

## OHCA Guideline

<b>Medical Procedure Class:</b>	Continuous Glucose Monitor (CGM)
Initial Implementation Date:	08/01/2016
Last Review Date:	10/01/2019
Effective Date:	3/11/2021
Next Review/Revision Date:	
<p>* This document is not a contract, and these guidelines do not reflect or represent every conceivable 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.</p>	
<input type="checkbox"/> New Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria	
<b>Summary</b>	
<b>Purpose:</b>	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
<b>Definitions</b>	
<p><b>Adjunctive devices:</b> Devices meant to complement, not replace, information used in making decisions are referred to as adjunctive or non-therapeutic.<sup>2</sup> These devices are used alongside other standard methods. Information derived from them needs confirmation before used in making treatment decisions.</p>	
<p><b>Blood Glucose Monitoring (BGM) a/k/a Self-Monitoring Blood Glucose (SMBG):</b> 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'.</p>	
<p><b>Continual Glucose Monitoring (CGM):</b> 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 sensor component contains a small wire inserted under the skin. The sensor is routinely changed following a specified period of use. A transmitter sends the glucose levels to a wireless monitor (i.e. receiver) that displays the readings. Software is available to download the collected data to a computer for tracking purposes and to monitor for trends or patterns in levels. The ability to track trends can be helpful in the treatment of reducing frequent hypoglycemic or hyperglycemic episodes.</p>	
<p><b>Durable Medical Equipment (DME):</b> Equipment that provides therapeutic benefits to a patient in need because of certain medical conditions and/or illnesses. A device considered as DME; 1.) Generally is not useful to the individual in the absence of an illness or injury, 2.) Is appropriate for use in the home, 3.) Includes a durable component that can withstand repeated use and has an expected lifetime of at least 3 years, and 4.) Is primarily and customarily used to serve a medical purpose.<sup>2</sup></p>	
<p><b>Intermittently scanning CGM (isCGM):</b> FDA approved for adult use only, isCGM does not have alarms and does not communicate continuously only on demand.<sup>14</sup> The sensor/transmitter component places a small wire under the skin. The isCGM has a receiver that, after scanning over the sensor by the individual, displays real-time glucose values and glucose trend arrows. The data can be uploaded</p>	

and a report created using available software. In the professional version, the patient does not carry a receiver; the data are blinded to the patient and the device is downloaded in the diabetes care provider's office using the provider's receiver and the software. The isCGM does not require calibration with SMBG because it is factory calibrated.<sup>3</sup>

**Medical Necessity:** Services provided within the scope of the Oklahoma Medicaid Program shall meet medical necessity criteria.<sup>7</sup> Requests by medical services providers for services in and of itself shall not constitute medical necessity. The Oklahoma Health Care Authority shall serve as the final authority pertaining to all determination of medical necessity. Medical necessity is established through consideration of the following standards:

- 1) Services must be medical in nature and must be consistent with accepted health care practice standards and guidelines for the prevention, diagnosis or treatment of symptoms of illness, disease or disability;
- 2) Documentation submitted in order to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the client's need for the service;
- 3) Treatment of the client's condition, disease or injury must be based on reasonable and predictable health outcomes;
- 4) Services must be necessary to alleviate a medical condition and must be required for reasons other than convenience for the client, family, or medical provider;
- 5) Services must be delivered in the most cost-effective manner and most appropriate setting; and
- 6) Services must be appropriate for the client's age and health status and developed for the client to achieve, maintain or promote functional capacity.<sup>11</sup>

**Non-Adjunctive CGM:** CGM devices provide results which do not need to be collaborated or confirmed with BGM results are referred to as non-adjunctive or therapeutic. Treatment and dosing decisions and may be based on the therapeutic CGM alone. It is expected that fingersticks will be performed to calibrate the CGM device. Because CGM is used directly in making diabetes treatment decisions they are therapeutic, not precautionary, in nature.<sup>2</sup>

