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VIA EMAIL TO DMERecon@noridian.com

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Re: LCD Reconsideration Request – Glucose Monitors (L33822)

Dear DME MAC Medical Directors:

Abbott Diabetes Care, Inc. (ADC) submits the enclosed reconsideration request for the local coverage determination (LCD) for Glucose Monitors (L33822) to revise the Medicare Part B coverage criteria for continuous glucose monitors (CGMs) and related supplies, described by HCPCS codes K0554 (therapeutic CGM device) and K0553 (related supply allowance). ADC manufactures and markets the FreeStyle Libre 2 and FreeStyle Libre 14-day Systems, which the Medicare Pricing and Data Analysis Contractor (PDAC) confirmed qualify as therapeutic CGMs.

As further discussed in the enclosed reconsideration request, ADC respectfully requests that the medical directors reevaluate L33822 and implement the following changes:

1. **Revise the requirement that patients administer insulin multiple (three or more) times daily or use a continuous insulin pump, to enable coverage for all insulin-using diabetic patients.** The clinical benefits of CGM have been demonstrated in diabetic patients that use insulin but who are not receiving multiple daily insulin administrations or using insulin pumps. Applicable clinical practice guidelines published by leading clinical organizations, including the American Diabetes Association (ADA), Endocrine Society, and the American Association of Clinical Endocrinologists (AACE), recommend use of CGM in insulin-using patients who do not require three or more daily insulin administrations or a continuous insulin pump. Accordingly, removing the requirement that patients have three or more insulin administrations per day is consistent with the state of clinical

evidence and accepted standards of practice for the reasonable and necessary use of CGM.

2. **Remove the requirement that the patient's insulin treatment regimen requires frequent adjustment on the basis of BGM or CGM testing results.** While the medical directors clarified that the LCD criterion does not require that frequent changes be made to the patient's insulin treatment plan in all cases, this requirement does not align with the evidence demonstrating improved outcomes in patients, regardless of the frequency of their insulin dose adjustments from CGM readings.

3. **Revise the 6-month in-person visit requirement after delivery of the CGM device to enable documentation of adherence through other objective evidence.** Practitioners are able to evaluate and document continued CGM adherence and diabetes management plan compliance through remote evaluation of CGM data. Where CMS has recognized the value of these remote services, allowing practitioners to document CGM regimen adherence through remote evaluation of data can help address health disparities in CGM access and align with more flexible care delivery options made available through the COVID-19 pandemic and beyond.

In support of this request, we have enclosed the following materials:

- Proposed revised coverage criteria for CGMs (Appendix 1); and
- Full-text copies of published clinical evidence cited herein (Appendix 2).

Please do not hesitate to contact me at [redacted] or [redacted] with any questions regarding this request. We appreciate your consideration of this request.

Sincerely,

Eileen M. Bockoff

Eileen Bockoff
Sr. Director Corporate Reimbursement

cc: Latham & Watkins LLP

Abbott
A Promise for Life

I. BACKGROUND

Continuous glucose monitors (CGMs) are used by individuals with diabetes mellitus to monitor their blood glucose levels. In contrast to standard BGMs, CGMs measure blood glucose levels from interstitial fluid on a continuous basis, rather than requiring diabetic patients to perform periodic finger sticks to obtain blood samples for testing. CGM technology provides actionable information to patients and clinicians and has been shown to benefit patients by reducing hypoglycemia and HbA1c, increasing the amount of time the patient's glycemic levels are within target range ("time in range" or "TIR"), and lowering rates of hospitalization for acute glycemic events.

This LCD reconsideration request focuses on three of the existing Medicare coverage criteria – the "multiple daily administration" (MDA) requirement (#2), the "frequent adjustment" requirement (#3), and the "6-month in-person visit" requirement (#5) (highlighted in red in Table 1). Based on the reasonable and necessary standard for coverage, ADC requests revisions to these coverage limitations to align with the published clinical evidence and accepted standards of medical practice (as expressed in consensus clinical practice guidelines) supporting use of CGM in the Medicare population. With the development of evidence not available at the time of the LCD's adoption, and clinical standards that now consistently recommend CGM use in a wider population, updates to these coverage criteria will maintain consistency among Medicare policies, published evidence, and the accepted standards of clinical care.

