Washington State Health Care Authority

Continuous Glucose Monitoring - Update

Draft Evidence Report: Public Comment and Response

February 20, 2025

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Continuous Glucose Monitoring - Update
Draft Evidence Report
Public Comment and Response

Provided by:

Center for Evidence-based Policy
Oregon Health & Science University

February 20, 2025

Responses to Public Comment on Draft Evidence Report

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:

- Hazma Alshannaq, MD, MPH, Senior Manager, Health Economics and Outcomes Research - Global Access, Dexcom (including on behalf of others)
- Kathaleen Briggs Early, PhD, RDN, CDCES, Professor of Nutrition, Pacific Northwest University of Health Sciences, College of Osteopathic Medicine
- Tara Cardinal, CNM, ARNP
- Timothy Cordova, Associate, Alston & Bird (on behalf of the Diabetes Technology Access Coalition)
- Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute, including on behalf of others
- Glen Felias-Christensen RN, MPH, CDCES, Diabetes Care and Education Specialist
- Line Goulet RN, M. Ed, BSN, CDCDES, Diabetes Education Program Coordinator, Whidbey Health
- Diane Hood
- Jane King, Family Physician and Clinical IT Consultant
- Pam Kramer, RDN, CDCES, Manager of Diabetes and Nutrition Services Ambulatory Pharmacy Services, MultiCare Health System
- [redacted], PhD, ARNP, CDCES
- Cricket McCleary, UW Medicine
- Tammy Ninh, Pharmacy Resident
- Qaashif Panjwani, PharmD, MPH, RPH, AHEOR, Medical Outcomes Manage, Abbott Diabetes Care
- 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
- Donna Rice, MBA, BSN, RN, CDCES, FADCES, Chief Operations Officer, DiabetesSisters, Inc.
- Amber Robbins-Ghormley, RN, Diabetes Educator
- Jeb Shepard, Director of Policy, Washington State Medical Association (including on behalf of others)
- Sarah Skidmore, RN, CDCES
- Carrie S. Swift, MS, RDN, CD, BC-ADM, CDCES, FADCES
- Dawn Travelstead MS, RD, CDCES, Diabetes Educator and Dietician, Lower Elwha Health Clinic
- Nicole Treanor, MS, RD, CD, CDCES, Diabetes care and education specialist/Program coordinator for outpatient diabetes education, Virginia Mason Franciscan Health

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

Table 1. Responses to Comments on Draft Evidence Report for Continuous Glucose Monitoring – Update

Comments		Response
Commenter: Hazma Alshannaq, MD, MPH, Senior Manager, Health Economics and Outcomes Research - Global Access, Dexcom		
General Comments:		
Dexcom appreciates the Washington State Health Care Authority's positive recommendations for CGM use in all insulin-treated individuals and supports efforts to expand access to this life-changing technology. [See Specific Comments] We hope these insights will be incorporated into the final assessment to ensure equitable access to CGM for all eligible populations. We appreciate the opportunity to provide input and look forward to continued collaboration.		Thank you for your comments and for sharing your organization's views on this topic. Please see responses to specific points below.
Specific Comments:		
Included Studies	**KQ1a)** Clinical Effectiveness in Adults with T2D on Oral Hypoglycemic Medications **New RCT Evidence Published:** We recognize that the scope of the literature review covers only studies published before September 2024. However, an additional RCT that meets the inclusion criteria, including sufficient CGM use, and shows significant reductions in HbA1c has recently been published; including this more recent RCT could change the review recommendations. This is particularly important given that when the GLIMPSE trial was excluded from the meta-analysis in the report, CGM was found to be more effective for T2D individuals on oral hypoglycemic medications. **a. Lau et al. 2024** (Available Online October 19, 2024): This RCT enrolled 105 participants with T2D not on insulin who were randomized to CGM with telemonitoring vs. enhanced usual care. The results showed that, after adjusting for baseline HbA1c, CGM was superior (0.65% greater HbA1c reduction [95% CI 0.17-1.12%], p = 0.008). CGM participants were 92% (RR = 1.92, 1.19-3.06, p = 0.007) more likely to have an HbA1c reduction ≥ 0.5%, lose more weight (difference in weight reduction 2.17 kg, 0.22-4.11, p = 0.029) and were more satisfied with their treatment.	Thank you for notifying us of this study. This is an area of ongoing interest, and we acknowledge that relevant studies may have published since we conducted our official search. However, to complete the systematic review process within the allotted timeframe, we are unable to accept studies (such as Lau et al., 2024) published beyond the review search dates.
Real-world Evidence	**RWE Demonstrates CGM Efficacy Across Patient Populations:** Real-world evidence (RWE) further substantiates the effectiveness of CGM in managing T2D, with several studies evaluating outcomes for both insulin-treated and non-insulin therapy (NIT) populations. Notably, these studies have often revealed that CGM is equally, if not more, effective in NIT populations. Several RWE studies have shown significant reductions in HbA1c, ranging from -0.4% to -2.3%. Wright et al. (2021) explored glycemic outcomes among T2D patients on basal insulin and NIT; both groups showed a significant	Thank you for your comments and for providing these references. The scope of the effectiveness review (KQs 1-3) was limited to data from published RCTs. Publications with

Comments		Response
Commenter: Hazma Alshannaq, MD, MPH, Senior Manager, Health Economics and Outcomes Research - Global Access, Dexcom		
	reduction in HbA1c with a higher reduction in the NIT versus basal insulin group (1.6% vs 1.1%). The findings from Wright et al. (2021) and other retrospective studies highlight that T2D individuals on NIT often achieve greater HbA1c reductions than those on insulin therapy (Norman et al., 2024; Garg et al., 2024; Shields et al., 2023; Bergenstal et al., 2021). Garg et al. (2024), using OPTUM Market Clarity data, reported that people treated with NIT achieved higher HbA1c reductions compared to patient treated with prandial insulin (-1.1% vs. -0.9%) despite having lower baseline HbA1c levels (8.6% vs. 9.0%). Norman et al. (2024) examined HbA1c changes using Aetna's administrative claims data, including commercially insured and Medicare Advantage beneficiaries. This study found that T2D NIT individuals had a higher decline in HbA1c (-0.9%) than T2D individuals on intensive insulin therapy (IIT; -0.05%) and non-intensive insulin therapy (NIIT; -0.7%). In a retrospective analysis using electronic health records and administrative claims, Shields et al., (2023) reported a -1.13% reduction in HbA1c among T2D NIT primary care patients with baseline HbA1c >7.5% compared to a -0.76% reduction in T2D primary care patients on IIT with baseline HbA1c >7.5%. These findings suggest that patients undergoing IIT typically exhibit more advanced diabetes, marked by substantial insulin resistance and deficiency. Consequently, their treatment targets are often moderated to lower the risk of hypoglycemia and manage comorbid conditions, necessitating less aggressive glycemic goals than NIT patients. In contrast, NIT patients usually have less severe disease and better-preserved beta-cell function, which allows for more significant reductions in HbA1c when using interventions like CGM. These observations advocate for the early adoption of CGM in the disease course for NIT patients to optimize glycemic control to potentially prevent or slow disease progression. Implementing CGM early could help address glycemic variability and prevent complications at a more manageable disease stage, potentially improving long-term outcomes. <u>References</u> 1. Norman G, Fernandes J, Nemlekar P, Andrade SB, Lupton L, Berk A. Initiating Continuous Glucose Monitoring is Associated with Improvements in Glycemic Control and Reduced Healthcare Resource Utilization for People with Diabetes in a Large US Insured Population: A Real-World Evidence Study. *JMCP*. 2024; TBD 2. Garg SK, Hirsch IB, Repetto E, et al. Impact of continuous glucose monitoring on hospitalizations and glucose control in	observational study designs, such as these, were not eligible for inclusion with respect to assessment of glycemic outcomes (e.g., change in HbA1c). We reviewed these studies for potential cost outcomes (KQ4) but determined that none were eligible due to lack of relevant outcomes or publication outside of the formal search range.

Comments		Response
Commenter: Hazma Alshannaq, MD, MPH, Senior Manager, Health Economics and Outcomes Research - Global Access, Dexcom		
	people with type 2 diabetes: real-world analysis. *Diabetes Obes Metab*. Nov 2024;26(11):5202-5210. doi:10.1111/dom.15866 3. Shields S, Norman GJ, Thomas R, Ciemins EL. HbA1c Improvements After Initiation of Real-Time Continuous Glucose Monitoring in Primary Care Patients With Type 2 Diabetes. J *Diabetes Sci Technol*. Sep 2023;17(5):1423-1424. doi:10.1177/19322968231171176 4. Bergenstal RM, Layne JE, Zisser H, et al. Remote Application and Use of Real-Time Continuous Glucose Monitoring by Adults with Type 2 Diabetes in a Virtual Diabetes Clinic. *Diabetes Technol Ther*. Nov 5 2021;23(4):128-132. doi:10.1089/dia.2020.0396 5. Fonseca VA. Defining and characterizing the progression of type 2 diabetes. *Diabetes Care*. Nov 2009;32 Suppl 2(Suppl 2):S151-6. doi:10.2337/dc09-S301 6. Cosentino F, Grant PJ, Aboyans V, et al. 2019 ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD: The Task Force for diabetes, pre-diabetes, and cardiovascular diseases of the European Society of Cardiology (ESC) and the European Association for the Study of Diabetes (EASD). *European Heart Journal*. 2019;41(2):255-323. doi:10.1093/eurheartj/ehz486 7. American Diabetes Association Professional Practice Committee 6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes-2024. *Diabetes Care*. 2023;47(Supplement_1):S111-S125. doi:10.2337/dc24-S006 8. American Diabetes Association Professional Practice Committee 7. Diabetes Technology: Standards of Care in Diabetes-2025. *Diabetes Care*. 2024;48(Supplement_1):S146-166. doi:10.2337/dc25-S007	
Clinical Practice Guidelines	**New American Diabetes Association guidelines on CGM use in non-insulin populations:** The American Diabetes Association (ADA) has recently updated its guidelines for the use of CGM systems, reflecting evolving evidence and expanding the utility of this technology across broader patient populations. The 2025 Standards of Care now recommend the consideration of real-time CGM and intermittently scanned CGM for adults with T2D who are treated with glucose-lowering medications other than insulin. This change underscores the recognized benefits of CGM in helping achieve and maintain individualized glycemic targets effectively.	Thank you for alerting us to this update of the ADA Standards of Care. Although we are unable to formally incorporate literature published beyond the search dates in our technical report, we have informed the HTCC staff that this update is available for the purposes of

Comments		Response
Commenter: Hazma Alshannaq, MD, MPH, Senior Manager, Health Economics and Outcomes Research - Global Access, Dexcom		
	Recommendations 7.16 *"Consider using rtCGM and isCGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals. The choice of device should be made based on the individual's circumstances, preferences, and needs. B"* The ADA strengthened recommendations for CGM use in pregnancy for individuals with T1D and recognized its potential benefit in other types of diabetes in pregnancy. **Recommendation 7.18** *"CGM can help achieve glycemic goals (*e.g., *time in range and time above range) A and A1C goal B in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy. E"* **The ADA strengthened recommendations for CGM use in pregnancy for individuals with T1D** and recognized its potential benefit in other types of diabetes in pregnancy. **Recommendation 7.18** *"CGM can help achieve glycemic goals (e.g., time in range and time above range) A and A1C goal B in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy. E"* The current assessment of CGM use in GDM relies primarily on randomized controlled trials (RCTs), which, while valuable, are limited in detecting meaningful differences in maternal and fetal outcomes. These outcomes—particularly maternal and neonatal complications and long-term health effects—require larger sample sizes and longer follow-up periods for accurate assessment. The lack of statistical significance in some findings does not indicate a lack of clinical benefit but reflects the challenges of studying pregnancy-related health measures. Incorporating real-world evidence (RWE) alongside RCT data would provide a more comprehensive and policy-relevant evaluation of CGM's impact. We encourage the Washington HTA to consider these research challenges and integrate RWE with RCT findings to better assess CGM's value in GDM <u>References</u> American Diabetes Association Professional Practice Committee; 7. Diabetes Technology: Standards of Care in Diabetes-2025. Diabetes Care 1 January 2025; 48 (Supplement_1): S146- S166	comparison with the 2024 Standards of Care, which are included.
Economic Outcomes	**KQ4)** Economic evaluations and reduction in healthcare resource utilization after initiation of CGM use	Thank you for notifying us of these analyses.

Comments		Response
Commenter: Hazma Alshannaq, MD, MPH, Senior Manager, Health Economics and Outcomes Research - Global Access, Dexcom		
	CGM use results in significant reduction in costs and healthcare resource utilization (HCRU): Key Question 4 aimed to evaluate the costs and cost-effectiveness of CGM for the T2D population. However, we believe that the assessment should have included multiple U.S.-based studies that examined costs and HCRU outcomes following the initiation of CGM, particularly those based on real- world data. Real-world outcomes and claims data are invaluable resources for monitoring cost trends and disease burden. For instance, the 2024 study by Garg et al. provides evidence of CGM's potential economic benefits in a diverse cohort of adults with T2D. This retrospective analysis utilized data from over 79 million people to demonstrate significant decreases in all-cause hospitalizations and acute diabetes-related emergency room visits after transitioning to CGM. These findings suggest substantial cost savings and underscore the importance of including real-world studies in economic assessments to fully capture the cost-effectiveness of CGM in managing T2D. Emerging evidence further supports the cost-effectiveness of CGM use in the NIT population. A recent analysis, accepted for presentation at the 2025 Advanced Technologies & Treatments for Diabetes (ATTD) conference, but not yet published, demonstrates that CGM is cost-effective from a Canadian public payer perspective. Moreover, the study suggests that CGM could potentially yield cost-savings when considering indirect societal costs. <u>References</u> Garg SK, Hirsch IB, Repetto E, et al. Impact of continuous glucose monitoring on hospitalizations and glucose control in people with type 2 diabetes: real-world analysis. *Diabetes Obes Metab.* 2024;26(11):5202-5210. doi:10.1111/dom.15866 Alshannaq H, Cost-effectiveness of Real-Time CGM in indivdiuals with Type 2 diabetes not using Insulin. Advanced Technologies & Treatments for Diabetes (ATTD 2025)	This is an area of ongoing interest and we acknowledge that relevant studies may have been published since we conducted our official search. However, to complete the systematic review process within the allotted timeframe, we are unable to accept studies published beyond the review search dates (i.e., September 2024).
Coverage Policy (Pregnancy)	**Medicaid Coverage Policy for GDM:** As noted in the report, Oregon Medicaid limits CGM coverage for individuals with gestational diabetes mellitus (GDM) to those using insulin. However, it is important to recognize that the majority of state Medicaid programs, such as California, New York, and Texas, extend CGM coverage to all individuals with GDM, regardless of insulin use. These 26 states collectively account for more than 70% of annual live births in the US. This	Thank you for your comment.

Comments		Response
Commenter: Hazma Alshannaq, MD, MPH, Senior Manager, Health Economics and Outcomes Research - Global Access, Dexcom		
	substantial coverage reflects a growing potential for more improved and equitable maternal and neonatal outcomes across a significant portion of the population.	
Coverage Policy **(Adults with T2D not on Insulin)**	**Payors perspective recognize the clinical value of CGM for Adults with T2D who are not on insulin therapy** The value of CGM for non-insulin users is increasingly being recognized at a national level. Recently, two of the largest Pharmacy Benefit Managers (PBMs) in the United States have started to cover CGM for all patients with T2D. This shift in coverage policy reflects a significant acknowledgment of CGM's benefits in managing diabetes more effectively across diverse patient populations, including those not dependent on insulin.	Thank you for your comment.

Comments	**Response**
Commenter: Kathaleen Briggs Early, PhD, RDN, CDCES, Professor of Nutrition, Pacific Northwest University of Health Sciences, College of Osteopathic Medicine	
General Comments:	
I would like to voice my support for the state of Washington to provide better coverage for CGM access in Washington residents. The report released Jan 9, 2025, WA Health Technology Assessment demonstrates evidence in support of improving quality of life and reduced healthcare costs for people with diabetes using CGM and I presume you are familiar with that report's findings. As a diabetes care and education specialist for almost 20 years, I witnessed the early days of CGMs when they were only covered for those with type 1 diabetes and people on intensive insulin regimens. In those early days, CGMs were only covered for people in extreme situations — such as experiencing a car accident due to a low glucose episode. More recently, we have seen CGMs being used by a variety of individuals, both with and without diabetes. However, the WA Technology Assessment Report clearly summarizes the evidence for the benefits of CGM across a variety of adult and pediatric populations with diabetes regardless of insulin status. The advantage of CGMs is that they help people understand how food, stress, physical activity, and sleep impact blood glucose. They help us teach people how to live better with a chronic condition, and more importantly, they can help reverse or prevent those chronic conditions in the first place through behavior change inducements. CGMs are more likely to be used compared to finger-stick glucose measurements, which are widely recognized as a challenging daily behavior for many people living with diabetes. Perhaps most importantly, they can help people PREVENT hyperglycemia as opposed to	Thank you for your comments and for sharing your professional experience.