**Real-time CGM:** Glucose monitors which continuously report glucose levels to a receiver and include alarms for hypoglycemic and hyperglycemic excursions.<sup>3</sup>

**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 one month period.

**Type I Diabetes (DM1):** Diabetes due to autoimmune beta-cell destruction, usually leading to absolute insulin deficiency. Per American Diabetes Association. 2. Classification and diagnosis of diabetes<sup>3</sup>

**Type II Diabetes (DM2):** Diabetes due to a progressive loss of beta-cell insulin secretion frequently on the background of insulin resistance. Per American Diabetes Association. 2. Classification and diagnosis of diabetes.<sup>3</sup>

### Description

Continuous glucose monitoring automatically tracks blood glucose levels throughout the day and night. Glucose levels may be seen anytime at a glance and changes observed over a few hours or days to see trends. CGM provides blood glucose levels and 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.

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

### Approval Criteria

#### I. RECOMMENDATIONS

American Diabetes Association recommendations for consideration of CGM.<sup>5</sup>

- A. "Recommendation 7.6. Most patients using intensive insulin regimens (multiple daily injections or insulin pump therapy) should assess glucose levels using self-monitoring of blood glucose (or continuous glucose monitoring) prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic and prior to critical tasks such as driving."<sup>5</sup>
- B. "Recommendation 7.10. Sensor-augmented pump therapy may be considered for children, adolescent and adults to improve glycemic control without any increase in hypoglycemia or severe hypoglycemia."<sup>5</sup>
- C. "Recommendation 7.13. Real-time continuous glucose monitoring should be considered in children and adolescents with type 1 diabetes, whether using multiple daily injection or continuous subcutaneous insulin infusion, as an additional tool to help improve glucose control and reduce the risk of hypoglycemia."<sup>5</sup>
- D. "Recommendation 14.10. Continuous glucose monitoring, when used in addition to self-monitoring of blood glucose, targeting traditional pre- and postprandial targets can reduce macrosomia and neonatal hypoglycemia I pregnancy complications due to Type 1 diabetes."<sup>5</sup>

#### II. 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 needs for the service.<sup>11</sup>
- B. CGM device requested must be approved by FDA as non-adjunctive and must be used for therapeutic purposes.<sup>14,15,17</sup> Devices may only be used for members within the age range for which the device has been FDA approved.<sup>11</sup>
- C. CGM must be prescribed by a physician, physician assistant, or an advanced practice registered nurse.<sup>11</sup>
- D. CGM readings are intended to supplement, not replace, fingersticks.
- E. Prior Authorization for children less than 21 years old with medically documented diagnosis of Type I Diabetes (DM1) may be approved for a prescribed CGM or isCGM.

- F.** Prior Authorization for pregnant women with medically documented diagnosis of Type I Diabetes (DM1) may be approved for a prescribed CGM or isCGM.<sup>5</sup>
- G.** Children less than 21 years old who do not have a medically documented diagnosis of DM1 should submit medical documentation for **all** of the following criteria (1-7). AND adults  $\geq$ 21 years old should submit medical documentation demonstrating **all** of the following coverage criteria (1-7).
1. The member has diagnosis of Type I diabetes (DM1), Type 2 diabetes (DM2), or Gestational Diabetes mellitus meeting the criteria of American Diabetes Association Standards of Medical Care in Diabetes.
  2. The member has been using BGM/SBGM and performing frequent testing (four or more times a day)<sup>3,4</sup> as documented in the medical records;
  3. The member is insulin-treated with multiple daily injections (three or more) OR using insulin pump therapy<sup>3,8</sup> as documented in the medical records;
  4. The member's insulin treatment regimen requires frequent adjustment by the member or provider on the basis of BGM or CGM testing results;<sup>1,3</sup>
  5. Documentation must include recent history (within the past 6 months) of two or more Level 2 (Glucose  $<$ 54 mg/dl (3.0 mmol/L) hypoglycemic) or one Level 3 (severe event characterized by altered mental and/or physical status requiring assistance as a result of hypoglycemia or ketoacidosis, hyperglycemia) episodes in spite of appropriate therapy.<sup>3</sup>
  6. Within six (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 determined that criteria (1-5) above are met;<sup>1,3</sup>
  7. The member and/or family member has participated in age appropriate diabetes education, training, and support prior to beginning CGM.<sup>3,8</sup>
- H.** CGM Devices:
1. Real-time CGM continuously reports glucose levels and includes alarms for hypoglycemic and hyperglycemic excursions.<sup>2,8,12</sup>
  2. Intermittently scanning CGM (isCGM) does not have alarms and does not communicate continuously, reports blood glucose on demand.<sup>3,13</sup>
  3. An implantable CGM device and/or an automated insulin delivery system (artificial pancreas device system) are not a covered benefit.

