

MEDICAL POLICY

POLICY TITLE	CONTINUOUS GLUCOSE MONITORING (CGM)
POLICY NUMBER	MP-6.004
Effective Date:	8/1/2023

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I. POLICY

Short-term or long-term use with an FDA approved Continuous Glucose Monitor System (CGM) may be considered **medically necessary** when ONE of the following is met:

- The member’s medication history includes use of a rapid acting insulin, regular insulin, or basal insulin within the past 90 days: **OR**
- Information has been provided that the member is currently being treated with the requested CGM within the past 90 days.

All other uses for short-term or long-term interstitial CGMs are considered **not medically necessary** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Non-invasive CGMs are considered **investigational** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Several insulin pump systems have a built-in CGM. This policy is evaluating the CGM-device only; the policy does not evaluate insulin pumps (see MP 6.007).

CGM includes real-time devices (i.e., Dexcom G6, FreeStyle Libre 3, Eversense® E3 implantable CGM, Medtronic Guardian™ 3) and intermittently scanned devices (i.e., FreeStyle Libre, FreeStyle Libre 2).

CGM sensors may have interference from certain medications which can result in inaccurate sensor glucose readings. Providers should thoroughly assess each person’s medication list and recommend devices best suited for each individual.

Cross-reference:

- MP 6.007** External Infusion Pumps for Insulin Delivery
- MP 6.026** Durable Medical Equipment (DME) and Supplies

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy Manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

III. DESCRIPTION/BACKGROUND

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Glucose measurements are critical to effective diabetes management. While measurement of glycated hemoglobin (HbA_{1c}) has been the traditional method for assessing glycemic control, it does not reflect intra- and inter day glycemic excursions that may lead to acute events (such as hypoglycemia) or postprandial hyperglycemia. These events have been linked to both microvascular and macrovascular complications. While self-monitoring of blood glucose (SMBG) has been shown to improve glycemic control and quality of life in patients, it cannot predict impending hypoglycemia or alert for hypoglycemia. Real-time continuous glucose monitoring (rtCGM) and intermittently viewed CGM (iCGM) address many of the limitations inherent in HcA_{1c} testing and SMBG. rtCGM uniformly tracks the glucose concentrations in the body's interstitial fluid, providing near real-time glucose data; iCGM uses similar methodology to show continuous glucose measurements retrospectively at the time of checking. Both rtCGM and iCGM facilitate monitoring of time spent in the target glucose range ("time in range"). However, only rtCGM can warn users if glucose is trending toward hypoglycemia or hyperglycemia. With iCGM, these trends can only be viewed after physically scanning the sensor.

CGM affords 2 major benefits over the current standard of SMBG coupled with A_{1c} testing: first, a vast increase in the quantity of blood glucose information, which provides a more comprehensive view of glycemic control. Rather than snapshots in time, continuous information allows us to capture important metrics like time in range, time in hypoglycemia, glucose variability, and many other emerging "glycometrics." These additional metrics cannot be captured with SMBG, even in the most diligent patients. A CGM recording blood glucose every 5 minutes will record 105,120 BG readings per year compared with between just 1000 to 2000 for a person doing frequent SMBG.

Second is the ability of CGM systems to provide real-time biofeedback. With real-time data now seamlessly available on a user's mobile device and the internet, easily visible trends and trajectories can help a person understand their own glycemic response in a more meaningful way. Patients can observe which foods and exercises affect them the most. Iterative exposure to this immediate biofeedback allows patients to learn about their own bodies and physiologic responses.

High costs and uncertainty over efficacy and necessity have kept CGM from widespread use in people with type 2 diabetes. However, the newest CGM models, the Abbott Freestyle Libre and

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Dexcom G6, have begun to overcome many of these technical barriers to use of CGM systems. The sensors are inserted painlessly, are small enough to fit easily under clothing, can remain in place for 10 to 14 days, and are FDA approved as sufficiently accurate to use in lieu of fingersticks to make insulin-dosing decisions. Overcoming another significant barrier to use, data can now be seamlessly and continuously uploaded wirelessly to the cloud via a user’s smartphone. When prescribing CGM devices, robust diabetes education, training, and support are required for optimal CGM device implementation and ongoing use.

