Continuous Glucose Monitors (CGM)
Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Continuous Glucose Monitors (CGM)		
MNG #: 113	☒ CCA Senior Care Options (HMO D-SNP) (MA) ☒ CCA One Care (FIDE SNP) (MA)	**Prior Authorization Needed?** ☒ **Yes (always required)** ☐ **Yes (only in certain situations. See this MNG for details)** ☐ **No**
Benefit Type: ☒ **Medicare** ☒ **Medicaid**	**Original Approval Date:** 10/06/2022	**Effective Date:** 12/24/2022; 08/08/2024; 01/01/2025; 08/01/25; 03/12/2026
Last Revised Date: 06/08/2023; 11/09/2023; 08/08/2024; 01/25/2025; 05/08/2025; 03/12/2026	**Next Annual Review Date:** 10/06/2023; 06/08/2024; 11/09/2024; 03/12/2027	**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.

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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 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. Non-adjunctive CGMs are considered to be therapeutic as they 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. Continuous Glucose Monitoring Medical Necessity Guideline provides guidance for non- adjunctive (i.e., therapeutic) CGMs only.

DEFINITIONS:

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

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Durable Medical Equipment: Equipment that meets the definition outlined in 130 CMR 409.000, equipment that

(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 over an extended period; and

(4) is appropriate for use in any setting in which normal life activities take place, other than a hospital, nursing facility, ICF/IID, or any setting in which payment is or could be made under Medicaid inpatient services that includes room and board, except as allowed pursuant to 130 CMR 409.415 and 130 CMR 409.419(C).Per 42 CFR §414.202, equipment, furnished by a supplier or a home health agency that meets the following conditions:

- Can withstand repeated use; i.e., could normally be rented and used by successive patients;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;
- Is primarily and customarily used to serve a medical purpose;
- Generally, is not useful to a person in the absence of illness or injury; and,
- Is appropriate for use in a patient's home.

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:

Prior authorization is required for initial, continued use and replacement requests for CGM. All CGM prior authorization submissions must include Standardized Prior Authorization Request Form.

Clinical Coverage Criteria:

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 is 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 is submitted:

a. The member has documentation of **one or more** of the following:

i. Two or more level 2 hypoglycemic events that persist despite more than one attempt to adjust medications and/or modify the diabetes treatment plan. Documentation must include one previous medication adjustment and/or modification to the treatment plan prior to the most recent level two event **and one or more** 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. A history of 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 **one or more** 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);

OR

iv. Documented needle phobia (trypanophobia), including **one or more** of the following:

I. Marked fear or anxiety about receiving an injection or seeing a needle or blood; or
II. Fear or anxiety out of proportion to the actual danger posed by a needle, injection, or blood; or
III. Actively avoiding an injection, needle, or sight of blood ; or
IV. The fear, anxiety, or avoidance of needle, injection or blood causes clinically significant distress or impairment in social, occupational, or other important areas of functioning; or
V. The disturbance is not better explained by another mental disorder including fear, anxiety, and avoidance of situations associated with panic-like symptoms or other incapacitating symptoms such as but not limited to agoraphobia, obsessive-compulsive disorder, and posttraumatic stress disorder;
AND

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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 CGM, 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*
   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. Member is new to Commonwealth Care Alliance 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:

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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.

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 are 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

         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; *or*
   d. Non-FDA approved CGM devices

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CODING:

When applicable, a list(s) of codes requiring prior authorization is provided. This list is for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment.

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.

CPT/HCPCS CODE	DESCRIPTION
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

Disclaimer

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses evidence based InterQual© criteria, 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. 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.

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. 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).

This Medical Necessity Guideline is not a rigid rule. As with all 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.

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REVISION LOG:

REVISION DATE	DESCRIPTION
03/12/2026	Annual Review. Updated Criteria 2.a. to remove “a history of problematic hypoglycemia with” for clarity that criteria (a) i, ii, iii and iv should be standalone criteria. Updated references and formatting.
05/08/2025	Updated DME definition. Added documented needle phobia as covered indication. Added non-FDA devices to limitations.
01/01/2025	Update template and CCA products.
08/08/2024	Effective 8/8/24: Prescription is not required at time of prior authorization submissions
04/18/2023	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; Added: New Criteria #2 The member for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the following – 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: 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 Added: New criteria section C. Replacement criteria. Added term: “replacements" to Authorization requirements section #1. Updated Medicare Local Coverage Determination and Article links and effective dates.
10/12/2023	Updated, language clarification. Replaced “therapeutic” CGM with “non-adjunctive” CGM
12/31/2023	Utilization Management Committee approval

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APPROVALS:

Jeffrey Sedlack	Senior Medical Director Utilization Review and Medical Policy
CCA Clinical Lead	**Title**
	3/12/2026
Signature	**Date**
CCA Senior Operational Lead	**Title**
Signature	**Date**
CCA CMO or Designee	**Title**