Medical Policy Bulletin

Title:
Local Coverage Determination for Glucose Monitors
Policy #:
L33822

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

HOME BLOOD GLUCOSE MONITORS (BGM)

To be eligible for coverage of home blood glucose monitors and related accessories and supplies, the beneficiary must meet both of the following basic criteria (1)-(2):

1. The beneficiary has diabetes (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,
2. The beneficiary's treating practitioner has concluded that the beneficiary (or the beneficiary's caregiver) has sufficient training using the particular device prescribed as evidenced by providing a prescription for the appropriate supplies and frequency of blood glucose testing.

For all glucose monitors and related accessories and supplies, if the basic coverage criteria (1)-(2) are not met, the item(s) will be denied as not reasonable and necessary.

Home blood glucose monitors with special features (HCPCS codes E2100, E2101) are covered when the basic coverage criteria (1)-(2) are met and the treating practitioner certifies that the beneficiary has a severe visual impairment (i.e., best corrected visual acuity of 20/200 or worse in both eyes) requiring use of this special monitoring system.

Code E2101 is also covered for those with impairment of manual dexterity when the basic coverage criteria (1)-(2) are met and the treating practitioner certifies that the beneficiary has an impairment of manual dexterity severe enough to require the use of this special monitoring system. Coverage of code E2101 for beneficiaries with manual dexterity impairments is not dependent upon a visual impairment.

If a glucose monitor (code E2100 or E2101) is provided and basic coverage criteria (1)-(2) plus the additional criteria stated above are not met, it will be denied as not reasonable and necessary.

Lancets (code A4259), blood glucose test reagent strips (code A4253), glucose control solutions (code A4256) and spring powered devices for lancets (code A4258) are covered for beneficiaries for whom the glucose monitor is covered.

More than one spring powered device (code A4258) per 6 months is not reasonable and necessary.

The medical necessity for a laser skin piercing device (code E0620) and related lens shield cartridge (code A4257) has not been established; therefore, claims for code E0620 and/or code A4257 will be denied as not reasonable and necessary.

The quantity of test strips (code A4253) and lancets (code A4259) that are covered depends on the usual medical needs of the beneficiary and whether or not the beneficiary is being treated with insulin, regardless of their diagnostic classification as having Type 1 or Type 2 diabetes mellitus. Coverage of testing supplies is based on the following guidelines:

Usual Utilization

For a beneficiary who is not currently being treated with insulin administrations, up to 100 test strips and up to 100 lancets every 3 months are covered if the basic coverage criteria (1)-(2) (above) are met.

For a beneficiary who is currently being treated with insulin administrations, up to 300 test strips and up to 300 lancets every 3 months are covered if basic coverage criteria (1)-(2) (above) are met.

High Utilization

For a beneficiary who is not currently being treated with insulin administrations, more than 100 test strips and more than 100 lancets every 3 months are covered if criteria (a)–(c) below are met.

For a beneficiary who is currently being treated with insulin administrations, more than 300 test strips and more than 300 lancets every 3 months are covered if criteria (a)–(c) below are met.

a. Basic coverage criteria (1)-(2) listed above for all home glucose monitors and related accessories and supplies are met; and,
b. Within the six (6) months prior to ordering quantities of strips and lancets that exceed the utilization guidelines, the treating practitioner has had an in-person visit with the beneficiary to evaluate their diabetes control and their need for the specific quantity of supplies that exceeds the usual utilization amounts described above; and,
c. Every six (6) months, for continued dispensing of quantities of testing supplies that exceed the usual utilization amounts, the treating practitioner must verify adherence to the high utilization testing regimen.

If neither basic coverage criterion (1) or (2) is met, all testing supplies will be denied as not reasonable and necessary. If quantities of test strips or lancets that exceed the utilization guidelines are provided and criteria (a)–(c) are not met, the amount in excess will be denied as not reasonable and necessary.

CONTINUOUS GLUCOSE MONITORS (CGMs)

A non-adjunctive CGM can be used to make treatment decisions without the need for a stand-alone BGM to confirm testing results. An 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 non-adjunctive and adjunctive CGMs may be classified as DME.

Refer to the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES and CODING GUIDELINES sections in the LCD-related Policy Article for additional information regarding classification of CGMs as DME.

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

1. The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,

2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; and,
3. The CGM is prescribed in accordance with its FDA indications for use; and,
4. The beneficiary for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below:

    1.
        A. The beneficiary is insulin-treated; or,
        B. The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section of the LCD-related Policy Article (A52464)):

            - Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
            - A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

    2. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the beneficiary to evaluate their diabetes control and determined that criteria (1)-(4) above are met.

    5. If the beneficiary is eligible for a CGM based upon the aforementioned LCD criteria, the beneficiary MUST have an adequate trial and failure of Dexcom OR FreeStyle Libre Continuous Glucose Monitors prior to trying Medtronic Guardian Sensor 3 and Sensionics Eversense.

CGM Continued Coverage

Every six (6) months following the initial prescription of the CGM, the treating practitioner conducts an in-person or Medicare-approved telehealth visit with the beneficiary to document adherence to their CGM regimen and diabetes treatment plan.

When a CGM (code E2102 or E2103) is covered, the related supply allowance (code A4238 or A4239) is also covered. Supplies (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 the initial coverage criteria (1)-(5), or the continued coverage criterion are not met, the CGM and related supply allowance will be denied as not reasonable and necessary.

The supply allowance (code A4238 or A4239) is billed as one (1) unit of service (UOS) per thirty (30) days. Only one (1) UOS of code A4238 or A4239 may be billed to the DME MACs at a time. Billing more than one (1) UOS per thirty (30) days of code A4238 or A4239 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 E2103) and associated supply allowance (code A4239), will be denied.

Adjunctive CGM devices do not replace a standard home BGM. The supply allowance for an adjunctive CGM (A4238) encompasses all items necessary for the use of the device and includes but is not limited to, CGM sensors and transmitters. Code A4238 does not include a home BGM and related BGM testing supplies. These items may be billed separately, in addition to 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 E2103 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 E2102 or E2103 but the CGM system is not on the PCL for that 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 A4238 or A4239. Only one (1) UOS of code A4238 or A4239 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.

