Subject: Continuous Glucose Monitoring of the Interstitial Fluid		Original Effective Date: 11/20/2008
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DISCLAIMER

This Molina Clinical Policy (MCP) 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 Clinical Policy (MCP) 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.

FDA:

Examples of FDA approved CGMS devices include but are not limited to the MiniMed CGMS® System Gold™ device, MiniMed Guardian® Real-Time CGMS device, MiniMed Paradigm Revel® Real-Time system, DexCom STS-7® System, and the FreeStyle Navigator®. The MiniMed Paradigm Revel® Real-Time system and MiniMed Guardian® Real-Time CGMS device are recommended for adults, age 18 years and over and, children and adolescents with diabetes age 7 to 17 years. The DexCom STS-7 System and FreeStyle Navigator™ are not recommended for children under 18 years. The Dexcom G5® Mobile is the only CGM approved for adults and pediatric patients two years of age and older. The FDA approved a PMA application for the Eversense CGM system on June 21, 2018. The Eversense CGM is indicated for continually measuring glucose levels in adults aged 18 years and older with either type 1 or type 2 diabetes for up to 90 days. The system is intended to supplement, not replace, blood glucose monitoring via fingerstick. This is the first FDA-approved CGM system to include a fully implantable sensor.

RECOMMENDATION [1-3 4-9 10-46]

- ❑ 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 type 1 diabetics when ALL of the following criteria have been met: **[ALL]** [3-7 10 18 19]
    - MD Board certified endocrinologist or maternal fetal medicine 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); and

- ❑ 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 who are 18 years of age or older with type 1 diabetes (including gestational diabetes of pregnancy) 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
- HbA1c above 7% and have demonstrated compliance with an intensive insulin regimen and blood glucose monitoring 4 or more times a day and is willing and able to use the CGM device on a daily basis; and
- Compliance with frequent self-monitoring of blood glucose (i.e., at least four times daily).

- Children who are age 2-18 years with type 1 diabetes who meet all of the following criteria:
  - Board certified endocrinologist prescribing CGMS confirms the member or caregiver is capable of using a long-term CGM system; AND
  - CGMS devise is FDA approved for use in pediatric patients; AND
  - HbA1c levels below 7.0%, and the CGM device is medically necessary to limit the risk of hypoglycemia; OR
  - HbA1c levels greater than 7.5% and have demonstrated compliance with an intensive insulin regimen and blood glucose monitoring 4 or more times a day and is willing and able to use the CGM device on a daily basis

SUMMARY OF MEDICAL EVIDENCE [10-36 37-46]

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.

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.

CGMS use in Pregnancy, Children and Adolescents and type 2 Diabetes [37-46]

The evidence is sufficient and supports the safety and efficacy of CGMS in women with gestational diabetes, and in children and adolescents with type 1 diabetes. In the pediatric population, studies found that constant or nearly constant use of CGM for 3 to 12 months was associated with statistically significant absolute reductions of 0.2% to 1.0% in mean HbA1c (e.g., an HbA1c level decreasing from 8.0% to 7.0% represents an absolute decrease of 1.0%). RCT's, systematic reviews and meta-analysis reported that CGMS improves glycemic control and reductions in A1c levels. In pregnancy RCT's found that use of CGM was associated with statistically significant improvements in mean HbA1c, mean infant birth weight, and risk of macrosomia. In type 2 diabetes a large trial (n= >600) treated with oral agents were randomly assigned to SMBG or non-SMBG groups. After 27 weeks, A1C decreased in both groups but, there was a significantly greater reduction in A1C in the SMBG group (between-group difference 0.25 percent). The evidence is insufficient to support CGMS in adults with type 2 diabetes.

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
95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording. *New code effective 1/1/18*
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, 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; analysis, 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-10	Description: [For dates of service on or after 10/01/2015]
	All diagnoses

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Peer Review: *MCP reviewed by AMR practicing physician board certified in Internal Med, Endocrinology and Pediatric Endocrinology. 10/9/17.*

Revision History: *12/17: The following revisions were added: Gestational diabetes of pregnancy was included as a medically necessary indication for long term CGMS and criteria were added for children and adolescents age 2-18 years. Summary of medical evidence, professional guidelines and reference sections were updated.*
9/13/18: Policy reviewed, no changes to criteria. Added one additional FDA approved device called the Eversense CGM.