Comments	Response
Commenter: Kathaleen Briggs Early, PhD, RDN, CDCES, Professor of Nutrition, Pacific Northwest University of Health Sciences, College of Osteopathic Medicine	
react to and correct hyperglycemia — in my world we call this "chasing highs" or "correcting highs" — dealing with a physiological problem after it has already occurred. Remember that chronic hyperglycemia is the leading cause of diabetes-related complications, so preventing hyperglycemia is essential in our battle against diabetes-related health care costs and diabetes-related quality of life impairments. Additionally, CGMs are an important tool in preventing and early recognition of HYPOglycemia, which is a leading cause of ER visits in WA and across the country. CGMs can show "trends" of glucose direction rapidly falling or rapidly rising thereby allowing users to take action early, before these trends become a real problem. Thank you for considering my views. I should note I submit these comments independently from my role as a faculty member at PNWU. PNWU does not endorse my comments and they are my own personal and professional views.	

Comments	Response
Commenter: Tara Cardinal, CNM, ARNP	
General Comments:	
I recommend coverage for Continuous Glucose Monitors for pregnant people with any evidence of hyperglycemia at any time in pregnancy. Glucose tests by conventional means have been inadequate to address the multitude of opportunities for early intervention and risk reduction. KQ 1: Effectiveness vs. other forms of monitoring A method that is not used cannot be effective. Significant barriers exist for individuals to poke fingers, particularly infection risk concerns, time, having necessary supplies when needed, social stigma, working conditions and ability for breaks, needle phobias among many more. With goals for glycemic control being more strict during pregnancy, mirroring normal levels, the use of continuous glucose monitoring for individuals experiencing hyperglycemia (pre- diabetes, gestational diabetes or type 2 diabetes) NOT ON MEDICATION to manage their blood sugars, continuous glucose monitors (CGM) can help us more precisely target medication start and adjustment recommendations when finger stick blood glucoses cannot. Further, we can better understand individual patterns over the course of the day and use the graphs for educational and counseling tools with patients - which is much more challenging with a few point in time measurements a day. KQ 2: I have never seen any evidence these devices are not safe. With alarms for low blood glucose, they exponentially increase safety over finger stick measurements. Pregnant and postpartum people have died of hyperglycemia unawareness and alarms for high sugars can be invaluable.	Thank you for your comments and for sharing your professional experience. Please see responses to specific points below.

Comments		Response
Commenter: Tara Cardinal, CNM, ARNP		
[Specific comments] KQ 4: Offering individuals continuous glucose monitors who are pregnant and experiencing any type of hyperglycemia (pre-diabetes, GDM or diabetes) is cost effective across the lifetime for mothers and their children. The Hyperglycemia and Adverse Pregnancy Outcomes studies have demonstrated that there is no set level of hyperglycemia before impacts can be made in the pregnancy, birth and beyond. Diabetes and comorbid associated impacts on health contribute to what we spend most of our healthcare dollars on. When we know that hyperglycemia contributes to pathophysiologic disturbances to the development of the placenta and fetus that can contribute to conditions such a preeclampsia in the pregnancy or obesity later in life AND that maintaining glucose levels as close to normal in pregnancy reduces these risks, we are profiting by using continuous glucose monitors in pregnancy. Further, as we are learning more and more about potential of epigenetic impacts on the offspring of mothers with hyperglycemia, the role these have to play on the child's future risk of metabolic disorders such as diabetes and obesity. I advocate for the Precautionary Principle and to limit exposure to factors that may cause harm until they can be better understood versus delaying care and treatment that we know is causing harm because we don't know how much of the factor is harmful. Do not hesitate to reach out with any questions, concerns or opportunities for further engagement.		
Specific Comments:		
Outcomes	KQ 3: A1c, particularly in pregnancy, is not an appropriate measure to judge when treatment or monitoring decisions could be made. Someone with normal blood glucoses can have an identical A1c to someone with severe highs and lows. I have seen this in clinical practice for someone who had blood glucose bouncing between 50's up to 300's who had an A1c of 5.4%. Additionally, the A1c is impacted in pregnancy by factors such as anemia and hemodilution of pregnancy. It is an important component to use as an adjunct to the rest of the clinical picture - especially fetal growth, biometric symmetry and blood/interstitial glucose	Thank you for your comment. In addition to A1c, we further considered patient-important outcomes such as severe hypoglycemia, quality of life, and severe perinatal events.

Comments	Response
Commenter: Timothy Cordova, Associate, Alston & Bird (on behalf of the Diabetes Technology Access Coalition)	
General Comments:	

Comments		Response
Commenter: Timothy Cordova, Associate, Alston & Bird (on behalf of the Diabetes Technology Access Coalition)		
On behalf of the Diabetes Technology Access Coalition (DTAC), please see the attached letter regarding Washington State Health Care Authority's Draft Evidence Report on continuous glucose monitors. DTAC is a cross-industry group of diabetes stakeholders. Collectively, the coalition members represent millions of Americans with diabetes, health care professionals who treat them, and major manufacturers that develop diabetes therapies, equipment, and supplies. Thus, our coalition represents those who manufacture and develop diabetes technology, the health care professionals who rely on this technology to best treat their patients, and the patients who benefit from the technologies. DTAC supports efforts to remove unnecessary coverage and access barriers to critical diabetes interventions including CGMs. In keeping with this goal, our comments to this draft evidence report address promoting access to technological interventions for individuals with diabetes that is consistent with the latest standards of care and evidence. We therefore recommend that the Authority expand the scope of its draft evidence report in two ways: (1) to consider using markers of long-term glycemic control beyond hemoglobin A1c (HbA1c); and (2) to consider prioritizing evidence that rely on real-world evidence, in addition to those that rely on randomized control trials (RCTs). Considering these additional two factors, along with the current standards of care, will support the use of CGMs among individuals with type 2 diabetes who do not use insulin. [Specific comments] We appreciate the opportunity to weigh in on this important issue and please let us know if you have any questions or if you would like to discuss further.		Thank you for your comments and for sharing your organization's views on this topic. Please see responses to specific points below.
Specific Comments:		
Outcomes	**a. Markers Selected for Long-Term Glycemic Control** Measuring optimal glycemic control must include a range of clinical measures, such as HbA1c, time in range (TIR), time below range (TBR), time above range (TAR), and the Glucose Management Indicator (GMI). Combined, these measures can provide critical insight into a patient's glycemic variability and examining only one measure in isolation is an opaque view of an individual's diabetes. Recognizing the value of examining a range of clinical measures, in a recent Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting on Devices for Self-Management of Type 1 and Insulin- Dependent Type 2 Diabetes,1 the expert panel came to a consensus that HbA1c, TIR and TBR should be emphasized as outcomes in clinical studies when assessing the evidence to support the use of CGMs. However, in its literature review, the Authority gives overwhelming weight to just one marker of optimal glycemic control: HbA1c. By focusing on HbA1c without examining other	Thank you for your comment. In the case of this review, HbA1c was selected as the primary measure of glycemic control during scope development, whereas other CGM-derived measures (i.e., TBR, TIR, TAR) were not prioritized for inclusion.

Comments		Response
Commenter: Timothy Cordova, Associate, Alston & Bird (on behalf of the Diabetes Technology Access Coalition)		
	measures of glycemic control, the Authority does not have a holistic picture of the evidence that supports the use of CGMs among the non-insulin using type 2 diabetes population. We note that studies and consensus statements validate the importance of TIR in preventing an array of diabetes complications such as retinopathy, microalbuminuria, and cardiovascular autonomic neuropathy.2Additionally, multiple RCT studies, including studies cited by the Authority,3 demonstrate that the non-insulin using type 2 diabetes population show a marked improvement in TIR when using a CGM. As such, we urge the Authority to strongly consider assessing CGM coverage by examining the literature in a holistic light that assesses critical markers of glycemic control other than HbA1c. References 1. Devices for Self-management of Type 1 and Insulin-Dependent Type 2 Diabetes, Centers for Medicare & Medicaid Services (May 21, 2024), https://www.cms.gov/medicare-coverage-database/view/medcac-meeting.aspx?medcacid=81. LEGAL02/45536390v3 2. Roy W. Beck, et. al., Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials, 42 Diabetes Care 400 (2019), https://diabetesjournals.org/care/article/42/3/400/36115/Validation-of-Time-in-Range-as-an-Outcome-Measure Qingyu Guo, 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, 2020 Journal of Diabetes Research 1 (2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7026737/; Jingyi Lu, et. al., Association of Time in Range, as Assessed by Continuous Glucose Monitoring, With Diabetic Retinopathy in Type 2 Diabetes, 41 Diabetes Care 2370 (2018), https://diabetesjournals.org/care/article/41/11/2370/36582/Association-of-Time-in-Range-as-Assessed-by; Tadej Battelino, et. al., Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range, 42 Diabetes Care 1593 (2019), https://diabetesjournals.org/care/article/42/8/1593/36	

Comments		Response
Commenter: Timothy Cordova, Associate, Alston & Bird (on behalf of the Diabetes Technology Access Coalition)		
	184/Clinical-Targets-for- Continuous-Glucose-Monitoring. 3. See, e.g., Ronnie Aronson, et. al., IMpact of flash glucose Monitoring in pEople with type 2 Diabetes Inadequately controlled with non-insulin Antihyperglycaemic ThErapy (IMMEDIATE): A randomized controlled trial, 25 Diabetes, Obesity, and Metabolism 1024 (2023), https://dom-pubs.pericles-prod.literatumonline.com/doi/10.1111/dom.14949; David A. Price, et. al., Episodic Real-Time CGM Use in Adults with Type 2 Diabetes: Results of a Pilot Randomized Controlled Trial, 12 Diabetes Therapy 2089 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8177263/	
Real-world Evidence	**b. Use of Real-World Evidence Studies** The draft evidence report relies primarily on the use of RCTs as its evidence base. While we acknowledge that RCTs remain highly valuable for testing efficacy, RCTs should be considered in conjunction with real- world evidence that is more apt at assessing effectiveness within a heterogenous population. As the Authority knows, studies have shown that there are significant disparities between the study sample in RCTs and the patient population, as racial minorities are often underenrolled in RCTs.[4] The underrepresentation of ethnic minorities in RCTs is especially critical given that ethnic minorities are disproportionately impacted by diabetes.[5] By failing to examine real-world evidence, the Authority fails to study the current literature holistically, as large real-world studies demonstrate that this population achieves equal or better results than those who currently have coverage for CGMs by virtue of using insulin. For example, a study found that among 74,679 adults with type 2 diabetes, of which 25,269 used no insulin therapy, 16,264 used basal insulin therapy only, and 33,146 used prandial insulin therapy, all subgroups saw significant reductions in all-cause hospitalizations, acute diabetes-related hospitalizations, and acute diabetes-related emergency department (ED) visits at both the six month post-index period and the six to twelve month post-index period when using a CGM.[6] In another study of 7,336 fully insured commercial and Medicare Advantage beneficiaries, researchers found that beneficiaries realized significant improvement in HbA1c after CGM initiation including a -0.9 percent change in the non-insulin using type 2 diabetes population.[7]	Thank you for your comments and for providing these references. The scope of the effectiveness review (KQs 1-3) was limited to data from published RCTs. Publications with observational study designs, such as these, were not eligible for inclusion with respect to assessment of glycemic outcomes (e.g., change in HbA1c). We reviewed these studies for potential cost outcomes (KQ4) but determined that none were eligible due to lack of relevant outcomes or publication outside of the formal search range.

Comments		Response
Commenter: Timothy Cordova, Associate, Alston & Bird (on behalf of the Diabetes Technology Access Coalition)		
	References 4. See, e.g., Halis Akturk, Inequity in Racial-Ethnic Representation in Randomized Controlled Trials of Diabetes Technologies in Type 1 Diabetes: Critical Need for New Standards, 44 Diabetes Care e121 (2021), https://diabetesjournals.org/care/article/44/6/e121/138690/Inequity-in-Racial-Ethnic-Representation-in. 5. Yiling Cheng, et. al., Prevalence of Diabetes by Race and Ethnicity in the United States, 2011-2016, 322 JAMA 2389 (2019), https://jamanetwork.com/journals/jama/fullarticle/2757817. 6. Satish Garg, et. al., Impact of continuous glucose monitoring on hospitalizations and glucose control in people with type 2 diabetes: real-world analysis, 26 Diabetes, Obesity, and Metabolism 5202 (2024), https://dom-pubs.pericles-prod.literatumonline.com/doi/10.1111/dom.15866. 7. Gregory Norman, et. al., Initiating Continuous Glucose Monitoring is Associated with Improvements in Glycemic Control and Healthcare Resource Utilization for People With Diabetes in a Large US Insured Population: A Real-World Evidence Study, 31 Journal of Managed Care and Specialty Pharmacy 15 (2025), https://www.jmcp.org/doi/10.18553/jmcp.2024.24255?.	
Clinical Practice Guidelines	**c. Applying the Most Recent Standards of Care for Diabetes** On December 9, 2025, the American Diabetes Association (ADA) updated their Standards of Care in Diabetes, which now recommends that clinicians consider using real time CGMs and intermittently scanned CGMs in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals.8 This updated recommendation stems from multiple real-world studies that show individuals with non-insulin using type 2 diabetes who use CGM achieve equal or better results than those who currently have access to CGMs by virtue of using insulin, some of which we described above. The Authority, in light of this new recommendation and considering that the draft evidence report cites to an older version of the ADA's standards of care, should reevaluate its assessment of clinical practice guidelines to reflect this recommendation. 8. Standards of Care in Diabetes – 2025, 48 Diabetes Care S1 (2025), https://diabetesjournals.org/care/issue/48/Supplement 1	Thank you for alerting us to this update of the ADA Standards of Care. Although we are unable to formally incorporate literature published beyond the search dates in our technical report, we have informed the program staff that this update is available for the purposes of comparison with the 2024 Standards of Care, which are included.

<table>
<tr><th colspan="2">Comments</th><th>Response</th></tr>
<tr><td colspan="3">Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute, including on behalf of others</td></tr>
<tr><td colspan="3">General Comments:</td></tr>
<tr><td colspan="2">Dear Members of Washington State's Health Technology Clinical Committee,

I have additional comments on the CGM 2025 report. We support increased access to continuous glucose monitoring (CGM) for Type 2 diabetes patients in our state.

[Specific comments]

Ensuring that all patients with Type 2 diabetes have access to this life-changing technology will not only improve individual health outcomes but also reduce long-term healthcare costs associated with unmanaged diabetes.

Thank you for your attention to this important matter. I look forward to your favorable response and the positive impact it will have on our community.</td><td>Thank you for your comments and for sharing your professional experience.

Please see responses to specific points below.</td></tr>
<tr><td colspan="3">Specific Comments:</td></tr>
<tr><td>Clinical Practice Guidelines</td><td>Recent advancements in CGM technology have shown significant benefits and are now standard of care according to the American Diabetes Association guidelines:

American Diabetes Association Professional Practice Committee.

7. Diabetes Technology: Standards of Care in Diabetes—2025 | Diabetes Care | American Diabetes Association

• 7.15 Recommend real-time CGM (rtCGM) A or intermittently scanned CGM (isCGM) for diabetes management to youth C and adults B with diabetes on any type of insulin therapy. The choice of CGM device should be made based on the individual's circumstances, preferences, and needs.
• 7.16 Consider using rtCGM and isCGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals B (1).</td><td>Thank you for alerting us to this update of the ADA Standards of Care.

This information was published beyond the search dates in our technical report. We informed the program staff that this update is available for the purposes of comparison with the 2024 Standards of Care, which are included.</td></tr>
<tr><td>Real-world Evidence</td><td>Real-World Clinical Data on CGM with Regional Washington State Data*

<table><tr><th>Reference</th><th>Type of Study</th><th>Duration (months)</th><th>Number of Participants</th><th>Type of Diabetes Medications</th><th>Baseline HbA1C</th><th>% HbA1C Change</th></tr><tr><td>Grace et al. (2)</td><td>Single arm prospective study</td><td>6</td><td>237</td><td>Insulin (42%) Non-</td><td>9.4%</td><td>2.4%</td></tr></table></td><td>Thank you for your comments and for providing these references.

