

Continuous Glucose Monitors

Policy Number: PA-034
Last Review Date: 02/13/2020
Effective Date: 01/01/2020

Policy

Evolent Health considers **Continuous Glucose Monitors** medically necessary for the following indications (see Medicare Variation below regarding Dexcom):

INITIAL AND CONTINUATION OF REQUEST FOR CONTINUOUS GLUCOSE MONITORING SYSTEMS (CGMS): The initial request covers *six month trial* of the device and reevaluation of the device effectiveness before further authorization is provided to the member

Long-term use of continuous interstitial glucose monitoring devices as an adjunct to standard care is considered medically necessary for all of the following indications:

1. The device must be prescribed by a physician who should have appropriate interfacing equipment with the member's monitoring system to receive reports.
2. The member has demonstrated compliance with a physician ordered diabetic treatment plan for at least three months prior to the request
3. Insulin injections are required three or more times per day or an insulin pump is used for maintenance of blood sugar control.
4. Four or more finger sticks are required per day, including the two times needed to calibrate the CGMS.
5. The member (parent or caregiver if member is a child) must have the ability to understand the technology and be willing to use the monitor (i.e., hear alarms, read and interpret glucose data, and can take action based on the data interpretation).
6. The member experiences at least two of the following:
 - i. The member must experience severe hypoglycemia, defined as a blood glucose levels less than 50 mg/dl or recurrent, or hypoglycemia unawareness *70 or below despite frequent blood glucose monitoring.
 - ii. The member's A1C is <7% and they wish to continue good control or the member's A1C is ≥7% and they are candidates for improving their control to < 7%.
 - iii. The member is pregnant with unexplained hypoglycemic episodes, hypoglycemic unawareness despite frequent blood glucose monitoring
7. If the member is less than 18 years of age, they must experience recurrent episodes of severe hypoglycemia, defined as 2 or more episodes of hypoglycemia in a 30-day period with unawareness, despite treatment modification and glucose monitoring with at least 4 fingersticks a day.

Note:

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- Blood glucose (audible devices) monitors with special features to allow easy use for members with visual impairment are considered medically necessary if the device and the special features are approved by the FDA.
- Dexcom system does not require finger sticks 4x per day. This system can be calibrated with the finger sticks 2x per day

REQUEST FOR CGM SENSORS AFTER INITIAL SIX MONTHS APPROVAL:

Continuation of sensors for the CGM devices as an adjunct to standard care is considered medically necessary for the following:

1. Members meet all of the above criteria; and
2. Downloaded CGMS logs for three months demonstrating the member is utilizing the CGM on a daily basis.

Limitations

1. CGMS that are not approved by the FDA are not covered.
2. CGMS with an integrated insulin pump require prior authorization.
3. CGMS is not currently approved by the FDA for use in children under seven years old and is therefore not recommended in children under seven years old.
4. MiniMed Paradigm REAL-Time Closed-Loop Continuous Insulin Infusion and Blood Glucose Monitoring System is considered experimental and investigational, and therefore not covered.

Background

Diabetes is increasing worldwide at an unprecedented pace and has become a serious health concern during the last two decades, causing the World Health Organization (WHO) to declare it a global epidemic. Diabetes is also one of the most common diseases in the United States, affecting more than 29 million Americans. Type I diabetes mellitus refers to the juvenile onset stage when the pancreas cannot produce sufficient insulin, while type II diabetes mellitus reflects the inability of the body to use the secreted insulin.

Diabetes management involves monitoring to ensure an individual's glucose levels remain within the normal range. Continuous Glucose Monitoring Systems (CGMS) measure glucose levels frequently and allow for patient-specific adjustments to therapy. Current CGMS indicate the glucose level, the direction and magnitude of change of glucose levels, and can be used to assess glycemic variability. In addition, real-time

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CGMS sensors can serve as a tool to predict impending glucose excursions, thereby providing alarm signals of hypo- and hyperglycemic values warning the patient to take preventative actions.

