FirstChoice VIP CARE
by Select Health of South Carolina

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 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 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

Sources of Information

Reserved for future use.

Bibliography

1. Centers for Disease Control. National Diabetes Statistics Report 2022: Estimates of Diabetes and Its Burden in the United States. https://www.cdc.gov/diabetes/data/statistics-report/index.html. (Accessed April 22, 2022).
2. Draznin B, Aroda VR, Bakris G, et al. 6. Glycemic Targets: Standards of Medical Care in Diabetes-2022. *Diabetes Care.* 2022;45(Suppl 1):S83-s96.
3. Aleppo G, Beck RW, Bailey R, et al. The Effect of Discontinuing Continuous Glucose Monitoring in Adults With Type 2 Diabetes Treated With Basal Insulin. *Diabetes Care.* 2021.
4. Ehrhardt NM, Chellappa M, Walker MS, Fonda SJ, Vigersky RA. The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. *J Diabetes Sci Technol.* 2011;5(3):668-675.
5. Martens T, Beck RW, Bailey R, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial. *Jama.* 2021;325(22):2262-2272.
6. Vigersky RA, Fonda SJ, Chellappa M, Walker MS, Ehrhardt NM. Short- and long-term effects of real-time continuous glucose monitoring in patients with type 2 diabetes. *Diabetes Care.* 2012;35(1):32-38.
7. Elliott T, Beca S, Beharry R, Tsoukas MA, Zarruk A, Abitbol A. The impact of flash glucose monitoring on glycated hemoglobin in type 2 diabetes managed with basal insulin in Canada: A retrospective real-world chart review study. *Diabetes & vascular disease research.* 2021;18(4):14791641211021374.
8. Gehlaut RR, Dogbey GY, Schwartz FL, Marling CR, Shubrook JH. Hypoglycemia in Type 2 Diabetes—More Common Than You Think: A Continuous Glucose Monitoring Study. *J Diabetes Sci Technol.* 2015;9(5):999-1005.
9. Munshi MN, Segal AR, Suhl E, et al. Frequent hypoglycemia among elderly patients with poor glycemic control. *Arch Intern Med.* 2011;171(4):362-364.
10. Ida S, Kaneko R, Murata K. Utility of Real-Time and Retrospective Continuous Glucose Monitoring in Patients with Type 2 Diabetes Mellitus: A Meta-Analysis of Randomized Controlled Trials. *Journal of diabetes research.* 2019;2019:4684815.
11. Janapala RN, Jayaraj JS, Fathima N, et al. Continuous Glucose Monitoring Versus Self-monitoring of Blood Glucose in Type 2 Diabetes Mellitus: A Systematic Review with Meta-analysis. *Cureus.* 2019;11(9):e5634.
12. Poolsup N, Suksomboon N, Kyaw AM. Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. *Diabetology & metabolic syndrome.* 2013;5:39.
13. diabetes ADAJC. Standards of Medical Care in Diabetes—2022 Abridged for Primary Care Providers. 2022;40(1):10-38.

14. LeRoith D, Biessels GJ, Braithwaite SS, et al. Treatment of Diabetes in Older Adults: An Endocrine Society* Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2019;104(5):1520-1574.
15. Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus. *Endocr Pract.* 2021;27(6):505-537.
16. Fonseca VA, Grunberger G, Anhalt H, et al. Continuous Glucose Monitoring: A Consensus Conference of the American Association of Clinical Endocrinologists and American College of Endocrinology. *Endocr Pract.* 2016;22(8):1008-1021.
17. Diabetes Canada. Diabetes Canada 2018 Clinical Practice Guidelines for the prevention and control of Diabetes. Can J Diabetes. (Suppl 1):S1-S325. 2018;42. .
18. National Institute for Clinical Excellence (NICE). Type 2 diabetes in adults: management NICE guideline [NG28].https://www.nice.org.uk/guidance/ng28. Updated March 31, 2022 (Accessed April 28, 2022).
19. Wada E, Onoue T, Kobayashi T, et al. Flash glucose monitoring helps achieve better glycemic control than conventional self-monitoring of blood glucose in non-insulin-treated type 2 diabetes: a randomized controlled trial. *BMJ Open Diabetes Res Care.* 2020;8(1).
20. Coca SG, Ismail-Beigi F, Haq N, Krumholz HM, Parikh CR. Role of intensive glucose control in development of renal end points in type 2 diabetes mellitus: systematic review and meta-analysis intensive glucose control in type 2 diabetes. *Arch Intern Med.* 2012;172(10):761-769.
21. Joubert M, Fourmy C, Henri P, Ficheux M, Lobbedez T, Reznik Y. Effectiveness of continuous glucose monitoring in dialysis patients with diabetes: the DIALYDIAB pilot study. *Diabetes Res Clin Pract.* 2015;107(3):348-354.
22. de Boer IH, Caramori ML, Chan JC, et al. KDIGO 2020 clinical practice guideline for diabetes management in chronic kidney disease. 2020;98(4):S1-S115.
23. Dexcom, Inc. Dexcom G6 Continuous Glucose Monitoring System Evaluation of Automatic Class III Designation [Decision Summary]. U.S. Food and Drug Administration website.
24. Abbott Diabetes Care Inc. FreeStyle Libre 2 Flash Glucose Monitoring System 501(k) Substantial Equivalence Determination [Decision Summary]. U.S. Food and Drug Administration website.
25. Medtronic MiniMed, Inc. Guardian Connect system [Safety and Effectiveness Data Summary]. U.S. Food and Drug Administration website.
26. Wickham ME, Hohl CM. Relationship between GP visits and time spent in-hospital among insulin-dependent Canadians with type 2 diabetes. *Can Fam Physician.* 2020;66(2):e69-e77.
27. Morrison F, Shubina M, Turchin A. Encounter frequency and serum glucose level, blood pressure, and cholesterol level control in patients with diabetes mellitus. *Arch Intern Med.* 2011;171(17):1542-1550.
28. Hafida S, Ganda OP, Gabbay RA. CHAPTER 1. Clinical guideline for adults with diabetes. *The American journal of managed care.* 2018;24(7 Spec No.):Sp209-sp225.
29. Centers for Disease Control and Prevention: Your Diabetes Care Schedule. https://www.cdc.gov/diabetes/managing/care-schedule.html (Accessed April 28, 2022).
30. Percentage of US Adults Aged 18 or Older with Diagnosed Diabetes, by Racial and Ethnic Group, 2013—2015. From Addressing Health Disparities in Diabetes. Centers for Disease Control and Prevention website. https://www.cdc.gov/diabetes/health-equity/diabetes-by-the-numbers.html. Accessed July 28, 2022.

