

Clinical Policy: Continuous Glucose Monitors

Reference Number: CP.CPA.355

Effective Date: 03.01.21 Last Review Date: 02.25 Line of Business: Commercial

Coding Implications
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 health plans affiliated with Centene Corporation® 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. Diagnosis of diabetes mellitus;
- 2. Frequent adjustments to the member's treatment regimen are necessary based on glucose testing results;
- 3. Member meets one of the following (a or b):
 - a. Member requires intensive insulin therapy as evidenced by one of the following (i or ii):
 - i. Requires insulin injections ≥ 3 times per day;
 - ii. Uses a continuous insulin infusion pump;
 - b. Member is \geq 18 years of age and has a diagnosis of type 2 diabetes that is currently managed with basal injections and/or oral agents;
- 4. Member must use the health-plan preferred product, if available, unless member is younger than the FDA-approved age for the product;
- 5. Request does not exceed health-plan quantity limit.

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)

^{*}If request is for a CGM that is also an insulin delivery system, additional approval criteria apply. Refer to CP.PHAR.534 Insulin Delivery Systems (V-Go, Omnipod, InPen).



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 or member has previously met the initial approval criteria;
- 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;
- 3. Member must use the health-plan preferred product, if available, unless member is younger than the FDA-approved age for the product;
- 4. Request does not exceed health-plan quantity limit.

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 – CP.CPA.09 for commercial.

IV. 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
 - o 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
 - o 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
 - 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

V. Dosage and Administration

Usage regimen is individualized based on patient goals.

VI. Product Availability

Monitor and test strip packaging vary by product and manufacturer.

VII. References

- 1. InterQual March 2024 Durable Medical Equipment Criteria, Therapeutic continuous glucose monitor (CGM) with supply allowance.
- 2. InterQual March 2024 Durable Medical Equipment Criteria, Adjunctive real time continuous glucose monitor.
- 3. American Diabetes Association. Standards of medical care in diabetes—2024. Diabetes Care. 2024; 47(suppl 1): S1-S322. Accessed July 30, 2024.
- 4. Samson SL, Vellanki P, Blonde L, et al. American Association of Clinical Endocrinology Consensus statement: Comprehensive type 2 diabetes management algorithm 2023 update. Endocr Pract. 2023 May;29(5):305-340. doi: 10.1016/j.eprac.2023.02.001.



- 5. 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.
- 6. FreeStyle Libre 14 Day Flash Glucose Monitoring System User's Manual. ART39764-201 Rev. A 08/23. Available at https://www.freestylelibre.us/support/overview.html. Accessed July 19, 2024.
- 7. 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 July 19, 2024.
- 8. Dexcom C7 CGM System User Guide. AW00078-10 Rev 003 MT-00078-10. Revision Date: April 2024. Available at https://dexcompdf.s3.us-west-2.amazonaws.com/en-us/G7-CGM-Users-Guide.pdf. Accessed July 19, 2024.
- 9. FreeStyle Libre 3 Continuous Glucose Monitoring System User's Manual. ART41641-001. Rev. A 04/24. Available at https://freestyleserver.com/payloads/ifu/2024/q2/ART49385-001 rev-A Web.pdf. Accessed July 19, 2024.

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 Codes	Description
A4238	Supply 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	Date	P&T
		Approval Date
Policy created per October ad hoc SDC, adapted from	11.02.21	02.22
CP.PMN.214.		
4Q 2022 annual review: revised to align with InterQual medical	07.18.22	11.22
criteria as follows: <i>initial criteria</i> – removed requirements for a		
prescribing physician who has seen the member in person in the		
last 6 months, blood glucose testing 4 or more times per day, and in		



Reviews, Revisions, and Approvals	Date	P&T Approval Date
person visits every 6 months; added additional pathway to approval for members not receiving intensive insulin therapy (adults with		
type 2 diabetes); added requirement for participation in a comprehensive diabetes management program; <i>continued criteria</i> – added additional pathways to receive replacement devices based on		
the age/lifetime of the current device and added requirement for ongoing monitoring from a physician/clinical specialist; clarified		
that the preferred product redirection applies only when the member is an appropriate age to use the product per FDA labeling;		
references reviewed and updated. 4Q 2023 annual review: updated Appendix D with examples of	08.07.23	11.23
Dexcom G7 and Libre 3; updated Appendix E with content area of		
reviewed and updated.		
4Q 2024 annual review: no significant changes; for continued	07.30.24	11.24
1 1 1		
Per SDC, removed requirement for participation in a	01.07.25	02.25
comprehensive diabetes management program.	04.28.25	
"weight management" per ADA 2023 guidelines; references reviewed and updated. 4Q 2024 annual review: no significant changes; for continued therapy, added option for member to have previously met the initial approval criteria; references reviewed and updated. Per SDC, removed requirement for participation in a		

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.



This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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