Formal Request for LCD Reconsideration
Local Coverage Determination (LCD): Glucose Monitors (L33822)

Pursuant to the process described in Chapter 13 of the Medicare Program Integrity Manual, we the undersigned individuals and organizations write to formally request a revision of the Local Coverage Determination (LCD): Glucose Monitors (L33822), which became effective on July 18, 2021.

We wish first to express sincere thanks for the recent revisions to this LCD. Those changes will help facilitate provision of better care for numerous Medicare beneficiaries who live with diabetes, and we applaud the Durable Medical Equipment Medicare Administrative Contractors' (DME MACs') willingness to make those revisions. We have carefully reviewed that document and the associated response to public comments (A58798) and Policy Article (A52464). We noted the numerous instances when responding to public comments that the DME MACs indicated they could not take action on submitted comments because those comments were outside of the scope of the proposal or the precipitating revision request. We were particularly heartened by the DME MACs' expression of sensitivity and shared concern for several comments and the indication that response to such comments would require another revision request. It is in response to those statements, as well as a firm belief in the validity of the clinical literature supporting the expanded coverage criteria for continuous glucose monitors (CGM) as outlined below, that we submit this revision request.

Attached for your use in consideration of this request are the peer reviewed studies upon which it is based. We look forward to working with the DME MACs to facilitate better care for the nation's Medicare beneficiaries.

Current Coverage Requirements

The current LCD lists five distinct requirements that must be met, in order for a Medicare beneficiary to obtain and continue CGM therapy:

1. The beneficiary has diabetes mellitus (documented by provision of an applicable ICD-10 code from the related Policy Article); and,
2. The beneficiary is insulin-treated with multiple (three or more) daily administrations of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,
3. The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of blood glucose monitoring (BGM) or CGM testing results; and,
4. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-3) above are met; and,
5. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan.

We believe that the current body of clinical evidence justifies specific changes to these criteria. We have outlined our recommended revisions below.

Proposed Revised Coverage Criteria

We believe that CGM should be covered for beneficiaries who meet any one of first six criteria and who also meet the seventh criterion.

1. Diagnosed with Type 1 diabetes;

   or,

2. Diagnosed with Type 2 diabetes and treated with any insulin therapy;

   or,

3. Diagnosed with Type 2 diabetes and documented problematic hypoglycemia regardless of diabetes therapy (i.e., whether or not the patient uses insulin). This would include a history of at least one of the following conditions:

   - Level 2 (moderate) hypoglycemia, characterized by glucose levels <54 mg/dL.
   - Level 3 (severe) hypoglycemia, characterized by physical/mental dysfunction requiring third-party assistance.
   - Nocturnal hypoglycemia.
   - Hypoglycemia unawareness.

   or,

4. Diagnosed with Type 2 diabetes and with stage 3, 4 or 5 chronic kidney disease (CKD);

   or,

5. Pregnancy with diagnosed diabetes; or
6. Have undergone bariatric surgery or have other rare causes of hypoglycemia such as pancreatectomy.

   and,

7. In any of the above situations, an in-person or telehealth visit with the prescribing healthcare provider prior to CGM initiation and every six (6) months thereafter while continuing CGM therapy.

Below we discuss the evidence backing this proposal as well as the modification of the existing criteria.

Expected Expanded Population

The table below outlines what we would expect to be the expanded population covered under our recommended revisions.

Patient Group	Population that would Qualify Under the Proposed Revisions Who Would Not Qualify Under the Existing LCD
Diagnosed with Type 1	Individuals diagnosed with Type 1 who could not previously document three or more administrations of insulin per day or frequent adjustment of insulin dosage based on BGM/CGM reading would be able to access CGM.
Diagnosed with Type 2 and on Any Insulin Therapy	Individuals diagnosed with Type 2 who could not previously document three or more administrations of insulin per day or frequent adjustment of insulin dosage based on BGM/CGM reading would be able to access CGM.
Diagnosed with Type 2 with Documented Problematic Hypoglycemia Regardless of Insulin Therapy	Individuals diagnosed with Type 2 who are using less than three administrations of insulin per day, or no insulin, who can document occurrence of problematic hypoglycemic events.
Diagnosed with Type 2 and Stage 3-5 Chronic Kidney Disease	Individuals who are diagnosed with Type 2 who do not use insulin and who cannot document problematic hypoglycemic events, but can document a diagnosis of stage 3, 4, or 5 chronic kidney disease.
Pregnancy with Diagnosed Diabetes	This requested revision would clarify in the LCD that pregnancy is not an exclusionary criterion, so long as the woman has a diagnosis of Type 1, Type 2 or gestational diabetes.
Have Undergone Bariatric Surgery or have Other Rare Cause of Hypoglycemia such as Pancreatectomy	Individuals who could not qualify under any of the other recommended coverage criterion, but who have undergone bariatric surgery or pancreatectomy.

Section 1: Coverage for Individuals Diagnosed with Type 1 Diabetes

Type 1 diabetes is a life-long, incurable disease that rapidly results in death if not treated. Survival depends on regular dosing of insulin and changes in diet and activity, based on accurate glucose data. When a diagnosis of Type 1 diabetes is present, it is not necessary to prove any other behaviors or treatments to demonstrate the need for CGM.

The body of evidence demonstrating the benefit of CGM therapy for individuals with Type 1 diabetes is large and incontrovertible. For example, in this population, CGM has been demonstrated to:

- Reduce A1c.[1, 2, 3, 4, 5, 6, 7, 8, 9, 10]
- Reduce the occurrence of severe hypoglycemic events.[11, 12, 13]
- Increase the proportion of time patients spend in the optimal glucose range.[14, 15, 16, 17]
- Decrease the proportion of time patients spend below the optimal range.[18, 19]
- Reduce diabetes-related emergency room visits and hospitalizations.[20, 21, 22, 23, 24]
- Improve neonatal outcomes for pregnant women.[25]
- Reduce hospitalizations from hypoglycemia and diabetic ketoacidosis.[26]

The American Diabetes Association (ADA) has stated in its Standards of Medical Care in Diabetes – 2021, that, "Access to CGM devices should be considered from the outset of the diagnosis of diabetes that requires insulin management." There is no provision for waiting to demonstrate a frequency of insulin use or variation in dosing. Rather, ADA states that CGM should be considered from the inception of the condition.[27]

The current Clinical Practice Guidelines of the American Association of Clinical Endocrinologists (AACE) state that, "CGM is strongly recommended for all persons with diabetes treated with intensive insulin therapy." By the nature of their disease, people with Type 1 diabetes will be intensively treated with insulin. Notably, AACE recommends BGM testing only for persons who "have limited success with or are unable or unwilling to use CGM."[28]

Given the level of evidence supporting use of CGM in the Type 1 diabetes population, we believe that diagnosis with Type 1 diabetes, in conjunction with a periodic visit with the prescribing provider, is clearly sufficient to justify coverage of CGM therapy for this population and that no other criteria need be met to demonstrate medical necessity. Specifically, we believe that the existing requirements to demonstrate use of multiple administrations of insulin per day and adjustment of insulin dosing based on BGM or CGM readings should be eliminated for the Type 1 population. The diagnosis can be documented by inclusion of an applicable ICD-10 code in the written order. Such a simplification will have the beneficial impact of easing access to a critical technology and thus improve health outcomes. Further, eliminating the need to repeatedly document insulin use and frequent dose adjustment will significantly reduce the administrative burden currently experienced by patients, providers, and suppliers.