31. American Diabetes Association CGM Utilization White Paper. https://www.diabetes.org/sites/default/files/2021-10/ADA%20CGM%20Utilization%20White%20Paper.pdf. Accessed August 1, 2022.
32. Appalachian Diabetes Control and Translation Project. Centers for Disease Control and Prevention website. https://www.cdc.gov/diabetes/health-equity/appalachian.html. Accessed August 18, 2022.
33. Rural Health Strategy Guide. https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf. Accessed July 15, 2022.
34. Paving the Way to Equity: A Progress Report. https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf. Accessed July 21, 2022.
35. Sadowski D, Devlin M, Hussain A. Diabetes self-management activities for Latinos living in non-metropolitan rural communities: a snapshot of an underserved rural state. *J Immigr Minor Health.* 2012;14(6):990-998.
36. American Diabetes Association. Disparities in Healthcare Access & Financial Security in People with Diabetes 2021 Slide Deck. https://diabetes.org/sites/default/files/2021-08/ADA_2021_Deck.pdf. Accessed July 15, 2022.
37. Pettus JH, Zhou FL, Shepherd L, et al. Incidences of Severe Hypoglycemia and Diabetic Ketoacidosis and Prevalence of Microvascular Complications Stratified by Age and Glycemic Control in U.S. Adult Patients With Type 1 Diabetes: A Real-World Study. *Diabetes Care.* 2019;42(12):2220-2227.
38. Bailey JE, Gurgol C, Pan E, et al. Early patient-centered outcomes research experience with the use of telehealth to address disparities: scoping review. 2021;23(12):e28503.
39. Care ADAJD. 1. Promoting health and reducing disparities in populations. 2017;40(Supplement_1):S6-S10.
40. Fantasia KL, Wirunsawanya K, Lee C, Rizo IJJods, technology. Racial disparities in diabetes technology use and outcomes in type 1 diabetes in a safety-net hospital. 2021;15(5):1010-1017.
41. Golden SH, Joseph JJ, Hill-Briggs FJTJoCE, Metabolism. Casting a health equity lens on endocrinology and diabetes. 2021;106(4):e1909-e1916.
42. Walker AF, Hood KK, Gurka MJ, et al. Barriers to technology use and endocrinology care for underserved communities with type 1 diabetes. 2021;44(7):1480-1490.
43. Hill-Briggs F, Adler NE, Berkowitz SA, et al. Social determinants of health and diabetes: a scientific review. 2021;44(1):258-279.
44. GRADEpro GDT: GRADEpro Guideline Development Tool [Software]. McMaster University, 2015 (developed by Evidence Prime, Inc.). gradepro.org. (Accessed April 28, 2022).
45. Abrahamsson N, Eden Engstrom B, Sundbom M, Karlsson FA. Hypoglycemia in everyday life after gastric bypass and duodenal switch. *Eur J Endocrinol.* 2015;173(1):91-100.
46. Adler AI, Stevens RJ, Manley SE, et al. Development and progression of nephropathy in type 2 diabetes: the United Kingdom Prospective Diabetes Study (UKPDS 64). *Kidney Int.* 2003;63(1):225-232.
47. Agarwal S, Mathew J, Davis GM, et al. Continuous Glucose Monitoring in the Intensive Care Unit During the COVID-19 Pandemic. *Diabetes Care.* 2021;44(3):847-849.
48. Alva S, Bailey T, Brazg R, et al. Accuracy of a 14-Day Factory-Calibrated Continuous Glucose Monitoring System With Advanced Algorithm in Pediatric and Adult Population With Diabetes. *J Diabetes Sci Technol.* 2020:1932296820958754.

49. American Diabetes Association Professional Practice C, American Diabetes Association Professional Practice C, Draznin B, et al. 15. Management of Diabetes in Pregnancy: Standards of Medical Care in Diabetes-2022. *Diabetes Care.* 2022;45(Suppl 1):S232-S243.
50. Bailey R, Calhoun P, Chao C, Walker TC. With or Without Residual C-Peptide, Patients with Type 2 Diabetes Realize Glycemic Benefits from Real-Time Continuous Glucose Monitoring. *Diabetes Technol Ther.* 2022;24(4):281-284.
51. Bajaj HS, Bergenstal RM, Christoffersen A, et al. Switching to Once-Weekly Insulin Icodec Versus Once-Daily Insulin Glargine U100 in Type 2 Diabetes Inadequately Controlled on Daily Basal Insulin: A Phase 2 Randomized Controlled Trial. *Diabetes Care.* 2021;44(7):1586-1594.
52. Bansal N, Weinstock RS. Non-Diabetic Hypoglycemia. In: Feingold KR, Anawalt B, Boyce A, et al., eds. *Endotext.* South Dartmouth (MA)2000.
53. Bao S, Bailey R, Calhoun P, Beck RW. Effectiveness of Continuous Glucose Monitoring in Older Adults with Type 2 Diabetes Treated with Basal Insulin. *Diabetes Technol Ther.* 2022;24(5):299-306.
54. Bao Y, Chen L, Chen L, et al. Chinese clinical guidelines for continuous glucose monitoring (2018 edition). *Diabetes Metab Res Rev.* 2019;35(6):e3152.
55. Barnard K, Thomas S, Royle P, Noyes K, Waugh N. Fear of hypoglycaemia in parents of young children with type 1 diabetes: a systematic review. *BMC pediatrics.* 2010;10:50.
56. Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. *Diabetes Care.* 2019;42(8):1593-1603.
57. Beck RW, Riddlesworth T, Ruedy K, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. *Jama.* 2017;317(4):371-378.
58. Bergenstal RM, Kerr MSD, Roberts GJ, Souto D, Nabutovsky Y, Hirsch IB. Flash CGM Is Associated With Reduced Diabetes Events and Hospitalizations in Insulin-Treated Type 2 Diabetes. *J Endocr Soc.* 2021;5(4):bvab013.
59. Bergenstal RM, Layne JE, Zisser H, et al. Remote Application and Use of Real-Time Continuous Glucose Monitoring by Adults with Type 2 Diabetes in a Virtual Diabetes Clinic. *Diabetes Technol Ther.* 2021;23(2):128-132.
60. Bergenstal RM, Mullen DM, Strock E, Johnson ML, Xi MX. Randomized comparison of self-monitored blood glucose (BGM) versus continuous glucose monitoring (CGM) data to optimize glucose control in type 2 diabetes. *J Diabetes Complications.* 2022;36(3):108106.
61. Boeder S, Kobayashi E, Ramesh G, Serences B, Kulasa K, Majithia AR. Accuracy and Glycemic Efficacy of Continuous Glucose Monitors in Critically Ill COVID-19 Patients: A Retrospective Study. *J Diabetes Sci Technol.* 2022:19322968221113865.
62. Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kröger J, Weitgasser R. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. *Lancet (London, England).* 2016;388(10057):2254-2263.
63. Bremer JP, Jauch-Chara K, Hallschmid M, Schmid S, Schultes B. Hypoglycemia unawareness in older compared with middle-aged patients with type 2 diabetes. *Diabetes Care.* 2009;32(8):1513-1517.
64. Cariou B, Fontaine P, Eschwege E, et al. Frequency and predictors of confirmed hypoglycaemia in type 1 and insulin-treated type 2 diabetes mellitus patients in a real-life setting: results from the DIALOG study. *Diabetes & metabolism.* 2015;41(2):116-125.