Summary of Evidence

Background

Diabetes mellitus describes diseases of abnormal carbohydrate metabolism characterized by hyperglycemia that are associated with an absolute or relative impairment in insulin secretion, peripheral resistance to the action of insulin, or both. According to the Centers for Disease Control (CDC) National Diabetes Statistics Report 2022, the estimated prevalence of diabetes for 2019 in the US was 37.3 million people or 11.3% of the population. The percentage of adults with diabetes increases with age, reaching 29.2% among those aged 65 years or older.[1]

Continuous glucose monitoring (CGM) devices measure the glucose content of interstitial fluid every 1 to 15 minutes, depending on the device. Interstitial fluid is accessed by a sensor inserted subcutaneously by the patient and worn for up to 14 days. A transmitter is attached to the sensor or worn over the sensor and transmits the glucose data to a receiver/smartphone. CGM systems provide visualization of the current glucose value as well as trend analysis, which indicates the direction of changing glucose. This technology can help patients fine-tune diabetic treatment. There are two main types of CGM systems: real time CGM (RT-CGM) and devices that require intermittent scanning, also known as flash continuous glucose monitoring (FGM).

CGMs are designated by the Food and Drug Administration (FDA) as either adjunctive or non-adjunctive. A non-adjunctive CGM can be used to make treatment decisions without the need for a stand-alone home blood glucose monitor to confirm testing results. Non-adjunctive CGMs can be either RT-CGM or FGM technology. Adjunctive CGMs are CGMs that beneficiaries use to check their glucose levels and trends which must be verified by use of a blood glucose monitor to make diabetes treatment decisions.

The aim of this summary of evidence was to determine if the application of CGM technology (adjunctive and non-adjunctive) will improve health outcomes for diabetic Medicare beneficiaries who do not administer insulin ≥3 times daily, evidenced by a clinically significant reduction in HbA1c, increased time in range, or a reduction in rate or severity of hypoglycemic events compared to self-monitoring of blood glucose (SMBG). For this analysis, hypoglycemic events were classified as one of three levels consistent with the ADA Standards for Medical Care in 2022[2]:

- *Level 1 hypoglycemia is defined as a measurable glucose concentration <70 mg/dL (3.9 mmol/L) but ≥54 mg/dL (3.0 mmol/L)*
- *Level 2 hypoglycemia (defined as a blood glucose concentration <54 mg/dL [3.0 mmol/L])*
- *Level 3 hypoglycemia is defined as a severe event characterized by altered mental and/or physical functioning that requires assistance from another person for recovery*

The summary of evidence specifically addresses requests for coverage of CGM during pregnancy, for patients with chronic kidney disease (CKD) stage 3-5, and for patients with other rare causes of hypoglycemia. Additionally, the summary of evidence outlines the appropriateness of requiring in-person physician visits every six months to support continued need of the CGM, the allowance for telehealth visits, and limitations on billing the supply allowance monthly versus quarterly.

Food and Drug Administration (FDA) Approvals

Dexcom G6 Continuous Glucose Monitoring System: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170088.pdf

Freestyle Libre Flash Glucose Monitoring System: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160030A.pdf

Freestyle Libre 2 Flash Glucose Monitoring System: https://www.accessdata.fda.gov/cdrh_docs/reviews/K193371.pdf

Medtronic Guardian Connect System: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160007A.pdf

Literature Analysis

CGM for beneficiaries with diabetes administering insulin 1-2 times daily

Four randomized controlled trials (RCTs)[3-6] and one observational trial[7] assessed the effects of CGM on HbA1c and/or Time in Range (TIR) in type 2 diabetes mellitus (T2DM) patients administering basal insulin. Ehrhardt et al.[4] conducted a prospective, 12-week, two-arm RCT which compared RT-CGM (n = 50) versus SMBG (n = 50) in people with T2DM not taking prandial insulin with an initial HbA1c ≥ 7%. HbA1c decreased by 1.0% (±1.1%) for the RT-CGM group and 0.5% (±0.8%) for the SMBG group at 12 weeks ($p = 0.006$).[4] The RT-CGM group had an adjusted decline in HbA1c of 0.60% greater than the SMBG group ($p = 0.002$).[4] Vigersky et al.[6] conducted a 40-week follow-up study which showed the significant difference in HbA1c between CGM and SMBG was sustained during the 40-week follow-up time period. Martens et al.[5] conducted an 8-month, open-label, 2:1 randomized, multicenter, clinical trial across 15 centers which evaluated the effectiveness of CGM (n=116) versus SMBG (n=59) in T2DM patients treated with only basal insulin. At the 8-month follow-up, the mean HbA1c levels decreased from 9.1% in the CGM group and 9.0% in the SMBG group to 8.0% vs. 8.4%, respectively (adjusted difference in mean change in HbA1c -0.4% [95%CI, -0.8% to –0.1%] $p = 0.02$.[5] In the CGM group, compared with the SMBG group, the mean percentage of time at 70 to 180 mg/dL was 59% vs 43% (adjusted mean difference, 15% [95% CI, 8% to 23%]; $p < 0.001$; equivalent to 3.6 hours more per day).[5] A 6-month extension study conducted by Aleppo et al.[3] aimed to determine the long-term benefits of continued CGM use or the detriments of discontinuing CGM. Upon completion of the 8-month visit for the initial RCT[5], participants in the CGM group were randomly assigned to either discontinue CGM (n=53) or continue CGM (n=53) at a 1:1 ratio with the primary outcome being TIR.[3] In the discontinue CGM group, mean TIR 70–180 mg/dL, which improved from 38% before initiating CGM to 62% after 8 months of CGM use, decreased after discontinuing CGM to 50% at 14 months (mean change from 8 to 14 months -12% [95% CI -21% to -3%], $p = 0.01$).[3] In the group that continued CGM use, little change was found in TIR from 8 to 14 months (baseline 44%, 8 months 56%, 14 months 57%, mean change from 8 to 14 months 1% [95% CI -11% to 12%], $p = 0.89$).[3] Comparing the two groups at 14 months, the adjusted treatment group difference in mean TIR was -6% (95% CI -16% to 4%, $p = 0.20$).[3] These studies[3-6] included several limitations such

as relatively small sample sizes, missing data for some participants during the follow-up periods, and the possibility of confounding.