Codes:

HCPCS Codes	
Code	Description
A9276	Sensor; invasive (e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one 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
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
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 continuous glucose monitor system

HCPCS Codes – DEXCOM	
Code	Description
E1399	Durable Medical Equipment, Miscellaneous
A9999	Durable Medical Equipment, Miscellaneous Supply (1 unit of service per month)

References

1. American Diabetes Association. Clinical Diabetes 2019 Jan; 37(1): 11-34. <https://doi.org/10.2337/cd18-0105>.
<https://clinical.diabetesjournals.org/content/37/1/11>

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2. [American Diabetes Association. Hypoglycemia \(Low Blood Sugar\). 2019. Accessed: 01/09/2020. https://www.diabetes.org/diabetes/medication-management/blood-glucose-testing-and-control](https://www.diabetes.org/diabetes/medication-management/blood-glucose-testing-and-control)
3. Block C, Vertommen J, Manuel-y-Keenov B, et al. Minimally-invasive and non-invasive continuous glucose monitoring systems: indications, advantages, limitations and clinical aspects. *Curr Diabetes Rev*, 2008 Aug;4(3); 159=68. <http://www.ncbi.nlm.nih.gov/pubmed/18690896>
4. Centers for Medicare and Medicaid Services (CMS). MLN Matters. Two New “K” Codes for Therapeutic Continuous Glucose Monitors. July 1, 2017. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10013.pdf>
5. Centers for Medicare and Medicaid Services (CMS). Local Coverage Article: External Infusion Pumps – Policy Article – A52507 (Contractor: NHIC, Corp.). Revision Effective Date: 01/01/2020. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52507&ver=55&Date=&DocID=A52507&bc=hAAAABAAAA&&>
6. Centers for Medicare and Medicaid Services (CMS) Rulings. Ruling No.: [CMS-1682-R]. January 12, 2017. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf>
7. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L33822 - Glucose Monitors. (Contractor: NHIC Corp.) Revision Effective Date: 01/12/2019. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33822&ver=21&Date=&DocID=L33822&bc=iAAAABAAAA&&>
8. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No L33794 External Infusion Pumps. (Contractor: NHIC, Corp.) Revision Effective Date: 01/01/2019. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794&ver=83&Date=&DocID=L33794&bc=iAAAABAAAA&&De>
9. Fonseca V et al. Continuous Glucose Monitoring: A Consensus Conference of the American Association of Clinical Endocrinologists and American College of Endocrinology. *Endocr Pract*. 2016;22(No. 8). <https://journals.aace.com/doi/pdf/10.4158/EP161392.CS>
10. Garber A et al. Consensus Statement by The American Association Of Clinical Endocrinologists And American College Of Endocrinology On The Comprehensive Type 2 Diabetes Management Algorithm – 2019 Executive Summary. *Endocrine Practice*: January 2019, Vol. 25, No. 1, pp. 69-100. <https://journals.aace.com/doi/10.4158/CS-2018-0535>
11. Hayes. Medical Technology Directory. Continuous Glucose Monitoring Systems. Published August 13, 2015. Reviewed: October 1, 2019

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12. Kerssen A, De Valk HW, Visser GH. The Continuous Glucose Monitoring System during pregnancy of women with type 1 diabetes mellitus: accuracy assessment. *Diabetes Technol Ther.* 2004 Oct; 6(5): 645-651. doi:10.1089/dia.2004.6.645. <http://www.ncbi.nlm.nih.gov/pubmed/15628818>
13. Klonoff, DC. Continuous Glucose Monitoring: Roadmap for 21st century diabetes therapy. *Diabetes Care*, May 2005 Vol. 28 no. 5 1231-1239. <http://care.diabetesjournals.org/content/28/5/1231.full>
14. Maran A, Crepaldi C, Tiengo A, et al. Continuous subcutaneous glucose monitoring in diabetic patients; a multicenter analysis. *Diabetes Care.* 2002 Feb; 25(2):347-352. <http://care.diabetesjournals.org/cgi/content/abstract/25/2/347>
15. Patton SR, Williams LB, Eder SJ, et al. Use of continuous glucose monitoring in young children with type 1 diabetes: Implications for behavioral research. *Pediatric Diabetes.* 2011 Feb; 12(1): 18-24. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3285484/>
16. Tanenberg R, et al. Use of the continuous glucose monitoring system to guide therapy in patients with insulin- treated diabetes. *Mayo Clin Proc.* 2004; 17: 1521-1526. <https://www.ncbi.nlm.nih.gov/pubmed/15595336>
17. Vashist, SK. Continuous Glucose Monitoring Systems: A Review. *Diagnostics* 2013, 3, 385-412. <http://www.mdpi.com/2075-4418/3/4/385/pdf>

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