65. Carlson A, Daniel T, Desantis AJADAsSS, Virtual. Glucose control after initiation of flash glucose monitoring in type 2 diabetes managed with basal insulin; a retrospective real-world chart review study from the US. 2021.
66. Castorino K, Polsky S, O'Malley G, et al. Performance of the Dexcom G6 Continuous Glucose Monitoring System in Pregnant Women with Diabetes. *Diabetes Technol Ther.* 2020;22(12):943-947.
67. Charleer S, De Block C, Van Huffel L, et al. Quality of Life and Glucose Control After 1 Year of Nationwide Reimbursement of Intermittently Scanned Continuous Glucose Monitoring in Adults Living With Type 1 Diabetes (FUTURE): A Prospective Observational Real-World Cohort Study. *Diabetes Care.* 2020;43(2):389-397.
68. Charleer S, Mathieu C, Nobels F, et al. Effect of Continuous Glucose Monitoring on Glycemic Control, Acute Admissions, and Quality of Life: A Real-World Study. *J Clin Endocrinol Metab.* 2018;103(3):1224-1232.
69. Charpentier G, Benhamou PY, Dardari D, et al. The Diabeo software enabling individualized insulin dose adjustments combined with telemedicine support improves HbA1c in poorly controlled type 1 diabetic patients: a 6-month, randomized, open-label, parallel-group, multicenter trial (TeleDiab 1 Study). *Diabetes Care.* 2011;34(3):533-539.
70. Chow KW, Kelly DJ, Rieff MC, et al. Outcomes and Healthcare Provider Perceptions of Real-Time Continuous Glucose Monitoring (rtCGM) in Patients With Diabetes and COVID-19 Admitted to the ICU. *J Diabetes Sci Technol.* 2021;15(3):607-614.
71. Collier IA, Baker DM. Implementation of a pharmacist-supervised outpatient diabetes treatment clinic. *Am J Health Syst Pharm.* 2014;71(1):27-36.
72. Committee ADAPP, Care ADAPPCJD. 7. Diabetes Technology: Standards of Medical Care in Diabetes—2022. 2022;45(Supplement_1):S97-S112.
73. Cryer PE. Hypoglycemia begets hypoglycemia in IDDM. *Diabetes.* 1993;42(12):1691-1693.
74. Danne T, Nimri R, Battelino T, et al. International Consensus on Use of Continuous Glucose Monitoring. *Diabetes Care.* 2017;40(12):1631-1640.
75. Davis G, Bailey R, Calhoun P, Price D, Beck RW. Magnitude of Glycemic Improvement in Patients with Type 2 Diabetes Treated with Basal Insulin: Subgroup Analyses from the MOBILE Study. *Diabetes Technol Ther.* 2022;24(5):324-331.
76. de Boer IH, Rue TC, Hall YN, Heagerty PJ, Weiss NS, Himmelfarb J. Temporal trends in the prevalence of diabetic kidney disease in the United States. *JAMA.* 2011;305(24):2532-2539.
77. Dehghani Zahedani A, Shariat Torbaghan S, Rahili S, et al. Improvement in Glucose Regulation Using a Digital Tracker and Continuous Glucose Monitoring in Healthy Adults and Those with Type 2 Diabetes. *Diabetes Ther.* 2021;12(7):1871-1886.
78. Divani M, Georgianos PI, Didangelos T, et al. Comparison of Glycemic Markers in Chronic Hemodialysis Using Continuous Glucose Monitoring. *Am J Nephrol.* 2018;47(1):21-29.
79. Dixon RF, Zisser H, Layne JE, et al. A Virtual Type 2 Diabetes Clinic Using Continuous Glucose Monitoring and Endocrinology Visits. *J Diabetes Sci Technol.* 2020;14(5):908-911.
80. Draznin B, Aroda VR, Bakris G, et al. 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes-2022. 2022;45(Supplement_1):S17-S38.
81. Drinkwater JJ, Davis TME, Davis WA. Incidence and predictors of vision loss complicating type 2 diabetes: The Fremantle Diabetes Study Phase II. *J Diabetes Complications.* 2020;34(6):107560.