Table 1. Coverage Criteria Subject to Reconsideration Request

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 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 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.***

In addition to aligning with clinical evidence and standards of care, the proposed revisions to these coverage limitations will help address health disparities that may be exacerbated by these restrictions on the reasonable and necessary use of CGM devices. These criteria create the most acute barriers to initial and continued CGM use among lower-income and minority populations, where the inability to afford multiple daily administrations of insulin, or limited transportation options to comply with an ongoing six-month visit requirement, will

disqualify beneficiaries who would otherwise depend on CGM devices to effectively manage their diabetes. As CMS focuses significant effort on addressing health disparities among patient groups of different backgrounds, ethnicities, and means, we ask that the DME MACs also take into consideration these practical barriers to access when evaluating CGM policy—barriers that have become more pressing as demonstrated in recent evaluations of beneficiary behavior during the COVID-19 Public Health Emergency (PHE).[1]

II. PUBLISHED EVIDENCE AND CONSENSUS TREATMENT STANDARDS SUPPORT MEDICARE COVERAGE OF CGM FOR DIABETIC PATIENTS ON ANY INSULIN THERAPY.

The current LCD requires that the beneficiary must be insulin-treated with multiple daily administrations (MDA) of insulin or a continuous subcutaneous insulin infusion (CSII) pump. This criterion further specifies that "multiple" refers to three or more administrations. By restricting coverage to patients that administer insulin three or more times per day or that use a CSII pump, the MDA requirement places a limitation on coverage that restricts access to CGM technology among patient populations for whom there is clear evidence of clinical benefit, as recognized in the leading clinical practice guidelines.[2] On the other hand, ADC is not aware of evidence establishing that the clinical benefits of CGM are limited only to diabetic patients requiring MDA or CSII pump use, or that the benefits are materially reduced among patients on any form of insulin therapy as compared to MDA and CSII pump patients. Accordingly, ADC requests that the criteria be amended to remove the requirement that the insulin-treated patient require multiple daily administrations of insulin or a CSII pump.

A. Published clinical trials and real-world studies demonstrate the efficacy of CGM in patients receiving fewer than three insulin administrations per day.

The basis for reevaluating the MDA requirement arises from recently published clinical trial data and real-world evidence supporting the clinical benefits of CGM in patients receiving fewer than three insulin administrations per day.

For example, Martens et al. (2021) conducted an 8-month randomized, multicenter, clinical trial comparing CGM to BGM monitoring in 156 patients with type 2 diabetes treated with basal insulin, without prandial insulin. Patients were eligible for participation if they were diagnosed with type 2 diabetes and were treated with 1 or 2 daily injections of long- or intermediate-acting basal insulin (but not prandial insulin) for at least 6 months. The primary outcome was HbA1c level at 8 months adjusted for the baseline value. The results, published recently in JAMA, demonstrate that mean HbA1c levels in the CGM group decreased from 9.1% to 8.0%, as compared to the BGM group, which experienced a reduction from 9.0% to 8.4%. This differential improvement in outcomes in the CGM group was statistically significant when

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[1] Monaghesh, E., Hajizadeh, A. The role of telehealth during COVID-19 outbreak: a systematic review based on current evidence. BMC Public Health 20, 1193 (2020). https://doi.org/10.1186/s12889-020-09301-4.