The scope of the effectiveness review (KQs 1-3) was limited to data from published RCTs. Publications</td></tr>
</table>

Comments							Response
Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute, including on behalf of others							
				insulin (58%)			with observational study designs, such as these, were not eligible for inclusion with respect to assessment of glycemic outcomes (e.g., change in HbA1c). We reviewed these studies for potential cost outcomes (KQ4) but determined that none were eligible due to lack of relevant outcomes or publication outside of the formal search range.
	Garg et al. (3)	Retrospective cohort study	3	74,679 (6030 HbA1c analysis)	Basal insulin (60%) Non-insulin (40%)	8.8%	1.1%	
	Shields et al. (4)	Prospective cohort study	3	182 (CGM=91 C=91)	Basal insulin (35%) Non-insulin (65%)	9.2%	CGM 1.4% C 0.8%	
	*Ehrhardt et al. (5)	Randomized control trial	3	120 (CGM=61 ED=59)	Basal insulin (26%) Non-insulin (74%)	10.7%	CGM 2.4% ED 1.5% (Difference 0.9%)	
	*Vidovic et al. (9)	Dual arm prospective study	6	66 (CGM=30 C=36)	Insulin (≥1 injections)	9.0%	CGM 1.4% C 0.8% (Difference 0.6%)	
	ED= Education only, C=Control, CGM= Continuous Glucose Monitor CGM provides real-time feedback on glucose levels, enabling patients to make informed decisions about their diet, physical activity, and medication. Numerous studies show that CGM can significantly improve glycemic control, with some patients experiencing an average HbA1c reduction of 0.3-1% or more. Notably, real-world data often shows even greater improvements of HbA1c. For instance, a community CGM program reported a 2% reduction in HbA1c levels, highlighting the efficacy of this technology when barriers to access, such as pre-authorization requirements, are removed (2). A large database review examined changes in all-cause hospitalizations, diabetes-related hospitalizations, and emergency room visits within 6 and 12 months after transitioning from blood glucose monitoring to CGM for type 2 diabetes patients. Results showed reduced healthcare resource utilization and improved glucose control over one year (3). It is noteworthy that the aforementioned studies, as well as this recent prospective cohort study, were all conducted within primary care settings. Another recent study, which included basal insulin-treated (35.7%) and non-insulin-treated (64.3%) T2D patients (n=182), compared the use of continuous glucose monitoring (CGM) with usual care. The mean difference between groups demonstrated							

Comments		Response
Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute, including on behalf of others		
	a 0.5% reduction in HbA1c at three months in favor of the CGM group. Furthermore, significantly more patients in the CGM group achieved HbA1c levels below 7% and 8% at the same time point compared to the control group (9% vs. 22%, p=0.01 for HbA1c < 7%; 21% vs. 40%, p=0.04 for HbA1c < 8%) (4). I would also like to share the impact that CGM has had in our own community in Washington State. Recently, we conducted a Randomized Controlled Trial (RCT) with 120 participants in collaboration with our local Sea Mar population. The Sea Mar participants with type 2 diabetes had significant disadvantages in social determinants of health, such as lower income, food insecurity, and less education. We observed an approximate 0.9% improvement in HbA1c levels after 12 weeks of rtCGM usage, in addition to the significant improvement all participants had from diabetes education which is a cornerstone of diabetes management. However, this effect was diminished by six months when participants no longer had access to the devices. The study involved a significantly younger population with an average age of 48, where only 26% were on basal insulin, and most did not require insulin. The initial average HbA1c was above 10%, but 50% of participants using CGM achieved an HbA1c of less than 7.0% by 12 weeks, while 73% met HEDIS goals of less than 8.0% (5). There is clear evidence that improved glycemic control prevents complications. Additionally, there is increasing evidence that improvements in A1c and Time in Range, as measured by CGM, are correlated with reduced microvascular and macrovascular complications (6). Additionally, CGM has been shown to encourage healthier lifestyle behaviors. Participants in our local Sea Mar population study reported significant improvements in their daily habits. Among rtCGM users, 81% read food labels more carefully, 83% limited or excluded rice, and 78% were more likely to engage in physical activity. Furthermore, 97% of participants felt that CGM led to a healthier lifestyle overall (7).	
New Studies in Washington populations	I would also like to share the impact that CGM has had in our own community in Washington State. Recently, we conducted a Randomized Controlled Trial (RCT) with 120 participants in collaboration with our local Sea Mar population. The Sea Mar participants with type 2 diabetes had significant disadvantages in social determinants of health, such as lower income, food insecurity, and less education. We observed an approximate 0.9% improvement in HbA1c levels after 12 weeks of rtCGM usage, in addition to the significant improvement all participants had from diabetes education which is a cornerstone of diabetes management. However, this effect was diminished by six months when participants no longer had access to the devices. The study involved a significantly younger population with an	This is an area of ongoing interest and we acknowledge that relevant studies may have been published since we conducted our official search. However, to complete the systematic review process within the allotted timeframe, we are unable to accept in-press studies or

Comments		Response
Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute, including on behalf of others		
	average age of 48, where only 26% were on basal insulin, and most did not require insulin. The initial average HbA1c was above 10%, but 50% of participants using CGM achieved an HbA1c of less than 7.0% by 12 weeks, while 73% met HEDIS goals of less than 8.0% (5). There is clear evidence that improved glycemic control prevents complications. Additionally, there is increasing evidence that improvements in A1c and Time in Range, as measured by CGM, are correlated with reduced microvascular and macrovascular complications (6). Additionally, CGM has been shown to encourage healthier lifestyle behaviors. Participants in our local Sea Mar population study reported significant improvements in their daily habits. Among rtCGM users, 81% read food labels more carefully, 83% limited or excluded rice, and 78% were more likely to engage in physical activity. Furthermore, 97% of participants felt that CGM led to a healthier lifestyle overall (7). The impact of CGM extends beyond the individual to their household members. In a pilot study, family members of CGM users also reported positive lifestyle changes, with 80% becoming more active, 70% reducing sugary beverages, and 80% decreasing rice consumption (8). Another study conducted at Harborview Medical Center recruited patients with Medicaid insurance or institutional financial assistance, HbA1C >7%, and one 1 or more insulin injections per day, who were provided 6 months of CGM through a grant (9). They compared the results of this group with a "control group" of insulin treated patients who did not use CGM technology. Baseline mean HbA1c was 9.55% ±1.5 vs 8.86% ±1.78 (n = 36) in the control group. In the CGM arm, HbA1c decreased from baseline by -1.52% ± 1.76 (n=30) at 3 months and -1.35% ± 2.04 (n=27) at 6 months; in the control group A1c decreased by -0.96% ± 2.26 (n=26) at 3 months and -0.83% ± 2.49 (n=36) at 6 months. Sensor usage remained >70% throughout the study period. Mean Time In Range (70-180 mg/dL; TIR) increased from 50.14 ±24.50 % at 2 weeks to 52.90 ± 23.59 % and 56.52±23.30 % at 3 months and 6 months respectively. Mean CGM glucose decreased from 194.7 ± 47.09 mg/dL at 2 weeks to 191.50 ±43.09 and 184.55 ±36.11 mg/dL at 3 and 6 months, respectively. Mean Time Below Range (<70 and <54 mg/dL; TBR) did not change significantly (9).	those published beyond the review search dates.
Coverage Requirements	Given these compelling benefits and potential to reduce complications in the large term, I urge the Washington Health Technology Clinical Committee to consider lifting restrictions and pre-authorization requirements for CGM devices in both insulin and non-insulin requiring populations. At the very minimum, bringing patients insured by Washington State	Thank you for your comment.

Comments		Response
Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute, including on behalf of others		
	Medicaid on parity with those on Medicare is essential. To do so, the Medicaid coverage policy needs to eliminate the requirement for patients to demonstrate 4 glucose checks per day and even the use of 1 injection of insulin daily should qualify them for access to CGM technology. This is consistent with current ADA guidelines in the 2025 Standards of Care for management of diabetes, as referenced above (1).	
References	1. American Diabetes Association Professional Practice Committee. 7. Diabetes Technology: Standards of Care in Diabetes-2025. Diabetes Care. 2025 Jan 1;48(Supplement_1):S146-S166. doi: 10.2337/dc25-S007. Erratum in: Diabetes Care. 2025 Jan 23:dc25er04b. 2. Grace TP, Edgington A, Reinhart L, Burkart T, Dyer E, Halsey J, Baroudi K, Hicks C, Layne JE, Walker TC. The Dexcom Community Glucose Monitoring Project: 6-Month Results Using Continuous Glucose Monitoring in Type 2 Diabetes. Clin Diabetes. 2024 Aug 9;42(4):540-546 3. Garg SK, Hirsch IB, Repetto E, Snell-Bergeon J, Ulmer B, Perkins C, Bergenstal RM. Impact of continuous glucose monitoring on hospitalizations and glucose control in people with type 2 diabetes: real-world analysis. Diabetes Obes Metab. 2024 Nov;26(11):5202-5210. 4. Shields, S., Thomas, R., Durham, J. *et al.* Continuous glucose monitoring among adults with type 2 diabetes receiving noninsulin or basal insulin therapy in primary care. *Sci Rep* **14**, 31990 (2024). 5. Ehrhardt N, Montour, Berberian B, Comstock B, Vasconcelos A,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. Submitted manuscript to Journal of Diabetes Science and Technology January 2025; under peer review. 6. David C Mohr, Libin Zhang, Julia C Prentice, Richard E Nelson, Donglin Li, Erin Pleasants, Paul R Conlin - Association of hemoglobin A1c time in range with risk for diabetes complications: BMJ Open Diabetes Research & Care 2022;10:e002738. 7. Vidovic J, Gil D, Jones E, Berberian P, Wright L, Comstock, B, Ehrhardt N .The CUT Diabetes Trial: A Randomized Study of Culturally Tailored Diabetes Self-Care and Management Education Support (DSMES) for Type 2 Diabetes(T2DM) with and without Real-Time Continuous Glucose Monitoring (RT-	Thank you for providing these references. The listed studies do not meet inclusion criteria, but we appreciate the context that these provide.

Comments		Response
Commenter: Nicole Ehrhardt, MD, Assistant Professor of Medicine, University of Washington Diabetes Institute, including on behalf of others		
	CGM) and Its Effect on Lifestyle. Submitted abstract to American Diabetes Association Annual Meeting 2025. 8. Ehrhardt N, Gil D, Jones E, Berberian P, Vasconcelos A , Comstock B, Wright L. The CUT Diabetes Trial: A Randomized Study of Culturally Tailored Diabetes Self-Care and Management Education Support (DSMES) for Type 2 Diabetes (T2DM) with and without Real-Time Continuous Glucose Monitoring (RT-CGM), and the Impact on Household Members' Lifestyle Choices. Summited abstract to Endocrine Society Annual Meeting 2025. 9. Vidovic J, Deng A, Mitsuuchi T, Weber M, Lin J, Cheng K, Thirumalai A. Efficacy of Continuous Glucose Monitoring in Diabetes Management of Underserved Populations. Submitted abstract to Endocrine Society Annual Meeting 2025.	

Comments	Response
Commenter: Glen Felias-Christensen RN, MPH, CDCES, Diabetes Care and Education Specialist	
General Comments:	
I am a Certified Care and Diabetes Education Specialist (RN, CDCES) and experience firsthand the positive impact that Continuous Glucose Monitors (CGM's) have had on our patients. At the Community Health Center where I work, many of our patients have at least sampled a CGM and the results have been dramatic. The majority of these patients were not on insulin or were using only long-acting insulin. Below are true events that we regularly see with CGM use: • Drop of A1c levels by up to 5 points in less than a year - patients consistently report that the immediate feedback they receive makes the biggest difference in their diabetes management and consider these devices "life-changing" or "life-saving" • Patients finally able to get their surgery scheduled who have been waiting years to get their A1c levels below 8% to qualify for surgery - only after using CGM that they were able to do this, within months of using it • Patients who drop too low during sleep even on just one insulin finally feel reassured that they can be safe with CGM use and are getting better sleep, which improve blood sugar levels Activity levels increasing due to patients seeing the effects of their physical activity while using CGM - who otherwise could not be convinced of the value of exercise in managing diabetes. Then there are the patients who cannot get access to CGM because of the current requirements, who are losing hope as their blood sugar levels continue to rise even with great effort to manage their disease. Do we really want them	Thank you for your comments and for sharing your professional experience. Please see responses to specific points below.

Comments		Response
Commenter: Glen Felias-Christensen RN, MPH, CDCES, Diabetes Care and Education Specialist		
to get worse enough so they need to be on 3 shots of insulin per day? Wouldn't we rather prevent this and help them get the feedback they can get from CGM's so they don't need insulin or more of it? [Specific comments] In summary, these current requirements are burdensome, not clinically relevant, and delay access to CGMs. We need to get rid of them and give more access to CGM's!		
Specific Comments:		
Coverage Requirements (Treatment Regimen)	The use of intensive-insulin therapy (at least 3 injections per day) should not be required to obtain a CGM. We need to give more access to more individuals with diabetes who are not on intensive insulin therapy. The science shows they are clinically beneficial, and our patients have clearly demonstrated this reality.	Thank you for your comment.
Coverage Requirements (Testing Frequency)	The requirement to test at least 4 times a day before qualifying for CGM coverage is a huge barrier and completely unnecessary! It's a catch-22 for one thing, because a big part for needing CGM is because patients are unable to do this level of testing (very little blood coming out of fingers, pain from poking their fingers so many times, tremors, vision issues, poor dexterity and so on). And even when they do test this much, it still doesn't give the full picture of a patient's blood sugar levels. Who tests while they're asleep? How would you know if a patient has Dawn Phenomenon, when blood sugar rise just before waking up, if they can't poke their finger to test while they're asleep? Dawn Phenomenon can raise A1c levels and cannot be detected easily otherwise. I like to give the analogy of driving in the rain. If you only had 4 swipes of your windshield wiper for the whole day while driving, would you feel safe where you are heading? How can you see where you are going in between the swipes? This is like fingerstick BG testing. Whereas with a CGM, you get continuous swiping capacity to be able to see out of your windshield every minute. Isn't that a safer and more guaranteed way to take control of your destiny? I think all diabetic patients would like the opportunity to take this kind of control over the destiny of their diabetes through CGM use.	Thank you for your comment.

Comments	Response
Commenter: Line Goulet RN, M. Ed, BSN, CDCDES, Diabetes Education Program Coordinator, Whidbey Health	
General Comments:	
Dear Washington Heath Care Authority, Washington Health Technology Clinical Committee [Specific comments] In 2018, I was awarded Diabetes Educator of the Year for Washington State. I have been an RN since 1979. At that time, decisions for diabetes management, including insulin adjustment were made on urine testing for glucose. Microvascular and macrovascular complications were believed to be inevitable. Severe hypoglycemia was common, requiring stays in the ICU for persistent hypoglycemia. In the early 1980's, blood glucose monitors became available, cost in the 100's of dollars, and usually prescribed to individuals with Type 1 diabetes (as that was the "worse" one). It was about saving money. Even if it took 2 minutes to get results, and a very large drop of blood, this was the start of empowering people to make decisions about their self-diabetes care based on a real number. Even more exciting was the release of the DCCT trial results on the impact of lower glucose levels and A1C on people with Type 1 diabetes, years in advance of its trial completion. Why was I excited about that? In 1989 I became a diabetes educator, and then in 1991, a Certified Diabetes Educator. I was also co-chair for the 1992 the Canadian Diabetes Educator Annual Diabetes Conference held in Ottawa. One of speakers was aa researcher for the DCCT and shared those results with us. From the DCCT, the recommendation was made for having A1C below 7%. Finally, we had proof that complications were not inevitable. When people with diabetes were given the information and the tools they needed, they were able to take charge and reduce not only the risk but the prevention and progression of complications. I moved to Washington State. In 1998 our diabetes program became more structured, eventually obtaining accreditation for our Diabetes Education Program here at WhidbeyHealth. The biggest barrier then to receiving diabetes education was not having insurance. As Diabetes Educators, we are passionate about the people we work with, and diabetes can affect everyone. To manage it, people with diabetes need information, providers need information. Data is necessary for safe medication changes and overall management. The A1C alone is not enough. Data helps with behavior change and being proactive prevents complications. The expectation is that people with diabetes will jump at the chance to check their blood glucose 4 times a day is unrealistic, burdensome, and unnecessary depending on their regime. It also is not what happens in the real world for many reasons: it is pain, food insecurity, missed meals, 2 meals a day, fear of needles, forgetting to check, 4 x or more a day testing supplies not covered for more testing, difficulty obtaining enough blood, error messages, resulting in wasted strips without replacement, not having supplies at hand, diabetes burnout and diabetes distress. When I worked in Ottawa, a group of diabetes educators along with the endocrinologists trained the second-year medical students to live 2 weeks with diabetes. That meant that they had to inject saline 4 times a day, check their	Thank you for your comments and for sharing your professional experience. Please see responses to specific points below.