Section 2: Coverage for Individuals Diagnosed with Type 2 Diabetes and Treated with Any Insulin Therapy

Current research regarding the Type 2 diabetes population has demonstrated significant benefit to CGM therapy in both those treated with multiple daily insulin administrations and those treated with less intensive regimens.

Just before the issuance of the current LCD, two important studies related to CGM use in the Type 2 diabetes population were published that highlight the value of CGM in this population.

First, the MOBILE study was a randomized controlled trial involving 175 adults (53% of whom were racial/ethnic minorities) with Type 2 diabetes who were using *only one or two injections of basal insulin per day*. Study participants were not using any prandial insulin. The study was conducted at 15 centers across the US and compared randomized groups of CGM and BGM users. This study found that:

- Mean A1c level decreased from 9.1% at baseline to 8.0% at 8 months in the CGM group and from 9.0% to 8.4% in the BGM group (adjusted between group difference, −0.4% [95% CI, −0.8% to −0.1%]; P = .02).
- In the CGM group, compared with the BGM group, the mean percentage of CGM-measured time in the target glucose range of 70 to 180 mg/dL was 59% vs 43% (adjusted difference, 15% [95% CI, 8% to 23%]; P < .001), the mean percentage of time at greater than 250 mg/dL was 11% vs 27% (adjusted difference, −16% [95% CI, −21% to

−11%]; P < .001), and the mean glucose values were 179 mg/dL vs 206 mg/dL (adjusted difference, −26 mg/dL [95% CI, −41 to −12]; P < .001). These percent differences translate to a reduction of 3.8 hours daily above 250 mg/dL and an increase of 3.6 hours daily within the target range.[29]

Time in Range (TIR) has been increasingly accepted by the clinical community as a measure of treatment success that is complementary to or even of more value than A1c. A patient can manifest an acceptable A1c, while still experiencing significant highs and lows. The TIR measurement will show such dysglycemic swings and consequently can be of more use than the A1c.[30] In fact, a 2019 study concluded that "There is a good correlation between HbA1C and %TIR that may permit the transition to %TIR as the preferred metric for determining the outcome of clinical studies, predicting of the risk of diabetes complications, and assessing of an individual patient's glycemic control."[31] TIR cannot be calculated in the absence of CGM. To facilitate the use of this important new metric by clinicians, access to CGM will be broadly needed among those with diabetes, including those treated with basal insulin only, or as noted in the section below, with no insulin at all.

There is an extension phase of the MOBILE study during which half of the 106 completers in the CGM group were randomized to continued CGM therapy, while the other half were randomized to discontinued CGM therapy and returned to BGM. Of the 57 trial participants randomized to BGM initially, 55 continued into the six-month extension phase where they remained on BGM. The preliminary results of the extension phase are striking. Time in range for the group that ceased using CGM rapidly fell from 62% to 50% and A1c in this same group rose from 7.9% to 8.2%. The BGM group maintained essentially the same A1c, moving to 8.4% from 8.5%. The group that continued on CGM had an A1c of 8.2% at the end of the primary study and an A1c of 8.1% at the end of the extension phase. Those who continued on CGM had a higher time in range (57%) than both the discontinuers (50%) and the BGM group (45%). The trend lines for mean glucose and time in range for the CGM discontinuing group also tracked the BGM group much more closely than they did the CGM continuing group. In addition, the median time wearing CGM during the last month of the study remained high at 6.2 days/ week.[32] (Note that four of the clinicians signed onto this LCD revision request were co-investigators on the MOBILE extension study and that the study results shown here have been accepted for publication in *Diabetes Care* and will be provided to the DME MAC medical directors as soon as they have been made public.)

An unpublished sub-analysis of the MOBILE data (soon to be submitted for publication) examined the impact of CGM on patients age 65+ and found similar benefits to those experienced by the younger population. (Requesters will submit the results to the DME MACs as soon as they are available).

Second, a large real-world study examining CGM use in the Type 2 diabetes population has also been recently published. This retrospective analysis looked at more than 36,000 patients with Type 2 diabetes and compared those within the cohort who initiated CGM therapy to those who did not. The CGM users had lower rates of hyper- and hypoglycemia, had more improved A1c values (mean A1c declined among CGM users from 8.17% to 7.76% and from 8.28% to 8.19% among those who did not use CGM), and lower rates of emergency department and inpatient visits.[33]

The results of these two studies were compelling enough to motivate the authors of a commentary article published in the Journal of the American Medical Association (JAMA) to conclude that, "The time has come to broaden access to CGM for patients with Type 2 diabetes."[34]

Another recently released study examined the use of CGM among patients with Type 2 diabetes using basal insulin only. It found a significant drop in A1c of 2.9% as well as a 12.3% increase in the amount of time spent in the optimal glucose range and a 12.3% reduction in the time spent above the optimal range.[35] Another 2021 study of CGM use by individuals with Type 2 diabetes who were not using insulin also found significant improvements in time in range.[36]

A recent presentation at the ADA scientific meeting of a retrospective analysis of data for nearly 83,000 people examined the difference in A1c for those using BGM testing, real time CGM or any CGM therapy. The group was further subdivided into those using insulin multiple times per day and those using basal insulin only and non-insulin medications. The results showed that among those who used only basal or non-insulin medications, the A1c dropped by 0.67% among the Any CGM group and by 0.87% among those using real time CGM therapy, both significantly greater than the A1c drop in the BGM testing group of 0.09%.[37]

A Canadian retrospective real-world study published this year evaluated the change in A1c after initiating flash CGM therapy among adults with Type 2 diabetes managed with basal insulin. The researchers examined medical records for 91 individuals in six different diabetes centers. They found that prior to CGM therapy, these patients had an A1c in the range of 8.0%–12.0%. These same patients' A1c was recorded 3–6 months after starting CGM use and had decreased 0.8%±1.1 (mean±SD).[38]

Other studies of CGM use in the Type 2 diabetes population have shown results similar to those noted above, including:

- Reductions in A1c.[39, 40, 41, 42, 43, 44, 45, 46, 47, 48]
- Increases in the proportion of time patients spend in the optimal glucose range.[49, 50]
- Decreases in the proportion of time patients spend below the optimal glucose range.[51, 52]
- Reductions in diabetes-related hospitalizations.[53, 54, 55]

Of note, half of the studies cited in the preceding four bullets included Type 2 individuals treated with basal insulin only or no insulin. In addition to this evidence, we note that the ADA's Standards of Care, when making recommendations for CGM, do not distinguish among individuals using varying forms of insulin therapy. Specifically, the ADA recommendation states that, "When used properly, real-time continuous glucose monitors in conjunction with multiple daily injections and continuous subcutaneous insulin infusion and other forms of insulin therapy are a useful tool to lower and/or maintain A1C levels and/or reduce hypoglycemia in adults and youth with diabetes."[56] The previously cited AACE guidelines state that, "CGM may be recommended for individuals with T2D who are treated with less intensive insulin therapy."[57]

Note that these guidelines were published before the results of the MOBILE study were available and therefore do not reflect that important new information.