[2] ADC is not requesting elimination of the requirement that the beneficiary be insulin-treated. Rather, ADC is only requesting elimination of the MDA / CSII pump portion of this criterion on the basis that the MDA requirement is not supported by the relevant clinical literature and clinical treatment guidelines.

compared to the BGM group, with a p-value=0.02 for the difference between groups. The CGM group also experienced improved rates of TIR and mean glucose levels, and these differences were statistically significant when compared to the BGM group.3 The clinical improvements detected in this study were consistent with or superior to those reported in prior RCTs comparing CGM to BGM use in patients receiving at least 2 insulin injections per day,4 or an unspecified number of basal and/or prandial, or pump-based insulin administrations daily.[5]

Similar findings of efficacy were demonstrated in type 2 diabetes patients not treated with insulin. In a 24-week multicenter RCT comparing CGM and BGM in 93 patients, Wada et al. (2020) reported statistically significant reduction in HbA1c levels in patients treated with CGM. In contrast, patients treated with BGM did not experience a statistically significant reduction in HbA1c. The difference in HbA1c outcomes between groups was itself statistically significant and favored CGM.

In addition, several published observational studies evaluated the impact of CGM on real-world outcomes in patients other than intensive insulin users and found statistically significant improvements among patients receiving fewer than 3 insulin administrations per day:

- In a retrospective analysis of adults with type 2 diabetes (n = 1034), patients were assessed to determine the effectiveness of CGM among subjects not treated with intensive insulin therapy (basal insulin and noninsulin users). Thirty percent of patients were receiving basal insulin therapy and 70% of patients were receiving noninsulin therapy. The researchers compared HbA1c levels at follow-up 60-300 days after CGM prescription to baseline levels, defined as the value within 180 days closest to CGM prescription. Findings were stratified by insulin vs. noninsulin users. The researchers found statistically significant reductions in noninsulin and insulin users (-1.6 percentage points vs. -1.1, respectively).[6]
- A retrospective multicenter study using medical records from Canadian diabetes centers (n = 91) was designed to determine the effect of CGM use among type 2 basal-only insulin users over a 3- to 6-month period of CGM use. The researchers reported a statistically significant decrease in HbA1c of 0.8 percentage points from baseline over the follow-up period. The authors noted that the observed

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[3] Martens T. 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. doi:10.1001/jama.2021.7444.

[4] 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. doi:10.2337/dc18-0166.

[5] Haak, T., Hanaire, H., Ajjan, R. et al. 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 8, 55–73 (2017). https://doi.org/10.1007/s13300-016-0223-6.

[6] 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 Spectr. 2021;34(2):184-189. doi:10.2337/ds20-0069

improvements in patient outcomes were consistent with prior clinical trials and analyses in basal insulin and noninsulin users.[7]

- In a study of a virtual diabetes clinic program, all study participants (n = 594) were prescribed a CGM device and diabetes outcomes were tracked using CGM sensors over a mean follow-up period of 10.2 months. Inclusion criteria specified HbA1c > 8%, use of insulin or a sulfonylurea, ED/urgent care visit within prior 6 months, no PCP visit in prior year, or inclusion at endocrinologist discretion. The study included 217 insulin users (frequency of insulin use unspecified) and 377 noninsulin (sulfonylurea) users. Results demonstrated statistically significant reductions in HbA1c in both the insulin and non-insulin patient groups, with greater reduction in the noninsulin user group. 93.1% percent of noninsulin users reached the treatment target (HbA1c <8%) at follow-up, as well as 65.3% in the insulin population.[8]

Several additional observational / retrospective studies, collectively involving over 2,000 patients on CGM, reported significant improvements in HbA1c and other outcomes in patients not treated with insulin 3 or more times per day, nor using CSII pumps.[9,10,11,12,13]

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[7] Elliot T, et al. 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. July-August 2021: 1–4. doi: 10.117/14791641211021374.

[8] 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 2020 Oct 7. doi: 10.1089/dia.2020.0396.

[9] Carlson AL et al. 71-LB: Glucose Control after Initiation of Flash Glucose Monitoring in Type 2 Diabetes Managed with Basal Insulin: A Retrospectve Real-World Chart Review Study from the U.S. [abstract from Late Breaking Poster Presentations: Clinical Diabetes/Therapeutics] Diabetes 2021 June; 70 (Supplement 1). doi: 10.2337/db21-64-LB.

