

Continuous Glucose Monitors (CGM) Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Continuous Glucose Monitors (CGM)		
MNG #: 113	<input checked="" type="checkbox"/> SCO <input checked="" type="checkbox"/> One Care <input checked="" type="checkbox"/> MA Medicare Premier <input checked="" type="checkbox"/> MA Medicare Value <input checked="" type="checkbox"/> MA Medicare Premier <input checked="" type="checkbox"/> RI Medicare Preferred <input checked="" type="checkbox"/> RI Medicare Value <input checked="" type="checkbox"/> RI Medicare Maximum	Prior Authorization Needed? <input checked="" type="checkbox"/> Yes (always required) <input type="checkbox"/> Yes (only in certain situations. See this MNG for details) <input type="checkbox"/> No
Clinical: <input checked="" type="checkbox"/>	Operational: <input type="checkbox"/>	Informational: <input type="checkbox"/>
Benefit Type: <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid	Approval Date: 10/6/2022;	Effective Date: 12/24/2022;
Last Revised Date: 6/8/2023; 11/9/2023	Next Annual Review Date: 10/6/2023; 6/8/2024; 11/9/2024	Retire Date:

OVERVIEW:

Diabetes mellitus (DM) is a group of metabolic diseases characterized by impaired secretion of insulin or peripheral resistance to the action of insulin that results in high blood sugar. DM can be classified as type I, type II, gestational, and diabetes due to other causes. The goal in DM management is to keep daily blood glucose levels and glycosylated hemoglobin (*Hb1Ac*) within the recommended target range. When blood glucose levels are *poorly controlled*, people are at risk of complications including nerve damage, kidney disease, heart disease, peripheral vascular disease, stroke, and severely reduced quality of life. Glycemic control has been shown to slow the onset of DM and the progression to these complications. This can be achieved by self-monitoring of blood glucose, laboratory testing of HbA1c, and maintaining blood glucose levels near the target range by using insulin or other glucose-lowering medications.

Traditional blood glucose self-monitoring requires a blood drop sample, test strips, and a glucometer to provide an immediate blood glucose level reading. Continuous glucose monitoring is an alternative and safe method that has been shown to significantly reduce both HbA1c and mean glucose levels. The two main types of continuous glucose monitors (CGM) are systems that provide real-time data or those that require and provide intermittent scanning. These CGMs introduce the ability to measure glucose in interstitial fluid which allows results to be obtained on a more continuous basis. The CGM has a sensor that is inserted into the subcutaneous tissue of the patient and obtains a reading every 1 to 15 minutes. These results are then transmitted to the receiver or system that displays and records the current glucose value, trend analysis, and direction of the changing glucose. Currently, CGM offers the most benefit for individuals who are willing to use the devices consistently and who are at risk or have a history of severe recurrent hypoglycemia. Decisions to use CGM should be collaboratively made between the patient and the provider, and should carefully consider the individual's circumstances, preferences, and needs.

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According to the Food and Drug Administration (FDA), CGMs are designated as either adjunctive or non-adjunctive. Adjunctive CGMs require patients to concurrently use a blood glucose monitor to verify glucose levels prior to making diabetic treatment decisions. Non-adjunctive CGMs do not need additional confirmatory testing in order to make treatment decisions. These CGMs are considered to be therapeutic as these devices would primarily and customarily be used to serve a medical purpose under the Centers for Medicare and Medicare Services' (CMS) definition for a durable medical equipment. Therapeutic CGMs have been approved to replace blood glucose monitors for making diabetic treatment decisions. For the purpose of our medical necessity guideline, we will provide guidance for and refer to non-adjunctive or therapeutic CGMs only.

DEFINITIONS/ACRONYMS:

Continuous glucose monitor (CGM): A device that measures glucose content of interstitial fluid every 1 to 15 minutes. The interstitial fluid correlates with plasma glucose and is detected by the CGM's electrochemical enzymatic sensor. The glucose readings are transmitted to a device-specific receiver to provide visualization on the current glucose values and direction of change, which helps to fine-tune insulin dosing. The two main types of CGMs are devices that provide real-time data or that require and provide intermittent scanning.

