Washington State Health Care Authority

Continuous Glucose Monitoring - Update

Draft Key Questions: Public Comment and Response

September 30, 2024

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Continuous Glucose Monitoring - Update
Draft Key Questions
Public Comment and Response

Provided by:

Center for Evidence-based Policy
Oregon Health & Science University

September 30, 2024

Responses to Public Comment on Draft Key Questions

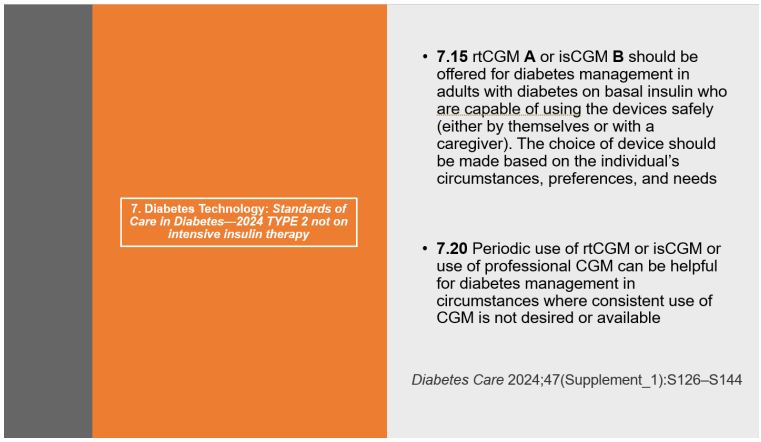
The Center for Evidence-based Policy is an independent vendor contracted to produce evidence assessment reports for the Washington Health Technology Assessment (HTA) program. For transparency, all comments received during the public comment periods are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

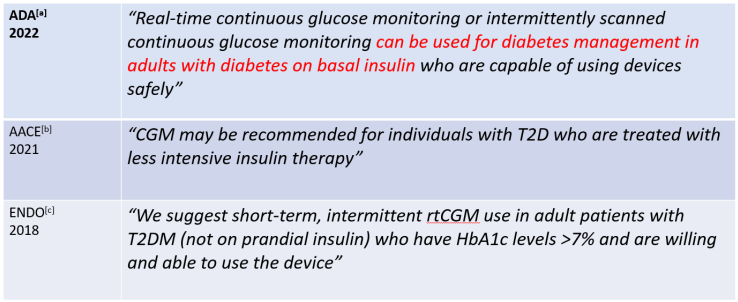
Draft key question document comments received from:

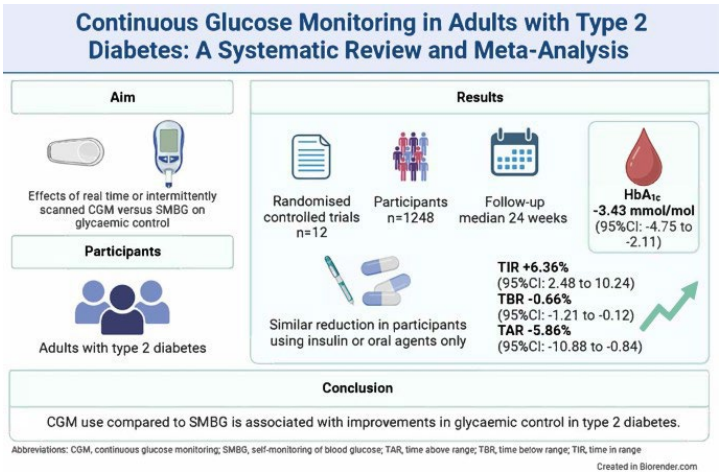
- Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute, including on behalf of others
- Mariham Fahim, PharmD, RPh, Contingent Medical Outcomes Manager, Abbott Diabetes Care
- Dawn Hebert, MT (ASCP), RN, MSN, CDCES, Diabetes RN Educator
- Natalie Hellman, MS, RD, CD, Abbot Diabetes Care
- Alyssa Huang, MD, Pediatric Endocrinologist, Seattle Children's Hospital (submitted by Nicole Ehrhardt)
- Leo Morales, MD, PhD, Attending Physician UW Diabetes Institute, Adjunct Professor of Public Health and Social Work, University of Washington, Arthi Thirumalai, MBBS, UW Medicine, and Irl Hirsch, MD, MACP Professor and Diabetes Treatment and Teaching Chair, UW Medicine (submitted by Leo Morales)
- Bindu Nayak, MD, Endocrinologist, Confluence Health
- Greg Norman, PhD, Senior Director of Health Econ & Outcomes Research, Dexcom
- Matt Prokop, Director, State Government Affairs (Northwest and North Central; AK, ID, KS, MN, MT, ND, NE, OR, SD, WA, and WY), American Diabetes Association
- Anita Reed, RN, Certified Diabetes Care and Education Specialist
- Nancy Schwartz, Vice President, US Market Access Diabetes, Medtronic
- Kathleen Thompson, BSN, RN, CDCES, Certified Diabetes Care and Education Specialist
- Patti Walton, PharmD, BCACP, BCGP, BC-ADM, TTS, Columbia Network Ambulatory Pharmacy Manager, PeaceHealth Medical Group

Specific responses pertaining to submitted comments are shown in Table 1.

Table 1. Responses to Comments on Draft Key Questions for Continuous Glucose Monitoring - Update

Comments		Response
Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute		
General Comments:		
I am writing as a clinical endocrinologist, diabetologist, and researcher from the University of Washington Diabetes Institute with more than 15 years of experience using CGM. [Comments] Please let me know if you have any further questions.		Thank you for your comments. Please see detailed responses to specific points below.
Specific Comments:		
Population	**KQ1: Key Question: What is the comparative effectiveness of continuous glucose monitoring in adults and children with diabetes versus self-monitoring?** Medicaid currently covers CGM for type 2 diabetes patients only on intensive insulin therapy (3 or more daily shots). I strongly support its use for those on basal insulin and non-insulin treatments as well. **American Diabetes Association (ADA) Standards of Medical Care in Diabetes -2024**  *rtCGM: real time CGM; isCGM: intermittently scanned CGM* The ADA and other professional bodies have long advocated for the use of CGM in individuals living with type 2 diabetes who are on basal insulin or using insulin-sparing agents.	Thank you for your comments. We plan to review any eligible studies of CGM in people with type 2 diabetes who are not on an intensive insulin treatment regimen (i.e., those who use basal insulin and noninsulin treatments).

Comments		Response
Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute		
	CGM in Type 2 Diabetes in Those on Basal Insulin  ADA[a] 2022: *"Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring can be used for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely"* AACE[b] 2021: *"CGM may be recommended for individuals with T2D who are treated with less intensive insulin therapy"* ENDO[c] 2018: *"We suggest short-term, intermittent rtCGM use in adult patients with T2DM (not on prandial insulin) who have HbA1c levels >7% and are willing and able to use the device"* • a. American Diabetes Association Professional Practice Committee, et al. **Diabetes Care. 2022 Jan 1;45(Suppl 1):S97-S112; b. Grunberger G, et al. Endocr Pract. 2021;27:505-537; c. Peters AL, et al. J Endocr Soc. 2018;2:1214-1225.** I would like to present the findings of our recently concluded but not yet published CUT Diabetes study, a randomized controlled trial that further validates CGM's application in non-intensive insulin therapy. Conducted in the greater Seattle area in collaboration with our community partner Sea Mar at their primary care clinics, the study aimed to focus on younger Latino patients who were solely on basal insulin or insulin-sparing agents with an A1c greater than 8.0%. A total of 120 participants received culturally tailored diabetes education, and 50% utilized Rt-CGM cyclically over 12 weeks, targeting 50 days of usage. Notably, only 23% of participants were on basal insulin. Our primary outcome was the change in A1c levels. *Unpublished results were provided by the commenter but are not reproduced here.*	
Population	**KQ3 :What is the differential efficacy or safety by patient and clinical factors, such as: a. age, b. gender, c. race and ethnicity, d. type of diabetes, e. presence of comorbidities (e.g., hypertension), f. severity of disease (e.g., baseline HbA1c, number of self-tests per day), g. use of other medications (e.g., insulin use), h. level of adherence to CGM use, i. Type of CGM (i.e., rtCGM vs. isCGM)** **Key Q3: C , D, F** Our population had uncontrolled diabetes (mean A1c 10.4%), primarily spoke Spanish, many earned less than $25,000 annually, only 30% had more than a high school education, and nearly 50% experienced some level of food insecurity, yet CGM proved effective in this vulnerable group. *Unpublished results were provided by the commenter but are not reproduced here.* Overall: our data indicates the advantage of CGM in a younger group (mean age 48) that did not require intensive insulin (basal insulin only or insulin sparing) but had many social determinants of health. In 2012, my mentor and I published pioneering research highlighting the advantages of CGM for individuals with type 2 diabetes. The study	Thank you for your comments. We plan to review any eligible studies of CGM in people with type 2 diabetes who are not on an intensive insulin treatment regimen (i.e., those who use basal insulin and noninsulin treatments).

Comments		Response
Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute		
	demonstrated an improvement in A1c levels by 0.8% compared to finger sticks alone. This benefit was maintained at 52 weeks; however, significant and sustained glycemic improvements were only observed in participants who wore the CGM for at least 48 days *Commenter provided figures; these are not reproduced here.* Diabetes Care. 2012 Jan;35(1):32-8. doi: 10.2337/dc11-1438. Epub 2011 Nov 18. PMID:22100963; PMCID: PMC3241321. A recent community based CGM program showed improved A1c of >2% over 6 months and more people reaching health effectiveness and data information (HEDIS) goal of <8.0% with most participants baseline A1c being great than 9.0%. *Commenter provided figures; these are not reproduced here.* Thomas P. Grace, Andrew Edgington, Laura Reinhart, Timothy Burkart, Elisa Dyer, Jessica Halsey, Karim Baroudi, Christian Hicks, Jennifer E. Layne, Tomas C. Walker; The Dexcom Community Glucose Monitoring Project: Six-Month Results Using Continuous Glucose Monitoring in Type 2 Diabetes. *Clin Diabetes* 2024; cd240030. https://doi.org/10.2337/cd24-0030 Even with our initial and resent research and similar studies from others, many people with type 2 diabetes still don't have access to RT-CGM in 2024.  *Diabetologia* **67**, 798–810 (2024). https://doi.org/10.1007/s00125-024-06107-6 A1c reduction of (−0.31%). This effect was comparable among users of insulin and other oral agents. In summary, our ongoing interactions with patients who have diabetes reinforce the findings of CGM research: CGM is crucial for everyone managing diabetes. Let's not delay providing this lifesaving technology to people living with diabetes, especially those who are living with suboptimal	We will also check the suggested references against our review inclusion criteria.

Comments		Response
Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute		
	and uncontrolled diabetes and early in the disease process before complications develop. We strongly recommend CGM be available for those on any insulin. While we acknowledge the most benefit has been shown in those with higher baseline A1c, we also recommend that CGM be available to non-insulin-requiring patients irrespective of A1c. Imposing step or A1c requirements for this technology will place an extra burden on providers and restrict access to this essential technology.	
Population	**Key Questions What is the comparative effectiveness of continuous glucose monitoring in adults and children with diabetes versus self-monitoring?** **e. Pregnant people with gestational diabetes who are not using insulin** Gestational diabetes mellitus (GDM) is becoming more common and prevalence is now greater than 10-15%1 GDM increases risk for maternal, fetal and neonatal complications2 (Capobianco). Glycemic control is a modifiable risk factor and more tools are needed in GDM management to improve outcomes. Continuous glucose monitoring (CGM) is a tool for gathering more data about glucose in real time (RT). RT- CGM provides interstitial glucose data every 1-5 minutes giving patients and providers significantly more information about glucose including excursions, variability and real-time changes compared to self-monitored blood glucose readings via glucometer (SMBG). In 2023 the FDA approved RT-CGM use for management of all types of diabetes in pregnancy, including GDM3 Studies in non-pregnant patients with diabetes on insulin therapy have demonstrated that RT-CGM use results in improvement in HbA1c and/or a reduced frequency of hypoglycemia and there is growing evidence of improvement in those with type 2 diabetes, even for those not on insulin4–6. There is also evidence of benefit in patients with Type 1 diabetes in pregnancy, a large randomized control trial showed improvement in glucose control and neonatal outcomes7 Data on GDM and CGM use is limited. The largest study on CGM use in GDM found that glycemic indices on CGM were significantly lower in the CGM group compared with those in the routine care group (P < .001)8. A recent meta-analysis reviewed 14 studies that evaluated RT-CGM in GDM but most were limited by short duration of sensor wear and smaller numbers9. However, improvements were seen for those using CGM including more patients qualifying for insulin therapy and better detection of nocturnal hypoglycemia and postprandial hyperglycemia. Interestingly, in one of the large studies (n=110) with duration of CGM use > 14 days showed less gestational weight gain in CGM group10. Additionally, a more recent study showed association of large for gestational age and macrosomia in those with higher post prandial glucose seen on CGM11. A second study also saw higher fasting and post prandial glucose in SMBG as compared to flash CGM with more macrosomia seen in the neonates of those using SMBG12.	Thank you for your comments. We are specifically looking at the use of CGM during pregnancy in people who are not using insulin. CGM use is currently covered for people with diabetes who use insulin during pregnancy.

Comments		Response
Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute		
	Unpublished data from a recent Oregon state randomized control study (RTC on 100 GDM participants showed improved glycemic indices, including time in range (TIR) and time above (TAR). Notably, 40% of participants were not on insulin, suggesting benefits for all with GDM, even without insulin. This single-center randomized,open-label clinical trial compared real-time CGM with concurrent SMBG (intervention) to SMBG alone (referent; blinded CGM) in pregnant patients with GDM. The intervention group had significantly higher time-in-range (TIR; 60-140 mg/dL) due to better daytime TIR and lower time above range (>140 mg/dL). *Unpublished results were provided by the commenter but are not reproduced here.* Recently, we completed a randomized controlled trial involving 107 participants, where half were assigned continuous glucose monitoring (CGM) and the rest continued with standard care. Our study began enrollment later than some other studies, averaging around 30 weeks. We did not find a significant benefit in glycemic indices. However, it was notable that over 60% of participants assigned to fingerstick/standard care dropped out, with 31 out of 32 citing a preference for CGM as their reason for withdrawal. Satisfaction with CGM in our group was high. The adapted Joslin experience survey revealed a positive correlation between CGM use and improved diabetes management during pregnancy. Questions such as "Does it help in making diabetes-related decisions?" and "Does it provide insights on how diet affects blood sugar levels?" received more than 90% positive responses. Negatively phrased questions also showed support for CGM usage. *Unpublished results were provided by the commenter but are not reproduced here.* In summary, CGM should be made available early for all individuals with GDM, regardless of whether they require insulin since insulin needs often develop later in gestation, delaying access to CGM in these groups. Furthermore, our study comprised a well-educated and well-resourced population who could afford out-of-pocket purchase if not randomized to CGM. Therefore, the use of CGM shouldn't be restricted to those requiring insulin, as it otherwise remains accessible only to those who can afford to buy it, excluding other high-risk pregnancy participants with GDM.	
References	• https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170088.pdf. • https://www.cdc.gov/nchs/data/nvsr/nvsr71/nvsr71-03.pdf. • American Diabetes Association Professional Practice C. 7. Diabetes technology: Standards of Care in diabetes-2024. *Diabetes Care*. 2024;47(Suppl 1):S126-S144. doi: 10.2337/dc24-S007. • American Diabetes Association Professional Practice Committee, and American Diabetes Association Professional Practice Committee:. "7. Diabetes technology: standards of medical care in diabetes—2022." *Diabetes Care* 45.Supplement_1 (2022): S97-S112.	Thank you for providing these references. We will check these for inclusion against our review

Comments		Response
Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute		
	• Battelino T, Phillip M, Bratina N, Nimri R, Oskarsson P, Bolinder J. Effect of continuous glucose monitoring on hypoglycemia in type 1 diabetes. *Diabetes Care*. 2011;34(4):795-800. doi:10.2337/dc10-1989 • Capobianco G, Gulotta A, Tupponi G, et al. Materno-Fetal and Neonatal Complications of Diabetes in Pregnancy: A Retrospective Study. *J Clin Med*. 2020;9(9):2707. doi:10.3390/jcm9092707 • Ehrhardt, Nicole, et al. "Effectiveness of a culturally tailored diabetes education curriculum with real-time continuous glucose monitoring in a Latinx population with type 2 diabetes: the CUT-DM with CGM for Latinx randomised controlled trial study protocol." *BMJ open* 13.12 (2023): e082005. • Feig DS, Donovan LE, Corcoy R, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. *Lancet*. 2017;390(10110):2347-2359. doi:10.1016/S0140-6736(17)32400-5 • Grace, Thomas P., et al. "The Dexcom Community Glucose Monitoring Project: Six-Month Results Using Continuous Glucose Monitoring in Type 2 Diabetes." *Clinical Diabetes* (2024): cd240030. • Grunberger, George, et al. "American Association of Clinical Endocrinology clinical practice guideline: the use of advanced technology in the management of persons with diabetes mellitus." *Endocrine practice* 27.6 (2021): 505-537. • Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Tamborlane WV, Beck RW, et al. Continuous glucose monitoring and intensive treatment of type 1 diabetes. *N Engl J Med*. 2008;359(14):1464-1476. doi:10.1056/NEJMoa0805017 • Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, Bode B, Beck RW, et al. Sustained benefit of continuous glucose monitoring on A1C, glucose profiles, and hypoglycemia in adults with type 1 diabetes. *Diabetes Care*. 2009;32(11):2047-2049. doi:10.2337/dc09-0846 • Majewska A, Stanirowski PJ, Tatur J, Wojda B, Radosz I, Wielgos M, Bomba-Opon DA. Flash glucose monitoring in gestational diabetes mellitus (FLAMINGO): a randomised controlled trial. Acta Diabetol. 2023 Sep;60(9):1171-1177. doi: 10.1007/s00592-023-02091 • Majewska A, Stanirowski PJ, Wielgoś M, Bomba-Opoń D. Efficacy of Continuous Glucose Monitoring on Glycaemic Control in Pregnant Women with Gestational Diabetes Mellitus-A Systematic Review. J Clin Med. 2022 May 23;11(10):2932. doi: 10.3390/jcm11102932. PMID: 35629058 • Márquez-Pardo R, Baena-Nieto MG, Córdoba-Doña JA, Cruzado-Begines C, García-García-Doncel L, Aguilar-Diosdado M, Torres-Barea IM. Glycemic variability in diagnosis of gestational diabetes as predictor of pharmacological treatment. Endocrinol Diabetes Nutr (Engl Ed). 2024 Mar;71(3):96-102. • Peters, Anne L., et al. "Advances in glucose monitoring and automated insulin delivery: supplement to Endocrine Society clinical practice guidelines." *Journal of the Endocrine Society* 2.11 (2018): 1214-1225.	protocol as part of report development.

Comments		Response
Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute		
	• Thomas P. Grace, Andrew Edgington, Laura Reinhart, Timothy Burkart, Elisa Dyer, Jessica Halsey, Karim Baroudi, Christian Hicks, Jennifer E. Layne, Tomas C. Walker; The Dexcom Community Glucose Monitoring Project: Six-Month Results Using Continuous Glucose Monitoring in Type 2 Diabetes. Clin Diabetes 2024; cd240030. https://doi.org/10.2337/cd24-0030 • Vigersky, Robert A., et al. "Short-and long-term effects of real-time continuous glucose monitoring in patients with type 2 diabetes." *Diabetes Care* 35.1 (2012): 32-38. • Yu F, Lv L, Liang Z, et al. Continuous glucose monitoring effects on maternal glycemic control and pregnancy outcomes in patients with gestational diabetes mellitus: a prospective cohort study. J Clin Endocrinol Metab 2014;99:4674– 4682 • Zhang X, Jiang D, Wang X. The effects of the instantaneous scanning glucose monitoring system on hypoglycemia, weight gain, and health behaviors in patients with gestational diabetes: a randomised trial. Ann Palliat Med. 2021 May;10(5):5714-5720. doi: 10.21037/apm-21-439. Epub 2021 May 7. PMID: 33977739.	

Comments		Response
Commenter: Mariham Fahim, PharmD, RPh, Contingent Medical Outcomes Manager, Abbott Diabetes Care		
General Comments:		
Thank you for allowing us to present you with the current and most compelling data for use of Continuous Glucose Monitoring (CGM) to help improve the lives of people living with Diabetes. Attached to this is the body of evidence currently available to aid in your decision making below populations. a) Adults with type 2 diabetes who are not using insulin, b) Children with type 2 diabetes (regardless of insulin use) c) Adults and children whose diabetes is well-controlled (defined as within target HBA1c and not experiencing severe hypoglycemic events) d) Pregnant people with type 2 diabetes who are not using insulin *e)* Pregnant people with gestational diabetes who are not using insulin *[Comments]* I would be happy to set up a time to discuss the impact of CGM, and any of these studies in greater detail.		Thank you for your comments. Please see detailed responses to specific points below.
Specific Comments:		
Study design	This data is collected from Randomized controlled trials (RCTs) and Real World Evidence (RWEs) are the two most common forms for collecting data, and both forms have their value in assessing the role of a drug or medical device. RCTs tend to have	Thank you for your comments.

Comments		Response
Commenter: Mariham Fahim, PharmD, RPh, Contingent Medical Outcomes Manager, Abbott Diabetes Care		
	the highest internal validity and is required for initial approval by the FDA. The importance of RWE cannot be ignored, RWE for decision making presents new methodological and analytical challenges whereas RCTs have limited set data for patient randomization, inclusion and exclusion criteria, and regulated follow-up protocols, the external validity of RCTs is relatively low, hence there is limitation in terms of generalization. RWE tend to have less constrained study designs (e.g. non-randomized treatment allocation, longer patient follow-up and broader patient populations) and essentially RWE can provide longer term patient outcomes and include a broader population Cost Savings[1]. Due to the limitation with RCTs, RWE may provide a more generalizable picture of treatment effects in clinical practice. Consequently, the extrapolation of drug/device efficacy to drug/device effectiveness in clinical practice remains difficult when only assessing RCTs. Many payers and regulatory agencies such as the FDA now request pharmaceutical and medical device manufacturers to submit RWE in conjunction with findings from their RCTs when assessing the safety, effectiveness, and cost–benefit parameters of new medications and medical devices[2]. The publication of FDA's RWE framework is expected to accelerate the use of RWE for approval and coverage decisions. 21st Century Cures Act mandated the US FDA to develop guidance for the use of RWE in regulatory decisions[3]. It is also important to take into consideration that Diabetes technologies such as CGM continue to evolve at an increasingly rapid pace in comparison to drugs. Seventeen new CGM devices have been introduced to the market during the past decade. The introduction of each new system is supported by well-designed RCTs and real-world retrospective and prospective studies. However, translation of the evidence into clinical guidelines and coverage policies often lags behind the current times. Assessing RCTs alone poses major limitations of the current approach to clinical evidence assessment. Inclusion of RWE data presents a more appropriate method for evaluating rapidly evolving technologies such as CGM[4]. Diabetes is a complex disease state that could be well managed with the help of advancing technology such as CGMs. With health equity being a concern for Medicaid population, expanding access to CGM for the Medicaid population can be not only beneficial for the patients, but also cost saving for the state. Please note that utilizing a different set of review standards with a narrow subset which ultimately excludes data used by CMS and other state agencies which have expanded coverage can negatively impact clinical outcomes for the patient, and economical outcomes for the state. Ignoring the critical issue of health equity places burdensome criteria on patients to access	For this update, we will be using the approach taken in the prior HTA reviews, which is including only evidence on effectiveness from published RCTs. However, we will also consider device-related safety from FDA sources, as well as input from a subject-matter expert and peer reviewers. We also give information on relevant guideline recommendations and payer policies. We believe this provides the committee with the most robust evidence, along with related contextual information, on which to base a coverage determination. We will also check the suggested references against our review inclusion criteria.

Comments		Response
Commenter: Mariham Fahim, PharmD, RPh, Contingent Medical Outcomes Manager, Abbott Diabetes Care		
	CGM and leaves these Medicaid patients out of reach for CGM technology they can stand to benefit from. We respectfully ask that you include this valuable set of information provided only by RWEs in your consideration for policy changes. 1. Real world evidence (RWE) – an introduction; how is it relevant for the medicines regulatory system. https://www.ema.europa.eu/en/documents/presentation/presentation-real-world-evidence-rwe-introduction-how-it-relevant-medicines-regulatory-system-emas-pcwp-and-hcpwp-joint-meeting-hans-georg-eichler_en.pdf 2. Food and Drug Administration. Real World Evidence. https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence 3. Food and Drug Administration. Framework for FDA's RWE Program. https://www.fda.gov/media/120060/download?attachment 4. Rickson, Michael, et al. "Advancements in diabetes technology are outpacing the evidence." *Diabetes Technology & Therapeutics* 25.S3 (2023): S-35.	
Safety	Continuous glucose monitoring (CGM) systems are generally considered safe for both adults and children with diabetes, but they come with certain device-related risks and limitations. However, proper training and regular consultation with healthcare providers are essential to minimize any-device-related issues. Some of the safety considerations include: a) Skin irritation or allergies. Some users may experience skin reactions, such as rashes, itching, or irritation at the sensor site. This is usually due to the adhesive used to keep the sensor in place. b) Lag time readings difference. While CGM systems are highly accurate and provides real-time glucose readings, it is important to remember that all CGMs measure glucose in the interstitial fluid (ISF), which lag in comparison to blood glucose reading, particularly during rapid changes in glucose levels (e.g., after eating or exercise). It is recommended that a fingerstick testing is performed if symptoms do not match the CGM readings. c) User error. Some CGMs require calibration, if not calibrated properly, or other errors are performed such as improper sensor placement, or not following the manufacturer's guidelines, these can lead to inaccurate readings or device malfunction. **CGM User Manuals** • https://freestyleserver.com/Payloads/IFU/2023/q3/ART48230-001_rev-A-web.pdf	Thank you for your comments. For this update, we will be using the approach taken in the prior HTA reviews, which is including only evidence on effectiveness, including any adverse effects, from published RCTs. We will however also consider device-related safety from FDA sources.

Comments		Response
Commenter: Mariham Fahim, PharmD, RPh, Contingent Medical Outcomes Manager, Abbott Diabetes Care		
	• https://freestyleserver.com/payloads/ifu/2023/q3/ART41641-001_rev-A-web.pdf	
Economics	Glucose monitoring with the CGM offers considerable cost savings compared with BGM in the T2DM on MDI, and pediatric patients with diabetes. Increasing CGM the uptake in these populations could reduce overall diabetes healthcare costs. For Medicaid plans, although acquisition costs were higher for CGM systems relative to BGM, cost offsets related to reduced HCRU over time (e.g., reducing hospitalizations for hypoglycemia and DKA) would enable Medicaid plans to recover the higher system costs. Increased access to FreeStyle Libre systems is budget-neutral for both commercial insurance and Medicaid payer types[36]. Results are presented as a net cost difference per patient for each patient group for the FreeStyle Libre 2 and FreeStyle Libre 3 systems relative to routine BGM. The base case simulated the budget impact for the total Medicaid population (plan size of 36.6 million adults and 40.1 million pediatric patients) For this model, it was assumed that uptake of CGM would increase from 23% to 33% . Total costs for the full Medicaid population were approximately $2.92 billion in the current scenario and $2.89 billion in the alternate scenario. Therefore, increasing the proportion of patients treated with CGM resulted in an annual saving of about $28.7 million, which translates to a net budget reduction of about $0.37 Per Member Per Year (PMPY). The BIM reports total costs for a current and alternative scenario, annual net budget impact, and cost over a time horizon of 3 years. Base Case Analysis, Per Patient Per Year (PPPY) In the T2DM Intensive Insulin Treated (IIT) population, annual acquisition costs were $1,350 higher with CGM than with BGM. When all cost offsets were applied, the use of CGM was associated with cost savings of $278 PPPY. Severe hypoglycemic events (SHEs) - Costs due to SHEs for Medicaid populations were calculated using a baseline event rate with BGM adjusted for treatment effect with utilization of CGM.[36] For the Budget Impact Model (BIM) for FreeStyle Libre 2 and FreeStyle Libre 3 systems, separate analyses were conducted from the perspective of Medicaid plans for the following patient groups: • Adult patients with T2DM on MDI- Medicaid Population, T2DM on MDI: One-Way Sensitivity Analysis of Annual Cost Differences (PPPY) Between (A) the FreeStyle Libre 2 system and BGM, and (B) the FreeStyle Libre 3 system and BGM • Pediatric patients (aged 4 – 18 years) with T1DM or T2DM on MDI - Population, Pediatric: One-Way Sensitivity Analysis of Annual Cost Differences (PPPY) Between (A) the	Thank you for your comments. We will search for economic studies for the use of CGM that meet our specific inclusion criteria, as outlined in the key questions document. We will also check the suggested published references against our review inclusion criteria.

