

**Continuous Glucose Monitoring
 DME-006**

Iowa Medicaid Program:	Prior Authorization	Effective Date:	2/12/2015
Revision Number:	12	Last Rev Date:	1/19/2024
Reviewed By:	Medicaid Medical Director	Next Rev Date:	1/17/2025
Approved By:	Medicaid Clinical Advisory Committee	Approved Date:	11/2/2020

Descriptive Narrative

Continuous glucose monitoring (CGM) measures interstitial glucose, which correlates well with plasma glucose. There are two basic types of CGM devices: those that provide unblinded data to the member and those that are blinded with data available to the member and their healthcare provider for retrospective analysis. For devices that provide the member unblinded data, most of the published randomized controlled trials (RCTs) have been performed using real-time CGM devices that have alarms and alerts. It is difficult to determine how much impact having these notices makes in terms of reacting to glucose levels. There is one small study in patients at risk for hypoglycemia that compares real-time CGM with intermittently scanned CGM. The study showed improvement in time spent in hypoglycemia with real-time CGM. Some real-time systems require calibration by the user, which varies in frequency depending on the device. Additionally, for some CGM systems, the FDA suggests SMBG (self-monitoring blood glucose) for making treatment decisions. Devices that require SMBG confirmation are called “adjunctive” while those that do not are called “nonadjunctive.” An RCT of 226 adults suggested that a CGM device could be used safely and effectively without regular confirmatory SMBG in members with well-controlled type 1 diabetes at low risk of severe hypoglycemia. Two CGM devices are approved by the FDA for making treatment decisions without SMBG calibration or confirmation.

GM is an FDA-approved device with three components (transmitter, receiver, and sensors) used by placement of a subcutaneous sensor, that continuously monitors and records glucose levels obtained from interstitial fluid. Real-time readings allow the member to monitor alerts indicating glucose issues and take immediate corrective action. This device does not replace fingerstick readings.

If approved, CGM is expected to be used continuously, for at least 6 days a week during most weeks.

Criteria

Prior authorization is required.

A CGM device is medically necessary when **ONE** of the following is met:

1. Member has a diagnosis of Type 1 or Type 2 diabetes mellitus and **ALL** the following are met:
 - a. Requires the use of insulin daily or are on an insulin pump; **AND**
 - b. The member (or their caretaker) has demonstrated the ability to use such a device and analyze the data to make adjustments; **AND**
 - c. Treatment guidelines have been provided to the member (or their caretaker) that allows them to safely and effectively take advantage of the information provided by the device; **AND**
 - d. The member has **ONE** of the following:
 - 1) Experiencing reoccurring episodes of hypoglycemia; **OR**
 - 2) Inadequate glycemic control, as demonstrated by HbA1c measurements 7.0% or greater, despite multiple alterations in self-monitoring and insulin administration regimens to optimize care; **OR**
 - 3) Type 1 diabetes and 18 years of age or younger; **OR**
2. Member has a diagnosis of gestational diabetes or any type of diabetes in pregnancy and **ALL** the following are met:
 - a. The member (or their caretaker) has demonstrated the ability to use such a device and analyze the data to make adjustments; **AND**
 - b. Treatment guidelines have been provided to the member (or their caretaker) that allows them to safely and effectively take advantage of the information provided by the device.

For members who are approved under criterion #2, continued approval for use of the device would default back to criterion #1.

These criteria refer to outpatient chronic interstitial real-time CGM. They do not include acute CGM in a hospital setting. Only long-term use is approved for coverage. CGM is not covered for convenience of the member, provider, or caretaker.

Coding

The following list of codes is provided 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, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service.
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver.

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

EncoderPro Optum 360.

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analysis of randomized clinical trials. Diabetes Medicine. 2022 Jan;39(1):e14703. doi: 10.1111/dme.14703. Epub 2021 Oct 13. PMID: 34564868.

Chang VYX, Tan YL, Ang WHD, Lau Y. Effects of continuous glucose monitoring on maternal and neonatal outcomes in perinatal women with diabetes: A systematic review and meta-analysis of randomized controlled trials. Diabetes Res Clin Practice. 2022 Feb;184:109192. doi: 10.1016/j.diabres.2022.109192. Epub 2022 Jan 12. PMID: 35032563.


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Murphy, HR, et al. Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomized clinical trial. BMJ. 2008 Sep 25;337:a1680. doi: 10.1136/bmj.a1680.

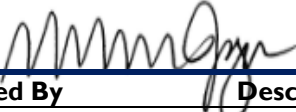

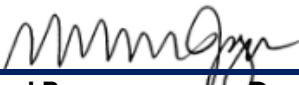

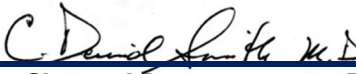

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Grunberger G, Sherr J, et al. American Association of Clinical Endocrinology Clinical Practice Guidelines: The Use of Advanced Technology in the Management of Persons with Diabetes. AACE. Endocrine Practice 27 (2021) 505e537.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History			
Change Date	Changed By	Description of Change	Version
Signature			
Change Date	Changed By	Description of Change	Version
Signature			
Change Date	Changed By	Description of Change	Version
1/19/2024	CAC	Revised Criteria – Removed multiple doses of insulin daily from criterion 1a. Added criterion #2 for gestational diabetes. Revised Code section. Updated References.	12
Signature			
William (Bill) Jagiello, DO 			

Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
10/20/2023	CAC	Revised Criteria. References updated..	11
Signature William (Bill) Jagiello, DO 			
Change Date	Changed By	Description of Change	Version
7/15/2022	CAC	Changed frequency requirement – criterion #2. Added references to support this change.	10
Signature William (Bill) Jagiello, DO 			
Change Date	Changed By	Description of Change	Version
10/15/2021	CAC	Annual review.	9
Signature William (Bill) Jagiello, DO 			
Change Date	Changed By	Description of Change	Version
9/9/2020	CAC	Added Descriptive Narrative. Updated criteria. Updated references.	8
Signature William (Bill) Jagiello, DO 			
Change Date	Changed By	Description of Change	Version
1/20/2017	CAC	Removed criterion #2 regarding PRN and over-the-counter medications.	7
Signature C. David Smith, MD  William (Bill) Jagiello, DO 			
Change Date	Changed By	Description of Change	Version
1/15/2016	CAC	Added #4 under telephone monitoring. Remove paragraph regarding investigational and non-coverage of artificial pancreas units (CGM and insulin pump therapies).	6
Signature			
Change Date	Changed By	Description of Change	Version
1/16/2015	CAC	Added last paragraph in References.	5
Signature			
Change Date	Changed By	Description of Change	Version
12/12/2013	Medical Director	Formatting changes.	4
Signature			
Change Date	Changed By	Description of Change	Version
4/26/2013	Medical Director	Definitions of automated medication dispenser and telephone monitoring added.	3
Signature			

Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
4/19/2013	CAC	Criterion #2 - removed "and requires medication administration more than once per day".	2

Signature

Change Date	Changed By	Description of Change	Version
10/19/2012	CAC	Criterion #2 - remove "two or more prescribed medications".	1

Signature