Clinical Policy: Continuous Glucose Monitors

Reference Number: AR.QC.PMN.214
Effective Date: 1.1.25
Last Review Date: 1.1.26
Line of Business: **Commercial** Revision Log

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

If request is for True Metrix®, this policy does not apply. The True Metrix meter is covered at no cost by the manufacturer by billing BIN # 018844, PCN # 3F, ID # TRPT5023493, Group # FVTRUEPORT50. Call 1-855-282-4888 for additional information.

Description

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

**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).*
**For review of CGM NOT on the formulary refer to HIM.PA.103*

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, b or c):
   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 has gestational diabetes;

c. Member has a history of problematic hypoglycemia with documentation of at least one of the following (i or ii):
   - **i** Recurrent level 2 hypoglycemic events (glucose <54 mg/dL) that persist despite two or more attempts to adjust medication, modify the diabetes treatment plan, or both;
   - **ii** A history of a level 3 hypoglycemic event (glucose <54 mg/dL) characterized by altered mental or physical state requiring third-party assistance for treatment for hypoglycemia;

4. Request is for a formulary 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*)

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. Request is for a formulary 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 – HIM.PA.154 for health insurance marketplace.

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:
  - 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
  - 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-CGMUsers-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/ART49385001_rev-A_Web.pdf. Accessed July 19, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Initial Policy creation and review	11.1.24	01.25
Removed requirement for participation in a comprehensive diabetes management program.	04.08.25	04.25
4Q 2025 annual review: per SDC, removed option for management with oral agents for type 2 diabetes; per GA regulation, added options for gestational diabetes and history of problematic hypoglycemia	8.1.25	11.25
2026 annual review: per SDC, removed age requirement for initial approval.	10.29.25	01.26

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.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.