Comments		Response
Commenter: Mariham Fahim, PharmD, RPh, Contingent Medical Outcomes Manager, Abbott Diabetes Care		
	FreeStyle Libre 2 system and BGM, and (B) the FreeStyle Libre 3 system and BGM *Commenter provided figures; these are not reproduced here.* Another BIM was conducted for people living with diabetes who are insulin using patients (IUP) that are not on MDI.[37] This BIM considered acquisition costs – continuous glucose monitors (including sensor, reader), BGM testing strips, lancets, meters, as well as healthcare resource utilization (HCRU) costs – all cause hospitalization inpatient visits, outpatient office visits and ER visits for a period of 3 years, The output of the model was measures in budget impact (total and PPPY). The scenario assumed in the model is CGM market penetration to increase to 2%, 4% and 6% of the T2 basal population in years, 1, 2 and 3 respective, as well as decreased direct costs from all-cause hospital inpatient visits, outpatient visits and ER visits associated with CGM use. In the example used in this model, outcome acquisition costs from coverage of CGMs are offset by lower BGM utilization and reduced direct healthcare resource utilization costs by -$316 (Figure A) PPPY. Reimbursement of CGMs for people with T2D on basal insulin is associated with a cumulative cost savings of $1.7MM over 3 years (Figure B).[37] *Commenter provided figures; these are not reproduced here.* 36. Frank, Jerry R, Deirdre Blissett, Richard Hellmund, and Naunihal Virdi. "Budget Impact of the Flash Continuous Glucose Monitoring System in Medicaid Diabetes Beneficiaries Treated with Intensive Insulin Therapy." Diabetes Technol Ther 23, no. S3 (Sep 2021): S36-S44. https://doi.org/10.1089/dia.2021.0263 37. Abbott Data on File	
References	*Commenter also provided summary study characteristics; these are not reproduced here.* **Key Question 1** • Brown, Ruth E., and Ronnie Aronson. "95-OR: Impact of Flash Glucose Monitoring in People with Type 2 Diabetes Inadequately Controlled with Noninsulin Antihyperglycemic Therapy: IMMEDIATE study." *Diabetes* 71.Supplement_1 (2022). • Campbell, Fiona M., et al. "Outcomes of using flash glucose monitoring technology by children and young people with type 1 diabetes in a single arm study." *Pediatric diabetes* 19.7 (2018): 1294-1301. • Choe, Hun Jee, et al. "Effects of patient-driven lifestyle modification using intermittently scanned continuous glucose monitoring in patients with type 2 diabetes: results	Thank for providing these references. We will check these for inclusion against our review protocol as part of report development.

Comments		Response
Commenter: Mariham Fahim, PharmD, RPh, Contingent Medical Outcomes Manager, Abbott Diabetes Care		
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Comments		Response
Commenter: Mariham Fahim, PharmD, RPh, Contingent Medical Outcomes Manager, Abbott Diabetes Care		
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Comments		Response
Commenter: Mariham Fahim, PharmD, RPh, Contingent Medical Outcomes Manager, Abbott Diabetes Care		
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Comments		Response
Commenter: Mariham Fahim, PharmD, RPh, Contingent Medical Outcomes Manager, Abbott Diabetes Care		
	• Wright Jr, Eugene E, Miller, Eden,, Anita Bindal, and Yeesha Poon. "Ev265 / #1249 E-Poster Topic:As05. Continuous Glucose Monitoring (CGM) in Practice: Using Freestyle Libre Cgm with Glp-1 Treatment Is a Cost-Effective Combination for People Living with Type 2 Diabetes ". *Diabetes Technol Ther* 26, no. S2 (2024): A-247. https://doi.org/10.1089/dia.2024.2525.abstracts. **Key Question 4** • Frank, Jerry R, Deirdre Blissett, Richard Hellmund, and Naunihal Virdi. "Budget Impact of the Flash Continuous Glucose Monitoring System in Medicaid Diabetes Beneficiaries Treated with Intensive Insulin Therapy." *Diabetes Technol Ther* 23, no. S3 (Sep 2021): S36-S44. https://doi.org/10.1089/dia.2021.0263 • Hirsch, Irl B , B S Brandner Burugapalli, Laura , Yeesha Poon, M Frazzitta, and Naunihal Virdi. "O015 / #633 Oral Presentations 02: Impact of Continuous Glucose Monitoring on Healthcare Resource Utilization among Medicaid Beneficiaries with Type 2 Diabetes Treated with Basal Insulin ". *Diabetes Technol Ther* 26, no. S2 (2024): A-48. https://doi.org/10.1089/dia.2024.2525.abstracts. • Hirsch, Irl, B S Brandner Burugapalli, Laura, Yeesha Poon, M Godavarthi Frazzitta, L, and Naunihal Virdi. "O080 / #789 Oral Presentations 10: Impact of Continuous Glucose Monitoring on Healthcare Resource Utilization among Medicaid Beneficiaries with Type 2 Diabetes Treated with Multiple Daily Injection Therapy." *Diabetes Technol Ther* 26, no. S2 (2024): A-81. https://doi.org/10.1089/dia.2024.2525.abstracts. • Roussel, Ronan, Jean-Pierre Riveline, Eric Vicaut, Gerard de Pouvourville, Bruno Detournay, Corinne Emery, Fleur Levrat-Guillen, *et al.* "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* 44, no. 6 (Jun 2021): 1368-76. https://doi.org/10.2337/dc20-1690.	

Comments	Response
Commenter: Dawn Hebert, MT (ASCP), RN, MSN, CDCES, Diabetes RN Educator	
General Comments:	
Hello, I'm writing to bring your attention to the importance of Continuous Glucose Monitoring (CGM) coverage for patients with Type 2 diabetes. Over the past four years, I have personally experienced the benefits of using a CGM, as well	Thank you for your comments and sharing your personal experience.

Comments	Response
Commenter: Dawn Hebert, MT (ASCP), RN, MSN, CDCES, Diabetes RN Educator	
as observed its impact on various patients in the geriatric population. For many of us, the struggle with the discomfort and inconvenience of frequent fingerstick testing has been ongoing for years. Traditional fingerstick tests, which often occur at random intervals that may not align optimally with meals, provide only limited insight into how food choices affect blood sugar levels. In contrast, CGM provides immediate, continuous feedback, offering real-time insights into how different foods impact glucose levels. Personally, this technology has transformed my approach to diet. For example, I used to have oatmeal for breakfast, but after seeing how it spiked my glucose levels, I now opt for more balanced meals with protein, like eggs, bacon, and whole wheat toast, which have a much smaller effect. The constant feedback from CGM helps users make informed decisions, linking their food intake, exercise habits, and other lifestyle choices to their glucose levels in real-time. This level of awareness promotes better diabetes management and long-term health outcomes by enabling individualized care. I've also seen many patients, especially those with needle aversion or other barriers, avoid monitoring their glucose levels. Regular monitoring is crucial for tracking how blood sugar responds to diet, exercise, medications, and other factors. CGM not only provides this vital information but also assists healthcare teams in making timely adjustments to treatment plans. The ability to see real-time data, instead of waiting for results every three months, has made a significant difference in my own diabetes management. Despite its benefits, I personally pay over $900 every six months for CGM access, which is unaffordable for most. The cost of testing strips alone, if one were to check blood sugar seven times a day, is prohibitive. Currently, most insurance plans only cover testing up to 100 times in three months for those not on insulin, which is far from sufficient. Given the significant benefits of CGM, I strongly encourage broader consideration of its coverage for patients who are motivated to improve their diabetes management. Thank you for your attention to this matter.	

Comments	Response
Commenter: Natalie Hellman, MS, RD, CD, Abbot Diabetes Care	
General Comments:	
Hello, In response to open comment period, I would like to address a few things. Under the draft key questions, the list of available CGM devices has expanded to include the FreeStyle Libre 3 Plus and the Lingo. Additionally, there are SO many patients who do not or cannot fingerstick and that is WHY they need a continuous glucose monitor. Additionally, one of the benefits of a CGM is that it helps patients manage their diabetes much better, preventing them from having to go	Thank you for your comments. Please see detailed responses to specific points below.

Comments		Response
Commenter: Natalie Hellman, MS, RD, CD, Abbot Diabetes Care		
on insulin in the first place. By requiring patients to be on insulin to get a CGM device, you are putting those not on insulin at greater risk for mismanaged diabetes and all of the complications associated with this disease state. Also, Washington State you will end up paying way more money down the road in associated healthcare costs (medications, hospitalizations, surgeries, the cost of glucose test strips) by preventing patients from getting this valuable tool. Requiring patients to be on insulin to get a CGM is short-sighted and unfair.		
Specific Comments:		
Intervention	Under the draft key questions, the list of available CGM devices has expanded to include the FreeStyle Libre 3 Plus and the Lingo.	Thank you for highlighting these new devices. We will check the latest list of FDA-approved CGM devices, including any new devices that meet inclusion criteria at the time of drafting the report.

Comments	Response
Commenter: Alyssa Huang, MD, Pediatric Endocrinologist, Seattle Children's Hospital (submitted by Nicole Ehrhardt)	
General Comments:	
I would like to advocate to expand access to CGM for our pediatric population – particularly children with type 2 diabetes (on basal insulin only or non-insulin requiring), who have been traditionally overlooked for new technology to treat diabetes. CGMs have been instrumental in the care of youth with type 1 diabetes – improving quality of life and health outcomes. Data from longstanding RISE consortium and the TODAY study have shown that type 2 diabetes in youth is a far more aggressive disease than type 2 diabetes in adulthood – demonstrating more rapid decline in beta cells and failure requiring insulin initiation. By 9 years after diagnosis of T2D in youth, 50% of youth developed 1 microvascular complication including hypertension, kidney disease, nerve disease, etc. This should be the prime of their young adult lives and yet they are facing end organ damage. These complications were more common among youth in minority race and ethnic groups. It is imperative that we provide youth with type 2 diabetes access to diabetes technologies like CGMs to help improve management of their diabetes. First, CGM can decrease the stigmatization that kids face at school while checking blood sugars by the traditional finger stick. CGMs allow patients to be aware of their glycemic control more acutely and intervene earlier and ultimately could help prevent uncontrolled hyperglycemia and mitigate complications mentioned above. Our goal of helping children lead healthier	Thank you for your comments. Please see detailed responses to specific points below.

Comments		Response
Commenter: Alyssa Huang, MD, Pediatric Endocrinologist, Seattle Children's Hospital (submitted by Nicole Ehrhardt)		
lives requires us to provide them with the tools to do so and this includes access to CGMs. Furthermore, expanding access to CGMs can help address some health inequities that our patients with type 2 diabetes face. I am strongly advocating for the expansion of CGM use in youth with type 2 diabetes on basal insulin only or those that are non-insulin requiring. Hope this can be of help!		
Specific Comments:		
Population	I would like to advocate to expand access to CGM for our pediatric population – particularly children with type 2 diabetes (on basal insulin only or non-insulin requiring), who have been traditionally overlooked for new technology to treat diabetes. CGMs have been instrumental in the care of youth with type 1 diabetes – improving quality of life and health outcomes.	Thank you for your comments. We plan to review any eligible studies of CGM in people with type 2 diabetes who are not on an intensive insulin treatment regimen (i.e., those who use basal insulin and noninsulin treatments). This includes children and adolescents.

Comments	Response
Commenter: Leo Morales, MD, PhD, Attending Physician UW Diabetes Institute, Adjunct Professor of Public Health and Social Work, University of Washington, Arthi Thirumalai, MBBS, UW Medicine, and Irl Hirsch, MD, MACP Professor and Diabetes Treatment and Teaching Chair, UW Medicine (submitted by Leo Morales)	
General Comments:	
Access to Continuous Glucose Monitoring (CGM) for people with diabetes, who are treated with insulin and/or at risk for hypoglycemia is current standard of care [1]. This aligns with current CGM coverage policies for patients covered by Medicare and most commercial insurances, but Medicaid criteria are far more restrictive. Standardizing these criteria for our Medicaid beneficiaries to align with Medicare is a crucial component of improved diabetes outcomes, healthcare equity and eventual healthcare savings; here's why: *[Comments]* In conclusion, standardizing criteria for access to CGM for all insulin-treated people with diabetes, regardless of socio-economic status, background or circumstances, is not just a matter of luxury or convenience; it's a matter of equity and social justice that will	Thank you for your comments. Please see detailed responses to specific points below.

Comments		Response
Commenter: Leo Morales, MD, PhD, Attending Physician UW Diabetes Institute, Adjunct Professor of Public Health and Social Work, University of Washington, Arthi Thirumalai, MBBS, UW Medicine, and Irl Hirsch, MD, MACP Professor and Diabetes Treatment and Teaching Chair, UW Medicine (submitted by Leo Morales)		
improve health outcomes, improve quality of life, reduce disparities, and promote a more equitable healthcare system for all without a negative impact on health-care costs.		
Specific Comments:		
Equity	1. Health Outcomes: CGM technology provides real-time data on blood glucose levels, allowing for more precise management of diabetes in a way unattainable using traditional glucose meters. Medicaid beneficiaries also have strict limitations on the number of glucose test strips that are covered under various plans and obtaining them outside of insurance coverage can be cost-prohibitive. For underserved and marginalized communities who may have limited access to regular healthcare services, CGM can be a lifeline in preventing acute complications of diabetes such as hypoglycemia and severe hyperglycemia. Studies have shown consistent improvement in glycemic control with the use of CGM in insulin-treated patients with diabetes [2,3 4]. These, in turn may result in improved longer-term outcomes with regards to neuropathy, kidney failure, and vision loss. By ensuring access to CGM, we can significantly improve health outcomes and reduce the burden of diabetes among underserved populations. Unfortunately, recent research shows that access to CGM is inequitable [5]. 2. Empowerment and Autonomy: Diabetes management is a full-time job for people with diabetes, and CGM empowers them to take control of their health by providing them with timely actionable data [6]. For underserved and marginalized communities facing cultural and linguistic barriers to healthcare access, CGM can provide a sense of autonomy and agency over their health. These patients also come from a background of low health literacy and the use of CGM offers immediate biofeedback on the impact their diet choices have on their glucose. It enables them to make informed decisions about diet, exercise, and medication adjustments, leading to better self-management of their condition. Studies have shown consistent improvement in patient satisfaction with diabetes care with the use of CGM [7].	Thank you for your comments. A goal of the HTA program in WA is to develop common coverage policy for enrollees/beneficiaries of state purchased programs (Medicaid, workers' compensation, public employees).

Comments		Response
Commenter: Leo Morales, MD, PhD, Attending Physician UW Diabetes Institute, Adjunct Professor of Public Health and Social Work, University of Washington, Arthi Thirumalai, MBBS, UW Medicine, and Irl Hirsch, MD, MACP Professor and Diabetes Treatment and Teaching Chair, UW Medicine (submitted by Leo Morales)		
	3. Cost-Effectiveness in the Long Run: While CGM technology may have upfront costs, it can result in long-term cost savings for both individuals and healthcare systems [8]. Studies have shown reduction in acute diabetes-related events (hypoglycemia, diabetic ketoacidosis, hyperosmolarity) and all-cause hospitalizations with the use of CGM in patients treated with short-acting insulin containing regimens [9] as well as basal insulin/non-insulin regimens [10]. By preventing costly complications and hospital admissions, CGM ultimately reduces the economic burden of diabetes on individuals, families, and society as a whole. In fact, a budget impact analysis investigating this showed demonstrable and significant cost-savings with expansion of CGM coverage among Medicaid patients [11]. Ensuring equitable access to CGM can thus be seen as a cost-effective investment in public health. 4. Promotion of Health Equity: Health equity means that everyone has the opportunity to attain their highest level of health, regardless of their social identity or economic status. Access to CGM aligns with this principle by providing all individuals with the tools they need to manage their diabetes effectively. By prioritizing equity in healthcare policies and interventions, we can work towards a more just and inclusive society where everyone has the opportunity to live a healthy life.	
References	• Kompala T, Neinstein A. A new era: increasing continuous glucose monitoring use in type 2 diabetes. *Am J Manag Care.* 2019;25(4 Spec No.):SP123-SP126. • American Diabetes Association Professional Practice C. 7. Diabetes Technology: Standards of Care in Diabetes-2024. *Diabetes Care.* 2024;47 (Suppl 1):S126-S144. • 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. • Frank JR, BlisseO D, Hellmund R, Virdi N. Budget Impact of the Flash Continuous Glucose	Thank for providing these references. We will check these for inclusion against our review protocol as part of report development.

Comments		Response
Commenter: Leo Morales, MD, PhD, Attending Physician UW Diabetes Institute, Adjunct Professor of Public Health and Social Work, University of Washington, Arthi Thirumalai, MBBS, UW Medicine, and Irl Hirsch, MD, MACP Professor and Diabetes Treatment and Teaching Chair, UW Medicine (submitted by Leo Morales)		
	Monitoring System in Medicaid Diabetes Beneficiaries Treated with Intensive Insulin Therapy. *Diabetes Technol Ther*. 2021;23(S3):S36-S44. • 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*. 201ti;8(1):55-73. • 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. • Martens T, Beck RW, Bailey R, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial. *Jama*. 2021;325(22):2262-2272. • Miller E, Kerr MSD, Roberts GJ, Nabutovsky Y, Wright E. Flash CGM associated with event reduction in nonintensive diabetes therapy. *Am J Manag Care*. 2021;2ti(11):e372-e377. • Taylor PJ, Thompson CH, Brinkworth GD. Effectiveness and acceptability of continuous glucose monitoring for type 2 diabetes management: A narrative review. *J Diabetes Investig*. 2018;9(4):713-725. • Vrany EA, Hill-Briggs F, Ephraim PL, Myers AK, Garnica P, Fitzpatrick SL. Continuous glucose monitors and virtual care in high-risk, racial and ethnic minority populations: Toward promoting health equity. *Front Endocrinol (Lausanne)*. 2023;14:1083145. • 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.	

Comments		Response
Commenter: Bindu Nayak, MD, Endocrinologist, Confluence Health		
General Comments:		
To whom it may concern, Hello, I am an endocrinologist and the medical director of health equity at Confluence Health in Wenatchee, Washington. I am sharing evidence to support expansion of Medicaid coverage of continuous glucose monitors for more individuals with diabetes in the state of Washington. To address health disparities in Washington state, it is critical for Medicaid to increase coverage for individuals with a diagnosis of Diabetes. A first step could be to increase coverage to be similar to Medicare requirements: to cover cgm for anyone with diabetes who is on at least one injection of insulin daily and to eliminate the need to have fingerstick blood sugar testing four times daily. Ideally, it would be best if Medicaid can offer CGM coverage for all individuals with a diagnosis of Diabetes. Thank you for your time and consideration. Please contact me with any questions about this data.		Thank you for your comments. Please see detailed responses to specific points below.
Specific Comments:		
Equity	I am sharing below data on all patients who receive their primary care through Confluence Health and have a diagnosis of Diabetes Mellitus. Confluence Health has multiple locations including Wenatchee, East Wenatchee, Omak, Moses Lake and other smaller locations. *Commenter provided figures; these are not reproduced here.* The graph below in the upper left corner shows the total numbers of individuals with a diagnosis of Diabetes stratified by ethnicity: Non-Hispanic or Hispanic. The upper right graph shows the total number of individuals with a diagnosis of diabetes who are American Indian, Asian or Black. The bottom graphs are assessing the percent of these patients who have uncontrolled Diabetes Mellitus, defined as a Hemoglobin A1C greater than or equal to 9%. In the lower left graph, you can see that there is a significant disparity in diabetes control between Non-Hispanic individuals and Hispanic individuals with diabetes, with more than double the percentage of uncontrolled diabetes among Hispanic individuals with Diabetes. In the lower right graph, this graph looks at the percentage of individuals with diabetes by race with a Hemoglobin A1C >9% among American Indian, Asian, and Black individuals. You can see also that there is a significant health disparity here with more than double the rate of uncontrolled diabetes for American Indian and Black individuals. In the regions of North Central Washington that Confluence Health serves, the percentage of individuals who use Medicaid among Hispanic, American Indian and Black individuals is high. So, many of these individuals cannot afford to pay for a	Thank you for your comments. A goal of the HTA program in WA is to develop common coverage policy for enrollees/beneficiaries of state purchased programs (Medicaid, workers' compensation, public employees).

Comments		Response
Commenter: Bindu Nayak, MD, Endocrinologist, Confluence Health		
	continuous glucose sensor based on current Medicaid coverage requirements. As you know from all of the evidence showing that using CGM reduces Hemoglobin A1C (even without changing medications), expanding Medicaid coverage to cover continuous glucose monitors would help to reduce this health disparity that is disproportionately affecting Hispanic, Black and American Indian individuals with Diabetes Mellitus in the state of Washington. When patients have the knowledge of their own blood sugars and effects of certain foods and medications on blood sugars, people with diabetes can make changes in real time to their diet and lifestyle that make significant improvements in blood sugar control. By improving blood sugar control and decreasing Hemoglobin A1C, Medicaid will save money in the long run by preventing complications of diabetes for individuals with diabetes.	

Comments		Response
Commenter: Greg Norman, PhD, Senior Director of Health Econ & Outcomes Research, Dexcom		
General Comments:		
RE: Public Comment on the draft key questions for Continuous Glucose Monitoring Update Dexcom, Inc. appreciates the opportunity to submit this letter in response to the Washington State Health Care Authority's request for public comments on the update of the health technology assessment of Continuous Glucose Monitoring (CGM), particularly for adults with Type 2 Diabetes (T2D) not using insulin, children with T2D, and patients with type 2 or gestational diabetes during pregnancy who are not using insulin. We commend the Authority for updating the evidence review in light of new advancements in CGM technology and would like to highlight several key areas where the scope and criteria of the review could be expanded or modified to reflect the full clinical value of CGM in coverage decisions. *[Comments]*		Thank you for your comments. Please see detailed responses to specific points below.
Specific Comments:		
Outcomes	**1. Limitations of Current primary Intermediate Outcomes** The current inclusion and exclusion criteria limited the outcomes to HbA1c. While HbA1c is a valuable marker of long-term glycemic control, the exclusion of CGM-specific glycemic measures such as Glucose Management Indicator (GMI), Time in Range (TIR), Time Below Range (TBR), and Time Above Range (TAR) presents a significant limitation. These metrics offer a more granular view of glycemic variability and have been shown to	Thank you for your comments. We have defined the primary outcome to be that of diabetes control, as measured using HbA1c. This allows for a direct comparison

Comments		Response
Commenter: Greg Norman, PhD, Senior Director of Health Econ & Outcomes Research, Dexcom		
	correlate strongly with clinical outcomes, such as hypoglycemia and hyperglycemia, that HbA1c alone cannot capture. • **Adoption of CGM Metrics in Clinical Practice**: GMI is already set to be used by the National Committee for Quality Assurance (NCQA) as part of HEDIS measures, underscoring its growing role in clinical care and quality benchmarks[1]. Furthermore, the panel of experts consulted during the recent Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting recommended that CMS include Time in Range (TIR) as a clinically relevant metric for monitoring diabetes in clinical studies, with a 5% improvement in TIR being recognized as a meaningful clinical outcome, aligning with emerging standards in diabetes care.[2] • **Supporting Evidence for CGM Metrics such as Percentage of time in acceptable glucose range (70-180 mg/dL)**: Numerous studies and international consensus statements validate the importance of TIR and other CGM-specific metrics in preventing complications like retinopathy, microalbuminuria, and cardiovascular autonomic neuropathy. For example, A 2019 study utilized finger stick data from the Diabetes Control and Complications Trial (DCCT) to estimate time in range (TIR) and examined the rates of retinopathy and microalbuminuria across different TIR percentages. Although changes in complications for every 5% increase in TIR were not specifically calculated (as TIR was estimated in 10% increments), the data revealed a smooth curve indicating that even smaller changes in TIR, such as less than 10%, would follow the same pattern and be clinically significant.[3] A separate study examining TIR in relation to cardiovascular autonomic neuropathy in individuals with type 2 diabetes also found a continuous curve, with rates of complications increasing as TIR decreased. [4] Similar associations were observed between TIR and the development of retinopathy.[5] An international consensus statement on TIR, published that same year, concluded that even small improvements—such as a 5% increase in TIR—are clinically meaningful.[6] This statement further noted that a 10% increase in TIR correlates with a 0.5% reduction in A1c. Since smaller shifts in A1c are recognized as significant, the statement affirms that a 5% improvement in TIR is equally impactful. A more recent consensus statement, published in Lancet, supported this, providing B-level evidence that a ≥5% increase in TIR is clinically meaningful for individual participants in clinical studies, and a 3% difference is meaningful for treatment group outcomes.[7] **Recommendation**: We strongly recommend that the outcomes assessed in the review incorporate these CGM-specific metrics alongside HbA1c to better reflect the real-world benefits of	between CGM and other forms of monitoring, whereas the metrics (such as time in range) are only available for people using CGMs. For this review and for the prior reviews, we believe this to be the most appropriate outcome for the committee when determining coverage for CGMs.

Comments		Response
Commenter: Greg Norman, PhD, Senior Director of Health Econ & Outcomes Research, Dexcom		
	CGM in preventing acute and long-term complications in people with diabetes.	
	2. Limiting Study Design requirements to Randomized Controlled Trials (RCT): The draft key questions currently prioritize RCTS as the primary evidence base. While RCTs provide valuable insights into efficacy, this approach may inadvertently exclude important real-world evidence (RWE), particularly when addressing questions of adherence, patient diversity, and real-world effectiveness of CGM. • **Diversity in Age, Gender, and Race/Ethnicity**: RCTs often do not adequately reflect the diversity seen in real-world populations, leading to limited generalizability. Studies have shown that participants in RCTs tend to be younger, healthier, and less racially/ethnically diverse than real-world patients, which can skew the results when applied to broader populations in clinical practice. This gap is particularly evident when assessing diabetes interventions, where racial minorities and older adults may show different patterns of adherence or outcomes that RCTs do not capture effectively.[8] • **Comorbidities and Disease Severity**: RCTs often exclude patients with multiple comorbidities or advanced disease severity, resulting in a population that does not reflect the complexity of real-world clinical settings. For example, real-world data on diabetes management often show higher rates of adverse events, such as hypoglycemia, among patients with comorbidities, a factor that may not be captured in RCTs due to strict eligibility criteria.[9] • **Medication Use**: In clinical practice, many patients with diabetes are prescribed other medications, such as oral antidiabetics or basal insulin, alongside CGM therapy. However, RCTs often fail to fully reflect the variability in how these medications are used in real-world settings. In RCTs, medication regimens are strictly controlled and monitored, leading to higher adherence and more consistent dosing than is typical in everyday practice. RWE shows that patients often struggle with medication management due to factors like complex regimens, side effects, or lifestyle barriers. For example, in the real world, patients on basal insulin or oral medications may exhibit significant variations in adherence, persistence, and outcomes due to challenges in maintaining treatment consistency. [8, 10] • **Adherence to CGM**: The challenge of capturing CGM adherence in clinical trials is twofold. First, there is a limited number of head-to-head studies comparing different CGM systems, leaving gaps in the comparative data needed to guide optimal CGM system selection. This limitation makes it	Thank you for your comments. For this update, we will be using the approach taken in the prior HTA reviews, which is including only evidence on effectiveness, including any adverse effects from published RCTs. We will however also consider device-related safety from FDA sources.

Comments		Response
Commenter: Greg Norman, PhD, Senior Director of Health Econ & Outcomes Research, Dexcom		
	difficult to assess which CGM systems foster better adherence or outcomes in specific populations. Second, adherence is a real-world behavior that does not naturally emerge in the controlled environments of RCTs. In RCTs, patients are closely monitored and supported, which typically leads to higher adherence rates than in everyday practice. **Recommendation**: We recommend the inclusion of real-world evidence (RWE), observational studies, and pragmatic trials in the review to complement the RCT data. This will provide a more comprehensive understanding of how CGM performs across diverse populations and clinical contexts.	
References	• Battelino T, Alexander CM, Amiel SA, et al. Continuous glucose monitoring and metrics for clinical trials: an international consensus statement. *Lancet Diabetes Endocrinol*. Jan 2023;11(1):42-57. doi:10.1016/S2213-8587(22)00319-9 • Battelino T, Danne T, Bergenstal RM, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. *Diabetes Care*. Aug 2019;42(8):1593-1603. doi:10.2337/dci19-0028 • Beck RW, Bergenstal RM, Riddlesworth TD, et al. Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials. *Diabetes Care*. Mar 2019;42(3):400-405. doi:10.2337/dc18-1444 • Gimeno EJ, Bøgelund M, Larsen S, et al. Adherence and Persistence to Basal Insulin Among People with Type 2 Diabetes in Europe: A Systematic Literature Review and Meta-analysis. *Diabetes Therapy*. 2024/05/01 2024;15(5):1047-1067. doi:10.1007/s13300-024-01559-w • Guo Q, Zang P, Xu S, et al. 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. doi:10.1155/2020/5817074 • Lu J, Ma X, Zhou J, et al. Association of Time in Range, as Assessed by Continuous Glucose Monitoring, With Diabetic Retinopathy in Type 2 Diabetes. *Diabetes Care*. Nov 2018;41(11):2370-2376. doi:10.2337/dc18-1131 • Monti S, Grosso V, Todoerti M, Caporali R. Randomized controlled trials and real-world data: differences and similarities to untangle literature data. *Rheumatology*. 2018;57(Supplement_7):vii54-vii58. doi:10.1093/rheumatology/key109 • National Committee for Quality Assurance. HEDIS MY 2024: What's New, What's Changed, What's Retired. Updated	Thank for providing these references. We will check these for inclusion against our review protocol as part of report development.

Comments		Response
Commenter: Greg Norman, PhD, Senior Director of Health Econ & Outcomes Research, Dexcom		
	2023 Aug 01. Accessed 21 May, 2024. https://www.ncqa.org/blog/hedis-my-2024-whats-new-whats-changed-whats-retired/ • Roberts MH, Ferguson GT. Real-World Evidence: Bridging Gaps in Evidence to Guide Payer Decisions. *PharmacoEconomics - Open*. 2021/03/01 2021;5(1):3-11. doi:10.1007/s41669-020-00221-y • Services CfMM. Medicare Evidence Development & Coverage Advisory Committee Meeting: Devices for Self-Management of Type 1 and Insulin-Dependent Type 2 Diabetes. . Accessed September 16, 2024. https://www.cms.gov/medicare-coverage-database/view/medcac-meeting.aspx?medcacid=81	

Comments	Response
Commenter: Matt Prokop, Director, State Government Affairs (Northwest and North Central; AK, ID, KS, MN, MT, ND, NE, OR, SD, WA, and WY), American Diabetes Association	
General Comments:	
Dear Washington State Health Technology Clinical Committee Members: The American Diabetes Association (ADA) appreciates the opportunity to work with the Health Technology Clinical Committee to review access to continuous glucose monitors (CGMs) for people living with diabetes. In our initial request for this review, our objective was to seek to broaden access to CGMs so more Medicaid beneficiaries could benefit from improvements in health outcomes from the utilization of these devices. Specifically, the ADA supports removing the following existing, coverage requirements: 1. Remove the requirement that a patient be on intensive insulin therapy and replace it with "beneficiary is insulin-treated", and 2. Remove the requirement that a beneficiary must test their blood glucose 4 times or more a day. Our standards of care and extensive research done by experts in the field of diabetes can assist the committee's work to review appropriate changes to CGM Medicaid coverage to help patients better manage their diabetes and prevent life-threatening complications. Recent changes in Medicare coverage by the Centers for Medicare and Medicaid Services (CMS) (1) for CGMs recognize the broader value of CGMs for diabetes management, and thus the ADA encourages this committee to align its coverage criteria with that of Medicare. *[Comments]* As the committee considers CGM coverage we encourage action to minimize administrative requirements that can be burdensome for prescribing	Thank you for your comments. Please see detailed responses to specific points below.