A retrospective non-interventional single-arm chart review[7] investigated the change in HbA1c in T2DM patients using only basal insulin and commencing use of a FGM monitoring system. Eligible medical records ($n = 103$) from six diabetes centers in Canada showed HbA1c significantly decreased by 0.8% ± 1.1 mean ± SD (95% confidence interval for change –1.1 to –0.6 [−9.1 mmol/mol ± 12.1, −11.6 to −6.6], $p < 0.0001$) from baseline HbA1c 8.9% ± 0.9 (74.1 mmol/mol ± 9.7) to 8.1% ± 1.0 (65.0 mmol/mol ± 10.5) 3–6 months after initiation of FGM use.[7] Several limitations exist including relatively small sample size, lack of a comparator (such as SMBG), short study duration, and the possibility of confounded results due to inclusion of patients making drug therapy changes.

Two prospective clinical trials assessed the patterns of hypoglycemia and glycemic variability in adult patients with insulin treated and non-insulin treated T2DM.[8,9] In a study conducted by Munshi et al.[9], a blinded CGM measured interstitial glucose levels at intervals of 5 minutes for a 3-day period while T1DM (n=12) or T2DM (n=28) participants conducted their usual daily activities and conducted SMBG 4 times a day.[9] Of a total of 102 hypoglycemic episodes, 95 (93%) were unrecognized by SMBG or symptoms despite only 2 patients reporting "hypoglycemia unawareness". In a study conducted by Gehault et al.[8], a total of 108 patients with T2DM wore a blinded CGM for 5 days which tracked the severity, timing, and the number of hypoglycemic events while the participants kept daily 4-point SMBG logs and tracked any self-perceived hypoglycemic episodes.[8] Episodes of hypoglycemia were detected in 49.1% (53 of 108 patients), which extrapolated out to 1.74 ± SD 2.54 episodes per patient per 5 days of CGM.[8] Out of the 53 patients who had hypoglycemic episodes, 10 (18.9%) were on none of the medications that typically cause lows. The majority (75%) of patients were not aware of their hypoglycemic episodes detected by CGM ($p < 0.001$).[8] Both studies were limited by the observational design, use of a professional CGM as opposed to a personal CGM, short study duration, and a relatively small heterogenous sample which included insulin and non-insulin treated diabetics.[8,9]

Three systematic reviews with meta-analyses (SRMAs) attempted to examine the efficacy of CGM use in patients with T2DM compared to SMBG.[10-12] CGM was associated with a significant reduction in HbA1c levels for the combination of T2DM patients (insulin and non-insulin treated) in all three SRMAs. [10-12] Only one SRMA reported data related to hypoglycemia with the combined CGM group from 3 trials exhibiting shorter time spent with hypoglycemia than the SMBG group (SMD, −0.35; 95% CI, −0.59 to −0.10; $p = 0.006$; I2 = 0% $p = 0.86$).[10]

The American Diabetes Association (ADA) Standards of Medical Care in Diabetes 2022[13] specify that RT-CGM (Grade: A) or intermittently scanned continuous glucose monitoring (isCGM) (Grade: C) can be used for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely. The choice of device should be made based on patient circumstances, desires, and needs.[13] The Endocrine Society Clinical Practice Guideline for the treatment of diabetes in older adults in 2019[14] recommends frequent fingerstick glucose monitoring and/or continuous glucose monitoring (to assess glycemia) for patients aged 65 years and older with insulin treated diabetes.

The American Association of Clinical Endocrinology (AACE) Clinical Practice Guideline on the use of Advanced Technology in the Management of Persons with Diabetes Mellitus in 2021[15] recommends CGM for all individuals with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness) (Grade A; Intermediate-High Strength of Evidence; BEL 1). The AACE guideline further states that CGM may be recommended for individuals with T2DM who are treated with less intensive insulin therapy. (Grade B; Intermediate Strength of Evidence; BEL 1).[15] The AACE and American College of Endocrinology Consensus Conference on Continuous Glucose Monitoring in 2016[16] unanimously agreed that RT-CGM should be available to all insulin-using patients regardless of diabetes type, however this conclusion was based entirely on studies conducted in type 1 diabetes mellitus (T1DM) at the time of the recommendation.

The Diabetes Canada Clinical Practice Guidelines for 2018[17] indicate that FGM may be offered to people with diabetes to decrease time spent in hypoglycemia [Grade B, Level 2 for type 1 diabetes; Grade B, Level 2 for type 2 diabetes]. The National Institute for Health and Care Excellence (NICE) guidelines for 2022[18] suggest offering a CGM to adults with insulin-treated T2DM who would otherwise need help from a care worker or healthcare professional to monitor their blood glucose.

CGM for beneficiaries with T2DM not administering insulin (oral hypoglycemic agents only)

A 24-week, multicenter, open-label, randomized parallel-group trial[19] evaluated the effects of flash glucose monitoring (FGM) and conventional SMBG on HbA1c in patients with non-insulin-treated T2DM. At 24 weeks, HbA1c was significantly decreased from baseline values in the FGM group, but not in the SMBG group (FGM: −0.46% (−5.0 mmol/mol), 95% CI −0.59 to −0.32, $p < 0.001$; SMBG: −0.17% (−1.8 mmol/mol), 95% CI −0.05 to 0.11, $p = 0.124$); a significant statistical between-group difference in this respect was observed −0.29% (−3.2 mmol/mol), 95% CI −0.54 to −0.05; $p=0.022$). The authors concluded that among patients with non-insulin treated T2DM, glycemic control was better with FGM than with SMBG after cessation of glucose monitoring. Several limitations exist including the small sample size, short study duration (24 weeks), non-evaluation of lifestyle changes of enrolled participants, and non-fixed antidiabetic drugs throughout the study. Additionally, the slight reduction in HbA1c may not be clinically significant or long lasting.