For these reasons, we believe that the clinical literature support use of CGM by individuals diagnosed with Type 2 diabetes and using any form of insulin therapy and that this justifies the criterion we have recommended above. Compliance with this requirement could be easily documented by provision of an applicable ICD-10 code associated with a Type 2 diagnosis and insulin use (e.g. Z79.4).

Section 3: Coverage for Individuals with Diagnosed Type 2 Diabetes and Documented Hypoglycemia

Hypoglycemia is a significant problem for people with diabetes.[58] Severe hypoglycemia is known to increase the rates of acute cerebrovascular disease, myocardial infarction, neurocognitive dysfunction, and loss of vision; inadequate treatment of hypoglycemia has significant impacts on morbidity and mortality.[59, 60, 61] Nocturnal hypoglycemia and a loss of the ability to sense hypoglycemia are significant contributors to occurrence of severe hypoglycemic events.[62, 63, 64] Studies have demonstrated that the occurrence of a level 2 hypoglycemic event increases the chances of the person experiencing a Level 3 event in the future.[65, 66, 67, 68] Older people with diabetes are at particularly high risk for severe hypoglycemic events.[69, 70, 71, 72, 73, 74] A recent Dutch study found that, "Almost one out of ten people with Type 2 diabetes on insulin had IAH [impaired awareness of hypoglycemia] and >30% had a history of severe hypoglycemia [an event requiring external assistance to recover] in the past year."[75] Incidence of severe hypoglycemia is associated with much higher odds of reduced visual acuity.[76] Hypoglycemia is also a significant marker of increased mortality risk. A 2020 study in the UK that looked at nearly 75,000 individuals with Type 2 diabetes found that for a 60-year-old person with a history of severe hypoglycemia, the 5-year absolute risk of death was 6.6%, 1.1% for cardiovascular causes, 1.1% for cancer and and 13.1% for other causes of death. For similar subjects without severe hypoglycemia the risks were 4.7%, −1.4%, and 11.1% respectively.[77]

Multiple studies have shown that hypoglycemia is a problem even for patients who are not intensively treated with insulin, or for some patients not using insulin.[78, 79, 80, 81, 82, 83]

- One study found a correlation between the use of eight different non-insulin diabetes drugs and rates of hypoglycemia.[84]
- A 2015 systematic review and meta-analysis of 46 studies looking at the rate of hypoglycemia among people with Type 2 diabetes found that, "For treatment regimens that included a sulphonylurea, mild/moderate prevalence was 30% and incidence 2 events per person-year, and severe prevalence was 5% and incidence 0.01 events per person-year. A similar prevalence of 5% was found for treatment regimens that did not include sulphonylureas."[85]
- A 2016 study of nearly 32,000 US adults with Type 2 diabetes who were not treated with insulin found that more than 45% received treatment that nearly doubled the chances of them experiencing severe hypoglycemia.[86]
- A 2016 study of diabetes center patients in Germany and Austria treated without insulin

found “Severe hypoglycemic events were reported in 826 (2.8%) of all patients during their most recent year of sulfonylurea treatment. Of these, n = 531 (1.8%) had coma, n = 501 (1.7%) were hospitalized at least once.”[87]

- Results of the GRADE study presented at the 2021 ADA Scientific Sessions showed that 2.3% of participants randomized to using glimepiride (a sulfonylurea agent) had a severe hypoglycemic event requiring assistance from another person.[88]

Use of CGM among those with hypoglycemia has been shown to confer several benefits, including:

- Lower rates of severe and nocturnal hypoglycemic events and reductions in the proportion of time spent below target glucose ranges.[89, 90, 91]
- For patients ages 60 and above, reductions in hypoglycemia and A1c.[92]
- Reductions in hospitalizations.[93, 94]
- Reductions in the level of fear experienced by patients, and greater confidence in their ability to avoid and treat hypoglycemia.[95, 96] When patients are more confident in their ability to manage their condition, they also tend to be more adherent.[97, 98]

Based on these studies, we recommend covering CGM for any beneficiary who, in addition to meeting with their provider, is:

- Diagnosed with Type 2 diabetes and has documented problematic hypoglycemia regardless of diabetes therapy. This would include a history of at least one of the following conditions:
  - Level 2 (moderate) hypoglycemia, characterized by glucose levels ≤54 mg/dL as measured by laboratory test or fingerstick values.
  - Level 3 (severe) hypoglycemia – characterized by physical/mental dysfunction requiring third-party assistance.
  - Nocturnal hypoglycemia.

While in the past not all CGM systems covered by Medicare provided automatic alarms triggered by a dysglycemic event, current models of both such CGMs can alarm in this manner. These systems and their alarms have been demonstrated to provide accurately actionable data.[99, 100, 101, 102, 103]

Documenting that a person has met this criterion could be easily done by requiring the treating practitioner to provide an ICD-10 code demonstrating a Type 2 diagnosis and an appropriate ICD-10 code to indicate occurrence of one of the specified hypoglycemic events.

Section 4: Coverage for Individuals Diagnosed with Type 2 Diabetes and with Stage 3, 4 or 5 Chronic Kidney Disease

One in three American adults is at risk for chronic kidney disease (CKD), the ninth leading cause of death in the country.[104] Of those with end-stage renal disease (ESRD), 47% have a primary diagnosis of diabetes, making it a key contributor to ESRD.[105]

Of those in the US over age 65 who have diabetes, approximately 37% have an estimated Glomerular Filtration Rate (eGFR) of <60 mL/min/1.73 m^2.[106] Since about 20% of gluconeogenesis occurs in the kidney, a lower eGFR is a risk factor for hypoglycemia.[107] Patients may need their diabetes medications adjusted or changed significantly as renal function declines.[108] As a result, it can be difficult to select the correct drugs for treating people who are pre-dialysis or who need dialysis.

A recent review article on the state of clinical knowledge of CKD concluded that, within this population, CGM is a helpful tool for patients who have serious challenges managing glucose levels. Specifically, the authors state that:

- Glucose and insulin metabolism are profoundly altered by advanced CKD.
- Risk of hypoglycemia is increased by failure of kidney gluconeogenesis, impaired insulin clearance by the kidney, defective insulin degradation due to uremia, increased erythrocyte glucose uptake during hemodialysis, impaired counterregulatory hormone responses (cortisol, growth hormone), nutritional deprivation, and variability of exposure to oral antihyperglycemic agents and exogenous insulin.
- Patients with end-stage kidney disease frequently experience wide glycemic excursions, with common occurrences of both hypoglycemia and hyperglycemia.
- Assessment of glycemia by glycated hemoglobin (A1c) is hampered by a variety of CKD-associated conditions that can bias the measure either to the low or high range.
- Alternative glycemic biomarkers, such as glycated albumin or fructosamine, are not fully validated. Therefore, A1c remains the preferred glycemic biomarker despite its limitations.
- Emerging data on the use of CGM in this population suggest promise for more precise monitoring and treatment adjustments to permit fine-tuning of glycemic management in patients with diabetes and advanced CKD.[109]

Maintaining good glycemic control can slow a patient's progression to CKD.[110, 111, 112] The use of CGM has been shown to help in the management of patients with CKD because it directly impacts patients' ability to understand and modulate their glucose levels. Among those with diabetes on dialysis, iterative CGM use was shown to prompt frequent treatment changes and improved glycemic levels without pushing patients toward greater incidence of hypoglycemia.[113]

