Therapeutic Continuous Glucose Monitors (CGM)
Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Therapeutic Continuous Glucose Monitors (CGM)		
MNG #: 113	☒ **SCO** ☒ **One Care** ☒ **MA Medicare Premier** ☒ **MA Medicare Value** ☒ **RI Medicare Preferred** ☒ **RI Medicare Value** ☒ **RI Medicare Maximum**	**Prior Authorization Needed?** ☒ **Yes (always required)** ☐ **Yes (only in certain situations. See this MNG for details)** ☐ **No**
Clinical: ☒	**Operational:** ☐	**Informational:** ☐
Benefit Type: ☒ **Medicare** ☒ **Medicaid**	**Approval Date:** 10/6/2022;	**Effective Date:** 12/24/2022;
Last Revised Date: 1/3/2023;	**Next Annual Review Date:** 10/6/2023; 1/3/2024;	**Retire Date:**

OVERVIEW:

Diabetes mellitus (DM)—is a chronic progressive condition in which the body is unable to fuel itself adequately and consequently, leaves a surplus of glucose in the blood stream. In persons with DM the key transporting hormone insulin is either not produced, produced at minimal levels to support body needs or the body unable to use the insulin it produces effectively to transport the glucose from blood stream to cells for energy to fuel the body. The origin of this disruption in turning glucose into fuel is related to:

1) Autoimmune destruction of pancreatic cells that produce insulin creating an absence of the hormone as is seen in Type 1 DM
2) The pancreas produces too little insulin to support the body's needs as is seen in Type 2 DM
3) The pancreas secretes enough insulin, but the body is unable to use the insulin effectively to remove glucose from the blood stream to fuel known as insulin resistance and is seen in Type 2 DM.

Ineffective Diabetes control can lead to a host of complications including neuropathy (nerve damage), retinopathy (atherosclerosis of blood vessels in the eye), kidney disease, and cardiovascular disease, and severely reduce quality of life. The condition is readily manageable through the monitoring of blood glucose levels and proper medication regimens.

Continuous glucose monitors (CGM) allow individuals and care providers to monitor blood glucose levels and identify glycemic trends in order to improve management of diabetes. Available in both a personal and clinical setting, these devices can be installed for up to two weeks and eliminate the need for finger pricking. Based on the obtained data, care providers can make appropriate adjustment to medications and insulin use, as well as identify periods of hypoglycemia which can be useful in helping users to achieve their glycemic goals.

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DEFINITIONS/ACRONYMS:

CGM (Continuous glucose monitor): A device that regularly measures glucose levels in the wearer consistently over time.

HbA1c (Hemoglobin A1c): Glycated hemoglobin reflects average levels of blood glucose over the prior 3 months.

DECISION GUIDELINES:

Clinical Coverage Criteria:

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.

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations, contractual requirements, and uses InterQual Smart Sheets, when available, to review prior authorization requests for medical necessity. This MNG applies unless a less restrictive and applicable CMS National Coverage Determination (NCD), Local Coverage Determination (LCD), or state-specific medical necessity guideline exists.

Clinical Coverage Criteria:

SENIOR CARE OPTIONS AND ONE CARE

A. Initial: Therapeutic CGMs and related supplies are covered when coverage either criteria 1, 2, and 3 are met or if criteria 4 is met:

1. The beneficiary has diabetes mellitus diagnosis; AND,

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; AND

3. One of the following:
    a) Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control; OR

    b) Clinical documentation by the provider ordering practitioner of the supporting rationale for the requested device (insulin pump or CGM) must show that the member's blood sugar remains poorly controlled despite appropriate adjustments to a physician-ordered and physician-monitored treatment

plan based on previous self-monitoring. Specifically, documentation of medical necessity must include all of the following:

i. Documentation that indicates that the member remains compliant with the insulin therapy recommended by a practitioner for at least 3 months. Exceptions: Providers may request and exception to the compliance requirement due to co-morbidities that inhibit the ability to self-monitor blood sugar or self-administer insulin. Requests for exceptions will be considered on a case-by-case basis; AND