Two prospective clinical trials assessed the patterns of hypoglycemia and glycemic variability in adult patients with insulin treated and non-insulin treated T2DM.[8,9] In a study conducted by Munshi et al.[9], a blinded CGM measured interstitial glucose levels at intervals of 5 minutes for a 3-day period while T1DM (n=12) or T2DM (n=28) participants conducted their usual daily activities and conducted SMBG 4 times a day.[9] Of a total of 102 hypoglycemic episodes, 95 (93%) were unrecognized by SMBG or symptoms despite only 2 patients reporting "hypoglycemia unawareness". In a study conducted by Gehault et al.[8], a total of 108 patients with T2DM wore a blinded CGM for 5 days which tracked the severity, timing, and the number of hypoglycemic events while the participants kept daily 4-point SMBG logs and tracked any self-perceived hypoglycemic episodes.[8] Episodes of hypoglycemia were detected in 49.1% (53 of 108 patients), which extrapolated out to 1.74 ± SD 2.54 episodes per patient per 5 days of

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The ADA "Standards of Medical Care in Diabetes" for 2022[13] specifies that periodic use of RT-CGM or isCGM or use of professional CGM can be helpful for diabetes management in circumstances where continuous use of CGM is not appropriate, desired, or available. (Grade: C) Additionally, the ADA "Standards of Medical Care in Diabetes" Chapter 6 indicates that "recurrent level 2 hypoglycemia and/or level 3 hypoglycemia is an urgent medical issue and requires intervention with medical regimen adjustment, behavioral intervention, and, in some cases, use of technology to assist with hypoglycemia prevention and identification".[2]

The AACE Clinical Practice Guideline on the use of Advanced Technology in the Management of Persons with Diabetes Mellitus in 2021[15] recommends CGM for all individuals with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness). (Grade A; Intermediate-High Strength of Evidence; BEL 1) The Diabetes Canada Clinical Practice Guidelines for 2018[17] state that FGM may be offered to people with diabetes to decrease time spent in hypoglycemia [Grade B, Level 2 for type 2 diabetes]. The AACE and American College of Endocrinology Consensus Conference on Continuous Glucose Monitoring in 2016[16] included that T2DM patients who use antihyperglycemic agents other than insulin might also benefit from CGM, but the evidence base was inadequate to make a strong recommendation.

CGM for beneficiaries with diabetes and chronic kidney disease (CKD) stage 3-5

A systematic review[20] evaluated the role of intensive glucose control in the development of renal end points in T2DM patients (n=28,065) based on the results of seven clinical trials. The meta-analysis concluded that intensive glucose control reduces the risk for microalbuminuria and macroalbuminuria, but evidence is lacking that intensive glycemic control reduces the risk for significant clinical renal outcomes, such as doubling of the serum creatinine level, end-stage renal disease (ESRD), or death from renal disease during the years of follow-up of the trials. The meta-analysis did not compare the use of SMBG to CGM and was considered indirect evidence of the efficacy of CGM in this population.[20]

A before–after monocentric 12-week pilot study[21] addressed the contribution of iterative sequences of CGM on glucose control in dialysis patients with diabetes (n=15). The study

included two 6-week periods: during the first period, patients were asked to perform 3-6 SMBG per day with their own glucometer device (SMBG period). During the second 6-week period, a 5-day blinded CGM was performed at 2-week intervals using the iPro21 CGM (Medtronic) (CGM period). Among the 15 patients, 2 had T1DM (13.3%), 9 had T2DM (60%) and 4 had secondary diabetes (26.7%). Treatments were diet alone (20%) or diet plus insulin (80%). Mean CGM glucose level was 8.3 ± 2.5 mmol/l at baseline, 8.2 ± 1.6 mmol/l at the end of the SMBG period and 7.7 ± 1.6 mmol/l at the end of the CGM period ($p < 0.05$ compared to baseline). Only the mean CGM glucose level decrease remained significant after exclusion of patients on diet alone in a subgroup analysis (baseline: 8.8 ±2.5 mmol/l; at the end of the SMBG period: 8.1 ± 1.5 mmol/l; $p < 0.05$; n = 12). The authors concluded that in patients with diabetes on chronic dialysis, iterative CGM was associated with more frequent treatment changes and better glucose control without increased risk of hypoglycemia. The study has several limitations including the small and heterogenous sample size, short duration of the study, and use of a professional CGM as opposed to a personal CGM. Additionally, the before-after study design lacked statistical power and had the potential risk of a "carry-over" effect of SMBG on CGM use.

The Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guidelines for Diabetes Management 2020[22] state that daily glycemic monitoring with CGM or SMBG may help prevent hypoglycemia and improve glycemic control when antihyperglycemic therapies associated with risk of hypoglycemia are used.

CGM for pregnant beneficiaries including those with gestational diabetes mellitus (GDM)

Non-adjunctive CGMs are not indicated for use during pregnancy based on the FDA labeling.[23,24] Adjunctive CGMs may be used during pregnancy based on the FDA labeling.[25] However, the only adjunctive CGM on the US market does not have a standalone CGM receiver and therefore is only classified as DME when an insulin infusion pump is used to display glucose values. Coverage of a CGM integrated into an insulin infusion pump requires that both the coverage criteria for a CGM and an insulin infusion pump are met. Beneficiaries qualifying for an insulin infusion pump would likely meet the current coverage criteria for a CGM and therefore no additional literature analysis was conducted on this topic.

American Association of Clinical Endocrinology (AACE) Clinical Practice Guideline on the use of Advanced Technology in the Management of Persons with Diabetes Mellitus for 2021[15] recommends CGM for pregnant women with T1D and T2D treated with intensive insulin therapy (Grade A; Intermediate-High Strength of Evidence; BEL 1) and women with gestational diabetes mellitus (GDM) on insulin therapy (Grade A; Intermediate Strength of Evidence; BEL 1). Additionally, the guidelines state that CGM may be recommended for women with GDM who are not on insulin therapy. (Grade B; Intermediate Strength of Evidence; BEL 1).[15]

CGM for other rare causes of hypoglycemia

Beneficiaries with a confirmed diagnosis of diabetes mellitus secondary to pancreatectomy or bariatric surgery may be eligible for coverage of a CGM if the coverage criteria outlined in the LCD are met. The Glucose Monitors National Coverage Determination (NCD) 40.2 limits the coverage of home blood glucose monitors to patients diagnosed with diabetes. Therefore,

patients prescribed a CGM due to bariatric surgery or other rare causes of hypoglycemia without a confirmed diagnosis of diabetes would not qualify under the NCD.