Comments	Response
Commenter: Line Goulet RN, M. Ed, BSN, CDCDES, Diabetes Education Program Coordinator, Whidbey Health	
glucose 4 times a day, and follow a" diabetic" diet. There were about 70 students. Out of 70 plus, 3 managed to do this for 2 weeks. Yes, that was only 3! They said sometimes they only had 2 meals, or work shifts, or went out with friends. It was eye opening to them. If a person has had diabetes for years, the last thing they want to do is more testing. To be even more unfair, depending on the insulin regime, people will be unable to meet the 4 injections requirement when taking premixed insulin such as Humulin 70/30 insulin. This is twice a day injection regime, with 2 different kinds of insulin in 1 syringe, which would be 4 injections if they were taken separately. Premixed insulin is sometimes prescribed to simplify a regime, often in older adults however it also has a higher risk of causing nocturnal hypoglycemia because the peak activity is in the middle of the night. Based on the current requirement anyone taking premixed insulin would be denied. What is even more frustrating is when person does so well because of CGM, that we can reduce doses or stop meal insulin to the point that they are only on long acting, then they no longer qualify for CGM coverage because of the decreased number of injections. So essentially, we are telling people, if you improved your A1C because of CGM, you reduce your risk of complications such as lower extremity amputations by 43%, your medication is reduced, and you are re-engaged, then your CGM won't be covered. In my practice, I have seen dramatic improvement in A1C, often decreasing 2% or more in just a few months, in people whose diabetes has been uncontrolled for years, who may or may not be injecting insulin. They see what impacts their glucose, they make changes to their breakfast choices, they stop that soda that they have once a week. They get reengaged in the diabetes management. Why should it be accessible to all people on insulin and not just intensive insulin therapy? Therapy needs to be individualized. People have different lifestyles and challenges. Here are a few examples: I have a person with Type 1 diabetes who sometimes has only one meal a day because of food insecurity, so he may only take 2 injections that day; also some people do only have 2 meals a day; I have used a sample CGM on several people who are not on insulin, but may have experienced lows, they often don't confirm a low with a BG check since they know their symptom and they treat it the low. There is then no documentation on how frequent or serious the low was. People have a tendency to keep their numbers higher because they are scared they won't wake up. I have had people tell me that they are finally sleeping. I work with cancer patients, receiving and taking steroids where they receive chemo every other week, requiring on and off again insulin injections. I had someone who kept bananas in his bathroom because when he would have a low, he had them at hand; he was afraid of falling and he was too weak to get to his kitchen downstairs. He eventually did have a serious low with seizure which he did not recover from. He did not have a CGM. Prior auths take time, and often must be appealed despite the person being on 4-6 injections, checking BG 4-6 times, having lows in the 50's and highs in the 300's because they didn't have a written log. It has to be transcribed to a form	

Comments		Response
Commenter: Line Goulet RN, M. Ed, BSN, CDCDES, Diabetes Education Program Coordinator, Whidbey Health		
from the meter memory. What if there was a day that they missed because they didn''t have their meter. Some have argued that checking blood sugars does not improve control. Indeed, there is an article published in the early 2000 that supports this and has been used by insurances to even deny more than once a day testing. However, while the Standards of Diabetes Care 2024 S127 blood glucose monitoring in non insulin therapies has not consistently shown clinical reduction in A1C, it also states it is of little benefit unless education and training is provided. People who attend diabetes education programs, have a diabetes educator and a team to help them manage diabetes do improve. It is likewise with CGM. Some will use the data very effectively, some less so, but all improved. This year a referral to a diabetes educator/education is now part of the standard at diagnosis. I believe that having broad coverage for CGM will reduce the costs through prevention of diabetes related complications such as CVD, CHF, CKD, retinopathy, neuropathy, MI, amputations, dementia, hypoglycemia. Because of clinical inertia, delay in putting people on insulin when they need it, then waiting until they go on intensive insulin therapy to cover CGM, putting barriers accessing CGM, after their diabetes has been out of control for 5 years costs all of us thousands of dollars because of need to treat and manage these complication instead of preventing them. I have a friend who has proliferative retinopathy and sees a retinal specialist ever 6 weeks for injections. We calculated that this has cost in well over $200,000 so far. His A1C was in the 9 range for years, with his CGM his A1C is <7%. I believe that all people with diabetes should have access to CGM coverage and especially when they go on insulin even if it is one injection daily. Diabetes is a disease, not a condition and not about willpower. Having data that CGM provides makes a difference in choices which will not only save money but improves quality of life. I encourage each of you who are involved in this decision to start checking your own blood sugars at least 4 times a day for the next month. Write down your numbers and what you ate. Go to Walmart, buy a Reli On Meter ($12), a lancing device $6, enough lancets for a month (125), 125 test strips, you will need 2 bottles, one of 100, and another 25 strips in a separate bottle. $18 +$5. Then imagine doing this for years. CMS Medicare removed the requirements for multiple injections and multiple testing. This should also be part of your policy.		
Specific Comments:		
Coverage Requirements	The current coverage for CGM: • Limit access to CGMs to only people with diabetes who are on intensive insulin, and, • Limit access to CGMs to those who check their blood glucose levels 4 or more times a day	Thank you for your comment.

Comments		Response
Commenter: Line Goulet RN, M. Ed, BSN, CDCDES, Diabetes Education Program Coordinator, Whidbey Health		
	I am recommending the removal of the requirement that the patient be on intensive insulin therapy to qualify for CGM and instead expand to all insulin therapy users. Current CMS guidelines removed the multiple injection requirement in 2021. Also, I recommend the removal of the requirement for the patient to test their blood glucose 4 times or more a day. My comments are below.	

Comments	Response
Commenter: Diane Hood	
General Comments:	
Please remove restrictions. I have witnessed people with frail, slender fingers are sore with even two needle tests daily. The monitors are very, very helpful. I have also witnessed caregiver in DSHS program and hospitals use aggressive pen pricks to take the blood. The meter removed this issue. Next, please allow hospital staff to use the device. Why is the glucose meter restricted in hospitals? Please remove this restriction also I would like a follow up on this effort. Thank you for what you do.	Thank you for your comments and for sharing your lived experience.

Comments	Response
Commenter: Jane King, Family Physician and Clinical IT Consultant	
General Comments:	
I appreciate the opportunity to provide comments on the Health Technology Clinical Committee's draft report reviewing evidence related to the patient populatil appreciate the opportunity to provide comments on the Health Technology Clinical Committee's draft report reviewing evidence related to the patient populations who would benefit from using CGMs. I understand that the draft report concludes: • CGMs are safe and effective devices to reduce HbA1c levels in adults with T2D on non-intensive insulin regimens compared with daily self-monitoring blood glucose (SMBG) testing. • CGMs are cost-effective for monitoring glucose levels compared with daily SMBG testing in adults with T2D using basal insulin As a doctor in a community health center I want to share my personal/ professional experiences that support these findings. Further, I urge the HTCC to view these findings as evidence of the benefits of further enhancing CGM access.	Thank you for your comments and for sharing your professional experience. Please see responses to specific points below.

Comments		Response
Commenter: Jane King, Family Physician and Clinical IT Consultant		
[Specific comments] I have personally helped several people bring their diabetes from completely out of control to well controlled using CGM data. Thank you for taking the time to read and consider my comments.		
Specific Comments:		
Coverage Requirements	Specifically, I am advocating for elimination of coverage requirements that limit access and clinical benefit to only people with diabetes who are on intensive insulin and who check their blood glucose levels four or more times a day. The findings support eliminating such requirements, given the clinical benefit that can be gained through the use of CGMs by others with diabetes. In alignment with these conclusions, I hope you will expand access to all people with diabetes who are on insulin so that we can help more Washingtonians manage their diabetes through the utilization of a continuous glucose monitor.	Thank you for your comment.

Comments	Response
Commenter: Pam Kramer, RDN, CDCES, Manager of Diabetes and Nutrition Services Ambulatory Pharmacy Services, MultiCare Health System	
General Comments:	
The Evolution of Diabetes Management: A Diabetes Educator's Perspective As a diabetes educator with nearly 40 years of experience, I've witnessed the remarkable evolution of blood glucose monitoring technology. This progression has significantly improved diabetes management and patient outcomes. Early Methods • Initially, patients used urine test strips, which indicated if blood glucose present and described simply as Negative, 100, 250, 500, >2,000 mg/dl • This method was imprecise and often led to complications due to inadequate information. First-Generation Glucometers • Required a large blood sample and a 60-120 second wait time. • The deep finger prick needed was often painful and discouraged regular testing. Improved Glucometers • While more advanced, these still required blood samples through skin puncture.	Thank you for your comments and for sharing your professional experience. These perspectives provide important context for our review of this topic.

Comments	Response
Commenter: Pam Kramer, RDN, CDCES, Manager of Diabetes and Nutrition Services Ambulatory Pharmacy Services, MultiCare Health System	

• The ongoing need for blood draws remained a barrier for many patients.
 	
Current Technology: Continuous Glucose Monitoring (CGM)
 	
• Painless and provides continuous data.
• Benefits:
  ○ Clinicians receive accurate, real-time data for better decision-making.
  ○ Patients experience both short-term and long-term health improvements.
  ○ Encourages positive behavior change, which is crucial for managing chronic diseases.
 	
Request for Medicaid Coverage
 	
CGM technology has been a game-changer in diabetes management. I strongly urge consideration for Medicaid coverage of CGM devices, as they have the potential to significantly improve the lives of many patients with diabetes.	

Comments	Response
Commenter: [redacted] PhD, ARNP, CDCES	
General Comments:	
Thank you for the extensive work involved in the review of available research regarding the effectiveness of using CGM on people with Type 2 Diabetes (T2D). I submitted a letter/opinion earlier last year and upon reviewing the results of your research continue to feel that the use of CGMs do have a niche in the treatment of people with T2D who also take insulin. My comments are based on reviews of the literature as well as my own clinical experience. I recently retired after functioning as an ARNP in WA for the past 23 years, having focused on internal medicine and diabetes. In 2005 I earned my CDCES (Certified Diabetes Care and Education Specialist). Prior to retiring, I worked in the Endocrinology Department at MAMC, and for 3 years conducted research to justify my position. During that time, 249 patients were referred to me for intensive management of their Type 2 Diabetes (T2D) 235 showed up for the initial visit. Despite assertive efforts, a significant percentage of patients were lost to follow-up, resulting in a study cohort of 150. Of the retained group, only three (3) used CGMs. Patients were taking either oral medications and/or insulin. Fifty-eight (58%) were on Lantus and 27% were also taking meal-time insulin. The equivalent information labeled as Time in Range (TIR) for CGMs is also attainable from a glucometer report. It is labeled as the Standard Deviation (SD) and the 'variance'.	Thank you for your comments and for sharing your professional experience. Please see responses to specific points below.

Comments	Response
Commenter: [redacted] PhD, ARNP, CDCES	

Admittedly, effectively managing people with Type 2 Diabetes is labor intensive. After an average of 7 visits, the average A1c dropped from 9.838 (at their initial visit) to 7.001 upon discharge from the clinic.
 	
Summary of the HTCC Findings
 	
In the report by the HTCC (p. 8), it was noted that, "adults with poorly controlled T2D on oral glucose-lowering medications, no statistically significant subgroup interaction was found according to CGM or SMBG adherence level".
 	
In my experience following such patients over 3 years, I found that, those persons whose diabetes is poorly controlled must develop a desire to manage their diabetes and establish a therapeutic relationship with a provider before meaningful improvement is consistent (regardless of the monitoring method).
 	
[Specific Comments]
 	
I would recommend the following measures be taken when the use of any CGM is considered/prescribed.
 	
CGMs should not be dispensed to individuals without active involvement by the health care provider/team. Diabetes education should be incorporated into managing all persons with diabetes. The rate of compliance in self-management is significantly improved when patients understand the disease and treatment process. I recall an adage, "If you prescribe it, you manage it".
 	
Prior to prescribing the use of a CGM, the provider would:
• Complete an assessment of
  ○ the motives of the person with T2D,
  ○ the history of following through on recommendations given by the provider
• Have the person with T2D wear a "professional CGM" during which time, the pt. would keep a diet diary.
• Conduct an analysis of the CGM results alongside the diet diary
• Discuss the findings during a follow-up appointment. Often this discussion alone is insufficient to alert the pt. where improvements need to be made.
• Understand that if a CGM reading is below 70 or above 250 a SMBG reading should be taken.
• If at that point, both the provider and pt. agree that a CGM would be useful, then a prescription would be given. There would be a follow-up visit in 3 months to determine,
• If the pt was changing their lifestyle to improve their condition
• There was compliance with medication AEB some improvement in the A1C.
 	
If use of the CGM is continued, prescriptions should be limited to 12 months after which the patient returns for re-evaluation of progress, and other diabetes related care needs, i.e. referral for annual eye exam as well as immunizations, foot exam, and medication review.	

Comments		Response
Commenter: [redacted] PhD, ARNP, CDCES		
Summary • CGMs do have a valid and important niche in the treatment of people with T2D especially those persons taking insulin. • Providers need to first consider using a short term professional CGM coupled with a dietary report before prescribing the long-term use of a CGM. • The use and cost of SMBGs can be minimal if testing measures both fasting and post-meal glucose levels. • Efforts need to be made so that prescribed CGMs are used by the intended patient and not become a saleable commodity as has been seen with glucose test strips. • When a medication or device is prescribed it needs to be managed by the prescriber. As stewards of this planet, we need to be aware of the potential waste and long- term consequences of adding to the use plastic. Thank you for being open to comments from the community, and for reading this to the end.		
Specific Comments:		
Outcomes	**CGM is safe and effective in reducing A1C in adults with T2D on non-intensive insulin regimens, compared with SBMG** The terms “safe” and “effective” need a bit more clarification. Was there a number at which device recalls, local skin reaction, or need to use an additional sensor determined? Being a sterile device, once a sensor has been inserted it cannot be reinserted elsewhere on the body. In most studies, a reduction of A1c was noted but not clearly statistically better than with SBMG.	Thank you for your close read of this topic. Our task in this systematic review was to consider the effectiveness of CGM across the body of relevant studies. To that end, we conducted a pooled analysis of changes in A1c using widely accepted methods for meta-analysis. So, while several individual studies did not demonstrate a clear statistical benefit with CGM, the aggregate finding was statistically significant. Similarly, safety findings were reviewed across the body of literature. We determined the risk of serious adverse events was low and that

Comments		Response
Commenter: [redacted] PhD, ARNP, CDCES		
		most nonserious events (as reported by study authors) were of mild severity and rarely resulted in discontinuation of CGM use.
Coverage Requirements	**The current coverage requirements: *Limit access to CGMs to only people with diabetes who are on intensive insulin,** The word "intensive" should be omitted from the requirements for CGM coverage. All patients taking insulin are at risk of hypoglycemia. Having a hypoglycemic reaction causes extreme stress to the body.	Thank you for your comment.
Coverage Requirements	***Limit access to CGMs to those who check their blood glucose levels 4 or more times a day. (see previous comment re: frequency of testing)** Regarding the cost comparison between using a CGM vs. SMBG, the practice of testing one's blood sugar 4 times per day can be both burdensome and not necessary. Patients often cannot afford to purchase extra supplies to test 4x day, because if they are not on insulin, insurance usually only covers supplies for twice daily testing. Testing two times per day can reveal enough useful information to manage non-insulin blood sugars effectively. Let me explain further. As a provider I consider the A1c, which reflects the average between the fasting blood sugar and the post meal blood sugars (the lowest and highest). If a person tests before breakfast and after breakfast i.e. the first day of the week, and then every third day, a pattern can be charted for the fasting blood sugar. On the second day and then every third day thereafter, s/he tests before and after lunch, another pattern can be studied. Finally, on the third day and every third day thereafter, the before and after dinner values are charted, within a week, both the pt. and the provider have much data on which to make changes. Limiting use of the SMBG would minimize any cost differences between using the CGM vs SMBG.	Thank you for your comment.

Comments	Response
Commenter: Cricket McCleary, UW Medicine	
Specific Comments:	

Comments		Response
Commenter: Cricket McCleary, UW Medicine		
Coverage Requirements	I have been a manager working in outpatient diabetes care for 7 years. Current criteria for Washington State Medicaid patients for getting a Continuous glucose monitor (CGM) covered requires injecting insulin 3 times a day and checking blood sugars 4 times a day. I am asking the WA Health care authority to change that to allow more patients access to this technology. The ask is to change the criteria so that patients on once daily insulin, similar to Medicare criteria, will get access to this technology. Liberalizing the criteria will allow more patients access to this technology. CGM technology is CRUCIAL for managing patients' diabetes and preventing fluctuations in blood glucose levels which cause long term damage to the body.	Thank you for your comment.

Comments	Response
Commenter: Tammy Ninh, Pharmacy Resident	
General Comments:	
My name is Tammy Ninh, I am currently a PGY1 Pharmacy Resident working in a community/ambulatory care setting. As a student and current resident that works closely with diabetic patients, I would like to share my experiences, and my patients experiences about CGM's and their importance in their care. CGM's have been important for the patients I help manage get a better sense of how their sugars are throughout the day. It has been essential to help identify and prevent further complications from their diabetes. One example is an older patient I have with type 2 diabetes in her mid-70's. She lives by herself and manages her own diabetes; the alarm alerts have been essential in helping her identify lows that occur overnight. These have alerted her to wake up and treat lows if needed and has also helped me identify that her basal insulin needed adjusting to prevent overnight hypoglycemia from occurring. Her A1c was within her goal of less than 7% and her morning FBG's were always within goal. Had we not seen the CGM data we would not have known that this was a recuring trend that was happening to her. There are several patients that also have hypoglycemia unawareness during the day, having a CGM that is able to alert patients when their blood sugar is low has also been helpful for the people around them to be aware and help the patients if needed. CGM's have also been helpful in identifying trends and patterns in patients. They also keep track of how many units of insulin they give at a certain time in day and what they eat which is helpful and easy to read and assess. This has also been helpful in identifying what adjustments to their insulin are needed, for example some patients overcorrect with their prandial insulin causing drops in their sugars.	Thank you for your comments and for sharing your professional experience.

Comments	Response
Commenter: Tammy Ninh, Pharmacy Resident	
Overall, I think CGM's have been very beneficial for my diabetes patients.	