Diabetes Mellitus (DM): Condition that is characterized by abnormal carbohydrate metabolism, inadequate insulin secretion, and/or impaired function of insulin that results in hyperglycemia. According to the American Diabetes Association (ADA), diabetes mellitus can be classified as type I, II, specific type due to other causes, and gestational diabetes mellitus.

Table 1. Types of Diabetes and their Causes.

Type of Diabetes	Cause of Diabetes
Type I Diabetes	Due to autoimmune β -cell destruction that leads to absolute insulin deficiency, including latent autoimmune diabetes of adulthood
Type II Diabetes	Due to a progressive loss of adequate β -cell insulin secretion frequently on the background of insulin resistance
Specific Type due to Other Causes	Monogenic diabetes syndromes (such as neonatal diabetes and maturity-onset diabetes of the young), Diseases of the exocrine pancreas (such as cystic fibrosis and pancreatitis), Drug- and chemical-induced diabetes (such as with glucocorticoid use, in the treatment of HIV/AIDS, or after organ transplantation)
Gestational Diabetes Mellitus	Diabetes that is diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation

Durable Medical Equipment: Equipment that meets the definition outlined in *130 CMR 409.000* and/or *Section 110.1 of Chapter 15 of the Medicare Benefit Policy Manual (Pub.100-02)*, whereby it (1) is used primarily and customarily to serve a medical purpose, (2) is generally not useful in the absence of disability, illness, or injury, (3) can withstand repeated use, and (4) is appropriate for use in any setting in which normal life activities take place (other than a hospital, nursing facility, ICF/IID).

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Hemoglobin A1c or Glycated Hemoglobin (HbA1c): Test that provides the average blood glucose levels over the past 3 months. It measures the attachment of glucose to hemoglobin and provides an estimation of the overall glucose trends.

Hypoglycemic Events: According to the ADA, hypoglycemia is a major limiting factor in the glycemic management of type I and II diabetes, and can be classified into one of three levels for medical care:

Table 2. Classification of Hypoglycemia.

Level of Hypoglycemia	Glycemic Criteria/Description
Level 1	Glucose < 70 mg/dL (3.9 mmol/L) and ≥ 54 mg/dL (3.0 mmol/L)
Level 2	Glucose < 54 mg/dL (3.0 mmol/L)
Level 3	A severe event characterized by altered mental and/or physical status requiring assistance for treatment of hypoglycemia.

DECISION GUIDELINES:

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses InterQual Smart Sheets, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline (MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists.

Clinical Coverage Criteria:

Senior Care Options and One Care

1. Commonwealth Care Alliance may provide **initial coverage** of therapeutic CGMs and related supplies for members who are **diagnosed with diabetes mellitus and are being treated with insulin (including members who are pregnant)**, when **all** of the following criteria are met, and relevant supporting documentation are submitted:

- a. The treating practitioner has concluded that the member or their caregiver has sufficient training using the CGM prescribed as evidenced by providing a prescription; *and*
- b. The CGM is prescribed to improve glycemic control and in accordance with the device's FDA indications; *and*
- c. The treating practitioner had an in-person or Medicare-approved telehealth visit, within 6 months prior to ordering the CGM, with the beneficiary to evaluate their diabetes control and determined that the member meets the criteria for a therapeutic CGM.