Comments		Response
Commenter: Matt Prokop, Director, State Government Affairs (Northwest and North Central; AK, ID, KS, MN, MT, ND, NE, OR, SD, WA, and WY), American Diabetes Association		
clinicians and in turn can unnecessarily delay or prevent timely access to CGMs and the improvements they can support. We thank you for the opportunity to comment and look forward to working with the Health Technology Clinical Committee on efforts to improve access to CGMs and address health disparities for Washingtonians living with diabetes. Should you have any questions regarding these comments please contact me at *[redeacted]*		
Specific Comments:		
Intervention	1. We recommend including automated insulin delivery systems (AID) – insulin pumps that include a CGM component – for review under topics listed for question three.	Thank you for your comments. We will include studies where the effect of CGM can be isolated from the delivery system.
Population	2. The ADA also recommends examining CGM access to other insulin users. The current draft scope does not appear to include addressing the benefits of CGMs for insulin users who are not on an intensive insulin regimen.	Thank you for your comments. We plan to review any eligible studies of CGM in people with type 2 diabetes who are not on an intensive insulin treatment regimen (i.e., those who use basal insulin and noninsulin treatments).
References	• Center for Medicare and Medicaid (CMS) updated coverage requirements: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822	Thank for providing these references. We will check these for inclusion against our review protocol as part of report development.

Comments	Response
Commenter: Anita Reed, RN, Certified Diabetes Care and Education Specialist	
General Comments:	
As a Certified Diabetes Care and Education Specialist and Registered Nurse , working with diabetes patients for 11 years, I cannot overstate the value of CGM as a tool for both providers , patients , and insurance companies, in reducing the costs of diabetes care and complications, while also improving the	Thank you for your comments.

Comments		Response
Commenter: Anita Reed, RN, Certified Diabetes Care and Education Specialist		
quality of life of those with diabetes, and reducing the burdens on the health care system thru out. This is true for patients not treated with insulin as well . In fact , the use of CGM helps keep Type 2 diabetes patients off insulin by giving them real time feedback that they can use immediately to curb their carbohydrate intake and plan exercise , capture high and low glucoses when they are occurring (or prevent them if about to occur) , prevents falls, informs triage decisions over the phone for both providers and nurses, reduce A1C's, goes a long way in helping the provider dose medication properly based on patients CGM patterns, otherwise indeterminable with intermittent fingerstick testing alone, and when used with good patient teaching, and follow thru, provides no end to the benefits of avoiding further complications in disease states and mounting costs to the insurance companies and everyone else. It's about time the benefits were understood by insurance companies trying to save a buck the hard way… by waiting til your patients are all so far gone with their disease that now you are covering heart disease, hospitalizations, dialysis, amputated limbs, prosthesis, home health services , and more in ever increasing quantities. Truly, it's a black and white no brainer. Health Care Authority, please forward the establishment of insurance coverage of continuous glucometers that have alarms for highs and lows for all patients who want to wear them for all diabetes and even pre-diabetes diagnosed patients. PS It will also save everyone billions if you take out the Prior Authorization Piece as Well. The correct diagnosis code on the prescription and some regular auditing on that should be all that is required.		
Specific Comments:		
References	• Beck RW, Riddlesworth TD, Ruedy K, et al. (2017) Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial. Ann Intern Med 167(6): 365-374. 10.7326/M16-2855 • Cox DJ, Banton T, Moncrief M, Conaway M, Diamond A, McCall AL (2020) Minimizing Glucose Excursions (GEM) With Continuous Glucose Monitoring in Type 2 Diabetes: A Randomized Clinical Trial. J Endocr Soc 4(11): bvaa118. 10.1210/jendso/bvaa118 • Martens T, Beck RW, Bailey R, et al. (2021) Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial. JAMA 325(22): 2262-2272. 10.1001/jama.2021.7444	Thank for providing these references. We will check these for inclusion against our review protocol as part of report development.

Comments		Response
Commenter: Nancy Schwartz, Vice President, US Market Access Diabetes, Medtronic		
General Comments:		
Re: Public Comment to Continuous Glucose Monitoring – Draft Key Questions Dear Health Technology Clinical Committee Members: Medtronic is the world's leading medical technology company, specializing in implantable and interventional therapies that alleviate pain, restore health, and extend life. We are committed to the continual research and development necessary to produce high-quality products and innovative therapies that improve health outcomes for all patients. The Medtronic Diabetes Group has a comprehensive portfolio of diabetes technology, including insulin pumps, continuous glucose monitors, and automated insulin delivery pens. We appreciate the opportunity to comment on the draft key questions for Continuous Glucose Monitoring (CGM). Medtronic acknowledges Washington State's commitment to providing coverage and access to diabetes technology inclusive of CGM, insulin pumps, and other forms of insulin delivery. With the pace of innovation, we applaud the State's review of new evidence and standards to support CGM access. Medtronic highlights 3 key areas of focus we'd like to see incorporated as you continue to refine your questions and develop a revised policy: 1. Incorporate American Diabetes Association (ADA) 2024 Standards of Care 2. Evaluate Stand-alone CGM Diagnostic Criteria 3. Assess the Benefits of CGM Integration with Insulin Delivery Systems *[Comments]* Medtronic thanks Washington State Health Care Authority for the opportunity to provide comment and looks forward to reviewing the State's proposed CGM policy. If you would like to discuss our comments or have any questions, please contact me at *[redacted]*		Thank you for your comments. Please see detailed responses to specific points below.
Specific Comments:		
Guidelines	**Consideration #1: Incorporate American Diabetes Association (ADA) 2024 Standards of Care** The State should review the newly released 2024 Standards of Care to guide recommendations on access to diabetes technology, specifically: • Ability to prescribe automated insulin delivery (AID*) to patients at time of Type 1 diabetes diagnosis, without requiring a waiting period • Maintaining consistency and continuity of care and technology access for established insulin-dependent patients; patients who transition to a new health plan due to a life-event change must be able to maintain access to their current diabetic treatment regimen and should not be required to meet utilization management criteria used for de novo patients	Thank you for your comments. We will review relevant guidelines and payer policies as part of the evidence update.

Comments		Response
Commenter: Nancy Schwartz, Vice President, US Market Access Diabetes, Medtronic		
	*Automated insulin delivery systems assist people with insulin-required diabetes by using an algorithm to adjust insulin delivery in response to continuous glucose monitoring levels. There are three main components: 1. insulin pump 2. continuous glucose monitor 3. algorithm. Source: *Diabetes Technology: Standards of Care in Diabetes—2024*, 47 Diabetes Care S126 (2024), https://diabetesjournals.org/care/article/47/Supplement_1/S126/153939/7-Diabetes-Technology-Standards-of-Care-in.	
Population	**Consideration #2: Stand-Alone CGM Diagnostic Criteria** Please evaluate published literature to assess the value of Blood Glucose log capture, along with other diagnostic criteria. This requirement creates an impediment for patients using stand-alone CGM or Smart CGM (eg paired with automated insulin pens). As outlined in the ADA Standard of Care guidelines, CGM use is standard of care for patients requiring basal insulin, who use multiple daily insulin injections or an insulin pump.	Thank you for your comments. We plan to review any eligible studies of CGM in people with type 2 diabetes who are not on an intensive insulin treatment regimen (i.e., those who use basal insulin and noninsulin treatments).
Intervention	**Consideration #3: Assess the Benefits of CGM Integration with Insulin Delivery Systems** For patients using AID systems, the CGM is integral to the functioning of the insulin pump. As the State reevaluates coverage policies (medical or formulary design) it's important to ensure broad inclusion of CGMs. For example, the Medtronic insulin pump requires a Medtronic CGM to power the automated insulin delivery system; a Medtronic insulin pump will not pair with a non-Medtronic CGM. In addition, coverage policies for insulin pumps / automated insulin pens and CGMs should have consistent eligibility criteria so patients can benefit from the improved clinical outcomes. Specific examples include: • Key Question 3: add another criterion under subsection (i) to evaluate stand-alone CGM vs AID CGM use • Key Question 4: add another criterion under subsection (e) to evaluate stand-alone	Thank you for your comments. We will include studies where the effect of CGM can be isolated from the delivery system.
References	• *Diabetes Technology: Standards of Care in Diabetes—2024*, 47 Diabetes Care S126 (2024), https://diabetesjournals.org/care/article/47/Supplement_1/S126/153939/7-Diabetes-Technology-Standards-of-Care-in.	Thank for providing these references. We will check these for inclusion against our review protocol as part of report development.

Comments		Response
Commenter: Kathleen Thompson, BSN, RN, CDCES, Certified Diabetes Care and Education Specialist		
General Comments:		
I am a Certified Diabetes Care and Education Specialist (nurse) working in the home health environment. I do not work with children or pregnant women. I can only share my personal experience over the last 6 years. I have had several patients to whom I recommended CGM because they were motivated to be euglycemic (one patient who paid cash for a monitor because their insurance didn't cover it). They made significant changes in their eating habits because they could see the immediate effect of the food they ate. I have also had patients who started CGM after I advised them that they were probably having hypoglycemia that they were unaware of. In the population I care for (elderly, cognitive and physical limitations) hypoglycemia is a big cause of falls. Because I had the CGM data I was able to show both the patient and the provider that they were getting too much insulin. In some cases, I was able to get meal time insulin discontinued all together. From my experience, CGM has been a game changer for my patients who were lucky enough to get it.		Thank you for your comments.

Comments		Response
Commenter: Patti Walton, PharmD, BCACP, BCGP, BC-ADM, TTS, Columbia Network Ambulatory Pharmacy Manager, PeaceHealth Medical Group		
General Comments:		
Hello, I wanted to send in some comments regarding the continuous glucose monitoring key draft questions. I compiled information from some of our expert staff here at PeaceHealth St. John Medical Center in Longview. Our comments are in purple addressing some of the key draft questions. We appreciate your coordination and hard work on this for our patients with diabetes!		Thank you for your comments. Please see detailed responses to specific points below.
Specific Comments:		
Evidence	**What is the comparative effectiveness of continuous glucose monitoring in adults and children with diabetes versus self-monitoring?** • Adults with type 2 diabetes who are not using insulin This study provides answers / comments to a lot of these questions below regarding adults with T2DM: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10954850/	Thank for providing these references, along with your comments on the findings. We will check these for inclusion against our review protocol as part of report development.

Comments		Response
Commenter: Patti Walton, PharmD, BCACP, BCGP, BC-ADM, TTS, Columbia Network Ambulatory Pharmacy Manager, PeaceHealth Medical Group		
	In over 50% of the retrospectively reviewed studies, CGM was favored in efficacy (measured by A1c control) regardless of age, duration of treatment, duration of diabetes, and average glucose. However, regarding safety, when looking at all the studies together there was no statistically significant difference in macrovascular complications, coefficient of variation, and severe hypoglycemia in CGM vs fingerstick use. Attached is a wonderful study the discusses limitations of A1c and provides framework for time in target ranges (Battelino et al., 2019)	
Evidence	**What is the comparative effectiveness of continuous glucose monitoring in adults and children with diabetes versus self-monitoring?** • Children with type 2 diabetes (regardless of insulin use) This study (although poorly powered) does show some positive behavioral outcomes for children with T2DM and CGM therapy: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10258317/	Thank for providing these references, along with your comments on the findings. We will check these for inclusion against our review protocol as part of report development.
References	• Battelino, Tadej, et al. "Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range." *Diabetes care* 42.8 (2019): 1593-1603. • Jancev, Milena, et al. "Continuous glucose monitoring in adults with type 2 diabetes: a systematic review and meta-analysis." *Diabetologia* 67.5 (2024): 798-810. • Manfredo, Jacquelyn, et al. "Short-term use of CGM in youth onset type 2 diabetes is associated with behavioral modifications." *Frontiers in Endocrinology* 14 (2023): 1182260.	Thank for providing these references. We will check these for inclusion against our review protocol as part of report development.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment for CGM WHA
Date: Monday, September 16, 2024 5:51:20 AM
Attachments: image001.png
CGMpubliccommentsehrhardt9162024.docx

External Email

Please let me know if I can answer any additional questions or speak in support of this technology.

Nicole Ehrhardt, MD

Nicole Ehrhardt
Assistant Professor of Medicine
UW Medicine Diabetes Institute
[redacted]

UW Medicine
DIABETES INSTITUTE

CARDIOMETABOLIC PROJECT ECHO

URL: https://uw.cloud-cme.com/CardiometabolicECHO

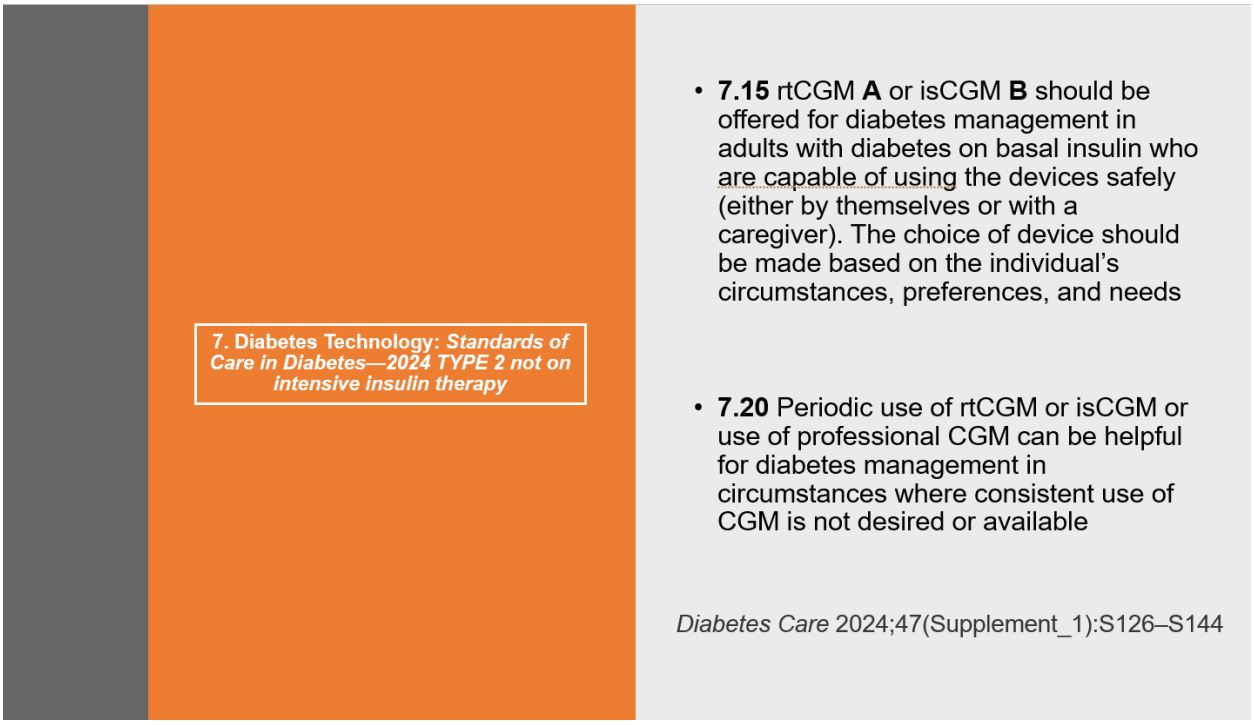
Public comment on the draft key Continuous Glucose Monitoring (CGM) Questions

I am writing as a clinical endocrinologist, diabetologist, and researcher from the University of Washington Diabetes Institute with more than 15 years of experience using CGM.

KQ1: Key Question: What is the comparative effectiveness of continuous glucose monitoring in adults and children with diabetes versus self-monitoring? A).

Medicaid currently covers CGM for type 2 diabetes patients only on intensive insulin therapy (3 or more daily shots). I strongly support its use for those on basal insulin and non-insulin treatments as well.

American Diabetes Association (ADA) Standards of Medical Care in Diabetes -2024



rtCGM: real time CGM

isCGM: intermittently scanned CGM

The ADA and other professional bodies have long advocated for the use of CGM in individuals living with type 2 diabetes who are on basal insulin or using insulin-sparing agents.

[redacted]

CGM in Type 2 Diabetes in Those on Basal Insulin

ADA[a] 2022	*"Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring can be used for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely"*
AACE[b] 2021	*"CGM may be recommended for individuals with T2D who are treated with less intensive insulin therapy"*
ENDO[c] 2018	*"We suggest short-term, intermittent rtCGM use in adult patients with T2DM (not on prandial insulin) who have HbA1c levels >7% and are willing and able to use the device"*

- a. American Diabetes Association Professional Practice Committee, et al. **Diabetes Care. 2022 Jan 1;45(Suppl 1):S97-S112; b. Grunberger G, et al. Endocr Pract. 2021;27:505-537; c. Peters AL, et al. J Endocr Soc. 2018;2:1214-1225.**

I would like to present the findings of our recently concluded but not yet published CUT Diabetes study, a randomized controlled trial that further validates CGM's application in non-intensive insulin therapy. Conducted in the greater Seattle area in collaboration with our community partner Sea Mar at their primary care clinics, the study aimed to focus on younger Latino patients who were solely on basal insulin or insulin-sparing agents with an A1c greater than 8.0%. A total of 120 participants received culturally tailored diabetes education, and 50% utilized Rt-CGM cyclically over 12 weeks, targeting 50 days of usage. Notably, only 23% of participants were on basal insulin. Our primary outcome was the change in A1c levels. While both groups showed improvements in their A1c, those using CGM exhibited an additional reduction of 0.9%, compared to the education group alone. Forty percent of participants in the RT-CGM had A1c Less than 7.0 %at end of intervention versus 23% of Educational only group.

[redacted]

Figure 1: Change in A1c in Education only(blinded) Group and RT-CGM Group over 12 v

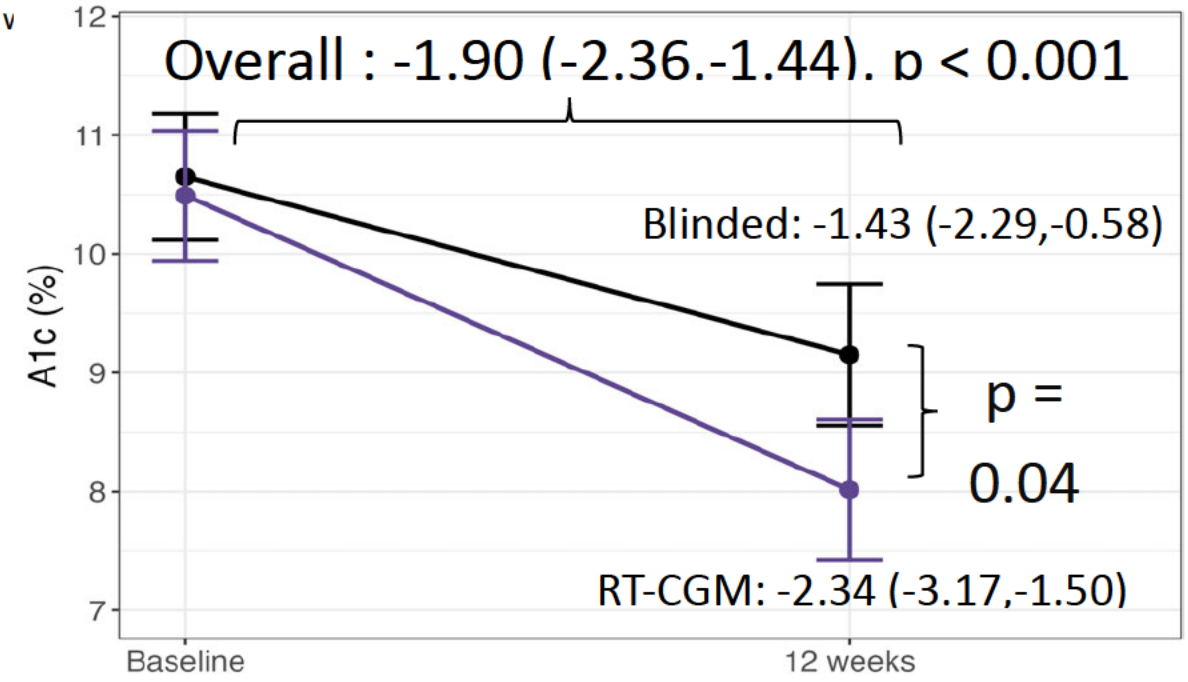
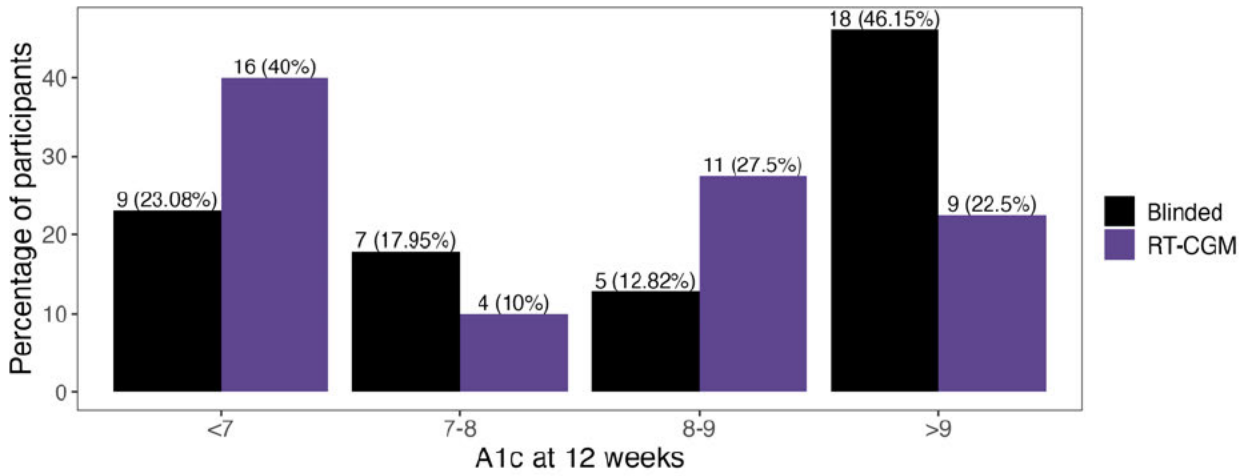


Figure 2: Participants meeting A1c goals at 12 weeks



[redacted]

KQ3 :What is the differential efficacy or safety by patient and clinical factors, such as: a. Age, b. Gender, c. Race and ethnicity, d. Type of diabetes, e. Presence of comorbidities (e.g., hypertension), f. Severity of disease (e.g., baseline HbA1c, number of self-tests per day), g. Use of other medications (e.g., insulin use), h. Level of adherence to CGM use, i. Type of CGM (i.e., rtCGM vs. isCGM)

Key Q3: C , D, F

Our population had uncontrolled diabetes (mean A1c 10.4%), primarily spoke Spanish, many earned less than $25,000 annually, only 30% had more than a high school education, and nearly 50% experienced some level of food insecurity, yet CGM proved effective in this vulnerable group.

DEMOGRAPHICS

Characteristics	Overall N = 120	Blinded N = 59	RT-CGM N = 61
Age	46 (42, 52)	46 (43, 51)	47 (40, 52)
Female	53 (44%)	24 (41%)	29 (48%)
Spanish Language Preferred	117 (98%)	58 (98%)	59 (97%)
Education <High School	67 (56%)	36 (61%)	31 (52%)
Household Income <25,000/year	36 (30%)	22 (37%)	14 (23%)
A1c %	10.47 (1.80)	10.54 (1.82)	10.40 (1.78)
Mean Glucose mg/dL	246 (76)	247 (74)	244 (80)
PAID-5 Summary Score	7.5 (6.3)	7.0 (6.7)	8.0 (5.9)
Compatible Smart Phone	106 (88 %)	52(88 %)	54(88%)
Basal Insulin Use	28 (23%)	16 (27%)	12 (20%)

KQ3: Level of adherence to CGM use

Our participants used their CGM for 12 weeks, aiming for 50 days of usage, with over half wearing it for more than 30 days.

Figure 3: Average wear of CGM

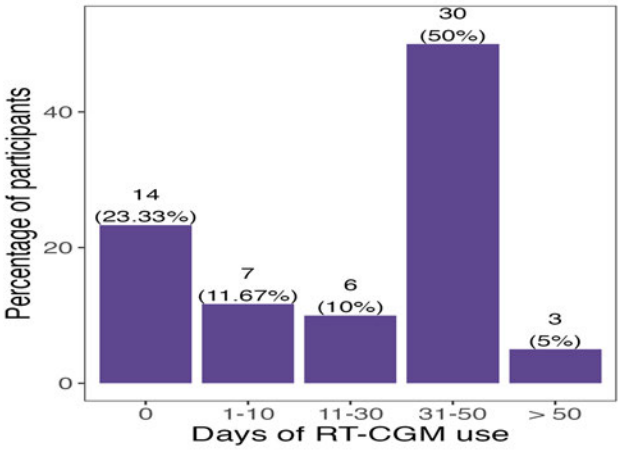
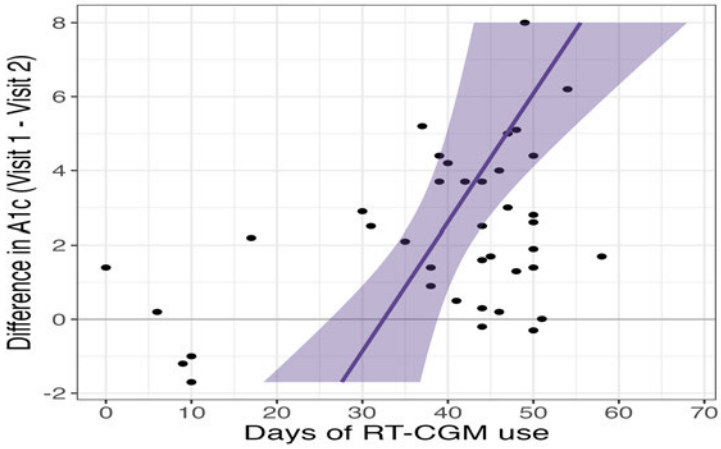
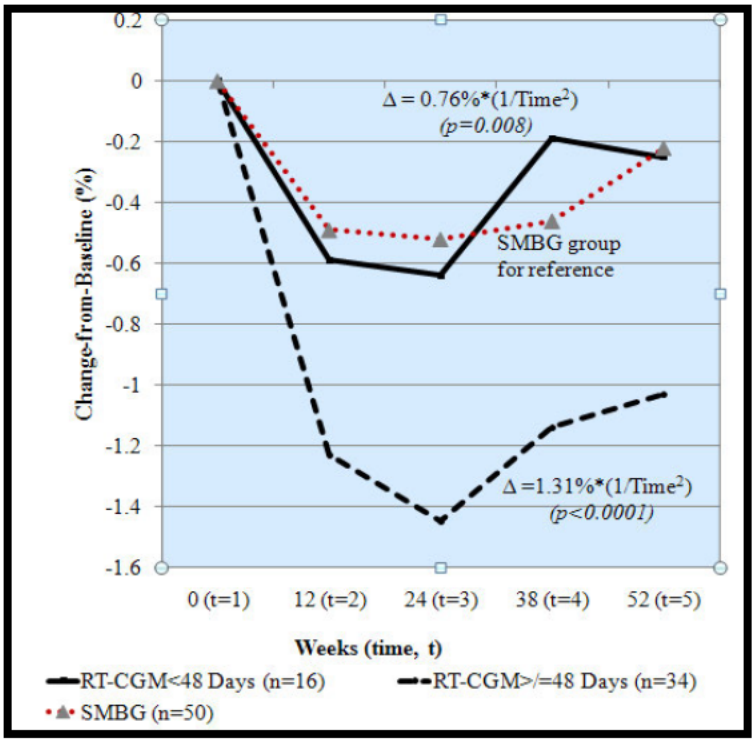


Figure 4: A1c based on duration of wear



Overall: Our data indicates the advantage of CGM in a younger group (mean age 48) that did not require intensive insulin (basal insulin only or insulin sparing) but had many social determinants of health.

In 2012, my mentor and I published pioneering research highlighting the advantages ofCGM for individuals with type 2 diabetes. The study demonstrated an improvement in A1c levels by 0.8% compared to finger sticks alone. This benefit was maintained at 52 weeks; however, significant and sustained glycemic improvements were only observed in participants who wore the CGM for at least 48 days



Diabetes Care. 2012 Jan;35(1):32-8. doi: 10.2337/dc11-1438. Epub 2011 Nov 18. PMID:22100963; PMCID: PMC3241321.

[redacted]

A recent community based CGM program showed improved A1c of >2% over 6 months and more people reaching health effectiveness and data information (HEDIS) goal of <8.0% with most participants baseline A1c being great than 9.0%.

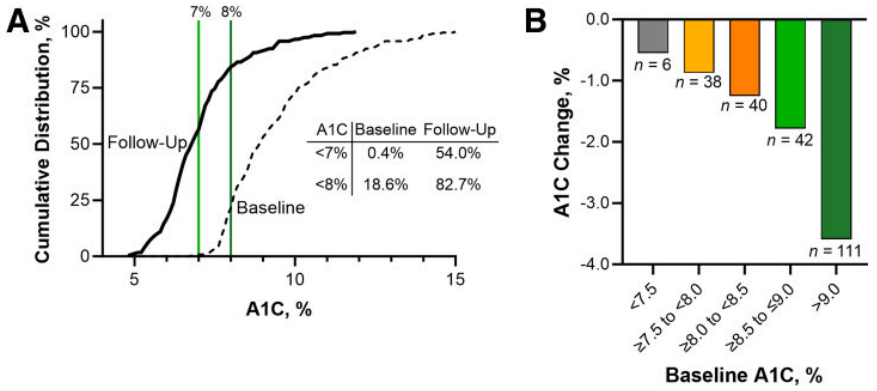


FIGURE 1 Change in A1C among participants (N = 237) in the Dexcom Community Glucose Monitoring Project. *A*) Cumulative distribution of A1C values and proportions meeting ADA treatment target of A1C <7.0% and the Health Effectiveness and Data Information Set (HEDIS) target of A1C <8.0%. *B*) Comparison of A1C outcomes at 6 months stratified by baseline A1C.

