

MEDICAL POLICY STATEMENT GEORGIA MARKETPLACE PLANS

Policy Name		Policy Number	Date Effective
Continuous Glucose Monitoring Systems (CGMS)		MM-0884	1/1/2020
Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

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A. Subject

Continuous Glucose Monitoring Systems (CGMS)

B. Background

30.3 million or 9.4 percent of the population in the United States are estimated to have diabetes. This does not include the estimated 7.2 million adults aged 18 years or older that are considered undiagnosed. Over 90 percent of cases in the US, Canada and Europe consist of Type II DM; Type I DM accounting for an additional 5 to 10 percent and the remainder due to other causes such as: genetic defects or syndromes, diseases of the exocrine pancreas, endocrinopathies, infections and drug or chemically induced disease. Three-quarters of all cases of type 1 diabetes are diagnosed in individuals <18 years of age.

Patients with diabetes need to be closely monitored. When blood glucose levels are poorly controlled patients are at risk of complications including: heart disease, stroke, peripheral vascular disease, retinal damage, kidney disease, impotence and nerve damage. Patients should also be monitored for comorbidities that may not be present during the early stages of the disease, but develop as the disease progresses, these include: hearing impairment, fatty liver disease, sleep apnea, periodontal disease, depression, anxiety, cognitive impairment and fractures.

Reasonable glycated hemoglobin (A1C) goals for diabetic patients should be customized for the individual patient balancing established benefits with prevention of complications and risk of hypoglycemia. Goals vary depending on age, patients with comorbidities, limited lifetime expectancy and benefits of intensive therapy. Patients with type 1 diabetes and pregnancy may require stricter control.

For patients with type I diabetes, tight glucose control is critical because they require ongoing treatment with exogenous insulin. Self-monitoring of blood glucose (SMBG) is normally accomplished by measuring blood glucose concentration through intermittent capillary blood sampling with a reagent strip, cartridge or cuvette and a drop of capillary blood from a finger puncture. Different testing frequency may be indicated for type 1 and type 2 diabetes. Devices are available for continuous glucose monitoring from interstitial fluid, but SMBG testing must still be used in conjunction with CGM to confirm high and low continuous glucose monitoring values. CGM offers the most benefit in patients or patient's parents that are willing to use them consistently and in patients with hypoglycemic unawareness who are at risk or have a history of severe recurrent hypoglycemia. Recent studies show that continuous glucose monitoring is associated with improved glycemic control in adult patients with type 1 diabetes. The same benefits have not been observed in children and adolescents overall, but have been indicated in children and adolescents between the ages of 8-14.



Professional Societies

The following professional society's recommendations are derived from the latest guidelines and scientific based literature available.

American Diabetes Association (ADA)

Continuous glucose monitoring (CGM) is useful for A1C lowering in select adults (aged ≥ 25 years) with type 1 diabetes who require intensive insulin regimens. CGM may be a useful supplement to SMBG among individuals with hypoglycemia unawareness and/or frequent hypoglycemic episodes. CGM should be considered in children and adolescents with type 1 diabetes, whether using injections or continuous subcutaneous insulin infusion, as an additional tool to help improve glycemic control. Benefits of continuous glucose monitoring correlate with adherence to ongoing use of the device.

National Institute of Health (NIH)

National Institute for Health and Care Excellence

In 2015, the National Institute for Health and Care Excellence released guidelines on diagnosis and management of type 1 diabetes in adults. The guidelines state:

- "Do not offer real-time continuous glucose monitoring routinely to adults with type 1 diabetes"
- "Consider real-time continuous glucose monitoring for adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimized use of insulin therapy and conventional blood glucose monitoring:
 - More than one episode a year of severe hypoglycemia with no obviously preventable precipitating cause.
 - Complete loss of awareness of hypoglycemia.
 - Frequent (more than two episodes a week) asymptomatic hypoglycemia that is causing problems with daily activities.
 - Extreme fear of hypoglycemia
 - Hyperglycemia (HbA_{1c} level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. Continue real-time continuous glucose monitoring only if HbA can be sustained at or below."

