Subject: Continuous Glucose Monitoring of the Interstitial fluid	Original Effective Date: 11/20/08
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DISCLAIMER

This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members.[1]

SUMMARY

Continuous glucose monitoring systems (CGMS) (also known as REAL-Time or interstitial) are implantable or noninvasive devices that measure glucose levels in interstitial fluid. A sensor transmits results to a small recording device that can be worn on clothing, placed in a purse or kept within a short distance of the person. The sensor will display and record blood glucose levels at short intervals, allowing observation of these levels. An alarm display can be set to notify a patient of high or low glucose levels. The information can be obtained in real time or retrospectively to guide a physician in therapy adjustments, with an overall goal of improving glycemic control. The glucose values obtained from these devices are not intended to replace standard finger stick self-monitoring of blood glucose (SMBG) but are used as an adjunct technique to supply additional information on glucose trends that are not available from self-monitoring. There are three types of CGMS:

- ***Short Term***: Utilizes the ability of glucose sensors to measure and record glucose levels in interstitial fluid and produce data that shows trends in glucose measurements over a 1-3 day period (short term). The stored information is retrieved and evaluated by the physician for widely varying glucose readings that may be missed by intermittent measurements. The information may be used by the physician to alter the current testing regimen and, ultimately obtain tighter control of glucose levels.

- ***Long Term*:** (Interstitial for Monitoring only), measures glucose in the interstitial fluid using a wire-like sensor that is implanted subcutaneously into the abdomen. The sensor tip reacts with the glucose in the interstitial fluid to generate an electrical current that is converted to a glucose reading. The monitor

displays the reading, the direction of the glucose trend, and sounds an alarm when high-or low-glucose values are detected. Monitoring is used by the patient to closely monitor their glucose levels and better manage their diabetes.

- ***Long Term Interstitial Integrated with Insulin Pump*** (also known as "open loop" system). Some CGMS can integrate with an external insulin pump. The sensor can transmit glucose data to an external insulin pump. The pump can also calculate recommended insulin doses, which the patient can accept or modify. The insulin is delivered using an infusion set (a flexible delivery cannula with a small needle on the end) through a pump about the size of a pager which can be worn on a belt. The pump displays the reading, the direction of the glucose trend, and sounds an alarm when high-or low-glucose values are detected.

RECOMMENDATION

- ❑ Continuous glucose monitoring system (CGMS) of interstitial fluid for **short** term use (up to 3 days or 72 hours) may be considered medically necessary for adult members ≥ 18 years of age with type 1 insulin dependent diabetes when ALL of the following criteria have been met: **[ALL]** [3-7 10 18 19]
  - Board certified endocrinologist prescribing CGMS; and
  - Completion of a comprehensive diabetic education program; and
  - Frequency of glucose self-testing at least 4 times per day during the previous month; and
  - Compliance with a plan recommended by a board certified endocrinologist; and
  - Insulin injections are required 3 or more times per day; and
  - FDA approved Device; and
  - Insulin dose is adjusted based on self-testing results, and:
    - Inadequate glycemic control despite compliance with frequent self-testing; and
    - Fasting hyperglycemia (greater than 150 mg/dl) or
    - Recurring episodes of severe hypoglycemia (less than 50 mg/dl)

- ❑ CGMS for intermittent short term use (up to 3 days or 72 hours) is limited to once every 6 months.

- ❑ CGMS for **long** term use (> 72 hours) and/or in combination with an external insulin pump may be considered medically necessary for any the following indications: [12 14 16 17 20 21 23-29]
  - Adults ≥ 18 years of age with type 1 diabetes who meet all of the above criteria for short term CGMS; and any of the following:
    - Persistent , recurrent unexplained severe hypoglycemic events; or
    - Hypoglycemia unawareness, or
    - Episodes of ketoacidosis, or
    - Hospitalizations for uncontrolled glucose levels, or
    - Frequent nocturnal hypoglycemia despite appropriate modifications in insulin therapy; and
    - Compliance with frequent self-monitoring of blood glucose (i.e., at least four times daily).

- ❑ Continuous glucose monitoring of interstitial fluid is considered NOT medically necessary for the following indications: [3 5 12 13 15-18 22]
  - In adult patients with type 2 diabetes
  - In pregnant women with gestational type 1 or 2 diabetes
  - In children and adolescents with type 1 or 2 diabetes

SUMMARY OF MEDICAL EVIDENCE

Short Term 72 hour Intermittent CGMS

There is a large body of evidence in the published peer-reviewed literature that supports short term intermittent 72-hour CGMS when used in conjunction with SMBG to aid in the management of adults with type 1diabetes who are difficult to control and not achieving treatment goals. Many study sizes were large (up to 500), and follow-up was between 1-18 months. Studies included systematic reviews, meta-analysis and randomized controlled trials that reported the use of CGM was associated with a reduction in glycosylated hemoglobin level, as a measure of glycemic control, or stabilization of blood glucose levels. [3-7 10 18 19]

Long Term CGMS

Evidence also supports the safety and efficacy of long-term CGMS with or without insulin pump therapy in the management of adults with type 1 diabetes with uncontrolled blood glucose levels despite appropriate management and adherence to a prescribed diabetic regimen. Study sizes were large (n=60 to >500), and follow-up was between 1-18 months. Cochrane, systematic reviews, meta-analysis, and randomized controlled trials reported reductions in A1c levels that were maintained throughout the studies, as well as fewer hypo- and hyperglycemic events. [12 14 16 17 20 21 23-29]

CGMS use in Pregnancy, Children and Adolescents

The evidence is insufficient to assess whether intermittent use of real-time CGM in in addition to SMBG improves glycemic control or outcomes in women with gestational diabetes, and in children and adolescents with type 1 or 2 diabetes. [3 5 12 13 15-18 22]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 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 up to 72 hours; physician interpretation and report

HCPCS	Description

A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
S1030	Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)

ICD-9	Description: [For dates of service prior to 10/01/2015]
250-250.93	Diabetes Mellitus

ICD-10	Description: [For dates of service on or after 10/01/2015]
E10-E10.9	Type 1 diabetes mellitus

RESOURCE REFERENCES

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2015 Updated Review

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