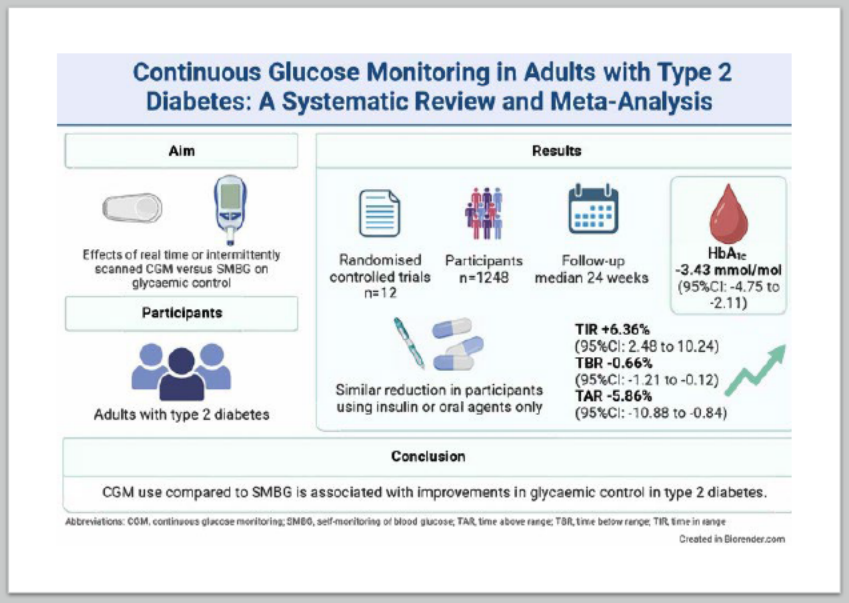
Thomas P. Grace, Andrew Edgington, Laura Reinhart, Timothy Burkart, Elisa Dyer, Jessica Halsey, Karim Baroudi, Christian Hicks, Jennifer E. Layne, Tomas C. Walker; The Dexcom Community Glucose Monitoring Project: Six-Month Results Using Continuous Glucose Monitoring in Type 2 Diabetes. *Clin Diabetes* 2024; cd240030. https://doi.org/10.2337/cd24-0030

Even with our initial and resent research and similar studies from others, many people with type 2 diabetes still don't have access to RT-CGM in 2024.

[redacted]

A1c reduction of (−0.31%)

This effect was comparable among users of insulin and other oral agents.



Diabetologia 67, 798–810 (2024). https://doi.org/10.1007/s00125-024-06107-6

In summary, our ongoing interactions with patients who have diabetes reinforce the findings of CGM research: CGM is crucial for everyone managing diabetes. Let's not delay providing this lifesaving technology to people living with diabetes, especially those who are living with suboptimal and uncontrolled diabetes and early in the disease process before complications develop. We strongly recommend CGM be available for those on any insulin. While we acknowledge the most benefit has been shown in those with higher baseline A1c, we also recommend that CGM be available to non-insulin-requiring patients irrespective of A1c.

Imposing step or A1c requirements for this technology will place an extra burden on providers and restrict access to this essential technology.

Please let me know if you have any further questions

Nicole Ehrhardt, MD
Assistant Professor of Medicine
University of Washington Diabetes Institute

[redacted]

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Additional References:

Ehrhardt N, Cedeno B, Montour L, Sinclair K, Ferguson G, Berberian P, Comstock B, Wright L. Effectiveness of a culturally tailored diabetes education curriculum with real-time continuous glucose monitoring in a Latinx population with type 2 diabetes: the CUT-DM with CGM for Latinx randomized controlled trial study protocol. BMJ Open. 2023 Dec 28;13(12):e082005. doi: 10.1136/bmjopen-2023-082005. PMID: 38154895;

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: RE: Public Comment for CGM WHA
Date: Monday, September 16, 2024 12:15:37 PM
Attachments: image001.png
advacocy gdm9162024.docx

External Email

Additional comments related to GDM and CGM

Thank you for your time

Nicole Ehrhardt

Nicole Ehrhardt
Assistant Professor of Medicine
UW Medicine Diabetes Institute
[redacted]

UW Medicine
DIABETES INSTITUTE

CARDIOMETABOLIC PROJECT ECHO

URL: https://uw.cloud-cme.com/CardiometabolicECHO

From: Nicole M. Ehrhardt
Sent: Monday, September 16, 2024 5:53 AM
To: shtap@hca.wa.gov
Subject: Public Comment for CGM WHA

Please let me know if I can answer any additional questions or speak in support of this technology.

Nicole Ehrhardt, MD

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UW Medicine
DIABETES INSTITUTE

CARDIOMETABOLIC PROJECT ECHO

URL: https://uw.cloud-cme.com/CardiometabolicECHO

Key Questions What is the comparative effectiveness of continuous glucose monitoring in adults and children with diabetes versus self-monitoring?

e. Pregnant people with gestational diabetes who are not using insulin

Response for public comments for CGM in GDM

Gestational diabetes mellitus (GDM) is becoming more common and prevalence is now greater than 10-15%[1] GDM increases risk for maternal, fetal and neonatal complications[2] (Capobianco). Glycemic control is a modifiable risk factor and more tools are needed in GDM management to improve outcomes.

Continuous glucose monitoring (CGM) is a tool for gathering more data about glucose in real time (RT). RT- CGM provides interstitial glucose data every 1-5 minutes giving patients and providers significantly more information about glucose including excursions, variability and real-time changes compared to self-monitored blood glucose readings via glucometer (SMBG). In 2023 the FDA approved RT-CGM use for management of all types of diabetes in pregnancy, including GDM[3]

Studies in non-pregnant patients with diabetes on insulin therapy have demonstrated that RT-CGM use results in improvement in HbA1c and/or a reduced frequency of hypoglycemia and there is growing evidence of improvement in those with type 2 diabetes, even for those not on insulin[4–6]. There is also evidence of benefit in patients with Type 1 diabetes in pregnancy, a large randomized control trial showed improvement in glucose control and neonatal outcomes[7] Data on GDM and CGM use is limited. The largest study on CGM use in GDM found that glycemic indices on CGM were significantly lower in the CGM group compared with those in the routine care group ($P < .001$)[8]. A recent meta-analysis reviewed 14 studies that evaluated RT-CGM in GDM but most were limited by short duration of sensor wear and smaller numbers[9]. However, improvements were seen for those using CGM including more patients qualifying for insulin therapy and better detection of nocturnal hypoglycemia and postprandial hyperglycemia. Interestingly, in one of the large studies (n=110) with duration of CGM use > 14 days showed less gestational weight gain in CGM group[10]. Additionally, a more recent study showed association of large for gestational age and macrosomia in those with higher post prandial glucose seen on CGM[11]. A second study also saw higher fasting and post prandial glucose in SMBG as compared to flash CGM with more macrosomia seen in the neonates of those using SMBG[12].

Unpublished data from a recent Oregon state randomized control study (RTC on 100 GDM participants showed improved glycemic indices, including time in range (TIR) and time above (TAR). Notably, 40% of participants were not on insulin, suggesting benefits for all with GDM, even without insulin.

This single-center randomized,open-label clinical trial compared real-time CGM with concurrent SMBG (intervention) to SMBG alone (referent; blinded CGM) in pregnant patients with GDM. The intervention group had significantly higher time-in-range (TIR; 60-140 mg/dL) due to better daytime TIR and lower time above range (>140 mg/dL).

24-hr TIR: 60-140mg/dL % mean ± SD	CGM N=71 93.6 ± 5.8	CBG N=34 87.6 ± 13.9	*P* 0.030
Time above range (>140mg/dL; % mean ± SD)	**5.7 ± 5.9**	**11.8 ± 14.0**	**0.026**

Unpublished data courtesy of Dr Valent, Program Director, Maternal-Fetal Medicine and combined MFM/MGG Fellowships, Division Maternal-Fetal Medicine, Department Obstetrics & Gynecology, Oregon Health & Science University

Recently, we completed a randomized controlled trial involving 107 participants, where half were assigned continuous glucose monitoring (CGM) and the rest continued with standard care. Our study began enrollment later than some other studies, averaging around 30 weeks. We did not find a significant benefit in glycemic indices. However, it was notable that over 60% of participants assigned to fingerstick/standard care dropped out, with 31 out of 32 citing a preference for CGM as their reason for withdrawal. Satisfaction with CGM in our group was high. The adapted Joslin experience survey revealed a positive correlation between CGM use and improved diabetes management during pregnancy. Questions such as "Does it help in making diabetes-related decisions?" and "Does it provide insights on how diet affects blood sugar levels?" received more than 90% positive responses. Negatively phrased questions also showed support for CGM usage.

Frequency Distribution of Responses for Selected Questions from the CGM Satisfaction Survey

Question										% Positive
Positively worded questions										
Makes adjusting insulin easier*	2	2	5	7	7					60.9
Helps me to be sure about making diabetes decisions	2	2		22					20	91.3
Helps to keep low blood sugars from happening*	1		8	9	5					60.9
Has taught me new things about diabetes that I didn't know before	1	3		20				22		91.3
Teaches me how eating affects blood sugar	1	2		21				22		93.5
Helps me to relax, knowing that unwanted changes in blood sugar will be de	1		6	2	18			19		80.4
Has made it easier to accept doing blood sugar tests	1	1		13		21			10	67.4
Shows patterns in blood sugars that we didn't see before		3	7		25			11		78.3
Allows more freedom in daily life			8	10	13		15			60.9
Makes it clearer how some everyday habits affect blood sugar levels	1	4			27		14			89.1
If possible, I want to use the device when the research study is over		3	3	11		16		13		63.0
Negatively worded questions										
Causes me to be more worried about controlling blood sugars			7	12		10		12	5	41.3
Has been harder or more complicated than expected			11		19		6	7	3	65.2
Shows more glitches and bugs than it should		6		12		18		6	4	39.1
The feedback from the device is not easy to understand or useful				16		21		6	2	80.4

Unpublished data RTC UW GDM study. Ehrhart and Fay

In summary, CGM should be made available early for all individuals with GDM, regardless of whether they require insulin since insulin needs often develop later in gestation, delaying access to CGM in these groups. Furthermore, our study comprised a well-educated and well-resourced population who could afford out-of-pocket purchase if not randomized to CGM. Therefore, the use of CGM shouldn't be restricted to those requiring insulin, as it otherwise remains accessible only to those who can afford to buy it, excluding other high-risk pregnancy participants with GDM.

Thank you for your time

Nicole Ehrhardt, MD Emily Fay, MD

[redacted]

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Abbott Submission Regarding CGM
Date: Monday, September 16, 2024 2:24:14 PM
Attachments: WA Medicaid- Answers to Key Questions and Evidence Tables 9.16.24.pdf

External Email

Hello,
I hope this email finds you well.

On behalf of Abbott Diabetes Care, we'd like to respectfully submit responses to key questions and pertinent data regarding Continuous glucose Monitors (CGM) for your consideration.

Please do not hesitate to reach out should any questions arise regarding our submission.

Sincerely,
Mariham Fahim, Pharm D, RPh

Abbott
Mariham Fahim
Medical Outcomes Manager
Contingent
Medical Affairs
Abbott Diabetes Care
[redacted]

For Health Care Professionals, please submit medical information inquiries to: https://adc-north-america.irmscare.com

Sept 16th, 2024

Attention: Washington State Health Care Authority

Thank you for allowing us to present you with the current and most compelling data for use of Continuous Glucose Monitoring (CGM) to help improve the lives of people living with Diabetes. Attached to this is the body of evidence currently available to aid in your decision making below populations.

a. Adults with type 2 diabetes who are not using insulin,
b. Children with type 2 diabetes (regardless of insulin use)
c. Adults and children whose diabetes is well-controlled (defined as within target HBA1c and not experiencing severe hypoglycemic events)
d. Pregnant people with type 2 diabetes who are not using insulin
e. Pregnant people with gestational diabetes who are not using insulin

This data is collected from Randomized controlled trials (RCTs) and Real World Evidence (RWEs) are the two most common forms for collecting data, and both forms have their value in assessing the role of a drug or medical device. RCTs tend to have the highest internal validity and is required for initial approval by the FDA. The importance of RWE cannot be ignored, RWE for decision making presents new methodological and analytical challenges whereas RCTs have limited set data for patient randomization, inclusion and exclusion criteria, and regulated follow-up protocols, the external validity of RCTs is relatively low, hence there is limitation in terms of generalization. RWE tend to have less constrained study designs (e.g. non-randomized treatment allocation, longer patient follow-up and broader patient populations) and essentially RWE can provide longer term patient outcomes and include a broader population Cost Savings[1]. Due to the limitation with RCTs, RWE may provide a more generalizable picture of treatment effects in clinical practice. Consequently, the extrapolation of drug/device efficacy to drug/device effectiveness in clinical practice remains difficult when only assessing RCTs. Many payers and regulatory agencies such as the FDA now request pharmaceutical and medical device manufacturers to submit RWE in conjunction with findings from their RCTs when assessing the safety, effectiveness, and cost–benefit parameters of new medications and medical devices[2]. The publication of FDA's RWE framework is expected to accelerate the use of RWE for approval and coverage decisions. 21st Century Cures Act mandated the US FDA to develop guidance for the use of RWE in regulatory decisions[3]. It is also important to take into consideration that Diabetes technologies such as CGM continue to evolve at an increasingly rapid pace in comparison to drugs. Seventeen new CGM devices have been introduced to the market during the past decade. The introduction of each new system is supported by well-designed RCTs and real-world retrospective and prospective studies. However, translation

of the evidence into clinical guidelines and coverage policies often lags behind the current times. Assessing RCTs alone poses major limitations of the current approach to clinical evidence assessment. Inclusion of RWE data presents a more appropriate method for evaluating rapidly evolving technologies such as CGM[4].

Diabetes is a complex disease state that could be well managed with the help of advancing technology such as CGMs. With health equity being a concern for Medicaid population, expanding access to CGM for the Medicaid population can be not only beneficial for the patients, but also cost saving for the state. Please note that utilizing a different set of review standards with a narrow subset which ultimately excludes data used by CMS and other state agencies which have expanded coverage can negatively impact clinical outcomes for the patient, and economical outcomes for the state. Ignoring the critical issue of health equity places burdensome criteria on patients to access CGM and leaves these Medicaid patients out of reach for CGM technology they can stand to benefit from. We respectfully ask that you include this valuable set of information provided only by RWEs in your consideration for policy changes.

I would be happy to set up a time to discuss the impact of CGM, and any of these studies in greater detail.

Thank you,

Mariham Fahim, PharmD, RPh
Contingent Medical Outcomes Manager
Medical Affairs
Abbott Diabetes Care
[redacted]

Key Questions

1. **What is the comparative effectiveness of continuous glucose monitoring in adults and children with diabetes versus self-monitoring?**

Study	Design/patient eligibility criteria	Interventions	Outcomes
Adults with Type 2 Diabetes			
RCTs			
Brown and Aronson, 2022[5] Trial identifier: NCT04562714	**Study population:** Adults with T2DM (non-insulin users) **Baseline HbA1c:** 8.6% (study population) **Duration:** 16 weeks **Setting:** Canada	FreeStyle Libre system + DSME (n=41) DSME (n=41)	**Outcomes** HbA1c: 0.4% reduction between groups ($p < 0.03$) TIR (70–180 mg/dL): 11.5% difference between groups ($p < 0.01$) TAR (> 180 mg/dL): −9.6% difference between groups ($p = 0.03$) No significant differences between groups in CV, TBR. **Conclusion** FreeStyle Libre system use with DSME was associated with greater TIR, greater satisfaction in glucose monitoring and reduction in HbA1c in adults with T2DM using non-insulin therapies.
Choe et al, 2022[6] Trial identifier: NCT04932928	**Study population:** Adults (19 − 80 years) with T2DM, HbA1c: 7.0 – 10.0% and without any change in anti-diabetes medication in the previous 3 months. **Baseline HbA1c:** 7.9 ± 0.6% (intervention); 7.9 ± 0.7% (control) **Duration:** 12 weeks **Setting:** South Korea **Exclusions:** T1DM, use of short-acting insulin in the past 3 months or planning to initiate prandial or short-acting insulin, pregnant or planning pregnancy, use of medications affecting glycemic control, use of anti-obesity drugs.	Structured education + isCGM, FreeStyle Libre system (intervention group, n=63). Conventional diabetes care with BGM (control group, n=63).	**Primary outcomes** Mean (± SD) HbA1c level at 12 weeks, $p < 0.001$ Intervention group: 7.3 ± 0.6% Control group: 7.8 ± 0.9% **Conclusion** Patient-driven lifestyle modification using FreeStyle Libre system lowered HbA1c levels in patients with T2DM.

Wada et al, 2020[7] Trial identifier: UMIN000026452, jRCTs041180082	**Study population:** Adults with T2DM (non-insulin users) with HbA1c 7.5 – 8.5%, 20 – 69 years of age. **Baseline HbA1c:** 7.8% (intervention group), 7.8% (SMBG group) **Duration:** 24 weeks **Setting:** Japan **Exclusions:** Treated with insulin, used SMBG or flash glucose monitoring, on dialysis, severe renal failure (GFR < 30 mL/min/1.73 m^2), diabetic retinopathy, inability to properly operate device.	FreeStyle Libre system (n=49) SMBG (n=51)	**Primary outcome** HbA1c: 0.46% reduction within intervention group at 24 weeks ($p < 0.001$) **Conclusion** For adults with non-insulin-treated T2DM, better glycemic control was seen with FreeStyle Libre system than with BGM during the 12 weeks after stopping BGM.
RWEs			
Elliott et al, 2021[8] Trial identifier: N/R	**Study population:** Adults (age ≥ 18 years) with T2DM on only basal insulin ≥ 1 year, using FreeStyle Libre system for ≥ 3 months, HbA1c 8.0 – 12.0% within ≤ 3 months before device use, and HbA1c results recorded 3 – 6 months after initiation. **Study type:** Retrospective chart review **Duration:** 3 – 6 months **Baseline HbA1c:** 8.9% **Setting:** Canada **Exclusions:** Prandial insulin use after study initiation.	FreeStyle Libre system (N=91)	**Primary outcomes** HbA1c: 0.8% reduction ($p < 0.0001$). Sensitivity analysis evaluating change in HbA1c based on final values for different time windows (121 – 149, 107 – 163, and 90 – 180 days) showed the same reductions in HbA1c over time. **Conclusion** Reductions in HbA1c were seen after the start of FreeStyle Libre system use in patients with T2DM treated with basal insulin.
Miller et al, 2021[9] Trial identifier: N/R	**Study population:** Adults (age ≥ 18 years) with T2DM, CGM-naïve using basal insulin or non-insulin medications. **Study type:** Retrospective cohort database analysis **Duration:** 12 months (6 months pre- and post-index date) **Setting:** US (IBM MarketScan Commercial Claims and Medicare	FreeStyle Libre system: N=10,282	**Primary outcomes** Comparison of ADE rates during the 6 months before and 6 months after FreeStyle Libre system acquisition showed the rate decreased from 0.076 to 0.052 events per patient year (HR, 0.68; 95% CI: 0.58 –0.80; $p < 0.001$). • Overall ADEs: 36% reduction • Inpatient ADEs: 71% reduction • Outpatient ADEs: 28% reduction All-cause hospitalization decreased from 0.177 to 0.151 events per patient year (HR, 0.85; 95% CI: 0.77 – 0.94; p

	Supplemental claims data). **Exclusions:** Purchase of short- or rapid-acting insulin in 6 months before CGM acquisition, absence of 6 months of database enrollment before flash continuous glucose monitoring purchase, GDM.		= 0.002). **Conclusion** FreeStyle Libre system acquisition is associated with decreases in adverse diabetic events and all-cause hospitalizations of adults with T2DM not treated with short- or rapid-acting insulin.
Miller et al, 2020[10] Sponsor: Abbott Diabetes Care Trial identifier: N/R	**Study population:** Patients with T2DM, age not reported; HbA1c ≥ 6.5% in prior 6 months on basal or non-insulin therapy. **Study type:** Retrospective database analysis using linked data from the LibreView® data management platform, DRG (a commercial medical and pharmacy claims database), and HbA1c data from Quest Diagnostics. **Baseline HbA1c:** 8.5% **Setting:** US **Exclusions:** None reported	FreeStyle Libre system, 6-month cohort (N=774). FreeStyle Libre system, 12-month cohort (N=207).	**Primary outcomes** 6-month cohort HbA1c: • Overall: 0.8% reduction ($p < 0.0001$) • Basal: 0.6% reduction ($p < 0.0001$) • Non-insulin: 0.9% reduction ($p < 0.0001$) 12-month cohort HbA1c: • Overall: 0.6% reduction ($p < 0.0001$) • Basal: 0.5% reduction ($p = 0.0014$) • Non-insulin: 0.7% reduction ($p < 0.0001$) **Conclusion** This real-world study shows that HbA1c decreases after the start of FreeStyle Libre system use by patients with T2DM treated with long-acting insulin or non-insulin therapy.
Evans et al, 2022[11] Sponsor: Abbott Diabetes Care Trial identifier: N/R	**Study type:** Meta-analysis of real-world studies published between 2013 and December 31, 2020, among adult and pediatric patients with T1DM or T2DM using the FreeStyle Libre system. Analyzed and reported on 75 studies (of 771 identified) reporting changes in HbA1c over 1 – 24 months.	FreeStyle Libre system (N=30,478)	**Primary outcomes** T1DM (n=28,063; 62 trials) • HbA1c: 0.53% reduction at 3 – 4 months; 0.42% reduction at 4.5 – 7.5 months. • Reduction sustained for 24 months. T2DM (n=2415; 13 trials) • HbA1c: 0.45% reduction at 3 – 4 months; 0.59% reduction at 4.5 – 7.5 months. • Reduction sustained for 12 months. Children with T1DM • HbA1c: 0.54% reduction at 1 month. • Effect lessened with time up to 15 months and stabilized through 24 months. No significant differences in HbA1c reductions between adults with T1DM or T2DM. Greater HbA1c reductions for those with higher baseline HbA1c. **Conclusion** For adult and pediatric patients with T1DM or T2DM, use of FreeStyle Libre system is associated with reductions in

			HbA1c, particularly if HbA1c at baseline is high. FreeStyle Libre system use is also associated with sustained HbA1c reductions for 24 months in patients with T1DM and for 12 months in patients with T2DM.
Ferreira et al, 2024[12] Trial identifier: N/R	**Study type:** Systematic review and meta-analysis of randomized clinical trials comparing CGM systems with SMBG in non-insulin-treated patients with T2DM published from inception to August 2023. **Baseline HbA1c:** Range of 7.83 – 8.9% **Exclusions:** Observational studies, studies including patients with T2DM treated with insulin, and studies that reported no outcomes relevant to the review.	N=407 patients n=228 (56%) randomized to CGM (either rtCGM [Dexcom G5, G6, or SevenPlus; Medtronic Guardian 3] or isCGM [FreeStyle Libre system]).	**Baseline characteristics** Diabetes duration (range): 5.4 – 13.9 years Mean age: 57.9 years **Outcomes** Compared with SMBG, CGM use led to significant reduction in the following: • HbA1c (WMD −0.31%; 95% CI: from −0.42 to −0.21; I^2 = 0%). • Time in hypoglycemia level 2 (WMD −0.28%; 95% CI: from −0.52 to −0.03; I^2 = 91%). • Glucose level (WMD −11.16 mg/dL; 95% CI: from −19.94 to −2.39; I^2 = 0%). • Glucose time > 180 mg/dL (WMD −7.75%; 95% CI: from −12.04 to −3.45; I^2 = 0%). • SD of glucose variation (WMD −4.00 mg/dL; 95% CI: from −6.86 to −1.14; I^2 = 0%). CGM also increased TIR (WMD 8.63%; 95% CI: 4.54 – 12.71; I^2 = 0%) and treatment satisfaction (SMD 0.79; 95% CI: 0.54 – 1.05; I^2 = 0%). **Conclusion** Glycemic control improved upon rtCGM and isCGM use, compared with SMBG, among people with T2DM not using insulin therapy.

Adults and Children with well controlled diabetes			
RWEs			
Zahedani et al, 2021[13] Trial identifier: NCT04621656	**Study population:** 25 participants with prediabetes (self-reported), 192 patients with non-insulin-dependent T2DM (self-reported), 448 healthy patients. **Study design:** Prospective, observational, unblinded study **Fasting BG:** 87.8 ± 33.6 mg/dL **Duration:** 10 days **Setting:** US **Exclusions:** Vitamin C use (> 200% of US RDA); allergy to skin adhesive; pregnancy, lactation, or planned pregnancy; use of insulin, oral hypoglycemic drugs, progesterone, atypical antipsychotics, oral contraceptives, or blood thinners.	FreeStyle Libre flash glucose monitoring system and LibreLink app, heart rate monitor, Sugar AI app (n=665).	**Primary outcome** Mean improvement in TIR: 6.4% ($p < 0.001$). • Proportion with mean improvement: 51.4% of all participants. **Secondary outcomes** For participants with suboptimal TIR at baseline (TIR < 83%) in the healthy and prediabetes group (n=24), 91.7% showed a mean improvement of 23.2% in TIR. For participants with suboptimal TIR at baseline (TIR < 83%) in the non-insulin-dependent T2DM group (n=60), 58.3% showed a mean improvement of 22.7% in TIR. *Safety was not reported.* **Conclusion** Use of CGM as part of a multimodal approach may lead to better glycemic control in patients with prediabetes or non-insulin-dependent diabetes and in healthy persons.
Study	**Design/patient eligibility criteria**	**Interventions**	**Outcomes**
Children Studies			
RCTs			
Campbell et al, 2018[13] Trial identifier: NCT02821117	**Study population:** Children (4 – 17 years of age) with T1DM for ≥ 1 year on current insulin regimen for ≥ 2 months. **Study type:** Single-arm, open-label prospective trial **Baseline HbA1c:** 7.9% **Duration:** 10 weeks **Setting:** UK, Ireland, and Germany **Exclusions:** Allergy to medical-grade adhesives, CGM or FreeStyle Libre system use in previous 3 months, pregnancy, breastfeeding, oral steroid use.	FreeStyle Libre system for days 1 – 70 (N=76). SMBG during baseline (days 1 − 14) and the last 14 days of treatment (days 57 – 70).	**Primary outcomes** TIR (70 – 180 mg/dL): • 1 h/day (95% CI, 0.30 − 1.65) increase from baseline to end of study (PP analysis). • 0.9 h/day increase from baseline to end of study period (FAS analysis). Lower confidence limit from PP analysis exceeded the non-inferiority margin of −1.2 h/day. Results of FAS analysis indicate superiority of FreeStyle Libre system vs. SMBG. Additional outcomes are described in Section 3.2. **Conclusion** FreeStyle Libre system was non-inferior and superior to SMBG in achieving glycemic control in children and adolescents with T1DM. Improved TIR and lower HbA1c

			were noted for patients using FreeStyle Libre system vs. those using SMBG.
RWEs			
Deja et al, 2018[14] Trial identifier: N/R	**Study population:** Children (aged 6.2 – 16.5 years) with T1DM (mean duration, 6.5 years) who used insulin pump or pens and attended a summer camp for children with diabetes. **Study type:** Observational study **Baseline HbA1c:** 7.81% **Duration:** 14 days **Setting:** Poland **Exclusions:** Absence of parental/guardian consent	FreeStyle Libre system (N=75)	**Primary outcomes** • 92% rated FreeStyle Libre system as being easier to use than glucometer. • 92% rated ease of glucose reading as good or very good. • 86% rated wearing/comfort of the system as very good or good. • 94% rated ease of installation of the system as very good or good. • 82% would use the system again. • Sensor remained intact for 62% (amid harsh camp conditions). **Conclusion** Children who had T1DM and used FreeStyle Libre system during summer camp responded favorably regarding their satisfaction with the device.

Study	Design/patient eligibility criteria	Interventions	Outcomes
Diabetes in Pregnancy- T2DM, or Gestational Diabetes			
RCTs			
Tumminia et al, 2021[15] Trial identifier: NCT04666818	**Study population:** Pregnant women with inadequately controlled pregestational T1DM (n=34) or T2DM (n=6) at conception, using MDI (75%) or insulin pumps (25%). **Study design:** Prospective multicenter randomized pilot trial. **HbA1c at first visit:** 6.8% for FreeStyle Libre system group, 7.0% for the SMBG group. **Duration:** During pregnancy **Setting:** Italy	FreeStyle Libre system (n=21) SMBG (n=19)	**Primary outcome** HbA1c: 0.65% decrease in FreeStyle Libre system group, with no significant between-group differences. **Other outcomes** Average TBR was significantly lower with FreeStyle Libre system use than with SMBG at the end of second trimester (12.1% vs. 19.6%, p = 0.04). Inter-day GV index was significantly lower with FreeStyle Libre system use than with SMBG (59.1 vs. 77.7, p = 0.02). No differences in TIR or TAR or indices of intra-day GV were seen between groups during pregnancy. **Conclusion** Although FreeStyle Libre system and SMBG showed similar efficacy in glycemic control for pregnant women with pre-GDM, FreeStyle Libre system use led to improvement in TBR and glucose variability.