Requirement for an in-person treating practitioner visit every 6 months to assess adherence and allowance for telehealth visits

A cross-sectional survey[26] examined the relationship between primary care physician visit frequency and nights spent in the hospital for a group of Canadian insulin treated T2DM patients (n=2,203). The authors concluded that insulin-dependent T2DM patients who visit general practitioners (GPs) more frequently spend less time in-hospital than those who do not visit their GPs, after adjusting for confounders. Additionally, a large retrospective cohort study (n=26,496) conducted by Morrison et al. 2011[27] assessed the relationship between frequent patient-provider visits and diabetic patient health outcomes. The authors concluded that increased primary care provider encounters are associated with faster achievement of targets for HbA1c, blood pressure, and LDL for patients with diabetes.

The 2022 ADA Standards of Care[13] recommend that glycemic status (HbA1c or other glycemic measurement such as time in range or glucose management indicator) be assessed at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control) and at least quarterly in patients whose therapy has recently changed or who are not meeting their glycemic goals. The 2018 Joslin Clinical Oversight Committee Clinical Practice Guidelines[28] recommend monitoring diabetic patient progress through medical visits at least 2 to 4 times/year. Additionally, the guidelines state that intensive diabetes education and support are essential for optimal CGM implementation and monitoring.[28] The CDC Diabetes Care Schedule[29] recommends patients with diabetes visit their physician every 3 months if not meeting their treatment goals and every 6 months when they are meeting their treatment goals.

The in-person treating practitioner visits specified in the coverage criteria may be conducted via CMS-approved telehealth visits; therefore, no additional research on this topic was necessary.

Allowance for CGM supplies to be billed in 90-day increments

The requirement for CGM supplies to be billed as a monthly allowance is a billing and payment rule established by CMS and not within the purview of the DME MACs.

Health Disparities & Health Equity Assessment

Despite diabetes mellitus being more prevalent in non-Asian ethnic minorities and rural Americans, diabetic technology such as CGMs is less accessible to them.[30,31] In 2011, the Centers for Disease Control (CDC) identified a 644-county area of the U.S. where the incidence of DM was statistically higher in prevalence (11.7%) than that of the rest of the country (8.5%). More than a third of the ‘diabetes belt’ counties are in central and southern Appalachia, much of which is rural.[32] There are notable differences in provider access, transportation barriers, financial challenges, housing, and food security/access amongst particularly vulnerable diabetic patient populations, including Native Americans, Alaskan Natives, and African Americans.[33-35]

A study commissioned by the ADA to determine whether access to CGMs is a health disparity issue, found that young people are more likely to manage their diabetes using CGMs than older Americans and that Americans of African descent on fee-for-service Medicare or Medicare Advantage have disproportionately lower CGM utilization rates.[31] Additionally, a significant portion of patients with diabetes do not receive their diabetes care from an endocrinologist which likely contributes to this disparity.[36,37] In surveys of patients in vulnerable communities, two of the most frequently cited hindrances to diabetes technology such as CGMs are at the provider level (provider doesn't prescribe) and affordability due to lack of insurance coverage.[38-42] Health care policy requirements for in-person, face-to-face office visits may further potentiate health disparities among rural and urban non-Asian ethnic minorities for various reasons including, but not limited to, expense, lack of transportation, and health-professional shortages.[33-36]

Based on the available evidence, a patient-centered multidisciplined approach may be necessary to improve health equity in diabetes management. Studies examining the impact of interventions designed to overcome social determinants of health (e.g., access, affordability, transportation, literacy, environment, quality of care) consistently demonstrate improvement in the outcomes of diabetic patients.[38,43] Affordability is almost universally cited as a barrier to accessing diabetic technology.[42] Disparate coverage policies can contribute to the health disparities of diabetic technology adoption. Therefore, in light of the high prevalence of fee-for-service Medicare and Medicare Advantage insurance among diabetic patients, the expansion of Medicare coverage policies for CGMs in this revised policy may help improve access for some of the most underserved Medicare-eligible populations.[31,36,38]

Analysis of Evidence (Rationale for Determination)

Certainty of Evidence[43]

CGM for beneficiaries with diabetes administering insulin 1-2 times daily

Outcome: HbA1c reduction for diabetics with an HbA1c of ≥7%

Certainty: Moderate

Outcome: Hypoglycemia reduction/identification

Certainty: Moderate

Outcome: Time in range

Certainty: Low

CGM for beneficiaries with T2DM not administering insulin (oral hypoglycemic agents only)

Outcome: HbA1c reduction for diabetics with an HbA1c of ≥7%

Certainty: Very Low

Outcome: Hypoglycemia reduction/identification

Certainty: Moderate

CGM for beneficiaries with diabetes and chronic kidney disease (CKD) stage 3-5

Outcome: Hypoglycemia and Hyperglycemia reduction/identification

Certainty: Very Low

Outcome: Slowing the progression of CKD

Certainty: N/A (No relevant evidence identified)

CGM for pregnant beneficiaries including those with gestational diabetes mellitus (GDM)

Certainty: N/A

CGM for other rare causes of hypoglycemia

Certainty: N/A

Treating practitioner visits every six months to assess adherence

Certainty: N/A

Allowance for telehealth visits to document initial and continued need

Certainty: N/A

Allowance for CGM supplies to be billed in 90-day increments

Certainty: N/A

Conclusion

The CGM coverage criteria have been modified to allow coverage of a CGM for beneficiaries with diabetes mellitus who are insulin treated or have a history of problematic hypoglycemia. Problematic hypoglycemia, defined as:

- Recurrent (more than one) level 2 hypoglycemic events (<54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust the medication(s) and/or modify the diabetes treatment plan; or,
- A history of one level 3 hypoglycemic event (<54mg/dL (3.0mmol/L)) characterized by an altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia.

