MEDICAL POLICY STATEMENT
KENTUCKY MARKETPLACE

Policy Name		Policy Number	Date Effective
Continuous Glucose Monitoring (CGM)		MM-0206	09/01/2021-07//31/2022
Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

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.

Table of Contents

A. Subject

Continuous Glucose Monitoring (CGM)

B. Background

34.2 million people or 10.5 percent of the population in the United States have diabetes (DM). This does not include the estimated 7.3 million adults aged 18 years or older that are considered undiagnosed. 5 to 10% of cases in the United States, Canada and Europe include Type 1, Type 2 accounts for the remaining 90% of cases. 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 size of the patient and inability to communicate symptoms of hypoglycemia. Health care resources spent on diabetes are considered to be the highest among all other health conditions. Immediate impacts on both physical and mental well-being are common with 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, 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 patients with diabetes 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 and pregnancy may require stricter control.

For patients with Type 1, 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. 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.

Professional Society Recommendations:

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

American Diabetes Association (ADA) Standards of Medical Care in Diabetes (2020)

- When used properly, real-time continuous glucose monitors in conjunction with insulin therapy are a useful tool to lower A1C levels and/or reduce hypoglycemia in adults with type 1 diabetes who are not meeting glycemic targets, have hypoglycemia unawareness and/or have episodes of hypoglycemia
- When used properly, real-time and intermittently scanned continuous glucose monitors in conjunction with insulin therapy are useful tools to lower A1C and/or reduce hypoglycemia in adults with type 2 diabetes who are not meeting glycemic targets
- Continuous glucose monitoring (CGM) should be considered in all children and adolescents with type 1 diabetes, whether using injections or continuous subcutaneous insulin infusion, as an additional tool to help improve glucose control. Benefits of CGM correlate with adherence to ongoing use of the device
- Real-time continuous glucose monitoring (CGM) devices should be used as close to daily as possible for maximal benefit. Intermittently scanned CGM devices should be scanned frequently, at a minimum once every 8 h
- Real-time continuous glucose monitors may be used effectively to improve A1C levels, time in range, and neonatal outcomes in pregnant women with type 1 diabetes

American Diabetes Association (ADA) (2019)

The ADA issued recommended time-in-range targets for CGM use, recommending CGM users stay within a certain range 70% of the time

Type 1 or Type 2 Diabetes Users

- The target of 70 mg/dL to 180 mg/dL should be maintained at least 70% of the time.
- CGM users should allow low blood glucose levels of at least 70 mg/dL for less than 4% of the day, or about 1 hour, and very low levels of less than 54 mg/dL for no more than 1% of the day, or 15 minutes
- Users should allow blood glucose of more than 180 mg/dL for less than 25% of the time, and very high levels of more than 250 mg/dL for less than 5% of the time.

Older/High-Risk Users: Both Type 1 and Type 2 Diabetes

- The target of 70 mg/dL to 180 mg/dL should be maintained more than 50% of the time
- Avoiding hypoglycemia is a priority in this population, so CGM users should allow low blood glucose levels of less than 70 mg/dL for less than 1% of the day, or 15 minutes
- Users should allow blood glucose of more than 180 mg/dL for less than 50% of the time, and very high levels of more than 250 mg/dL for less than 10% of the time

Pregnant Users with Type 1 Diabetes

- A target of 63 mg/dL to 140 mg/dL should be maintained more than 70% of the time
- Pregnant CGM users with T1D should allow low blood glucose levels of less than 63 mg/dL for less than 4% of the day (1 hour) and very low levels of less than 54 mg/dL for less than 1% of the day (15 minutes)

- Users can keep blood glucose of more than 140 mg/dL to less than 25% of the time, or 6 hours

Pregnant Users with Type 2 or Gestational DM

- A target of 63 mg/dL to 140 mg/dL should be maintained
- Because of the lack of evidence on CGM targets for women with gestational diabetes or T2D in pregnancy, percentages of time spent in range, below range and above range were not provided

American Association of Clinical Endocrinologists (AACE)/ American College of Endocrinology (ACE) (2015)

- A1C should be measured at least twice yearly in all patients with DM and at least 4 times yearly in patients not at target
- SMBG should be performed by all patients using insulin (minimum of twice daily and ideally before any insulin injection). More frequent SMBG after meals or in the middle of the night may be required for insulin-taking patients with frequent hypoglycemia, patients not at A1C targets, or those with hypoglycemic symptoms. Patients not requiring insulin therapy may benefit from SMBG, especially to provide feedback about the effects of their lifestyle and pharmacologic therapy; testing frequency must be personalized
- Continuous glucose monitoring (CGM) should be considered for patients with T1D and T2D on basal-bolus therapy to improve A1C levels and reduce hypoglycemia. Early reports suggest that even patients not taking insulin may benefit from CGM

C. Definitions

- **Continuous Glucose Monitors (CGM) -** A subcutaneous sensor that measures interstitial glucose levels every 5 to 15 minutes (depending on the device) and sends the information to a monitor.
- **Real Time Continuous Glucose Monitors -** Monitors which alert the patient of hypoglycemia or hyperglycemia and measure and transmit glucose values every 5 minutes.
- **Intermittently Scanned (Flash) Continuous Glucose Monitors -** Monitors which measure glucose every minute and record the measurement every fifteen minutes.
- **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 considers short-term and long-term continuous glucose monitoring medically necessary for Type 1 and Type 2 (insulin dependent) Diabetes 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.