The normal lifespan of a red blood cell in adults is approximately 110 to 120 days. Since measurement of A1c is directly impacted by average red blood cell lifespan, it is important to understand the impact of CKD on red blood cells. A 2019 study examined this question. The investigators concluded that, "CKD progression was associated with decreases in (Hb) and RBC lifespan. RBC lifespan durations in CKD stages 1–5 were 122 ± 50, 112 ± 26, 90 ± 32, 88 ± 28,

and 60 ± 24 days, respectively. RBC lifespan means for the stage 3, 4 and 5 groups were significantly shorter than those for the stage 1 and 2 groups."[114] The International Society for Nephrology's Clinical Practice Guidelines for the Evaluation and Management of Chronic Kidney Disease point out that A1c is not a reliable measurement of glucose control in patients with reduced red blood cell lifespan and notes the value of CGM in tracking glucose levels in these patients.[115]

For these reasons, we believe the clinical literature supports CGM use for patients diagnosed with diabetes with stage 3, 4, or 5 CKD (as defined by the KDIGO Clinical Practice Guidelines) and recommend this as one of the criteria under which a beneficiary should qualify for CGM coverage. Documenting that a person has met this criterion could be easily done by requiring the treating practitioner to provide an ICD-10 code for diabetes and an ICD-10 code for CKD.

Section 5: Coverage for Individuals Who are Pregnant

While Medicare is typically thought of as a program for the elderly, because it also covers the disabled, there are many women of childbearing age covered under the program and each year the Medicare program covers thousands of births. A provision in the CGM policy should be made for beneficiaries who can benefit from CGM therapy during pregnancy, as a number of studies have shown the value of CGM for this population.

The CONCEPTT trial, published in The Lancet, assessed the clinical impacts of CGM use vs BGM within a cohort of 325 women with Type 1 diabetes who were pregnant (≤13-week gestation) or planning to become pregnant.[116] Investigators reported significant increases in time in target with CGM compared with BGM use (68% vs 61%; p=0.0034, respectively) with lower incidence of "large for gestational age" (p=0.0210), fewer neonatal intensive care admissions lasting more than 24 hours (p=0.0157), fewer incidences of neonatal hypoglycemia (p=0.0250), and one-day shorter length of hospital stay (p=0.0091).

An earlier randomized trial by Murphy et al., involving women with Type 1 diabetes (n=46) and insulin-treated Type 2 diabetes (n=25) demonstrated lower mean A1c levels from 32 to 36 week gestation in women randomized to CGM compared with women randomized to standard antenatal care with BGM (from 7.4% to 5.8% and from 7.2% to 6.4%, respectively, p=0.007).[117] CGM use was also associated with decreased birthweight centiles and reduced risk of macrosomia.

A large prospective cohort study of CGM use by women with gestational diabetes reported significantly improved daily blood glucose levels and lower glycemic variability assessed by mean amplitude of glucose excursion (MAGE) compared with BGM.[118] The MAGE score was significantly associated with birth weight (p<0.001) and found to be an independent factor for preeclampsia and composite neonatal outcomes. A more recent randomized trial showed an association between CGM use and reductions in body weight in women with gestational diabetes mellitus (GDM).[119]

A 2019 systematic review of the use of CGM in pregnancy concluded that "Current updated

evidence suggests that CGM is superior to BGM among GDM pregnancies in terms of detecting hypoglycemic and hyperglycemic episodes, which might result in an improvement of maternal and fetal outcomes. In addition, CGM detects a wider glycemic variability in GDM mothers than non-GDM controls."[120]

A study of the use of CGM to monitor glucose levels among women with GDM concluded that "The use of CGM after the diagnosis of GDM (as defined by the oral glucose tolerance test) reveals an increased probability of requiring pharmacological treatment."[121] Thus, CGM was shown to be a useful tool in assisting with the treatment of pregnant women with GDM.

Furthermore, a large randomized controlled trial with an estimated completion date of October 2021 is underway and will provide more data on the use of CGM in women with GDM. The study divides a group of 372 women with a recent diagnosis of GDM into two cohorts, one using CGM and the other using BGM, to monitor glucose levels. The study assesses differences in the proportion of "large for gestational age" newborns, as well as rates of neonatal hypoglycemia, Caesarean section, and shoulder dystocia. A comparison of glucose metabolism and quality of life during and after pregnancy is part of the scope of this study.[122]

The ADA's Standards of Care stipulate that "When used as an adjunct to pre- and postprandial self-monitoring of blood glucose, continuous glucose monitoring can help to achieve A1C targets in diabetes and pregnancy."[123] Similarly, the AACE guidelines recommend CGM for women with diagnosed Type 1 diabetes, Type 2 diabetes or GDM. They indicate that CGM may even be used for women with GDM who are not on insulin therapy.[124]

Given the proven benefits to mothers and infants, we believe that CGM should be available to women who are pregnant with a diagnosis of any type of diabetes. We acknowledge that the FDA has indicated that the two CGM products currently covered by the Medicare program do not currently have an indication specifically for use by pregnant women. However, they are both approved for people with diabetes and there are many women who have diabetes of one type or another during pregnancy. We are concerned that there may be denials for CGM coverage for pregnant women who have diabetes based on the FDA statements about these devices. We recommend that the LCD clarify that if a woman has diagnosed diabetes and meets any of the previously discussed criteria, she can receive coverage for a CGM even if she is pregnant. Documentation that a person has met this criterion could be accomplished by requiring the treating practitioner to provide ICD-10 codes for pregnancy and Type 1, Type 2 or GDM.

Section 6: Coverage for Individuals After Bariatric Surgery, or With Other Rare Causes of Hypoglycemia

There is a growing body of evidence that patients undergoing bariatric surgery experience hypoglycemic events of which they are often unaware. As discussed above, hypoglycemic events are problematic for a variety of reasons and use of CGM to identify and respond to their occurrence is understood to be an important treatment tool for these patients.

