I am Andrew Ahmann. I am a Professor of Medicine at OHSU and Director of the Harold Schnitzer Diabetes Health Center that serves about 7500 individuals with diabetes. I want to submit written testimony supporting the use of continuous glucose monitoring (CGM) in type 2 diabetes for those on insulin.

I have been active in diabetes specialty care emphasizing intensive therapy of type 1 (T1D) and type 2 diabetes (T2D) for over 35 years. The use of CGM has made more difference in treatment effectiveness and safety than any other modality during that time for those using insulin. Self-management of diabetes is critical as patients make therapeutic decisions multiple times each day. For patients with type 1 diabetes the use of CGM is well recognized as the standard of care. In the most recent update on the most respected diabetes standards of care, the American Diabetes Association now recommends CGM for all patients using basal insulin alone or in combination with meal insulin (Diabetes Care 2023; 46, Suppl 1: S114.

CGM has been shown to improve glucose control (Time in Range and A1C) with a relative reduction of hypoglycemia and glucose variability. These factors are very important in T1D but possibly even more important in type 2 diabetes where patients are at risk for more severe consequences of hypoglycemia (cardiac arrhythmias, falls with fractures, worsening cognitive function) than is typical in younger T1D patients. While the glucose reductions may be greater with use of CGM in T1D, the improvements in T2D are nevertheless significant. Although the tools for determining patient reported outcomes are inconsistent, almost every study show patients prefer CGM and show some objective evidence of improved quality of life.

On a practical basis, two points are particularly relevant for the discussion of CGM approval for T2D Medicaid patients in Oregon: (1) Most commercial insurances cover CGM now for those with T2D on insulin as does Medicare. This emphasizes not only the general conviction that this tool is beneficial but also casts a focus on issues of equity. There is good evidence that this technology is effective across a spectrum of socioeconomic groups and many of those on Medicaid are disproportionately affected by the burden of diabetes both in terms of prevalence and consequences of poor control or hypoglycemia. They should not be left behind. (2) Just consider that we have all learned the benefit of technology that we could not have imagined 20 years ago. Almost everyone would utilize a GPS navigation app if they were traveling into a large city. We have all become comfortable with this tool to increase safety, reduce time and reduce the stress of the commute. That is what CGM does for those with any form of diabetes where the challenges of insulin therapy are seldom adequately monitored by using painful fingersticks using a separate meter and requiring extra time, inconvenience and social anxiety.

I will leave the review of important trials such as the DIAMOND trial and the MOBILE Study to the HERC committee. At this point I simply want to endorse the proposed guidance the HERC rendered for use of CGM in Type 2 Diabetes. I think they are practical, evidence based and address a need for this population that is their own medical provider 99.9% of the time with an enormous burden added to the typical burden of everyday life with which we are all familiar.

Thank you for your serious consideration of this topic.

Andrew Ahmann, MD

From: April V
To: OHPR - HERC Info
Subject: CGM coverage by OHP
Date: Tuesday, April 18, 2023 9:59:42 AM

To whom it may concern,

I am writing in full support of coverage of continuous glucose monitoring for patients who need daily insulin injection, or at high risk of hypoglycemic events due to their age and strong hypoglycemic (low blood sugar causing) medications.

This technology is life changing, improves outcomes, reduces the overall discomfort and disease burden, and improves daily experiences of diabetes management for persons with diabetes. It provides information about blood glucose patterns that are otherwise missed (consider getting 0.06% versus 100% of the data – that's the difference between the standard of care of one glucose check in the morning versus CGM). The technology is literally revolutionary.

Additionally it is supported by evidence and by the 2023 American Diabetes Association guidelines.

I applaud OHA for considering the acceptance of this life changing technology.
Please let me know what question you have.
Warm regards,
April Von Allmen, PharmD, BCACP
Clinical Pharmacist

April 20, 2023

Dear Members of the Evidence-based Guidelines Subcommittee:

I am writing on behalf of the American Diabetes Association (ADA), the nation's largest voluntary health organization concerned with the health of people with diabetes. An estimated 37 million Americans and nearly 306,000 individuals in Oregon have diabetes[1], a chronic illness that requires continuing medical care and ongoing patient self-management to prevent acute complications and reduce the risk of long-term complications, such as blindness, amputation, kidney failure, heart attack, and stroke.

