter (3 feet) of water. Do not immerse longer than 30 minutes

[8] Data on file, Abbott Diabetes Care

[9] Data on file, Abbott Diabetes Care

SOURCE Abbott

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