82. Dunkley AJ, Fitzpatrick C, Gray LJ, et al. Incidence and severity of hypoglycaemia in type 2 diabetes by treatment regimen: A UK multisite 12-month prospective observational study. *Diabetes, obesity & metabolism.* 2019;21(7):1585-1595.
83. Edridge CL, Dunkley AJ, Bodicoat DH, et al. Prevalence and Incidence of Hypoglycaemia in 532,542 People with Type 2 Diabetes on Oral Therapies and Insulin: A Systematic Review and Meta-Analysis of Population Based Studies. *PloS one.* 2015;10(6):e0126427.
84. Escott GM, da Silveira LG, Cancelier VDA, Dall'Agnol A, Silveiro SP. Monitoring and management of hyperglycemia in patients with advanced diabetic kidney disease. *J Diabetes Complications.* 2021;35(2):107774.
85. Faruque LI, Wiebe N, Ehteshami-Afshar A, et al. Effect of telemedicine on glycated hemoglobin in diabetes: a systematic review and meta-analysis of randomized trials. *CMAJ.* 2017;189(9):E341-E364.
86. Feig DS, Donovan LE, Corcoy R, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. *Lancet (London, England).* 2017;390(10110):2347-2359.
87. Fokkert M, van Dijk P, Edens M, et al. Improved well-being and decreased disease burden after 1-year use of flash glucose monitoring (FLARE-NL4). *BMJ Open Diabetes Res Care.* 2019;7(1):e000809.
88. Gal RL, Cohen NJ, Kruger D, et al. Diabetes Telehealth Solutions: Improving Self-Management Through Remote Initiation of Continuous Glucose Monitoring. *J Endocr Soc.* 2020;4(9):bvaa076.
89. Galindo RJ, Aleppo G, Klonoff DC, et al. Implementation of Continuous Glucose Monitoring in the Hospital: Emergent Considerations for Remote Glucose Monitoring During the COVID-19 Pandemic. *J Diabetes Sci Technol.* 2020;14(4):822-832.
90. Galindo RJ, Beck RW, Scioscia MF, Umpierrez GE, Tuttle KR. Glycemic Monitoring and Management in Advanced Chronic Kidney Disease. *Endocr Rev.* 2020;41(5).
91. Galindo RJ, Migdal AL, Davis GM, et al. Comparison of the FreeStyle Libre Pro Flash Continuous Glucose Monitoring (CGM) System and Point-of-Care Capillary Glucose Testing in Hospitalized Patients With Type 2 Diabetes Treated With Basal-Bolus Insulin Regimen. *Diabetes Care.* 2020;43(11):2730-2735.
92. Gallieni M, De Salvo C, Lunati ME, et al. Continuous glucose monitoring in patients with type 2 diabetes on hemodialysis. *Acta diabetologica.* 2021;58(8):975-981.
93. Giorda CB, Ozzello A, Gentile S, et al. Incidence and risk factors for severe and symptomatic hypoglycemia in type 1 diabetes. Results of the HYPOS-1 study. *Acta diabetologica.* 2015;52(5):845-853.
94. GRACE T, SALYER J. 600-P: Real-Time CGM Coverage Eligibility Should Include Type 2 Diabetes Patients Treated with Less-Intensive Therapy. In: Am Diabetes Assoc; 2021.
95. Grace T, Salyer J. Use of Real-Time Continuous Glucose Monitoring Improves Glycemic Control and Other Clinical Outcomes in Type 2 Diabetes Patients Treated with Less Intensive Therapy. *Diabetes Technol Ther.* 2022;24(1):26-31.
96. Griesdale DE, de Souza RJ, van Dam RM, et al. Intensive insulin therapy and mortality among critically ill patients: a meta-analysis including NICE-SUGAR study data. *Cmaj.* 2009;180(8):821-827.
97. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Use of Flash Glucose-Sensing Technology for 12 months as a Replacement for Blood Glucose Monitoring in Insulin-treated Type 2 Diabetes. *Diabetes Ther.* 2017;8(3):573-586.

98. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Flash Glucose-Sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-Treated Type 2 Diabetes: a Multicenter, Open-Label Randomized Controlled Trial. *Diabetes Ther.* 2017;8(1):55-73.
99. Halperin F, Patti ME, Skow M, Bajwa M, Goldfine AB. Continuous glucose monitoring for evaluation of glycemic excursions after gastric bypass. *J Obes.* 2011;2011:869536.
100. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists and American College of Endocrinology—Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan—2015—Executive Summary. *Endocr Pract.* 2015;21(4):413-437.
101. Haugstvedt A, Wentzel-Larsen T, Graue M, Søvik O, Rokne B. Fear of hypoglycaemia in mothers and fathers of children with Type 1 diabetes is associated with poor glycaemic control and parental emotional distress: a population-based study. *Diabet Med.* 2010;27(1):72-78.
102. Haw JS, Shah M, Turbow S, Egeolu M, Umpierrez G. Diabetes Complications in Racial and Ethnic Minority Populations in the USA. *Curr Diab Rep.* 2021;21(1):2.
103. Heinemann L, Freckmann G, Ehrmann D, et al. Real-time continuous glucose monitoring in adults with type 1 diabetes and impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial. *Lancet (London, England).* 2018;391(10128):1367-1377.
104. Higgins JP, Sterne JA, Savovic J, et al. A revised tool for assessing risk of bias in randomized trials. 2016;10(Suppl 1):29-31.
105. Hirsch IB, Kerr MS, Roberts GJ, Souto D, Nabutovsky Y, Bergenstal RM. 875-P: Utilization of Continuous Glucose Monitors Is Associated with Reduction in Inpatient and Outpatient Emergency Acute Diabetes Events Regardless of Prior Blood Test Strip Usage. In: Am Diabetes Assoc; 2020.
106. Hissa MRN, Hissa PNG, Guimaraes SB, Hissa MN. Use of continuous glucose monitoring system in patients with type 2 mellitus diabetic during hemodialysis treatment. *Diabetology & metabolic syndrome.* 2021;13(1):104.
107. Hollander PA, Kiljanski J, Spaepen E, Harris CJ. Risk of clinically relevant hypoglycaemia in patients with type 2 diabetes self-titrating insulin glargine U-100. *Diabetes, obesity & metabolism.* 2019;21(11):2413-2421.
108. Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HA. 10-year follow-up of intensive glucose control in type 2 diabetes. *N Engl J Med.* 2008;359(15):1577-1589.
109. Huhn EA, Linder T, Eppel D, et al. Effectiveness of real-time continuous glucose monitoring to improve glycaemic control and pregnancy outcome in patients with gestational diabetes mellitus: a study protocol for a randomised controlled trial. *BMJ Open.* 2020;10(11):e040498.
110. Isaacson B, Kaufusi S, Sorensen J, et al. Demonstrating the Clinical Impact of Continuous Glucose Monitoring Within an Integrated Healthcare Delivery System. *J Diabetes Sci Technol.* 2020:1932296820955228.
111. Isitt JJ, Roze S, Sharland H, et al. Cost-Effectiveness of a Real-Time Continuous Glucose Monitoring System Versus Self-Monitoring of Blood Glucose in People with Type 2 Diabetes on Insulin Therapy in the UK. *Diabetes Ther.* 2022;13(11-12):1875-1890.
112. Iyengar R, Franzese J, Gianchandani R. Inpatient Glycemic Management in the Setting of Renal Insufficiency/Failure/Dialysis. *Curr Diab Rep.* 2018;18(10):75.

