Abbott's FreeStyle Libre® Continuous Glucose Monitoring Systems Obtain Significantly Expanded Coverage For Medicare Beneficiaries

- The Medicare program has expanded access to continuous glucose monitoring systems like the FreeStyle Libre 2 system and the FreeStyle Libre 14 day system for insulin-using[1] Medicare beneficiaries with diabetes, removing the prior requirement of multiple daily insulin injections
- Medicare beneficiaries with diabetes and a history of problematic hypoglycemia[2] may also be eligible to have their FreeStyle Libre 2 system or FreeStyle Libre 14 day system covered for reimbursement
- Abbott is working to get the latest-generation FreeStyle Libre 3 system added to Medicare's list of covered systems as soon as possible[3]

ABBOTT PARK, Ill., April 17, 2023 /PRNewswire/ -- More Medicare beneficiaries than ever before who are living with diabetes and use insulin[1] will now be eligible for reimbursement when using Abbott's (NYSE: ABT) FreeStyle Libre® portfolio[3,4] – the most prescribed and affordable continuous glucose monitoring system (CGM) in the United States.[5,6]

"FreeStyle Libre technology was designed from the start to be affordable and accessible," said Jared Watkin, senior vice president for Abbott's diabetes care business. "We've been focused on highlighting the tremendous benefits of continuous glucose monitoring to help people living with diabetes manage their care easily and pain-free. Increasing access is a monumental step by Medicare to allow more people to have access to FreeStyle Libre so they can spend less time worrying and more time living healthier, better lives."

The prevalence of American adults living with diabetes continues to grow. Almost 11 million adults over the age of 65 are living with diabetes in the United States.[7] There could be more than two million Medicare beneficiaries living with diabetes that use insulin who will now be eligible to use FreeStyle Libre CGMs to manage their condition.[3,4,8]

"Providing access to CGMs, like the FreeStyle Libre systems, for Medicare insulin users is a powerful affirmation that access to the best available, patient-centered technologies can optimize the clinical impact and safety of life-saving, longstanding therapies like insulin," said James Gavin III, M.D., Ph.D., chief executive officer and chief medical officer of Healing Our Village, Inc., a firm specializing in helping economically challenged, ethnically diverse and medically underserved people feel empowered to take control of their diabetes.

The expansion also allows Medicare beneficiaries with problematic hypoglycemia[2] – where a person's blood glucose is lower than normal and can lead to dizziness or becoming unconscious – to qualify for coverage of a FreeStyle CGM to manage their diabetes.[3,4]

"We applaud Medicare's decision allowing for all insulin-dependent people as well as others who have a history of problematic hypoglycemia to have access to a continuous glucose monitor, a potentially life-saving tool for diabetes management," said Chuck Henderson, chief executive officer, American Diabetes Association.

The U.S Food and Drug Administration (FDA) just cleared a reader for the FreeStyle Libre 3 system. With the FDA's clearance of a standalone reader, Abbott is working to get the FreeStyle Libre 3 system added to Medicare's list of covered systems as soon as possible.[3]

The FreeStyle Libre systems are prescribed by more doctors for their Medicare patients than any other CGM.[8,9] Visit FreeStyle.Abbott to learn more about Abbott's Medicare coverage.

Important Safety Information
FreeStyle Libre 14 day system: Failure to use FreeStyle Libre 14 day system as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury. If readings do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions. Seek medical attention when appropriate or contact Abbott at 855-632-8658 or FreeStyleLibre.us for safety info.

FreeStyle Libre 2 and FreeStyle Libre 3 systems: Failure to use FreeStyle Libre 2 or FreeStyle Libre 3 systems as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury. If glucose alarms and readings do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions. Seek medical attention when appropriate or contact Abbott at 855-632-8658 or FreeStyleLibre.us for safety info.

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, nutritionals and branded generic medicines. Our 115,000 colleagues serve people in more than 160 countries.

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[1] Centers for Medicare & Medicaid Service Local Coverage Determination Coverage Guidance L33822 from the Medicare

Administrative Contractors https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33822. Published and accessed on March 2, 2023. For coverage of a CGM, patients must be diagnosed with diabetes; have sufficient training on using a CGM based on their healthcare provider's conclusion; be prescribed a CGM device in accordance with its FDA indications for use; use insulin or have a history of problematic hypoglycemia; have seen their healthcare provider in-person or through a Medicare-approved telehealth visit to evaluate their diabetes control within six months before the CGM was ordered; and every six months following their initial CGM prescription must go in-person or have a Medicare-approved telehealth visit with their healthcare provider to document their CGM adherence and diabetes treatment plan.

[2] Centers for Medicare & Medicaid Service's definition of problematic hypoglycemia is: recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or, a history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia.

[3] Abbott is in process of filing a standard code verification request with the Medicare Pricing Data Analysis and Coding (PDAC) contractor to assign the FreeStyle Libre 3 system to the appropriate CGM durable medical equipment (DME) code, as required for Medicare coverage. *See* Glucose Monitor – Policy Article A52464, available at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52464&ver=43&.

[4] Currently, only the FreeStyle Libre 14 day and FreeStyle Libre 2 systems are available for Medicare coverage.

[5] Data on file, Abbott Diabetes Care. Based on the number of patients assigned to each manufacturer based on last filed prescription data in U.S. Retail Pharmacies and Durable Medical Equipment Suppliers.

[6] Based on a comparison of list prices of FreeStyle Libre 2 and FreeStyle Libre 14 day systems versus competitors' CGM systems. The actual cost to patients may or may not be lower than other CGM systems, depending on the amount covered by insurance, if any. Abbott provides this information as a courtesy, it is subject to change and interpretation. The customer is ultimately responsible for determining the appropriate codes, coverage, and payment policies for individual patients. Abbott does not guarantee third-party coverage or payment for our products or reimburse customers for claims that are denied by third-party payers.

[7] Centers for Disease Control and Prevention. National Diabetes Statistics Report website, https://www.cdc.gov/diabetes/data/statistics-report/index.html. Accessed March 2, 2023.

[8] Data on file. Abbott Diabetes Care.

[9] Data based total active Medicare patients with CGM readers.

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