Advances in treatments, including continuous glucose monitoring (CGM), have been shown to be effective tools in diabetes management and the prevention of tragic and costly complications associated with the disease. Unfortunately, there continue to be gaps in access to CGM and other technologies among under-served populations, including – and perhaps most acutely – in the Medicaid population. ADA recommends you implement measures to broaden access for people with diabetes to these technologies that will enable them to better manage their diabetes, and which may result in fewer adverse health outcomes, disability, or premature deaths.

The ADA appreciates the work that the committee has done to review access to continuous glucose monitors. We support the recommendation to expand access for CGMs to people with type 2 and gestational diabetes who are on insulin. This recommendation is in line with similar legislation, House Bill 3380, being considered this legislative session and we are actively advocating for ways and means committee to support the legislation and ensure patients have access to the technology that they need. We encourage the committee to take steps to implement the draft proposal quickly so people with diabetes can begin to access this life-saving technology.

The ADA respectfully urges the committee to take extra care to avoid making choices that would limit access for people with diabetes to CGM or any technology that those individuals and their doctors believe is most appropriate to manage their diabetes. ADA's 2022 *Standards* provide that the choice of technology should be individualized based on patient's needs, desires, skill level, and availability of devices. These are determinations that should be made by a patient in conjunction with their health care provider.[2]

The American Diabetes Association appreciates the opportunity to submit comments for your consideration and looks forward to working with you to implement measures aimed at increasing access to CGMs to Medicaid beneficiaries in Oregon.

Should you have any questions regarding these comments, please contact me at

Sincerely,

Carissa Kemp
Director of State Government Affairs

[1] http://main.diabetes.org/dorg/docs/state-fact-sheets/ADV_2020_State_Fact_sheets_OR.pdf
[2] https://diabetesjournals.org/care/article/46/Supplement_1/S111/148041/7-Diabetes-Technology-Standards-of-Care-in

From: Jessi Ortiz (Pinnock) FNP
To: OHPR - HERC Info
Subject: written testimony for CGM use in type II diabetic patients
Date: Monday, April 17, 2023 10:47:48 AM
Attachments: image001.jpg
image002.jpg

4/20/2023 (2:00-5:00 pm) Evidence-based Guidelines Subcommittee (EbGS)
(Deadline 4/18/2023, by noon pacific time)

Hello, My name is Jessi Ortiz and I am a Nurse Practitioner who manages a care team called the Salud program at One Community Health in Hood River – our focus is diabetes education, prevention and comprehensive care. We work primarily with patients who are low income, undocumented or have Medicaid or state insurance – out of pocket costs for CGM blood glucose monitoring is completely cost prohibitive to our patients unless it were covered by insurance or grant funding. I am writing to you in written testimony for the use of CGMs for diabetics with type II diabetes who are currently using insulin or who have documented severe low blood glucose events. The use of CGMs for the above scenarios is well established best practice for those managing diabetes due to frequent monitoring needs of blood glucose. Having a CGM significantly reduces low blood glucose events because the trend of low blood glucoses can be stopped before they are critically low. CGMs are also extremely easy to use once training has been completed for patients and they are less painful and invasive than frequent finger pokes for monitoring BG. For patients who use insulin or have frequent low BG events the reality is they have more knowledge of their current blood glucose with a CGM because they utilize this tool with far greater frequency than finger pokes. Increasing access to CGMs in type II diabetics will help reduce the wide care gap that is present for many patients who are insulin dependent and require frequent monitoring of their blood glucoses. CGMs effectively help patients decrease adverse events when using insulin or managing low blood glucoses, and helps inform their healthcare provider of their current BG control and medication needs. We had a grant funded CGM cohort within our Salud program this past year which provided free CGMs for diabetic patients to continually monitor their BG while managing their diabetes with insulin or oral therapy – patients reported significant improvements in their knowledge of their diabetes, began to correlate specific foods and diet changes with their blood glucose trends, were able to reduce hypoglycemic events and objectively reduced

their A1Cs across the board. After the trial, none of these patients were able to afford the sensor replacements of the CGMs – it simply was not sustainable financially for them – but the benefits were incredible and anyone who saw this small cohort from start to finish would agree that use of CGMs in type II diabetic patients was necessary for improving the care and knowledge of these patients.