Comments		Response
Commenter: Qaashif Panjwani, PharmD, MPH, RPH, AHEOR, Medical Outcomes Manage, Abbott Diabetes Care		
General Comments:		
Thank you for allowing us the opportunity to provide additional comments on the Washington CGM Policy that is currently in revision. We would like to respectfully provide the most updated National guidelines recommendations that are pertinent information for this policy, as well as clinical data to support the removal of the hypoglycemia and fingerstick requirements, change the hypoglycemia definition of 50mg/dL to 54 mg/dL and expansion to support CGM use in pregnancy.[1] ADA defines Level 2 hypoglycemia as a blood glucose concentration < 54 mg/dL, which is the threshold at which neuroglycopenic symptoms being to occur and requires immediate action to resolve the hypoglycemic event.[1] [Specific comments] Thank you for your consideration in allowing us to provide additional comments to the Washington CGM policy in current revision.		Thank you for your comments and for sharing your organization's views on this topic. Please see responses to specific points below.
Specific Comments:		
Clinical Practice Guidelines	**National Guideline Recommendations Summary:** • Diabetes devices should be offered to people with diabetes.[1] • CGM is recommended for all insulin using patients (pediatrics and adults) and those at risk for hypoglycemia. [1,2,3] • Consideration of CGM use for adults with type 2 diabetes on glucose-lowering agents other than insulin.[1] • Based on ADA 2025 guidelines, the ADA recommends that CGM can help achieve glycemic goals (time in range, time above range) and A1c goal in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy.[1] • Choice of the device should be individualized based on the person's needs.[1] • AACE states that use CGM metrics can be used as a surrogate to HbA1c.[2] • ADA cautions providers that if they use HbA1c alone to assess glycemic control they should do so with	Thank you for this summary of relevant clinical guidelines. We presented the most recent AACE guidance, as referenced here, in the Clinical Practice Guidelines section of our report. However, to complete the systematic review process within the allotted timeframe we are unable to accept literature published beyond the review search dates, such as the 2025 ADA Standards of Care. Considering this review limitation, we informed the program staff that this update is available

Comments		Response
Commenter: Qaashif Panjwani, PharmD, MPH, RPH, AHEOR, Medical Outcomes Manage, Abbott Diabetes Care		
	caution- they advise on the use of CGM metrics for comprehensive assessment.[1] • Lifestyle intervention and on- going glucose monitoring with CGM is preferred.[3] • CGM is highly recommended for all patients to reach glycemic goals safely.[3]	for the purposes of comparison with the 2024 ADA Standards of Care, which are included in the technical report.
Coverage Criteria	**Removal of hypoglycemia*** / adverse event requirement for coverage of CGM** a. Requiring an adverse event such as Hypoglycemia or DKA prior to coverage poses a serious health threat to the patient as both conditions are life threating, as well as hypoglycemia can cause cognitive decline. CGM is a patient safety tool where studies have demonstrated statistically significant outcomes in the reduction of hypoglycemia and DKA. [4,5] b. Being proactive regarding prevention of these life altering events improves quality of life as well as have a positive impact of reducing cost of care by preventing avoidable utilization. c. the National Organizations recommend CGM for those at risk for hypoglycemia which CMS aligned to. The reason being is that hypoglycemia is an acute event that can lead to loss of consciousness, coma, seizures and even death if left untreated[1].People using insulin or oral hypoglycemic agents (e.g. sulfonylureas, meglitinides) to manage their diabetes are at risk for this complication and can experience detrimental outcomes with the first hypoglycemic episode. Requiring a person that is utilizing a high- risk medication to first experience a hypoglycemic episode to quality for CGM, could put the person at risk for severe adverse outcomes. d. The American Diabetes Care and Education Specialists (ADCES) Diabetes Education Core Curriculum recommends teaching patients the signs, symptoms, and treatment of hypoglycemia at the time insulin or a hypoglycemic agent is initiated, rather than after the first event because of the associated risk of hypoglycemia[5]. e. There is also evidence that people with diabetes may be less adherent to hypoglycemia causing medications due to fear of hypoglycemia. CGM may be a tool to help them detect potential risk for hypoglycemia or intervene even before the hypoglycemic event occurs, reducing the risk of ED or hospital admission[6]. ***Recurrent level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L) that persist despite multiple (2 or more) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or; a history of one level 3 hypoglycemic event (glucose	Thank you for your comment.

Comments		Response
Commenter: Qaashif Panjwani, PharmD, MPH, RPH, AHEOR, Medical Outcomes Manage, Abbott Diabetes Care		
	<54mg/dL (3.0mmol/L) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia	
Coverage Criteria	**SMBG requirement (4 test-strips/day) to be eliminated in alignment with CMS's CGM criteria.** f. Requirement removed from CMS as of July 2021 g. As reported in the DIAMOND study, only 48% of the rtCGM users (T1D and T2D) were performing fingerstick testing ≥4 times per day at baseline; however, there was no association between Hb1c reductions at study end and baseline fingerstick frequency. [7] h. In a study of adult T2D patients, the mean self-reported fingerstick frequency at baseline for the BGM and rtCGM and BGM groups was 3.2 and 3.3, respectively. 2 The mean change in HbA1c at 6 months, was significantly greater in the rtCGM group (−1.0) compared with BGM users (−0.6%), P = 0.005. [8] i. A post hoc analysis of the REPLACE study shows no association between baseline BGM frequency and rtCGM outcomes. [9] j. Findings from a recent retrospective claims data analysis have also shown no association between prior BGM frequency and reductions in acute diabetes events (ADE) associated with CGM use. A cohort of 12,521 individuals with T1D and T2D experienced reductions in ADE from 0.245 to 0.132 events/patient-year (P < 0.001), with similar reductions observed in patients testing <4 and ≥4 times per day. [10] k. Only 1 out of 3 patients adhere to BGM as recommended by their HCP. [11] l. <1 out of 4 patients using insulin achieve their HbA1c target (<7%). [12]	Thank you for your comment. Under the current review scope, we assessed the effectiveness of CGM use in populations with 3 or fewer daily insulin injections (including the DIAMOND and REPLACE trials), and who may be presumed to be conducting less than 4 SMBG tests per day. The results of this analysis are included in the technical report under "Adults with T2D on Nonintensive Insulin Regimens" and will be reviewed by the HTCC.
Covered Populations	**Expansion to CGM use in pregnancy.** m. CGM indication is now expanded to include pregnancy, which will enhance care in this population.[1] n. Based on ADA 2025 guidelines, the ADA recommends that CGM can help achieve glycemic goals (time in range, time above range) and A1c goal in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy.[1] o. A randomized controlled trial found the use of CGM during pregnancy in patients with type 1 diabetes is associated with reduction in maternal hyperglycemia, more pregnancy-specific time in range, reduction in large-for-gestational-age	As described above we are unable to incorporate the 2025 ADA Standards of Care (referenced here) in our technical report as it was published beyond our review search dates.

Comments		Response
Commenter: Qaashif Panjwani, PharmD, MPH, RPH, AHEOR, Medical Outcomes Manage, Abbott Diabetes Care		
	births, infant hospital length of stay, and severe neonatal hypoglycemia. [13]	
References	1. American Diabetes Association. Diabetes Care (2025) https://doi.org/10.2337/dc25-S007 2. AACE Clinical Practice Guidelines, (2022): https://doi.org/10.1016/j.eprac.2022.08.002 3. AACE American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm – 2023 Update (2023): https://doi.org/10.1016/j.eprac.2023.02.001 4. Klimontov, V. et. al. Glucose Variability: How Does It Work? Int. J. Mol. Sci. (2021). DOI: 10.3390/ijms22157783] 5. Association of Diabetes Care and Education Specialists. Diabetes Care and Education Curriculum 3rd Edition.] 6. Trief, P. et. al. Psychosocial factors predict medication adherence in young adults with youth onset type 2 diabetes: Longitudinal results from the TODAY2 iCount study. Wiley Online Library(2023). https://doi.org/10.1111/dme.15062] 7. Ruedy KJ, Parkin CG, Riddlesworth TD, Graham C; for the DIAMOND Study Group. Continuous glucose monitoring in older adults with type 1 and type 2 diabetes using multiple daily injections of insulin: results from the DIAMOND trial. J Diabetes Sci Technol. 2017;11(6):1138-1146. DOI: 10.1177/1932296817704445 8. Beck RW, Riddlesworth TD, Ruedy K, et al. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections: a randomized trial. Ann Intern Med. 2017;167:365-374. DOI: 10.7326/M16-2855 9. 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;8:573-586. DOI: 10.1007/s13300-017-0255-6 10. Hirsch IB, Kerr MSD, Roberts GJ, et al. Utilization of continuous glucose monitors is associated with reduction in inpatient and outpatient emergency acute diabetes events regardless of prior blood test strip usage. Diabetes. 2020;69(suppl 1):875- P. 11. Vincze G, et al. Diabetes Educ. 2004;30(1):112-25. https://doi.org/10.1177/014572170403000119;	Thank you for providing these references. We were unable to incorporate any of the listed studies in our review as none met the scoped inclusion criteria or were otherwise published beyond our review search dates, but we appreciate the context that these studies provide.

Comments		Response
Commenter: Qaashif Panjwani, PharmD, MPH, RPH, AHEOR, Medical Outcomes Manage, Abbott Diabetes Care		
	12. Foster NC, et al. Diabetes Technol Ther. 2019;21(2):66-72. https://doi.org/10.1089/dia.2018.0384 13. 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 [published correction appears in Lancet. 2017 Nov 25;390(10110):2346. doi: 10.1016/S0140-6736(17)32712-5]. Lancet. 2017;390(10110):2347-2359. doi:10.1016/S0140-6736(17)32400-5.	

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:		
On behalf of the American Diabetes Association (ADA), we respectfully submit the following comments and recommendations for your consideration regarding the release of your draft report. Our objective in asking for this review was to improve access to continuous glucose monitors (CGM) for those that would clinically benefit in accordance with the current clinical evidence. We were encouraged to see the following conclusions in the report. [Specific comments] We thank the committee for considering removal of coverage barriers. Our comments and proposed recommendations reflects the American Diabetes Association's clinical evidence and aligns with CMS coverage policy in Medicare. As we mentioned previously, we would appreciate the committee's consideration to cover CGMs for non-insulin using people living with Type 2 diabetes, which would further align with ADA's most recent recommendations for 2025. People with diabetes in Washington would now be one step closer to having access to this important device, which is central to managing their diabetes.		Thank you for your comments and for sharing your organization's views on this topic. Please see responses to specific points below.
Specific Comments:		
Coverage Criteria	**Draft Report Conclusion #1: "CGMs are safe and effective devices to reduce HbA1c levels in adults with T2D on non-intensive insulin regimens compared with daily self-monitoring blood glucose (SMBG) testing."** The ADA's Standards of Care in Diabetes - 2025 recommends "real-time CGM (rtCGM) or intermittently scanned CGM (isCGM) for diabetes management to youth and adults with	Thank you for alerting us to the release of the 2025 update of the ADA Standards of Care. Although we are unable to formally incorporate literature published

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		
	diabetes on any type of insulin therapy." Randomized control trial (RCT) data from rtCGM use in individuals with type 2 diabetes on MDI, mixed therapies, and basal insulin have consistently shown reductions in A1C levels and increases in time in range. Based on the report's conclusion and the revised recommendations in ADA's Standards of Care, we respectfully ask the committee to recommend changes in coverage guidelines to support patients who are on any type of insulin therapy, not just intensive insulin therapy. We also wanted to provide information from our Standards of Care relative to your examination of CGMs for pregnant people and other adults with type 2 diabetes who do not use insulin, ADA's 2025 Standards recommend the following: "Consider using rtCGM and isCGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals."	beyond the search dates in our technical report, we have informed the HTCC staff that this update is available for the purposes of comparison with the 2024 Standards of Care, which are included.
Coverage Criteria	**Draft Report Conclusion #2: "CGMs are cost-effective for monitoring glucose levels compared with daily SMBG testing in adults with T2D using basal insulin."** Based on this conclusion, we respectfully ask the committee to change the coverage guidelines to remove the 4 times a day blood glucose checking requirements in the coverage criteria. This will align both with the ADA's Standards of Care, as well as the Medicare local coverage determination (LCD) (DL33822) for blood glucose monitors, which removed the coverage criterion for 4 times a day blood glucose testing requirement for CGM coverage on July 18, 2021. In its proposed LCD, the Centers for Medicare and Medicaid Services (CMS) stated that "CGM can be particularly useful for improving safety in patients with nocturnal hypoglycemia, hypoglycemia unawareness, and/or frequent episodes of hypoglycemia. However, there is no evidence to support that frequent self-monitoring of blood glucose ≥4 times per day as a prerequisite for initiating CGM use is predictive of improved health outcomes."[1] Proposed Local Coverage Determination (LCD): Glucose Monitors (DL33822), p. 13	Thank you for your comment.

Comments	Response
Commenter: Donna Rice, MBA, BSN, RN, CDCES, FADCES, Chief Operations Officer, DiabetesSisters, Inc.	
General Comments:	

Comments		Response
Commenter: Donna Rice, MBA, BSN, RN, CDCES, FADCES, Chief Operations Officer, DiabetesSisters, Inc.		
On behalf of DiabetesSisters, I appreciate the opportunity to provide comments on the draft report reviewing the clinical benefits of continuous glucose monitors (CGMs). As a strong advocate for those living with diabetes, I urge you to support expanded access to this life-changing technology, ensuring that all individuals—regardless of their medication regimen—can benefit from CGM use. The draft report clearly outlines the significant advantages of CGMs, including: • Their safety and effectiveness in reducing HbA1c levels in adults with type 2 diabetes (T2D) on non-intensive insulin regimens compared to self-monitoring blood glucose (SMBG) testing. • Their cost-effectiveness as a glucose-monitoring tool for adults with T2D using basal insulin. As a **Certified Diabetes Care and Education Specialist**, I have witnessed firsthand how CGMs transform diabetes management, improving glycemic control and overall quality of life. These benefits extend beyond those on intensive insulin therapy to many individuals who could better manage their condition with real-time glucose data. [Specific comments] I appreciate your time and consideration of these comments and hope you will prioritize policies that ensure more Washingtonians can manage their diabetes effectively with the help of CGM technology.		Thank you for your comments and for sharing your professional experience. Please see responses to specific points below.
Specific Comments:		
Coverage Requirements	Given these findings, I strongly urge the Health Technology Clinical Committee to remove restrictive coverage requirements that limit CGM access solely to individuals on intensive insulin therapy who check their blood glucose four or more times daily. The evidence clearly supports expanding eligibility to all individuals with diabetes who are on insulin, as broader access would lead to improved health outcomes and a reduced burden on the healthcare system.	Thank you for your comment.

Comments	Response
Commenter: Amber Robbins-Ghormley, RN, Diabetes Educator	
General Comments:	
I am a diabetes educator and every day I see continuous glucose monitors change patient behaviors for the better. I believe that more access to continuous glucose monitors for people with diabetes will ultimately save money. The sooner people change their behaviors, the less likely they are to have a costly hospital stay. When people can see what different foods do to their blood sugars with immediate feedback, they make changes. When they	Thank you for your comments and for sharing your professional experience.

Comments	Response
Commenter: Amber Robbins-Ghormley, RN, Diabetes Educator	
can see that taking their medications or exercising brings blood glucose control, they adhere to their plans. I strongly urge consideration for Medicaid coverage of CGM devices, as they have the potential to significantly improve the lives of many patients with diabetes.	

Comments	Response
Commenter: Jeb Shepard, Director of Policy, Washington State Medical Association (including on behalf of others)	
General Comments:	
On behalf of the Washington State Medical Association (WSMA) and our nearly 13,000 physician members across the state, I am writing to express support for Medicaid coverage of glucose monitoring devices for beneficiaries in our state. Apple Health has historically committed to ensuring that all beneficiaries receive necessary care, as evidenced by policies designed to expand access and reduce disparities in healthcare delivery. We applaud your efforts and offer our support per the 2024 WSMA House of Delegates Resolution as stated below: *RESOLVED, that the WSMA advocate for Medicaid to establish uniform coverage for all Medicaid beneficiaries with diabetes per current Medicare guidelines (New HOD Policy); and BE IT FURTHER* *RESOLVED, that the WSMA supports legislative efforts to ensure consistent and comprehensive coverage of Continuous Glucose Monitors for all diabetes patients across different insurance plans, including Medicaid (New HOD Policy).* Should you have any further questions on our policy, please contact our policy department anytime.	Thank you for your comments and for sharing your organization's views on this topic.

Comments	Response
Commenter: Sarah Skidmore, RN, CDCES	
General Comments:	
I am a nurse and diabetes educator with Providence in Lewis County. I strongly support the use of cgms in our Medicaid population. They are safe, result in improved A1C's and are cost effective. Over and over again, we see improved outcomes with our Medicare patients who inject insulin daily and have coverage for cgms. It is an empowering tool, spurring patients to take more control of their diabetes in terms of lifestyle change and often they end up requiring less insulin. Our Medicaid patients who inject insulin once daily should have this same access!	Thank you for your comments and for sharing your professional experience.

Comments	Response
Commenter: Sarah Skidmore, RN, CDCES	
I have worked with several elderly Medicare patients who live many miles away in small rural towns, but because they use insulin, have cgms and are able to connect their data with our clinic, we are able to do telehealth visits and help them with adjustments for their diabetes care with improved outcomes. I want the same for my patients with Medicaid coverage. I am certain they would have improved outcomes and would also be cost effective.	

Comments		Response
Commenter: Carrie S. Swift, MS, RDN, CD, BC-ADM, CDCES, FADCES		
General Comments:		
As a certified diabetes care and education specialist (CDCES), registered dietitian nutritionist (RDN) and certified dietitian (CD), practicing in Richland, WA, I've seen firsthand how CGMs have benefitted people with type 2 diabetes. I frequently hear from people that they don't want to stick their finger to check blood glucose (BG), many of them, with T2D wait until their next primary care visit, to get their lab work done rather than checking BG. Then 3 to 6 months later, they have found out their BG is elevated - contributing to diabetes complications, and increased healthcare costs. Key points from the Washington Health Care Authority (HCA) report – in support of covering CGMs: • Continuous glucose monitoring (CGM) is safe and effective to reduce hemoglobin A1C (A1C) in adults with type 2 diabetes (T2D) on non-intensive insulin regimens, compared with self- monitoring of blood glucose (SMBG) with traditional blood glucose monitoring (BGM). • CGM is cost-effective in adults with T2D using basal insulin, as compared with SMBG [Specific comments] I ask that you follow through with the requested changes to support increased coverage of cost- effective diabetes management for people with T2D in Washington State by supporting expanded coverage of CGMs. Please let me know if you have any additional questions.		Thank you for your comments and for sharing your professional experience. Please see responses to specific points below.
Specific Comments:		
Coverage Requirements	Recommendations for the request to Washington Health Care Authority (HCA): 1. Remove the requirement to be on multiple daily injections of insulin for coverage of CGM. The current CMS (Medicare) guidelines don't include the requirement of multiple daily insulin injections for coverage of CGMs for people with T2D. Therefore, the HCA should not make this a requirement.	Thank you for your comment.