### **III. FREQUENCY**

The PA for CGM system may be approved for up to 1 year. A maximum of one 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.

#### IV. CONTINUED MEDICAL NECESSITY

- A. At least every six (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.<sup>3</sup>
- 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.<sup>3,4</sup>
- C. Real-time CGM and isCGM should be used as close to daily as possible for maximal benefit.<sup>10</sup> Submit documentation (i.e. trend graphs or CGM reports) demonstrating member's daily use of the CGM.<sup>3,4</sup>
- D. PA request for the initial one year will include sensors, a transmitter, and a receiver. It is important to note, the transmitter may not be disposable; however the receiver battery does have a limited life of three years or greater.
- E. To renew the PA after one 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 **II. 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 SoonerCare 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.<sup>1,2</sup>

#### References

1. CMS Local Coverage Determination, Glucose Monitor policy article A52464. Retrieved from <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=52464>
2. 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>
3. 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>
4. 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>
5. Diabetes Care, January 1, 2021. (ADA) American Diabetes Association Diabetes Care 2021 Jan; 44 (Supplement 1): S73-S84. <https://doi.org/10.2337/dc21-S006>
6. Diabetes Care, December 2018. The Use of CGM with remote monitoring improves Psychosocial Measures in Parent of Children with Type 1 Diabetes: A randomized crossover trial. Vol 41. Retrieved from [www.care.diabetesjournals.org](http://www.care.diabetesjournals.org)

7. Diabetes Care, June 2018. Cost-effectiveness of CGM for Adults with Type 1 Diabetes compared with SMBG. Vol 41;1227-1234, <https://doi.org/10.2337/dc17-1821>
8. Diabetes Research and Clinical Practice 2019. CGM use and glucose variability in pre-school Children with type 1 diabetes. I 47; 76-80. <https://doi.org/10.1016/j.diabres.2018.10.005>
9. Diabetology (2019) Continuous Glucose Monitoring in pregnant women with type 1 diabetes: an observational cohort study of 186 pregnancies. 62:1143-1153. <https://doi.org/10.1007/s00236-029-5860-0>
10. Journal of the American Medical Association JAMA. January 2017. Effect of CGM on Glycemic control in adults with Type 1 Diabetes using Insulin Injections. Vol 317, No 4. doi:10.1001/jama.2016.19975
11. 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>
12. Hays Technology Assessment Annual Review; July 2018. Continuous Glucose Monitoring Systems. Retrieved from <https://evidence.hayesinc.com/report/dir.cont0004>
13. Oklahoma Health Care Authority, Policies Rules, Chapter 30, Subchapter 3, Part 1; Subchapter 5, Part 1, Part 17 & Part 20.
14. 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>
15. US Food & Drug Administration news release, September 2017. FDA approves first continuous glucose monitoring system for adults not requiring blood sample calibration. Retrieved from <https://www.fda.gov/news-events/press-announcements/fda-approves-first-continuous-glucose-monitoring-system-adults-not-requiring-blood-sample>