Jessi Ortiz (Pinnock) FNP
Salud Manager
One Community Health

From: Edward Saito, PharmD
To: OHPR - HERC Info
Subject: Comments in favor of proposed coverage criteria for CGM
Date: Monday, April 17, 2023 1:53:49 PM
Attachments: image001.png
image002.png
image003.png
image004.png

To whom it may concern,

I am writing in support of the proposed coverage criteria for continuous glucose monitoring (CGM) in individuals with type 2 diabetes. I am a clinical pharmacist specializing in diabetes care at Virginia Garcia Memorial Health Center, a local FQHC. I routinely prescribe continuous glucose monitoring for my patients with type 2 diabetes, in accordance with the recommendations published in the American Diabetes Association Standards of Care in Diabetes, 2023 (Diabetes Care December 2022, Vol.46, S111-S127. doi:https://doi.org/10.2337/dc23-S007). With the recent revision of Medicare coverage criteria to include individuals with type 2 diabetes using at least 1 daily injection of insulin, many of my patients have become newly eligible for this important monitoring technology, and I have witnessed significant improvements not only in objective measures of disease control such as A1c, but also in quality of life, care engagement and medication adherence. Many of the patients I serve face tremendous barriers to accessing care and experience the impact of health disparities. Many of these individuals work in the agriculture industry and daily engage in physically strenuous activities which increase their risk for hypoglycemia (low blood sugar) especially if they are taking insulin. Having access to a continuous glucose monitor can provide potentially life-saving alerts to a farmworker or construction worker who is experiencing critically low blood sugar in the middle of their workday. Moreover, the long work hours that many of these individuals face, with limited breaks, makes frequent self-monitoring of blood glucose not feasible and nearly impossible. Yet, current coverage of CGM by many payers continues to require evidence that patients are self-monitoring their blood glucose at least 4 times per day. I applaud the subcommittee's proposed revision of the coverage criteria, based on compelling evidence, to include patients with type 2 diabetes using at least 1 daily insulin injection, without additional requirements for frequent self-monitoring of blood glucose. While this change represents an increased investment of healthcare resources, I believe it will help to improve diabetes outcomes, reduce future healthcare costs, and begin to address health disparities faced by many Oregonians.

Regards,
Edward Saito

Edward M. Saito, PharmD, BCACP
Clinical Pharmacist

6340 Sequence Drive
San Diego, CA 92121
T: 858.200.0200
F: 858.200.0201
www.dexcom.com

April 18, 2023

Oregon Health Authority
Health Evidence Review Commission (HERC)
500 Summer Street NE, E-20
Salem, OR 97301

Dear HERC Members:

On behalf of Dexcom, Inc., I am writing to provide comments regarding HERC's Coverage Guidance for Continuous Glucose Monitoring (CGM) for Type 2 Diabetes (T2D). We have two requests for the Committee's consideration: 1) broadening coverage to all insulin-treated people with T2D as well as individuals with T2D and problematic hypoglycemia; 2) considering outcomes beyond HbA1c when evaluating the benefits of CGM in people with T2D and gestational diabetes mellitus (GDM).

1. Broadening Coverage in Type 2 Diabetes

We applaud HERC's decision to recommend CGM coverage for individuals with T2D who are receiving daily insulin but disagree that coverage should be restricted to individuals with high HbA1c (>8%), severe hypoglycemia, or hypoglycemia unawareness. Evidence supporting the benefits of CGM in people with insulin-treated T2D has shown that CGM provides important benefits regardless of treatment regimen.[1,2,3,4,5,6] In addition, although the greatest impact of CGM is on T2D individuals with the worst baseline glycemic control, benefits are apparent across the range of baseline glycemic control.[7,8] Because benefits of CGM may be experienced by all insulin-treated people with T2D, CGM coverage should not be restricted to people with poor baseline glycemic control.