113. JENDLE JH, EEG-OLOFSSON K, SVENSSON A-M, FRANZÉN S, LAMOTTE M, LEVRAT-GUILLEN F. 135-LB: Cost Effectiveness of the FreeStyle Libre System vs. Self-Monitoring of Blood Glucose in People with Type 2 Diabetes on Insulin Treatment Not Reaching Glycemic Goals in Sweden. In: Am Diabetes Assoc; 2021.
114. Jones LV, Ray A, Moy FM, Buckley BS. Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes. *Cochrane Database Syst Rev.* 2019;5(5):CD009613.
115. Jones MS, Goley AL, Alexander BE, Keller SB, Caldwell MM, Buse JB. Inpatient Transition to Virtual Care During COVID-19 Pandemic. *Diabetes Technol Ther.* 2020;22(6):444-448.
116. Kalra S, Mukherjee JJ, Venkataraman S, et al. Hypoglycemia: The neglected complication. *Indian journal of endocrinology and metabolism.* 2013;17(5):819-834.
117. Karter AJ, Parker MM, Moffet HH, Gilliam LK, Dlott R. Association of Real-time Continuous Glucose Monitoring With Glycemic Control and Acute Metabolic Events Among Patients With Insulin-Treated Diabetes. *Jama.* 2021;325(22):2273-2284.
118. Keesara S, Jonas A, Schulman K. Covid-19 and Health Care's Digital Revolution. *N Engl J Med.* 2020;382(23):e82.
119. Klonoff DC, Lias C, Vigersky R, et al. The surveillance error grid. *J Diabetes Sci Technol.* 2014;8(4):658-672.
120. Kovatchev BP, Cox DJ, Farhy LS, Straume M, Gonder-Frederick L, Clarke WL. Episodes of severe hypoglycemia in type 1 diabetes are preceded and followed within 48 hours by measurable disturbances in blood glucose. *J Clin Endocrinol Metab.* 2000;85(11):4287-4292.
121. Kröger J, Fasching P, Hanaire H. Three European Retrospective Real-World Chart Review Studies to Determine the Effectiveness of Flash Glucose Monitoring on HbA1c in Adults with Type 2 Diabetes. *Diabetes Ther.* 2020;11(1):279-291.
122. Lai CW, Lipman TH, Willi SM, Hawkes CP. Racial and Ethnic Disparities in Rates of Continuous Glucose Monitor Initiation and Continued Use in Children With Type 1 Diabetes. *Diabetes Care.* 2021;44(1):255-257.
123. Lazar LO, Sapojnikov S, Pines G, et al. Symptomatic and Asymptomatic Hypoglycemia Post Three Different Bariatric Procedures: A Common and Severe Complication. *Endocr Pract.* 2019.
124. Lee WC, Balu S, Cobden D, Joshi AV, Pashos CL. Medication adherence and the associated health-economic impact among patients with type 2 diabetes mellitus converting to insulin pen therapy: an analysis of third-party managed care claims data. *Clin Ther.* 2006;28(10):1712-1725; discussion 1710-1711.
125. Leonard CE, Han X, Brensinger CM, et al. Comparative risk of serious hypoglycemia with oral antidiabetic monotherapy: A retrospective cohort study. *Pharmacoepidemiology and drug safety.* 2018;27(1):9-18.
126. Li JH, Luo JF, Jiang Y, et al. Red Blood Cell Lifespan Shortening in Patients with Early-Stage Chronic Kidney Disease. *Kidney Blood Press Res.* 2019;44(5):1158-1165.
127. Lind M, Polonsky W, Hirsch IB, et al. Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults With Type 1 Diabetes Treated With Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. *JAMA.* 2017;317(4):379-387.
128. Lingvay I, Buse JB, Franek E, et al. A Randomized, Open-Label Comparison of Once-Weekly Insulin Icodec Titration Strategies Versus Once-Daily Insulin Glargine U100. *Diabetes Care.* 2021;44(7):1595-1603.

