



MEDICAL POLICY STATEMENT Marketplace

Policy Name & Number	Date Effective
Continuous Glucose Monitors-MP-MM-1319	IN,WV,KY: 08/01/2022-12/31/2022 OH:09/01/2022- 12/31/2022
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

This policy applies to the following Marketplace(s):

<input type="checkbox"/> Georgia	<input checked="" type="checkbox"/> Indiana	<input checked="" type="checkbox"/> Kentucky	<input checked="" type="checkbox"/> Ohio	<input checked="" type="checkbox"/> West Virginia
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A. Subject

Continuous Glucose Monitors

B. Background

37.3 million people or 11.3% of the population in the United States have diabetes (DM), not including the estimated 8.5 million adults who are undiagnosed. Approximately 5 to 10% of individuals with diabetes have type 1 (DM1), while type 2 (DM2) accounts for the majority of cases (90-90%). The incidence of both type 1 and type 2 in children and adolescents has significantly increased, according to the Centers for Disease Control's (CDC's) National Diabetes Statistic Report. Some of the unique challenges associated with caring for children and adolescents include the patient's size, developmental concerns, and inability to communicate symptoms of hypoglycemia. Health care resources spent on diabetes are considered to be higher than all other health conditions. Immediate impacts on both physical and mental well-being are common with both severe hypoglycemia and extreme hyperglycemia.

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, nerve damage, and impotence. Patients should also be monitored for comorbidities that may not be present during the early stages of the disease but may develop as the disease progresses, including 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, comorbidities, and benefits of intensive therapy. Patients who are pregnant and have DM1 may require stricter control.

For patients with DM1, tight glucose control is critical. 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 DM1 and DM2. 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 caregivers, 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 DM1.

C. Definitions

- **Continuous Glucose Monitors (CGM)** - A compact medical system that uses a subcutaneous sensor to measure interstitial glucose levels in close to real-time (every 5 to 15 minutes, depending on the device), sending the data wirelessly to a monitor device which displays the glucose data.

- **Intermittently Scanned (Flash) Continuous Glucose Monitor** - Measures glucose every minute and records the measurement every fifteen minutes. Users must purposely scan the sensor to obtain information, as it does not have alerts or alarms.
- **Real Time Continuous Glucose Monitor** - Measures glucose every 5 minutes, transmits glucose data, and provides alerts and active alarms to the patient regarding hypoglycemia and hyperglycemia.
- **Type 1 Diabetes** - A metabolic disease normally occurring during childhood in which the pancreas cannot produce the correct amount of insulin.
- **Type 2 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 considers short-term and long-term continuous glucose monitoring medically necessary for type 1 and type 2 (insulin dependent) diabetes (DM1, DM2, respectively) as an addition to standard care for blood glucose evaluation to optimize therapy in patients who experience problems controlling blood glucose levels. Coverage is provided for all physician or podiatrist prescribed medically necessary equipment for the management of diabetes.
 - A. Short-term use (up to 7 days) does not require a medical necessity review, but appropriate and complete documentation must be presented at the time of a requested review to validate medical necessity, based on **ALL** the following criteria:
 1. Patient has a confirmed diagnosis of type 1 or type 2 diabetes (DM2 must be insulin dependent);
 2. Patient is unresponsive to standard medical therapy;
 3. Patient requires 3 or more insulin injections per day or an insulin pump to control glucose;
 4. The patient must have **at least ONE** of the following:
 - a. Patient has hypoglycemia unawareness;
 - b. Patient has recurrent hypoglycemia (< 50 mg/dl) and hyperglycemia (> 150 mg/dl); or
 - c. Patient experiences uncontrolled glucose levels although they are compliant with current treatment, including self-monitoring at least 4 times per day.
 - B. Long-term use DOES require a medical necessity review and the member must meet **ALL** the following criteria:
 1. Patient has a confirmed diagnosis of DM1 or DM2 (DM2 must be insulin dependent);
 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. The patient must have **at least ONE** of the following:
 - a. HgbA1C \geq 7% despite appropriate adjustments to therapy based on previous short-term CGM 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 CGM and/or self-monitoring;
 - c. The patient is pregnant with poorly controlled DM1, where poorly controlled is defined as unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected post-prandial hyperglycemia, or recurrent diabetic ketoacidosis;
 - 5. A letter of medical necessity must be attached with the medical necessity review documentation, including, but not limited to:
 - a. Documentation of diagnosis;
 - b. Test result reports;
 - c. Chart notes from the providers office;
 - d. Hospital admission notes;
 - 6. Documentation that the patient has completed a comprehensive diabetes education program within the last 12 months;
 - 7. Patient has ongoing access to a certified diabetes educator.
 - C. Continuation (after 1 year) of CGM: use is considered medically necessary when both of the following criteria are met:
 - 1. There is objective documented evidence of improvement in control of diabetes (specific to baseline status of disease for individual patients);
 - 2. There is documented evidence of compliance to CGM defined as at least 50% use rate of device (must be based on log data of the device).
- II. Device Replacement or Repair: CareSource may cover the repair, adjustment, and replacement of purchased equipment, supplies or appliances when approved.
- A. The repair, adjustment or replacement of the purchased equipment, supply, or appliance is covered if:
 - 1. The equipment, supply, or appliance is a covered service;
 - 2. The continued use of the item is medically necessary; and
 - 3. There is reasonable justification for the repair, adjustment, or replacement. Replacement of a functioning device just because the warranty has expired is not considered medically necessary.
 - B. Replacement of purchased equipment, supply, or appliance may be covered if:
 - 1. The equipment, supply, or appliance is worn out or no longer functions.
 - 2. Repair is not possible or would equal or exceed the cost of replacement. An assessment by a rehabilitation equipment specialist or vendor should be done to estimate the cost of repair.
 - 3. The equipment, supply, or appliance is damaged and cannot be repaired.
 - C. Benefits for repairs and replacement do not include:
 - 1. Repair and replacement due to misuse, malicious breakage; or gross neglect;
 - 2. Replacement of lost or stolen items.
- III. CareSource will NOT approve the use of CGM for the following:
- A. Pregnant women with gestational diabetes;

