Continuous Glucose Monitoring (CGM) Systems Prior Authorization Criteria - Medicare Part B

This program applies to Capital Blue Cross

The preferred agents for the CGM program are:
Dexcom G6, Dexcom G7, FreeStyle Libre, FreeStyle Libre 2, and FreeStyle Libre 3

PA applies to nonpreferred products only

Requirement of ONE preferred CGM system (Dexcom OR FreeStyle) before a non-preferred CGM.

Continuous Glucose Monitors

Agent(s)
Dexcom G6® CGM System
Dexcom G7® CGM System
FreeStyle Libre®
FreeStyle Libre 2®
FreeStyle Libre 3®
Minimed Enlite®
Minimed Guardian™, Guardian™ Pediatric
Minimed™ 630G
Minimed Minilink®
Minimed Paradigm®

CLINICAL RATIONALE

Glucose measurements are critical to effective diabetes management. While measurement of glycated hemoglobin (HbA1c) has been the traditional method for assessing glycemic control, it does not reflect intra- and interday 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 HcA1c 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.[1]

CGM affords 2 major benefits over the current standard of SMBG coupled with A1c 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.[2]

The American Diabetes Association (ADA) guidelines recommend that rtCGM should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely. The use of CGM and blood glucose monitoring (BGM) devices should be considered from the outset of the diagnosis of diabetes that requires insulin management. The choice of CGM device should be made based on the individual's circumstances, preferences, and needs. CGM use allows for close tracking of glucose levels with adjustments of insulin dosing and lifestyle modifications and removes the burden of frequent BGM. In addition, early CGM initiation after diagnosis of type 1 diabetes in youth has been shown to decrease A1C levels and is associated with high parental satisfaction and reliance on this technology for diabetes management. According to the ADA, the evidence is insufficient regarding when to prescribe BGM and how often monitoring is needed for insulin-treated people with diabetes who do not use intensive insulin therapy, such as those with type 2 diabetes taking basal insulin with or without oral agents and/or noninsulin injectables. However, for those taking basal insulin, assessing fasting glucose with BGM to inform dose adjustments to achieve blood glucose goals results in lower A1C levels.[3]

REFERENCES

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2. Kompala T, and Neinstein A. "A New Era: Increasing Continuous Glucose Monitoring Use in Type 2 Diabetes". Evidence-based Diabetes Management. March 2019, Volume 25, Issue 4. Available at: https://www.ajmc.com/view/a-new-era-increasing-continuous-glucose-monitoring-use-in-type-2-diabetes.
3. ElSayed NA, McCoy RG, Aleppo G, et al. 7. Diabetes Technology: Standards of Care in Diabetes—2025. Diabetes Care. 2024;48(Supplement 1):S146-S166. doi:10.2337/dc25-s007.

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Continuing Glucose Monitoring (CGM) Systems Prior Authorization Criteria – Medicare Part B

OBJECTIVE

The intent of the CGM Prior Authorization (PA) Program is to determine if the requested CGM is reasonable and medically necessary in alignment with the coverage criteria provided in Local Coverage Determination (LCD) Glucose Monitors L33822 and Local Coverage Article (LCA): Glucose Monitor – Policy Article A52464.

TARGET AGENT(S)

Brand (generic)	GPI	Multisource Code
Continuous Blood Glucose Monitoring (CGM) Systems		
Dexcom G6 receiver	97202012026200	M, N, O, or Y
Dexcom G6 transmitter	97202012066300	M, N, O, or Y
Dexcom G6 sensor	97202012046300	M, N, O, or Y
Dexcom G7 receiver	97202012026200	M, N, O, or Y
Dexcom G7 sensor	97202012046300	M, N, O, or Y
Enlite Glucose sensor	97202012046300	M, N, O, or Y
FreeStyle Libre reader	97202012026200	M, N, O, or Y
FreeStyle Libre sensor	97202012046300	M, N, O, or Y
FreeStyle Libre 2 Reader	97202012026200	M, N, O, or Y
FreeStyle Libre 2 Sensor	97202012046300	M, N, O, or Y
FreeStyle Libre 2 Plus Sensor	97202012046300	M, N, O, or Y
FreeStyle Libre 3 Reader	97202012026200	M, N, O, or Y
FreeStyle Libre 3 Sensor	97202012046300	M, N, O, or Y
FreeStyle Libre 3 Plus Sensor	97202012046300	M, N, O, or Y
Guardian Link 3 transmitter	97202012066300	M, N, O, or Y
Guardian Real-Time, Real-Time Pediatric replacement monitor	97202012026200	M, N, O, or Y
Guardian Sensor 3	97202012046300	M, N, O, or Y
Guardian 4 sensor	97202012046300	M, N, O, or Y
Guardian 4 transmitter kit	97202012066300	M, N, O, or Y
Minilink Real Time transmitter	97202012066300	M, N, O, or Y
Minimed 630G Guardian Press Starter transmitter kit	97202012066300	M, N, O, or Y
Paradigm Real-Time transmitter	97202012066300	M, N, O, or Y
Simplera Sync Sensor	97202012046300	M, N, O, or Y

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Evaluation

Target CGM Agent(s) will be approved when ALL of the following are met:

1. The beneficiary has diabetes mellitus
   AND
2. ONE of the following:
   A. The beneficiary is insulin treated

OR

B. The beneficiary has non-insulin treated diabetes AND ONE of the following:
    i. A history of recurrent (more than one) level 2 hypoglycemic events AND documentation of BOTH of the following:
        a At least ONE of the following:
            1. The glucose values for the qualifying event(s) [glucose less than 54 mg/dL (3.0 mmol/L)]
            OR
            2. Classification of the hypoglycemic episode(s) as level 2 event(s)
            OR
            3. Incorporate a copy of the beneficiary's BGM testing log into the medical record reflecting the specific qualifying events [glucose less than 54 mg/dL (3.0 mmol/L)]

        AND

        b Documentation of more than one previous medication adjustment and/or modification to the treatment plan (such as raising A1c targets) prior to the most recent level two event

    OR

    ii. A history of at least one level 3 hypoglycemic events characterized by altered mental and/or physical state AND documentation of BOTH of the following:
        a At least ONE of the following:
            1. The glucose values for the qualifying event(s) [glucose less than 54 mg/dL (3.0 mmol/L)]
            OR
            2. Classification of the hypoglycemic episode(s) as level 3 event(s)
            OR
            3. Incorporate a copy of the beneficiary's BGM testing log into the medical record reflecting the specific qualifying event [glucose less than 54 mg/dL (3.0 mmol/L)]

        AND

        b An indication that the beneficiary required third party assistance for treatment of hypoglycemia

AND

3. ONE of the following:
    A. The prescriber has indicated that the beneficiary had an in-person visit or telehealth visit to evaluate their diabetes condition within six (6) months prior to ordering the CGM and determined that criteria (1-2) above are met
    OR
    B. If previously approved through the plan's Prior Authorization criteria, the prescriber has indicated the beneficiary has had an in-person visit or telehealth visit to determine that the beneficiary continues to adhere to their diabetes treatment regimen and use of the CGM device

AND

4. ONE of the following:
    A. The requested CGM is a preferred CGM (as determined by client)

OR

B. The prescriber has indicated the beneficiary has failed or has limitations of use of the preferred CGM

Length of Approval: 12 months

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.