Study	Design/patient eligibility criteria	Interventions	Outcomes
Scott et al, 2018[16] Trial identifier: NCT02665455	**Study population:** Adult pregnant women (aged ≥ 18 years) at ≥ 12 weeks of gestation with T1DM, T2DM, or GDM, testing BG ≥ 2-times/day. **Study type:** Prospective single-arm study comparing FreeStyle Libre system to SMBG (all patients used both types of measurement). **Baseline HbA1c:** T1DM 6.6%, T2DM 5.7%, GDM 5.4% **Duration:** 14 days **Setting:** UK, Austria	FreeStyle Libre system (N=74): T1DM (n=24) T2DM (n=11) GDM (n=39)	**Primary outcomes** Consensus error grid analysis: • 88.1% of results in zone A • 99.8% of results in zones A and B Total of 5031 paired SMBG to sensor glucose values: • Overall MARD: 11.8% • MARD for BG ≥ 5.6 mmol/L: 11.7% • HbA1c: T1DM: 6.5% (0.1% reduction); T2DM: 5.7% (no change); GDM: 5.4% (no change) Frequency of hypoglycemic and hyperglycemic events/day: < 70 mg/dL, 1.86; > 180 mg/dL, 0.80 **Adverse events** 23 participants reported 27 AEs; five participants reported 11 AEs (mild) associated with sensor application or insertions sites. **Conclusion** Comparison of FreeStyle Libre system with SMBG showed good agreement between the two; safety and accuracy of FreeStyle Libre system were not affected by patient characteristics for use in pregnant women with diabetes.
Mammadova et al, 2022[17] **Trial identifier:** NR	**Study population:** Case series on minority pregnant (< 14 weeks, single live fetus at enrollment) women with pregestational T2DM, rtCGM users during pregnancy; average age: 30.3 years; no chronic illnesses apart from hypertension. **Baseline HbA1c:** 6.6 (mean) **Setting:** US	rtCGM N=4	At 34 weeks, mean HbA1c reduced to 6.0. Delivery via C-sections in all except one who delivered via vaginal route. Live infant having weight appropriate with gestational age. Gestational ages of babies: one of 32.3 weeks (due to maternal severe pre-eclampsia); remaining three born at 38 – 39 weeks of gestation. No baby had neonatal complications including hypoglycemia. **Conclusion** Pregnant women with pregestational T2DM could benefit from rtCGM use during pregnancy in terms of improved perinatal glycemic control and reduction of neonatal complications.

Key Question :

2. **What is the device-related safety of continuous glucose monitoring in adults and children with diabetes?**

Continuous glucose monitoring (CGM) systems[18,19] are generally considered safe for both adults and children with diabetes, but they come with certain device-related risks and limitations. However, proper training and regular consultation with healthcare providers are essential to minimize any device-related issues.

Some of the key safety considerations include:

a. Skin Irritation or Allergies: Some users may experience skin reactions, such as rashes, itching, or irritation at the sensor site. This is usually due to the adhesive used to keep the sensor in place.

b. Lag time Readings difference: While CGM systems are highly accurate and provides real-time glucose readings, it is important to remember that all CGMs measure glucose in the interstitial fluid (ISF), which lag in comparison to blood glucose reading, particularly during rapid changes in glucose levels (e.g., after eating or exercising). It is recommended that a fingerstick testing is performed if symptoms do not match the CGM readings.

c. User Error: some CGM devices require calibration, if not calibrated correctly, or other errors are performed such as improper sensor placement, or not following the manufacturer's guidelines, these can lead to inaccurate readings or device malfunction.

Key Question:

3. What is the differential efficacy or safety by patient and clinical factors, such as:

a. Age, b. Gender, c. Race and ethnicity, d. Type of diabetes, e. Presence of comorbidities , f. Severity of disease (e.g., baseline HbA1c, number of self-tests per day), g. Use of other medications (e.g., insulin use), h. Level of adherence to CGM use, i. Type of CGM (i.e., rtCGM vs. isCGM)

Study	Design/patient eligibility criteria	Interventions	Outcomes
Age (RWEs)			
Hirsch et al, 2024[20] Trial identifier: N/A	**Study population:** Medicare beneficiaries (age < 65 years) with T2DM treated with basal insulin. **Study type:** Retrospective study using Inovalon Insights claims data on Managed Medicaid beneficiaries. **Duration:** 1 year (6 months pre-CGM and 6 months post-CGM data were analyzed).	CGM N=9574 Medicaid beneficiaries with Inovalon Insight claims data. CGM	**Primary outcomes** Significant reductions in HCRU were noted when the 6-months pre-CGM and post-CGM periods were compared: • Inpatient hospitalizations: 0.37 – 0.31, $p < 0.001$. • Emergency department visits: 0.95 – 0.84, $p < 0.001$. • Outpatient visits: 9.11 – 8.60, $p < 0.001$. Subgroup analyses (for patients with ≥ 1 visit during the pre-CGM period, stratified as low [≤ 2 visits] or high [≥ 3 visits]) revealed consistent trends across all subgroups, except for the

	Setting: US **Exclusions:** N/R	acquisition between January 1, 2017, and September 2022.	outpatient visits of the subgroup with 1 – 2 visits during the pre-CGM period: • Inpatient hospitalizations: 1.35 – 0.62, p < 0.001 (1 – 2 visits); 4.82 – 1.54, p < 0.001 (≥ 3 visits). • Emergency department visits: 1.32 – 0.94, p < 0.001 (1 – 2 visits); 4.92 – 2.78, p < 0.001 (≥ 3 visits). • Outpatient visits: 1.6 – 3.57, p < 0.001 (1 – 2 visits); 10.47 – 9.52, p < 0.001 (≥ 3 visits). **Conclusion** CGM use is associated with HCRU reductions in hospitalizations and emergency department visits among Medicaid beneficiaries with T2DM on basal insulin. These HCRU reductions may translate into cost savings.
Huang et al, 2023[21] Trial identifier: NR	**Study population:** Patients with T2DM, aged ≥ 65 years **Duration:** 6-month follow-up period preceding a 6-month baseline period **Setting:** US **Exclusions:** NR	FreeStyle Libre system and BGM N=267	**Primary outcomes** FreeStyle Libre system use was associated with: • Significant increase in DTS (mean total DTS change score: +15.3), p < 0.005. • Significant reduction in perceived frequency of hypoglycemia (mean score: −0.2), p = 0.017. Daily scan frequency was associated with HbA1c reduction; each additional scan resulted in a decrease of 0.036% (adjusted 95% CI: from −0.070 to −0.003), adjusted p = 0.032. **Conclusion** FreeStyle Libre system use resulted in improvement in diabetes treatment satisfaction among the elderly, along with HbA1c reduction.
Study	**Design/patient eligibility criteria**	**Interventions**	**Outcomes**
Race and Ethnicity (RWE)			

Ni et al, 2023[22] Trial Identifier: N/R	**Study population:** Adults (age ≥ 18 years) with T1DM or T2DM who visited a primary care or endocrine provider in the healthcare system between October 2020 and March 2022. **Study type:** Retrospective analysis of Epic EMR data **Duration:** April 2019 to June 2022 **Setting:** US Medicaid **Exclusions:** Pregnancy	CGM: FreeStyle Libre 2 system, Dexcom G6 CGM prescribed (n=628): T1DM: 180; T2DM: 448 CGM dispensed (n=591): T1DM: 169; T2DM: 422	**Primary outcomes** **CGM uptake and adherence** Mean MPR • T1DM: 0.78 • T2DM: 0.72; p = 0.06 **HbA1c change, % (95% CI)** • T1DM: −0.19 (−0.7 to 0.3) • T2DM: −1.2 (−1.5 to −0.8); p < 0.001 **Conclusion** CGM use was associated with improved HbA1c across all major racial/ethnic groups, highlighting broad CGM appeal, utilization, and effectiveness across an underprivileged patient population.
Study	**Design/patient eligibility criteria**	**Interventions**	**Outcomes**
Presence of Comorbidities			
RCTs			
Shen et al, 2021[23] Trial identifier: Chinese Clinical Trial Registry (ChiCTR2000030436)	**Study population:** Patients with COVID-19 and DM during hospitalization (isCGM for blood glucose testing, n=35; POC BG testing, n=35) **Study design:** Prospective study using propensity score matching **Setting:** China **Exclusions:** N/R	isCGM (N=70)	**Primary outcomes** Adverse outcomes (need for ICU admission, need for mechanical ventilation, or death): • 15 in patients with isCGM • 21 in patients with POC BG testing Deaths: • 0 among patients with isCGM • among patients with POC BG testing Multivariable adjusted HR of adverse outcomes for patients without isCGM when compared with those with isCGM: 2.76 (1.40 – 5.43). **Conclusion** Compared with POC BG testing, the isCGM system (FreeStyle Libre system) was associated with better outcomes for patients with DM and COVID-19; however, additional studies with larger sample sizes are needed before isCGM can replace POC BG testing in this population.

Hissa et al, 2021[24] Sponsor: N/R Trial identifier: N/R	**Study population:** Adults (ages 18 – 80 years) who were undergoing HD (for ≥ 30 days) and had T2DM (> 4 months) and a BMI of 22 – 40 kg/m^2. **Study design:** Prospective, single-center, exploratory study **Duration:** 3 weeks **Setting:** Brazil **Exclusions:** Pregnancy or nursing, allergy to sensor adhesive, extensive skin lesions or scars or infection/edema at application site, medication use that could interfere with the sensor's glucose measurements, T1DM or secondary forms of diabetes, acute metabolic conditions (e.g., ketoacidosis) in the prior 6 months, liver disease.	FreeStyle Libre system (n=12) Capillary blood glucose (n=12)	**Primary outcomes** Pre-dialysis MARD: • Session 0: 9.4 ± 6.3% • Session 1: 11.2 ± 12.8% • Session 2: 15.3 ± 16.5% • Session 3: 23.6 ± 17.0%, p = 0.0013) • Session 4: 21.5 ± 19.0% Session 5: 21.1 ± 21.8%
RWEs			
Gomez et al, 2021[25] Trial identifier: N/R	**Study population:** Adults (age > 18 years) with an RT-PCR-confirmed diagnosis of COVID-19 and with T2DM (n=44) or new-onset hyperglycemia (2 POC capillary blood glucose > 180 mg/dL) (n=16); treatment was basal-bolus insulin. **Study design:** Prospective, single-center, cohort study **Mean HbA1c at hospital admission:** 9.03% **Setting:** Colombia **Exclusions:** Active malignancy, drug dependence, poorly controlled psychiatric illness, pregnancy, or use of CGM before hospital admission.	FreeStyle Libre flash glucose monitoring system and LibreView online platform (N=60).	**Primary outcomes** Total number of CGM data points: 190,080. TIR (BG 70 – 180 mg/dL): median, 72.5% (IQR, 54 – 87.5). TBR (BG < 70 mg/dL): median, 3% (IQR, 1 – 6). TAR (BG > 180 mg/dL): median, 22% (IQR, N/R). CV: median, 30.0% (IQR, 25.8 – 37.8) (CV > 36% defined as high variability). TIR, TAR, TBR, CV, and GMI values did not differ between the following: • Patients who were or were not in ICU. • Patients who had or did not have ARDS. • Patients who had or did not have AKI. **Conclusion** Glycemic metrics determined from CGM readings were similar to those previously reported TIR, TAR, TBR, and glycemic variability (Gómez, 2020) for patients with DM without COVID-19.
Hirsch et al, 2024[26] Trial identifier: N/A	**Study population:** Medicare beneficiaries (age < 65 years) with T2DM treated with basal insulin. **Study type:** Retrospective study using Inovalon Insights claims data on Managed Medicaid beneficiaries.	CGM N=9574 Medicaid beneficiaries with Inovalon Insight claims data.	**Primary outcomes** Significant reductions in HCRU were noted when the 6-months pre-CGM and post-CGM periods were compared: • Inpatient hospitalizations: 0.37 – 0.31, p < 0.001. • Emergency department visits: 0.95 – 0.84, p < 0.001. • Outpatient visits: 9.11 – 8.60, p < 0.001.

	Duration: 1 year (6 months pre-CGM and 6 months post-CGM data were analyzed). **Setting:** US **Exclusions:** N/R	CGM acquisition between January 1, 2017, and September 2022.	Subgroup analyses (for patients with ≥ 1 visit during the pre-CGM period, stratified as low [≤ 2 visits] or high [≥ 3 visits]) revealed consistent trends across all subgroups, except for the outpatient visits of the subgroup with 1 – 2 visits during the pre-CGM period: • Inpatient hospitalizations: 1.35 – 0.62, p < 0.001 (1 – 2 visits); 4.82 – 1.54, p < 0.001 (≥ 3 visits). • Emergency department visits: 1.32 – 0.94, p < 0.001 (1 – 2 visits); 4.92 – 2.78, p < 0.001 (≥ 3 visits). • Outpatient visits: 1.6 – 3.57, p < 0.001 (1 – 2 visits); 10.47 – 9.52, p < 0.001 (≥ 3 visits). **Conclusion** CGM use is associated with HCRU reductions in hospitalizations and emergency department visits among Medicaid beneficiaries with T2DM on basal insulin. These HCRU reductions may translate into cost savings.
Horne et al, 2023[27] Trial identifier: ISRCTN 58101486	**Study population:** 69 adults (age ≥ 18 years) undergoing HD with diagnosis of T1DM or T2DM treated with insulin and with access to SMBG. **Study design:** Single-center observational study **Duration:** 14 days **Setting:** UK **Exclusions:** Acute prescription of drugs that could increase serum glucose, expected change in RRT modality, expected imaging during the study, enrollment in other studies related to glycemic control.	FreeStyle Libre Pro system (n=69). SMBG and/or capillary checks in HD unit or lab-measured plasma glucose (n=69).	**Primary outcomes** Blood glucose levels were paired to the nearest time-point interstitial glucose levels. Clarke error grid analysis: • 97.9% of 706 paired levels (69 patients) were within acceptable range (zones A and B). • 97.3% of 481 paired levels on dialysis day were within acceptable range (zones A and B). • 99.1% of 225 paired levels on non-dialysis day were within acceptable range (zones A and B). *Safety was not reported.* **Conclusion** For patients with T1DM or T2DM who undergo HD, glucose measurements made by FreeStyle Libre Pro system are well correlated with reference glucose measurements (capillary glucose testing on SMBG or lab-based plasma glucose testing from venous blood).

Study	Design/patient eligibility criteria	Interventions	Outcomes
Severity of the disease (RWEs)			
Carlson et al, 2022[28] Trial identifier: N/R	**Study population:** Adults (age ≥ 18 years) with T2DM on basal insulin ≥ 1 year, HbA1c 8.0 – 12.0% before using FreeStyle Libre system ≥ 3 months, HbA1c recorded 3 months before and 3 – 6.5 months after initiating FreeStyle Libre system use. **Study type:** Retrospective chart review and meta-analysis **Duration:** 6.5 months **Baseline HbA1c:** 9.4% for chart review; 9.2% for meta-analysis **Setting:** For chart review, US; for meta-analysis, US and Canada **Exclusions:** Current pregnancy or dialysis, bolus insulin use, or participation in another study that affected their glycemic control.	FreeStyle Libre system (N=100) Meta-analysis (N=191)	**Primary outcome** HbA1c: 1.4% overall reduction **Meta-analysis results** HbA1c: 1.1% reduction HbA1c reduction findings supported by sensitivity analysis demonstrating consistent HbA1c values for all time windows ($p < 0.0001$). **Conclusion** FreeStyle Libre system use was associated with a significant decrease in HbA1c in adults with T2DM treated with basal insulin and without prandial insulin use.
Wright et al, 2021[29] Trial identifier: N/R	**Study population:** Adults (age < 65 years) who had T2DM treated with basal insulin or non-insulin therapy and were CGM-naïve. **Study type:** Retrospective database analysis **Duration:** 159 days (mean follow-up) **Baseline HbA1c:** HbA1c level available within 180 days before or on prescription date: 10.1% (insulin therapy), 10.1% (non-insulin therapy). **Setting:** US EHR dataset (IBM Explorys EHR database) **Exclusions:** N/R	FreeStyle Libre system (N=1034)	**Primary outcomes** HbA1c: 1.5% reduction overall ($p < 0.001$) • Basal insulin users: 1.1% reduction ($p < 0.001$) • Non-insulin users: 1.6% reduction ($p < 0.001$) The highest reductions were observed in patients with the highest baseline HbA1c levels ($p < 0.001$ for all). **Conclusion** In this real-world study, prescription of the FreeStyle Libre system was associated with significantly lower HbA1c of adults with T2DM, regardless of the use of basal insulin or non-insulin therapy.

Sgroi et al, 2023[30] Trial identifier: NR	**Study population:** Patients with T2DM, HbA1c > 8.0% who were referred to be enrolled in CGM. **Baseline HbA1c:** 9.64% (mean) **Duration:** 2 weeks **Setting:** US **Exclusions:** NR	FreeStyle Libre 2 system (CGM) N=50	76% participants reported > 50% CGM active time. Average glucose at 2 weeks: 195 mg/dL. Hypoglycemia, particularly overnight events, reduced over time. Patients reported better understanding of disease process. FreeStyle Libre 2 system data use prompted clinicians to change medication; provider survey showed an increased likelihood of medication change based on glycemic trend. **Conclusion** Use of the FreeStyle Libre system in under-resourced primary care settings helped determine glycemic trends and make appropriate recommendations regarding diabetes medication.
Study	**Design/patient eligibility criteria**	**Interventions**	**Outcomes**
Use with Other Medications (RWEs)			
Wong, 2023[31] Trial identifier: N/R	**Study population:** Adults (age > 18 years) with T1DM or T2DM treated with SC insulin. Factors on which patients were selected for CGM use: multiple insulin injections daily, frequent or nocturnal hypoglycemia, wide GV, occupational factors (e.g., shift work), or suboptimal glycemic control. **Study design:** Single-center retrospective cohort study with propensity score matching. **Setting:** Hong Kong (Mar 2021 – Mar 2022) **Exclusions:** Newly diagnosed DM, pregnancy, hospitalization, unstable dosing of corticosteroids, active malignancy, no baseline or subsequent HbA1c levels, patients with <5 days of CGM data.	CGM group (n=90): received usual care + additional CGM training; tracking food, activity, and insulin dosing; treatment changes and explanation based on CGM report. Usual-care group: n=401; after matching, n=90. CGM: FreeStyle Libre system (isCGM) or Dexcom G6 (rtCGM).	**Primary outcome** Mean change in HbA1c from baseline to next visit (interval of 12 – 20 weeks): −0.40% (95% CI: −0.68 to −0.12%; p = 0.005). **Secondary outcomes** Percentages of patients who achieved HbA1c reduction (CGM group vs. usual-care group): 70% vs. 50%; p = 0.006. • 69% in the CGM group had adjustments in diabetic drug therapy. • 60% in the CGM group received dietary guidance. • 13.3% in the CGM group had insulin doses corrected to match carbohydrates. **GMSS survey results** • 71.4% of CGM users with T1DM and 89.8% of CGM users with T2DM "agreed or strongly agreed" that CGM use led to greater satisfaction with "how things were going with their diabetes". • 71.4% of users with T1DM and 64.4% of users with T2DM "disagreed or strongly disagreed" that CGM use led them to feel frustrated with their disease. • 77.9% of CGM users with T2DM "agreed or strongly agreed" that CGM aided in their understanding of the effects of diet and activity. **Conclusion** CGM use with HCP support in an outpatient clinic benefits by improving glycemic control in patients treated with insulin. Using

			CGM, HCPs can personalize and optimize DM treatment and management. Patients feel CGM is beneficial in managing their disease.
Guerci et al, 2023[32] Trial identifier: N/R	**Study population:** Patients with T2DM treated with basal-only insulin who were initiating FreeStyle Libre system use between Aug 2017 and Dec 2018. **Study design:** Longitudinal retrospective cohort study (RELIEF) of data extracted from the French national claims database (Jan 2015 – Dec 2019). **Duration:** 24 – 36 months (12 months before and 12 – 24 months after FreeStyle Libre system initiation) **Setting:** France **Exclusions:** Only one FreeStyle Libre system reimbursement during study period, death before first sensor reimbursement, age < 18 years, no insulin therapy 6 months before and 6 months after FreeStyle Libre system use.	FreeStyle Libre system (N=5933) 1250 (21.1%) treated with basal-only insulin only; 4683 (78.9%) treated with basal-only insulin + ≥ 1 other anti-hyperglycemic drug.	**Primary outcomes** Primary outcomes (i.e., hospitalizations for ADEs) are presented in Section 5.4. **Other outcomes** • Therapy was intensified with rapid-acting insulin for 22.1% of patients 6 – 12 months after first FreeStyle Libre system use; proportion increased to 26.9% after 18 – 24 months of FreeStyle Libre system use. • 0.3% and 1.6% of patients were treated with insulin pump therapy after 6 – 12 months and after 18 – 24 months of FreeStyle Libre system use, respectively. • 11.7% of patients stopped using insulin after 6 – 12 months of FreeStyle Libre system use: 5.5% switched to non-insulin antihyperglycemic therapy and 6.2% stopped treatment altogether; after 18 – 24 months of FreeStyle Libre system use, 18.8% of patients had stopped insulin therapy: 6.4% had switched to non-insulin drug therapy and 12.4% had ceased treatment. **Conclusion** Treatment intensification with rapid-acting insulin and cessation of insulin therapy have been observed in subgroups of patients during their initial 6 – 24 months of FreeStyle Libre system use.
Wright et al, 2024[33] Trial identifier: N/A	**Study population:** Adults with T2DM, HbA1c ≥ 8.0%, and treatment with a GLP-1 RA beginning in 2018 – 2022. Patients with FreeStyle Libre system acquired it within 30 days of their initial GLP-1 RA acquisition. **Study type:** Real-world study utilizing de-identified EHR database (Optum's Market Clarity Data) **Duration:** 6 months **Setting:** United States **Exclusions:** N/R	n=24,246 with GLP-1 RA n=478 with GLP-1 RA and FreeStyle Libre system Cohorts matched according to sex, age, baseline HbA1c, GLP-1 RA type, and baseline insulin therapy.	**Primary outcome** (Paired change in HbA1c between matched groups at 6 months.) HbA1c reduction at 6 months: −2.4% vs −1.7% for GLP-1 RA and FreeStyle Libre system group vs. GLP-1 RA group ($p < 0.001$). Result confirmed when matching was 5:1 (GLP-1 RA and FreeStyle Libre system vs. GLP-1 RA only): −2.43% vs −2.06% for GLP-1 RA and FreeStyle Libre system group vs. GLP-1 RA group (DID = −0.37; $p < 0.001$). Greater HbA1c reductions at 6 months in the GLP-1 RA and FreeStyle Libre system group were observed when subgroups (e.g., bolus insulin vs. no bolus insulin) were analyzed. Significantly greater percentage of patients achieved an HbA1c < 8.0% in the GLP-1 RA and FreeStyle Libre system group than in the GLP-1 RA group (62.1% vs. 55.6%; $p = 0.01$). **Conclusion** Compared with a GLP-1RA alone, the combination of a GLP-1 RA and FreeStyle Libre system may result in greater improvement in HbA1c in adults with poorly controlled T2DM.

Wright et al, 2024[34] Trial identifier: N/A	**Study population:** Patients with T2DM treated with GLP-1 RAs in a real-world study cohort; subgroup was treated with non-intensive insulin. **Study type:** Cost-effectiveness analysis using the Determination of Diabetes Utilities, Costs, and Effects (DEDUCE) model. Perspective: US payer Discount: 3.0% for costs and outcomes Time horizon: lifetime	GLP-1 RAs vs. GLP-1 RAs + FreeStyle Libre system	**Base case** FreeStyle Libre system with GLP-1 RA was cost-effective when compared with GLP-1 RA only; the ICER was less than the US threshold of $100,000 per QALY gained. • Overall, FreeStyle Libre system with GLP-1 RA increased QALYs by 0.27 and costs by $21,084 with an ICER of $78,550 per QALY gained. **Subgroup analysis** Similar results were obtained: ICER of $81,349 per QALY gained. **Conclusion** FreeStyle Libre system is a cost-effective combination with GLP-1 RA among patients with T2DM at a willingness-to-pay threshold of $100,000 per QALY gained.
Miller et al, 2024[35] Trial identifier: N/R	**Study population:** Adults with T2DM, HbA1c ≥ 8.0%, and treatment with an initial FreeStyle Libre system acquisition in 2018 – 2022. Patients had to have at least one GLP-1 RA prescription within 180 days before FreeStyle Libre system acquisition. The start of GLP-1 RA therapy was defined as the earliest GLP-1 RA prescription from 2017 and beyond. **Study type:** Real-world study utilizing de-identified EHR database (Optum's Market Clarity Data). **Duration:** 6 months **Setting:** United States **Exclusions:** N/R	FreeStyle Libre system N=1781	**Baseline characteristics** Mean age: 55 years; male: 52%; bolus insulin therapy: 38%; average time from GLP-1 start to FreeStyle Libre system acquisition: 499 days; baseline HbA1c: 9.8 ± 1.5%. **Primary outcomes** (Paired change in HbA1c at 6 months after the initial FreeStyle Libre system acquisition.) Significant HbA1c reduction at 6 months, overall group: −1.5% ± 2.0% before FreeStyle Libre system vs. after (9.8% vs. 8.3%; $p < 0.001$). Significant HbA1c reductions were also observed before vs. after FreeStyle Libre system initiation for the subgroups based on insulin therapy (bolus or no bolus insulin) and type of GLP-1 RA (dulaglutide, liraglutide, or semaglutide). Patients who began GLP-1 RA therapy > 1 year before FreeStyle Libre system also experienced a significant HbA1c reduction (−1.2 ± 1.8%, $p < 0.001$). **Conclusion** Significant HbA1c improvement was observed after FreeStyle Libre acquisition for adults with T2DM treated with a GLP-1 RA. This finding was irrespective of the duration of GLP-1 RA therapy, type of GLP-1 RA, or type of insulin.

Key Question:
4. What are the costs and cost-effectiveness of continuous glucose monitoring in adults and children with diabetes?

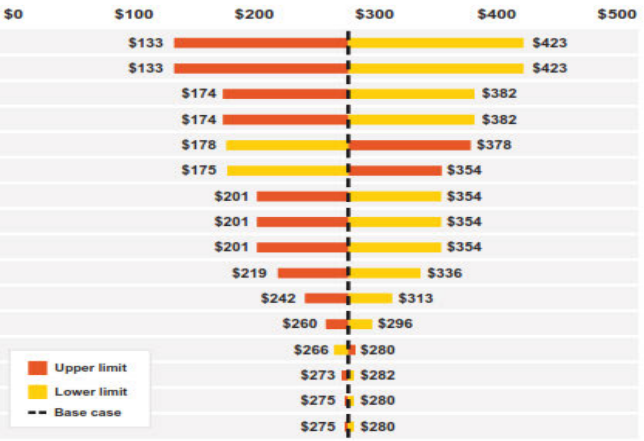
Glucose monitoring with the CGM offers considerable cost savings compared with BGM in the T2DM on MDI, and pediatric patients with diabetes. Increasing CGM the uptake in these populations could reduce overall diabetes healthcare costs. For Medicaid plans, although acquisition costs were higher for CGM systems relative to BGM, cost offsets related to reduced HCRU over time (e.g., reducing hospitalizations for hypoglycemia and DKA) would enable Medicaid plans to recover the higher system costs. Increased access to FreeStyle Libre systems is budget-neutral for both commercial insurance and Medicaid payer types[36].
Results are presented as a net cost difference per patient for each patient group for the FreeStyle Libre 2 and FreeStyle Libre 3 systems relative to routine BGM. The base case simulated the budget impact for the total Medicaid population (plan size of 36.6 million adults and 40.1 million pediatric patients) For this model, it was assumed that uptake of CGM would increase from 23% to 33% . Total costs for the full Medicaid population were approximately $2.92 billion in the current scenario and $2.89 billion in the alternate scenario. Therefore, increasing the proportion of patients treated with CGM resulted in an annual saving of about $28.7 million, which translates to a net budget reduction of about $0.37 Per Member Per Year (PMPY). The BIM reports total costs for a current and alternative scenario, annual net budget impact, and cost over a time horizon of 3 years. Base Case Analysis, Per Patient Per Year (PPPY) In the T2DM Intensive Insulin Treated (IIT) population, annual acquisition costs were $1,350 higher with CGM than with BGM. When all cost offsets were applied, the use of CGM was associated with cost savings of $278 PPPY. Severe hypoglycemic events (SHEs) - Costs due to SHEs for Medicaid populations were calculated using a baseline event rate with BGM adjusted for treatment effect with utilization of CGM. [36]

For the Budget Impact Model (BIM) for FreeStyle Libre 2 and FreeStyle Libre 3 systems, separate analyses were conducted from the perspective of Medicaid plans for the following patient groups:

1. Adult patients with T2DM on MDI- Medicaid Population, T2DM on MDI: One-Way Sensitivity Analysis of Annual Cost Differences (PPPY) Between (A) the FreeStyle Libre 2 system and BGM, and (B) the FreeStyle Libre 3 system and BGM

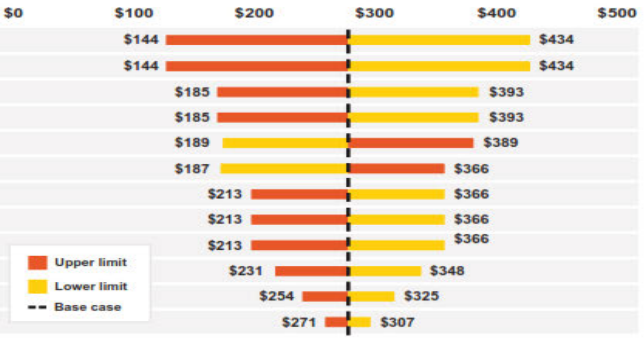
(A)

Parameters	Base	Lower	Upper
Treatment effect with CGM: Reduction in HbA1c: T2 MDI	0.90%	0.70%	1.10%
HbA1c, cost per % reduction in HbA1c	$804.67	$643.74	$965.60
Medicaid adjustment: All	2.43	1.94	2.91
Incidence of SHE, hospital events PPPY: T2 MDI	0.13	0.10	0.15
DKA, Rate ratio for FreeStyle Libre Portfolio/G6: T2 MDI	0.57	0.45	0.68
SHE, Rate ratio for FreeStyle Libre Portfolio/G6: T2 MDI	0.39	0.30	0.51
Medicaid adjustment: All	2.43	1.94	2.91
Incidence of DKA, events PPPY: T2 MDI	0.09	0.07	0.11
Cost of DKA hospital admission: DKA	$9,733.00	$7,786.40	$11.679.60
BGM tests per day: Type 2	3.80	3.04	4.56
BGM test strip unit cost	$0.14	$0.11	$0.17
BGM lancet unit cost	$0.07	$0.06	$0.08
% using FreeStyle Libre Portfolio reader	50.00%	40.00%	100.00%
FreeStyle Libre Portfolio, additional BGM tests: Type 2	0.30	0.24	0.36
FreeStyle Libre Portfolio reader duration (years)	3.0	2.4	3.6
FreeStyle Libre Portfolio reader unit cost	$70.00	$56.00	$84.00