1. The member must meet ALL of the following criteria:
   a. Patient has a confirmed diagnosis of Type 1 or Type 2 Diabetes (if Type 2 must be insulin dependent).
   b. Patient is unresponsive to standard medical therapy.
   c. Patient requires three (3) or more insulin injections per day or an insulin pump to control glucose.
2. The member must meet ONE of the following criteria:
   a. Patient has hypoglycemia unawareness;
   b. Patient has recurrent hypoglycemia (< 50 mg/dl) and hyperglycemia (> than 150 mg/dl); or
   c. Patient experiences uncontrolled glucose levels although he/she is compliant with current treatment including, self-monitoring at least four (4) times per day.

B. Long-term use DOES require a medical necessity review and the member must meet ALL of the following criteria:

1. Patient has a confirmed diagnosis of Type 1 or Type 2 Diabetes (if Type 2, must be insulin dependent).
2. Patient is unresponsive to standard medical therapy.
3. Insulin injections are required three (3) or more times per day or an insulin pump is used.
4. The patient meets one or more of the following:
   a. HgbA1C ≥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 type 1 diabetes
      01. 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; and

d. Hospital admission notes.

C. Documentation that the patient has completed a comprehensive diabetes education program within the last 12 months; by a certified, registered or licensed provider with expertise in diabetes
D. Continuation of CGM (after one (1) year): A medical necessity review is required and use is considered medically necessary for the following:
   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 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.
         a. Replacement of a functioning device just because the warranty has expired is not considered medically necessary.
   B. Replacement of purchased equipment, supplies or appliances 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.

   Note: Benefits for repairs and replacement do not include:
   - Repair and replacement due to misuse, malicious breakage or gross neglect
   - 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; and
   C. Artificial pancreas device systems (APDS).

E. Conditions of Coverage

N/A

F. Related Polices/Rules

N/A

G. Review/Revision History

	DATE	ACTION
Date Issued	04/15/2018	
Date Revised	04/15/2020	Policy Criteria: Addition of Type II Diabetes coverage; Prior Authorization for continuation of coverage after one year; removal of FDA-approved device list.
	09/30/2020	Policy Criteria: Revision to prior authorization medical necessity requirements I. A. 1-2; three (3) month monitoring log no longer required; CGM compliance changed from 80% to 50%.
	06/09/2021	Annual Update: Removed PA language; removed Endocrinologist letter of necessity requirement; updated self-management education requirements; updated Device Replacement or Repair criteria.
Date Effective	09/01/2021	
Date Archived	07//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. National Diabetes Statistics Report (2020). Estimates of Diabetes and Its Burden in the United States. Retrieved on June 1, 2021 from www.cds.gov
2. Levitsky, Lynne L MD (October 24, 2019). Management of type 1 diabetes mellitus in children and adolescents. Retrieved on June 1, 2021 from www.UpToDate.com
3. Handelsman, Yehuda MD, Bloomgarden, Zachary T. MD. (2015) American Association of Clinical Endocrinologists and American College of Endocrinology—Clinical Practice Guidelines for Developing A Diabetes Mellitus Comprehensive Care Plan 2015. Retrieved on June 1, 2021 from www.journals.aace.com
4. Weinstock, Ruth S. MD. (November 18, 2019). Management of blood glucose in adults with type 1 diabetes mellitus. Retrieved on June 1, 2021 from www.UpToDate.com
5. American Diabetes Association (ADA) (2020). Standards of Medical Care in Diabetes—2020. Retrieved on June 1, 2021 from www.diabetesjournals.org
6. American Diabetes Association (ADA) (2019). Glycemic Targets: Standards of Medical Care in Diabetes – 2020. Retrieved on June 1, 2021 from www.diabetesjournals.org
7. Wexler, Deborah, J MD. (January 6, 2020). Overview of general medical care in nonpregnant adults with diabetes mellitus. Retrieved on June 1, 2021 from UpToDate.com

8. Beck, RW; Bode, BW (2008). Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group (2018). Continuous glucose monitoring and intensive treatment of type 1 diabetes. Retrieved on June 1, 2021 from ncbi.nlm.nih.gov
9. National Institute of Diabetes and Digestive and Kidney Diseases. Continuous Glucose Monitoring (2017). Retrieved on April 3, 2021 from www.niddk.nih.gov
10. Marketplace Plan Evidence of Coverage and Health Insurance Contract Kentucky 2021. Retrieved from www.caresource.com on June 2, 2021.

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

Independent medical review – March 2018