OHCA Guideline

Medical Procedure Class:	**Continuous Glucose Monitor (CGM)**
Initial Implementation Date:	08/01/2016
Last Review Date:	12/06/2022
Effective Date:	6/1/2023
Next Review/Revision Date:	June 2026

* This document is not a contract, and these guidelines do not reflect or represent every conceived situation. Although all items contained in these guidelines may be met, this does not reflect, or imply any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.

☐ New Criteria ☒ Revision of Existing Criteria

Summary

Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.

Definitions

Blood Glucose Monitoring (BGM) also known as Self-Monitoring Blood Glucose (SMBG): a way of testing the concentration of glucose in the blood (glycemia); particularly important in diabetes management, a blood glucose test is typically performed by piercing the skin to draw blood (i.e., fingersticks), then applying the blood to a chemically active disposable 'test strip'.

Continuous Glucose Monitor (CGM): a minimally invasive system that measures glucose levels in subcutaneous or interstitial fluid; the measurements are completed at frequent intervals over a period of several days; the ability to track trends can be helpful in the treatment of reducing frequent hypoglycemic or hyperglycemic episodes.

Durable Medical Equipment (DME): equipment that provides therapeutic benefits to a patient in need because of certain medical conditions and/or illnesses.

Gestational Diabetes Mellitus (GDM): a condition in which a pregnant person has elevated glucose levels and other symptoms of diabetes but did not have diabetes before pregnancy.

Intermittently scanned CGM (isCGM): FDA-approved for adult use only, isCGM does not have alarms and does not communicate continuously but only on demand; the isCGM does not require calibration with SMBG because it is factory calibrated.

Non-Adjunctive CGM: CGM devices provide results which do not need to be confirmed with BGM results are referred to as non-adjunctive or therapeutic; treatment and dosing decisions may be based on the therapeutic CGM alone; because CGM is used directly in making diabetes treatment decisions they are therapeutic, not precautionary, in nature.

Other types of Insulin Dependent Diabetes: Insulin dependent diabetes not described by T1DM, T2DM or gestational diabetes.

Real-time CGM (rtCGM): glucose monitors which continuously report glucose levels to a receiver and include alarms for hypoglycemic and hyperglycemic excursions.

Supply Allowance: refers to the payment method for DME; the supply allowance for therapeutic CGM encompasses all items necessary for the use of the device over a 1 month period.

Type I Diabetes Mellitus (T1DM): diabetes due to autoimmune beta-cell destruction, usually leading to absolute insulin deficiency.

Type II Diabetes Mellitus (T2DM): diabetes due to a progressive loss of beta-cell insulin secretion frequently on the background of insulin resistance.

Description

- CGMs automatically tracks blood glucose levels throughout the day and night.
- Glucose levels may be seen anytime at a glance, and changes can be observed over a few hours or days in order to see trends.
- CGMs can help members make more informed management decisions throughout the day.

Product Information Requiring Prior Authorization (PA)

Therapeutic CGM system includes, but is not limited to: CGM sensor, CGM transmitter, dedicated receiver and batteries.

For FreeStyle Libre 3, members must be capable and willing to use the FreeStyle Libre 3 mobile app, follow the Instructions for Use, and ensure the FreeStyle Libre 3 app is compatible with their specific smartphone.

Supply allowances for therapeutic continuous glucose monitor (CGM) includes all supplies and accessories; 1 month supply = 1 unit of service.

Approval Criteria

I. INDICATIONS

A. Medical Necessity: documentation submitted to request services or substantiate previously provided services must demonstrate, through adequate medical records, evidence sufficient to justify the member's need for the service in accordance with OAC 317:30-3-1(f).

B. CGM device requested must be approved by FDA as non-adjunctive and must be used for therapeutic purposes; devices may only be used for members within the age range for which the device has been FDA approved

C. CGM must be prescribed by a physician, physician assistant or an advanced practice registered nurse.

D. For a member who has a medically documented diagnosis of **diabetes mellitus** the provider should submit medical documentation demonstrating the following criteria (1-5):

1. The member has a diagnosis of diabetes meeting the criteria of American Diabetes Association Standards of Medical Care in Diabetes; **AND**
2. The member's treating practitioner has determined that the member (or member's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; **AND**
3. The CGM is prescribed in accordance with its FDA indications for use; **AND**
4. The member for whom a CGM is prescribed, to improve glycemic control, meets at least one of the criteria below:
   a. The member is insulin-treated; **OR**
   b. The member is 20 years of age or under and has a history of problematic hypoglycemia with documentation of at least one of the following:

i. Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; **OR**

ii. A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia.

5. Within 6 months prior to ordering the CGM the treating practitioner has an in-person or telehealth visit with the member and/or family to evaluate their diabetes control and determines that criteria (1-4) above are met.

****NOTE:** An implantable CGM device and/or an automated insulin delivery system (artificial pancreas device system) are not a covered benefit.

II. FREQUENCY

The PA for CGM system may be approved for 1 year intervals. A maximum of 1 supply allowance claim for therapeutic CGM is allowed for one month's prospective billing;1 month supply=1 unit of service. Readers, transmitters and sensors to be replaced as medically necessary.

III. CONTINUED MEDICAL NECESSITY

A. At least every 6 months following the initial prescription of the CGM, the treating practitioner has an in-person or telehealth visit with the member to assess adherence to their CGM regimen and diabetes treatment plan. CGM requires proper review and interpretation of the data by both the patient and the provider to ensure that data are used in an effective and timely manner.