2. Commonwealth Care Alliance may provide **initial coverage** of therapeutic CGMs and related supplies for members who are **diagnosed with diabetes mellitus and who are not being treated with insulin**, when **all** the following criteria are met, and relevant supporting documentation are submitted:

- a. The member has a history of problematic hypoglycemia with documentation of at least **one** of the following:
 - i. At least two level 2 hypoglycemic events that persist despite more than one attempt to adjust medical treatment and/or modify the diabetes treatment plan. Documentation must include one previous

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medication adjustment and/or modification to the treatment plan prior to the most recent level two event and at least **one** of the following:

- I. The glucose values for the qualifying event (glucose < 54 mg/dL or 3.0 mmol/L); *or*
- II. Classification of the hypoglycemic episode as level 2 event(s); *or*
- III. Incorporation of a copy of the beneficiary's blood glucose monitoring testing log into the medical record reflecting the specific qualifying event(s) (glucose < 54 mg/dL or 3.0 mmol/L);

OR

- ii. At least one level 3 hypoglycemic event characterized by altered mental and/or physical state requiring assistance for the treatment of hypoglycemia. Documentation must include that the member required third party assistance for treatment and at least **one** of the following:

- I. The glucose values for the qualifying event (glucose < 54 mg/dL or 3.0 mmol/L); *or*
- II. Classification of the hypoglycemic episode as level 3 event; *or*
- III. Incorporation of a copy of the beneficiary's blood glucose monitoring testing log into the medical record reflecting the specific qualifying event(s) (glucose < 54 mg/dL or 3.0 mmol/L);

OR

- iii. The member has Diabetes Mellitus but is not receiving or unable to receive insulin due to a physical disability, visual impairment, or cognitive impairment. Other comorbidities will be reviewed on a case-by-case basis (Providers may request an exception for these members); **and**

- b. The treating practitioner has concluded that the member or their caregiver has sufficient training using the CGM prescribed as evidenced by providing a prescription; **and**
- c. The CGM is prescribed to improve glycemic control and in accordance with the device's FDA indications; **and**
- d. The treating practitioner had an in-person or Medicare-approved telehealth visit, within 6 months prior to ordering the CGM, with the beneficiary to evaluate their diabetes control and determined that the member meets the criteria for a therapeutic CGM.

3. Commonwealth Care Alliance may provide **initial coverage** of therapeutic CGMs and related supplies for members who have another **non-diabetes-based condition** causing disorder of glucose metabolism or improper endogenous insulin secretion resulting in frequent hypoglycemia, nocturnal hypoglycemia, or hypoglycemic unawareness. Examples of disorders may include, but are not limited to, seizure disorder, insulinoma, genetic conditions causing hyperinsulinemia, and effects from post-surgical conditions (post-esophagectomy, post-fundoplication, post-gastrectomy, post-gastric bypass, and post-sleeve gastrectomy).

4. Commonwealth Care Alliance may provide **continued coverage** of therapeutic CGMs and related supplies if any **one** of the following criteria are met, and relevant supporting documentation are submitted:

- a. Every 6 months following the initial prescription of the, the treating practitioner conducts an in-person or Medicare-approved telehealth visit with the member to assess their adherence to the CGM regimen and diabetes treatment plan; *or*

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- b. There is objective documented evidence of improvement in control of diabetes (specific to the baseline status of disease for individual members); *or*
- c. There is documented evidence of compliance with a current CGM treatment plan based on log data of the device; *or*
- d. If a member is new to MassHealth from another insurer and is stable on CGM.

5. Commonwealth Care Alliance may cover the **replacement** of the same therapeutic CGM device and related supplies when **all** the following are met:

- a. The treating practitioner has provided supporting documentation for the medical necessity of the replacement of the current CGM device; **and**
- b. The present CGM device has been rendered ineffective or inoperable due to:
 - i. Loss or irreparable damage that is not attributable to abuse or neglect on the part of the user; *or*
 - ii. A change in the member's condition that the current monitor is unable to accommodate; *or*

Note that if the therapeutic CGM is still covered under the manufacturer's warranty then the warranty will be used to replace the item and CCA will not be responsible for replacement costs.

