

Continuous Glucose Monitoring Systems, DME 10

Table of Content
Purpose
Description & Definitions
Criteria
Coding
Document History
References
Special Notes
Keywords

<u>Effective Date</u>	10/2007
<u>Next Review Date</u>	7/2024
<u>Coverage Policy</u>	DME 10
<u>Version</u>	5

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member’s condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

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 Systems may be indicated for **one 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:
 - Intensive insulin regimen (3 or more short acting insulin injections per day), or use of **COMPATIBLE** continuous subcutaneous insulin infusion pump.
 - Individual consistently monitors blood glucose 3 or more times per day as documented on **ALL** of the following:
 - Medical record documentation
 - Personal blood glucose log showing consistent measurements over 2 weeks. Individual and/or caregiver is adherent, capable of using the devices safely (either by themselves or a

caregiver), knowledgeable and able to follow a diabetic treatment plan, and participates in ongoing education and support.

- 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.
- Continued coverage of Continuous Glucose Monitoring System devices are considered medically necessary with **ALL** of the following:
 - Member continues to meet above coverage criteria.
 - Non-Adherence to treatment has been addressed and documentation supports continued use.

Authorization request is limited to the following. Requests for equipment outside of recommended utilization must have supporting documentation:

- For Dexcom: 3 sensors per 30 days, 1 transmitter per 90 days
- For Freestyle: 2 sensors per 28 days
- Other FDA approved CGM system

Continuous Glucose Monitoring Systems are considered not medically necessary for any use other than those indicated in clinical criteria.

Coding:

Medically necessary with criteria:

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
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver

Considered Not Medically Necessary:

Coding	Description

	None
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Document History:

Revised Dates:

- 2024: April
- 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).

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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: <https://www.cms.gov/medicare-coverage-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>

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: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

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.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to “correct or ameliorate” (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

All medically necessary medical equipment and supplies under the Virginia Administrative Code (12VAC30-50-165) may be covered only if they are necessary to carry out a treatment prescribed by a practitioner. Only supplies, equipment, and appliances that are determined medically necessary may be covered for reimbursement by DMAS. (12VAC30-50-165) The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to DMAS, or its contractor. Medically necessary DME and supplies shall be:

- Ordered by the practitioner on the CMN/DMAS-352;

- A reasonable and medically necessary part of the individual's treatment plan;
- Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual; • Not furnished for the safety or restraint of the individual, or solely for the convenience of the family, attending practitioner, or other practitioner or supplier;
- Consistent with generally accepted professional medical standards (i.e., not experimental or investigational);
- Furnished at a safe, effective, and cost-effective level; and
- Suitable for use, and consistent with 42 CFR 440.70(b)(3), that treats a diagnosed condition or assists the individual with functional limitations.

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