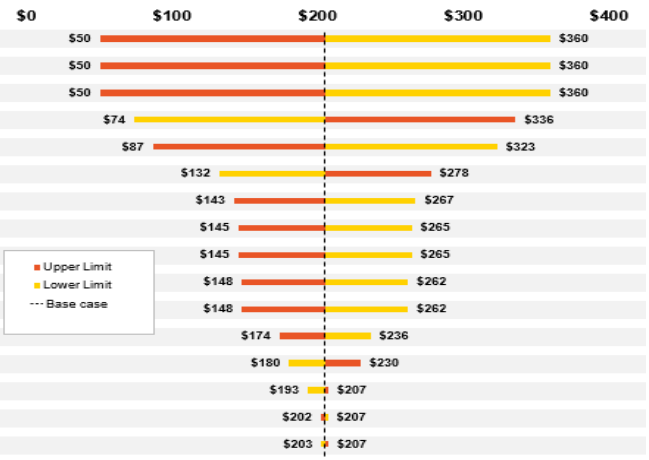
(B)

Parameters	Base	Lower	Upper
Treatment effect with CGM: Reduction in HbA1c: T2 MDI	0.90%	0.70%	1.10%
HbA1c, cost per % reduction in HbA1c	$804.67	$643.74	$965.60
Medicaid adjustment: All	2.43	1.94	2.91
Incidence of SHE, hospital events PPPY: T2 MDI	0.13	0.10	0.15
DKA, rate ratio for FreeStyle Libre Portfolio/G6: T2 MDI	0.57	0.45	0.68
SHE, rate ratio for FreeStyle Libre Portfolio/G6: T2 MDI	0.39	0.30	0.51
Medicaid adjustment: All	2.43	1.94	2.91
Incidence of DKA events PPPY: T2 MDI	0.09	0.07	0.11
Cost of DKA hospital admission: DKA	$9,733.00	$7,786.40	$11,679.60
BGM tests per day: Type 2	3.80	3.04	4.56
BGM test strip unit cost	$0.14	$0.11	$0.17
BGM lancet unit cost	$0.07	$0.06	$0.08



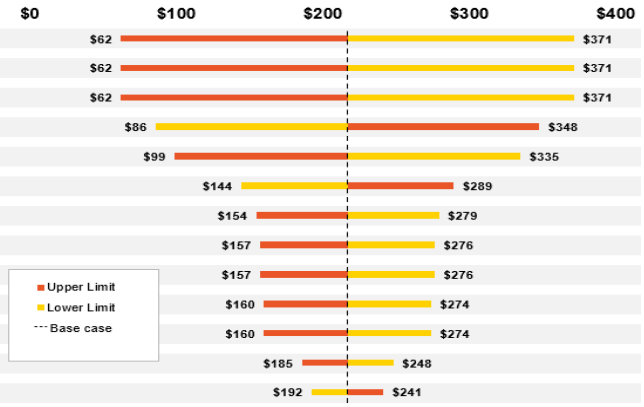
2. Pediatric patients (aged 4 – 18 years) with T1DM or T2DM on MDI - Population, Pediatric: One-Way Sensitivity Analysis of Annual Cost Differences (PPPY) Between (A) the FreeStyle Libre 2 system and BGM, and (B) the FreeStyle Libre 3 system and BGM

Parameters	Base	Lower	Upper
Incidence of DKA, events PPPY: Ped.	0.15	0.12	0.18
Medicaid adjustment: All	2.43	1.94	2.91
Cost of DKA hospital admission: DKA	$9,733.00	$7,786.40	$11,679.60
DKA, Rate ratio for FreeStyle Libre Portfolio/G6: Ped.	0.46	0.37	0.55
BGM tests per day: Ped.	7.700	6.160	9.240
SHE, Rate ratio for FreeStyle Libre Portfolio/G6: Ped.	0.56	0.45	0.67
BGM test strip unit cost	$0.14	$0.11	$0.17
Treatment effect with CGM: Reduction in HbA1c: Ped.	.4%	.3%	.4%
HbA1c, cost per % reduction in HbA1c	$804.67	$643.74	$965.60
Medicaid adjustment: All	2.43	1.94	2.91
Incidence of SHE, hospital events PPPY: Ped.	0.23	0.19	0.28
BGM lancet unit cost	$0.07	$0.06	$0.08
FreeStyle Libre Portfolio, additional BGM tests: Ped.	1.60	1.28	1.92
% using FreeStyle Libre Portfolio reader	50.0%	40.0%	100.0%
FreeStyle Libre Portfolio reader duration (years)	3.00	2.40	3.60
FreeStyle Libre Portfolio reader unit cost	$70.00	$56.00	$84.00



B

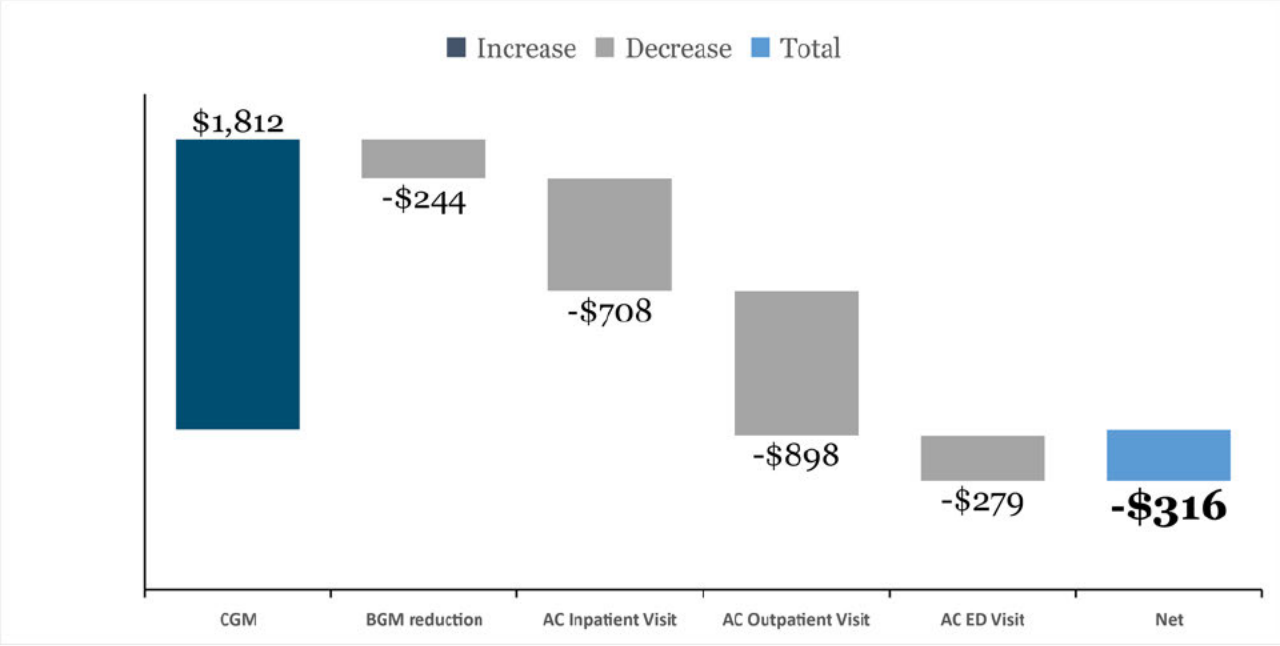
Parameters	Base	Lower	Upper
Medicaid adjustment: All	2.43	1.94	2.91
Incidence of DKA, events PPPY: Ped.	0.15	0.12	0.18
Cost of DKA hospital admission: DKA	$9,733.00	$7,786.40	$11,679.60
DKA, Rate ratio for FreeStyle Libre Portfolio/G6: Ped.	0.46	0.37	0.55
BGM tests per day: Ped.	7.700	6.160	9.240
SHE, Rate ratio for FreeStyle Libre Portfolio/G6: Ped.	0.56	0.45	0.67
BGM test strip unit cost	$0.14	$0.11	$0.17
Treatment effect with CGM: Reduction in HbA1c: Ped.	.4%	.3%	.4%
HbA1c, cost per % reduction in HbA1c	$804.67	$643.74	$965.60
Medicaid adjustment: All	2.43	1.94	2.91
Incidence of SHE, hospital events PPPY: Ped.	0.23	0.19	0.28
BGM lancet unit cost	$0.07	$0.06	$0.08
FreeStyle Libre Portfolio, additional BGM tests: Ped.	1.60	1.28	1.92



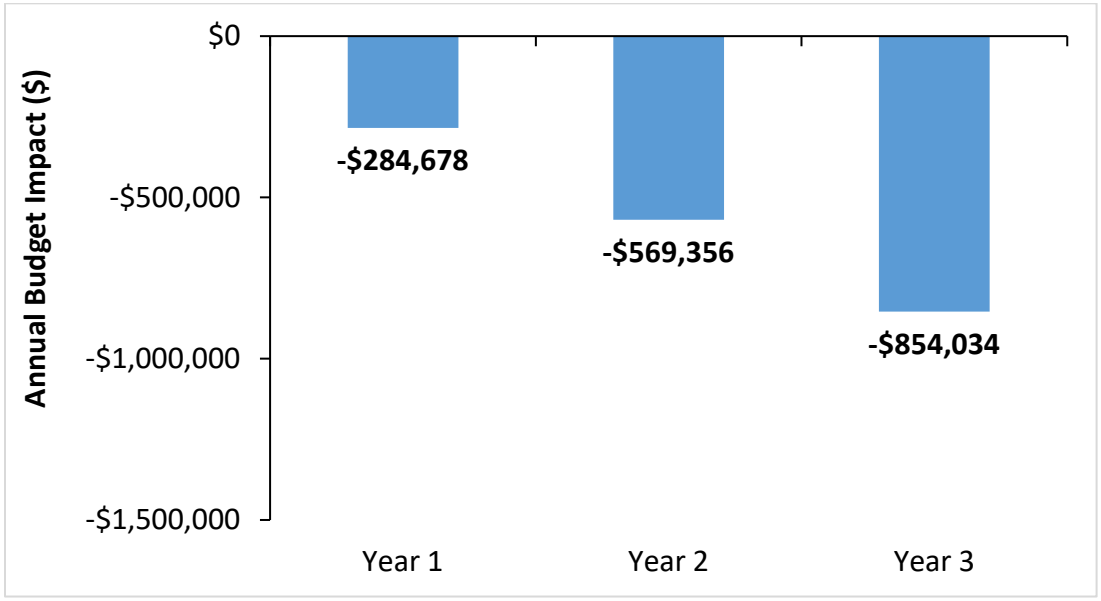
3. Another BIM was conducted for people living with diabetes who are Insulin Using Patients (IUP) that are not on MDI[37]. This BIM considered Acquisition costs – Continuous glucose monitors(including sensor, reader), BGM testing strips, lancets, meters, as well as Healthcare Resource Utilization (HCRU) costs – All-cause hospitalization inpatient visits, outpatient office visits and ER visits for a period of 3 years. The output of the model was measured in Budget Impact (Total and PPPY)

   The scenario assumed in the model is CGM market penetration to increase to 2%, 4%, and 6% of the T2 basal population in years 1, 2 and 3, respective, as well as decreased direct costs from reductions in all-cause hospital inpatient visits, outpatient visits and ER visits associated with CGM use. In the example used in this model, outcome acquisition costs from coverage of CGMs are offset by lower BGM utilization and reduced direct healthcare resource utilization costs by -$316 (Figure A) PPPY. Reimbursement of CGMs for people with T2DM on basal insulin is associated with a cumulative cost savings of $1.7MM over 3 years (Figure B)[37].

(A) Per Patient Per Year Budget Impact



(B) Total Annual Budget Impact



Other Economic Outcomes Studies- Diabetes Related Events				
Study	**Population**	**Clinical evidence**	**Country**	**Economic outcomes**
Hirsch et al, 2024[38]	T2DM treated with MDI	Inovalon Insight claims data on managed Medicaid beneficiaries (N=35,367). Analysis of ≥ 6 months of data pre- and post-CGM use. CGM acquisition between January 1, 2017, and September 30, 2022.	US	Significant reductions in HCRU were noted when the 6-month pre-CGM and post-CGM periods were compared: • Inpatient hospitalizations: 0.70 – 0.50, p < 0.001 • ED visits: 1.33 to 1.10, p < 0.001 • Outpatient visits: 10.96 to 10.20, p < 0.001 Subgroup analyses (for patients with ≥ 1 visit during the pre-CGM period, stratified as low [1 – 2 visits] or high [≥ 3 visits]), revealed consistent trends across all subgroups, except for the outpatient visits of the subgroup with low utilization during the pre-CGM period: • Inpatient hospitalizations: 1.39 – 0.66, p < 0.001 (1 – 2 visits); 5.14 – 2.15, p < 0.001 (≥ 3 visits) • ED visits: 1.35 – 1.03, p < 0.001 (1 – 2 visits); 5.24 – 2.99, p < 0.001 (≥ 3 visits) • Outpatient visits: 1.62 – 3.43, p < 0.001 (1 – 2 visits); 12.1 – 11.03, p < 0.001 (≥ 3 visits) **Conclusion** CGM acquisition was associated with HCRU reductions among Medicaid beneficiaries with T2DM receiving MDI. This finding may translate into economic benefit.
Hirsch et al, 2024[39] Sponsor: Abbott Diabetes Care	T2DM treated with basal insulin	Inovalon Insight claims data for managed Medicaid beneficiaries (N=9574). CGM acquisition between January 1, 2017, and September 30, 2022.	US	Significant reductions in HCRU were noted when the 6-month periods pre-CGM and post-CGM were compared: • Inpatient hospitalizations: 0.37 – 0.31, p < 0.001 • ED visits: 0.95 – 0.84, p < 0.001 • Outpatient visits: 9.11 – 8.60, p < 0.001 Subgroup analyses (for patients with ≥ 1 visit during the pre-CGM period, stratified as low [≤ 2 visits] or high [≥ 3 visits]), revealed consistent trends across all subgroups, except for the outpatient visits of the subgroup with 1 – 2 visits during the pre-CGM period: • Inpatient hospitalizations: 1.35 – 0.62, p < 0.001 (1 – 2 visits); 4.82 – 1.54, p < 0.001 (≥ 3 visits) • ED visits: 1.32 – 0.94, p < 0.001 (1 – 2 visits); 4.92 – 2.78, p < 0.001 (≥ 3 visits) • Outpatient visits: 1.6 – 3.57, p < 0.001 (1 – 2 visits); 10.47 – 9.52, p < 0.001 (≥ 3 visits) **Conclusion** CGM use is associated with HCRU reductions in hospitalizations and ER visits among Medicaid beneficiaries with T2DM on basal insulin. These HCRU reductions may translate into cost savings.
Roussel et al, 2021[40] RELIEF study	Patients with T1DM or T2DM	French national claims database, SNDS (N=74,011 [all FreeStyle	France	Hospitalizations for acute diabetes complications were reduced (pre- vs. post-Free Style Libre system use) by 49.0% (T1DM) and 39.4% (T2DM): • Hospitalizations for DKA were reduced by 56.2% for T1DM and 52.1% for

Other Economic Outcomes Studies- Diabetes Related Events				
Study	**Population**	**Clinical evidence**	**Country**	**Economic outcomes**
	initiating FreeStyle Libre system use.	Libre system users]): • T1DM: n=33,165 • T2DM: n=40,846. 88% of all patients were on MDI (n=46,828) or CSII (n=18,593). 12% of mainly patients with T2DM received single basal insulin or oral agents.		T2DM. • Hospitalizations for diabetes-related comas were reduced by 39.6% (T1DM) and 31.9% (T2DM). • Hospitalizations for hypoglycemia and hyperglycemia were reduced by 10.8% and 26.5%, respectively, among people with T2DM. Persistence with FreeStyle Libre system use was 98.1% across all users at 12 months. **Conclusion** FreeStyle Libre system is associated with a reduced incidence of hospital admission for DKA and for diabetes-related coma in patients with T1DM or T2DM.

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Continuous Glucose Monitoring Public Comments
Date: Thursday, September 5, 2024 11:49:53 AM
Attachments: Outlook-nr43li2p.png
Outlook-noce4ebt.png

External Email

Hello,

I'm writing to bring your attention to the importance of Continuous Glucose Monitoring (CGM) coverage for patients with Type 2 diabetes. Over the past four years, I have personally experienced the benefits of using a CGM, as well as observed its impact on various patients in the geriatric population. For many of us, the struggle with the discomfort and inconvenience of frequent fingerstick testing has been ongoing for years. Traditional fingerstick tests, which often occur at random intervals that may not align optimally with meals, provide only limited insight into how food choices affect blood sugar levels.

In contrast, CGM provides immediate, continuous feedback, offering real-time insights into how different foods impact glucose levels. Personally, this technology has transformed my approach to diet. For example, I used to have oatmeal for breakfast, but after seeing how it spiked my glucose levels, I now opt for more balanced meals with protein, like eggs, bacon, and whole wheat toast, which have a much smaller effect. The constant feedback from CGM helps users make informed decisions, linking their food intake, exercise habits, and other lifestyle choices to their glucose levels in real-time. This level of awareness promotes better diabetes management and long-term health outcomes by enabling individualized care.

I've also seen many patients, especially those with needle aversion or other barriers, avoid monitoring their glucose levels. Regular monitoring is crucial for tracking how blood sugar responds to diet, exercise, medications, and other factors. CGM not only provides this vital information but also assists healthcare teams in making timely adjustments to treatment plans. The ability to see real-time data, instead of waiting for results every three months, has made a significant difference in my own diabetes management. Despite its benefits, I personally pay over $900 every six months for CGM access, which is unaffordable for most. The cost of testing strips alone, if one were to check blood sugar seven times a day, is prohibitive. Currently, most insurance plans only cover testing up to 100 times in three months for those not on insulin, which is far from sufficient.

Given the significant benefits of CGM, I strongly encourage broader consideration of its coverage for patients who are motivated to improve their diabetes management.

Thank you for your attention to this matter.

Sincerely,

Dawn Hebert, MT (ASCP), RN, MSN, CDCES
Diabetes RN Educator
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Open Comment
Date: Tuesday, September 10, 2024 11:51:23 AM

External Email

Hello,

In response to open comment period, I would like to address a few things. Under the draft key questions, the list of available CGM devices has expanded to include the FreeStyle Libre 3 Plus and the Lingo.

Additionally, there are SO many patients who do not or cannot fingerstick and that is WHY they need a continuous glucose monitor. Additionally, one of the benefits of a CGM is that it helps patients manage their diabetes much better, preventing them from having to go on insulin in the first place. By requiring patients to be on insulin to get a CGM device, you are putting those not on insulin at greater risk for mismanaged diabetes and all of the complications associated with this disease state.

Also, Washington State you will end up paying way more money down the road in associated healthcare costs (medications, hospitalizations, surgeries, the cost of glucose test strips) by preventing patients from getting this valuable tool. Requiring patients to be on insulin to get a CGM is short-sighted and unfair.

Natalie Hellman MS, RD, CD
Abbott Diabetes Care

From: [redacted]
To: Huang, Alyssa
Cc: HCA ST Health Tech Assessment Prog
Subject: RE: WA Health Care Authority CGM Coverage Review - DUE 09/16
Date: Monday, September 16, 2024 4:29:23 PM

External Email

Dr Huang would like to add her comments

From: Huang, Alyssa[redacted]
Sent: Monday, September 16, 2024 4:03 PM
To: Nicole M. Ehrhardt[redacted]

KQ1 Key Questions What is the comparative effectiveness of continuous glucose monitoring in adults and children with diabetes versus self-monitoring?
b. Children with type 2 diabetes (regardless of insulin use) c. Adults and children whose diabetes is well-controlled (defined as within target HBA1c and not experiencing severe hypoglycemic events)

KQ3 What is the differential efficacy or safety by patient and clinical factors, such as: a. Age b. Gender c. Race and ethnicity d. **Type of diabetes** e. Presence of comorbidities (e.g., hypertension) f. Severity of disease (e.g., baseline HbA1c, number of self-tests per day) g. Use of other medications (e.g., insulin use) h. Level of adherence to CGM use i. Type of CGM (i.e., rtCGM vs. isCGM

I would like to advocate to expand access to CGM for our pediatric population – particularly children with type 2 diabetes (on basal insulin only or non-insulin requiring), who have been traditionally overlooked for new technology to treat diabetes. CGMs have been instrumental in the care of youth with type 1 diabetes – improving quality of life and health outcomes. Data from longstanding RISE consortium and the TODAY study have shown that type 2 diabetes in youth is a far more aggressive disease than type 2 diabetes in adulthood – demonstrating more rapid decline in beta cells and failure requiring insulin initiation. By 9 years after diagnosis of T2D in youth, 50% of youth developed 1 microvascular complication including hypertension, kidney disease, nerve disease, etc. This should be the prime of their young adult lives and yet they are facing end organ damage. These complications were more common among youth in minority race and ethnic groups. It is imperative that we provide youth with type 2 diabetes access to diabetes technologies like CGMs to help improve management of their diabetes. First, CGM can decrease the stigmatization that kids face at school while checking blood sugars by the traditional finger stick. CGMs allow patients to be aware of their glycemic control more acutely and intervene earlier and ultimately could help prevent

uncontrolled hyperglycemia and mitigate complications mentioned above. Our goal of helping children lead healthier lives requires us to provide them with the tools to do so and this includes access to CGMs. Furthermore, expanding access to CGMs can help address some health inequities that our patients with type 2 diabetes face. I am strongly advocating for the expansion of CGM use in youth with type 2 diabetes on basal insulin only or those that are non-insulin requiring.

Hope this can be of help!

Alyssa Huang
Pediatric Endocrinologist
Seattle Children's Hospital

Comments on Health Equity and Access to CGMs

Access to Continuous Glucose Monitoring (CGM) for people with diabetes, who are treated with insulin and/or at risk for hypoglycemia is current standard of care [1]. This aligns with current CGM coverage policies for patients covered by Medicare and most commercial insurances, but Medicaid criteria are far more restrictive. Standardizing these criteria for our Medicaid beneficiaries to align with Medicare is a crucial component of improved diabetes outcomes, healthcare equity and eventual healthcare savings; here's why:

1. Health Outcomes: CGM technology provides real-time data on blood glucose levels, allowing for more precise management of diabetes in a way unattainable using traditional glucose meters. Medicaid beneficiaries also have strict limitations on the number of glucose test strips that are covered under various plans and obtaining them outside of insurance coverage can be cost-prohibitive. For underserved and marginalized communities who may have limited access to regular healthcare services, CGM can be a lifeline in preventing acute complications of diabetes such as hypoglycemia and severe hyperglycemia. Studies have shown consistent improvement in glycemic control with the use of CGM in insulin-treated patients with diabetes [2,3] [4]. These, in turn may result in improved longer-term outcomes with regards to neuropathy, kidney failure, and vision loss. By ensuring access to CGM, we can significantly improve health outcomes and reduce the burden of diabetes among underserved populations. Unfortunately, recent research shows that access to CGM is inequitable [5].

2. Empowerment and Autonomy: Diabetes management is a full-time job for people with diabetes, and CGM empowers them to take control of their health by providing them with timely actionable data [6]. For underserved and marginalized communities facing cultural and linguistic barriers to healthcare access, CGM can provide a sense of autonomy and agency over their health. These patients also come from a background of low health literacy and the use of CGM offers immediate biofeedback on the impact their diet choices have on their glucose. It enables them to make informed decisions about diet, exercise, and medication adjustments, leading to better self-management of their condition. Studies have shown consistent improvement in patient satisfaction with diabetes care with the use of CGM [7].

3. Cost-Effectiveness in the Long Run: While CGM technology may have upfront costs, it can result in long-term cost savings for both individuals and healthcare systems [8]. Studies have shown reduction in acute diabetes-related events (hypoglycemia, diabetic ketoacidosis, hyperosmolarity) and all-cause hospitalizations with the use of CGM in patients treated with short-acting insulin containing regimens [9] as well as basal insulin/non-insulin regimens [10]. By preventing costly complications and hospital admissions, CGM ultimately reduces the economic burden of diabetes on individuals, families, and society as a whole. In fact, a budget impact analysis investigating this showed demonstrable and significant cost-savings with expansion of CGM coverage among Medicaid patients [11]. Ensuring equitable access to CGM can thus be seen as a cost-effective investment in public health.

4. Promotion of Health Equity: Health equity means that everyone has the opportunity to attain their highest level of health, regardless of their social identity or economic status. Access to CGM aligns with this principle by providing all individuals with the tools they need to manage their diabetes effectively. By prioritizing equity in healthcare policies and interventions, we can work towards a more just and inclusive society where everyone has the opportunity to live a healthy life.

In conclusion, standardizing criteria for access to CGM for all insulin-treated people with diabetes, regardless of socio-economic status, background or circumstances, is not just a matter of luxury or convenience; it's a matter of equity and social justice that will improve health outcomes, improve quality of life, reduce disparities, and promote a more equitable healthcare system for all without a negative impact on health-care costs.

Leo S. Morales, MD, PhD, MPH
Professor and Assistant Dean, Office of Healthcare Equity | UW Medicine
Co-Director | Latino Center for Health | University of Washington
Attending Physician | Latinx Diabetes Clinic | UW Diabetes Institute
Adjunct Professor of Public Health and Social Work | University of Washington

Arthi Thirumalai, MBBS
Associate Professor of Medicine, Division of Metabolism, Endocrinology and Nutrition
UW Medicine
Section Head of Endocrinology, Harborview Medical Center

Irl B. Hirsch, MD, MACP
Professor and Diabetes Treatment and Teaching Chair
Professor of Medicine, Division of Metabolism, Endocrinology and Nutrition
UW Medicine

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From:	[redacted]
To:	HCA ST Health Tech Assessment Prog
Cc:	Nayak, Bindu M.D.
Subject:	Public comment on Continuous Glucose Monitoring Update- Expanding continuous glucose sensor coverage is essential to address health inequities with Diabetes control
Date:	Monday, September 16, 2024 10:52:37 AM
Attachments:	image001.png UW Medicine_HTCC CGM Comments[30].pdf

External Email

To Whom it May Concern-

Please find attached our comments on CGM access for patients with Medicaid. Please feel free to contact if you have any questions.

Best Regards,

Leo S. Morales, MD, PhD
Professor and Assistant Dean
Office of Healthcare Equity | UW Medicine
Attending Physician | Latinx Diabetes Clinic | UW Diabetes Institute
Adjunct Professor of Public Health and Social Work
Co-Director | Latino Center for Health | University of Washington #LCHUW
[redacted]
Pronouns | he, him

From: [redacted]
To: HCA SI Health Tech Assessment Prog
Cc: Leo S Morales; Schnur, Maddy; Beam, Emelia; Poteet, Madison
Subject: Public comment on Continuous Glucose Monitoring Update- Expanding continuous glucose sensor coverage is essential to address health inequities with Diabetes control
Date: Monday, September 16, 2024 10:00:46 AM
Attachments: image001.png

External Email

To whom it may concern,

Hello, I am an endocrinologist and the medical director of health equity at Confluence Health in Wenatchee, Washington. I am sharing evidence to support expansion of Medicaid coverage of continuous glucose monitors for more individuals with diabetes in the state of Washington.

I am sharing below data on all patients who receive their primary care through Confluence Health and have a diagnosis of Diabetes Mellitus. Confluence Health has multiple locations including Wenatchee, East Wenatchee, Omak, Moses Lake and other smaller locations. The graph below in the upper left corner shows the total numbers of individuals with a diagnosis of Diabetes stratified by ethnicity: Non-Hispanic or Hispanic. The upper right graph shows the total number of individuals with a diagnosis of diabetes who are American Indian, Asian or Black.

The bottom graphs are assessing the percent of these patients who have uncontrolled Diabetes Mellitus, defined as a Hemoglobin A1C greater than or equal to 9%. In the lower left graph, you can see that there is a significant disparity in diabetes control between Non-Hispanic individuals and Hispanic individuals with diabetes, with more than double the percentage of uncontrolled diabetes among Hispanic individuals with Diabetes. In the lower right graph, this graph looks at the percentage of individuals with diabetes by race with a Hemoglobin A1C >9% among American Indian, Asian, and Black individuals. You can see also that there is a significant health disparity here with more than double the rate of uncontrolled diabetes for American Indian and Black individuals.

In the regions of North Central Washington that Confluence Health serves, the percentage of individuals who use Medicaid among Hispanic, American Indian and Black individuals is high. So, many of these individuals cannot afford to pay for a continuous glucose sensor based on current Medicaid coverage requirements. As you know from all of the evidence showing that using cgm reduces Hemoglobin A1C (even without changing medications), expanding Medicaid coverage to cover continuous glucose monitors would help to reduce this health disparity that is disproportionately affecting Hispanic, Black and American Indian individuals with Diabetes Mellitus in the state of Washington. When patients have the knowledge of their own blood sugars and effects of certain foods and medications on blood sugars, people with diabetes can make changes in real time to their diet and lifestyle that make significant improvements in blood sugar control. By improving blood sugar control and decreasing Hemoglobin A1C, Medicaid will save money in the long run by preventing complications of diabetes for individuals with diabetes.

To address health disparities in Washington state, it is critical for Medicaid to increase coverage for individuals with a diagnosis of Diabetes. A first step could be to increase coverage to be similar to Medicare requirements: to cover cgm for anyone with diabetes who is on at least one injection of insulin daily and to eliminate the need to have fingerstick blood sugar testing four times daily. Ideally, it would be best if Medicaid can offer cgm coverage for all individuals with a diagnosis of Diabetes.

Thank you for your time and consideration. Please contact me with any questions about this data.