6. Commonwealth Care Alliance may cover the **replacement** of the current therapeutic CGM for a different CGM system and related supplies when **all** of the following are met:

- a. The treating practitioner has conducted an in-person or Medicare-approved telehealth visit with the member to assess their adherence to the CGM regimen and diabetes treatment plan within the last 6 months; **and**
- b. The treating practitioner has provided supporting documentation for the medical necessity of the replacement of the current device for a different CGM system; **and**
- c. The member has a prescription for the use of the CGM from the treating practitioner and it is in accordance with the device's FDA indications.

Medicare Advantage (MA Medicare Preferred, MA Medicare Value, RI Medicare Preferred, RI Medicare Value, RI Medicare Maximum)

CCA follows applicable Medicare regulations, and InterQual Smart Sheets are used to review prior authorization requests for medical necessity.

LIMITATIONS/EXCLUSIONS:

- 1. In addition to the criteria above, Commonwealth Care Alliance may cover CGM-related supplies for the following:
 - a. When the member uses a stand-alone receiver or insulin infusion pump classified as DME to display glucose data; *or*
 - b. When the member uses a non-DME device (e.g., watch, smartphone, tablet, laptop, computer, etc.) in conjunction with a durable CGM receiver.
 - i. For example, Related supplies is covered when a member uses a durable CGM receiver to display their glucose data and also transmits that data to a caregiver through a smartphone or non-DME receiver, OR

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when a member uses a durable CGM receiver on some days to review their glucose data but uses a non-DME device on other days.

- ii. CCA does not cover the watch, smartphone, table, laptop, or computer.
- 2. Commonwealth Care Alliance will not cover **any** of, but not limited to, the following:
 - a. CGM devices and related supply allowance under certain circumstances where effectiveness has not been established; *or*
 - b. CGM devices and related supplies that do not meet the above clinical coverage criteria, and/or are determined that it is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member; *or*
 - c. CGM devices or related supplies that do not meet the definition of *durable medical equipment*. Please refer to the definitions section above for further information.
 - i. For example, CGM devices that solely display results on a smartphone and do not have a stand-alone receiver or integration into an insulin infusion pump, OR smart devices do not meet the definition of DME (e.g., not primarily medical in nature and are useful in the absence of illness) and will be denied as non-covered.

AUTHORIZATION:

- 1. Prior authorization is required for initial, continued use and replacements of the CGM requests.
- 2. If the CGM device (code E2103) has been determined to be medically necessary by meeting the criteria listed above for the indication requested, then the related supply allowance (Code A4239) may also be approved in accordance with CCA's billing and coding guidelines.
- 3. All CGM prior authorization submissions must include the following:
 - a. Standardized Prior Authorization Request Form; *and*
 - b. Prescription; *and*
 - c. Medical documentation demonstrating the medical necessity requirements outlined above.

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not signify that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

Code	Description	Coverage	
		SCO/One Care	Medicare Advantage
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver	Yes	Yes

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Code	Description	Coverage	
		SCO/One Care	Medicare Advantage
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service	Yes	Yes

REGULATORY NOTES:

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria. This MNG references the specific regulations, coverage, limitations, service conditions, and/or prior authorization requirements in the following:

