Clinical Policy: Continuous Glucose Monitors

Reference Number: SC.CP.MP.02 Date of Last Revision: 06/25

Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Description

Continuous glucose monitors (CGMs) measure interstitial glucose, which correlates well with plasma glucose.

FDA Approved Indication(s)

CGMs are indicated for use in patients with diabetes mellitus to monitor blood glucose levels.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Absolute Total Care that CGMs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

- A. Diabetes Mellitus (must meet all):
 - **Replacement of functional features of an existing monitor for an upgrade is not considered medically necessary**
 - 1. Provider must submit chart notes as supporting documentation for diagnosis of one of the following (a, b, or c):
 - a. Type 1 diabetes mellitus;
 - b. Gestational diabetes;
 - c. Type 2 diabetes with one of the following (i or ii):
 - i. Any type of insulin dependency;
 - ii. Non-insulin treated diabetes who have recurrent moderate (level 2) or have had at least one severe (level 3) hypoglycemic event (*Appendix F*);
 - 2. CGM must be prescribed by one of the following qualified healthcare providers (a, b, or c):
 - a. primary care provider (physician, physician assistant or advanced practice registered nurse);
 - b. obstetrician;
 - c. endocrinologist.
 - 3. If request is for a non-preferred CGM, member must try and fail ALL of the following preferred CGMs (a, b, c, d, and e):
 - a. Dexcom G6;
 - b. Dexcom G7:
 - c. Freestyle Libre 2;
 - d. Freestyle Libre 3;

- e. Freestyle Libre 14 day;
- 4. If member was previously approved for any CGM device/receiver in the last 12 months, documentation in chart notes is required showing that a replacement or new device is necessary due to one of the following (i or ii):
 - i. Loss, theft, or damage that is not covered by manufacturer warranty;
 - ii. Age of device makes it incompatible with available medically necessary software, components, or accessories required for function or integration and is not covered by manufacturer warranty;

Approval duration: 12 months (1 receiver per 12 months only; other components [such as transmitters and sensors] may be replaced as needed – see Appendix D for examples)

B. Other diagnoses/indications: Not applicable

II. Continued Therapy

A. Diabetes Mellitus (must meet all):

Replacement of functional features of an existing monitor for an upgrade is not considered medically necessary. If the replacement request is due to change in clinical status and features of a different device type are medically necessary, the request should be reviewed using the initial approval criteria

- 1. Previously received the requested product via Centene benefit;
- 2. Documentation supports all of the following (a, b, and c):
 - a. If the request is for a new receiver: A replacement device is necessary due to one of the following (i, ii, or iii):
 - i. Loss, theft, or damage that is not covered by manufacturer warranty;
 - ii. Age of device makes it incompatible with available medically necessary software, components, or accessories required for function or integration and is not covered by manufacturer warranty;
 - iii. The reasonable and useful lifetime of ≥ 5 years has passed;
 - b. Member is using the product properly and continues to benefit from it;
 - c. Ongoing physician or clinical specialist monitoring;

Approval duration: 12 months (1 replacement receiver per 12 months only; other components [such as transmitters and sensors] may be replaced as needed – see Appendix D for examples)

B. Other diagnoses/indications: Not applicable

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies.

Appendices/General Information

Appendix A: Abbreviation/Acronym Key CGM: continuous glucose monitoring FDA: Food and Drug Administration SMBG: self-monitoring of blood glucose

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings None reported

Appendix D: General Information

- Blood glucose monitoring (either with self-monitoring [SMBG] or CGM) is a tool used to evaluate whether glycemic targets are being achieved. It enables evaluation of response to both pharmacologic therapy and lifestyle modifications and can therefore help guide treatment decisions and/or self-management.
- The American Diabetes Association, American Association of Clinical Endocrinologists, and American College of Endocrinology do not prefer any one blood glucose monitor brand over another.
- The choice of device should be made on the individual's circumstance, preferences, and needs.
- Examples of CGMs and their components include, but are not limited to, the following:
 - o Dexcom G6® CGM System:
 - Receiver (Dexcom receiver*): replacement frequency not specified
 *A personal smart device (e.g., smart phone, smart watch) may also be used, either instead of or in addition to the Dexcom receiver
 - Transmitter (G6 transmitter): replaced every 3 months
 - Sensor (applicator with built-in sensor): replaced every 10 days
 - Dexcom G7[®] CGM System:
 - Receiver (Dexcom G7 receiver*): 3 years for typical use
 *A personal smart device (e.g., smart phone, smart watch) may also be used, either instead of or in addition to the Dexcom G7 receiver
 - Sensor (with built in transmitter): replace every 10 days
 - FreeStyle Libre 14 Day Flash Glucose Monitoring System:
 - Receiver (FreeStyle reader): replaced every 3 years
 - Sensor (sensor pack and sensor applicator): replaced every 14 days
 - o FreeStyle Libre 3 Glucose Monitoring System:
 - Receiver (Reader*): replace every 3 years
 *A personal smart device (e.g., smart phone, smart watch) may also be used instead of the receiver
 - Sensor: replaced every 14 days

