# Congress Must Protect Medicare Beneficiaries Access to Continue Glucose Monitors After the Public Health Emergency

**July 2022**

## OVERVIEW

**Congress needs to take action to protect Medicare beneficiaries who received continuous glucose monitors (CGMs) during the COVID-19 Public Health Emergency (PHE).**

- During the pandemic, the number of beneficiaries who benefited from CGM increased substantially. From January 2019 to December 2021, Medicare coverage for CGMs increased by 62%.[1]
- During the pandemic, the Centers for Medicare and Medicaid Services (CMS) waived clinical coverage criteria to ensure beneficiaries received the therapy they needed.
- Once the PHE ends, it will be important to streamline the coverage criteria and documentation requirements to ensure these beneficiaries continue to receive needed monitoring and therapy.
- **AAHomecare recommends that CMS allow these patients to continue utilizing their CGM devices as long as they qualify with the on-going LCD requirements. This will allow these beneficiaries to continue to receive necessary CGM supplies post-PHE without having to have met the clinical indications for initial coverage of the CGM device itself.**

Medicare began to provide coverage for CGM systems in 2017 as long as the device is classified as therapeutic, meaning beneficiaries can use these devices to make treatment decisions, which means using the CGM to modify the beneficiary's exercise regimen, diet, or insulin dosage. During the PHE, CMS **relaxed Medicare's clinical coverage criteria**. Prior to the PHE, Medicare coverage of CGM devices was limited to beneficiaries who met the following requirements:

- Have a diagnosis of either type 1 or type 2 diabetes,
- Use a traditional blood glucose meter and test blood sugar levels four or more times a day,
- Treated with insulin injections or insulin pump,
- Require frequent adjustments to their insulin regimen, and
- Have an in-person visit with a doctor to evaluate glycemic control and whether they meet the above criteria, as well as follow up appointments every 6 months after initial order.

**What has changed?** No longer are insulin injections the only acceptable form of insulin administration for those who are covered. Now, people with **diabetes who are treated with inhaled insulin will be eligible for coverage.** Additionally, **the requirement for self-testing up to four or more times a day with a fingerstick test has been removed,** so patients who test less frequently may also be eligible.

## THE ASK

**AAHomecare recommends that CMS allow these patients to continue to receive the benefit without having to "requalify." Congress should work with CMS to ensure CGM beneficiaries continue to be allowed to use this vital tool to fight diabetes.**

[1] Medicare Claims Data retrieved via Freedom of Information Act request. 2019 and 201 Sum of Claim Lines Allowed comparison for Healthcare Common Procedure Coding System code K0554.

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# Medicare Coverage Criteria for Continuous Glucose Monitors as Written in the Local Coverage Determination: Glucose Monitors (L33822)

***CONTINUOUS GLUCOSE MONITORS (CGM) BACKGROUND INFORMATION***

*The general term CGM refers to both therapeutic/non-adjunctive and non-therapeutic/adjunctive CGMs. For the purpose of this Local Coverage Determination (LCD), the term "therapeutic" may be used interchangeably with the term "non-adjunctive." Likewise, the term "non-therapeutic" may be used interchangeably with the term "adjunctive."*

*A therapeutic or non-adjunctive CGM can be used to make treatment decisions without the need for a stand-alone BGM to confirm testing results. A non-therapeutic or adjunctive CGM requires the user verify their glucose levels or trends displayed on a CGM with a BGM prior to making treatment decisions. On February 28, 2022, CMS determined that both therapeutic/non-adjunctive and non-therapeutic/adjunctive CGMs may be classified as DME.*

*Additional information regarding classification of CGMs as DME can be found in the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES and CODING GUIDELINES sections in the LCD-related Policy Article.*

*To be eligible for coverage of a CGM and related supplies, the beneficiary must meet all of the following coverage criteria (1)-(5):*

- *The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,*
- *The beneficiary is insulin-treated with multiple (three or more) daily administrations of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,*
- *The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results; and,*
- *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 and determined that criteria (1-3) above are met; and,*
- *Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan.*

*When a CGM (HCPCS code K0554 or E2102) is covered, the related supply allowance (HCPCS code K0553 or A4238) is also covered. Supplies (HCPCS code A4238) for an adjunctive CGM integrated into an external insulin infusion pump are covered when the beneficiary meets both the CGM coverage criteria and the coverage criteria for an external insulin infusion pump. Refer to the External Infusion Pumps LCD (L33794) for additional information regarding billing a CGM receiver incorporated into an insulin infusion pump.*

*If any of coverage criteria (1-5) are not met, the CGM and related supply allowance will be denied as not reasonable and necessary.*

*The supply allowance (HCPCS code K0553 or A4238) is billed as one (1) unit of service (UOS) per thirty (30) days. Only one (1) UOS of HCPCS code K0553 or A4238 may be billed to the DME MACs at a time. Billing more than one (1) UOS per thirty (30) days of HCPCS code K0553 or A4238 will be denied as not reasonable and necessary. Refer to the CODING GUIDELINES section in the LCD-related Policy Article for additional billing instructions.*

*Non-adjunctive CGM devices replace standard home BGMs (HCPCS codes E0607, E2100, E2101) and related supplies (HCPCS codes A4233, A4234, A4235, A4236, A4244, A4245, A4246, A4247, A4250, A4253, A4255, A4256, A4257, A4258, A4259). Claims for a BGM and related supplies, billed in addition to a non-adjunctive CGM device (code K0554) and associated supply allowance (code K0553), will be denied.*

*Adjunctive CGM devices do not replace a standard home BGM. The supply allowance for an adjunctive CGM (HCPCS A4238) encompasses all items necessary for the use of the device and includes but is not limited to, CGM sensors and transmitters. HCPCS code A4238 does not include a home BGM and related BGM testing supplies. These items may be billed separately, in addition to HCPCS code A4238. Refer to the CODING GUIDELINES section in the LCD-related Policy Article for additional information.*

*All CGM devices billed to Medicare using HCPCS code K0554 must be reviewed for correct coding by the Pricing, Data Analysis and Coding (PDAC) contractor and be listed on the Product Classification List (PCL). Effective July 1, 2022, all CGMs billed to Medicare using HCPCS code E2102 must be reviewed for correct coding by the PDAC contractor and be listed on the PCL. If a CGM system is billed using HCPCS code K0554 or E2102 (effective July 1, 2022) but the CGM system is not on the PCL for the particular HCPCS code, then the claim will be denied as incorrect coding. Refer to the CODING GUIDELINES section in the LCD-related Policy Article for additional information.*

***GENERAL***

*A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.*

*For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.*

*For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.*

*An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.*

*Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.*

***REFILL REQUIREMENTS***

*For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.*

*For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.*

*Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the treating practitioner that any changed or atypical utilization is warranted.*

*Regardless of utilization, a supplier must not dispense more than a three (3) month quantity of BGM testing supplies at a time.*

*Refill requirements do not apply to code K0553 or A4238. Only one (1) UOS of HCPCS code K0553 or A4238 may be billed to the DME MACs at a time and no more than a 90-day supply may be dispensed to the beneficiary at a time. Refer to the CODING GUIDELINES section in the LCD-related Policy Article for additional billing instructions.*