Endocrine Society

In 2016, the Endocrine Society published clinical practice guidelines that included the following recommendations on CGM for adult patients:

- We recommend real-time continuous glucose monitoring (RT-CGM) devices for adult patients with T1DM [type 1 diabetes mellitus] who have A1C levels above target and who are willing and able to use these devices on a nearly daily basis
- We recommend RT-CGM devices for adult patients with well-controlled T1DM who are willing and able to use these devices on a nearly daily basis
- We suggest short-term, intermittent RT-CGM use in adult patients with T2DM (not on prandial insulin) who have A1C levels $\geq 7\%$ and are willing and able to use the device



C. Definitions

- **Continuous Glucose Monitors (CGM):** subcutaneous sensor that measures interstitial glucose levels every few minutes and sends the information to a monitor
- **Type I diabetes:** a metabolic disease normally occurring during childhood in which the pancreas cannot produce the correct amount of insulin
- **Type II diabetes:** a metabolic disease normally occurring during adulthood in which it becomes difficult for the body's cells to absorb and use insulin

D. Policy

- I. CareSource will approve the use of CGM and consider it's use medically necessary for the following:
 - A. Short-term use (up to 7 days) as an addition to standard care for blood glucose evaluation to optimize therapy in patients who experience problems controlling blood glucose levels and meet the following criteria (**no prior authorization is required unless billed charges are >\$500.**):
 1. Patient is unresponsive to standard medical therapy
 2. Patient has hypoglycemia unawareness
 3. Patient has recurrent hypoglycemia and hyperglycemia
 4. Patient experiences uncontrolled glucose levels although he/she is compliant with current treatment including, self-monitoring at least 4 times per day.
 5. Patient requires 3 or more insulin injections per day or an insulin pump to control glucose

Note: Although short term CGM does not require a prior authorization unless billed charges are >\$500, CareSource may request documentation to support medical necessity. Appropriate and complete documentation must be presented at the time of review to validate medical necessity.

- B. Long-term use in patients who experience problems controlling blood glucose levels and meet **ALL** of the following criteria (**prior authorization is required when total billed charges are >\$500**):
 1. Has type 1 diabetes
 2. Patient is unresponsive to standard medical therapy
 3. Insulin injections are required 3 or more times per day or an insulin pump is used
 4. Patient experiences uncontrolled levels although he/she is compliant with current treatment including, self-monitoring at least 4 times per day.
 5. The patient meets **two or more** of the following :
 - a. HgbA1C \geq 7% despite appropriate adjustments to therapy based on previous short-term CGMS and self-monitoring
 - b. History of recurrent severe hypoglycemia (<50 mg/dl) with hypoglycemic unawareness requiring assistance of another individual (administering glucagon, oral carbohydrates or other measures) despite appropriate adjustments to a physician ordered and monitored treatment plan based on previous short-term CGMS and/or self-monitoring
 - c. The patient is pregnant with poorly controlled type I diabetes

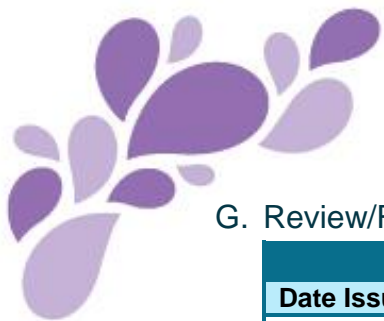


01. Poorly controlled is defined as unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected post-prandial hyperglycemia, or recurrent diabetic ketoacidosis
6. Obtains a letter of medical necessity from a board certified endocrinologist
7. Documentation that the patient has completed a comprehensive diabetes education program within the last 12 months; and has ongoing access to a certified diabetes educator. Remains compliant with the insulin therapy recommended by an endocrinologist as demonstrated by monitoring logs maintained for at least 3 months.
- C. Continuation of CGMS use **after one year** or device replacement is considered medically necessary for the following:
 1. If for replacement, the device is malfunctioning and out of warranty
 2. There is objective documented evidence of improvement in control of diabetes (specific to baseline status of disease for individual patients)
 3. There is documented evidence of compliance to CMGS defined as at least 80% use rate of device (must be based on log data of the device)
- D. CareSource will **NOT** approve the use of CGMS for the following:
 1. Type II diabetes
 2. Pregnant women with gestational diabetes
 3. Non FDA-approved devices
 4. GlucoWatch®
 5. Artificial pancreas device systems (APDS)
 6. Replacement of an existing CGMS for additional features which are not medically necessary
- E. CGM Systems approved by the Food and Drug Administration
 1. Continuous Glucose Monitoring System, MiniMed
 2. GlucoWatch G2 Biographer
 3. Guardian RT CGMS, Medtronic
 4. Paradigm RT System, Medtronic
 5. Dexcom STS CGMS System, Dexcom
 6. FreeStyle Navigator CGM System, Abbott
 7. Dexcom G4 Platinum, Dexcom
 8. Dexcom G5 Mobile CGM, Dexcom

Note: Documented diagnosis must be confirmed by contemporaneous portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes. **ALL** other uses of CGMS are considered not medically necessary and therefore, will follow CareSource's Off-Label policy.