Consistent with this evidence, in April 2023, CMS announced a policy change that will expand coverage of CGM to all insulin-using individuals with T2D and all individuals with T2D with a history of problematic hypoglycemia, regardless of treatment regimen.[9] Similarly, current American Diabetes Association Standards of Care strongly recommend that real-time CGM be offered for diabetes management in adults with diabetes on intensive insulin therapy or basal insulin therapy, and state that "access to CGM devices should be considered from the outset of the diagnosis of diabetes that requires insulin management" to allow for close tracking of glucose levels with adjustments of insulin dosing and lifestyle modifications and remove the burden of frequent fingerstick blood glucose monitoring (BGM).[10] In addition, the American Association of Clinical Endocrinology (AACE) recommends CGM for all people with T2D who are treated with insulin therapy *or* who have high risk for hypoglycemia and/or with hypoglycemia unawareness."[11]

To align with current evidence, CMS policy, and clinical guidelines, we believe HERC should broaden its recommendation to include all individuals with T2D who are on any insulin regimen as well as all individuals with T2D who experience problematic hypoglycemia. Expanding access to CGM in people with T2D, including Medicaid beneficiaries who have worse glycemic control, experience more barriers to care (including access to and coverage of CGM), and experience more acute- and long-term complications related to diabetes,[12,13,14] should help state Medicaid agencies' efforts to address health disparities.[15]

2. Considering Outcomes Beyond HbA1c for Patients with Type 2 Diabetes and GDM

We encourage HERC to consider outcomes beyond HbA1c, including time in range (TIR), quality of life, and acute diabetes-related complications. A growing body of evidence demonstrates that CGM-derived metrics have added value in clinical, research, and regulatory settings beyond the accepted gold standard of HbA1c. There has been an emerging consensus that proportion of TIR would be a suitable alternative to the use of HbA1c in clinical research[16,17,18] because TIR is correlated with long-term microvascular and macrovascular complications *to the same or greater extent* as HbA1c.[19,20,21,22,23,24] In addition, many studies have demonstrated that CGM contributes to improved diabetes-related quality of life for people with diabetes and caregivers.[25,26,27,28,29,30] Finally, large real-world observational studies have consistently shown that use of CGM reduces the incidence of acute diabetes-related complications.[4,31,32,33]

Currently, HERC recommends coverage of CGM in individuals with GDM on daily insulin, noting that benefits of CGM on HbA1c have not been demonstrated in non-insulin-treated GDM patients. We ask the Committee to consider additional outcomes, especially TIR, shown to be associated with improved pregnancy outcomes. A strong body of research has shown that TIR is associated with neonatal and maternal outcomes.[34,35] In addition, adherence to blood glucose monitoring (BGM) recommendations is associated with neonatal outcomes.[34,36] For every 10% increase in adherence to testing recommendations, the odds of Cesarean delivery, neonatal hypoglycemia, and large for gestational age fetuses decreases by 15-20%.[36] Although many women with GDM are highly motivated, poor compliance with BGM recommendations is common with only 62% of patients performing at least 80% of the required daily BGM tests.[37] Broader access to CGM would help address the problem of poor adherence to BGM recommendations in women with GDM and align with current guidelines that state that CGM may be recommended for women with GDM who are not on insulin therapy.[38]

Thank you for reviewing our comments and for your consideration. We look forward to working with the State of Oregon to help ensure that the most vulnerable populations have access to technologies they need to successfully manage their diabetes while reducing costs for the state. Please reach out if you have any questions or need additional information.

Sincerely,

Renee Taylor

Renee Taylor MS, RD, BC-ADM, CDCES
Director, Medical Science
Dexcom, Inc.

