MEDICAL POLICY

POLICY TITLE	**CONTINUOUS GLUCOSE MONITORING (CGM)**
POLICY NUMBER	**MP 6.004**

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**4/1/2025**

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 (e.g., Dexcom G6, FreeStyle Libre 3, Eversense® E3 implantable CGM, Medtronic Guardian™ 3) and intermittently scanned devices (e.g., FreeStyle Libre, FreeStyle Libre 2).

Cross-Reference:

MP 6.007 External Infusion Pumps for Insulin Delivery and Automated Insulin Delivery Systems

POLICY TITLE	CONTINUOUS GLUCOSE MONITORING (CGM)
POLICY NUMBER	MP 6.004

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.

Regulatory Status

Multiple CGM systems have been approved or cleared by the FDA (see Table 1). FDA product codes: [PMA] QCD, MDS, PQF; [510(k)] QBJ, QLG.

CGM devices labeled as "Pro" for specific professional use with customized software and transmission to health care professionals are not enumerated in this list.

The Flash glucose monitors (e.g. FreeStyle Libre, Abbott) use intermittent scanning. The current version of the FreeStyle Libre device includes real-time alerts, in contrast to earlier versions without this feature.

Table 1. CGM Systems Approved by the U.S. Food and Drug Administration

Device	Manufacturer	Approval or Clearance	Indications
Continuous Glucose Monitoring System (CGMS®)	MiniMed (now Medtronic)	1999	3-d use in physician's office
GlucoWatch G2® Biographer		2001	Not available since 2008
Guardian®-RT (Real-Time) CGMS	MiniMed (now Medtronic)	2005	
Dexcom® STS CGMS system	Dexcom	2006	
Paradigm® REAL-Time System (second-generation called Paradigm Revel System)	MiniMed (now Medtronic)	2006	Integrates CGM with a Paradigm insulin pump
FreeStyle Navigator® CGM System	Abbott	2008	
Dexcom® G4 Platinum	Dexcom	2012	Adults ≥ 18 y; can be worn for up to 7 d
		2014	Expanded to include patients with diabetes 2-17 y
Dexcom® G5 Mobile CGM	Dexcom	2016[a]	Replacement for fingerstick blood glucose testing in patients ≥2 y. System

Device	Manufacturer	Approval or Clearance	Indications
			requires at least 2 daily fingerstick tests for calibration purposes, but additional fingersticks are not necessary because treatment decisions can be made based on device readings
Dexcom® G6 Continuous Glucose Monitoring System	Dexcom	2018	Children, adolescents, and adults > 2 years; indicated for the management of diabetes in persons age ≥2 years. Intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems with 10-day wear
Freestyle Libre® Flash Glucose Monitoring System	Abbott	2017	Adults ≥18 y. Indicated for the management of diabetes and can be worn up to 10 days It is designed to replace blood glucose testing for diabetes treatment decisions.

Device	Manufacturer	Approval or Clearance	Indications
		2018	Adults ≥18 y. Extended duration of use to 14 days
Freestyle Libre® 2 Flash Glucose Monitoring System	Abbott	2020	Children, adolescents, and adults >2 years, including pregnant women
Guardian Connect	Medtronic MiniMed	2018	Adolescents and adults (14-75 years) Continuous or periodic monitoring of interstitial glucose levels. Provides real-time glucose values, trends, and alerts through a Guardian Connect app installed on a compatible consumer electronic mobile device
Eversense Continuous Glucose Monitoring System	Senseonics	2018/2019	Adults ≥18 y. Continually measuring glucose levels up to 90 days. Use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. Adults ≥18 y. Continually measuring glucose levels up to 90 days. Indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions. Historical

Device	Manufacturer	Approval or Clearance	Indications
			data from the system can be interpreted to aid in providing therapy adjustments.
Eversense E3 Continuous Glucose Monitoring System	Senseonics	2022	Adults ≥18 y. Continually measuring glucose levels up to 180 days. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions. The system is intended to provide real-time glucose readings, provide glucose trend information, and provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time.
FreeStyle Libre® 3 Continuous Glucose Monitoring System	Abbott	2022	Children, adolescents, and adults >2 years,

Device	Manufacturer	Approval or Clearance	Indications
			including pregnant women
Dexcom® G7 Continuous Glucose Monitoring System	Dexcom	2022	Children, adolescents, and adults >2 years, including pregnant women

CGM: continuous glucose monitoring.
[a] As a supplement to the G4 premarketing approval.

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 are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. 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' medical policies are developed to assist in administering a member's benefits. These medical policies 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; therefore, not covered:

Procedure Codes								
S1030	S1031							

Covered when medically necessary:

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

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

IX. REFERENCES

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X. POLICY HISTORY

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MP 6.004	**06/18/2018 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.
	03/22/2019 Administrative Update. FDA approved devices list now includes Dexcom ® G6.
	03/19/2019 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 07/01/2020.
	03/10/2021 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.
	03/15/2021 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.
	03/11/2022 Administrative Update. Added HCPCS A4238 and E2102. Effective date 04/01/2022.
	06/10/2022 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.
	11/29/2022 Administrative Update. Added procedure codes A4239 & E2103. Removed K0553, K0554, G0308 & G0309
	01/13/2023 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.
	03/14/2024 Consensus Review. Updated background and references. No changes to coding.
	12/11/2024 Administrative Update. Added codes G0564-5 effective 01/01/2025.
	03/11/2025 Administrative Update. Deleted codes G0564 & G0565 Effective 04/01/2025

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