- A study published in 2011 used CGM and mixed-meal tolerance testing (MMTT) to evaluate the occurrence of hypoglycemic events among patient who had undergone Roux-en-Y gastric bypass (RYGB) surgery. Some of the study participants had been diagnosed with neuroglycopenia while another cohort affirmed that they had no hypoglycemia symptoms. The researchers found that among those asserting a lack of symptoms, 60% of those measured with MMTT and 50% of those measured with CGM showed hypoglycemia. They concluded that asymptomatic hypoglycemia after RYGB is more frequent than commonly recognized and that for clinicians evaluating patients for post-bypass neuroglycopenia, CGM may be a valuable diagnostic tool.[125]
- A study published in 2015 looked at the occurrence of hypoglycemic events among patients undergoing gastric bypass (GB) and duodenal switch (DS) surgery, compared to a group of non-operated overweight controls. The investigators used CGM to monitor glucose levels during the study. The GB group displayed highly variable glucose levels and spent 2.9% of their time in hypoglycemia. The DS group had twice as much time in hypoglycemia (5.9%) and displayed little variation in glucose levels. Notably, only about one-fifth of the hypoglycemic episodes in the GB and DS groups were accompanied by symptoms so these patients were largely unaware of the majority of their hypoglycemic events. CGM use in this population would thus provide accurate data about hypoglycemic events of which they were previously unaware, allowing them to take appropriate steps to reduce or address their occurrence. No hypoglycemic events were seen in the control group during the study period.[126]
- A 2016 study examined the use of CGM in clinical decision-making including diagnosing hypoglycemia and evaluating treatment effects among patients who had undergone RYGB surgery. The researchers used CGM to evaluate hypoglycemic events in two groups of people, those who were symptomatic and those asymptomatic for hypoglycemia. They concluded that "CGM was a good method for demonstrating increased glycemic variability among RYGB individuals and for displaying dietary effects on reducing this glycemic variability, including hypoglycemic events."[127]
- A review article, published in 2016, looked at the state of evidence around post-bariatric hypoglycemic events and made several important conclusions. Specifically, the authors show that the most common form of bariatric surgery (RYGB) is increasingly known to carry with it the complication of hyperinsulinemic hypoglycemia with neuroglycopenia. They describe studies showing that many of these patients are unaware of their hypoglycemic events and advise that physicians should be aware of this complication to ensure timely and effective treatment of post-RYGB patients, who present to them with hypoglycemic symptoms. They conclude that Continuous glucose monitoring is a valuable tool, revealing the occurrence of the hypoglycemic episodes as well as the response to treatment once those events have been identified.[128]
- A 2019 study sought to determine the frequency, pattern and severity of symptomatic and asymptomatic hypoglycemia in subjects post three different types of bariatric procedures performed >1 year before evaluation and a group of obese subjects before surgery. Occurrence of hypoglycemic events among the study participants were evaluated by symptoms' questionnaire, mixed-meal tolerance test (MMTT) and finally through use of CGM. The investigators concluded that

- Meal-related complaints were reported in 11 (26%) of the surgical group and in one control subject.
- MMTT detected a much higher rate of hypoglycemic events among the patients who had had the different types of bariatric surgeries, specifically, 88%, 82% and 67% experienced hypoglycemia in the respective three groups vs. none of the controls. Severe hypoglycemia (glucose </= 40 mg/dL) occurred in 38%, 45% and 7% of the respective groups. Very importantly, only 10 of the total operated patients (24%) reported any symptoms.
- During use of CGM, fasting hypoglycemic events occurred in 55%, 63% and 17% of the three groups.[129]

Taken together, these studies demonstrate that hypoglycemia is a significant problem for many individuals who have undergone gastric surgery and that a significant proportion of patients experiencing hypoglycemia are not aware of its occurrence. Without a method for identifying its occurrence, these patients and their providers will be unable to respond appropriately to address this significant problem. For those reasons, we recommend that individuals who have had bariatric surgery be permitted to access CGM therapy. Documentation of meeting this criterion could be accomplished by provision of an applicable ICD-10 code (e.g. Z98.84).

In rare instances, patients present with life-threatening hypoglycemia that requires time for evaluation and definitive treatment. Causes of life-threatening hypoglycemia include insulinoma that can be metastatic, autoimmune (antibodies to either insulin or activating antibodies to the insulin receptor) and tumoral hypoglycemia. In these cases, CGM may prove lifesaving and should be allowed.[130] We note as well that individuals undergoing pancreatectomy entirely lose the ability to produce endogenous insulin and must of necessity manage their glucose levels very carefully. CGM is an invaluable tool for these individuals and should be covered post-surgery. Documentation of these conditions could be accomplished by provision of applicable ICD-10 codes.

Section 7: Issues Related to Health Disparities

It is well understood that minority populations in the U.S. are disproportionately represented among those diagnosed with diabetes. Further, they experience complications arising from diabetes at higher rates and consequently use emergency departments and inpatient services more frequently.[131] These disparities make it even more important to ensure that minority populations have access to appropriate resources and tools to best manage their condition. Since diabetes management is largely implemented by patients themselves, providing them with the data and feedback needed to understand and respond to their condition is critical. This is precisely what a CGM does.

In the MOBILE study, cited above, 53% of study participants were from racial/ethnic minority groups. In fact, most participants were non-White, with less than a college degree, and without private insurance. This study conclusively demonstrated that CGM use has a significant beneficial impact on the management of diabetes among that patient group.

An analysis of data on more than 21,000 individuals with Type 1 recently found that across that entire population, those who were black or Hispanic and age 65 or older had higher A1c levels than the white population. However, among those who used a CGM, the black population had *lower* A1c levels than the white population and the Hispanic population had A1c levels comparable to the white population.[132] This is a notable result given that it shows a disproportionate positive impact for CGM in the very population that most needs it.

An unpublished analysis of CGM utilization among fee-for-service (FFS) Medicare beneficiaries by the National Minority Quality Forum recently found that in 2018, 88.8% of CGM users were white, 4.7% black, 0.8% Hispanic, 3.5% were Other and 2.2%.[133] An analysis of 2018 FFS enrollment data by the Kaiser Family Foundation showed that among the Medicare population, 75.0% were white, 10.3% black, 8.9% Hispanic, 4.1% Asian/Native Hawaiian and Pacific Islander, <1.0% American Indian/Alaska Native and 1.2% of multiple races.[134] Given that minorities in the diabetic population are actually overrepresented, their low rates of CGM utilization are of significant concern.

We believe that the proposed LCD revisions will go a long way toward improving access to this important tool by minority populations and that its use by these individuals has been conclusively demonstrated to improve their ability to manage this difficult chronic condition.

Section 8: Use of Telehealth for Provider Visits

We support the existing requirement that Medicare beneficiaries meet with their prescribing provider within the six-month period before initiating CGM therapy and continue such visits every six months thereafter. We request that the coverage criteria be revised to permit these visits to occur via telehealth, rather than requiring that that they occur as a face-to-face visit. We note that 42 CFR 410.38(c)(5) defines "face-to-face encounter" as "an in-person or telehealth encounter between the treating practitioner and the beneficiary," and suggest that specific language in the LCD acknowledging this definition would be helpful.

Studies have shown that telehealth consults result in:

- Reductions in A1c.[135, 136, 137, 138, 139, 140]
- Reductions in the incidence of severe hypoglycemic events.[141]
- Reduced diabetes-related distress.[142]
- Improvements in medication adherence.[143]

In addition, during the COVID-19 pandemic, the option of having these visits conducted through telehealth has proven very useful in addressing some obstacles that will, to a degree, remain even after the pandemic.[144, 145, 146, 147, 148] We note in that one study found that telehealth services were more effective for residents of cities than others.[149]

While we recognize that current statute precludes Medicare coverage of telehealth services to beneficiaries in urban areas, there are significant efforts underway in the U.S. Congress to expand the availability of telehealth services to all geographical locations. We believe that the

wording of the LCD could be constructed to permit coverage of CGM when provider visits occur via telehealth, regardless of how the Congress may or may not act. For example, the language could reference a face-to-face visits and Medicare-covered telehealth visits. That language could accommodate current limitations on the use of telehealth, as well as future expansions. We suggest that the language for this criterion is revised as follows, "An in-person or telehealth visit with the prescribing healthcare provider prior to CGM initiation and every six (6) months thereafter while continuing CGM therapy."

