MEDICAL POLICY STATEMENT
GEORGIA MEDICAID

Policy Name		Policy Number	Date Effective
Continuous Glucose Monitoring (CGM)		MM-0223	05/01/2021-05/31/2022
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.

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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 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 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 device with three components (transmitter, receiver and sensors) used by placement of a sensor, subcutaneously, to continuously monitor and record glucose levels obtained from interstitial fluid.
- **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. This version does not alert the user to hypoglycemic or hyperglycemic episodes and only provides the last 8 hours of data, if the sensor is not scanned at a minimum of every 8 hours the data is lost.
- **Type I Diabetes -** Type 1 diabetes (previously known as insulin-dependent, juvenile or childhood-onset) is characterized by deficient insulin production and requires daily administration of insulin. The cause of type 1 diabetes is not known, and it is not preventable with current knowledge.
- **Type II Diabetes -** Type 2 diabetes (formerly called non-insulin-dependent or adult-onset) results from the body's ineffective use of insulin. Type 2 diabetes comprises 90% of people with diabetes around the world (5) and is largely the result of excess body weight and physical inactivity.

D. Policy

I. CareSource considers long-term continuous glucose monitoring medically necessary. Short-term continuous glucose monitoring is NOT a covered benefit.
   A. Prior Authorization is required for long-term use (over 30 days) in patients who experience problems controlling blood glucose levels and meet ALL of the following criteria:
      1. Obtains a letter of medical necessity from a board certified endocrinologist who is treating the condition for which the device is ordered.
         a. Documentation of diagnosis must be included in the prior authorization request confirming the presence of disease, including, but not limited to:
            01. A prescription order by the referring physician for the specific CGM device to be supplied to the member, number of sensors requested per month and length of need;
            02. Member's diagnosis;
            03. Documentation that the member has received sufficient training using the requested device;
            04. Test result reports;
            05. Chart notes form the providers office; and
            06. Hospital admission notes.
      2. The ordering Endocrinologist (his Physician Assistant, Nurse Practitioner, or Clinical Nurse Specialist) must have had a face-to-face examination with the member within the last six (6) months and prior to the start date of the written order for a CGM.
         a. The examination must be documented, including the member was evaluated and treated for Type I or Type II DM that supports the need for a CGM.
         b. After 12 months an additional face to face examination for continued use of the CGM will be required along with compliance of the criteria below for *Continuation of CGM* (after one year).
      3. Has a diagnosis of uncontrolled Type I DM or Type II DM requiring 3 or more injections of insulin per day and ONE of the following indications:
         a. Recurring episodes of at least moderately severe hypoglycemia (<50 mg/dl);
         b. Hypoglycemic unawareness: patient is not aware of symptoms, but it may be witnessed by others;
         c. Poor glycemic control despite at least 4 finger-sticks per day;
         d. Hypoglycemia overnight;
         e. Recurring diabetic ketoacidosis (DKA);
         f. Specific indications will be considered on a case by case basis when appropriate;
         g. Insulin pump usage with poor control; or
         h. Specific cases where CGM use led to improvement in control and the clinician feels that prolonged monitoring is needed for an insulin dependent diabetic.
   B. Continuation of CGM (after one (1) year): Prior authorization 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 CMG defined as at least

C. Device Replacement or Repairs

1. All repairs for purchased equipment over $200.00 require a prior authorization.
2. A detailed written order and/or certificate of medical necessity are required for repairs and must be signed by a physician and submitted with the prior authorization request.
3. The device must be malfunctioning or the warranty has expired.
4. Requests for repairs of equipment that has been damaged due to the member's negligence or abuse will be denied, and the equipment will not be replaced before it's normal life expectancy (reasonable useful lifetime) has been attained.
5. Replacement of an existing CGM for additional features which are not considered medically necessary will not be covered.

D. CareSource will NOT approve the use of CGMS for the following:
1. Non FDA-approved devices;
2. Artificial pancreas device systems (APDS); and
3. Items ordered for convenience.

E. Components of a continuous glucose monitor will be non-covered if billed in excess of the maximum allowed on the Schedule of Maximum Allowable Payments (SMAP).
1. Exception transmitters may be reviewed for medical necessity and replaced from six (6) to twelve (12) months but must have a detailed rationale for the need if less than twelve (12) months has elapsed since the last transmitter was issued.

E. Conditions of Coverage
F. Related Polices/Rules
G. Review/Revision History

	DATE	ACTION
Date Issued	04/05/2018	
Date Revised	04/15/2020 12/16/2020	Policy Criteria: Addition of Type II Diabetes coverage; Prior Authorization for continuation of coverage after one year; additional coverage criteria per GAMMIS; removal of FDA-approved device list Revision: Documentation of evidence of compliance with the device requirements have been revised to at least 50% rate of usage rather than 80%.
Date Effective	05/01/2021	
Date Archived	05/31/2022	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

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