

Continuous Glucose Monitoring Systems

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Effective Date 10/2007

Next Review Date 7/2024

Coverage Policy DME 10

<u>Version</u> 5

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details *.

Purpose:

This policy addresses Continuous Glucose Monitoring Systems.

Description & Definitions:

Continuous glucose monitoring measures glucose levels throughout the day with an electrode that is inserted under the skin. The electrode is connected to a transmitter that sends the information to a monitoring and display device that can notify the individual if their glucose is high or low.

Criteria:

Continuous glucose monitoring may be indicated for 1 or more of the following:

- Type 1 or type 2 diabetes mellitus or gestational diabetes, and long-term continuous glucose monitoring needed, as indicated by ALL of the following:
 - o Intensive insulin regimen (3 or more insulin injections per day, or use of continuous subcutaneous insulin infusion pump)
 - o Individual consistently monitors blood glucose 3 or more times per day.
 - Individual and/or caregiver is adherent, capable of using the devices safely (either by themselves or a caregiver), knowledgeable, and able to monitor blood glucose 3 or more times per day, follow diabetic treatment plan, and participates in ongoing education and support. Diabetic treatment plan, and participates in ongoing education and support.
 - Monitoring longer than 14 days
- Type 1 or type 2 diabetes mellitus or gestational diabetes, and short-term continuous glucose monitoring needed, as indicated by ALL of the following:
 - Additional information about blood glucose needed, as indicated by 1 or more of the following:
 - Abnormal early-morning increase in blood glucose ("dawn phenomenon"), known or suspected
 - Hypoglycemic unawareness (ie, individual does not have symptoms with hypoglycemia)
 - Nocturnal hypoglycemia, known or suspected

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- Postprandial hyperglycemia, known or suspected
- Significant change to diabetes treatment regimen (eg, initiation of insulin, change from multiple-dose insulin to insulin pump therapy)
- Unexplained hyperglycemia
- Hypoglycemia including unconsciousness, seizure, glucagon administration, and emergency attendance and/or admission to hospital and recurrent prolonged hospitalizations
- Individual is pregnant or planning pregnancy
- Monitoring limited to 3 to 14 days
- Replacement of Continuous Glucose Monitoring System is indicated with ALL of the following:
 - The problem(s) which limit the use of the current continuous glucose monitoring system is clearly identified (including misuse or abuse of the equipment)
 - There is documentation that the current continuous glucose monitoring system is not under warranty, including the date of warranty expiration

The following do not meet the definition of medical necessity, to include but not limited to:

- Diabetes Management Software
- Hypoglycemic wristband alarm (e.g., Diabetes Sentry, GlucoWatch)
- Nesidioblastosis (primary islet cell hypertrophy), neonatal hypoglycemia, and for monitoring blood glucose in non-diabetic persons
- Personal Digital Assistant-Based Blood Glucose Monitor (e.g., TheraSense FreeStyle Tracker, Accu-Check Advantage Module)
- Remote glucose monitoring device (e.g., mySentry, MiniMed Connect, Dexcom SHARE)

Coding:

Medically	/ necessary	/ with	criteria:
MEGLICALLY	/ IICCCSSai y	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	CHILEHIA.

Coding	Description
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic
A4238	Supply allowance for adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and
E2102	Adjunctive continuous glucose monitor or receiver
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories,
K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system

Considered Not Medically Necessary:

Considered Not including Necessary.		
Coding	Description	
	None	

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Document History:

Revised Dates:

- 2023: July
- 2021: August
- 2020: January
- 2019: September
- 2016: January, November
- 2015: August, October, November
- 2014: March, August, October
- 2013: April, March, October
- 2012: June, November
- 2011: June
- 2008: March, October

Reviewed Dates:

- 2022: July
- 2020: August
- 2019: March
- 2018: July
- 2017: January, May
- 2010: May
- 2009: May
- 2007: October

Effective Date:

January 1994

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2023). Retrieved June 19, 2023, from MCG 26th Edition: https://careweb.careguidelines.com/ed26/index.html

Code of Federal Regulations Title 21 CFR 862.1355 Integrated continuous glucose monitoring system. (2023, Mar 28). Retrieved June 20, 2023, from FDA:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=691

Continuous Glucose Monitoring Systems - ARCHIVED Sep 13, 2020. (n.d.). Retrieved June 19, 2023, from Hayes: https://evidence.hayesinc.com/report/dir.cont0004

Diabetes Technology: Standards of Care in Diabetes. (2023). Retrieved June 20, 2023, from Diabetes Care Journal:

https://watermark.silverchair.com/dc23s007.pdf?token=AQECAHi208BE49Ooan9kkhW_Ercy7Dm3ZL_9Cf3qfKAc485ysgAAArowggK2BgkqhkiG9w0BBwagggKnMIICowIBADCCApwGCSqGSIb3DQEHATAeBglghkgBZQMEAS4wEQQMLR3yRVsXKeKT3bXLAgEQgIICbcatYogXcOOOw0M1I9pHh3Ba1414sXe_2-fjkD8R8rbhCu

DME Manual - Appendix B. (2023). Retrieved June 19, 2023, from DMAS DME: https://www.dmas.virginia.gov/for-providers/long-term-care/services/durable-medical-equipment/

Eversense Continuous Glucose Monitoring System for Maintaining Glycemic Control in Adults with Diabetes Mellitus - Annual Review:. (n.d.). Retrieved June 19, 2023, from Hayes 2: https://evidence.hayesinc.com/report/htb.eversense4492

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Flash Continuous Glucose Monitoring: Implications for Use of Continuous Data in Daily Diabetes Management. (2019, Nov). Retrieved June 20, 2023, from National Library of Medicine – Diabetes spectrum Journal: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6858083/

FreeStyle Libre Flash Glucose Monitoring System For Maintaining Glycemic Control In Adults With Diabetes Mellitus - ARCHIVED Oct 4, 2021. (n.d.). Retrieved June 19, 2023, from Hayes 3: https://evidence.hayesinc.com/report/htb.freestyle4476

Local Coverage Determination LCD Implantable Continuous Glucose Monitors (I-CGM) (L38743). (2022, May 26). Retrieved June 19, 2023, from Centers for Medicare and Medicaid Services LCD: <a href="https://www.cms.gov/medicare-coverage-cover

<u>database/view/lcd.aspx?lcdid=38743&ver=9&keyword=Continuous%20Glucose%20Monitor&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1</u>

Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2018. (n.d.). Retrieved June 19, 2023, from American Diabetes Association (ADA): https://diabetesjournals.org/care/article/41/Supplement_1/S73/29735/8-Pharmacologic-Approaches-to-Glycemic-Treatment

Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

MUST SEE MEMBER BENEFIT FOR DETERMINATION.

We only cover DME that is Medically Necessary and prescribed by an appropriate Provider. We also cover colostomy, ileostomy, and tracheostomy supplies, and suction and urinary catheters. We do not cover DME used primarily for the comfort and wellbeing of a Member. We will not cover DME if We deem it useful, but not absolutely necessary for Your care. We will not cover DME if there are similar items available at a lower cost that will provide essentially the same results as the more expensive items.

Pre-Authorization is Required for All Rental Items.

Pre-Authorization is Required for All Repair and Replacement.

Keywords:

Continuous Glucose Monitoring, CGM, CGMS, MiniMed, shp dme, durable medical equipment 10, type 1 diabetes, type 2 diabetes, glycemic control, hypoglycemic, hyperglycemia, diabetes mellitus, Long-term continuous glucose monitoring, Short-term continuous glucose monitoring, gestational diabetes

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