Clinical Policy: Continuous Glucose Monitors

Reference Number: AZ.CP.PMN.214
Effective Date: 05.01.22
Last Review Date: 02.23
Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) 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.

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**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 Arizona Complete Health-Complete Care Plan and Care1st that CGMs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Diabetes Mellitus (must meet all)**:**

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 meets one of the following (a, b, or c):
   a. Member is equal to 2 years of age and less than 4 years of age and request is for Dexcom;
   b. Member is 4 years old or older and request is Freestyle Libre;
   c. Request is for Dexcom: Member is 4 years old or older and currently on an integrated system (insulin pump plus continuous glucose monitor) that interfaces with Dexcom;

5. Member has completed or is actively participating in a physician-directed comprehensive diabetes management program (*see Appendix E*);
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;
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 meets one of the following (a, b, or c):
   a. Member is equal to 2 years of age and less than 4 years of age and request is for Dexcom;
   b. Member is 4 years old or older and request is Freestyle Libre;
   c. Request is for Dexcom: Member is 4 years old or older and currently on an integrated system (insulin pump plus continuous glucose monitor) that interfaces with Dexcom;
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 – 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® 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
- Examples of insulin pumps that integrate with the CGM (as of 1/2023):

Insulin Pump	CGM Pair
Tandem t:slim X2 Pump with Basal-IQ Technology	Dexcom G6
Tandem t:slim X2 Pump with Control-IQ Technology	Dexcom G6
Medtronic MiniMed 630G	Guardian Sensor 3
Medtronic MiniMed 770G	Guardian Sensor 3
Omnipod 5	Dexcom G6

- 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

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 2022, 45: S1-S264; U.S. Department of Veteran Affairs, Management of Type 2 Diabetes Mellitus in Primary Care. 2017. update Mar 2021; 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 2020; Powers et al., Diabetes Care 2020, 43: 1636-49; National Institute for Health and Care Excellence (NICE), Type 2 diabetes in adults: management. Clinical guideline 28. 2015). 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
- 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 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; 44(suppl 1): S1-S232. Updated June 16, 2021. 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: March 2022. Available at https://www.dexcom.com/guides. Accessed July 6, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	03.23.22	04.22
Policy number change: AZ.CP.PMN.24 to AZ.CP.PMN.214 mirroring Corporate policy. 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; added information about 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); *initial approval criteria and continued criteria* – matched verbiage for requirements for Dexcom for consistency; references reviewed and updated.	01.27.23	02.23

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.

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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.