ii. Documentation that indicates the member's HbA1C level(s) (at least 2 readings representing at least 6 months); AND

iii. Documentation demonstrating that the Member meets at least one of the following:
   1. HbA1c ≥7% or at a value that does not meet documented target treatment; OR
   2. Frequent hypoglycemia or nocturnal hypoglycemia; OR
   3. History of hypoglycemic unawareness; OR
   4. Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL; OR
   5. History of emergency room visit, or hospitalization related to ketoacidosis or hypoglycemia; OR
   6. Use of a compatible insulin pump to achieve glycemic control; OR
   7. Pregnancy.

OR

4. The member has another non-diabetes-based condition causing disorder of glucose metabolism or improper endogenous insulin secretion resulting in frequent hypoglycemia or nocturnal hypoglycemia or hypoglycemic unawareness. Such disorders may include, but are not limited to, seizure disorder, insulinoma, genetic conditions causing hyperinsulinemia, effects from post-surgical conditions including post esophagectomy, post fundoplication, post gastrectomy, post gastric bypass, and post sleeve gastrectomy. Such cases should speak to hypoglycemic risk and events and will be reviewed on a case-by-case basis.

B. Continued Use: Continuation of CGM use is considered medically necessary if any of the following criteria are met:

1. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person or virtual visit with the Member to assess adherence to their CGM regimen and diabetes treatment plan; or
2. There is objective documented evidence of improvement in control of diabetes (specific to baseline status of disease for individual Members); or
3. There is documented evidence of compliance with a current CGM treatment plan based on log data of the device; or
4. If a member is new to CCA One Care or Senior Care Options from another insurer and is stable on a CGM.

MEDICARE ADVANTAGE

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

AUTHORIZATION:

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).

1. Prior authorization is required for initial and continued use CGM requests.
2. All CGM prior authorization submissions must include the following:
    a. Standardized Prior Authorization Request Form
    b. Prescription
    c. Medical documentation demonstrating the medical necessity requirements outlined above.

LIMITATIONS/EXCLUSIONS:

1. If any of the above coverage clinical criteria is not met, the CGM and related supply allowance will be denied as not reasonable and necessary.
2. When a therapeutic CGM (code E2103) is covered, the related supply allowance (code A4239) is also covered.

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:

1. MassHealth Guidelines for Medical Necessity Determination for Diabetes Management Devices: Continuous Glucose Monitoring Systems and Insulin Pumps. Version July 22, 2022.
2. Local Coverage Determination L33822 Glucose Monitors. Noridian Healthcare Solutions, LLC. Original effective date 10/1/2015, revision effective date 2/28/2022.
3. Local Coverage Article A52464 Glucose Monitor. Noridian Healthcare Solutions, LLC. Original effective date 10/1/2015, revision effective date 2/28/2022.

Disclaimer

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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:

1. MassHealth Guidelines for Medical Necessity Determination for Diabetes Management Devices: Continuous Glucose Monitoring Systems and Insulin Pumps. Version July 22, 2022. https://www.mass.gov/guides/masshealth-guidelines-for-medical-necessity-determination-for-diabetes-management
2. Local Coverage Determination L33822 Glucose Monitors. Noridian Healthcare Solutions, LLC. Original effective date 10/1/2015, revision effective date 2/28/2022. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822&ver=41&keywordtype=starts&keyword=glucose&bc=0
3. Local Coverage Article A52464 Glucose Monitor. Noridian Healthcare Solutions, LLC. Original effective date 10/1/2015, revision effective date 2/28/2022. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464&ver=38
4. American Diabetes Association. Standards of Medical Care in Diabetes – 2022 Abridged for Primary Care Providers. Clin Diabetes. 40(1); 10-38.
5. Longo S and Sperling S. Personal Versus Professional Continuous Glucose Monitoring: When to Use Which on Whom. Diabetes Spectr 2019;32(3):183-193

ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION

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APPROVALS:

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