MEDICAL POLICY STATEMENT
Arkansas PASSE

Policy Name & Number	Date Effective
Continuous Glucose Monitors-AR PASSE-MM-1143	06/01/2023-10/31/2023
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.

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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 (90-95%). 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 an 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 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 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 DM1.

C. Definitions

- **Continuous Glucose Monitors (CGM) -** An instrument or device, including repair and replacement parts, that:
  - Is designed and offered for the purpose of aiding an individual with diabetes;

- Measures glucose levels at set intervals by means of a small electrode placed under the skin and held in place by an adhesive; and
- Is generally not useful to an individual who has not been diagnosed with diabetes.

- **Glycogen Storage Disease -** Hereditary disorder caused by the buildup of glycogen, causing impairment of liver, kidneys, and small intestine, and short stature.
- **Hypoglycemia -** All episodes of an abnormally low plasma glucose concentration (with or without symptoms) that expose the individual to harm.
  - Level 1 – Blood glucose level < 70mg/dL by ≥ 54mg/dL.
  - Level 2 – Blood glucose level < 54mg/dL.
  - Level 3 – Hypoglycemic event that denotes severe cognitive impairment requiring external assistance (administration of carbohydrate, glucagon, or other resuscitative actions) for recovery.
- **Type 1 Diabetes -** A metabolic disease normally diagnosed in childhood in which the pancreas cannot produce the correct amount of insulin.
- **Type 2 Diabetes -** A metabolic disease normally diagnosed in adulthood in which it becomes difficult for the body's cells to absorb and use insulin.

D. Policy

I. CareSource considers short-term (up to 7 days) 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. Appropriate and complete documentation must be presented at the time of a requested review to validate medical necessity.

A. Long-term continuous glucose monitoring is considered medically necessary when the member meets **ALL** the following criteria:

1. One of the following:
   a. Patient has a confirmed diagnosis of DM1 or any other type of diabetes with:
      01. The use of insulin 3 or more times per day; or
      02. Evidence of level 2 or level 3 hypoglycemia;
   b. HgbA1C ≥ 7% despite appropriate adjustments to therapy based on previous short-term CGM and self-monitoring;
   c. Patient has a diagnosis of glycogen storage disease type 1a;
   d. Patient uses an insulin pump;
   e. Patient is pregnant with poorly controlled type 1 diabetes, where poorly controlled is defined as unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected post-prandial hyperglycemia, or recurrent diabetic ketoacidosis;
2. Patient is unresponsive to standard medical therapy;
3. A letter of medical necessity from a board certified endocrinologist is attached with the prior authorization, including, but not limited to:
   a. Documentation of diagnosis;
   b. Test result reports;
   c. Chart notes from the provider's office;

d. Hospital admission notes (when applicable);

4. Documentation that the patient has completed a comprehensive diabetes education program within the last 12 months;
5. Regular follow-up with a healthcare provider is planned at a minimum every 6 months to assess for ongoing benefit.

B. Continuation (after 1 year) of CGM 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
A. The device is malfunctioning.
B. Replacement of an existing CGM for additional features which are not considered medically necessary will not be covered.

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 Polices/Rules
NA

G. Review/Revision History

	DATE	ACTION
Date Issued	03/17/2021	New Policy
Date Revised	05/11/2022 03/15/2023	Annual Review: updated references, clarified indications Annual Review: added references, definitions, added glycogen storage disease type 1a. Approved at Committee.
Date Effective	06/01/2023	
Date Archived	10/31/2023	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

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

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Independent medical review – March 2018