The requirement for frequent adjustment of the beneficiary's insulin treatment regimen on the basis of BGM or CGM testing results has been removed. The requirement for a visit with the treating practitioner every six months to assess adherence has been retained and language clarified to specifically address the long-standing policy which allows for the use of Medicare-approved telehealth visits. Additionally, elimination of the intensive insulin management requirement and the inclusion of telehealth options may also promote health equity for vulnerable rural and non-Asian ethnic minorities, as well as Medicare beneficiaries in areas with healthcare-professional shortages. CGM coverage has not been extended to patients solely on the basis on having stage 3-5 chronic kidney disease, gestational diabetes mellitus, bariatric surgery, or pancreatectomy who do not otherwise meet the outlined coverage criteria. Additional coverage criteria have been added to ensure the CGM is being used in accordance with FDA indications and the beneficiary has received proper training in the use of the device. The CGM supply allowance will continue to be billed monthly as it is not within the purview of the DME MACs to modify this requirement.

Coding Information

CPT/HCPCS Codes

Expand All | Collapse All

Group 1

(7 Codes)

Group 1 Paragraph

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS

CG - Policy criteria applied

EY - No physician or other licensed health care provider order for this item or service

KF - Item designated by FDA as Class III device

KS - Glucose monitor supply for diabetic beneficiary not treated by insulin

KX - Requirements specified in the medical policy have been met

HCPCS

EQUIPMENT

Group 1 Codes

Code	Description
E0607	HOME BLOOD GLUCOSE MONITOR
E0620	SKIN PIERCING DEVICE FOR COLLECTION OF CAPILLARY BLOOD, LASER, EACH
E1399	DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS
E2100	BLOOD GLUCOSE MONITOR WITH INTEGRATED VOICE SYNTHESIZER
E2101	BLOOD GLUCOSE MONITOR WITH INTEGRATED LANCING/BLOOD SAMPLE
E2102	ADJUNCTIVE, NON-IMPLANTED CONTINUOUS GLUCOSE MONITOR OR RECEIVER
E2103	NON-ADJUNCTIVE, NON-IMPLANTED CONTINUOUS GLUCOSE MONITOR OR RECEIVER

Group 2

(22 Codes)

Group 2 Paragraph

ACCESSORIES/SUPPLIES

Group 2 Codes

Code	Description
A4233	REPLACEMENT BATTERY, ALKALINE (OTHER THAN J CELL), FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWNED BY PATIENT, EACH
A4234	REPLACEMENT BATTERY, ALKALINE, J CELL, FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWNED BY PATIENT, EACH
A4235	REPLACEMENT BATTERY, LITHIUM, FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWNREPLACEMENT BATTERY, LITHIUM, FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWN
A4236	REPLACEMENT BATTERY, SILVER OXIDE, FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWNED BY PATIENT, EACH
A4238	SUPPLY ALLOWANCE FOR ADJUNCTIVE, NON-IMPLANTED CONTINUOUS GLUCOSE MONITOR (CGM), INCLUDES ALL SUPPLIES AND ACCESSORIES, 1 MONTH SUPPLY = 1 UNIT OF SERVICE

A4239	SUPPLY ALLOWANCE FOR NON-ADJUNCTIVE, NON-IMPLANTED CONTINUOUS GLUCOSE MONITOR (CGM), INCLUDES ALL SUPPLIES AND ACCESSORIES, 1 MONTH SUPPLY = 1 UNIT OF SERVICE
A4244	ALCOHOL OR PEROXIDE, PER PINT
A4245	ALCOHOL WIPES, PER BOX
A4246	BETADINE OR PHISOHEX SOLUTION, PER PINT
A4247	BETADINE OR IODINE SWABS/WIPES, PER BOX
A4250	URINE TEST OR REAGENT STRIPS OR TABLETS (100 TABLETS OR STRIPS)
A4253	BLOOD GLUCOSE TEST OR REAGENT STRIPS FOR HOME BLOOD GLUCOSE MONITOR, PER 50 STRIPS
A4255	PLATFORMS FOR HOME BLOOD GLUCOSE MONITOR, 50 PER BOX
A4256	NORMAL, LOW AND HIGH CALIBRATOR SOLUTION / CHIPS
A4257	REPLACEMENT LENS SHIELD CARTRIDGE FOR USE WITH LASER SKIN PIERCING DEVICE, EACH
A4258	SPRING-POWERED DEVICE FOR LANCET, EACH
A4259	LANCETS, PER BOX OF 100
A9275	HOME GLUCOSE DISPOSABLE MONITOR, INCLUDES TEST STRIPS
A9276	SENSOR; INVASIVE (E.G., SUBCUTANEOUS), DISPOSABLE, FOR USE WITH NON-DURABLE MEDICAL EQUIPMENT INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM, ONE UNIT = 1 DAY SUPPLY
A9277	DURABLE MEDICAL EQUIPMENT INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM
A9278	RECEIVER (MONITOR); EXTERNAL, FOR USE WITH NON-DURABLE MEDICAL EQUIPMENT INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM
A9999	MISCELLANEOUS DME SUPPLY OR ACCESSORY, NOT OTHERWISE SPECIFIED

General Information

Associated Information

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

Appendices

Insulin does not exist in an oral form and therefore beneficiaries taking oral medication to treat their diabetes are not insulin-treated.

A severe visual impairment is defined as a best corrected visual acuity of 20/200 or worse in both eyes.

An order renewal is the act of obtaining an order for an additional period of time beyond that previously ordered by the treating practitioner.

An order refill is the act of replenishing quantities of previously ordered items during the time period in which the current order is valid.

Utilization Guidelines

Refer to Coverage Indications, Limitations and/or Medical Necessity

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Reserved for future use.