Comments		Response
Commenter: Carrie S. Swift, MS, RDN, CD, BC-ADM, CDCES, FADCES		
	2. Remove the requirement for HCA members to be checking their blood glucose (BG) 4 times a day as this is not cost effective, or a recommended standard for BGM for people with T2D.	

Comments	Response
Commenter: Dawn Travelstead MS, RD, CDCES, Diabetes Educator and Dietician, Lower Elwha Health Clinic	
General Comments:	
When I started working at the Elwha clinic no one was testing their blood sugars. With a small amount of money from my diabetes grant, I started patients with A1C > 10 on the Libre sensors. I only had enough money for 8 patients. Some patients had A1c >12. MY Quality assurance data for my grant is this: Patients with A1c< 8: 2019-30% 2020-60% 2021-54% (Covid) 2022-65% 2023-61% 2024-68% I even had 3 patients in 2024 newly dx with type 2 and aic >10; by being on the Libre all with improved their aic <8, 2 even low 6. So, please consider allowing **ALL** diabetic patients, oral and insulin controlled to have the opportunity to use these. If you would like more information about my success, please let me know. I would be happy to share!	Thank you for your comments and for sharing your professional experience.

Comments	Response
Commenter: Nicole Treanor, MS, RD, CD, CDCES, Diabetes care and education specialist/Program coordinator for outpatient diabetes education, Virginia Mason Franciscan Health	
General Comments:	
My name is Nicole Treanor, MS, RD, CD, CDCES, and I am a diabetes care and education specialist and program coordinator for outpatient diabetes education at Virginia Mason Franciscan Health. Over the past eight years, I have worked	Thank you for your comments and for

Comments	Response
Commenter: Nicole Treanor, MS, RD, CD, CDCES, Diabetes care and education specialist/Program coordinator for outpatient diabetes education, Virginia Mason Franciscan Health	
in endocrinology and primary care, treating patients with type 1 diabetes (including LADA), type 2 diabetes, gestational diabetes, and pre-existing diabetes during pregnancy. I have worked with newly diagnosed individuals and those managing diabetes for decades, from highly proactive patients to those facing social or cognitive barriers to self-management. My experience also includes both early adopters of diabetes technology and those hesitant due to cost or uncertainty. The majority of my patients use some form of continuous glucose monitoring (CGM), along with health apps, smart pens, or insulin pump therapy. I am often their first introduction to this technology, providing education and troubleshooting. This firsthand experience has reinforced my belief in the benefits of CGM for diabetes management. Beyond my clinical role, I have volunteered with the Washington Coordinating Body for the Association of Diabetes Care and Education Specialists since 2020, serving as a local networking group lead and, since 2022, as chair. I have also led or co-chaired the last three state education conferences and partnered with the Washington State Pharmacy Association to provide virtual diabetes education events. My focus has been on equipping healthcare professionals with the confidence and knowledge to support CGM use. I have also participated in the Foundation for Quality Health Care's Bree Collaborative committee which created a report and guidelines for Best Practices in Diabetes Care. https://www.qualityhealth.org/bree/diabetes-care/ With the above as my background, I did not come to this profession with a personal connection to diabetes. But in the past 10+ years, I have now developed personal connections to many people living with diabetes and have become very passionate about supporting people with diabetes. I have absorbed their experiences and emotions and feel deeply for anyone living with a chronic illness such as diabetes, that requires all-day attention and the complexity of making medical decisions several times a day [Specific comments] Many patients have struggled for years to implement behavioral changes despite repeated counseling. When given the opportunity to use CGM, they gain immediate, personal insight into how food, activity, and medication impact their glucose levels. This leads to meaningful behavior change, resulting in lower glucose levels, improved A1C, increased Time in Range, and weight loss. CGM empowers individuals to take control of their health. Patients with physical or intellectual disabilities may struggle with traditional glucose monitoring methods. For those not yet on insulin, this lack of monitoring can lead to poor disease management and progression. CGM offers an accessible alternative to help them maintain better health. Additionally, caregivers play a critical role in diabetes management, often juggling work and other responsibilities. CGM allows them to remotely monitor their loved one's glucose data, improving safety and peace of mind.	sharing your professional experience. Please see responses to specific points below.

Comments		Response
Commenter: Nicole Treanor, MS, RD, CD, CDCES, Diabetes care and education specialist/Program coordinator for outpatient diabetes education, Virginia Mason Franciscan Health		
CGM drives behavior change and improves clinical outcomes. I urge the HTCC to remove barriers to CGM eligibility and include it on the HCA preferred drug list. Expanding access will improve individual health and contribute to better public health outcomes in diabetes care.		
Specific Comments:		
Coverage Criteria (Populations)	The HTCC draft report supports CGM use for individuals on insulin therapy, a recommendation I strongly agree with. Regardless of insulin regimen - once-daily, mixed, multiple daily injections, or pump therapy- patients face hypoglycemia risk and benefit from CGM's continuous monitoring and alerts. I encourage the committee to expand CGM access to patients not on insulin, including those with type 2 diabetes on oral or non-insulin injectable medications, as well as individuals with gestational diabetes and pre-existing type 2 diabetes during pregnancy.	Thank you for your comments.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Comments on Continuous Glucose Monitors: New Populations Draft Evidence Report
Date: Friday, February 7, 2025 5:03:21 PM
Attachments: Dexcom Comments on WA HTA.pdf

External Email

Dear Washington State Health Care Authority,

Attached are our public comments on the Continuous Glucose Monitors- New Populations Draft Evidence Report.

Best Regards,

Thank you!

Hamza Alshannaq, MD, MPH:: DEXCOM
Senior Manager-Health Economics & Outcomes Research | Global Access
[redacted]

dexcom

[redacted]

February 07, 2025

RE: Public Comments on Continuous Glucose Monitors- New Populations Draft Evidence Report

To the Washington State Health Care Authority,

Dexcom appreciates the Washington State Health Care Authority's positive recommendations for CGM use in all insulin-treated individuals and supports efforts to expand access to this life-changing technology.

However, we are concerned that the non-insulin-treated (NIT) Type 2 diabetes population was not included in the positive recommendation. A growing body of randomized controlled trials and real-world studies consistently demonstrates that CGM improves glycemic control, weight management, and overall treatment satisfaction in NIT populations. The American Diabetes Association (ADA) now recommends CGM for adults with Type 2 diabetes on glucose-lowering medications, regardless of insulin use, reflecting its broader clinical value.

We hope these insights will be incorporated into the final assessment to ensure equitable access to CGM for all eligible populations. We appreciate the opportunity to provide input and look forward to continued collaboration.

Sincerely,

Greg Norman, PhD
Senior Director of Health Economics & Outcomes Research
Global Access & Evidence
Dexcom, Inc.
[redacted]

dexcom

[redacted]

Comments on Continuous Glucose Monitors: New Populations Draft Evidence Report

Key Questions	Comments on Results and Recommendations
KQ1a) Clinical Effectiveness in Adults with T2D on Oral Hypoglycemic Medications	**New RCT Evidence Published:** We recognize that the scope of the literature review covers only studies published before September 2024. However, an additional RCT that meets the inclusion criteria, including sufficient CGM use, and shows significant reductions in HbA1c has recently been published; including this more recent RCT could change the review recommendations. This is particularly important given that when the GLIMPSE trial was excluded from the meta-analysis in the report, CGM was found to be more effective for T2D individuals on oral hypoglycemic medications. **a. Lau et al. 2024** (Available Online October 19, 2024): This RCT enrolled 105 participants with T2D not on insulin who were randomized to CGM with telemonitoring vs. enhanced usual care. The results showed that, after adjusting for baseline HbA1c, CGM was superior (0.65% greater HbA1c reduction [95 % CI 0.17–1.12%], p = 0.008). CGM participants were 92% (RR = 1.92, 1.19–3.06, p = 0.007) more likely to have an HbA1c reduction ≥ 0.5%, lose more weight (difference in weight reduction 2.17 kg, 0.22–4.11, p = 0.029) and were more satisfied with their treatment. **RWE Demonstrates CGM Efficacy Across Patient Populations:** Real-world evidence (RWE) further substantiates the effectiveness of CGM in managing T2D, with several studies evaluating outcomes for both insulin-treated and non-insulin therapy (NIT) populations. Notably, these studies have often revealed that CGM is equally, if not more, effective in NIT populations. Several RWE studies have shown significant reductions in HbA1c, ranging from -0.4% to -2.3%. Wright et al. (2021) explored glycemic outcomes among T2D patients on basal insulin and NIT; both groups showed a significant reduction in HbA1c with a higher reduction in the NIT versus basal insulin group (1.6% vs 1.1%). The findings from Wright et al. (2021) and other retrospective studies highlight that T2D individuals on NIT often achieve greater HbA1c reductions than those on insulin therapy (Norman et al., 2024; Garg et al., 2024; Shields et al., 2023; Bergenstal et al., 2021). Garg et al. (2024), using OPTUM Market

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	Clarity data, reported that people treated with NIT achieved higher HbA1c reductions compared to patients treated with prandial insulin (-1.1% vs. -0.9%) despite having lower baseline HbA1c levels (8.6% vs. 9.0%). Norman et al. (2024) examined HbA1c changes using Aetna's administrative claims data, including commercially insured and Medicare Advantage beneficiaries. This study found that T2D NIT individuals had a higher decline in HbA1c (-0.9%) than T2D individuals on intensive insulin therapy (IIT; -0.05%) and non-intensive insulin therapy (NIIT; -0.7%). In a retrospective analysis using electronic health records and administrative claims, Shields et al., (2023) reported a -1.13% reduction in HbA1c among T2D NIT primary care patients with baseline HbA1c >7.5% compared to a -0.76% reduction in T2D primary care patients on IIT with baseline HbA1c >7.5%. These findings suggest that patients undergoing IIT typically exhibit more advanced diabetes, marked by substantial insulin resistance and deficiency. Consequently, their treatment targets are often moderated to lower the risk of hypoglycemia and manage comorbid conditions, necessitating less aggressive glycemic goals than NIT patients. In contrast, NIT patients usually have less severe disease and better-preserved beta-cell function, which allows for more significant reductions in HbA1c when using interventions like CGM. These observations advocate for the early adoption of CGM in the disease course for NIT patients to optimize glycemic control to potentially prevent or slow disease progression. Implementing CGM early could help address glycemic variability and prevent complications at a more manageable disease stage, potentially improving long-term outcomes. **References:** 1. Norman G, Fernandes J, Nemlekar P, Andrade SB, Lupton L, Berk A. Initiating Continuous Glucose Monitoring is Associated with Improvements in Glycemic Control and Reduced Healthcare Resource Utilization for People with Diabetes in a Large US Insured Population: A Real-World Evidence Study. *JMCP*. 2024; TBD 2. Garg SK, Hirsch IB, Repetto E, et al. Impact of continuous glucose monitoring on hospitalizations and glucose control in people with type 2 diabetes: real-world analysis. *Diabetes Obes Metab*. Nov 2024;26(11):5202-5210. doi:10.1111/dom.15866 3. Shields S, Norman GJ, Thomas R, Ciemins EL. HbA1c Improvements After Initiation of Real-Time Continuous Glucose Monitoring in Primary Care Patients With Type 2 Diabetes. *J Diabetes Sci Technol*. Sep 2023;17(5):1423-1424. doi:10.1177/19322968231171176

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[redacted]

	4. Bergenstal RM, Layne JE, Zisser H, et al. Remote Application and Use of Real-Time Continuous Glucose Monitoring by Adults with Type 2 Diabetes in a Virtual Diabetes Clinic. *Diabetes Technol Ther*. Nov 5 2021;23(4):128-132. doi:10.1089/dia.2020.0396 5. Fonseca VA. Defining and characterizing the progression of type 2 diabetes. *Diabetes Care*. Nov 2009;32 Suppl 2(Suppl 2):S151-6. doi:10.2337/dc09-S301 6. Cosentino F, Grant PJ, Aboyans V, et al. 2019 ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD: The Task Force for diabetes, pre-diabetes, and cardiovascular diseases of the European Society of Cardiology (ESC) and the European Association for the Study of Diabetes (EASD). *European Heart Journal*. 2019;41(2):255-323. doi:10.1093/eurheartj/ehz486 7. American Diabetes Association Professional Practice Committee 6. Glycemic Goals and Hypoglycemia: Standards of Care in Diabetes—2024. *Diabetes Care*. 2023;47(Supplement_1):S111-S125. doi:10.2337/dc24-S006 8. American Diabetes Association Professional Practice Committee 7. Diabetes Technology: Standards of Care in Diabetes—2025. *Diabetes Care*. 2024;48(Supplement_1):S146-S166. doi:10.2337/dc25-S007
New American Diabetes Association guidelines on CGM use in non-insulin populations	The American Diabetes Association (ADA) has recently updated its guidelines for the use of CGM systems, reflecting evolving evidence and expanding the utility of this technology across broader patient populations. The 2025 Standards of Care now recommend the consideration of real-time CGM and intermittently scanned CGM for adults with T2D who are treated with glucose-lowering medications other than insulin. This change underscores the recognized benefits of CGM in helping achieve and maintain individualized glycemic targets effectively. **Recommendations 7.16** "Consider using rtCGM and isCGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals. The choice of device should be made based on the individual's circumstances, preferences, and needs. B" [8] The ADA strengthened recommendations for CGM use in pregnancy for individuals with T1D and recognized its potential benefit in other types of diabetes in pregnancy.

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	Recommendation 7.18 "*CGM can help achieve glycemic goals (e.g., time in range and time above range) A and A1C goal B in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy. E*" References: American Diabetes Association Professional Practice Committee; 7. Diabetes Technology: Standards of Care in Diabetes—2025. *Diabetes Care* 1 January 2025; 48 (Supplement_1): S146–S166. https://doi.org/10.2337/dc25-S007
KQ4) Economic evaluations and reduction in healthcare resource utilization after initiation of CGM use	**CGM use results in significant reduction in costs and healthcare resource utilization (HCRU)**: Key Question 4 aimed to evaluate the costs and cost-effectiveness of CGM for the T2D population. However, we believe that the assessment should have included multiple U.S.-based studies that examined costs and HCRU outcomes following the initiation of CGM, particularly those based on real-world data. Real-world outcomes and claims data are invaluable resources for monitoring cost trends and disease burden. For instance, the 2024 study by Garg et al. provides evidence of CGM's potential economic benefits in a diverse cohort of adults with T2D. This retrospective analysis utilized data from over 79 million people to demonstrate significant decreases in all-cause hospitalizations and acute diabetes-related emergency room visits after transitioning to CGM. These findings suggest substantial cost savings and underscore the importance of including real-world studies in economic assessments to fully capture the cost-effectiveness of CGM in managing T2D. Emerging evidence further supports the cost-effectiveness of CGM use in the NIT population. A recent analysis, accepted for presentation at the 2025 Advanced Technologies & Treatments for Diabetes (ATTD) conference, but not yet published, demonstrates that CGM is cost-effective from a Canadian public payer perspective. Moreover, the study suggests that CGM could potentially yield cost-savings when considering indirect societal costs. **References** o Garg SK, Hirsch IB, Repetto E, et al. Impact of continuous glucose monitoring on hospitalizations and glucose control in people with type 2 diabetes: real-world analysis. *Diabetes Obes Metab*. 2024;26(11):5202-5210. doi:10.1111/dom.15866 o Alshannaq H, Cost-effectiveness of Real-Time CGM in indivdiuals with Type 2 diabetes not using Insulin. Advanced Technologies & Treatments for Diabetes (ATTD 2025)

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CGM use in Pregnancy: ADA 2025 Clinical Guidelines Updates and Medicaid States Coverage Policy	**Medicaid Coverage Policy for GDM**: As noted in the report, Oregon Medicaid limits CGM coverage for individuals with gestational diabetes mellitus (GDM) to those using insulin. However, it is important to recognize that the majority of state Medicaid programs, such as California, New York, and Texas, extend CGM coverage to all individuals with GDM, regardless of insulin use. These 26 states collectively account for more than 70% of annual live births in the US. This substantial coverage reflects a growing potential for more improved and equitable maternal and neonatal outcomes across a significant portion of the population. **The ADA strengthened recommendations for CGM use in pregnancy** for individuals with T1D and recognized its potential benefit in other types of diabetes in pregnancy. **Recommendation 7.18** "*CGM can help achieve glycemic goals (e.g., time in range and time above range) A and A1C goal B in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy. E*" The current assessment of CGM use in GDM relies primarily on randomized controlled trials (RCTs), which, while valuable, are limited in detecting meaningful differences in maternal and fetal outcomes. These outcomes—particularly maternal and neonatal complications and long-term health effects—require larger sample sizes and longer follow-up periods for accurate assessment. The lack of statistical significance in some findings does not indicate a lack of clinical benefit but reflects the challenges of studying pregnancy-related health measures. Incorporating real-world evidence (RWE) alongside RCT data would provide a more comprehensive and policy-relevant evaluation of CGM's impact. We encourage the Washington HTA to consider these research challenges and integrate RWE with RCT findings to better assess CGM's value in GDM. **References**: American Diabetes Association Professional Practice Committee; 7. Diabetes Technology: Standards of Care in Diabetes—2025. *Diabetes Care* 1 January 2025; 48 (Supplement_1): S146–S166. https://doi.org/10.2337/dc25-S007

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Payors perspective recognize the clinical value of CGM for Adults with T2D who are not on insulin therapy	The value of CGM for non-insulin users is increasingly being recognized at a national level. Recently, two of the largest Pharmacy Benefit Managers (PBMs) in the United States have started to cover CGM for all patients with T2D. This shift in coverage policy reflects a significant acknowledgment of CGM's benefits in managing diabetes more effectively across diverse patient populations, including those not dependent on insulin.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: CGM access public comment
Date: Friday, January 10, 2025 8:54:32 AM

External Email

Hello. I would like to voice my support for the state of Washington to provide better coverage for CGM access in Washington residents. The report released Jan 9, 2025, WA – Health Technology Assessment – demonstrates evidence in support of improving quality of life and reduced healthcare costs for people with diabetes using CGM and I presume you are familiar with that report's findings.