- Centers for Medicare & Medicaid Services, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 110.1 Definition of Durable Medical Equipment, Section 110.2 Repairs, Maintenance, Replacement, and Delivery. Effective date: 10/01/2003. Revised date: 11/08/21.
- Centers for Medicare & Medicaid Services, Publication 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 4: Section 280.1 Durable Medical Equipment Reference List, Effective date: 05/05/2009, Revised Date: 09/04/2014.
- Centers for Medicare & Medicaid Services, Publication 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 1: Section 40.2 Glucose Monitors, Effective date: 04/16/2023.
- Centers for Medicare & Medicaid Services, Local Coverage Article, Glucose Monitor – Policy Article (A52464), Effective date: 10/01/2015, Revised date: 04/16/2023.
- Code of Federal Regulations, Title 42 Public Health, Chapter IV Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter B Medicare Program, Subpart D Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices, Part 414 Payment for Part B Medical and Other Health Services, Section 414.202 Definitions, Effective date: 12/7/1992, Revised date: 04/12/2023.
- MassHealth, Guidelines for Medical Necessity Determination for Diabetes Management Devices: Continuous Glucose Monitoring Systems and Insulin Pumps. Effective date: 07/13/2022.
- MassHealth, 130 CMR 409.000: Durable Medical Equipment Manual, Subchapter 4 Program Regulations, Sections 409.402 Definitions; 409.405 Provider Responsibilities; 409.413 Covered Services, 409.414 Non-covered Services, 409.417 Medical Necessity Criteria, 409.418 Prior Authorization. Effective date: 07/01/2022.
- MassHealth, 130 CMR 450.000: Administrative and Billing Regulations, Section 450.204 Medical Necessity. Effective date: 01/21/2022.
- MassHealth, 130 CMR 409.000: Durable Medical Equipment Manual, Subchapter 6 Service codes. Effective date: 07/01/2022.
- Social Security Act §1862(a)(1)(A), Exclusions from Coverage and Medicare as Secondary Payer, Effective date: 08/14/1935.

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11. Social Security Act §1862(s)(6), Part E – Miscellaneous Provisions: Durable Medical Equipment, Effective date: 08/14/1935.

Disclaimer

This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

RELATED REFERENCES:

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2. American Diabetes Association. (2023). *Diabetes technology: Standards of care in diabetes – 2023*. Diabetes Care 2023;46(Suppl.1): S111-S127.
3. American Diabetes Association. (2023). *Glycemic targets: Standards of care in diabetes – 2023*. Diabetes Care 2023; 46(Suppl.1): S97-S110.
4. Bahrami, J., Tomlinson, G., Murphy, H. & Feig, D. (2022). Impaired awareness of hypoglycaemia in women with type I diabetes in pregnancy: Hypoglycaemia fear, glycaemic and pregnancy outcomes. *Diabetic Medicine*, 39(5): 1-12.
5. Center for Medicare & Medicaid Services. (2017). *CMS rulings: Ruling no. CMS-1682-R*. Retrieved from <https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf>
6. Centers for Medicare & Medicaid Services. (2023). *Local coverage article (A52464): Glucose monitors – Policy article*. Retrieved from <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464&ver=49>
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diabetes-mellitus-antenatal-glycemic-control?search=continuous%20glucose%20monitoring&source=search_result&selectedTitle=5~147&usage_type=default&display_rank=5#H1371183362

ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:


REVISION DATE	DESCRIPTION
4/18/2023	Removed: Criteria #2 Member requires multiple daily insulin injections, or an insulin pump is being used. Exceptions: Providers may request an exception from the insulin use requirement for individual members not receiving insulin due to physical disability, visual impairment, or cognitive impairment and such instances may bypass this requirement. Other comorbidities will be reviewed on a case-by-case basis;
4/18/2023	Added: New Criteria #2 The member for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the following. <ul style="list-style-type: none"> a) The member is insulin treated; or, b) The member has a history of problematic hypoglycemia with documentation of at least one of the following <ul style="list-style-type: none"> i. Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or, ii. A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia
4/18/2023	Added: New criteria section C. Replacement criteria.
4/18/2023	Term added: "replacements" to Authorization requirements section #1
4/18/2023	Updated Medicare Local Coverage Determination and Article links and effective dates.
10/12/23	Updated, language clarification. Replaced "therapeutic" CGM with "non-adjunctive" CGM
12/31/23	Utilization Management Committee approval


APPROVALS:

CCA Business Process Owner	
Print Name	Print Title

Continuous Glucose Monitors (CGM) Medical Necessity Guideline

Signature	Date

CCA Senior Clinical/Operational Lead	
Stephen Pelley	Manager, Durable Medical Equipment
Print Name	Print Title
	12/1/2023
Signature	Date

CCA CMO or Designee	
Nazlim Hagmann, MD	Chief Medical Officer
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	12/1/2023
Signature	Date