E. Conditions of Coverage

F. Related Policies/Rules



G. Review/Revision History

DATE		ACTION
Date Issued	1/1/2020	
Date Revised		
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H. References

1. Klonoff DC, Buckingham B, Christiansen JS, et al. Continuous glucose monitoring: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2011;96(10):2968.
2. McCulloch DK. Blood glucose self-monitoring in management of adults with diabetes mellitus. In: Mulder JE (Ed). *UpToDate* [database on the Internet]. Waltham (MA): UpToDate; 2014.
3. American Diabetes Association (ADA). 2012 Clinical Practice Recommendations. Accessed at: http://care.diabetesjournals.org/content/35/Supplement_1.toc
4. American Diabetes Association. (ADA). Diabetes Care. Continuous Glucose Monitoring. Accessed at: <http://care.diabetesjournals.org/search?fulltext=continuous+glucose+monitoring&submit=yes>
5. MCG, 21st Ed., 2017
6. Anon, (2017). 12. *Children and Adolescents: Standards of Medical Care in Diabetes—2018.*
7. Nde.org. (2017). *ADA Diabetes Guidelines Insulin & Glucose Monitoring SMBG | NDEI.* [online] Available at: <http://www.ndei.org/ADA-diabetes-management-guidelines-self-monitoring-blood-glucose-SMBG-insulin.aspx.html> [Accessed 28 Dec. 2017].
8. Information, H., Statistics, H., Statistics, D., Statistics, D., Center, T. and Health, N. (2017). *Diabetes Statistics | NIDDK.* [online] National Institute of Diabetes and Digestive and Kidney Diseases. Available at: <https://www.niddk.nih.gov/health-information/health-statistics/diabetes-statistics> [Accessed 29 Dec. 2017].
9. Uptodate.com. (2017). *Overview of medical care in adults with diabetes mellitus.* [online] Available at: https://www.uptodate.com/contents/overview-of-medical-care-in-adults-with-diabetes-mellitus?search=diabetes&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1 [Accessed 29 Dec. 2017].
10. Uptodate.com. (2018). *Self-monitoring of blood glucose in management of adults with diabetes mellitus.* [online] Available at: https://www.uptodate.com/contents/self-monitoring-of-blood-glucose-in-management-of-adults-with-diabetes-mellitus?search=glucose%20monitoring&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1 [Accessed 2 Jan. 2018].
11. Uptodate.com. (2018). *Management of type 1 diabetes mellitus in children and adolescents.* [online] Available at: https://www.uptodate.com/contents/management-of-type-1-diabetes-mellitus-in-children-and-adolescents?search=continuous%20glucose%20monitoring%20children&source=search_result&selectedTitle=2~48&usage_type=default&display_rank=2 [Accessed 2 Jan. 2018].
12. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, e. (2018). *Continuous glucose monitoring and intensive treatment of type 1 diabetes.* - *PubMed - NCBI.* [online] Ncbi.nlm.nih.gov. Available at: <https://www.ncbi.nlm.nih.gov/pubmed?term=18779236> [Accessed 2 Jan. 2018].
13. Hayesinc.com. (2018). *Cite a Website - Cite This For Me.* [online] Available at: https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=1882&searchStore=%24search_type%3Dall%24icd%3D%24keywords%3Dcontinuous%2Cglucose%2Cmonitoring%24status%3Dall%24page%3D1%24from_date%3D%24to_date%3D%24report_type_options%3D%24technology_type_options%3D%24organ_system_options%3D%24specialty_options%3D%24order%3DsearchRelevance [Accessed 2 Jan. 2018].
14. Information, H., Overview, D., Diabetes, M., Monitoring, C., Monitoring, C., Center, T. and Health, N. (2018). *Continuous Glucose Monitoring | NIDDK.* [online] National Institute of



- Diabetes and Digestive and Kidney Diseases. Available at: <https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/continuous-glucose-monitoring> [Accessed 2 Jan. 2018].
15. PubMed Health. (2018). *Type 1 Diabetes - National Library of Medicine - PubMed Health*. [online] Available at: <https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0024702/> [Accessed 2 Jan. 2018].

This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Archived