

Medicare Coverage Criteria¹

Check the criteria for coverage:

Therapeutic CGMs and related supplies are covered by Medicare when all the following coverage criteria are met:

- The beneficiary has diabetes mellitus; and
- The beneficiary has been using a blood glucose monitor (BGM) and performing frequent (4 or more times a day) testing; and
- The beneficiary is insulin-treated with multiple (3 or more) daily injections of insulin or a Medicare covered continuous subcutaneous insulin infusion (CSII) pump; and
- The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results; and
- Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-4) above are met; and
- Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan.



FreeStyle
Libre
FLASH GLUCOSE MONITORING SYSTEM



life. to the fullest.™

Abbott

Source:

1. "Coding and Coverage - Therapeutic Continuous Glucose Monitors (CGM)," Noridian Healthcare Solutions. Published March 23, 2017, med.noridianmedicare.com.
Learn more > <https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/coding-and-coverage-therapeutic-continuous-glucose-monitors>.

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.

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