As a diabetes care and education specialist for almost 20 years, I witnessed the early days of CGMs – when they were only covered for those with type 1 diabetes and people on intensive insulin regimens. In those early days, CGMs were only covered for people in extreme situations – such as experiencing a car accident due to a low glucose episode.

More recently, we have seen CGMs being used by a variety of individuals, both with and without diabetes. However, the WA Technology Assessment Report clearly summarizes the evidence for the benefits of CGM across a variety of adult and pediatric populations with diabetes – regardless of insulin status. The advantage of CGMs is that they help people understand how food, stress, physical activity, and sleep impact blood glucose. They help us teach people how to live better with a chronic condition, and more importantly, they can help reverse or prevent those chronic conditions in the first place through behavior change inducements. CGMs are more likely to be used compared to finger-stick glucose measurements, which are widely recognized as a challenging daily behavior for many people living with diabetes. Perhaps most importantly, they can help people PREVENT hyperglycemia as opposed to react to and correct hyperglycemia – in my world we call this "chasing highs" or "correcting highs" – dealing with a physiological problem after it has already occurred. Remember that chronic hyperglycemia is the leading cause of diabetes-related complications, so *preventing* hyperglycemia is essential in our battle against diabetes-related health care costs and diabetes-related quality of life impairments. Additionally, CGMs are an important tool in preventing and early-recognition of HYPOglycemia, which is a leading cause of ER visits in WA and across the country. CGMs can show "trends" of glucose direction – rapidly falling or rapidly rising – thereby allowing users to take action early, before these trends become a real problem.

Thank you for considering my views. I should note – I submit these comments independently from my role as a faculty member at PNWU. PNWU does not endorse my comments and they are my own personal and professional views.

Thank you.

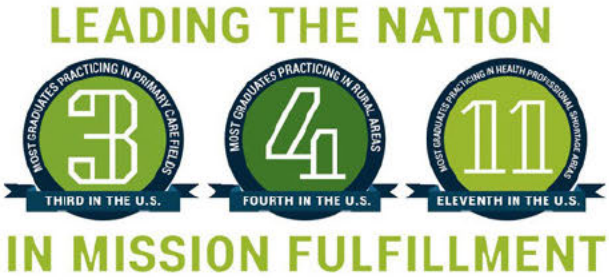
Kathaleen Briggs Early, PhD, RDN, CDCES (she/her) Why is this important?
Professor of Nutrition
Registered Dietitian Nutritionist, Certified Diabetes Care and Education Specialist

Registered Yoga Teacher – RYT500
Pacific Northwest University of Health Sciences | College of Osteopathic Medicine
[redacted]

Nutrition is not an opinion – it's a science.

Health is about much more than the absence of disease. It is about jobs, environment, education, economics, religion, politics, community, family and social well-being. –Dr. Joycelyn Elders, Former U.S. Surgeon General

If we are ever going to get to equity, we have to walk through truth, even when its unpleasant, even when it makes us uncomfortable. –Dr. Donald Warne, Associate Dean of Diversity, Equity and Inclusion; Director of the Indians Into Medicine (INMED) and Public Health Programs, and Professor of Family and Community Medicine at the School of Medicine and Health Sciences at the University of North Dakota.



From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: CGM comments
Date: Friday, February 7, 2025 4:59:49 PM

External Email

I recommend coverage for Continuous Glucose Monitors for pregnant people with any evidence of hyperglycemia at any time in pregnancy.
Glucose tests by conventional means have been inadequate to address the multitude of opportunities for early intervention and risk reduction.
Please see responses below.
Do not hesitate to reach out with any questions, concerns or opportunities for further engagement.
Respectfully,
Tara Cardinal, CNM, ARNP

KQ 1: Effectiveness vs. other forms of monitoring
A method that is not used cannot be effective. Significant barriers exist for individuals to poke fingers, particularly infection risk concerns, time, having necessary supplies when needed, social stigma, working conditions and ability for breaks, needle phobias among many more. With goals for glycemic control being more strict during pregnancy, mirroring normal levels, the use of continuous glucose monitoring for individuals experiencing **hyperglycemia (pre-diabetes, gestational diabetes or type 2 diabetes)** NOT ON MEDICATION to manage their blood sugars, continuous glucose monitors (CGM) can help us more precisely target medication start and adjustment recommendations when finger stick blood glucoses cannot. Further, we can better understand individual patterns over the course of the day and use the graphs for educational and counseling tools with patients – which is much more challenging with a few point in time measurements a day.

KQ 2: I have never seen any evidence these devices are not safe. With alarms for low blood glucose, they exponentially increase safety over finger stick measurements. Pregnant and postpartum people have died of hyperglycemia unawareness and alarms for high sugars can be invaluable.

KQ 3: A1c, particularly in pregnancy, is not an appropriate measure to judge when treatment or monitoring decisions could be made. Someone with normal blood glucoses can have an identical A1c to someone with severe highs and lows. I have seen this in clinical practice for someone who had blood glucose bouncing between 50's up to 300's who had an A1c of 5.4%. Additionally, the A1c is impacted in pregnancy by factors such as anemia and hemodilution of pregnancy. It is an important component to use as an adjunct to the rest of the clinical picture - especially fetal growth, biometric symmetry and blood/interstitial glucose

KQ 4: Offering individuals continuous glucose monitors who are pregnant and experiencing any type of hyperglycemia (pre-diabetes, GDM or diabetes) is cost effective across the lifetime for mothers and their children. The Hyperglycemia and Adverse Pregnancy Outcomes studies have demonstrated that there is no set level of hyperglycemia before impacts can be made in the pregnancy, birth and beyond.

Diabetes and comorbid associated impacts on health contribute to the what we spend most of our healthcare dollars on. When we know that hyperglycemia contributes to pathophysiologic disturbances to the development of the placenta and fetus that can contribute to conditions such a preeclampsia in the pregnancy or obesity later in life AND that maintaining glucose levels as close to normal in pregnancy reduces these risks, we are profiting by using continuous glucose monitors in pregnancy. Further, as we are learning more and more about potential of epigenetic impacts on the offspring of mothers with hyperglycemia, the role these have to play on the child's future risk of metabolic disorders such as diabetes and obesity. I advocate for the Precautionary Principle and to limit exposure to factors that may cause harm until they can be better understood versus delaying care and treatment that we know is causing harm because we don't know how much of the factor is harmful.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Diabetes Technology Access Coalition"s Comments to CGM Draft Evidence Report
Date: Friday, February 7, 2025 7:35:50 AM
Attachments: DTAC Comments to Washington State Health Care Authority CGM Draft Evidence Report.pdf

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External Email

On behalf of the Diabetes Technology Access Coalition (DTAC), please see the attached letter regarding Washington State Health Care Authority's Draft Evidence Report on continuous glucose monitors.

DTAC is a cross-industry group of diabetes stakeholders. Collectively, the coalition members represent millions of Americans with diabetes, health care professionals who treat them, and major manufacturers that develop diabetes therapies, equipment, and supplies. Thus, our coalition represents those who manufacture and develop diabetes technology, the health care professionals who rely on this technology to best treat their patients, and the patients who benefit from the technologies.

We appreciate the opportunity to weigh in on this important issue and please let us know if you have any questions or if you would like to discuss further.

Timothy Cordova
Associate
ALSTON & BIRD
[redacted]

February 7, 2025

Via email to shtap@hca.wa.gov

Health Technology Clinical Committee
Washington State Health Care Authority
Cherry Street Plaza
626 8th Avenue S.E.
Olympia, WA 98501

RE: Comments to the Washington State Health Care Authority's Draft Evidence Report on Continuous Glucose Monitors

Dear Members of the Health Technology Clinical Committee,

The Diabetes Technology Access Coalition (DTAC) appreciates the opportunity to provide comments to the Washington State Health Care Authority's (Authority) Draft Evidence Report on continuous glucose monitors (CGMs). DTAC is a cross-industry group of diabetes stakeholders. Collectively, the coalition members represent millions of Americans with diabetes, health care professionals who treat them, and major manufacturers that develop diabetes therapies, equipment, and supplies. Thus, our coalition represents those who manufacture and develop diabetes technology, the health care professionals who rely on this technology to best treat their patients, and the patients who benefit from the technologies.

DTAC supports efforts to remove unnecessary coverage and access barriers to critical diabetes interventions including CGMs. In keeping with this goal, our comments to this draft evidence report address promoting access to technological interventions for individuals with diabetes that is consistent with the latest standards of care and evidence. We therefore recommend that the Authority expand the scope of its draft evidence report in two ways: (1) to consider using markers of long-term glycemic control beyond hemoglobin A1c (HbA1c); and (2) to consider prioritizing evidence that rely on real-world evidence, in addition to those that rely on randomized control trials (RCTs). Considering these additional two factors, along with the current standards of care, will support the use of CGMs among individuals with type 2 diabetes who do not use insulin.

a. Markers Selected for Long-Term Glycemic Control

Measuring optimal glycemic control must include a range of clinical measures, such as HbA1c, time in range (TIR), time below range (TBR), time above range (TAR), and the Glucose Management Indicator (GMI). Combined, these measures can provide critical insight into a patient's glycemic variability and examining only one measure in isolation is an opaque view of an individual's diabetes. Recognizing the value of examining a range of clinical measures, in a recent Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting on Devices for Self-Management of Type 1 and Insulin-Dependent Type 2 Diabetes,[1] the expert panel came to a consensus that HbA1c, TIR and TBR should be emphasized as outcomes in clinical studies when assessing the evidence to support the use of CGMs.

However, in its literature review, the Authority gives overwhelming weight to just one marker of optimal glycemic control: HbA1c. By focusing on HbA1c without examining other measures of glycemic control, the Authority does not have a holistic picture of the evidence that supports the use of CGMs among the

[1] *Devices for Self-management of Type 1 and Insulin-Dependent Type 2 Diabetes*, Centers for Medicare & Medicaid Services (May 21, 2024), https://www.cms.gov/medicare-coverage-database/view/medcac-meeting.aspx?medcacid=81.

non-insulin using type 2 diabetes population. We note that studies and consensus statements validate the importance of TIR in preventing an array of diabetes complications such as retinopathy, microalbuminuria, and cardiovascular autonomic neuropathy.[2]Additionally, multiple RCT studies, including studies cited by the Authority,[3] demonstrate that the non-insulin using type 2 diabetes population show a marked improvement in TIR when using a CGM. As such, we urge the Authority to strongly consider assessing CGM coverage by examining the literature in a holistic light that assesses critical markers of glycemic control other than HbA1c.

b. Use of Real-World Evidence Studies

The draft evidence report relies primarily on the use of RCTs as its evidence base. While we acknowledge that RCTs remain highly valuable for testing efficacy, RCTs should be considered in conjunction with real-world evidence that is more apt at assessing effectiveness within a heterogenous population. As the Authority knows, studies have shown that there are significant disparities between the study sample in RCTs and the patient population, as racial minorities are often underenrolled in RCTs.[4] The underrepresentation of ethnic minorities in RCTs is especially critical given that ethnic minorities are disproportionately impacted by diabetes.[5]

By failing to examine real-world evidence, the Authority fails to study the current literature holistically, as large real-world studies demonstrate that this population achieves equal or better results than those who currently have coverage for CGMs by virtue of using insulin. For example, a study found that among 74,679 adults with type 2 diabetes, of which 25,269 used no insulin therapy, 16,264 used basal insulin therapy only, and 33,146 used prandial insulin therapy, all subgroups saw significant reductions in all-cause hospitalizations, acute diabetes-related hospitalizations, and acute diabetes-related emergency department (ED) visits at both the six month post-index period and the six to twelve month post-index period when using a CGM.[6] In another study of 7,336 fully insured commercial and Medicare Advantage beneficiaries, researchers found that beneficiaries realized significant improvement in HbA1c after CGM initiation including a -0.9 percent change in the non-insulin using type 2 diabetes population.[7]

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[2] Roy W. Beck, et. al., *Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials*, 42 Diabetes Care 400 (2019), https://diabetesjournals.org/care/article/42/3/400/36115/Validation-of-Time-in-Range-as-an-Outcome-Measure; Qingyu Guo, 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*, 2020 Journal of Diabetes Research 1 (2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7026737/; Jingyi Lu, et. al., *Association of Time in Range, as Assessed by Continuous Glucose Monitoring, With Diabetic Retinopathy in Type 2 Diabetes*, 41 Diabetes Care 2370 (2018), https://diabetesjournals.org/care/article/41/11/2370/36582/Association-of-Time-in-Range-as-Assessed-by; Tadej Battelino, et. al., *Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range*, 42 Diabetes Care 1593 (2019), https://diabetesjournals.org/care/article/42/8/1593/36184/Clinical-Targets-for-Continuous-Glucose-Monitoring.

[3] See, e.g., Ronnie Aronson, et. al., *IMpact of flash glucose Monitoring in pEople with type 2 Diabetes Inadequately controlled with non-insulin Antihyperglycaemic ThErapy (IMMEDIATE): A randomized controlled trial*, 25 Diabetes, Obesity, and Metabolism 1024 (2023), https://dom-pubs.pericles-prod.literatumonline.com/doi/10.1111/dom.14949; David A. Price, et. al., *Episodic Real-Time CGM Use in Adults with Type 2 Diabetes: Results of a Pilot Randomized Controlled Trial*, 12 Diabetes Therapy 2089 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8177263/.

[4] See, e.g., Halis Akturk, *Inequity in Racial-Ethnic Representation in Randomized Controlled Trials of Diabetes Technologies in Type 1 Diabetes: Critical Need for New Standards*, 44 Diabetes Care e121 (2021), https://diabetesjournals.org/care/article/44/6/e121/138690/Inequity-in-Racial-Ethnic-Representation-in.

[5] Yiling Cheng, et. al., *Prevalence of Diabetes by Race and Ethnicity in the United States*, 2011-2016, 322 JAMA 2389 (2019), https://jamanetwork.com/journals/jama/fullarticle/2757817.

[6] Satish Garg, et. al., *Impact of continuous glucose monitoring on hospitalizations and glucose control in people with type 2 diabetes: real-world analysis*, 26 Diabetes, Obesity, and Metabolism 5202 (2024), https://dom-pubs.pericles-prod.literatumonline.com/doi/10.1111/dom.15866.

[7]Gregory Norman, et. al., *Initiating Continuous Glucose Monitoring is Associated with Improvements in Glycemic Control and Healthcare Resource Utilization for People With Diabetes in a Large US Insured Population: A Real-World Evidence Study*, 31 Journal of Managed Care and Specialty Pharmacy 15 (2025), https://www.jmcp.org/doi/10.18553/jmcp.2024.24255?.

c. Applying the Most Recent Standards of Care for Diabetes

On December 9, 2025, the American Diabetes Association (ADA) updated their Standards of Care in Diabetes, which now recommends that clinicians consider using real time CGMs and intermittently scanned CGMs in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals.[8] This updated recommendation stems from multiple real-world studies that show individuals with non-insulin using type 2 diabetes who use CGM achieve equal or better results than those who currently have access to CGMs by virtue of using insulin, some of which we described above. The Authority, in light of this new recommendation and considering that the draft evidence report cites to an older version of the ADA's standards of care, should reevaluate its assessment of clinical practice guidelines to reflect this recommendation.

* * *

Thank you for the opportunity to provide comments to Washington State Health Care Authority's Draft Evidence Report on CGMs. Please feel free to contact Brian Lee at [redacted] should you have any questions or if there are more details we can provide.

Sincerely,

Timothy P. Trysla
Executive Director
Diabetes Technology Access Coalition

[8] *Standards of Care in Diabetes – 2025*, 48 Diabetes Care S1 (2025), https://diabetesjournals.org/care/issue/48/Supplement_1

Diabetes Technology Access Coalition
Represented by the Following

- American Diabetes Association
- Association of Diabetes Care & Education Specialists
- Dexcom, Inc.
- Diabetes Leadership Council
- Insulet Corporation
- Medtronic
- Sequel Med Tech
- Tandem Diabetes Care
- The Leona M. and Harry B. Helmsley Charitable Trust
- Tidepool

From: [redacted]
To: [redacted]; HCA ST Health Tech Assessment Prog
Subject: Public comment open on draft evidence report for CGM
Date: Friday, February 7, 2025 10:11:28 AM
Attachments: image001.png
11UWLetter to Washington Health AuthorityCGMletter202527.docx

External Email

Please accept our comments on the draft evidence report for CGM/

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: WA - Health Technology Assessment <shtap@public.govdelivery.com>
Sent: Thursday, January 9, 2025 3:28 PM
To: Nicole M. Ehrhardt [redacted]
Subject: Public comment open on draft evidence report for CGM

[redacted]

January 9, 2025

Can’t access the links? Add “lnks.gd” to the allowlist of your content blocking software.

