

Medical Policy

Continuous Glucose Monitors

Policy Number: 014

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization Required			
No Prior Authorization	X	X	X

Overview

The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine medical necessity for continuous glucose monitors.

Coverage Guidelines

Medical necessity for Continuous Glucose Monitor is determined through InterQual® criteria. To access the criteria, log in to Mass General Brigham Health Plan’s provider website at MassGeneralBrighamHealthPlan.org and click the InterQual® Criteria Lookup link under the Resources Menu. Mass General Brigham Health Plan covers continuous glucose monitors for individuals when it is recommended by the member’s providers and when the request meets the medical necessity criteria. In addition, the member’s endocrinologist is responsible for providing all necessary clinical information for the determination of medical necessity including: medical history, diabetes education received, treatment to date, glucose reading logs, pertinent laboratory testing, treatment plan, and medical necessity rational. The treating endocrinologist must sign a prescription for any requested continuous glucose monitor/supply at least yearly.

Continuous Glucose Monitors- Long Term –Exclusions

1. Use of sensors more frequently than every 72 hours.
2. Replacement or repair of home long-term (more than 7 days) continuous glucose monitors when:
 - a. It is still under manufacture warranty;
 - b. It is lost, stolen, or damaged due to improper care, or misuse, or neglect (Mass General Brigham Health Plan may require proof of the stolen or damaged item. Proof consists of a police report, pictures, or corroborating statement);
 - c. The member has a functioning model and a newer or upgraded model is not medically necessary;
3. Devices or device features that are to be principally used for convenience and are not medically necessary;
4. Devices or device features that are considered experimental and investigational.

Medicare Variations

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan’s medical policies are used for coverage determinations.

At the time of Mass General Brigham Health Plan’s most recent policy review, Medicare has the following:

- LCD: Glucose Monitors (L33822)
- Local Coverage Article – Policy Article (A5264)

Definitions

Continuous Glucose Monitors: Minimally invasive or noninvasive devices that measure glucose levels in the interstitial fluid surrounding skin cells over a short-term period of several days or for long-term use to provide continuous information about glucose fluctuations that is not otherwise captured by intermittent testing. The continuous glucose monitoring systems measure blood glucose with minimal invasiveness through continuous measurement of interstitial fluid (ISF) with a subcutaneously implanted sensor. These devices may require calibration with fingerstick glucose levels. Several CGMS have been approved by the FDA. In addition to stand-alone continuous glucose monitors, several insulin pump systems have included a built-in continuous glucose monitor. Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower hemoglobin A1C levels in highly selected patients.

Glycated hemoglobin: Also known as HbA1c, is a form of hemoglobin. (Hemoglobin is the iron-rich protein in red blood cells that gives blood its red color.) In the normal 120-day life span of a red blood cell, glucose molecules react with hemoglobin forming glycated hemoglobin. Individuals with diabetes have higher quantities of glucose in their capillary blood and as a result they also have increased numbers of glycated hemoglobin molecules. The 2018/2019 American Diabetes Association Standards of Medical Care include an HbA1c level $\geq 6.5\%$ as one of the criteria for diagnosing diabetes. Once a hemoglobin molecule is glycated, it remains that way. A build-up of glycated hemoglobin within the red blood cells therefore reflects the average level of glucose to which the cell has been exposed during its life cycle. Measuring glycated hemoglobin assesses the effectiveness of therapy for the treatment of diabetes.

Hypoglycemia: The International Hypoglycemia Study Group recommended a blood glucose value of 70 mg/dL or less as sufficiently low for treatment with fast-acting carbohydrates and less than 54 should be considered serious, clinically significant hypoglycemia. Severe hypoglycemia is defined as severe cognitive impairment requiring assistance from another person for recovery.

Optimum Glycemic Control per ADA 2019:

- Lowering A1C for non-pregnant adults to $<$ or about 7% to reduce microvascular and neuropathic complications of diabetes and, possibly, macrovascular disease.
- Lowering A1C for a selected individual adult to $<6.5\%$ without causing significant hypoglycemia or other adverse effects of treatment.
- Less stringent A1C goals (e.g. $<8\%$) may be appropriate for an adult patient with a history of: severe hypoglycemia, limited life expectancies, advanced microvascular or macrovascular complications, extensive comorbid conditions, or those with longstanding diabetes in whom the general goal is difficult to obtain despite education, monitoring, and appropriate medications.
- Lowering A1C for children to $< 7.5\%$ with special consideration for the unique risks of hypoglycemia in very young children.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

This list of codes applies to commercial and MassHealth plans only.

Authorized Codes	Code Description
A4238	Supply allowance for adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
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
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
E2102	Adjunctive continuous glucose monitor or receiver
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver

Effective

March 2023: Off-cycle update. Prior authorization no longer required. Table updated. Medicare language added. References updated.
 January 2023: Codes updated.
 April 2022: Added codes.
 December 2021: Annual update. References updated.
 December 2020: Annual update. References updated. InterQual criteria revised.
 December 2019: Annual update. References updated.
 December 2018: Annual update
 April 2018: Added codes.
 November 2017: Annual update.
 February 2017: McKesson’s InterQual® criteria replaced the criteria as indicated in the policy.
 July 2016: Annual update
 July 2015: Effective date.

References

American Diabetes Association. Glycemic targets: Standards of Medical Care in Diabetes 2018. *Diab Care* Jan 2019; 42(Suppl 1): S61-S70. S55-64.

American Diabetes Association. Standards of Medical Care in Diabetes – 2019. *Diabetes Care* Volume 42, Supplement 1, January 2019.

