Clinical Policy: Continuous Glucose Monitors

Reference Number: CP.PMN.214
Effective Date: 12.01.19
Last Review Date: 11.24
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®, 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 (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).

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 ≥ 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 has completed or is actively participating in a comprehensive diabetes management program (*see Appendix E*);
5. If age ≥ 4 years, member must use FreeStyle® Libre;

6. 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. If age ≥ 4 years, 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.
- 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

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: S1-S291; 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 2022; National Institute for Health and Care Excellence (NICE), Type 2 diabetes in adults: management. Clinical guideline 28. 2022; U.S. Department of Veteran Affairs, Management of Type 2 Diabetes Mellitus in Primary Care. 2017. update Mar 2021; Powers et al., Diabetes Care 2020, 43: 1636-49). Content areas include:
  - Description of the disease process
  - Treatment options

  - Incorporation of nutritional management
  - Incorporation of physical activity into lifestyle
  - Safe medication usage
  - Monitoring of blood glucose and HbA1c along with other lab values to make self-management 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.

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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	
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	
4Q 2022 annual review: revised to align with InterQual medical criteria as follows: *initial criteria* – 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 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; *continued criteria* – 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 FreeStyle Libre redirection applies only to age ≥ 4 years; references reviewed and updated.	07.18.22	11.22
4Q 2023 annual review: updated Appendix D with examples of Dexcom G7 and Libre 3; updated Appendix E with content area of "weight management" per ADA 2023 guidelines; references reviewed and updated.	08.07.23	11.23
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.	7.30.24	11.24

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.