Clinical Policy: Continuous Glucose Monitors

Reference Number: NE.PMN.214 Revision Log
Effective Date: 01.01.2023
Last Review Date: 06.2024
Line of Business: Nebraska Total Care Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

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

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 Nebraska Total Care that continuous glucose monitors 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. Member meets one of the following (a or b):
   a) Requires insulin injections
   b) has a history of problematic hypoglycemia with documentation of at least one of the following (i or ii):
      i) more than one hypoglycemic event with blood glucose <54mg/dL (3.0mmol/L) that persist despite more than one attempt to adjust medication(s) and / or modify the diabetes treatment plan
      ii) a history of one hypoglycemic event with blood glucose <54mg/dL (3.0mmol/L) characterized by altered mental and / or physical state requiring third-party assistance for treatment of hypoglycemia.
3. Member is being assessed every 6 months by the prescribing healthcare practitioner for adherence to a comprehensive diabetes treatment plan;
4. Request is for Dexcom or Freestyle Libre product on the formulary
5. Request is for Medtronic CGM product on the formulary and member is currently using a Medtronic Insulin Pump

Approval duration: 6 months

II. Continued Therapy

A. Diabetes Mellitus (must meet one):

1. Request is for a renewal of authorization and both of the following are met (and b):
    a. Request is for a product currently on the plan formulary
    b. Is being assessed every 6 months by the prescribing healthcare practitioner for adherence to the CGM and diabetes treatment plan
2. Request is for a replacement and one of the following (a or b):
    a. the device has exceeded the warranty period and is malfunctioning, and the required repairs would exceed the cost of replacement
    b. the device is at least 5 years old (this must be adjusted to the life of the specific model being covered)

Approval duration: 12 months

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

A. Per the state of Nebraska Medicaid and Long Term Care division, CGM using an implantable glucose sensor e.g., Eversense CGM system (CPT codes 0446T, 0447T, and 0448T) is considered investigational and not medically necessary due to insufficient evidence of clinical efficacy and long term health outcomes. Any related HCPC codes for implantable glucose sensors are also considered investigational and not medically necessary.

B. 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 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
CGM: Continuous Glucose Monitor

Appendix B: General Information
Dexcom G6® CGM System:

- Receiver (Dexcom receiver*): replace once per year.

*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 receiver*): replace once per year.

*A personal smart device (e.g., smart phone, smart watch) may also be used, either instead of or in addition to the Dexcom receiver

- Sensor (no separate transmitter needed): replaced every 10 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

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

Use regimen is individualized based on patient goals

VI. Product Availability

Monitor and test strip packaging vary by product and manufacturer

VII. References

1. Nebraska Medicaid Fee-For-Service Pharmacy Benefit Continuous Glucose Monitoring (CGM) Medical Necessity Criteria. Received November 2022.
2. 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 September 9, 2021.
3. Dexcom G6 CGM System User Guide. LBL014003 Rev 012 MT23976. Revision date: December 2020. Available at https://www.dexcom.com/guides. Accessed September 9, 2021.
4. Dexcom G6 CGM Provider prescribing guide. Available at provider.dexcom.com/education-research/clinic-resources/prescribing-info/learn-how-fill-dexcom-g6-pharmacy-prescription. Accessed November 21, 2022.
5. Dexcom G7 CGM Provider prescribing guide. Available at provider.dexcom.com/products/g7-personal-cgm. Accessed May 12, 2023

Revisions	Date
Policy created	11.22
Added "has recurring episodes of hypoglycemia" and updated Revisions Log format to be consistent with other pharmacy policies.	03.23
Updated Dexcom G6 to Dexcom to include future generations/updates. Updated references with Dexcom G7 product information	05.23
Clarified that the Dexcom and Freestyle product approved must be on formulary	04.24
Updated initial criteria to align with MLTC criteria- removed requirement for certain number of injections and/or insulin pump. Removal of requirements of A1C not at target and ability to hear/see alarms on CGM. Changed initial approval duration from 12 months to 6 months. For continued therapy, removed requirement for demonstration of improved glycemic control. Clarified the requirement of must be formulary product and be followed by healthcare practitioner. Added product information on new presentation of Freestyle Libre 3.	6.2024

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.

 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.