129. Lipska KJ, Yao X, Herrin J, et al. Trends in Drug Utilization, Glycemic Control, and Rates of Severe Hypoglycemia, 2006-2013. *Diabetes Care.* 2017;40(4):468-475.
130. Maiorino MI, Signoriello S, Maio A, et al. Effects of Continuous Glucose Monitoring on Metrics of Glycemic Control in Diabetes: A Systematic Review With Meta-analysis of Randomized Controlled Trials. *Diabetes Care.* 2020;43(5):1146-1156.
131. Majithia AR, Kusiak CM, Armento Lee A, et al. Glycemic Outcomes in Adults With Type 2 Diabetes Participating in a Continuous Glucose Monitor-Driven Virtual Diabetes Clinic: Prospective Trial. *J Med Internet Res.* 2020;22(8):e21778.
132. Malik S, Mitchell JE, Steffen K, et al. Recognition and management of hyperinsulinemic hypoglycemia after bariatric surgery. *Obes Res Clin Pract.* 2016;10(1):1-14.
133. Marquez-Pardo R, Torres-Barea I, Cordoba-Dona JA, et al. Continuous Glucose Monitoring and Glycemic Patterns in Pregnant Women with Gestational Diabetes Mellitus. *Diabetes Technol Ther.* 2020;22(4):271-277.
134. Matsuoka A, Hirota Y, Takeda A, et al. Relationship between glycated hemoglobin level and duration of hypoglycemia in type 2 diabetes patients treated with sulfonylureas: A multicenter cross-sectional study. *Journal of diabetes investigation.* 2020;11(2):417-425.
135. McCoy RG, Lipska KJ, Yao X, Ross JS, Montori VM, Shah ND. Intensive Treatment and Severe Hypoglycemia Among Adults With Type 2 Diabetes. *JAMA internal medicine.* 2016;176(7):969-978.
136. McQueen RB, Ellis SL, Campbell JD, Nair KV, Sullivan PW. Cost-effectiveness of continuous glucose monitoring and intensive insulin therapy for type 1 diabetes. *Cost Eff Resour Alloc.* 2011;9:13.
137. Meneghini LF, Lee LK, Gupta S, Preblick R. Association of hypoglycaemia severity with clinical, patient-reported and economic outcomes in US patients with type 2 diabetes using basal insulin. *Diabetes, obesity & metabolism.* 2018;20(5):1156-1165.
138. Miller E, Brandner L, WRIGHT E. 84-LB: HbA1c Reduction after Initiation of the FreeStyle Libre System in Type 2 Diabetes Patients on Long-Acting Insulin or Noninsulin Therapy. In: Am Diabetes Assoc; 2020.
139. Miller E, Brandner L, Wright E. HbA1c reduction after initiation of the FreeStyle Libre system in type 2 diabetes patients on long-acting insulin or noninsulin therapy. 80th scientific session of the American Diabetes Association. 2020. In:2021.
140. Miller KM, Beck RW, Foster NC, Maahs DM. HbA1c Levels in Type 1 Diabetes from Early Childhood to Older Adults: A Deeper Dive into the Influence of Technology and Socioeconomic Status on HbA1c in the T1D Exchange Clinic Registry Findings. *Diabetes Technol Ther.* 2020;22(9):645-650.
141. Mirani M, Berra C, Finazzi S, et al. Inter-day glycemic variability assessed by continuous glucose monitoring in insulin-treated type 2 diabetes patients on hemodialysis. *Diabetes Technol Ther.* 2010;12(10):749-753.
142. Misra-Hebert AD, Pantalone KM, Ji X, et al. Patient Characteristics Associated With Severe Hypoglycemia in a Type 2 Diabetes Cohort in a Large, Integrated Health Care System From 2006 to 2015. *Diabetes Care.* 2018;41(6):1164-1171.
143. Monaghesh E, Hajizadeh A. The role of telehealth during COVID-19 outbreak: a systematic review based on current evidence. *BMC Public Health.* 2020;20(1):1193.
144. Moon SJ, Kim KS, Lee WJ, Lee MY, Vigersky R, Park CY. Efficacy of intermittent short-term use of a real-time continuous glucose monitoring system in non-insulin-treated patients

with type 2 diabetes: A randomized controlled trial. *Diabetes, obesity & metabolism.* 2023;25(1):110-120.

145. Murphy HR, Feig DS, Sanchez JJ, de Portu S, Sale A, Group CC. Modelling potential cost savings from use of real-time continuous glucose monitoring in pregnant women with Type 1 diabetes. *Diabet Med.* 2019;36(12):1652-1658.
146. Murphy HR, Rayman G, Lewis K, et al. Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomised clinical trial. *BMJ.* 2008;337:a1680.
147. Nielsen JB, Abild CB, Pedersen AM, Pedersen SB, Richelsen B. Continuous Glucose Monitoring After Gastric Bypass to Evaluate the Glucose Variability After a Low-Carbohydrate Diet and to Determine Hypoglycemia. *Obes Surg.* 2016;26(9):2111-2118.
148. Noh RM, Graveling AJ, Frier BM. Medically minimising the impact of hypoglycaemia in type 2 diabetes: a review. *Expert opinion on pharmacotherapy.* 2011;12(14):2161-2175.
149. NORMAN GJ, PAUDEL ML, BANCROFT T, LYNCH PM. 77-LB: A Retrospective Analysis of the Association between HbA1c and Continuous Glucose Monitor Use for U.S. Patients with Type 2 Diabetes. 2021;70(Supplement 1):77-LB.
150. Olafsdottir AF, Andelin M, Saeed A, et al. Performance of Dexcom G5 and FreeStyle Libre sensors tested simultaneously in people with type 1 or 2 diabetes and advanced chronic kidney disease. *World J Clin Cases.* 2022;10(22):7794-7807.
151. Ólafsdóttir AF, Polonsky W, Bolinder J, et al. A Randomized Clinical Trial of the Effect of Continuous Glucose Monitoring on Nocturnal Hypoglycemia, Daytime Hypoglycemia, Glycemic Variability, and Hypoglycemia Confidence in Persons with Type 1 Diabetes Treated with Multiple Daily Insulin Injections (GOLD-3). *Diabetes Technol Ther.* 2018;20(4):274-284.
152. Oser TK, Litchman ML, Allen NA, et al. Personal Continuous Glucose Monitoring Use Among Adults with Type 2 Diabetes: Clinical Efficacy and Economic Impacts. *Curr Diab Rep.* 2021;21(11):49.
153. Oyaguez I, Gomez-Peralta F, Artola S, et al. Cost Analysis of FreeStyle Libre((R)) 2 System in Type 2 Diabetes Mellitus Population. *Diabetes Ther.* 2021;12(9):2329-2342.
154. Oyaguez I, Gomez-Peralta F, Artola S, et al. Correction to: Cost Analysis of FreeStyle Libre((R)) 2 System in Type 2 Diabetes Mellitus Population. *Diabetes Ther.* 2021;12(8):2263-2264.
155. Oyaguez I, Merino-Torres JF, Brito M, et al. Cost analysis of the flash monitoring system (FreeStyle Libre 2) in adults with type 1 diabetes mellitus. *BMJ Open Diabetes Res Care.* 2020;8(1).
156. Paris I, Henry C, Pirard F, Gérard AC, Colin IM. The new FreeStyle libre flash glucose monitoring system improves the glycaemic control in a cohort of people with type 1 diabetes followed in real-life conditions over a period of one year. *Endocrinology, diabetes & metabolism.* 2018;1(3):e00023.
157. Peek ME, Thomas CC. Broadening Access to Continuous Glucose Monitoring for Patients With Type 2 Diabetes. *Jama.* 2021;325(22):2255-2257.
158. Perez-Guzman MC, Duggan E, Gibanica S, et al. Continuous Glucose Monitoring in the Operating Room and Cardiac Intensive Care Unit. *Diabetes Care.* 2021;44(3):e50-e52.
159. Peters A, Cohen N, Calhoun P, et al. Glycaemic profiles of diverse patients with type 2 diabetes using basal insulin: MOBILE study baseline data. *Diabetes, obesity & metabolism.* 2021;23(2):631-636.

