

## Clinical Policy: Continuous Glucose Monitors

Reference Number: CP.PMN.214

Effective Date: 12.01.19

Last Review Date: 02.22

Line of Business: HIM\*, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

*\*For Health Insurance Marketplace members, if request is for True Metrix<sup>®</sup>, this policy does not apply. The True Metrix meter is covered at no cost by the manufacturer by billing BIN # 015251, PCN # PRX2000, ID #HB224289445, Group #TRUEport22. Call 1-855-282-4888 for additional information.*

### Description

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

### FDA Approved Indication(s)

Continuous glucose monitors 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<sup>®</sup> that continuous glucose monitors 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. Prescribed by a physician who has seen the member in person within the last 6 months;
3. Member currently requires blood glucose testing  $\geq 4$  times per day;
4. Frequent adjustments to the member's treatment regimen are necessary based on glucose testing results;
5. Member meets one of the following (a or b):
  - a. Requires insulin injections  $\geq 3$  times per day;
  - b. Uses a continuous insulin infusion pump;
6. In-person physician visits are planned every 6 months to assess adherence to both continuous glucose monitoring (CGM) regimen and diabetes treatment plan;
7. Member must use Freestyle<sup>®</sup> Libre;
8. 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\*\**

1. Previously received the requested product via Centene benefit;
2. Documentation supports both of the following (a and b):
  - a. If the request is for a new receiver: A replacement device is necessary due to loss, theft, or damage;
  - b. Member is using the product properly and continues to benefit from it;
3. Member must use Freestyle Libre;
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 and CP.PMN.53 for Medicaid.

**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.
- Examples of CGMs and their components include, but are not limited to, the following:
  - Dexcom G6<sup>®</sup> 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
  - 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

**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 April 2021 Durable Medical Equipment Criteria, Continuous Glucose Monitors - Therapeutic.
2. American Diabetes Association. Standards of medical care in diabetes—2021. Diabetes Care. 2021; 44(suppl 1): S1-S232. Updated June 16, 2021. Accessed June 28, 2021.
3. 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.
4. 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.
5. FreeStyle Libre 14 Day Flash Glucose Monitoring System User’s Manual. ART39764-001 Rev. A 08/18. Available at <https://www.freestylelibre.us/support/overview.html>. Accessed September 9, 2021.
6. Dexcom G6 CGM System User Guide. LBL014003 Rev 012 MT23976. Revision date: December 2020. Available at <https://www.dexcom.com/guides>. Accessed September 9, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.03.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	07.01.20	11.20
Added steerage to the health-plan preferred product.	05.06.21	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021 annual review: no significant changes; clarified that while only 1 receiver may be approved every 12 months, other CGM components such as transmitters and sensors may be approved more frequently; references to HIM.PHAR.21 revised to HIM.PA.154; added information about components of the Dexcom G6 and FreeStyle Libre CGMs to Appendix D; references reviewed and updated.	06.28.21	11.21
Per October ad hoc SDC, removed Commercial line of business; specified Freestyle Libre as the preferred product.	11.02.21	02.22
For HIM, revised notation that this policy applies only to formulary products to instead indicate that requests for True Metrix (non-formulary) can be covered by the manufacturer through specific billing per line of business owner.	05.19.22	

**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.

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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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