MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
07/17/2014	07/17/2016	07/15/2015

Policy Name	Policy Number
Continuous Glucose Monitoring Systems (CGMS)	**MM-0031**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) 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 CSMG Co. and its affiliates (including CareSource) 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.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Continuous Glucose Monitoring Systems (CGMS)

B. BACKGROUND

For patients with type I diabetes, tight glucose control is critical because they require chronic treatment with exogenous insulin. To constantly monitor and calculate the insulin dose needed to control their blood glucose level, the patients self-monitors their blood glucose level using samples obtained by finger sticks. However, there are still challenges remaining because the patients require several readings per day and the readings don't depict continuous real-time data.

Continuous glucose monitoring systems (CGMS) are invasive or noninvasive devices that use a tiny sensor inserted under the skin to measure glucose levels in tissue fluid at frequent intervals over a period of several days. CGMS are designed to obtain information regarding diurnal patterns in glucose levels that can guide adjustments to therapy, enabling better glucose control.

CGMS are FDA-approved in patients 8 years of age and older and have the most potential value in patients with hypoglycemic unawareness who are at risk or have a history of severe recurrent hypoglycemia. The Endocrine Society also recommends their use in patients who have HbA1c levels of at least 7% who have demonstrated that they are able to use these devices effectively on a daily basis. To affectively use such devices a patient must demonstrate adequate understanding and motivation to use intensive insulin therapy, and a history of compliance to frequent home glucose monitoring.

C. DEFINITIONS

N/A

D. POLICY

I. CareSource will approve the use of CGMS and consider its use as medically necessary for the following:
   A. Short-term use (up to 7 days) for blood glucose evaluation to optimize therapy does not require prior authorization.
   B. Long-term use for patients who meet **ALL** of the following:
      1. Has type 1 diabetes
      2. Is 8 years of age or older
      3. Letter of medical necessity is provided by an endocrinologist.
      4. A letter or documentation indicating the patient regularly works with a certified diabetes educator
      5. The patient has completed a comprehensive diabetes education program within the previous 12 months.
      6. The patient is compliant with the insulin therapy recommended by an endocrinologist as demonstrated by monitoring logs maintained for at least 3 months.
      7. Insulin injections are required ≥3 times per day or an insulin pump is used
      8. Self-home glucose monitoring is required ≥4 times per day.
      9. The patient meets **two or more** of the following :
         a. HgbA1C ≥7% despite diligent adjustments to therapy based on previous short-term CGMS and self-monitoring
         b. History of recurrent hypoglycemia (<50 mg/dl) or hypoglycemic unawareness (severe bouts requiring assistance of another individual to manager or when the first manifestation is neuroglycopenic as opposed to neurogenic) despite diligent adjustments to therapy based on previous short-term CGMS and self-monitoring
         c. The patient is pregnant with poorly controlled type I diabetes
            (1) Poorly controlled is defined as unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected post-prandial hyperglycemia, or recurrent diabetic ketoacidosis
   C. Continuation of CGMS use **after one year** or devise replacement is considered medically necessary for the following:
      1. If for replacement, the devise 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. Pregnant women with gestational diabetes
      2. Non FDA-approved devices
      3. GlucoWatch®
      4. Artificial pancreas device systems (APDS)
      5. Replacement of an existing CGMS for additional features which are not medically necessary

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.

For Medicare Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE

HCPCS 95250: Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251: Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report

CPT

AUTHORIZATION PERIOD
Prior Authorization Required

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued: 07/17/2014
Date Reviewed: 07/17/2014, 10/30/2014, 07/15/2015
Date Revised: 10/30/2014

G. REFERENCES

1. Hayes, Inc. The MimiMed Paradigm® Real-Time Closed –Loop Continuous Infusion and Blood Glucose Monitoring System. Hayes Brief. Lansdale, Penn: Winifred S. Hayes, Inc.; July 9, 2007
2. 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.
3. 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.
4. American Diabetes Association (ADA). 2012 Clinical Practice Recommendations. Accessed at: http://care.diabetesjournals.org/content/35/Supplement_1.toc
5. American Diabetes Association. (ADA). Diabetes Care. Continuous Glucose Monitoring. Accessed at: http://care.diabetesjournals.org/search?fulltext=continuous+glucose+monitoring&submit=yes

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.