Beato-Vibora PI, Gallego-Gamero F, Lazaro-Martin L, et al. Prospective Analysis of the Impact of Commercialized Hybrid Closed-Loop System on Glycemic Control, Glycemic Variability, and Patient-Related Outcomes in Children and Adults: A Focus on Superiority Over Predictive Low-Glucose Suspend Technology. *Diabetes Technol Ther.* Dec 2020; 22(12): 912-919.

Christiansen, MM, Klaff, LL, Bailey, TT, Brazg, RR, Carlson, GG, Tweden, KK. A Prospective Multicenter Evaluation of the Accuracy and Safety of an Implanted Continuous Glucose Sensor: The PRECISION Study. *Diabetes Technol. Ther.*, 2019 Mar 30;21(5). PMID 30925083.

Davidson MA. Continuous Glucose Monitoring in Patient with Type 1 Diabetes Taking Insulin Injections. *JAMA* 2017;317(4):363-364.

Danne T, Nimri R, BattelinoT et al. International consensus on use of continuous glucose monitoring. *Diab Care* 2017; 40: 1631-1640.

Deiss D, Irace C, Carlson G, et al. Real-World Safety of an Implantable Continuous Glucose Sensor Over Multiple Cycles of Use: A Post-Market Registry Study. *Diabetes Technol Ther.* Jan 2020; 22(1): 48-52. PMID 31418587



Dover AR, Stimson RH, Zammitt NN, Gibb FW. Flash glucose monitoring improves outcomes in a Type 1 diabetes clinic. *J Diabetes Sci Technol* 2017; 11: 442-443.

Edelman SV et al. Clinical Implications of Real Time and Intermittently Scanned Continuous Glucose Monitors. *Diab Care* 2018; 41:2265-2274

Fonseco VA, Grunberger G, Anhalt H et al. Continuous glucose monitoring: a consensus conference of the American Association of Clinical Endocrinologists and American College of Endocrinology. *Endocrine Practice* 2016; 22(8): 1008-1021.

Funtanilla VD, Candidate P, et al. Continuous Glucose Monitoring: A Review of Available Systems. P T. 2019 Sep;44(9):550-553.

Hayes. Health Technology Assessment. Eversense Continuous Glucose Monitor for Maintaining Glycemic Control in Adults with Diabetes Mellitus. September 2018. Annual Review completed July 4, 2020.

Hayes. Health Technology Assessment. FreeStyle Libre Flash Glucose Monitoring System for Maintaining Glycemic Control in Adults with Diabetes Mellitus. September 2018. Annual Review completed October 8, 2020.

Inzucchiu, S., Bergenstal, R., & Diamant, M, et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care* 2012; 35: 1364-1379.

Hoeks, LB., Greven, WL, de Valk, HW. Real-time continuous glucose monitoring system for treatment of diabetes: a systematic review. *Diabetic Medicine* 2011; 28:386-394.

Ida, SS, Kaneko, RR, Murata, KK. Utility of Real-Time and Retrospective Continuous Glucose Monitoring in Patients with Type 2 Diabetes Mellitus: A Meta-Analysis of Randomized Controlled Trials. *J Diabetes Res*, 2019 Feb 19;2019:4684815. PMID 30775385.

International Hypoglycemia Study Group. Glucose concentration of less than 3.0 mmol/L (54 mg/dL) should be reported in clinical trials: a joint position statement of the ADA and EASD. *Diabetes Care* 2017; 40:155-157.

Langendam, Miranda, et al. "Continuous glucose monitoring systems for type 1 diabetes mellitus." *Cochrane Database Syst Rev* 1 2012.

National Institute for Health and Care Excellence (NICE). Type 1 diabetes in adults: diagnosis and management [NG17]. 2016; <https://www.nice.org.uk/guidance/ng17?unlid=382286372016220232952>. Accessed November 5, 2019.

Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD): Glucose Monitors (L33822). Revision Effective Date: 02/28/2022. Available: <https://med.noridianmedicare.com/web/jddme/policies/lcd/active>

Noridian Healthcare Solutions, LLC. Local Coverage Article: Glucose Monitors – Policy Article (A52462). Revision Effective Date: 01/01/2023. Available: <https://med.noridianmedicare.com/web/jddme/policies/lcd/active>

Peters AL, Ahmann AJ, Battelino T et al. Diabetes technology – continuous subcutaneous insulin infusion therapy and continuous glucose monitoring in adults: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2016; 101:3922-3937.

Pickup J., Freeman, S., Sutton, A. Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self-monitoring of blood glucose: Meta- analysis of randomized controlled trials using individual patient data. *BMJ* 2011; 343: 3805. doi: <http://dx.doi.org/10.1136/bmj.d3805>



Pratley RE, Kanapka LG, Rickels MR, et al. Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults With Type 1 Diabetes: A Randomized Clinical Trial. *JAMA*. Jun 16 2020; 323(23): 2397-2406. PMID 32543682

Rasbach, L., Volkening, L, Markowitz., et al. Youth and parent measures of self-efficacy for continuous glucose monitoring: survey psychometric properties. *Diabetes Technology & Therapeutics* 2015;17(5):327-334.

Shah, V., Shoshes, A., Tawfik, B, et al. Closed-loop system in the management of diabetes: past, present and future. *Diabetes Technology & Therapeutics* 2014; 16: 447-490.

Tamborlane WV, Beck RW et al. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Continuous glucose monitoring and intensive treatment of Type 1 diabetes. *N Engl J Med* 2008; 359: 1464-1476.