B. Patients should receive ongoing instruction and regular evaluation of technique, results and their ability to use data from self-monitoring of blood glucose to adjust therapy.

C. PA request for the initial 1 year will include sensors, a transmitter and a receiver (as applicable). It is important to note the transmitter may not be disposable; however the receiver battery does have a limited life of 3 years or greater.

D. To renew the PA after 1 year for additional supplies, request must contain current documentation which substantiates the continued use of the device as prescribed by the provider. All required documentation listed above in **I. INDICATIONS** must also be submitted.

Additional Information

Items that do not meet the guideline criteria may not be covered. This includes any additional software and/or the coverage of any device that may be utilized for downloading the data such as a personal computer, smart phone and/or a tablet.

Coverage is limited to those therapeutic CGM systems where the member uses a receiver classified as DME to display glucose data. If a member uses a non-DME device (smart phone, tablet, etc.) as the display device, either separately or in combination with the dedicated receiver classified as DME, the non-DME device (smart phone, tablet, etc.) is non-covered.

References

CMS Local Coverage Determination, Glucose Monitors LCD L33822. Retrieved from LCD - Glucose Monitors (L33822) (cms.gov)

CMS Local Coverage Article, Glucose Monitor LCA A52464. Retrieved from Article - Glucose Monitor - Policy Article (A52464) (cms.gov)

CMS Rulings, January 12, 2017 [CMS-1682-R] Department of Health and Human Services, Centers for Medicare & Medicaid Services. Retrieved from https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf

Cochrane Database of Systematic Reviews. Different methods and settings for glucose monitoring for gestational diabetes during pregnancy. P. Raman, E. Shepherd, et.al. Version published: 29 October 2017. https://doi.org/10.1002/14651858.CD011069.pub2

Cochran Database of Systematic Reviews. Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes. Jones, A. Ray, F. Moy, B. Buckley. Version published: 23 May 2019. https://doi.org/10.1002/14651858.CD009613.pub4

ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 7. Diabetes Technology: Standards of Care in Diabetes – 2023. Diabetes Care 2023; 46(Suppl. 1):S111-S127 https://doi.org/10.2337/dc23-S007

ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 15. Management of diabetes in pregnancy: Standards of Care in Diabetes – 2023. Diabetes Care 2023; 46(Suppl. 1):S254-S266 https://doi.org/10.2337/dc23-S015

Journal of Clinical Endocrinology & Metabolism, March 2018. Effect of CGM on Glycemic Control, Acute Admissions and QOL. Vol 103, Issue 3:1224–1232. https://doi.org/10.1210/jc.2017-02498

Hays Technology Assessment Annual Review; October 2019. Continuous Glucose Monitoring Systems. Retrieved from https://evidence.hayesinc.com/report/dir.cont0004

Oklahoma Health Care Authority, Policies and Rules, OAC 317:30-3-1 and 30-5-211.25

U.S. Food & Drug Administration new release, March 2018. FDA authorizes first fully interoperable continuous glucose monitoring system. Retrieved from https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-fully-interoperable-continuous-glucose-monitoring-system-streamlines-review

Surrounding State Medicaid Policies & Rules Reviewed

Arkansas Medicaid. (2022). Division of Medical Services. Prosthetics (Includes DME and Orthotics) Provider Manual. Retrieved from https://humanservices.arkansas.gov/divisions-shared-services/medical-services/helpful-information-for-providers/manuals/prosthet-prov/

Colorado Department of Health Care Policy & Financing. (2022, March). Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Manual. Retrieved from https://hcpf.colorado.gov/DMEPOS-manual#Therapeutic%20Continuous%20Glucose%20Monitor%20(CGM)%20Benefit%20Coverage

Missouri MO HealthNet. (2022, February). Continuous Glucose Monitors. Retrieved from https://dss.mo.gov/mhd/cs/pharmacy/pdf/cgm-clinical-edit.pdf

Texas Medicaid and Healthcare Partnership. Texas Medicaid Provider Procedures Manual. May 2022. Retrieved from https://www.tmhp.com/sites/default/files/file-library/resources/provider-manuals/tmppm/pdf-chapters/2022/2022-05-may/2_DME_and_Supplies.pdf

Private Payer Policies & Rules Reviewed

Aetna Clinical Policy Bulletins. Diabetes Tests, Programs and Supplies. Number: 0070 (Includes DPB 121) Last review 5/25/2022. Retrieved from https://www.aetna.com/cpb/medical/data/1_99/0070.html

BCBSOK Medical Policies. Glucose Monitoring and Insulin Delivery Devices for Managing Diabetes. Number: DME101.005, effective date 9/15/2021. Retrieved from http://www.medicalpolicy.hcsc.net/medicalpolicy/activePolicyPage?lid=kboyu7iq&corpEntCd=OK1

Cigna Medical Coverage Policy. Diabetes Equipment and Supplies. Effective date 4/15/2022. Retrieved from https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0106_coveragepositioncriteria_blood_glucose_monitors.pdf

Humana, Medical and Pharmacy Converge Policies. Continuous Glucose Monitoring Systems, review date 5/25/2022. And Continuous Glucose Monitoring Systems and Insulin Pumps, review date 3/24/2022. Retrieved from http://apps.humana.com/tad/tad_new/Search.aspx?criteria=cgm&searchtype=freetext&policyType=both

United Healthcare community Plan, Medical Policy. Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes. Policy Number CS024.S, effective date 6/1/2022. Retrieved from https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medicaid-comm-plan/continuous-glucose-monitoring-insulin-delivery-managing-diabetes-cs.pdf