Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2022**
Policy Number: PA.CP.PMN.214	**Effective Date: 01/2020** **Revision Date: 10/2022**
Policy Name: Continuous Glucose Monitors	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

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 physician-directed 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; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Continuous Glucose Monitors

Reference Number: PA.CP.PMN.214
Effective Date: 01/2020
Last Review Date: 10/2022

Revision Log

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

FDA Approved Indication(s)
Continuous glucose monitors (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.

_____
**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).*

It is the policy of PA Health & Wellness® 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. For type 2 diabetes, frequent adjustments to the member's pharmacologic 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 physician-directed comprehensive diabetes management program;
5. Member must use Freestyle® Libre;
6. Request does not exceed quantity limit of 1 receiver per 12 months only; other components [such as transmitters and sensors] may be replaced as needed or 1 replacement device per 12 months.

Approval duration: 12 months

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. Currently receiving product via PA Health & Wellness benefit and documentation supports positive response to using the product or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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. Member must use Freestyle Libre;
4. Request does not exceed quantity limit of 1 receiver per 12 months only; other components [such as transmitters and sensors] may be replaced as needed or 1 replacement device per 12 months..

Approval duration: 12 months

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 – PA.CP.PMN.53

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® 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 2022 Durable Medical Equipment Criteria, Therapeutic continuous glucose monitor (CGM) with supply allowance..
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; 45(suppl 1): S1-S232. Updated May 31, 2022. Accessed July 6, 2022.
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. 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. ART39764-001 Rev. A 08/18. Available at https://www.freestylelibre.us/support/overview.html. Accessed July 6, 2022.
7. Dexcom G6 CGM System User Guide. LBL014003 Rev 012 MT23976. Revision date: December 2020. Available at https://www.dexcom.com/guides. Accessed July 6, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01/2020	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2020 annual review: revised criterion requiring frequent adjustments to member's pharmacologic treatment regimen to apply to type 2 diabetes only; references reviewed and updated.	07/2020	
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021	
Updated quantity limit wording	08/2022	
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 physician-directed 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; references reviewed and updated.	10/2022	