Clinical Policy: Continuous Glucose Monitor

Reference Number: IL.PHAR.17
Effective Date: 7.25.19
Last Review Date: 10.30.23
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 (CGM) measure interstitial glucose, which correlates well with plasma glucose

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**If request is for a CGM that is also an insulin delivery system, additional approval criteria apply. Refer to IL.PHAR.505 Insulin Delivery Systems (V-Go, Omnipod, InPen).*

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® that Continuous Glucose Monitors are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria:

A. Diagnosis of Type I Diabetes (must meet one of the following 1 or 2):

1. Patient is < 21 years of age and meets all of the following:
   a. Request is for Dexcom G6, Dexcom G7, Freestyle Libre 14 Day, or Freestyle 2;
   b. Has been trained on the use of the requested CGM system;
   c. Requires an intensive insulin regimen (2 or more insulin injection per day), or utilize an insulin pump;
2. Patient is 21 years of age or older and meets all of the following:
   a. Request is for Dexcom G6, Dexcom G7, Freestyle Libre 14 Day, or Freestyle 2;
   b. Has been trained on the use of the requested CGM systems;
   c. Requires an intensive insulin regimen (2 or more insulin injection per day), or utilize an insulin pump;
   d. Has documented failure to achieve glycemic goals;

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. Diagnosis of Type II Diabetes (must meet all of the following):

1. Request is for Dexcom G6, Dexcom G7, Freestyle Libre 14 Day, or Freestyle 2;
2. Prescribed by or in consultation with endocrinologist;
3. Receiving intensive insulin therapy and frequently testing blood glucose levels, and meets one of the following:
   a. Hypoglycemic unawareness;
   b. Recurrent documented hypoglycemia;
   c. Recurrent nocturnal hypoglycemia;
   d. Recurrent ketoacidosis;
   e. Suboptimal glycemic control including wide glycemic swings;

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*)

C. Diagnosis of Gestational Diabetes (Must meet all of the following):
1. Request is for Dexcom G6, Dexcom G7, Freestyle Libre 14 Day, or Freestyle 2;
2. Suboptimal glycemic control;

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*)

D. Diagnosis of Cystic Fibrosis-Related Diabetes (Must meet all of the following)
1. Request is for Dexcom G6, Dexcom G7, Freestyle Libre 14 Day, or Freestyle 2;
2. Suboptimal glycemic control including wide glycemic swings contributing to exacerbations;

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*)

E. For patient populations that do not meet the above criteria, or in which CGM has not been well studied, requests will be reviewed for medical necessity on a case-by-case basis.

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*)

II. Continued Therapy (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 following:
   a. Patient must have demonstrated compliance with the CGM in order to have continued authorization;

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*)

A. Other diagnoses/indications:

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized: Not Applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CGM: Continuous Glucose Monitor
BGM: Blood Glucose Monitor
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications

Not applicable

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® 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. Product Availability

Monitor and test strip packaging vary by product and manufacturer.

VI. References:

1. InterQual April 2022 Durable Medical Equipment Criteria, Continuous Glucose Monitors - Therapeutic.
2. InterQual April 2022 Durable Medical Equipment Criteria, Adjunctive real time continuous glucose monitor.
3. 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.
4. 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.
5. American Diabetes Association. Standards of medical care in diabetes—2018. Diabetes Care. 2018;41(Suppl. 1):S1–153.
6. Danne T, Nimri R, Battelino T, et al. International consensus on use of continuous glucose monitoring. Diabetes Care. 2017;40:1631–40.
7. Bailey TS, Grunberger G, Bode BW, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2016 outpatient 2019 UIC-COP and HFS. All rights reserved. Continuous Glucose Monitor 3/2019 glucose monitoring consensus statement. Endocr Pract. 2016;22:231–61.
8. Ajjan R, Slattery D, Wright E. Continous glucose monitoring: A brief review for primary care practitioners. Adv Ther. 2019.1:1-19. doi.org/10.1007/s12325-019-0870-x.
9. 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 December 8, 2021.
10. Dexcom G6 CGM System User Guide. LBL014003 Rev 012 MT23976. Revision date: December 2020. Available at https://www.dexcom.com/guides. Accessed December 8, 2021.
11. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	7.1.19	7.25.19
Added language to support migration to HFS PDL.	12.10.19	1.7.20
Q2 2021 annual review **Added to initial Criteria**: 1) In-person physician visits are planned every 6 months to assess adherence to both continuous glucose monitoring (CGM) regimen and diabetes treatment plan; 2) Prescribed by a physician who has seen the member in person within the last 6 months;	6.30.21	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3) Frequent adjustments to the member's treatment regimen are necessary based on glucose testing results; **Added to Continued request:** 1. Documentation supports both of the following (a and b): a. A replacement device is necessary due to loss, theft, or damage; b. Member is using the product properly and continues to benefit from it; 2. Member is requesting Dexcom G6 monitor 3. Request does not exceed health-plan quantity limit. Added References		
4Q2021 Annual Review -Updated per HFS Criteria; removed initial criteria; added criteria for Type I Diabetes, Type II Diabetes, Gestational Diabetes, and Cystic Fibrosis-related Diabetes; updated criteria for continued authorization; reviewed and updated the references	12.8.21	
1Q2022 Annual Review: added preferred agent Freestyle Libre 14 Day and Freestyle 2;	3.1.22	
1Q2023 Annual Review: No significant changes; references reviewed and updated	3.14.23	
Added Dexcom G7 to criteria	10.30.23	

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.