Sincerely,
Bindu Nayak, MD

Bindu Nayak, MD
Endocrinologist
Co-Medical Director of Health Equity
Co-Chair of Health Equity Council
Confluence Health | Endocrinology
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Washington HTA draft key questions for continuous glucose monitoring comments
Date: Monday, September 16, 2024 5:08:01 PM
Attachments: image001.png
Dexcom Comments on CGM HTA Draft Key Questions.pdf

External Email

Thank you for the opportunity to provide comments on the key questions drafted for the HTA rereview of continuous glucose monitoring. Please find attached our comments.
Sincerely,

Greg Norman, PhD
Senior Director of Health Econ & Outcomes Research
Global Access & Evidence | Dexcom
[redacted]

dexcom

[redacted]

[redacted]

www.dexcom.com

September 16, 2024

Washington State Health Care Authority

RE: Public Comment on the draft key questions for Continuous Glucose Monitoring Update

Dexcom, Inc. appreciates the opportunity to submit this letter in response to the Washington State Health Care Authority's request for public comments on the update of the health technology assessment of Continuous Glucose Monitoring (CGM), particularly for adults with Type 2 Diabetes (T2D) not using insulin, children with T2D, and patients with type 2 or gestational diabetes during pregnancy who are not using insulin. We commend the Authority for updating the evidence review in light of new advancements in CGM technology and would like to highlight several key areas where the scope and criteria of the review could be expanded or modified to reflect the full clinical value of CGM in coverage decisions.

Comments:

1. Limitations of Current primary Intermediate Outcomes

The current inclusion and exclusion criteria limited the outcomes to HbA1c. While HbA1c is a valuable marker of long-term glycemic control, the exclusion of CGM-specific glycemic measures such as Glucose Management Indicator (GMI), Time in Range (TIR), Time Below Range (TBR), and Time Above Range (TAR) presents a significant limitation. These metrics offer a more granular view of glycemic variability and have been shown to correlate strongly with clinical outcomes, such as hypoglycemia and hyperglycemia, that HbA1c alone cannot capture.

- **Adoption of CGM Metrics in Clinical Practice**: GMI is already set to be used by the National Committee for Quality Assurance (NCQA) as part of HEDIS measures, underscoring its growing role in clinical care and quality benchmarks[1]. Furthermore, the panel of experts consulted during the recent Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting recommended that CMS include Time in Range (TIR) as a clinically relevant metric for monitoring diabetes in clinical studies, with a 5% improvement in TIR being recognized as a meaningful clinical outcome, aligning with emerging standards in diabetes care.[2]
- **Supporting Evidence for CGM Metrics such as Percentage of time in acceptable glucose range (70-180 mg/dL)**: Numerous studies and international consensus statements validate the importance of TIR and other CGM-specific metrics in preventing complications like retinopathy, microalbuminuria, and cardiovascular autonomic neuropathy. For example, A 2019 study utilized finger stick data from the Diabetes Control and Complications Trial

(DCCT) to estimate time in range (TIR) and examined the rates of retinopathy and microalbuminuria across different TIR percentages. Although changes in complications for every 5% increase in TIR were not specifically calculated (as TIR was estimated in 10% increments), the data revealed a smooth curve indicating that even smaller changes in TIR, such as less than 10%, would follow the same pattern and be clinically significant.[3] A separate study examining TIR in relation to cardiovascular autonomic neuropathy in individuals with type 2 diabetes also found a continuous curve, with rates of complications increasing as TIR decreased. [4] Similar associations were observed between TIR and the development of retinopathy.[5] An international consensus statement on TIR, published that same year, concluded that even small improvements—such as a 5% increase in TIR—are clinically meaningful.[6] This statement further noted that a 10% increase in TIR correlates with a 0.5% reduction in A1c. Since smaller shifts in A1c are recognized as significant, the statement affirms that a 5% improvement in TIR is equally impactful. A more recent consensus statement, published in Lancet, supported this, providing B-level evidence that a ≥5% increase in TIR is clinically meaningful for individual participants in clinical studies, and a 3% difference is meaningful for treatment group outcomes.[7]

Recommendation: We strongly recommend that the outcomes assessed in the review incorporate these CGM-specific metrics alongside HbA1c to better reflect the real-world benefits of CGM in preventing acute and long-term complications in people with diabetes.

2. Limiting Study Design requirements to Randomized Controlled Trials (RCT):

The draft key questions currently prioritize RCTS as the primary evidence base. While RCTs provide valuable insights into efficacy, this approach may inadvertently exclude important real-world evidence (RWE), particularly when addressing questions of adherence, patient diversity, and real-world effectiveness of CGM.

- **Diversity in Age, Gender, and Race/Ethnicity**: RCTs often do not adequately reflect the diversity seen in real-world populations, leading to limited generalizability. Studies have shown that participants in RCTs tend to be younger, healthier, and less racially/ethnically diverse than real-world patients, which can skew the results when applied to broader populations in clinical practice. This gap is particularly evident when assessing diabetes interventions, where racial minorities and older adults may show different patterns of adherence or outcomes that RCTs do not capture effectively.[8]

- **Comorbidities and Disease Severity**: RCTs often exclude patients with multiple comorbidities or advanced disease severity, resulting in a population that does not reflect the complexity of real-world clinical settings. For example, real-world data on diabetes management often show higher rates of adverse events, such as hypoglycemia, among patients with comorbidities, a factor that may not be captured in RCTs due to strict eligibility criteria.[9]
- **Medication Use**: In clinical practice, many patients with diabetes are prescribed other medications, such as oral antidiabetics or basal insulin, alongside CGM therapy. However, RCTs often fail to fully reflect the variability in how these medications are used in real-world settings. In RCTs, medication regimens are strictly controlled and monitored, leading to higher adherence and more consistent dosing than is typical in everyday practice. RWE shows that patients often struggle with medication management due to factors like complex regimens, side effects, or lifestyle barriers. For example, in the real world, patients on basal insulin or oral medications may exhibit significant variations in adherence, persistence, and outcomes due to challenges in maintaining treatment consistency. [8, 10]
- **Adherence to CGM**: The challenge of capturing CGM adherence in clinical trials is twofold. First, there is a limited number of head-to-head studies comparing different CGM systems, leaving gaps in the comparative data needed to guide optimal CGM system selection. This limitation makes it difficult to assess which CGM systems foster better adherence or outcomes in specific populations. Second, adherence is a real-world behavior that does not naturally emerge in the controlled environments of RCTs. In RCTs, patients are closely monitored and supported, which typically leads to higher adherence rates than in everyday practice.

  Recommendation: We recommend the inclusion of real-world evidence (RWE), observational studies, and pragmatic trials in the review to complement the RCT data. This will provide a more comprehensive understanding of how CGM performs across diverse populations and clinical contexts.

References

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Comment Letter on Draft Questions For HTTC Continuous Glucose Monitoring Review
Date: Monday, September 16, 2024 3:00:38 PM
Attachments: HTCC Letter CGM Draft Questions 2024 Final .pdf

External Email

Attached is our letter with comments on the draft questions for HTCC's review of continuous glucose monitors. Can you please confirm that you received our letter. We appreciate the opportunity to provide this initial comments.

Matt Prokop *(He/Him/His)*
Director, State Government Affairs (Northwest and North Central: AK, ID, KS, MN, MT, ND, NE, OR, SD, WA, and WY)

Central Time Zone
[redacted]

September 16, 2024

Health Technology Clinical Committee (HTCC)
Washington Health Care Authority
626 8th Ave SE
Olympia, WA 98501

Re: Comments on draft questions relative to review of coverage for continuous glucose monitors

Dear Washington State Health Technology Clinical Committee Members:

The American Diabetes Association (ADA) appreciates the opportunity to work with the Health Technology Clinical Committee to review access to continuous glucose monitors (CGMs) for people living with diabetes.

In our initial request for this review, our objective was to seek to broaden access to CGMs so more Medicaid beneficiaries could benefit from improvements in health outcomes from the utilization of these devices. Specifically, the ADA supports removing the following existing, coverage requirements:

1. remove the requirement that a patient be on intensive insulin therapy and replace it with "beneficiary is insulin-treated", and
2. remove the requirement that a beneficiary must test their blood glucose 4 times or more a day.

Our standards of care and extensive research done by experts in the field of diabetes can assist the committee's work to review appropriate changes to CGM Medicaid coverage to help patients better manage their diabetes and prevent life-threatening complications. Recent changes in Medicare coverage by the Centers for Medicare and Medicaid Services (CMS) [(1)] for CGMs recognize the broader value of CGMs for diabetes management, and thus the ADA encourages this committee to align its coverage criteria with that of Medicare.

Regarding the proposed draft questions:

1. We recommend including automated insulin delivery systems (AID) – insulin pumps that include a CGM component – for review under topics listed for question three.

2. The ADA also recommends examining CGM access to other insulin users. The current draft scope does not appear to include addressing the benefits of CGMs for insulin users who are not on an intensive insulin regimen.

As the committee considers CGM coverage we encourage action to minimize administrative requirements that can be burdensome for prescribing clinicians and in turn can unnecessarily delay or prevent timely access to CGMs and the improvements they can support.

We thank you for the opportunity to comment and look forward to working with the Health Technology Clinical Committee on efforts to improve access to CGMs and address health disparities for Washingtonians living with diabetes. Should you have any questions regarding these comments please contact me at [redacted]

Sincerely,
Matt Prokop
Director, State Government Affairs

---

1. Center for Medicare and Medicaid (CMS) updated coverage requirements: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: HCA it only makes sense to cover CGM
Date: Wednesday, September 11, 2024 5:51:25 PM

External Email

As a Certified Diabetes Care and Education Specialist and Registered Nurse , working with diabetes patients for 11 years, I cannot overstate the value of CGM as a tool for both providers , patients , and insurance companies, in reducing the costs of diabetes care and complications, while also improving the quality of life of those with diabetes, and reducing the burdens on the health care system thru out. This is true for patients not treated with insulin as well . In fact , the use of CGM helps keep Type 2 diabetes patients off insulin by giving them real time feedback that they can use immediately to curb their carbohydrate intake and plan exercise , capture high and low glucoses when they are occurring (or prevent them if about to occur) , prevents falls, informs triage decisions over the phone for both providers and nurses, reduce A1C's, goes a long way in helping the provider dose medication properly based on patients CGM patterns, otherwise indeterminable with intermittent fingerstick testing alone, and when used with good patient teaching, and follow thru, provides no end to the benefits of avoiding further complications in disease states and mounting costs to the insurance companies and everyone else. It's about time the benefits were understood by insurance companies trying to save a buck the hard way… by waiting til your patients are all so far gone with their disease that now you are covering heart disease, hospitalizations, dialysis, amputated limbs, prosthesis, home health services , and more in ever increasing quantities. Truly, it's a black and white no brainer. Health Care Authority, please forward the establishment of insurance coverage of continuous glucometers that have alarms for highs and lows for all patients who want to wear them for all diabetes and even pre-diabetes diagnosed patients. PS It will also save everyone billions if you take out the Prior Authorization Piece as Well. The correct diagnosis code on the prescription and some regular auditing on that should be all that is required. Respectfully Submitted, Anita Reed, RN, Certified Diabetes Care and Education Specialist.

References for a type 2 population

- Beck RW, Riddlesworth TD, Ruedy K, et al. (2017) Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial. Ann Intern Med 167(6): 365-374. 10.7326/M16-2855
- Cox DJ, Banton T, Moncrief M, Conaway M, Diamond A, McCall AL (2020) Minimizing Glucose Excursions (GEM) With Continuous Glucose Monitoring in

Type 2 Diabetes: A Randomized Clinical Trial. J Endocr Soc 4(11): bvaa118. 10.1210/jendso/bvaa118

- Martens T, Beck RW, Bailey R, et al. (2021) Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial. JAMA 325(22): 2262-2272. 10.1001/jama.2021.7444

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: COMMENTS: Continuous Glucose Monitoring
Date: Monday, September 16, 2024 4:38:51 PM
Attachments: image001.png
WAState.MedtronicCommentLetter9.16.24.pdf

External Email

ELECTRONIC SUBMISSION

Washington State Health Care Authority
ATTN: Health Technology Clinical Committee
shtap@hca.wa.gov

Re: Public Comment to Continuous Glucose Monitoring – Draft Key Questions

Dear Health Technology Clinical Committee Members:

Medtronic is the world's leading medical technology company, specializing in implantable and interventional therapies that alleviate pain, restore health, and extend life. We are committed to the continual research and development necessary to produce high-quality products and innovative therapies that improve health outcomes for all patients. The Medtronic Diabetes Group has a comprehensive portfolio of diabetes technology, including insulin pumps, continuous glucose monitors, and automated insulin delivery pens. We appreciate the opportunity to comment on the draft key questions for Continuous Glucose Monitoring (CGM).

Medtronic acknowledges Washington State's commitment to providing coverage and access to diabetes technology inclusive of CGM, insulin pumps, and other forms of insulin delivery. With the pace of innovation, we applaud the State's review of new evidence and standards to support CGM access.

Medtronic highlights 3 key areas of focus we'd like to see incorporated as you continue to refine your questions and develop a revised policy:

1. Incorporate American Diabetes Association (ADA) 2024 Standards of Care
2. Evaluate Stand-alone CGM Diagnostic Criteria
3. Assess the Benefits of CGM Integration with Insulin Delivery Systems

Consideration #1: Incorporate American Diabetes Association (ADA) 2024 Standards of Care

The State should review the newly released 2024 Standards of Care to guide recommendations on access to diabetes technology, specifically:

- Ability to prescribe automated insulin delivery (AID*) to patients at time of Type 1 diabetes diagnosis, without requiring a waiting period
- Maintaining consistency and continuity of care and technology access for established insulin-dependent patients; patients who transition to a new health plan due to a life-event change must be able to maintain access to their current diabetic treatment regimen and should not be required to meet utilization management criteria used for de novo patients

*Automated insulin delivery systems assist people with insulin-required diabetes by using an algorithm to adjust insulin delivery in response to continuous glucose monitoring levels. There are three main components: 1. insulin pump 2. continuous glucose monitor 3. algorithm.

Source: *Diabetes Technology: Standards of Care in Diabetes—2024*, 47 Diabetes Care S126 (2024), https://diabetesjournals.org/care/article/47/Supplement_1/S126/153939/7-Diabetes-Technology-Standards-of-Care-in.

Consideration #2: Stand-Alone CGM Diagnostic Criteria

Please evaluate published literature to assess the value of Blood Glucose log capture, along with other diagnostic criteria. This requirement creates an impediment for patients using stand-alone CGM or Smart CGM (eg paired with automated insulin pens). As outlined in the ADA Standard of Care guidelines, CGM use is standard of care for patients requiring basal insulin, who use multiple daily insulin injections or an insulin pump.

Consideration #3: Assess the Benefits of CGM Integration with Insulin Delivery Systems

For patients using AID systems, the CGM is integral to the functioning of the insulin pump. As the State reevaluates coverage policies (medical or formulary design) it's important to ensure broad inclusion of CGMs. For example, the Medtronic insulin pump requires a Medtronic CGM to power the automated insulin delivery system; a Medtronic insulin pump will not pair with a non-Medtronic CGM. In addition, coverage policies for insulin pumps / automated insulin pens and CGMs should have consistent eligibility criteria so patients can benefit from the improved clinical outcomes.

Specific examples include:

- Key Question 3: add another criterion under subsection (i) to evaluate stand-alone CGM vs AID CGM use
- Key Question 4: add another criterion under subsection (e) to evaluate stand-alone

vs AID CGM use

Medtronic thanks Washington State Health Care Authority for the opportunity to provide comment and looks forward to reviewing the State's proposed CGM policy. If you would like to discuss our comments or have any questions, please contact me at [redacted] or [redacted]

Best regards,

Nancy S. Schwartz
Pronouns: She/Her
Vice President | US Market Access Diabetes

[redacted]

Medtronic
Engineering the extraordinary

Medtronic

Diabetes Group

[redacted]

September 16, 2024

ELECTRONIC SUBMISSION

Washington State Health Care Authority
ATTN: Health Technology Clinical Committee
shtap@hca.wa.gov

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Medtronic thanks Washington State Health Care Authority for the opportunity to provide comment and looks forward to reviewing the State's proposed CGM policy. If you would like to discuss our comments or have any questions, please contact me at [redacted] or [redacted]

Best regards,

Nancy Schwartz

Nancy Schwartz
VP, US Market Access
Medtronic

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: CGM public comment
Date: Friday, September 6, 2024 5:07:24 PM

External Email

I am a Certified Diabetes Care and Education Specialist (nurse) working in the home health environment. I do not work with children or pregnant women. I can only share my personal experience over the last 6 years.

I have had several patients to whom I recommended CGM because they were motivated to be euglycemic (one patient who paid cash for a monitor because their insurance didn't cover it). They made significant changes in their eating habits because they could see the immediate effect of the food they ate.

I have also had patients who started CGM after I advised them that they were probably having hypoglycemia that they were unaware of. In the population I care for (elderly, cognitive and physical limitations) hypoglycemia is a big cause of falls. Because I had the CGM data I was able to show both the patient and the provider that they were getting too much insulin. In some cases, I was able to get meal time insulin discontinued all together.

From my experience, CGM has been a game changer for my patients who were lucky enough to get it.

With Kind Regards,

Kathleen Thompson, BSN, RN, CDCES

Pronouns: She/Her

[redacted]

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Public Comments on Key Draft Questions - HCA Health Technology Assessment Program
Date: Monday, September 16, 2024 8:33:05 AM
Attachments: image001.png
image002.png
Battelino_Diabetes Care 2019_p1593-1603_v1.pdf

External Email

Hello,
I wanted to send in some comments regarding the continuous glucose monitoring key draft questions.
I compiled information from some of our expert staff here at PeaceHealth St. John Medical Center in Longview.
Our comments are in purple addressing some of the key draft questions.
We appreciate your coordination and hard work on this for our patients with diabetes!

Key Questions
What is the comparative effectiveness of continuous glucose monitoring in adults and children with diabetes versus self-monitoring?
a. Adults with type 2 diabetes who are not using insulin

This study provides answers / comments to a lot of these questions below regarding adults with T2DM: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10954850/
In over 50% of the retrospectively reviewed studies, CGM was favored in efficacy (measured by A1c control) regardless of age, duration of treatment, duration of diabetes, and average glucose. However, regarding safety, when looking at all the studies together there was no statistically significant difference in macrovascular complications, coefficient of variation, and severe hypoglycemia in CGM vs fingerstick use.

Attached is a wonderful study the discusses limitations of A1c and provides framework for time in target ranges.

b. Children with type 2 diabetes (regardless of insulin use)

This study (although poorly powered) does show some positive behavioral outcomes for children with T2DM and CGM therapy: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10258317/

Patti Haywood Walton, PharmD, BCACP, BCGP, BC-ADM, TTS | **PeaceHealth Medical Group**
Columbia Network Ambulatory Pharmacy Manager
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PeaceHealth

Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range

Diabetes Care 2019;42:1593–1603 | https://doi.org/10.2337/dci19-0028

Tadej Battelino,[1] Thomas Danne,[2] Richard M. Bergenstal,[3] Stephanie A. Amiel,[4] Roy Beck,[5] Torben Biester,[2] Emanuele Bosi,[6] Bruce A. Buckingham,[7] William T. Cefalu,[8] Kelly L. Close,[9] Claudio Cobelli,[10] Eyal Dassau,[11] J. Hans DeVries,[12,13] Kim C. Donaghue,[14] Klemen Dovc,[1] Francis J. Doyle III,[11] Satish Garg,[15] George Grunberger,[16] Simon Heller,[17] Lutz Heinemann,[18] Irl B. Hirsch,[19] Roman Hovorka,[20] Weiping Jia,[21] Olga Kordonouri,[2] Boris Kovatchev,[22] Aaron Kowalski,[23] Lori Laffel,[24] Brian Levine,[9] Alexander Mayorov,[25] Chantal Mathieu,[26] Helen R. Murphy,[27] Revital Nimri,[28] Kirsten Nørgaard,[29] Christopher G. Parkin,[30] Eric Renard,[31] David Rodbard,[32] Banshi Saboo,[33] Desmond Schatz,[34] Keaton Stoner,[35] Tatsuiko Urakami,[36] Stuart A. Weinzimer,[37] and Moshe Phillip[28,38]

Improvements in sensor accuracy, greater convenience and ease of use, and expanding reimbursement have led to growing adoption of continuous glucose monitoring (CGM). However, successful utilization of CGM technology in routine clinical practice remains relatively low. This may be due in part to the lack of clear and agreed-upon glycemic targets that both diabetes teams and people with diabetes can work toward. Although unified recommendations for use of key CGM metrics have been established in three separate peer-reviewed articles, formal adoption by diabetes professional organizations and guidance in the practical application of these metrics in clinical practice have been lacking. In February 2019, the Advanced Technologies & Treatments for Diabetes (ATTD) Congress convened an international panel of physicians, researchers, and individuals with diabetes who are expert in CGM technologies to address this issue. This article summarizes the ATTD consensus recommendations for relevant aspects of CGM data utilization and reporting among the various diabetes populations.

This international consensus report has been endorsed by the American Diabetes Association, American Association of Clinical Endocrinologists, American Association of Diabetes Educators, European Association for the Study of Diabetes, Foundation of European Nurses in Diabetes, International Society for Pediatric and Adolescent Diabetes, JDRF, and Pediatric Endocrine Society.

Adoption of continuous glucose monitoring (CGM), which includes both real-time CGM (rtCGM) and intermittently scanned CGM (isCGM), has grown rapidly over the past few years as a result of improvements in sensor accuracy, greater convenience and ease of use, and expanding reimbursement. Numerous studies have demonstrated significant clinical benefits of CGM use in people with diabetes regardless of insulin delivery method (1–15). In many countries, the benefits and utility of CGM are now recognized by national and international medical organizations for individuals with insulin-requiring diabetes and/or those at risk for hypoglycemia (16–21). However, despite increased CGM adoption (22,23), successful utilization of CGM data in routine clinical practice remains relatively low. This may be due in part to the lack of clear and agreed-upon glycemic targets toward which both diabetes teams and people with diabetes can work.

In 2012 the Helmsley Charitable Trust sponsored the first expert panel to recommend the standardization of CGM metrics and CGM report visualization (24). This was followed by a series of CGM consensus statements refining the core CGM metrics, but the conclusions were never in alignment. In 2017, several articles supported use of systematic approaches to CGM data evaluation (18–20). To date, the key CGM metrics remain as unified recommendations in three separate peer-reviewed articles, yet formal adoption by diabetes professional organizations and

[1]*Department of Pediatric Endocrinology, Diabetes and Metabolism, University Children's Hospital, University Medical Centre Ljubljana, and Faculty of Medicine, University of Ljubljana, Slovenia*
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[5]*Jaeb Center for Health Research, Tampa, FL*
[6]*Diabetes Research Institute, IRCCS San Raffaele Hospital, Vita-Salute San Raffaele University, Milan, Italy*
[7]*Division of Endocrinology and Diabetes, Department of Pediatrics, Stanford Medical Center, Stanford, CA*
[8]*American Diabetes Association, Alexandria, VA*

guidance in the practical application of these metrics in clinical practice have been lacking (19).

In February 2019, the Advanced Technologies & Treatments for Diabetes (ATTD) Congress convened an international panel of individuals with diabetes and clinicians and researchers with expertise in CGM. Our objective was to develop clinical CGM targets to supplement the currently agreed-upon metrics for CGM-derived times in glucose ranges (within target range, below target range, above target range) in order to provide guidance for clinicians, researchers, and individuals with diabetes in using, interpreting, and reporting CGM data in routine clinical care and research. Importantly, in order to make the recommendations generalizable and comprehensive, the consensus panel included individuals living with diabetes and had international representation from physicians and researchers from all geographic regions.

The panel was divided into subgroups to review literature and provide recommendations for relevant aspects of CGM data utilization and reporting among the various diabetes populations. Long-term trials demonstrating how CGM metrics relate to and/or predict clinical outcomes have not been conducted, and many of the published reports assessed here are not at the highest evidence level (25). However, there is suggestive evidence from a number of recent studies, including a cross-sectional study correlating current retrospective 3-day time in target range with varying degrees of diabetes retinopathy (26) and an analysis of the 7-point self-monitored blood glucose (SMBG) data from the Diabetes Control and Complications Trial (DCCT) (27), showing correlations of time in target range (70–180 mg/dL [3.9–10.0 mmol/L]) with diabetes complications. Relationships between time in target range and A1C (26,27) and number of severe and nonsevere hypoglycemic events (28–32) have also been observed. Recommendations from each subgroup were presented to the full panel and voted upon. This article summarizes the consensus recommendations and represents the panel members' evaluation of the issues.

NEED FOR METRICS BEYOND A1C

A1C is currently recognized as the key surrogate marker for the development of long-term diabetes complications in people with type 1 and type 2 diabetes and has been used as the primary end point for many CGM studies (1,3,4,6,33,34). While A1C reflects average glucose over the last 2–3 months, its limitation is the lack of information about acute glycemic excursions and the acute complications of hypo- and hyperglycemia. A1C also fails to identify the magnitude and frequency of intra- and interday glucose variation (35,36). Moreover, certain conditions such as anemia (37), hemoglobinopathies (38), iron deficiency (39), and pregnancy (40) can confound A1C measurements. Importantly, as reported by Beck et al. (41), the A1C test can fail at times to accurately reflect mean glucose even when none of those conditions are present. Despite these limitations, A1C is the only prospectively evaluated tool for assessing the risk for diabetes complications, and its importance in clinical decision making should not be undervalued. Rather, the utility of A1C is further enhanced when used as a complement to glycemic data measured by CGM.

Unlike A1C measurement, use of CGM allows for the direct observation of glycemic excursions and daily profiles, which can inform on immediate therapy decisions and/or lifestyle modifications. CGM also provides the ability to assess glucose variability and identify patterns of hypo- and hyperglycemia. However, potential drawbacks of CGM use include the need to be actively used in order to be effective; that it may induce anxiety;

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[11]Harvard John A. Paulson School of Engineering and Applied Sciences, Harvard University, Cambridge, MA
[12]Profil, Neuss, Germany
[13]Academic Medical Center, University of Amsterdam, Amsterdam, the Netherlands
[14]Children's Hospital at Westmead, University of Sydney, Sydney, Australia
[15]University of Colorado Denver and Barbara Davis Center for Diabetes, Aurora, CO
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[18]Science Consulting in Diabetes, Neuss, Germany
[19]Division of Metabolism, Endocrinology and Nutrition, Department of Medicine, University of Washington School of Medicine, Seattle, WA
[20]Wellcome Trust-MRC Institute of Metabolic Science, and Department of Paediatrics, University of Cambridge, Cambridge, U.K.
[21]Department of Endocrinology & Metabolism, Shanghai Clinical Center of Diabetes, Shanghai Diabetes Institute, Shanghai Key Laboratory of Diabetes Mellitus, Shanghai Jiao Tong University Affiliated Sixth People's Hospital, Shanghai, China
[22]Center for Diabetes Technology, University of Virginia, Charlottesville, VA
[23]JDRF, New York, NY
[24]Pediatric, Adolescent and Young Adult Section and Section on Clinical, Behavioral and Outcomes Research, Joslin Diabetes Center, Harvard Medical School, Boston, MA
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[26]Clinical and Experimental Endocrinology, KU Leuven, Leuven, Belgium
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[29]Steno Diabetes Center Copenhagen, Gentofte, Denmark
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[32]Biomedical Informatics Consultants LLC, Potomac, MD
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[34]Pediatric Endocrinology, University of Florida, Gainesville, FL
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This article contains Supplementary Data online at http://care.diabetesjournals.org/lookup/suppl/doi:10.2337/dci19-0028/-/DC1.

Table 1—Standardized CGM metrics

2017 international consensus on CGM metrics (18)
1. Number of days CGM worn
2. Percentage of time CGM is active
3. Mean glucose
4. Estimated A1C
5. Glycemic variability (%CV or SD)
6. Time >250 mg/dL (>13.9 mmol/L)
7. Time >180 mg/dL (>10.0 mmol/L)
8. Time 70–180 mg/dL (3.9–10.0 mmol/L)
9. Time <70 mg/dL (<3.9 mmol/L)
10. Time <54 mg/dL (<3.0 mmol/L)
11. LBGI and HBGI (risk indices)
12. Episodes (hypoglycemia and hyperglycemia) 15 min
13. Area under the curve
14. Time blocks (24-h, day, night)
Use of Ambulatory Glucose Profile (AGP) for CGM report

CV, coefficient of variation; LBGI, low blood glucose index; HBGI, high blood glucose index.

that it may have accuracy limitations, particularly with the delay in registering blood glucose changes in dynamic situations; and that it can provoke allergies. Another limitation of CGM is that this technology is not yet widely available in several regions of the world.

Effective use of CGM data to optimize clinical outcomes requires the user to interpret the collected data and act upon them appropriately. This requires *1*) common metrics for assessment of CGM glycemic status, *2*) graphical visualization of the glucose data and CGM daily profile, and *3*) clear clinical targets.

STANDARDIZATION OF CGM METRICS

In February 2017, the ATTD Congress convened an international panel of expert clinicians and researchers to define core metrics for assessing CGM data (18) (Table 1).

The list of core CGM metrics has now been streamlined for use in clinical practice based on the expert opinion of this international consensus group (18). Of the 14 core metrics, the panel selected that 10 metrics that may be most useful in clinical practice (Table 2).

Fundamental to accurate and meaningful interpretation of CGM is ensuring that adequate glucose data are available for evaluation. As shown in studies, >70% use of CGM over the most recent 14 days correlates strongly with 3 months of mean glucose, time in ranges, and hyperglycemia metrics (42,43). In individuals with type 1 diabetes, correlations are weaker for hypoglycemia and glycemic variability; however, these correlations have not been shown to increase with longer sampling periods (43). Longer CGM data collection periods may be required for individuals with more variable glycemic control (e.g., 4 weeks of data to investigate hypoglycemia exposure).

TIME IN RANGES

The development of blood glucose testing provided individuals with diabetes the ability to obtain immediate information about their current glucose levels and adjust their therapy accordingly. Over the past decades, national and international medical organizations have been successful in developing, harmonizing, and disseminating standardized glycemic targets based on risk for acute and chronic complications. CGM technology greatly expands the ability to assess glycemic control throughout the day, presenting critical data to inform daily treatment decisions and quantifying time below, within, and above the established glycemic targets.