References

[1]. Beck RW, Riddlesworth TD, Ruedy K, Ahmann A, Haller S, Kruger D, McGill JB, Polonsky W, Price D, Aronoff S, Aronson R, Toschi E, Kollman C, Bergenstal R. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections: A randomized trial. Ann Intern Med. 2017;167(6):365-374.
[2]. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Flash glucose-sensing technology as a replacement for blood glucose monitoring for the management of insulin-treated type 2 diabetes: A multicenter, open-label randomized controlled trial. Diabetes Ther. 2017;8(1):55-73.
[3]. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Use of flash glucose-sensing technology for 12 months as a replacement for blood glucose monitoring in insulin-treated type 2 diabetes. Diabetes Ther. 2017;8(3):573-586.
[4]. Karter AJ, Parker MM, Moffet HH, Gilliam LK, Dlott R. Association of real-time continuous glucose monitoring with glycemic control and acute metabolic events among patients with insulin-treated diabetes. JAMA. 2021;325(22):2273-2284.
[5]. Karter AJ, Parker MM, Moffet HH, Gilliam LK, Dlott R. Continuous glucose monitor use prevents glycemic deterioration in insulin-treated patients with type 2 diabetes. Diabetes Technol Ther. 2022;24(5):332-337.
[6]. Martens T, Beck RW, Bailey R, Ruedy KJ, Calhoun P, Peters AL, Pop-Busui R, Philis-Tsimikas A, Bao S, Umpierrez G, Davis G, Kruger D, Bhargava A, Young L, McGill JB, Aleppo G, Nguyen QT, Orozco I, Biggs W, Lucas KJ, Polonsky WH, Buse JB, Price D, Bergenstal RM. Effect of continuous glucose monitoring on glycemic control in patients with type 2 diabetes treated with basal insulin: A randomized clinical trial. JAMA. 2021;325(22):2262-2272.
[7]. Davis GM, Bailey R, Calhoun P, Price D, Beck RW. Magnitude of glycemic improvement in patients with type 2 diabetes treated with basal insulin: Subgroup analyses from the mobile study. Diabetes Technol Ther. 2021;24(5)::324-331.
[8]. Billings LK, Parkin CG, Price D. Baseline glycated hemoglobin values predict the magnitude of glycemic improvement in patients with type 1 and type 2 diabetes: Subgroup analyses from the diamond study program. Diabetes Technol Ther. 2018;20(8):561-565.
[9]. Glucose monitor - policy article. 2023. (Accessed March 15, 2023, at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52464&ver=49&contractorName=all&sortBy=updated&bc=13).
[10]. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, Collins BS, Hilliard ME, Isaacs D, Johnson EL, Kahan S, Khunti K, Leon J, Lyons SK, Perry ML, Prahalad P, Pratley RE, Seley JJ, Stanton RC, Gabbay RA, on behalf of the American Diabetes A. 7. Diabetes technology: Standards of care in diabetes-2023. Diabetes Care. 2023;46(Suppl 1):S111-s127.
[11]. Blonde L, Umpierrez GE, Reddy SS, McGill JB, Berga SL, Bush M, Chandrasekaran S, DeFronzo RA, Einhorn D, Galindo RJ, Gardner TW, Garg R, Garvey WT, Hirsch IB, Hurley DL, Izuora K, Kosiborod M, Olson D, Patel SB, Pop-Busui R, Sadhu AR, Samson SL, Stec C, Tamborlane WV, Jr., Tuttle KR, Twining C, Vella A, Vellanki P, Weber SL. American association of clinical endocrinology clinical practice guideline: Developing a diabetes mellitus comprehensive care plan-2022 update. Endocr Pract. 2022;28(10):923-1049.
[12]. Ebekozien O, Agarwal S, Noor N, Albanese-O'Neill A, Wong JC, Seeherunvong T, Sanchez J, DeSalvo D, Lyons SK, Majidi S, Wood JR, Acharya R, Aleppo G, Sumpter KM, Cymbaluk A, Shah NA, Van Name M, Cruz-Aviles L, Alonso GT, Gallagher MP, Sanda S, Feuer AJ, Cossen K, Rioles N, Jones NY, Kamboj MK, Hirsch IB. Inequities in diabetic ketoacidosis among patients with type 1 diabetes and covid-19: Data from 52 us clinical centers. J Clin Endocrinol Metab. 2021;106(4):e1755-e1762.
[13]. Noor N, Ebekozien O, Levin L, Stone S, Sparling DP, Rapaport R, Maahs DM. Diabetes technology use for management of type 1 diabetes is associated with fewer adverse covid-19 outcomes: Findings from the t1d exchange covid-19 surveillance registry. Diabetes Care. 2021;44(8):e160-e162.
[14]. Majidi S, Ebekozien O, Noor N, Lyons SK, McDonough R, Gandhi K, Izquierdo R, Demeterco-