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
4/16/2023	R12	Revision Effective Date: 04/16/2023	Provider Education/Guidance
		COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY:	Revisions Due To CPT/HCPCS Code Changes
		Revised: Coverage criteria to separate initial coverage and continued coverage requirements	Reconsideration Request
		Removed: “with multiple (three or more) daily administrations of insulin or a continuous subcutaneous insulin infusion (CSII) pump” from CGM coverage criterion pertaining to beneficiary being insulin-treated	

		Added: "The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription" as a CGM initial coverage criterion	
		Removed: "The beneficiary is insulin-treated with multiple (three or more) daily administrations of insulin or a continuous subcutaneous insulin infusion (CSII) pump" from CGM coverage criteria	
		Removed: "The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results" from CGM coverage criteria	
		Revised: Initial coverage criterion language pertaining to the in-person visit, to clarify that the visit may also be a "Medicare-approved telehealth visit"	
		Revised: Initial coverage CGM criterion language pertaining to the in-person visit, to change notation of "criteria (1-3) above" to "criteria (1)-(4) above"	

		Added: Initial coverage CGM criterion pertaining to history of problematic hypoglycemia	
		Revised: Continued coverage CGM criterion language pertaining to the in-person visit, to clarify that the visit may also be a “Medicare-approved telehealth visit” and that the practitioner must “document” adherence to the CGM regimen and diabetes treatment plan	
		Removed: “K0554” and “K0553” from reference to a non-adjunctive CGM device and associated supply allowance (respectively)	
		Added: “E2103” and “A4239” in reference to a non-adjunctive CGM device and associated supply allowance (respectively)	
		SUMMARY OF EVIDENCE:	
		Added: Information related to the modified coverage criteria for CGM	
		ANALYSIS OF EVIDENCE:	
		Added: Information related to the modified coverage criteria for CGM	
		BIBLIOGRAPHY:	
		Added: Section related to the modified coverage criteria for CGM	

		RELATED LOCAL COVERAGE DOCUMENTS:	
		Added: Response to Comments (A59330)	
1/1/2023	R11	Revision Effective Date: 01/01/2023	Provider Education/Guidance
		CONTINUOUS GLUCOSE MONITORS (CGM):	Revisions Due To CPT/HCPCS Code Changes
		Removed: Statement regarding general CGM term referring to both therapeutic/non-adjunctive and non-therapeutic/adjunctive	
		Removed: “therapeutic” and “non-therapeutic”	
		Removed: HCPCS codes K0554 and K0553	
		Added: HCPCS codes E2103 and A4239	
		REFILL REQUIREMENTS:	
		Removed: HCPCS code K0553	
		Added: HCPCS code A4239	
		HCPCS CODES:	
		Revised: Long descriptor for HCPCS code E2102 in Group 1 Codes	
		Added: HCPCS code E2103 to Group 1 Codes	
		Removed: HCPCS code K0554 from Group 1 Codes	
		Revised: Long descriptor for HCPCS code A4238 in Group 2 Codes	

		Added: HCPCS codes A4239, A9277, A9276 and A9278 to Group 2 Codes	
		Removed: HCPCS codes A9279 and K0553 from Group 2 codes	
		12/29/2022: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are non-discretionary updates to CMS HCPCS coding determinations.	
2/28/2022	R10	Revision Effective Date: 02/28/2022	Provider Education/Guidance
		HCPCS CODES:	
		Revised: Location of E2102 information, moving the information from Group 1 Paragraph text to Group 1 Codes HCPCS list (code remains effective for dates of service on or after 04/01/2022)	
		Revised: Location of A4238 information, moving the information from Group 2 Paragraph text to Group 2 Codes HCPCS list (code remains effective for dates of service on or after 04/01/2022)	

		04/28/2022: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are non-discretionary updates to CMS HCPCS coding determinations.	
2/28/2022	R9	Revision Effective Date: 02/28/2022	Provider Education/Guidance
		CMS NATIONAL COVERAGE POLICY:	Revisions Due To CPT/HCPCS Code Changes
		Removed: "CMS Ruling 1682R"	
		COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY:	
		Removed: Reference to CMS Ruling 1682R	
		Added: CGM refers to both therapeutic/nonadjunctive and non-therapeutic/adjunctive CGMs	
		Added: Language describing "therapeutic," "non-adjunctive," "non-therapeutic," and "adjunctive" terms and term usage	
		Added: Information regarding classification of CGMs as DME	
		Revised: Coverage information to include reference to adjunctive CGM (E2102) and related supply allowance (A4238)	

		Added: Statement referring to External Infusion Pumps LCD for information regarding billing of CGM receiver functionality integrated into external insulin infusion pump	
		Added: “Adjunctive CGM devices do not replace a standard home BGM”	
		Added: HCPCS code A4238 does not include a home BGM and related BGM testing supplies	
		Added: Reference to coding verification review requirement for HCPCS code E2102 (effective July 1, 2022)	
		Clarified: No more than a 90-day supply of CGM supplies may be dispensed at a time	
		Revised: “Refill requirements do not apply to code K0553” to “Refill requirements do not apply to code K0553 or A4238”	
		SUMMARY OF EVIDENCE:	
		Removed: Summary of evidence information, due to not being applicable to the non-discretionary changes	
		ANALYSIS OF EVIDENCE:	
		Removed: Analysis of evidence information, due to not being applicable to the non-discretionary changes	

		HCPCS CODES:	
		Added: HCPCS code E2102 to Group 1 Codes (information located in Group 1 Paragraph text) – code effective 04/01/2022	
		Added: HCPCS code E1399 to Group 1 Codes	
		Added: HCPCS code A4238 to Group 2 Codes (information located in Group 2 Paragraph text) – code effective 04/01/2022	
		Added: HCPCS codes A9279 and A9999 to Group 2 Codes	
		Removed: HCPCS codes A9276, A9277, and A9278 from Group 2 Codes	
		BIBLIOGRAPHY:	
		Removed: Bibliography information, due to not being applicable to the non-discretionary changes	
		03/24/2022: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are non-discretionary.	
7/18/2021	R8	Revision Effective Date: 07/18/2021	Provider Education/Guidance
		COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:	Reconsideration Request