Several recent studies have looked at the feasibility of initiating CGM therapy through telehealth. One such study used certified diabetes care and education specialists to provide instruction via videoconferencing or phone. In their reported results, the authors note that all study participants used CGM through the entire 12-week study period, with 94% of them using the device at least six days per week during the last quarter of the study. Participants' mean A1c decreased from 8.3% to 7.2%; their time in the ideal glucose range increased from an estimated 48% to 59%; and substantial benefits to quality of life were observed, with reduced diabetes distress, increased satisfaction with glucose monitoring, and fewer perceived technology barriers to management. The authors conclude that, "remote CGM initiation was successful in achieving sustained use and improving glycemic control," as well as being successful in "improving quality-of-life indicators."[150]

Another study looked at virtual training using Zoom during the ongoing pandemic for the initiation of therapy on the Medtronic MiniMedTM 670G, a device system that combines an insulin pump and a CGM. The authors conclude that, "The CGM metrics were comparable between Pre- and Intra-COVID-19 training." The use of Zoom video conferencing had a 98% satisfaction score and the net promotor score for this method of training rose from 78 for those in a traditional in-person training format prior to the COVID-19 pandemic to 84 for those doing so via Zoom during the COVID-19 pandemic. Notably, the time between the pump shipment and the first and last training was significantly reduced from 14 ± 7 days to 11 ± 5 days. The authors conclude that "Virtual training of individuals with diabetes on the MiniMedTM 670G system resulted in high satisfaction and short-term glycemic results comparable to in-person training."[151] While this study is specific to one model of insulin pump, at this point, all insulin pump manufacturers have the option of virtual training.

Researchers presenting at the 2020 Advanced Technologies Treatments for Diabetes Conference (ATTD) in Madrid, Spain reported on a study of virtual initiation of CGM therapy among nearly 600 adults with Type 2 diabetes. Their study found that:

- On a 1-5 scale, the overall CGM satisfaction score was 4.5 +/- 0.8.
- Nearly all respondents (94.8%) agreed/strongly agreed that they were comfortable inserting the sensor remotely with guidance from their coach and that real time CGM use:
    - improved understanding of the impact of eating (97.0%);
    - increased diabetes knowledge (95.6%); and
    - helped improve diabetes control when not wearing the sensor (79.5%).
- Most respondents (70.5%) disagreed/strongly disagreed that real-time CGM provided too much information.

- A1c (n = 372) decreased significantly from 7.7% +/- 1.6 to 7.1% +/- 1.2 overall and by 2.6% +/- 2.0, 0.9% +/- 1.4 and 0.4% +/- 0.8, for participants with baseline A1c levels of >9.0%, 8.0%-9.0%, and 7.0%-<8.0%, respectively (all p < 0.001; mean follow-up 10.2 months).

The authors concluded that it is feasible to provide CGM directly to individuals with Type 2 diabetes through virtual clinic visits without any in-office training and that use of the CGM was well-received by adults with Type 2 diabetes and associated with improved A1c.[152]

Permitting visits to take place via telehealth will make it easier and less costly for beneficiaries as they will not have to incur the costs of transportation or time away from any occupation. Some beneficiaries may also have limitations in their ability to drive and find travel arrangements to be particularly difficult. These individuals could be greatly benefited by a policy that permits them to interact with their providers via telehealth.

We understand the DME MAC Medical Directors' concerns that medical documentation from telehealth visits have generally been less detailed and informative than medical documentation from in-person visits. We believe there could be a concerted effort to help educate providers on documentation requirements and that these requirements apply to in-person and telehealth visits.

Given that the clinical evidence amply demonstrates improved outcomes for patients using telehealth for initial and ongoing visits, Medicare beneficiaries should be able to choose to utilize telehealth visits for initiation and maintenance of CGM use, regardless of their provider's ability to document the visit appropriately. Rather, the focus should be on educating providers to submit appropriate documentation. We believe that modifying the coverage criteria to allow both initial and ongoing visits with the treating practitioner to be conducted via telehealth or virtually will make it easier for providers and beneficiaries alike and improve outcomes for people with diabetes. For these reasons, we strongly recommend this change to the coverage criteria.

Section 9: Removal of the Requirement to Frequently Adjust Insulin Dosage Based on BGM or CGM Reading

As outlined above, we believe that the evidence strongly supports permitting access to CGM for individuals who use insulin less frequently than three times per day and, in several other situations outlined above, when they do not use any insulin at all. When these changes to the coverage criteria are made, the requirement that beneficiaries must frequently adjust their insulin dosage based on BGM or CGM reading is rendered moot and should therefore be eliminated.

People with diabetes may have a therapeutic regimen that involves many factors other than insulin dose adjustment. For example, based on CGM readings, individuals with diabetes might adjust timing of insulin dose, type of insulin, macronutrient content of a specific meal or of the overall diet, number of meals, timing of meals, duration/intensity/timing/type of exercise,

duration/timing of sleep, and myriad other factors that all contribute to glycemic and health outcomes. We note that the previously cited MOBILE study demonstrated that use of CGM resulted in significant glycemic benefits without changes in insulin dose or addition of prandial insulin.[153]

In the Response to Comments document released with the most recent revisions to the CGM coverage criteria, the DME MACs sought to provide clarification on the intention of this requirement. It appears from this clarification that the intent of the requirement is to ensure that beneficiaries continue to use their CGM once they have initiated therapy and that it is not a mandate that insulin dose adjustments must be made if the beneficiary's glucose levels are within the target range as established. If this is the case, we believe that there are two existing parts of the process for securing a CGM that already address this concern.

First, when suppliers send CGM supplies to a beneficiary, per the associated Policy Article, suppliers must confirm that the beneficiary continues to use their CGM. Suppliers verify continued CGM use in at least two ways. Due to criterion five in the current LCD, suppliers collect medical documentation and chart notes from providers every six months. Additionally, suppliers collect a new Standard Written Order (SWO) from the prescribing physician annually to continue to provide CGM supplies. Continued medical need is required to be documented every 12 months.[154,155] Suppliers are regularly ensuring that the beneficiary continues to use their CGM. It would be unreasonable to require prescribing providers to document frequent insulin dosage adjustment, even when beneficiaries are not adjusting their insulin, to prove continued use of CGM.

Second, beneficiaries pay 20% co-insurance for every purchase of CGM supplies. The Medicare allowed amount for a one-month supply of K0553 is currently $223.22. Beneficiary cost-sharing is thus $44.64 per month. If a beneficiary chose to discontinue CGM use, it is unlikely the beneficiary would permit a supplier to continue to ship and bill for monthly CGM supplies on an ongoing basis. It would not be in the beneficiary's financial interest to pay for something that is not being used, and the beneficiary would almost certainly cease to authorize such shipments.

Finally, while we fully believe that comments made by the DME MACs in the recently released Response to Comments document and Policy Article were meant to simplify compliance with this requirement, we believe that the way in which this requirement is being understood and implemented by stakeholders is potentially problematic. To explain, we need to look very carefully at the criterion and the statements meant to elucidate its application. When doing so, it is important to keep in mind that the DME MACs, suppliers, prescribing providers, and Medicare's various auditors may all have their own interpretation of the meaning of this requirement. Further, because suppliers may have terms in their commercial contracts that penalize them if they are sanctioned by the Medicare program, they are incentivized to use extreme caution when it comes to interpreting the meaning of this requirement.

The existing criterion states that:

> "The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results."