There is currently one FDA approved implantable CGM (i.e., Eversense®). The sensor is inserted by a trained health care provider in the upper arm and continuously measures glucose for up to 6 months. The Smart Transmitter, which is worn over the sensor, wirelessly sends data to the user’s mobile device. The transmitter is removable and rechargeable and provides unique on-body vibration alerts.

IV. RATIONALE

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Numerous studies have shown that use of rtCGM improves glycemic control and quality of life in both children and adults with type 1 diabetes treated with either continuous subcutaneous insulin infusion or multiple daily insulin injection therapy, improving HbA1c, shortening the time spent in hypoglycemia and hyperglycemia, and reducing moderate-to-severe hypoglycemia. Benefits of rtCGM use have also been reported in individuals with type 2 diabetes who are managed with or without intensive insulin treatment. There is limited data regarding the benefit of rtCGM as an outcome measure for individuals with gestational diabetes mellitus and type 2 diabetes, especially for those who do not use insulin. The benefit of rtCGM is directly correlated to persistence and frequency of use. A meta-analysis found that every 1-day increase of sensor usage per week increased the effect of CGM; the effect on HbA1c is more pronounced the higher the initial HbA1c. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

V. DEFINITIONS

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HEMOGLOBIN A1C is a lab test that measures mean plasma glucose levels over the preceding three (3) months. It is recorded in percentages and is generally performed at least twice a year unless patient’s self-monitored blood sugar levels are at uncontrollable ranges. Hemoglobin A_{1c} levels less than seven percent (7%) signify excellent glycemic control. Levels greater than seven and one-half percent (7.5%) are indicative of chronically elevated blood sugars and indicate the need for improved glycemic control.

INTERSTITIAL refers to spaces between a tissue and an organ.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member’s health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of

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benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational or Not Medically Necessary; therefore, not covered:

Procedure Codes								
S1030	S1031							

Covered when medically necessary:

Procedure Codes								
A4238	A4239	A9276	A9277	A9278	E2102	E2103	95249	95250
95251	0446T	0447T	0448T					

Note: Covered for a diagnosis of diabetes when the above criteria is met.

IX. REFERENCES

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X. POLICY HISTORY

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MP-6.004	6/18/18 Minor review. Policy Guidelines for CGM updated to contain a list of FDA approved devices. Policy statement added for artificial pancreas device that use of a hybrid closed loop insulin delivery system is considered investigational. Rational and references updated, and coding reviewed.
	3/22/19 Administrative update. FDA approved devices list now includes Dexcom ® G6.
	3/19/19 Minor review. Further clarification for the difference between short- and long-term monitoring. Note added that CGM and Artificial Pancreas devices need to be FDA approved, individual products removed. Added statement that no more than two instances of physician interpretation outside the office setting are covered per year.
	07/01/2020 Minor review. Added Type 2 diabetes as an indication for long term continuous glucose monitoring. Background, Rationale, References updated. Coding reviewed. Effective 7/1/2020.
	3/10/2021: Minor review. Moved note at top of policy and placed in artificial pancreas section. Took Replacement Criteria from Policy Guidelines section and placed in Policy Statement. Updated Rationale. Updated FEP and references.

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<p>3/15/2021 Added the following statement to policy guidelines: CGM sensors may have interference from certain medications which can result in inaccurate sensor glucose readings. Providers should thoroughly assess each person’s medication list and recommend devices best suited for each individual.</p>
<p>3/11/2022 Administrative review. Added HCPCS A4238 and E2102. Effective date 4/1/2022.</p>
<p>6/10/2022 Minor review. Modified criteria for CGM. Implantable CGM is now NMN. Added INV statement for non-invasive CGM. Added a note re: CGM monitoring. Moved Artificial Pancreas to MP 6.007. Changed title of policy. Updated FEP, background, rationale, coding, and references.</p>
<p>11/29/2022 Administrative update. Added procedure codes A4239 & E2103. Removed K0553, K0554, G0308 & G0309</p>
<p>1/13/2023 Minor review. Expanded criteria to include basal insulin. Implantable CGM is now MN and grouped as part of FDA approved CGMs. Updated policy guidelines, background, rationale, coding table, and references.</p>

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