		Removed: Four times or more per day testing with blood glucose monitor as prerequisite for CGM coverage	
		Revised: “injections” to “administrations” for insulin treatment regimen criterion for CGMs	
		Removed: “Medicare-covered” from CSII pump criterion language for CGMs	
		Clarified: Coding verification language for products billed as K0554	
		SUMMARY OF EVIDENCE:	
		Added: Information related to glucose testing and insulin administration	
		Revised: “5” to “1” minutes for measuring of interstitial fluid glucose content by CGM device	
		ANALYSIS OF EVIDENCE:	
		Added: Information related to glucose testing and insulin administration	
		APPENDICES:	
		Revised: Language of insulin-treated, by removing reference to insulin injections	
		BIBLIOGRAPHY:	
		Added: Section related to glucose testing and insulin administration	
		RELATED LOCAL COVERAGE DOCUMENTS:	

		Added: Response to Comments (A58798)	
1/1/2020	R7	Revision Effective Date: 01/01/2020	Provider Education/Guidance
		COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:	Other
		Removed: Statement to refer to ICD-10 Codes that are Covered section in the LCD-related PA	
		Added: Statement to refer to ICD-10 code list in the LCD-related Policy Article	
		Revised: “physician” to “treating practitioner”	
		Revised: "treating physician" to "treating practitioner"	
		Revised: “month” to “30 days,” as clarification of billing K0553	
		Revised: Format of HCPCS code references, from code spans to individually-listed HCPCS	
		Revised: Order information as a result of Final Rule 1713	
		REFILL REQUIREMENTS:	
		Revised: “ordering physician” to “treating practitioner”	
		CODING INFORMATION:	
		Removed: Field titled “Bill Type”	
		Removed: Field titled “Revenue Codes”	

		Removed: Field titled "ICD-10 Codes that Support Medical Necessity"	
		Removed: Field titled "ICD-10 Codes that DO NOT Support Medical Necessity"	
		Removed: Field titled "Additional ICD-10 Information"	
		GENERAL DOCUMENTATION REQUIREMENTS:	
		Revised: Prescriptions (orders) to SWO	
		APPENDICES:	
		Revised: "physician" to "practitioner"	
		02/20/2020: Pursuant to the 21st Century Cures Act , these revisions do not require notice and comment because they are due to non-discretionary coverage updates reflective of CMS FR-1713, HCPCS code changes, and non-substantive corrections (listing individual HCPCS codes instead of a HCPCS code-span).	
1/1/2019	R6	Revision Effective Date:01/01/2019	Other (ICD-10 code relocation per CMS instruction)
		COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY:	

		Removed: Statement to refer to diagnosis code section below	
		Added: Refer to Covered ICD-10 Codes in the LCD-related Policy Article	
		ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:	
		Moved: All diagnosis codes to the LCD-related Policy Article diagnosis code section per CMS instruction	
		ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY:	
		Moved: Statement about noncovered diagnosis codes moved to LCD-related Policy Article noncovered diagnosis code section per CMS instruction	
1/12/2017	R5	Revision Effective Date: 01/12/2017	Revisions Due To CPT/HCPCS Code Changes
		COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:	
		CPT/HCPCS Codes:	
		Revised: Incorporated K0554 into Group 1 Codes and HCPCS code K0553 into Group 2 Codes	

		04/19/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	
1/12/2017	R4	Revision Effective Date: 01/12/2017	Provider Education/Guidance
		COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:	Other (Revisions and updates based on CMS Ruling 1682R)
		Removed: Standard Documentation Language	
		Added: New reference language and Directions to Standard Documentation Requirements	
		Revised: Coverage criteria for home blood glucose monitors	
		Added: Documentation requirements for home blood glucose monitors	
		Added: Coverage criteria for continuous glucose monitors and supply allowance	
		Added: Documentation requirements for continuous glucose monitors	
		Added: General Requirements	
		Revised: Refill requirements	

		Added: HCPCS codes for therapeutic CGM (K0554) and supply allowance (K0553) out of sequence to allow early publishing of codes and narratives. (For dates of service on or after 07/01/2017)	
		DOCUMENTATION REQUIREMENTS:	
		Removed: Standard Documentation Language	
		Added: General Documentation Requirements	
		Added: New reference language and directions to Standard Documentation Requirements	
		POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:	
		Removed: Standard Documentation Language	
		Added: Directions to Standard Documentation Requirements	
		Removed: PIM reference under Appendices	
		RELATED LOCAL COVERAGE DOCUMENTS:	
		Added: LCD-related Standard Documentation Requirements article	
10/1/2016	R3	Revision Effective Date 10/01/2016	Provider Education/Guidance
		COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:	Revisions Due To ICD-10-CM Code Changes
		Revised: Standard Documentation language - ACA order requirements – Effective 04/28/16	

		ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:	
		Added: New ICD-10 codes	
		Deleted: Non-valid ICD-10	
		Revised: ICD-10 code descriptions	
		DOCUMENTATION REQUIREMENTS:	
		Revised: Standard documentation language for orders, added New order requirements, and Correct coding instructions; revised Proof of delivery instructions – Effective 04/28/16	
7/1/2016	R2	Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.	Change in Assigned States or Affiliated Contract Numbers
10/1/2015	R1	Revision Effective Date: 10/31/2014	Provider Education/Guidance
		COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:	
		Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility	
		DOCUMENTATION REQUIREMENTS:	
		Revised: Standard Documentation Language to add who can enter date of delivery date on the POD	

		Added: Instructions for Equipment Retained from a Prior Payer	
		Revised: Repair to beneficiary-owned DMEPOS	

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A52464 - Glucose Monitor - Policy Article

A59330 - Response to Comments: Glucose Monitors – DL33822

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

Related National Coverage Documents

N/A

Public Versions

Updated On	Effective Dates	Status	
5/2/2023	5/2/2023	Needs Approval by Committee	
2/23/2023	04/16/2023 - N/A	Currently in Effect	
12/22/2022	01/01/2023 - 04/15/2023	Superseded	View
4/22/2022	02/28/2022 - 12/31/2022	Superseded	View
3/18/2022	02/28/2022 - N/A	Superseded	View