- B. Non-FDA-approved devices;
- C. Artificial pancreas device systems (APDS).

E. Conditions of Coverage
NA

F. Related Policies/Rules
NA

G. Review/Revision History

DATE		ACTION
Date Issued	05/11/2022	New Policy
Date Revised		
Date Effective	IN, KY, WV: 08/01/2022 OH: 09/01/2022	
Date Archived	12/31/2022	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. American Diabetes Association Professional Practice Committee. Glycemic Targets: Standards of medical Care in Diabetes-2022. Diabetes Care 2022;45(Supplement_1):S83-S96. doi:10.2337/dc22-S006.
2. American Diabetes Association Professional Practice Committee. Pharmacologic Approaches to Glycemic Treatment: Standards of Medicare Care in Diabetes-2022. Diabetes Care 2022;45(Supplement_1):S125-143. doi:10.2337/dc22-S009.
3. Centers for Disease Control and Prevention. (2022 January 18). National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States. Retrieved April 18, 2022 from www.cdc.gov.
4. Edelman SV, Argento NB, Pettus J, Hirsch IB. Clinical implications of real-time and intermittently scanned continuous glucose monitoring. Diabetes Care. 2018 Nov;41:2265-2274. doi:10.2337/dc18-1150.
5. Evolving Evidence Review. (2022 April 5). Dexcom G6 (Dexcom, Inc.) Continuous Glucose Monitoring System for Type 2 Diabetes Mellitus. Hayes. Retrieved April 18, 2022 from www.evidence.hayesinc.com.
6. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists and American College of Endocrinology - Clinical Practice Guidelines for Developing A Diabetes Mellitus Comprehensive Care Plan - 2015. AACE/ACE Guidelines. 2015 April;21(4):413-437. doi:10.4158/EP15672.GL.
7. Health Technology Assessment. (2022 March 14). Eversense Continuous Glucose Monitoring System for Maintaining Glycemic Control in Adults with Diabetes Mellitus. Hayes. Retrieved April 18, 2022 from www.evidence.hayesinc.com.

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

8. Levitsky L. (2021 November 5). Overview of the management of type 1 diabetes mellitus in children and adolescents. UpToDate. Retrieved April 18, 2022 from www.uptodate.com.
 9. Levitsky L, Misra M. (2022 February 2). Hypoglycemia in children and adolescents with type 1 diabetes mellitus. UpToDate. Retrieved April 18, 2022 from www.uptodate.com.
 10. Tamborlane WV, Beck RW, Bode BW, et al. Continuous glucose monitoring and intensive treatment of type 1 diabetes: Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. N Engl J Med. 2008;359:1464-1476. doi:10.1056/NEJMoa0805017.
 11. Weinstock RS. (2021 February 15). Management of blood glucose in adults with type 1 diabetes mellitus. UpToDate. Retrieved April 18, 2022 from www.uptodate.com.
 12. Wexler DJ. (2021 December 20). Overview of general medical care in nonpregnant adults with diabetes mellitus. UpToDate. Retrieved April 18, 2022 from www.uptodate.com.
- I. State-Specific Information
- A. Indiana
 1. Effective: 08/01/2022
 2. Evidence of Coverage and Health Insurance Contract. Marketplace Plan, Indiana (2022). Retrieved April 19, 2022 from www.caresource.com.
 - B. Kentucky
 1. Effective: 08/01/2022
 2. Evidence of Coverage and Health Insurance Contract. Marketplace Plan, Kentucky (2022). Retrieved April 19, 2022 from www.caresource.com.
 - C. Ohio
 1. Effective: 09/01/2022
 2. Evidence of Coverage and Health Insurance Contract. Marketplace Plan, Ohio (2022). Retrieved April 19, 2022 from www.caresource.com.
 - D. West Virginia
 1. Effective: 08/01/2022
 2. Evidence of Coverage and Health Insurance Contract. Marketplace Plan, West Virginia (2022). Retrieved April 19, 2022 from www.caresource.com.

Independent medical review – March 2018