In response to public comments, the DME MACs stated that:

> "This criterion is intended to ensure that beneficiaries are using CGM readings to actively guide their diabetes therapy. It is not a mandate that insulin dose adjustments must be made if glucose levels are within the target range as established collaboratively with their treating practitioner. The Policy Specific Documentation Requirements section in the LCD-related policy article has been updated to clarify the intent of this criterion."[156]

The associated Policy Article states:

> "For criterion 3 [frequent adjustment of diabetes treatment regimen], it is not a mandate that insulin dose adjustments must be made if glucose levels are within the target range as established collaboratively with their treating practitioner and documented in the beneficiary's medical record.
>
> For the in-person treating practitioner visit that is required as part of the ongoing provision of a therapeutic CGM, there must be sufficient information in the beneficiary's medical record to determine that the beneficiary continues to adhere to their diabetes treatment regimen and use of the CGM device on a daily basis."

It appears from these statements, as noted above, that the DME MACs intention is that this criterion be used to demonstrate continued use of CGM. However, use of this language prompts several specific questions.

First, the term "frequent" is not defined in the criterion. Suppliers and auditors may take different approaches. One might say it means "daily" while another may say it means "three times per day." The fact is that it is not specified, and as a result can be interpreted differently, likely leads to frustration and confusion for the provider community. Likewise, it is problematic for suppliers if the various Medicare auditors do not have a consistent and clear standard as to what "frequent" means and apply their interpretations inconsistently.

Second, the criterion references the use of "BGM or CGM" testing results. Presumably, this means that when a beneficiary initiates CGM therapy, they would use BGM results to meet this criterion and that CGM readings would be used thereafter to demonstrate compliance with this criterion. However, it is unclear what is required in the case of a beneficiary who ages into Medicare while on a CGM, who does not have any BGM readings. We are aware of a policy statement from the DME MACs indicating that in the case of insulin pump coverage the use of CGM can stand in the place of BGM readings. We are also aware that the DME MACs have communicated directly with some stakeholders indicating that CGM can be used to meet this requirement upon aging into Medicare, but we believe that this clarification needs to be offered in a publicly available, formal policy statement, such as the LCD.[157] Without clear

guidance, suppliers may require the use of BGM by those who are currently on CGM before allowing access to Medicare-covered CGM therapy.

Third, the statements in the Response to Comments and the Policy Article appear to set up a two-part test. The first part is a verification as to whether the beneficiary is within the target range as established between the beneficiary and provider. From a supplier's perspective this means potentially verifying different ranges for numerous Medicare beneficiaries. It means that the supplier must find out exactly what that range is, for each beneficiary. It means that providers must document precisely what that range is and then supply that documentation to the supplier. This is a significant administrative burden.

Furthermore, this text does not specify what it means to be "in range." The ADA's Standards of Care note that glycemic targets can be adjusted based on patient and disease factors. Thus, the glycemic range may vary by patient.[158] Further, the percent that a patient is within that range could be interpreted in varying ways. Being in range could mean within the established range 51% of the time, 100% of the time, something in between, or some variable figure established between beneficiary and provider. Absent clarity, suppliers and auditors may differ on what it means to be "in range." In the alternative, as described above, suppliers may take the most cautious approach (i.e., documentation proving that the beneficiary was in range 100% of the time if not frequently adjusting insulin dosage), even if that is not the requirement.

The second step in complying with this requirement comes if the supplier determines that the person is not "in range." The Policy Article indicates that beneficiaries who are <u>not</u> "in range" would be required to demonstrate that they <u>are</u> varying their insulin dose based on BGM or CGM reading. Thus, the provider would have to document:

a) What the established range is,
b) Whether the beneficiary is within that range (and potentially what percentage of the time they are within range), and
c) If the beneficiary is not within range, then the beneficiary would need to show that they are varying their insulin dosage.

All this information would have to be passed on to the supplier in medical documentation.

It is not clear how providers would document that a beneficiary is within range in a manner that would, without question, satisfy any auditor that may examine those claims. DME MACs must provide clear guidance and examples regarding their expectations of medical documentation that clearly meets this criterion.

Considering that each provider is likely to be dealing with multiple suppliers and that each supplier may interact with more than one auditor, the possibility for problems arising from multiple interpretations is evident. In addition, the paperwork burden imposed by this requirement is substantial.

For these reasons, we strongly recommend removal of this criterion from the LCD. The DME MACs should instead rely on the fact that suppliers are ensuring ongoing use of CGM by the beneficiary and that beneficiaries will not want to be financially responsible for continuing to pay for supplies they do not use. If the DME MACs feel that the provider must be involved, then they should simply modify the criterion to require that, "The prescribing provider indicates to the supplier that the beneficiary continues to use the CGM."

Section 10: Coding Guidelines for CGM Supplies

In addition to the changes requested above, we believe that billing guidelines for CGM supplies (K0553) must be changed to better align with billing for other common supplies for beneficiaries with diabetes.

For therapeutic CGM supplies, the LCD-related Policy Article states that, "Suppliers must monitor usage of supplies. Billing for code K0553 may continue on a monthly basis as long as sufficient supplies remain to last for one (1) full month, thirty (30) days, as previously described. If there are insufficient supplies to be able to last for one (1) full month, thirty (30) days, additional supplies must be provided before the supply allowance is billed."[159] Per this guidance, suppliers are required to track each beneficiary's CGM supply usage on a monthly basis and may only bill for CGM supplies every 30 days.

This system causes a beneficiary with diabetes to deal with two different sets of Medicare billing rules (90-day billing and 30-day billing) when on dual insulin pump and CGM therapy, which is extremely common in beneficiaries with Type 1 diabetes. A beneficiary on insulin pump therapy and using test strips for BGM will get supplies every 90 days. A beneficiary on insulin pump therapy and CGM therapy will get pump supplies every 90 days and CGM supplies every 30 days. Currently, suppliers have the option to ship CGM supplies every 90 days but can only bill for one unit of service every 30 days. Shipping CGM supplies every 90 days creates a reimbursement uncertainty for suppliers since they can only bill for these supplies every 30 days. In our experience, many suppliers choose to bill and ship at the same time, every 30 days.

This current billing system causes beneficiary confusion and unnecessary additional steps for beneficiaries and suppliers, as suppliers must contact beneficiaries monthly to confirm supply usage amount. Especially for beneficiaries who are on insulin pump and CGM therapies with sensor augmented insulin pumps that rely on timely change of CGM supplies, any potential delay in new CGM supply delivery can result in harmful outcomes. Rather than to put this heavy burden on suppliers, the DME MACs should align billing for CGM supplies with insulin pump supplies and allow CGM supplies to be **shipped and billed** every 90 days. Allowing suppliers to choose to bill a single time for a 90-day supply (or three units of service) would help reduce confusion for beneficiaries who receive their various diabetes supplies on different cycles and would eliminate a hefty administrative burden for suppliers.

We suggest updating the coding guidance language in the Policy Article as follows:

"A supplier does not have to deliver supplies used with a therapeutic CGM every month in order to bill code K0553 every month **and may choose to bill a single time for a 90-day supply**. In order to bill code K0553, the supplier must have previously delivered quantities of supplies that are sufficient to l**ast for the amount of time for which they are billing the DME MACs.**

• If the supplier chooses to deliver a one (1) month supply, they must have delivered a full month (30 day) supply following the DOS on the claim. They would bill for one (1) unit of service (UOS) for the one-month (30 day) supply.

