Subject: Continuous Glucose Monitoring of the Interstitial Fluid		Original Effective Date: 11/20/2008
Policy Number: MCP- 054	**Revision Date(s):** 6/29/2012, 2/25/2015, 12/13/2017, 9/18/2019	
Review Date: 12/16/2015, 9/15/2016, 6/22/2017, 9/13/2018, 9/18/2019		
MCPC Approval Date: 12/13/2017, 9/13/2018, 9/18/2019		

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***: Short-term CGM may be used by the treating physicians as a one-time evaluation tool for up to 14 days utilizing the ability of glucose sensors to measure and record glucose levels in interstitial fluid and produce data that shows trends in glucose measurements. 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*:** Long-term CGM (> 14 days) are for personal use at home and measure 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. For most devices, glucose measurements provided during continuous monitoring are not intended to

replace standard self-monitoring of blood glucose (SMBG) obtained using fingerstick blood samples, but can alert individuals of the need to perform SMBG.

- ***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:

There are many examples of FDA approved short and long term CGMS devices. For additional information on any specific CGMS please see the following FDA websites: Short, long, and loop systems:

- Use Product code LZG: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- Use Product code MDS: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm
- Implantable Sensor CGM: Use Product Code QCD: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm

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

- ❑ Continuous glucose monitoring system (CGMS) of interstitial fluid for **short** term use (3 to 14 days) 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 **long** term use (> 14 days) 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).

o 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

CONTINUATION OF THERAPY

Short Term CGMS:

- ❑ CGMS for intermittent short term use (up to 14 days) is limited to once every 6 months.

Long Term CGMS

Continuation of CGMS is considered medically necessary under the following circumstances:

- ❑ For the monitor, initial authorization is allowed for 12 months (or up to purchase) and the supplies (accessories, sensors, pods) initial authorization of 6 months and reauthorization every 6 months thereafter; or
- ❑ For replacement, the device is malfunctioning and out of warranty; and
- ❑ There is objective documented evidence from the treating endocrinologist of improvement in control of diabetes (specific to baseline status of disease for each member); and
- ❑ There is objective documented evidence from the treating endocrinologist of compliance to CMGS defined as at least 80% use rate of device (must be based on log data of the device)

EXCLUSIONS [8 47-55]

Implantable glucose sensors, such as Eversense, for continuous glucose monitoring are considered experimental, investigational and unproven (E/I/U) based on insufficient evidence in the peer reviewed medical literature.

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 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.

Implantable Sensor CGMS [47-55]

The overall body of evidence is insufficient to support the safety and efficacy of the Implantable Sensor CGMS such as the Eversense in adults with type 1 or type 2 diabetes. Studies evaluating the clinical validity and clinical utility of the Eversense CGM system are small in size and low in quality due to inconsistencies and variability in assessments of clinical validity and insufficient evidence to evaluate the clinical utility. The evidence suggests moderate accuracy of the Eversense CGM, however the body of evidence is limited by an evidence base of fair to poor-quality studies, small number of patients, limited data assessing the accuracy of the CGM across different glucose parameters, and inconsistencies between studies. No studies compared the clinical utility of the Eversense CGM with SMBG. Limitations of individual studies include small sample size, lack of long-term data, limited reporting of statistical analyses, lack of power analysis, manufacturer funding, author conflicts of interest, and a lack of reporting of patient recruitment methods.

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
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training *(when used for the Eversense CGM system)*

0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision *(when used for the Eversense CGM system)*
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation *(when used for the Eversense CGM system)*

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)
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit of Service
K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system

ICD-10	Description: [For dates of service on or after 10/01/2015]
	All diagnoses

RESOURCE REFERENCES

Government Agency

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    - Premarket Approval (PMA). Product code MDS: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm
    - Eversense Continuous Glucose Monitoring System - P160048. Accessed at: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160048A.pdf
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Professional Society Guidelines, Hayes and Other Resources

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    - Children and Adolescents. Diabetes Care 2019 Jan; 42 (Supplement 1): S148-S164. Accessed at: https://doi.org/10.2337/dc19-S013
    - Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes 2019. Diabetes Care 2019 Jan; 42 (Supplement 1): S165-S172. Accessed at: https://doi.org/10.2337/dc19-S014

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Peer Review:

- Advanced Medical Review (AMR): MCP reviewed by AMR practicing physician board certified in Internal Med, Endocrinology and Pediatric Endocrinology. 10/9/17.
- Advanced Medical Review (AMR): MCP reviewed by AMR practicing physician Board certified in Endocrinology (Diabetes and Metabolism). 7/31/19

Review/Revision History:
11/20/08: New Policy
6/29/12 & 2/25/15: Policy reviewed and updated.
12/13/17: 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.
6/19: Added to K codes to the HCPCS coding table per PA Governance Committee.
9/18/19: Policy reviewed and the following revisions were added: Criteria section, changed short term CGMS from 3 days to up to 14 days as medically necessary based on newer FDA devices approved for use up to 14 days. Long term CGMS are medically necessary for > 14 days based on criteria. Exclusions section: The Eversense CGM is considered I/E/U based on insufficient evidence. Added the continuation of therapy criteria for short and long term CGMS. Updated coding table, FDA section, guidelines and references.