Berggren C, Polsky S, Basina M, Desimone M, Thomas I, Rioles N, Jimenez-Vega J, Malik FS, Miyazaki B, Albanese-O'Neill A, Jones N-HY, Group obotTDEQICS. Inequities in health outcomes in children and adults with type 1 diabetes: Data from the t1d exchange quality improvement collaborative. Clinical Diabetes. 2021;39(3):278-283.
[15]. Expanding medicaid access to continuous glucose monitors. 2022. (Accessed April 18, 2023, at file:///C:/Users/15103/Downloads/Expanding-Medicaid-Access-to-Continuous-Glucose-Monitors_011222.pdf).
[16]. El Malahi A, Van Elsen M, Charleer S, Dirinck E, Ledeganck K, Keymeulen B, Crenier L, Radermecker R, Taes Y, Vercammen C, Nobels F, Mathieu C, Gillard P, De Block C. Relationship between time in range, glycemic variability, hba1c, and complications in adults with type 1 diabetes mellitus. J Clin Endocrinol Metab. 2022;107(2):e570-e581.
[17]. Timmons JG, Boyle JG, Petrie JR. Time in range as a research outcome measure. Diabetes Spectr. 2021;34(2):133-138.
[18]. Dovc K, Battelino T. Time in range centered diabetes care. Clinical pediatric endocrinology : case reports and clinical investigations : official journal of the Japanese Society for Pediatric Endocrinology. 2021;30(1):1-10.
[19]. Raj R, Mishra R, Jha N, Joshi V, Correa R, Kern PA. Time in range, as measured by continuous glucose monitor, as a predictor of microvascular complications in type 2 diabetes: A systematic review. BMJ Open Diabetes Res Care. 2022;10(1).
[20]. Virk SA, Donaghue KC, Cho YH, Benitez-Aguirre P, Hing S, Pryke A, Chan A, Craig ME. Association between hba1c variability and risk of microvascular complications in adolescents with type 1 diabetes. J Clin Endocrinol Metab. 2016;101(9):3257-3263.
[21]. Li J, Li Y, Ma W, Liu Y, Yin X, Xie C, Bai J, Zhang M. Association of time in range levels withlower extremity arterial disease in patients with type 2 diabetes. Diabetes Metab Syndr. 2020;14(6):2081-2085.
[22]. Sheng X, Xiong GH, Yu PF, Liu JP. The correlation between time in range and diabetic microvascular complications utilizing information management platform. Int J Endocrinol. 2020;2020:8879085.
[23]. Guo Q, Zang P, Xu S, Song W, Zhang Z, Liu C, Guo Z, Chen J, Lu B, Gu P, Shao J. Time in range, as a novel metric of glycemic control, is reversely associated with presence of diabetic cardiovascular autonomic neuropathy independent of hba1c in chinese type 2 diabetes. J Diabetes Res. 2020;2020:5817074.
[24]. Mayeda L, Katz R, Ahmad I, Bansal N, Batacchi Z, Hirsch IB, Robinson N, Trence DL, Zelnick L, de Boer IH. Glucose time in range and peripheral neuropathy in type 2 diabetes mellitus and chronic kidney disease. BMJ Open Diabetes Res Care. 2020;8(1).
[25]. van Beers CA, DeVries JH, Kleijer SJ, Smits MM, Geelhoed-Duijvestijn PH, Kramer MH, Diamant M, Snoek FJ, Serne EH. Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycaemia (in control): A randomised, open-label, crossover trial. Lancet Diabetes Endocrinol. 2016;4(11):893-902.
[26]. Heinemann L, Freckmann G, Ehrmann D, Faber-Heinemann G, Guerra S, Waldenmaier D, Hermanns N. Real-time continuous glucose monitoring in adults with type 1 diabetes and impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (hypode): A multicentre, randomised controlled trial. Lancet. 2018;391(10128):1367-1377.
[27]. Lind M, Polonsky W, Hirsch IB, Heise T, Bolinder J, Dahlqvist S, Schwarz E, Olafsdottir AF, Frid A, Wedel H, Ahlen E, Nystrom T, Hellman J. Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: The gold randomized clinical trial. JAMA. 2017;317(4):379-387.
[28]. Beck RW, Riddlesworth T, Ruedy K, Ahmann A, Bergenstal R, Haller S, Kollman C, Kruger D, McGill JB, Polonsky W, Toschi E, Wolpert H, Price D. Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: The diamond randomized clinical trial. JAMA. 2017;317(4):371-378.