[10] Carlson AL et al. 64-LB: Meta-analysis of Two Real-World Chart Review Studies to Determine the Effectiveness of FreeStyle Libre Flash Glucose Monitoring System on HbA1c in Adults with Type 2 Diabetes Managed with Basal Insulin. [abstract from Late Breaking Poster Presentations: Clinical Diabetes/Therapeutics] Diabetes 2021 June; 70 (Supplement 1). doi: 10.2337/db21-71-LB.

[11] Miller E, et al. 84-LB: HbA1c Reduction after Initiation of the FreeStyle Libre System in Type 2 Diabetes Patients on Long-Acting Insulin or Noninsulin Therapy. [abstract from Late Breaking Poster Presentations: Clinical Diabetes/Therapeutics] Diabetes 2020 Jun; 69 (Supplement 1). doi: 10.2337/db20-84-LB.

[12] Grace T, Sayler J. 600-P: Real-Time CGM Coverage Eligibility Should Include Type 2 Diabetes Patients Treated with Less-Intensive Therapy. [abstract from Poster Presentations: Clinical Diabetes/Therapeutics] Diabetes 2021 June; 70 (Supplement 1). doi: 10.2337/db21-600-P.

13 Norman GJ, et al. 77-LB: A Retrospective Analysis of the Association between HbA1c and Continuous Glucose Monitor Use for U.S. Patients with Type 2 Diabetes. [abstract from Late Breaking Poster Presentations: Clinical Diabetes/Therapeutics] Diabetes Jun 2021, 70 (Supplement 1) 77-LB; DOI: 10.2337/db21-77-LB.

B. Accepted standards of diabetes care recommend CGM use for diabetes patients regardless of the frequency of insulin administration, not only among MDA and CSII pump patients.

Standards of clinical practice published by leading organizations in diabetes care do not characterize the benefits of CGM as being limited to patients who use insulin at least 3 times per day or require an insulin pump. Instead, these guidelines expressly support CGM's use in a broader patient population of all insulin users:

- ***The American Association of Clinical Endocrinologists.*** In specifying the patient populations "best served" by CGM based on published research, a consensus conference of the American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology stated that "Consensus conference participants unanimously agreed that real-time CGM should be available to all insulin-using patients regardless of diabetes type."[14]

- ***The Endocrine Society.*** The Clinical Practice Guidelines of the Endocrine Society[15] do not specify the frequency of insulin dosing necessary to deem CGM effective: "In patients aged 65 years and older with diabetes who are treated with insulin, we recommend frequent fingerstick glucose monitoring and/or continuous glucose monitoring (to assess glycemia) in addition to HbA1c."[16]

- ***The American Diabetes Association.*** The ADA *Standards of Care* (2021) state that CGM "can be useful and may lower A1C levels and/or reduce hypoglycemia in adults and youth with diabetes to replace self-monitoring of blood glucose" in patients receiving multiple daily injections, patients using CSII pumps, and patients on other forms of insulin therapy.[17] The ADA standards do not define "multiple daily injection" as requiring 3 or more administrations.[18]

In sum, the consistent recommendations of the leading, expert organizations focused on diabetes care standards recommend CGM use in insulin-treated patients, based on their own thorough evaluation of the evidence and understanding of accepted standards of clinical practice.

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[14] 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. doi:10.4158/EP161392.CS.

[15] Derek LeRoith, Geert Jan Biessels, Susan S Braithwaite, Felipe F Casanueva, Boris Draznin, Jeffrey B Halter, Irl B Hirsch, Marie E McDonnell, Mark E Molitch, M Hassan Murad, Alan J Sinclair, Treatment of Diabetes in Older Adults: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 5, May 2019, Pages 1520–1574, https://doi.org/10.1210/jc.2019-00198

[16] Id.

[17] American Diabetes Association, Diabetes Technology: Standards of Medical Care in Diabetes—2021. Diabetes Care Jan 2021, 44 (Supplement 1) S85-S99; DOI: 10.2337/dc21-S007.

[18] See id.