160. Peters AL, Ahmann AJ, Battelino T, et al. Diabetes Technology-Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2016;101(11):3922-3937.
161. Peters AL, Garg SK. The Silver Lining to COVID-19: Avoiding Diabetic Ketoacidosis Admissions with Telehealth. *Diabetes Technol Ther.* 2020;22(6):449-453.
162. Petrie JR, Peters AL, Bergenstal RM, Holl RW, Fleming GA, Heinemann L. Improving the clinical value and utility of CGM systems: issues and recommendations: A joint statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group. *Diabetologia.* 2017;60(12):2319-2328.
163. Polonsky WH, Layne JE, Parkin CG, et al. Impact of Participation in a Virtual Diabetes Clinic on Diabetes-Related Distress in Individuals With Type 2 Diabetes. *Clin Diabetes.* 2020;38(4):357-362.
164. Pratley RE, Kanapka LG, Rickels MR, et al. Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults With Type 1 Diabetes: A Randomized Clinical Trial. *Jama.* 2020;323(23):2397-2406.
165. Puhr S, Derdzinski M, Parker AS, Welsh JB, Price DA. Real-World Hypoglycemia Avoidance With a Predictive Low Glucose Alert Does Not Depend on Frequent Screen Views. *J Diabetes Sci Technol.* 2020;14(1):83-86.
166. Puhr S, Derdzinski M, Welsh JB, Parker AS, Walker T, Price DA. Real-World Hypoglycemia Avoidance with a Continuous Glucose Monitoring System's Predictive Low Glucose Alert. *Diabetes Technol Ther.* 2019;21(4):155-158.
167. Punthakee Z, Miller ME, Launer LJ, et al. Poor cognitive function and risk of severe hypoglycemia in type 2 diabetes: post hoc epidemiologic analysis of the ACCORD trial. *Diabetes Care.* 2012;35(4):787-793.
168. Raman P, Shepherd E, Dowswell T, Middleton P, Crowther CA. Different methods and settings for glucose monitoring for gestational diabetes during pregnancy. *Cochrane Database Syst Rev.* 2017;10(10):CD011069.
169. Rosenstock J, Bajaj HS, Janez A, et al. Once-Weekly Insulin for Type 2 Diabetes without Previous Insulin Treatment. *N Engl J Med.* 2020;383(22):2107-2116.
170. Roussel R, Riveline JP, Vicaut E, et al. Important Drop Rate of Acute Diabetes Complications in People With Type 1 or Type 2 Diabetes After Initiation of Flash Glucose Monitoring in France: The RELIEF Study. *Diabetes Care.* 2021;44(6):1368-1376.
171. Roze S, Isitt J, Smith-Palmer J, Javanbakht M, Lynch P. Long-term Cost-Effectiveness of Dexcom G6 Real-time Continuous Glucose Monitoring Versus Self-Monitoring of Blood Glucose in Patients With Type 1 Diabetes in the U.K. *Diabetes Care.* 2020;43(10):2411-2417.
172. Ruedy KJ, Parkin CG, Riddlesworth TD, Graham C. Continuous Glucose Monitoring in Older Adults With Type 1 and Type 2 Diabetes Using Multiple Daily Injections of Insulin: Results From the DIAMOND Trial. *J Diabetes Sci Technol.* 2017;11(6):1138-1146.
173. Sadhu AR, Serrano IA, Xu J, et al. Continuous Glucose Monitoring in Critically Ill Patients With COVID-19: Results of an Emergent Pilot Study. *J Diabetes Sci Technol.* 2020;14(6):1065-1073.
174. Salehi S, Olyaeemanesh A, Mobinizadeh M, Nasli-Esfahani E, Riazi H. Assessment of remote patient monitoring (RPM) systems for patients with type 2 diabetes: a systematic review and meta-analysis. *J Diabetes Metab Disord.* 2020;19(1):115-127.

175. Schloot NC, Haupt A, Schütt M, et al. Risk of severe hypoglycemia in sulfonylurea-treated patients from diabetes centers in Germany/Austria: How big is the problem? Which patients are at risk? *Diabetes Metab Res Rev.* 2016;32(3):316-324.
176. Seaquist ER, Anderson J, Childs B, et al. Hypoglycemia and diabetes: a report of a workgroup of the American Diabetes Association and the Endocrine Society. *Diabetes Care.* 2013;36(5):1384-1395.
177. Shah VN, Laffel LM, Wadwa RP, Garg SK. Performance of a Factory-Calibrated Real-Time Continuous Glucose Monitoring System Utilizing an Automated Sensor Applicator. *Diabetes Technol Ther.* 2018;20(6):428-433.
178. Siemens R. Remote Pharmacist-Assisted Flash Continuous Glucose Monitoring Improves Glycemic Outcomes in Patients With Poorly Controlled Diabetes: A Retrospective Case Series. *Clin Diabetes.* 2022;40(2):211-221.
179. Sola-Gazagnes A, Faucher P, Jacqueminet S, et al. Disagreement between capillary blood glucose and flash glucose monitoring sensor can lead to inadequate treatment adjustments during pregnancy. *Diabetes & metabolism.* 2020;46(2):158-163.
180. Šoupal J, Petruželková L, Flekac M, et al. Comparison of Different Treatment Modalities for Type 1 Diabetes, Including Sensor-Augmented Insulin Regimens, in 52 Weeks of Follow-Up: A COMISAIR Study. *Diabetes Technol Ther.* 2016;18(9):532-538.
181. Soupal J, Petruzelkova L, Grunberger G, et al. Glycemic Outcomes in Adults With T1D Are Impacted More by Continuous Glucose Monitoring Than by Insulin Delivery Method: 3 Years of Follow-Up From the COMISAIR Study. *Diabetes Care.* 2020;43(1):37-43.
182. Spanakis EK, Levitt DL, Siddiqui T, et al. The Effect of Continuous Glucose Monitoring in Preventing Inpatient Hypoglycemia in General Wards: The Glucose Telemetry System. *J Diabetes Sci Technol.* 2018;12(1):20-25.
183. Sreenan S, Andersen M, Thorsted BL, Wolden ML, Evans M. Increased Risk of Severe Hypoglycemic Events with Increasing Frequency of Non-severe Hypoglycemic Events in Patients with Type 1 and Type 2 Diabetes. *Diabetes Ther.* 2014;5(2):447-458.
184. Sterne JAC HM, Reeves BC, Savovic J, Berkman ND, Viswanathan M, Henry D, Altman DG, Ansari MT, Boutron I, Carpenter JR, Chan AW, Churchill R, Deeks JJ, Hróbjartsson A, Kirkham J, Jüni P, Loke YK, Pigott TD, Ramsay CR, Regidor D, Rothstein HR, Sandhu L, Santaguida PL, Schünemann HJ, Shea B, Shrier I, Tugwell P, Turner L, Valentine JC, Waddington H, Waters E, Wells GA, Whiting PF, Higgins JPT. ROBINS-I: a tool for assessing risk of bias in non-randomized studies of interventions. BMJ 2016; 355; i4919; doi: 10.1136/bmj.i4919.
185. Tchero H, Kangambega P, Briatte C, Brunet-Houdard S, Retali GR, Rusch E. Clinical Effectiveness of Telemedicine in Diabetes Mellitus: A Meta-Analysis of 42 Randomized Controlled Trials. *Telemed J E Health.* 2019;25(7):569-583.
186. Toyoda M, Murata T, Saito N, et al. Assessment of the accuracy of an intermittent-scanning continuous glucose monitoring device in patients with type 2 diabetes mellitus undergoing hemodialysis (AIDT2H) study. *Ther Apher Dial.* 2021;25(5):586-594.
187. Tyndall V, Stimson RH, Zammitt NN, et al. Marked improvement in HbA(1c) following commencement of flash glucose monitoring in people with type 1 diabetes. *Diabetologia.* 2019;62(8):1349-1356.
188. Unger J, Parkin C. Hypoglycemia in insulin-treated diabetes: a case for increased vigilance. *Postgraduate medicine.* 2011;123(4):81-91.