Although each of the core metrics established in the 2017 ATTD consensus conference (18) provides important information about various aspects of glycemic status, it is often impractical to assess and fully utilize many of these metrics in real-world clinical practices. To streamline data interpretation, the consensus panel identified "time in ranges" as a metric of glycemic control that provides more actionable information than A1C alone. The panel agreed that establishing target percentages of time in the various glycemic ranges with the ability to adjust the percentage cut points to address the specific needs of special diabetes populations (e.g., pregnancy, high-risk) would facilitate safe and effective therapeutic decision making within the parameters of the established glycemic goals.

The metric includes three key CGM measurements: percentage of readings and time per day within target glucose range (TIR), time below target glucose range (TBR), and time above target glucose range (TAR) (Table 3). The primary goal for effective and safe glucose control is to increase the TIR while reducing the TBR. The consensus group agreed that expressing time in the various ranges can be done as the percentage (%) of CGM readings, average hours and minutes spent in each range per day, or both, depending on the circumstances.

It was agreed that CGM-based glycemic targets must be personalized to meet the needs of each individual with diabetes. In addition, the group reached consensus on glycemic cutpoints (a target range of 70–180 mg/dL [3.9–10.0 mmol/L] for individuals with type 1 diabetes and type 2 diabetes and 63–140 mg/dL [3.5–7.8 mmol/L] during pregnancy, along with a set of targets for the time per day [% of CGM readings or minutes/

Table 2—Standardized CGM metrics for clinical care: 2019

1. Number of days CGM worn (recommend 14 days) (42,43)	
2. Percentage of time CGM is active (recommend 70% of data from 14 days) (41,42)	
3. Mean glucose	
4. Glucose management indicator (GMI) (75)	
5. Glycemic variability (%CV) target ≤36% (90)*	
6. Time above range (TAR): % of readings and time >250 mg/dL (>13.9 mmol/L)	Level 2
7. Time above range (TAR): % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)	Level 1
8. Time in range (TIR): % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)	In range
9. Time below range (TBR): % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)	Level 1
10. Time below range (TBR): % of readings and time <54 mg/dL (<3.0 mmol/L)	Level 2
Use of Ambulatory Glucose Profile (AGP) for CGM report	

CV, coefficient of variation. *Some studies suggest that lower %CV targets (<33%) provide additional protection against hypoglycemia for those receiving insulin or sulfonylureas (45,90,91).

Table 3—Guidance on targets for assessment of glycemic control for adults with type 1 or type 2 diabetes and older/high-risk individuals

	TIR		TBR		TAR	
Diabetes group	% of readings; time per day	Target range	% of readings; time per day	Below target level	% of readings; time per day	Above target level
Type 1*/type 2	>70%; >16 h, 48 min	70–180 mg/dL (3.9–10.0 mmol/L)	<4%; <1 h <1%; <15 min	<70 mg/dL (<3.9 mmol/L) <54 mg/dL (<3.0 mmol/L)	<25%; <6 h <5%; <1 h, 12 min	>180 mg/dL (>10.0 mmol/L) >250 mg/dL (>13.9 mmol/L)
Older/high-risk# type 1/type 2	>50%; >12 h	70–180 mg/dL (3.9–10 mmol/L)	<1%; <15 min	<70 mg/dL (<3.9 mmol/L)	<10%; <2 h, 24 min	>250 mg/dL (>13.9 mmol/L)

Each incremental 5% increase in TIR is associated with clinically significant benefits for individuals with type 1 or type 2 diabetes (26,27). *For age <25 years, if the A1C goal is 7.5%, set TIR target to approximately 60%. See the section CLINICAL APPLICATION OF TIME IN RANGES for additional information regarding target goal setting in pediatric management. #See the section OLDER AND/OR HIGH-RISK INDIVIDUALS WITH DIABETES for additional information regarding target goal setting.

hours]) individuals with type 1 diabetes and type 2 diabetes (Table 3) and women during pregnancy (Table 4) should strive to achieve. It should be noted that premeal and postprandial SMBG targets remain for diabetes in pregnancy (44), in addition to the new CGM TIR targets for overall glycemia.

Although the metric includes TIR, TBR, and TAR, achieving the goals for both TBR and TIR would result in reduced time spent above range and thereby improve glycemic control. However, some clinicians may choose to target the reduction of the high glucose values and minimize hypoglycemia, thereby arriving at more time in the target range. In both approaches, the first priority is to reduce TBR to target levels and then address TIR or TAR targets.

Note that for people with type 1 diabetes, the targets are informed by the ability to reach the targets with hybrid closed-loop therapy (11), the first example of which is now commercially available with several more systems in final stages of testing. Importantly, recent studies have shown the potential of reaching these targets with CGM in individuals using multiple daily injections (6). In type 2 diabetes, there is generally less glycemic variability and hypoglycemia than in type 1 diabetes (45). Thus, people with type 2 diabetes can often achieve more time in the target range while minimizing hypoglycemia (4). As demonstrated by Beck et al. (4), individuals with type 2 diabetes increased their TIR by 10.3% (from 55.6% to 61.3%) after 24 weeks of CGM use with slight reductions in TBR. Most recently, the beneficial effects of new medications, such as sodium–glucose cotransporter 2 agents have helped individuals with type 1 diabetes increase TIR (46–48). Targets for type 1 diabetes and type 2 diabetes were close enough to combine into one set of targets, outside of pregnancy.

Another way to visualize the CGM-derived targets for the four categories of diabetes is shown in Fig. 1, which displays and compares the targets for TIR (green), TBR (two categories in light and dark red), and TAR (two categories in yellow and orange). It becomes clear at a glance that there are different expectations for the various time in ranges relating to safety concerns and efficacy based on currently available therapies and medical practice.

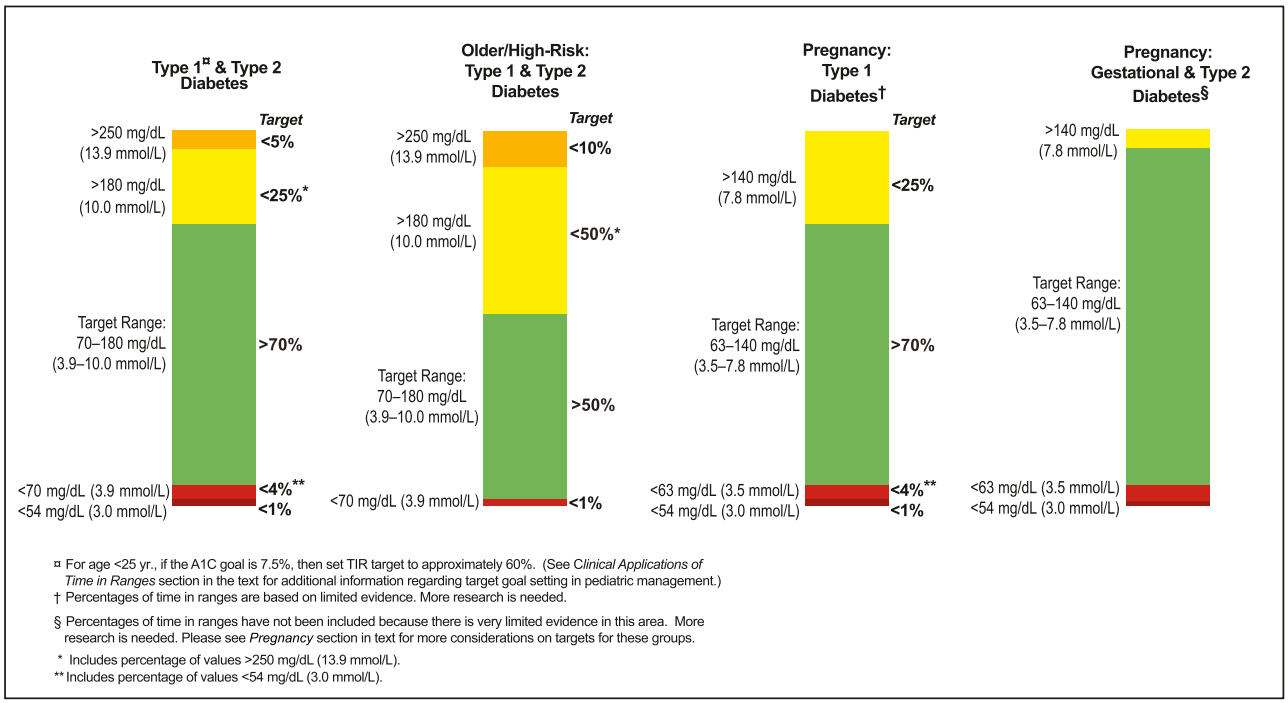
CLINICAL VALIDITY OF MEASURES

To fundamentally change clinical care with use of the new metrics, it would be important to demonstrate that the metrics relate to and predict clinical outcomes. In this regard, longer-term studies relating to time spent within specific CGM glycemic ranges, diabetes complications, and other outcomes are required. However, there is evidence from a number of recent studies that have shown correlations of TIR (70–180 mg/dL [3.9–10.0 mmol/L]) with diabetes complications (49,50) as well as a relationship between TIR and A1C (26,27). Although evidence regarding TIR for older and/or high-risk individuals is lacking, numerous studies have shown the elevated risk for hypoglycemia in these populations (51–56). Therefore, we have lowered the TIR target from

Table 4—Guidance on targets for assessment of glycemic control during pregnancy

	TIR		TBR		TAR	
Diabetes group	% of readings; time per day	Target range	% of readings; time per day	Below target level	% of readings; time per day	Above target level
Pregnancy, type 1§	>70%; >16 h, 48 min	63–140 mg/dL† (3.5–7.8 mmol/L†)	<4%; <1 h <1%; <15 min	<63 mg/dL† (<3.5 mmol/L†) <54 mg/dL (<3.0 mmol/L)	<25%; <6 h	>140 mg/dL (>7.8 mmol/L)
Pregnancy, type 2/GDM§	See PREGNANCY section	63–140 mg/dL† (3.5–7.8 mmol/L†)	See PREGNANCY section	<63 mg/dL† (<3.5 mmol/L†) <54 mg/dL (<3.0 mmol/L)	See PREGNANCY section	>140 mg/dL (>7.8 mmol/L)

Each incremental 5% increase in TIR is associated with clinically significant benefits for pregnancy in women with type 1 diabetes (59,60). †Glucose levels are physiologically lower during pregnancy. §Percentages of TIR are based on limited evidence. More research is needed.



¤ For age <25 yr., if the A1C goal is 7.5%, then set TIR target to approximately 60%. (See *Clinical Applications of Time in Ranges* section in the text for additional information regarding target goal setting in pediatric management.)
† Percentages of time in ranges are based on limited evidence. More research is needed.
§ Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed. Please see *Pregnancy* section in text for more considerations on targets for these groups.
* Includes percentage of values >250 mg/dL (13.9 mmol/L).
** Includes percentage of values <54 mg/dL (3.0 mmol/L).

Figure 1—CGM-based targets for different diabetes populations.

>70% to >50% and reduced TBR to <1% at <70 mg/dL (<3.9 mmol/L) to place greater emphasis on reducing hypoglycemia with less emphasis on maintaining target glucose levels (Table 3).

Type 1 Diabetes and Type 2 Diabetes

Association With Complications

Associations between TIR and progression of both diabetic retinopathy (DR) and development of microalbuminuria were reported by Beck et al. (50), using 7-point blood glucose profiles from the DCCT data set to validate the use of TIR as an outcome measure for clinical trials. Their analysis showed that the hazard rate for retinopathy progression increased by 64% for each 10% reduction in TIR. The hazard rate for microalbuminuria development increased by 40% for each 10% reduction in TIR. A post hoc analysis of the same DCCT data set showed a link between glucose of <70 mg/dL (<3.9 mmol/L) and <54 mg/dL (<3.0 mmol/L) and an increased risk for severe hypoglycemia (57).

Similar associations between DR and TIR were reported in a recent study by Lu et al. (49) in which 3,262 individuals with type 2 diabetes were evaluated for DR, which was graded as non-DR, mild nonproliferative DR (NPDR), moderate NPDR, or vision-threatening DR. Results showed that individuals with more advanced DR spent significantly less time within target range (70–180 mg/dL [3.9–10.0 mmol/L]) and that prevalence of DR decreased with increasing TIR.

Relationship Between TIR and A1C

Analyses were conducted utilizing datasets from four randomized trials encompassing 545 adults with type 1 diabetes who had central laboratory measurements of A1C (26). TIR (70–180 mg/dL [3.9–10.0 mmol/L]) of 70% and 50% strongly corresponded with an A1C of approximately 7% (53 mmol/mol) and 8% (64 mmol/mol), respectively. An increase in TIR of 10% (2.4 h per day) corresponded to a decrease in A1C of approximately 0.5% (5.0 mmol/mol); similar associations were seen in an analysis of 18 randomized controlled trials (RCTs) by Vigersky and McMahon (27) that included over 2,500 individuals with type 1 diabetes and type 2 diabetes over a wide range of ages and A1C levels (Table 5).

Pregnancy

During pregnancy, the goal is to safely increase TIR as quickly as possible, while reducing TAR and glycemic variability. Data from the first study of longitudinal CGM use in pregnancy demonstrated a 13–percentage point increase in TIR (43% to 56% TIR 70–140 mg/dL [3.9–7.8 mmol/L]) (58). TBR <50 mg/dL was reduced from 6% to 4%, although the higher TBR <70 mg/dL was high (13–15%) using older-generation sensors. With improved sensor accuracy, recent type 1 diabetes pregnancy studies report a lower threshold of <63 mg/dL (<3.5 mmol/L) for TBR and ≥63 mg/dL (≥3.5 mmol/L) for TIR (59,60). Data from Sweden, and the Continuous Glucose Monitoring in Women With Type 1 Diabetes in Pregnancy Trial (CONCEPTT) control group, report 50% TIR in the first trimester, improving to 60% TIR in the third trimester, reflecting contemporary antenatal care. Of note, these data confirm that the TBR <63 mg/dL (<3.5 mmol/L) recommendation of <4% is safely achievable, especially after the first trimester. Furthermore, 33% of women achieved the recommendation of 70% TIR 63–140 mg/dL (3.5–7.8 mmol/L) in the final (>34) weeks of pregnancy. Preliminary data suggest that closed-loop systems may allow pregnant women to safely achieve 70% TIR at an earlier (>24 weeks) stage of gestation (61,62). Law et al. (63) analyzed data from two early CGM trials (64,65) describing the associations between CGM measures and risk of large-for-gestational-age (LGA) infants. Taken together, the Swedish and CONCEPTT data confirm that a 5–7% higher

Table 5—Estimate of A1C for a given TIR level based on type 1 diabetes and type 2 diabetes studies

Beck et al. (26) (n = 545 participants with type 1 diabetes)			Vigersky and McMahon (27) (n = 1,137 participants with type 1 or type 2 diabetes)	
TIR 70–180 mg/dL (3.9–10.0 mmol/L)	A1C, % (mmol/mol)	95% CI for predicted A1C values, %	TIR 70–180 mg/dL (3.9–10.0 mmol/L)	A1C, % (mmol/mol)
20%	9.4 (79)	(8.0, 10.7)	20%	10.6 (92)
30%	8.9 (74)	(7.6, 10.2)	30%	9.8 (84)
40%	8.4 (68)	(7.1, 9.7)	40%	9.0 (75)
50%	7.9 (63)	(6.6, 9.2)	50%	8.3 (67)
60%	7.4 (57)	(6.1, 8.8)	60%	7.5 (59)
70%	7.0 (53)	(5.6, 8.3)	70%	6.7 (50)
80%	6.5 (48)	(5.2, 7.8)	80%	5.9 (42)
90%	6.0 (42)	(4.7, 7.3)	90%	5.1 (32)
Every 10% increase in TIR = ~0.5% (5.5 mmol/mol) A1C reduction			Every 10% increase in TIR = ~0.8% (8.7 mmol/mol) A1C reduction	

The difference between findings from the two studies likely stems from differences in number of studies analyzed and subjects included (RCTs with subjects with type 1 diabetes vs. RCTs with subjects with type 1 or type 2 diabetes with CGM and SMBG).

TIR during the second and third trimesters is associated with decreased risk of LGA and neonatal outcomes including macrosomia, shoulder dystocia, neonatal hypoglycemia, and neonatal intensive care admissions. More data are needed to define the clinical CGM targets for pregnant women with type 2 diabetes, who spend one-third less time hyperglycemic than women with type 1 diabetes and achieve TIR of 90% (58). Because of the lack of evidence on CGM targets for women with gestational diabetes mellitus (GDM) or type 2 diabetes in pregnancy, percentages of time spent in range, below range, and above range have not been included in this report. Recent data suggest that even more stringent targets (66) and greater attention to overnight glucose profiles may be required to normalize outcomes in pregnant women with GDM (63).

Older and/or High-Risk Individuals With Diabetes

Older and/or high-risk individuals with diabetes are at notably higher risk for severe hypoglycemia due to age, duration of diabetes, duration of insulin therapy, and greater prevalence of hypoglycemia unawareness (51–55). The increased risk of severe hypoglycemia is compounded by cognitive and physical impairments and other comorbidities (53,56). High-risk individuals include those with a higher risk of complications, comorbid conditions (e.g., cognitive deficits, renal disease, joint disease, osteoporosis, fracture, and/or cardiovascular disease), and those requiring assisted care, which can complicate treatment regimens (56). Therefore, when setting glycemic targets for high-risk and/or elderly people, it is important to individualize and be conservative, with a strong focus on reducing the percentage of time spent <70 mg/dL (<3.9 mmol/L) and preventing excessive hyperglycemia.

STANDARDIZATION OF CGM DATA PRESENTATION

As noted above, in 2013 a panel of clinicians with expertise in CGM published recommendations for use of the Ambulatory Glucose Profile (AGP) as a template for data presentation and visualization. Originally created by Mazze et al. (67), the standardized AGP report was further developed by the International Diabetes Center and now incorporates all the core CGM metrics and targets along with a 14-day composite glucose profile as an integral component of clinical decision making (24). This recommendation was later endorsed at the aforementioned international consensus conference on CGM metrics (18) and is referenced as an example in the American Diabetes Association 2019 "Standards of Medical Care in Diabetes" (16) and in an update to the American Association of Clinical Endocrinologists consensus on use of CGM (68). The AGP report, in slightly modified formats, has been adopted by most of the CGM device manufacturers in their download software. An example of the AGP report, updated to incorporate targets, is presented in Fig. 2. In the AGP report, glucose ranges are defined as "Very High" (Level 2), "High" (Level 1), "Low" (Level 1), and "Very Low" (Level 2). An "mmol/L" version is provided in Supplementary Fig. 1.

There is a general consensus that a useful CGM report is one that can be understood by clinicians and people with diabetes. While there may be some terms (e.g., glucose variability) that are less familiar to many people with diabetes, a single-page report that the medical team can review and file in the electronic medical record and that can be used as a shared decision-making tool with people with diabetes was considered to be of value (69–72). More detailed reports (e.g., adjustable data ranges, detailed daily reports) should remain available for individualized review by or with people with diabetes.

Clinical Application of Time in Ranges

Despite its demonstrated value, clinical utilization of CGM data has remained suboptimal. Although time constraints and reimbursement issues are clearly obstacles, clinician inexperience in data interpretation and lack of standardization software for visualization of CGM data have also played a role (73). The proposed standardized report enables clinicians to readily identify important metrics such as the percentage of time spent within, below, and above each individual's target range, allowing for greater personalization of therapy through shared decision making.

Using the standardized report, the clinician can also address glucose variability (e.g., the coefficient of variation

AGP Report

Name

MRN

GLUCOSE STATISTICS AND TARGETS

26 Feb 2019–10 Mar 2019	**13 days**
% Time CGM is Active	**99.9%**

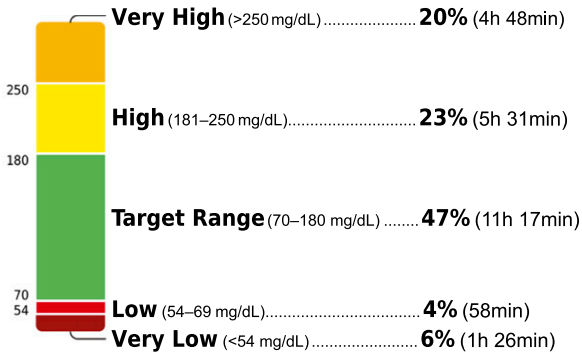
Glucose Ranges	**Targets** [% of Readings (Time/Day)]
Target Range 70–180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70–180 mg/dL) is clinically beneficial.

Average Glucose	**173 mg/dL**
Glucose Management Indicator (GMI)	**7.6%**
Glucose Variability	**49.5%**

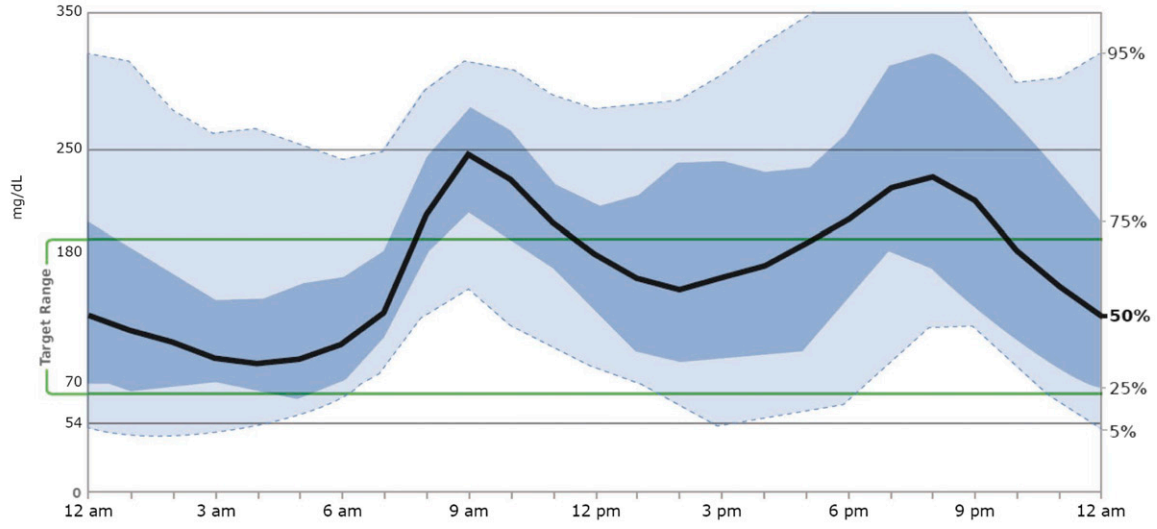
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

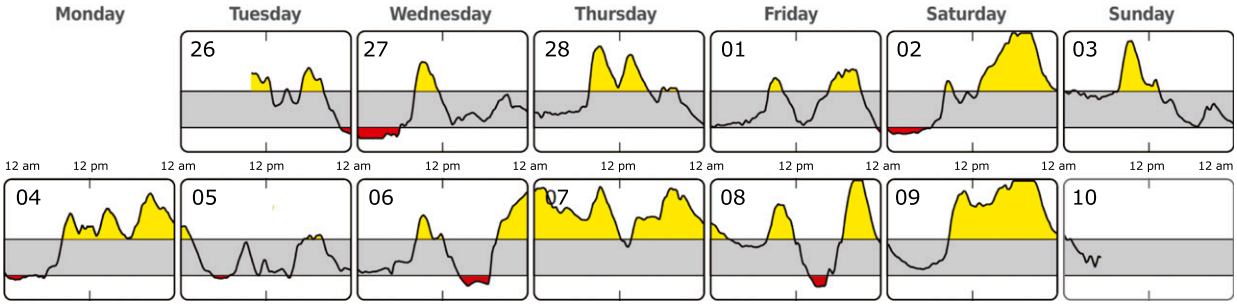


AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.



DAILY GLUCOSE PROFILES



Each daily profile represents a midnight-to-midnight period.

Figure 2—Ambulatory Glucose Profile.

[%CV] metric) (74) or use the glucose management indicator (GMI) metric (75) to discuss the possible discrepancies noted in glucose exposure derived from CGM data versus the individual's laboratory-measured A1C (41,76). With appropriate educational materials, time, and experience, clinicians will develop a systematic approach to CGM data analysis and the most effective ways to discuss the data with patients in person or remotely.

Goal Setting

Numerous studies have demonstrated the clinical benefits of early achievement of near-normal glycemic control in individuals with type 1 diabetes and type 2 diabetes (77–83). However, when advising people with diabetes, goal-setting must be collaborative and take into account the individual needs/capabilities of each patient and start with the goals that are most achievable. An early study by DeWalt et al. (84) found that setting small, achievable goals not only enhances people's ability to cope with their diabetes, but that people with diabetes who set and achieved their goals often initiated additional behavioral changes on their own. One approach to consider is the SMART goal (Specific, Measurable, Achievable, Relevant, Time-bound) intervention, which is directly applicable to setting targets for time in ranges. First described by Lawlor and Hornyak in 2012 (85), this approach incorporates four key components of behavioral change relevant to goal setting: *1*) the goal is specific and defines exactly what is to be achieved, *2*) the goal is measurable and there is tangible evidence when it has been achieved, *3*) the goal is achievable but stretches the patient slightly so that he/she feels challenged, and *4*) the goal should be attainable over a short period of time.

Effective goals should utilize CGM data to identify specific instances for the patient to take measurable action to prevent hypoglycemia. Although analysis of the AGP reports provides an opportunity for meaningful discussion, individuals should be counseled to look at patterns throughout the day to see when low glucose events are occurring and make adjustments in their therapy to reduce these events.

When applying the CGM metrics in clinical practice, it may be more meaningful and motivating to communicate to people with diabetes the importance of working to reduce the time spent $<$70 mg/dL ($<$3.9 mmol/L) to less than 1 h per day and time spent $<$54 mg/dL ($<$3.0 mmol/L) to less than 15 min per day, rather than using $<$4% and $<$1%, respectively, as the goal. However, as discussed earlier, targets must be personalized to meet the needs and capabilities of each person, focusing on small steps and small successes. Individuals with diabetes should work with their provider and/or educator to develop a SMART goal to reduce TBR.

Individualized goals are particularly important for pediatric and young adult populations. The International Society for Pediatric and Adolescent Diabetes recommends that targets for individuals $\leq$25 years of age aim for the lowest achievable A1C without undue exposure to severe hypoglycemia or negative effects on quality of life and burden of care (86). An A1C target of 7.0% (53 mmol/mol) can be used in children, adolescents, and adults $\leq$25 years old who have access to comprehensive care (86). However, a higher A1C goal (e.g., $<$7.5% [$<$58 mmol/mol]) may be more appropriate in the following situations: inability to articulate hypoglycemia symptoms, hypoglycemia unawareness, history of severe hypoglycemia, lack of access to analog insulins and/or advanced insulin delivery technology, or inability to regularly check glucose (86). This would equate to a TIR target of ~60% (Table 4).

The consensus group recognized that achieving the targets for the various time in ranges is aspirational in some situations, and many individuals will require ongoing support, both educational and technological, from their health care team. Importantly, as demonstrated by Beck et al. (26), Vigersky and McMahon (27), and Feig et al. (59), even small, incremental improvements yield significant glycemic benefits. Therefore, when advising individuals with diabetes (particularly children, adolescents, and high-risk individuals) about their glycemic goals, it is important to take a stepwise approach, emphasizing that what may appear to be small, incremental successes (e.g., 5% increase in TIR) are, in fact, clinically significant in improving their glycemia (26,27,59). However, when counseling women planning pregnancy and pregnant women, greater emphasis should be placed on getting to goal as soon as possible (59,60).

CONCLUSIONS

Use of CGM continues to expand in clinical practice. As a component of diabetes self-management, daily use of CGM provides the ability to obtain immediate feedback on current glucose levels as well as direction and rate of change in glucose levels. This information allows people with diabetes to optimize dietary intake and exercise, make informed therapy decisions regarding mealtime and correction of insulin dosing, and, importantly, react immediately and appropriately to mitigate or prevent acute glycemic events (87–89). Retrospective analysis of CGM data, using standardized data management tools such as the AGP, enables clinicians and people with diabetes to work collaboratively in identifying problem areas and then set achievable goals (70–72). We conclude that, in clinical practice, time in ranges (within target range, below range, above range) are both appropriate and useful as clinical targets and outcome measurements that complement A1C for a wide range of people with diabetes and that the target values specified in this article should be considered an integral component of CGM data analysis and day-to-day treatment decision making.

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He is a shareholder of Profil Institut für Stoffwechselforschung GmbH and ProSciento. I.B.H. receives research funding from Medtronic Diabetes and has received consulting fees from Abbott Diabetes Care, Bigfoot, Roche, and Becton Dickinson. R.H. reports having received speaker honoraria from Eli Lilly and Company, Novo Nordisk, and AstraZeneca, serving on an advisory panel for Eli Lilly and Company and Novo Nordisk, and receiving license fees from B. Braun and Medtronic. O.K. received honoraria from Amring, Eli Lilly and Company, Novo Nordisk, and Sanofi and owns shares from DreaMed Diabetes. B.K. declares research support handled by the University of Virginia from Dexcom, Roche, Sanofi, and Tandem; patent royalties handled by the University of Virginia from Johnson & Johnson, Sanofi, and Dexcom; and has served as a consultant for Sanofi and Tandem and on a speakers' bureau for Dexcom. 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S.A.W. has received consulting fees from Eli Lillyand Company, Sanofi, and Zealand and speaker honoraria from Medtronic, Insulet, and Tandem. M.P. is a member of the advisory board of AstraZeneca, Sanofi, Medtronic, Eli Lilly and Company, Novo Nordisk, and Insulet and is a consultant to RSP Systems A/S, Qulab Medical, and Pfizer. The institute headed by M.P. received research support from Medtronic, Novo Nordisk, Eli Lilly and Company, Dexcom, Sanofi, Insulet, OPKO Health, DreaMed Diabetes, Bristol-Myers Squibb, and Merck. M.P. is a stockholder/shareholder of DreaMed Diabetes, NG Solutions, and Nutriteen Professionals and reports two patent applications. No other potential conflicts of interest relevant to this article were reported.

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