[29]. Speight J, Choudhary P, Wilmot EG, Hendrieckx C, Forde H, Cheung WY, Crabtree T, Millar B, Traviss-Turner G, Hill A, Ajjan RA. Impact of glycaemic technologies on quality of life and related outcomes in adults with type 1 diabetes: A narrative review. Diabet Med. 2023;40(1):e14944.
[30]. Polonsky WH, Soriano EC, Fortmann AL. The role of retrospective data review in the personal use of real-time continuous glucose monitoring: Perceived impact on quality of life and health outcomes. Diabetes Technol Ther. 2022;24(7):492-501.
[31]. Bergenstal RM, Kerr MSD, Roberts GJ, Souto D, Nabutovsky Y, Hirsch IB. Flash cgm is associated with reduced diabetes events and hospitalizations in insulin-treated type 2 diabetes. J Endocr Soc. 2021;5(4):bvab013.
[32]. Riveline JP, Roussel R, Vicaut E, de Pouvourville G, Detournay B, Emery C, Levrat-Guillen F, Guerci B. Reduced rate of acute diabetes events with flash glucose monitoring is sustained for 2 years after initiation: Extended outcomes from the relief study. Diabetes Technol Ther. 2022;24(9):611-618.
[33]. Roussel R, Riveline JP, Vicaut E, de Pouvourville G, Detournay B, Emery C, Levrat-Guillen F, Guerci B. Important drop in rate of acute diabetes complications in people with type 1 or type 2 diabetes after initiation of flash glucose monitoring in france: The relief study. Diabetes Care. 2021;44(6):1368-1376.
[34]. O'Malley G, Wang A, Ogyaadu S, Levy CJ. Assessing glycemic control using cgm for women with diabetes in pregnancy. Curr Diab Rep. 2021;21(11):44.
[35]. Fishel Bartal M, Ashby Cornthwaite JA, Ghafir D, Ward C, Ortiz G, Louis A, Cornthwaite J, Chauhan SSP, Sibai BM. Time in range and pregnancy outcomes in people with diabetes using continuous glucose monitoring. Am J Perinatol. 2023;40(5):461-466.
[36]. Wernimont SA, Sheng JS, Tymkowicz A, Fleener DK, Summers KM, Syrop CH, Andrews JI. Adherence to self-glucose monitoring recommendations and perinatal outcomes in pregnancies complicated by diabetes mellitus. Am J Obstet Gynecol MFM. 2019;1(3):100031.
[37]. Cosson E, Baz B, Gary F, Pharisien I, Nguyen MT, Sandre-Banon D, Jaber Y, Cussac-Pillegand C, Banu I, Carbillon L, Valensi P. Poor reliability and poor adherence to self-monitoring of blood glucose are common in women with gestational diabetes mellitus and may be associated with poor pregnancy outcomes. Diabetes Care. 2017;40(9):1181-1186.
[38]. Grunberger G, Sherr J, Allende M, Blevins T, Bode B, Handelsman Y, Hellman R, Lajara R, Roberts VL, Rodbard D, Stec C, Unger J. American association of clinical endocrinology clinical practice guideline: The use of advanced technology in the management of persons with diabetes mellitus. Endocr Pract. 2021;27(6):505-537.