III. THE FREQUENT ADJUSTMENT REQUIREMENT SHOULD BE REMOVED AS A MEDICARE COVERAGE LIMITATION FOR CGM DEVICES.

The current LCD states that, in order to be eligible for coverage, the beneficiary's insulin treatment regimen must require "frequent adjustment by the beneficiary on the basis of BGM or CGM testing results." Based on comments submitted to the most recent LCD reconsideration of the Glucose Monitors LCD, the DME MACs clarified that the frequent adjustment requirement "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.*"[19] Similar language was included in the corresponding Local Coverage Article (LCA).[20]

While ADC appreciates the interim step of clarifying the limited scope of the frequent adjustment criterion, the DME MACs' explanation highlights that the requirement as currently stated is more focused on adherence than an independent requirement to support the medical necessity of an initial CGM order. Because published evidence supports the effectiveness of CGM use regardless of the frequency of insulin dose adjustments made in response to CGM readings—and the standard itself is duplicative and continues to create confusion among practitioners and suppliers—ADC requests the removal of this requirement from the LCD:

- **Published Evidence and Practice Guidelines Do Not Support a "Frequent Adjustment" Requirement:** The frequent adjustment requirement is not supported by the clinical evidence or clinical practice recommendations for use of CGM. As discussed above, a number of published studies demonstrate CGM's effectiveness in achieving improved outcomes in patients treated with 1-2 insulin administrations per day, or in combination with other hypoglycemic medications, which do not require frequent adjustment of insulin doses.
- **Duplicative of Other Documentation Requirements:** As noted below and as set out in the *Standard Documentation Requirements for All Claims Submitted to DME MACs*, providers and suppliers must also maintain documentation in the beneficiary's medical record to support the continued medical need and continued use of the item and related supplies,[21] and continued adherence to a CGM regimen must also be documented by the practitioner every 6 months. These requirements, which are satisfied through documentation in the beneficiary's medical record, already specify conditions under which CGMs qualify for continued coverage and are more consistent and understood than this "frequent adjustment" criterion as clarified in the LCA.

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[19] DME MACs, Local Coverage Article: Response to Comments: Glucose Monitors – DL33822 (A58798).

[20] DME MACs, Local Coverage Article: Glucose Monitors (A52464).

[21] DME MACs, Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)

For the foregoing reasons, and consistent with the request that CGM coverage not be limited to patients requiring multiple daily administrations of insulin or CSII pump use, ADC respectfully requests that the frequent adjustment requirement be removed from the LCD.

IV. PROVIDERS SHOULD BE AFFORDED THE FLEXIBILITY OF DOCUMENTING CONTINUED ADHERENCE TO A CGM REGIMEN THROUGH REMOTE REVIEW OF CGM AND GLUCOSE DATA.

Over the last 18 months of the COVID-19 pandemic, the Medicare program has recognized the value in utilizing technology-based services to provide real-time data to providers and help manage patient care remotely.[22] Use of remote monitoring and other communications technology-based services (CTBS) has improved beneficiary access to care and patient health by reducing exposure to COVID-19, while maintaining important communication between patients and providers through effective and efficient services.[23] Moreover, a Kaiser Family Foundation evaluation of patients who substituted remote telehealth visits for in-person visits during the COVID-19 PHE found that, among beneficiaries whose providers offered telehealth, a greater share of those with disabilities, with low incomes, and in communities of color used telehealth. The authors note that this data point suggests that the expansion of remote care options may help some of Medicare's more disadvantaged populations access needed care.[24] As a result, by enabling physicians to use objective evidence gathered remotely to confirm CGM adherence and diabetes management plan compliance, the CGM policy can help address ongoing health disparities, which are particularly acute among diabetic patients otherwise qualified for CGM therapy.[25]

All therapeutic CGM systems include optional features and software to enable treating practitioners to review data necessary to confirm patients' adherence to their recommended CGM and diabetes management regimen. For instance, patients can upload CGM data from their FreeStyle Libre Reader to the LibreView portal, or use the FreeStyle LibreView app installed on

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[22] CMS adopted a number of flexibilities in the Medicare Diabetes Prevention Program (MDPP) in recognition of the limitations faced by patients and the benefits of remote services during the pandemic. See Physician Fee Schedule – CY 2021 Final Rule, 85 Fed. Reg. 84,838, 84,544 (Dec. 28, 2020) ("We eliminated as many obstacles as possible to allow timely delivery of reasonable and necessary health care. We wanted patients to be able to access services quickly and without barriers.").