189. van Beers CA, DeVries JH, Kleijer SJ, et al. Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycaemia (IN CONTROL): a randomised, open-label, crossover trial. *The lancet Diabetes & endocrinology.* 2016;4(11):893-902.
190. van Meijel LA, de Vegt F, Abbink EJ, et al. High prevalence of impaired awareness of hypoglycemia and severe hypoglycemia among people with insulin-treated type 2 diabetes: The Dutch Diabetes Pearl Cohort. *BMJ Open Diabetes Res Care.* 2020;8(1).
191. Vigersky RA, McMahon C. The Relationship of Hemoglobin A1C to Time-in-Range in Patients with Diabetes. *Diabetes Technol Ther.* 2019;21(2):81-85.
192. Vigersky RA, Velado K, Zhong A, Agrawal P, Cordero TL. The Effectiveness of Virtual Training on the MiniMed 670G System in People with Type 1 Diabetes During the COVID-19 Pandemic. *Diabetes Technol Ther.* 2021;23(2):104-109.
193. Wallia A, Umpierrez GE, Rushakoff RJ, et al. Consensus Statement on Inpatient Use of Continuous Glucose Monitoring. *J Diabetes Sci Technol.* 2017;11(5):1036-1044.
194. Wang F, Wang D, Lu XL, Sun XM, Duan BH. Continuous glucose monitoring in diabetes patients with chronic kidney disease on dialysis: a meta-analysis. *Minerva Endocrinol (Torino).* 2022;47(3):325-333.
195. Wang X, Shu W, Du J, et al. Mobile health in the management of type 1 diabetes: a systematic review and meta-analysis. *BMC Endocr Disord.* 2019;19(1):21.
196. Wei Q, Sun Z, Yang Y, Yu H, Ding H, Wang S. Effect of a CGMS and SMBG on Maternal and Neonatal Outcomes in Gestational Diabetes Mellitus: a Randomized Controlled Trial. *Sci Rep.* 2016;6:19920.
197. Weinstock RS, DuBose SN, Bergenstal RM, et al. Risk Factors Associated With Severe Hypoglycemia in Older Adults With Type 1 Diabetes. *Diabetes Care.* 2016;39(4):603-610.
198. WRIGHT E, KERR MSD, REYES IJ, NABUTOVSKY Y, MILLER E. 78-LB: HbA1c Reduction Associated with a FreeStyle Libre System in People with Type 2 Diabetes Not on Bolus Insulin Therapy. 2020;69(Supplement 1):78-LB.
199. Wright EE, Jr., Kerr MSD, Reyes IJ, Nabutovsky Y, Miller E. Use of Flash Continuous Glucose Monitoring Is Associated With A1C Reduction in People With Type 2 Diabetes Treated With Basal Insulin or Noninsulin Therapy. *Diabetes spectrum: a publication of the American Diabetes Association.* 2021;34(2):184-189.
200. Yaron M, Roitman E, Aharon-Hananel G, et al. Effect of Flash Glucose Monitoring Technology on Glycemic Control and Treatment Satisfaction in Patients With Type 2 Diabetes. *Diabetes Care.* 2019;42(7):1178-1184.
201. Yeh T, Yeung M, Mendelsohn Curanaj FA. Managing Patients with Insulin Pumps and Continuous Glucose Monitors in the Hospital: to Wear or Not to Wear. *Curr Diab Rep.* 2021;21(2):7.
202. Yu F, Lv L, Liang Z, et al. Continuous glucose monitoring effects on maternal glycemic control and pregnancy outcomes in patients with gestational diabetes mellitus: a prospective cohort study. *J Clin Endocrinol Metab.* 2014;99(12):4674-4682.
203. Yu Q, Aris IM, Tan KH, Li LJ. Application and Utility of Continuous Glucose Monitoring in Pregnancy: A Systematic Review. *Front Endocrinol (Lausanne).* 2019;10:697.
204. Zaccardi F, Ling S, Lawson C, Davies MJ, Khunti K. Severe hypoglycaemia and absolute risk of cause-specific mortality in individuals with type 2 diabetes: a UK primary care observational study. *Diabetologia.* 2020;63(10):2129-2139.

205. Zisser H, Layne J, Bergenstal R, et al. Remote application and use of continuous glucose monitoring by adults with type 2 diabetes in a virtual diabetes clinic. Paper presented at: Diabetes Technology & Therapeutics2020.

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 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)	Provider Education/Guidance

		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 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:	Other (ICD-10 code relocation per CMS instruction)

		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 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.*	Revisions Due To CPT/HCPCS Code Changes
1/12/2017	R4	Revision Effective Date: 01/12/2017 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Standard Documentation Language	Provider Education/Guidance Other (Revisions and updates based on CMS Ruling 1682R)

		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