Medtronic

Medtronic Diabetes
18000 Devonshire Street
Northridge, CA 95130

Tel: 1.800.646.4633

www.medtronicdiabetes.com
www.medtronic.com

April 18, 2023

To: Health Evidence Review Commission's Evidence-based Guideline Subcommittee

Dear Members of the Guideline Subcommittee,

I am the Chief Medical Officer of Medtronic Diabetes with a long academic background (Walter Reed National Military Medical Center where I founded its Diabetes Institute in 2001) prior to joining Medtronic. On behalf of Medtronic, I am writing to respectfully recommend the omission of two listed criteria on the expanded continuous glucose monitoring (CGM) coverage scope statement for people who have type 2 diabetes (question 1, page 28 of EbGS Meeting Materials):

- Option B.: Uses the CGM 50% or more of the time by their first follow-up visit
- Option C.a.: Baseline HbA1c levels greater than or equal to 8%

Option B: Medtronic recommends that the criteria of 50% use of CGM be omitted from the coverage statement:
There is both a clinical and an administrative reason for this recommendation. Clinically, it is clear that CGM is a powerful behavior modification tool. In the RCT done by my group at Walter Reed Army Medical Center (Vigersky RA et al. Diabetes Care 2012; 35: 32-38), two-thirds of the subjects were on oral agents and one-third were with orals plus basal insulin. The study protocol specified that subjects wear real-time CGM for four sequential periods of 2 weeks on and 1 week off, and then not wear CGM for the next nine months. The study participants achieved clinically and statistically significant improvement in HbA1c at three (-0.5%) and twelve months (-0.6%) compared to the control group suggesting that continuous use of CGM is not necessary to improve glycemic outcomes. Of note is that these subjects were followed by their primary care providers and not the study staff or endocrinologists. A recent RCT by Moon SJ et al. (Diab Obes Metab 2022; https://doi.org/10.1111/dom.14852) in non-insulin treated subjects with type 2 diabetes demonstrated that there was a 0.6% improvement in HbA1c after either one or two one-week use of real-time CGM.

From an administrative standpoint, patients are seen roughly every three months to evaluate their treatment plans and assess changes, if needed. If the intent of HERC/EbGS including this requirement is to decrease the risk of overutilization and/or fraudulent use with Medicaid funds, please reference CMS LCD L33822 which states "every six (6) months following the initial prescription of the CGM, the treating practitioner conducts an in-person or Medicare-approved telehealth visit with the beneficiary to document adherence to their CGM regimen and diabetes treatment plan." CMS does not require a percentage of utilization be documented to provide continued medical authorization, but rather relies upon

documentation of adherence or non-adherence with using the CGM and treatment plan. The timing of a patient's 1st follow-up visit post-CGM implementation and training requires starting date documentation (CGM training can be performed by the office, self-instructed, or manufacturer-led) and assessing the number of viable CGM wear days. This adds additional burden to the healthcare provider and may divert attention from more clinically related matters during the follow-up visit. Medtronic recommends adopting CMS's LCD policy.

Option C.a. Medtronic recommends that an HbA1c levels greater than or equal to 8% be omitted from the coverage statement:

The minutes from the HERC/EbGS report of February 2, 2023, comprehensively document the recommendations for CGM use in people with type 2 diabetes from professional societies and criteria from other payers in Table 9 and related text. None of the three major professional societies in the diabetes space endorse an HbA1c threshold below which they do not recommend the use of CGM in persons with type 2 diabetes: the American Diabetes Association, the American Association of Clinical Endocrinology, nor the Endocrine Society. In addition, CMS, two Medicaid programs, other U.S. payers, and NICE have not established HbA1c criteria for use of CGM in type 2 diabetes in those on intensive insulin therapy and on basal insulin. All these organizations have done exhaustive evaluations of the risks vs. benefits of CGM in the type 2 diabetes population so it is unclear why the EbGS is proposing to institute an HbA1c threshold while these others have not.

We appreciate the opportunity to provide these recommendations to better align the proposed policy with the current universe of coverage for CGM in the population of people with type 2 diabetes. Should you have questions or require further information, please contact me at robert.a.vigersky@medtronic.com or 202-394-5395 (mobile).

Respectfully,

Robert A. Vigersky, M.D.

Chief Medical Officer, Global Medical and Clinical Affairs
Past-President, Endocrine Society
Professor of Medicine, Uniformed Services University of the Health Sciences
Colonel (retired), U.S. Army Medical Corps