• Alternatively, if the supplier chooses to deliver a three (3) month supply, they must have delivered three (3) months (90 day) supply following the DOS on the claim. They would bill for three (3) units of service (UOS) for the three-month (90 day) supply.

Billing for code K0553 may continue on a **regular** basis as long as sufficient supplies remain to last for one (1) full month, thirty (30) days, **or up to ninety (90) days**, as previously described. If there are insufficient supplies to be able to last for one (1) full month, thirty (30) days, **or ninety (90) days**, additional supplies must be provided before the supply allowance is billed.

No more than 1 unit of service (UOS) of HCPCS code K0553 is billable per thirty (30) days. **Suppliers may bill three (3) UOS at one time, when delivering a 90-day supply.**"

Most durable medical equipment supply items provided on a recurring basis can be dispensed with a three-month (90 day) supply, including diabetic testing supplies and insulin pump supplies.[160] It is unclear why CGM supplies are limited to a one-month (30 day) supply. We believe aligning the billing and shipping for CGM supplies with other diabetes supplies will reduce administrative burden in Medicare claims processing and for beneficiaries, providers, and suppliers.

Section 11: Cost Effectiveness of CGM Therapy

We are aware that the process for revising an LCD does not include consideration of the cost of the therapy under consideration, focusing instead on whether the "reasonable and necessary" standard has been demonstrated with applicable clinical literature and standards of care. However, we are not insensitive to concerns that expanding coverage for CGM therapy has cost implications, given the size of the population that could qualify for coverage under the revisions we are requesting. To allay those concerns we describe below a range of studies that have examined the cost effectiveness of CGM therapy.

- A 2011 study to determine the cost-effectiveness of CGM technology with intensive insulin therapy compared to BGM in adults with type 1 diabetes in the United States concluded that CGM appeared to be cost effective relative to BGM.[161]
- A 2019 study looked at the cost effectiveness of flash CGM use by individuals with Type 1 in Spain. The researchers concluded that the total annual cost/patient was €4437 for SMBG and €2526 for flash CGM. Thus, the use of flash CGM would be associated with

an annual savings in the costs of monitoring and managing hypoglycemic events of €1911 per patient-year.162 These same researchers examined the cost effectiveness of flash CGM among people with Type 2 and concluded that costs were €2700 and €2120/year/patient using SMBG or FreeStyle Libre 2 system, respectively.[163]

- A 2019 study in the UK estimated the total costs of managing pregnancy and delivery in women with Type 1 diabetes using BGM testing with and without real time CGM. The cost of glucose monitoring was estimated at £588 with BGM alone and £1820 with real time CGM. The total annual costs of managing pregnancy and delivery in women with Type 1 diabetes were £23,725,648 with BGM alone, and £14,165,187 with BGM and real time CGM; indicating potential cost savings of approximately £9,560,461 from using real time CGM. The principal drivers of cost savings were the daily cost of neonatal intensive care unit (NICU) admissions (£3,743) and the shorter duration of NICU stay (mean 6.6 vs. 9.1 days respectively). Sensitivity analyses showed that real time CGM remained cost saving, albeit to lesser extents, across a range of NICU costs and durations of hospital stay, and with varying numbers of daily BGM measurements. The researchers concluded that routine use of real time CGM by pregnant women with Type 1 diabetes would result in substantial cost savings, mainly through reductions in NICU admissions and shorter duration of NICU care.[164]
- A 2020 study examining the cost effectiveness of CGM vs. BGM among patients with Type 1 diabetes in the UK found that use of real-time CGM was associated with a mean incremental gain in quality-adjusted life expectancy of 1.49 quality-adjusted life years (QALYs) versus BGM and that CGM was "a cost-effective disease management option relative to BGM."[165]
- A 2021 real-world retrospective study analyzed commercial and Medicare Supplemental databases to assess the impact of flash CGM on diabetes-related events and hospitalizations in a cohort of 2463 individuals with Type 2 diabetes who were on short- or rapid-acting insulin therapy. The researchers found that rates of acute diabetes-related events decreased from 0.180 to 0.072 events/patient-year, and rates of all-cause in-patient hospitalizations decreased from 0.420 to 0.283 events/patient year. The reduction in acute diabetes-related events occurred regardless of age or gender.[166] Such reductions will clearly reduce the economic burden associated with hospitalizations for this population.
- A poster at the recent ADA Scientific Sessions presented the results of a study assessing the budget impact of providing flash CGM to individuals with Type 1 and Type 2 diabetes taking multiple daily injections of insulin (MDI). The study included the total US Medicaid and CHIP population. Using published data, the researchers estimated rates of severe hypoglycemic events, diabetic ketoacidosis and other severe hyperglycemic events as well as risk reduction from use of flash CGM for the various types of events and for reduction in A1c. They estimated that increasing the population proportion using flash CGM (and the remainder using BGM) from a hypothetical share of 23% to 33% was associated with a $23 million overall decrease to the budget in one year. The analysis illustrates that although the unit cost of CGM is greater than blood glucose monitoring, cost offsets due to reductions in complications can lead to overall cost savings.[167]

- Another ADA poster reported results of a study of medical costs associated with CGM use among people with Type 2 diabetes who were either intensive users of insulin, or who used basal insulin only or no insulin. The researchers found that average per person per month diabetes-related medical costs decreased by -$424, 95% CI -$816, -$31, p<0.035 after initiating real time CGM treatment (pre-index mean (SD) PPPM costs: $1,680 ($4,519); post-index: $1,256 ($3,679)). These reductions were driven, in part, by reductions in diabetes-related inpatient medical costs (-$358, 95% CI -$706, -10. p<.-044). Inpatient hospital stays were reduced on average -.006 PPPM and hospital days were reduced an average of -.042 PPPM. They concluded that "Increased access to rtCGM for patients with T2D may help to reduce diabetes-related cost of care."[168]
- Another ADA poster reported on a long-term health economic analysis performed in Sweden to establish the cost-effectiveness of the FreeStyle Libre® system versus BGM in T2D insulin treated patients not reaching their glycemic goals. The study concluded that for Sweden-based patients with T2D on insulin not reaching glycemic goals, the FreeStyle Libre system is associated with improvements in clinical outcomes and seems a cost-effective disease management option relative to BGM.[169]
- A study published in 2020 examined the clinical impact of CGM for people with Type 2 diabetes within a specific, large integrated health system. The study consisted of a parallel randomized, multisite prospective trial was conducted using a new CGM device (Dexcom G6) compared to a standard of care finger stick glucometer (FSG) (Contour Next One). All participants received usual care in primary care clinics for six consecutive months while using these devices. CGM patients significantly decreased A1c (p = .001), total visits (p = .009), emergency department encounters (p = .018), and labs ordered (p = .001). Among SelectHealth non-Medicare Advantage patients, per member per month savings were $417 for CGM compared to FSG, but $9 more for Medicare Advantage.[170]

We believe that this growing body of evidence should provide confidence that the use of CGM will result in reductions in hospitalizations and emergency room use and that these savings demonstrably offset the cost of CGM therapy itself.

CONCLUSION

We thank the DME MACs for their consideration of this reconsideration request and look forward to working with them to ensure that Medicare beneficiaries have access to the most efficacious therapies for their given situations. Should you have specific questions or wish to initiate discussions of this request, please reach out to our consultant, Jim Scott, via email at [redacted] or by phone at [redacted].

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