Clinical Policy: Continuous Glucose Monitors

Reference Number: OR.CP.MP.502
Effective Date: 12/2024
Last Review Date:
Line of Business: Medicaid

Revision Log

See Important Reminder 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. This policy is for the medical necessity review process for members receiving CGMs under their medical benefit for medical benefit.

*** Note for clinical policy reviewers: It is the intent of Trillium Community Health Plan (Trillium) to utilize this policy instead of Oregon Health Authority Prioritized List current Guideline Note regarding Continuous Glucose Monitors to align with current pharmacy policy. This policy follows Oregon Administrative Rule 410-141-3843 is no less than amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid. ***

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. 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 Trillium 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 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.

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. Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. 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.

CPT® Codes	Description
95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report
99091	Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training

CPT® Codes	Description
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation

HCPCS Codes	Description
A4238	Supply allowance for adjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for nonadjunctive, nonimplanted 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 nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply
A9277	Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
A9278	Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified
E2102	Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
G0308	Creation of subcutaneous pocket with insertion of 180-day implantable interstitial glucose sensor, including system activation and patient training
G0309	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180-day implantable sensor, including system activation
G0564	Creation of subcutaneous pocket with insertion of 365 day implantable interstitial glucose sensor, including system activation and patient training
G0565	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 365 day implantable sensor, including system activation
S1030	Continuous noninvasive glucose monitoring device, purchase
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor

VIII. References

1. Oregon Health Authority. Prioritized List Guidelines Note 108 Continuous Glucose Monitoring: Line 8 and 27. https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports-Blog.aspx?View={DE654D2C-76D6-4607-B754-C7862C05B54F}&SelectedID=5
2. InterQual March 2024 Durable Medical Equipment Criteria, Therapeutic continuous glucose monitor (CGM) with supply allowance.
3. InterQual March 2024 Durable Medical Equipment Criteria, Adjunctive real time continuous glucose monitor.

4. American Diabetes Association. Standards of medical care in diabetes—2024. Diabetes Care. 2024; 47(suppl 1): S1-S322. Accessed July 30, 2024.
5. 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.
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 08/23. Available at https://www.freestylelibre.us/support/overview.html. Accessed July 19, 2024.
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 July 19, 2024.
9. 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.
10. 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	Approval Date
Policy created to align Medical benefit with Pharmacy benefit	11/24	11/24
Added HCPC codes G0564 and G0565 per HERC Update – Pending January 1, 2025 Prioritized List of Health Services	12/24	12/24

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.

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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.