Appendix E: Comprehensive Diabetes Management Programs

• A comprehensive diabetes management program is based on an assessment of an individual's specific needs. Education is designed to promote self-management or assist caregivers when appropriate while offering support to improve health outcomes (American Diabetes Association, Diabetes Care 2023, 46: Supplement_1:S68-S96; U.S. Department of Veteran Affairs, Management of Type 2 Diabetes Mellitus in Primary Care. 2017. update Mar 2021; National Institute for Health and Clinical Excellence (NICE), Diabetes (type 1 and type 2) in children and young people: diagnosis and management. Clinical guideline 18. 2015. update 2020; Powers et al., Diabetes Care 2020, 43: 1636-49; National Institute for Health and Care Excellence (NICE), Type 2 diabetes in adults: management. Clinical guideline 28. 2015). Content areas include:

- Description of the disease process
- Treatment options
- o Incorporation of nutritional management
- o Incorporation of physical activity into lifestyle
- Safe medication usage
- Monitoring of blood glucose and HbA1c along with other lab values to make selfmanagement decisions
- Weight management
- Additional content areas include education in preventing, detecting, and treating acute
 and chronic conditions, as well as strategies to address psychosocial issues and to
 promote health and behavior changes. Continuous education, with reinforcement and
 periodic assessment of treatment goals, is necessary.

Appendix F: IHSG Definitions of Clinically Relevant Levels of Hypoglycemia

- Level 1 (mild) hypoglycemia: Blood glucose is less than 70 mg/dL (3.9 mmol/L) but is 54 mg/dL (3.0 mmol/L) or higher.
- Level 2 (moderate) hypoglycemia: Blood glucose is less than 54 mg/dL (3.0 mmol/L).
- Level 3 (severe) hypoglycemia: As defined by the ADA, severe cognitive impairment requiring external assistance for recovery.

Dosage and Administration

Usage regimen is individualized based on patient goals.

Product Availability

Monitor and test strip packaging vary by product and manufacturer.

References

- 1. InterQual July 2023. Release CP: Durable Medical Equipment Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Technology.
- 2. InterQual April 2022 Durable Medical Equipment Criteria, Therapeutic continuous glucose monitor (CGM) with supply allowance.
- 3. InterQual April 2022 Durable Medical Equipment Criteria, Adjunctive real time continuous glucose monitor.
- 4. American Diabetes Association. Standards of medical care in diabetes—2023. Diabetes Care. 2023; 45(suppl 1): S1-S280. Accessed June 2, 2025.
- 5. Garber AJ, Handelsman Y, Grunberger G, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm 2020 executive summary. Endocr Pract. 2020; 26(1): 107-139.
- 6. Grunberge G, SherrJ, Allende M, et al. American Association of Clinical Endocrinology clinical practice guideline: The use of advanced technology in the management of persons with diabetes mellitus. Endocrine Practice. 2021; 27: 505-537.
- 7. FreeStyle Libre 14 Day Flash Glucose Monitoring System User's Manual. ART39764-201 Rev. A 02/23. Available at https://www.freestylelibre.us/support/overview.html. Accessed June 2, 2025.
- 8. Dexcom G6 CGM System User Guide. AW-1000052-10 Rev 001 MT-1000052-10. Revision date: November 2022. Available at https://www.dexcom.com/guides. Accessed June 2, 2025.

- 9. Dexcom C7 CGM System User Guide. AW00078-10 Rev 002 MT-00078-10. Revision Date: April 2023. Available at https://dexcompdf.s3.us-west-2.amazonaws.com/en-us/G7-CGM-Users-Guide.pdf. Accessed June 2, 2025.
- 10. FreeStyle Libre 3 Continuous Glucose Monitoring System User's Manual. ART41641-001. Rev. A 05/23. Available at https://freestyleserver.com/payloads/ifu/2023/q3/ART41641-001 rev-A-web.pdf. Accessed June 2, 2025.
- 11. International Hypoglycaemia Study Group. Minimizing hypoglycemia in diabetes. *Diabetes Care*. 2015;38(8):1583-1591.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS	Description	
Codes		
A4238	oly allowance for adjunctive, non-implanted continuous glucose monitor	
	(cgm), includes all supplies and accessories, 1 month supply = 1 unit of service	
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor	
	(cgm), includes all supplies and accessories, 1 month supply = 1 unit of service	
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical	
	equipment interstitial continuous glucose monitoring system, one unit = 1 day	
	supply	
A9277	Transmitter; external, for use with non-durable medical equipment interstitial	
	continuous glucose monitoring system	
A9278	Receiver (monitor); external, for use with non-durable medical equipment	
	interstitial continuous glucose monitoring system	
E2102	Adjunctive, non-implanted continuous glucose monitor or receiver	
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy created.	06/25	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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