[23] In the context of opioid treatment programs (OTPs), CMS stated: "[W]e believe that allowing periodic assessments to be furnished via two-way interactive audio-video communication technology beyond the conclusion of the PHE for the COVID–19 pandemic would help to expand access to care for patients who may have a difficult time getting to the OTP in person." Physician Fee Schedule – CY 2021 Proposed Rule, 85 Fed. Reg. 50,208 (Aug. 17, 2020).

[24] Kaiser Family Foundation, Medicare and Telehealth: Coverage and Use During the COVID-19 Pandemic and Options for the Future, May 19, 2021, https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/.

[25] See, e.g., 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 Jan;44(1):255-257. doi: 10.2337/dc20-1663 (finding that Black children and young adults are less likely to start CGM therapy within one year of a Type 1 diabetes diagnosis than non-Hispanic white children, and that one year after starting CGM, fewer Black children than non-Hispanic white children were using CGM ($p<0.001$)).

a smartphone, to share their diabetes information with their healthcare team, including objective evidence of the patients' CGM use, glucose levels, and the glucose trends necessary to monitor and adjust patients' treatment regimens if needed. By reviewing the CGM data automatically captured and shared through LibreView, the treating practitioner can determine whether and how frequently the patient is using the CGM device, whether the patient is adhering to recommended therapies and activities to avoid high or low glucose levels, and whether further adjustments to the patient's treatment are necessary to improve time in range (and, ultimately, improve HbA1c). For certain patients, the CGM data—accessed remotely—can provide objective evidence of CGM adherence and the patient's compliance with the prescribed diabetes management plan. In these instances, an in-person visit may not be needed. For other patients, an in-person or telehealth visit may be necessary, either because the remote CGM data are not available, or because the data show that further engagement, management and potential adjustments are necessary through a real-time interaction.

Flexibility in documenting CGM adherence is especially appropriate where there have not been identified concerns with CGM adherence in published evidence evaluating CGM use. Suppliers are already required to maintain documentation of continued use and medical need for CGM every 12 months.[26] Continuing to impose an additional in-person visit requirement to confirm adherence every six months creates a barrier to continued CGM access, especially for patients with limited transportation options or restrictive work schedules. The remote monitoring approach proposed here is consistent with other LCDs, where documentation of therapy adherence may be demonstrated by "direct download or visual inspection of usage data, with documentation provided in a written report format to be reviewed by the treating practitioner and included in the beneficiary's medical record."[27]

Accordingly, ADC requests that the CGM coverage criteria be revised to allow practitioners, as an option, to utilize remote monitoring or other CTBS services to meet the ongoing care management and documentation requirements currently required to be completed through an in-person visit. Specifically, we request that the 6-month follow-up requirement be amended to allow the treating practitioner to review objective evidence of the patient's adherence to their CGM regimen and diabetes treatment plan, and include that evidence in the patient's medical record, rather than requiring the practitioner to document CGM adherence only through an in-person visit.

V. CONCLUSION

As currently written, LCD L33822 imposes coverage limitations and restrictions that are now inconsistent with published evidence and consensus clinical recommendations for CGM use among diabetic patients. In light of the foregoing, ADC respectfully requests the revisions to the current coverage criteria shown in Appendix 1.

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[26] See Standard Documentation Requirements, supra note 21.

[27] E.g., Noridian Health Services, Policy Article A52467, Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (eff. Aug. 8, 2021).

APPENDIX 1. PROPOSED COVERAGE CRITERIA

Therapeutic CGMs and related supplies are covered by Medicare when all of the following coverage criteria (~~1-5~~1-4) are met:

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 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 BGM or CGM testing results; and,~~

3. ~~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~~1-2) above are met; and,

4. ~~5.~~ Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary, **or documents review of objective evidence from the CGM device**, to assess adherence to their CGM regimen and diabetes treatment plan.