Public comment open on draft evidence report for CGM.

The draft evidence report on continuous glucose monitoring (CGM) has been posted on the Health Care Authority website.

Public comments on the draft report will be accepted January 9 until February 7, 2025 at 5 p.m. Pacific.

Submit all comments to the HCA HTA Program.

Thank you for subscribing to Health Technology Assessment (HTA)

If you have questions about our program, please contact us at: shtap@hca.wa.gov.

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There are three pillars of our work: Apple Health (Medicaid); the Public Employees Benefits Board (PEBB) and School Employees Benefits Board (SEBB) programs; and behavioral health and recovery. Under these pillars, HCA purchases health care, including behavioral health treatment for more than 2.7 million Washington residents and provides behavioral health prevention, crisis, and recovery supports to all

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UNIVERSITY of WASHINGTON
METABOLISM, ENDOCRINOLOGY & NUTRITION

Letter to Washington Health Technology Clinical Committee Date: 2/7/2025
Increasing Access to Continuous Glucose Monitoring for Type 2 Diabetes Patients

Dear Members of Washington State's Health Technology Clinical Committee,

I have additional comments on the CGM 2025 report. We support increased access to continuous glucose monitoring (CGM) for Type 2 diabetes patients in our state. Recent advancements in CGM technology have shown significant benefits and are now standard of care according to the American Diabetes Association guidelines:

American Diabetes Association Professional Practice Committee.7. Diabetes Technology: Standards of Care in Diabetes—2025 | Diabetes Care | American Diabetes Association

- **7.15** Recommend real-time CGM (rtCGM) **A** or intermittently scanned CGM (isCGM) for diabetes management to youth **C** and adults **B** with diabetes on any type of insulin therapy. The choice of CGM device should be made based on the individual's circumstances, preferences, and needs.
- **7.16** Consider using rtCGM and isCGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals **B (**1).

The table below summarizes recent real-world clinical data and regional data on the impact of CGM on patients in Washington State that are elaborated further in this letter:

Real-World Clinical Data on CGM with Regional Washington State Data*

Reference	Type of Study	Duration (months)	Number of Participants	Type of Diabetes Medications	Baseline HbA1C	% HbA1C Change
Grace et al. (2)	Single arm prospective study	6	237	Insulin (42%) Non-insulin (58%)	9.4%	2.4%
Garg et al. (3)	Retrospective cohort study	3	74,679 (6030 HbA1c analysis)	Basal insulin (60%) Non-insulin (40%)	8.8%	1.1%
Shields et al. (4)	Prospective cohort study	3	182 (CGM=91 C=91)	Basal insulin (35%) Non-insulin (65%)	9.2%	CGM 1.4% C 0.8%
*Ehrhardt et al. (5)	Randomized control trial	3	120 (CGM=61 ED=59)	Basal insulin (26%) Non-insulin (74%)	10.7%	CGM 2.4% ED 1.5% (Difference 0.9%)
*Vidovic et al. (9)	Dual arm prospective study	6	66 (CGM=30 C=36)	Insulin (≥1 injections)	9.0%	CGM 1.4% C 0.8% (Difference 0.6%)

ED= Education only, C=Control, CGM= Continuous Glucose Monitor

CGM provides real-time feedback on glucose levels, enabling patients to make informed decisions about their diet, physical activity, and medication. Numerous studies show that CGM can significantly improve glycemic control, with some patients experiencing an average HbA1c reduction of 0.3-1% or more. Notably, real-world data often shows even greater improvements of HbA1c. For instance, a community CGM program reported a 2% reduction in HbA1c levels, highlighting the efficacy of this technology when barriers to access, such as pre-authorization requirements, are removed (2). A large database review examined changes in all-cause hospitalizations, diabetes-related hospitalizations, and emergency room visits within 6 and 12 months after transitioning from blood glucose monitoring to CGM for type 2 diabetes patients. Results showed reduced healthcare resource utilization and improved glucose control over one year (3). It is noteworthy that the aforementioned studies, as well as this recent prospective cohort study, were all conducted within primary care settings. Another recent study, which included basal insulin-treated (35.7%) and non-insulin-treated (64.3%) T2D patients (n=182), compared the use of continuous glucose monitoring (CGM) with usual care. The mean difference between groups demonstrated a 0.5% reduction in HbA1c at three months in favor of the CGM group. Furthermore, significantly more patients in the CGM group achieved HbA1c levels below 7% and 8% at the same time point compared to the control group (9% vs. 22%, p=0.01 for HbA1c < 7%; 21% vs. 40%, p=0.04 for HbA1c < 8%) (4).

I would also like to share the impact that CGM has had in our own community in Washington State. Recently, we conducted a Randomized Controlled Trial (RCT) with 120 participants in collaboration with our local Sea Mar population. The Sea Mar participants with type 2 diabetes had significant disadvantages in social determinants of health, such as lower income, food insecurity, and less education. We observed an approximate 0.9% improvement in HbA1c levels after 12 weeks of rtCGM usage, in addition to the significant improvement all participants had from diabetes education which is a cornerstone of diabetes management. However, this effect was diminished by six months when participants no longer had access to the devices. The study involved a significantly younger population with an average age of 48, where only 26% were on basal insulin, and most did not require insulin. The initial average HbA1c was above 10%, but 50% of participants using CGM achieved an HbA1c of less than 7.0% by 12 weeks, while 73% met HEDIS goals of less than 8.0% (5). There is clear evidence that improved glycemic control prevents complications. Additionally, there is increasing evidence that improvements in A1c and Time in Range, as measured by CGM, are correlated with reduced microvascular and macrovascular complications (6).

Additionally, CGM has been shown to encourage healthier lifestyle behaviors. Participants in our local Sea Mar population study reported significant improvements in their daily habits. Among rtCGM users, 81% read food labels more carefully, 83% limited or excluded rice, and 78% were more likely to engage in physical activity. Furthermore, 97% of participants felt that CGM led to a healthier lifestyle overall (7).

The impact of CGM extends beyond the individual to their household members. In a pilot study, family members of CGM users also reported positive lifestyle changes, with 80% becoming more active, 70% reducing sugary beverages, and 80% decreasing rice consumption (8).

Another study conducted at Harborview Medical Center recruited patients with Medicaid insurance or institutional financial assistance, HbA1C >7%, and one 1 or more insulin injections per day, who were provided 6 months of CGM through a grant (9). They compared the results of this group with a "control group" of insulin treated patients who did not use CGM technology. Baseline mean HbA1c was 9.55% ±1.5 vs 8.86% ±1.78 (n = 36) in the control group. In the CGM arm, HbA1c decreased from baseline by -1.52% ± 1.76 (n=30) at 3 months and -1.35% ± 2.04 (n=27) at 6 months; in the control group A1c decreased by -0.96% ± 2.26 (n=26) at 3 months and -0.83% ± 2.49 (n=36) at 6 months. Sensor usage remained >70% throughout the study period. Mean Time In Range (70-180 mg/dL; TIR) increased from 50.14 ±24.50 % at 2 weeks to 52.90 ± 23.59 % and 56.52±23.30 % at 3 months and 6 months respectively. Mean CGM glucose decreased from 194.7 ± 47.09 mg/dL at 2 weeks to 191.50 ±43.09 and 184.55 ±36.11 mg/dL at 3 and 6 months, respectively. Mean Time Below Range (<70 and <54 mg/dL; TBR) did not change significantly (9).

Given these compelling benefits and potential to reduce complications in the large term, I urge the Washington Health Technology Clinical Committee to consider lifting restrictions and pre-authorization requirements for CGM devices in both insulin and non-insulin requiring populations. At the very minimum, bringing patients insured by Washington State Medicaid on parity with those on Medicare is essential. To do so, the Medicaid coverage policy needs to eliminate the requirement for patients to demonstrate 4 glucose checks per day and even the use of 1 injection of insulin daily should qualify them for access to CGM technology. This is consistent with current ADA guidelines in the 2025 Standards of Care for management of diabetes, as referenced above (1). Ensuring that all patients with Type 2 diabetes have access to this life-changing technology will not only improve individual health outcomes but also reduce long-term healthcare costs associated with unmanaged diabetes.

Thank you for your attention to this important matter. I look forward to your favorable response and the positive impact it will have on our community.

Sincerely,

Nicole Ehrhardt, MD
Assistant Professor of Medicine

Arthi Thirumalai, MBBS
Associate Professor of Medicine

Irl B. Hirsch, MD MACP
Professor of Medicine

University of Washington Diabetes Institute and Harborview Medical Center
Division of Metabolism, Endocrinology and Nutrition | UW Medicine

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Division of Metabolism, Endocrinology and Nutrition | UW Medicine

References:

1. American Diabetes Association Professional Practice Committee. 7. Diabetes Technology: Standards of Care in Diabetes-2025. Diabetes Care. 2025 Jan 1;48(Supplement_1):S146-S166. doi: 10.2337/dc25-S007. Erratum in: Diabetes Care. 2025 Jan 23:dc25er04b.
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Latinx randomized controlled trial study. Submitted manuscript to Journal of Diabetes Science and Technology January 2025; under peer review.

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7. Vidovic J, Gil D, Jones E, Berberian P, Wright L, Comstock, B, Ehrhardt N .The CUT Diabetes Trial: A Randomized Study of Culturally Tailored Diabetes Self-Care and Management Education Support (DSMES) for Type 2 Diabetes(T2DM) with and without Real-Time Continuous Glucose Monitoring (RT-CGM) and Its Effect on Lifestyle. Submitted abstract to American Diabetes Association Annual Meeting 2025.
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9. Vidovic J, Deng A, Mitsuuchi T, Weber M, Lin J, Cheng K, Thirumalai A. Efficacy of Continuous Glucose Monitoring in Diabetes Management of Underserved Populations. Submitted abstract to Endocrine Society Annual Meeting 2025.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Increase CGM access!
Date: Thursday, February 6, 2025 9:10:01 PM
Attachments: Outlook-a2dl2hnx.png
Importance: High

External Email

I am a Certified Care and Diabetes Education Specialist (RN, CDCES) and experience firsthand the positive impact that Continuous Glucose Monitors (CGM's) have had on our patients. At the Community Health Center where I work, many of our patients have at least sampled a CGM and the results have been dramatic. **The majority of these patients were not on insulin or were using only long-acting insulin.** Below are true events that we regularly see with CGM use:

- Drop of A1c levels by up to 5 points in less than a year - patients consistently report that the immediate feedback they receive makes the biggest difference in their diabetes management and consider these devices "life-changing" or "life-saving"
- Patients finally able to get their surgery scheduled who have been waiting years to get their A1c levels below 8% to qualify for surgery - only after using CGM that they were able to do this, within months of using it
- Patients who drop too low during sleep even on just one insulin finally feel reassured that they can be safe with CGM use and are getting better sleep, which improve blood sugar levels
- Activity levels increasing due to patients seeing the effects of their physical activity while using CGM - who otherwise could not be convinced of the value of exercise in managing diabetes

Then there are the patients who cannot get access to CGM because of the current requirements, who are losing hope as their blood sugar levels continue to rise even with great effort to manage their disease. Do we really want them to get worse enough so they need to be on 3 shots of insulin per day? Wouldn't we rather prevent this and help them get the feedback they can get from CGM's so they don't need insulin or more of it?

The use of intensive-insulin therapy (at least 3 injections per day) should not be required to obtain a CGM. We need to give more access to more individuals with diabetes who are not on intensive insulin therapy. The science shows they are clinically beneficial, and our patients have clearly demonstrated this reality.

The requirement to test at least 4 times a day before qualifying for CGM coverage is a huge barrier and completely unnecessary! It's a catch-22 for one thing, because a big part for needing CGM is because patients are unable to do this level of testing (very little blood coming out of fingers, pain from poking their fingers so many times, tremors, vision issues, poor dexterity and so on).

And even when they do test this much, it still doesn't give the full picture of a patient's blood sugar levels. Who tests while they're asleep? How would you know if a patient has Dawn Phenomenon, when blood sugar rise just before waking up, if they can't poke their finger to test while they're asleep? Dawn Phenomenon can raise A1c levels and cannot be detected easily otherwise.

I like to give the analogy of driving in the rain. If you only had 4 swipes of your windshield wiper for the whole day while driving, would you feel safe where you are heading? How can you see where you are going in between the swipes? This is like fingerstick BG testing. Whereas with a CGM, you get continuous swiping capacity to be able to see out of your windshield every minute. Isn't that a safer and more guaranteed way to take control of your destiny? I think all diabetic patients would like the opportunity to take this kind of control over the destiny of their diabetes through CGM use.

In summary, these current requirements are burdensome, not clinically relevant, and delay access to CGMs. We need to get rid of them and give more access to CGM's!

Glen Felias-Christensen RN, MPH, CDCES *(she/her)*
Diabetes Care and Education Specialist

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Comment Submission for Expanding Access for Continuous Glucose monitoring
Date: Thursday, February 6, 2025 1:24:11 PM
Attachments: image003.png
CGM HCA supporting letter.docx

External Email

Dear Washington HealthCare Authority,
I have attached my comments supporting expanding access for CGM to anyone on insulin and removing the requirement for 4 x day BG checks to qualify.

[redacted]

Line Goulet RN,MEd.BSN,CDCDES
Diabetes Education Program Coordinator
[redacted]
[redacted]

February 6th, 2025

Comment Submission for Expanding Access for Continuous Glucose Monitoring:

Dear Washington HeathCare Authority, Washington Health Technology Clinical Committee

The current coverage for CGM:

*Limit access to CGMs to only people with diabetes who are on intensive insulin, and,

*Limit access to CGMs to those who check their blood glucose levels 4 or more times a day

I am recommending the removal of the requirement that the patient be on intensive insulin therapy to qualify for CGM and instead expand to all insulin therapy users. Current CMS guidelines removed the multiple injection requirement in 2021. Also, I recommend the removal of the requirement for the patient to test their blood glucose 4 times or more a day. My comments are below.

In 2018, I was awarded Diabetes Educator of the Year for Washington State. I have been an RN since 1979. At that time, decisions for diabetes management, including insulin adjustment were made on urine testing for glucose. Microvascular and macrovascular complications were believed to be inevitable. Severe hypoglycemia was common, requiring stays in the ICU for persistent hypoglycemia. In the early 1980's, blood glucose monitors became available, cost in the 100's of dollars, and usually prescribed to individuals with Type 1 diabetes (as that was the "worse" one). It was about saving money. Even if it took 2 minutes to get results, and a very large drop of blood, this was the start of empowering people to make decisions about their self-diabetes care based on a real number. Even more exciting was the release of the DCCT trial results on the impact of lower glucose levels and A1C on people with Type 1 diabetes, years in advance of its trial completion. Why was I excited about that? In 1989 I became a diabetes educator, and then in 1991, a Certified Diabetes Educator. I was also co-chair for the 1992 the Canadian Diabetes Educator Annual Diabetes Conference held in Ottawa. One of speakers was aa researcher for the DCCT and shared those results with us. From the DCCT, the recommendation was made for having A1C below 7%. Finally, we had proof that complications were not inevitable. When people with diabetes were given the information and the tools they needed, they were able to take charge and reduce not only the risk but the prevention and progression of complications.

I moved to Washington State. In 1998 our diabetes program became more structured, eventually obtaining accreditation for our Diabetes Education Program here at WhidbeyHealth. The biggest barrier then to receiving diabetes education was not having insurance.

As Diabetes Educators, we are passionate about the people we work with, and diabetes can affect everyone. To manage it, people with diabetes need information, providers need information. Data is necessary for safe medication changes and overall management. The A1C alone is not enough. Data helps with behavior change and being proactive prevents complications. The expectation is that people with diabetes will jump at the chance to check their blood glucose 4 times a day is unrealistic, burdensome, and unnecessary depending on their regime. It also is not what happens in the real world for many reasons: it is pain, food insecurity, missed meals, 2 meals a day, fear of needles, forgetting to check, 4 x or more a day testing supplies not covered for more testing, difficulty obtaining enough blood, error messages, resulting in wasted strips without replacement, not having supplies at hand, diabetes burnout and diabetes distress.

When I worked in Ottawa, a group of diabetes educators along with the endocrinologists trained the second-year medical students to live 2 weeks with diabetes. That meant that they had to inject saline 4 times a day, check their glucose 4 times a day, and follow a" diabetic" diet. There were about 70 students. Out of 70 plus, 3 managed to do this for 2 weeks. Yes, that was only 3! They said sometimes they only had 2 meals, or work shifts, or went out with friends. It was eye opening to them.

If a person has had diabetes for years, the last thing they want to do is more testing. To be even more unfair, depending on the insulin regime, people will be unable to meet the 4 injections requirement when taking premixed insulin such as Humulin 70/30 insulin. This is twice a day injection regime, with 2 different kinds of insulin in 1 syringe, which would be 4 injections if they were taken separately. Premixed insulin is sometimes prescribed to simplify a regime, often in older adults however it also has a higher risk of causing nocturnal hypoglycemia because the peak activity is in the middle of the night. Based on the current requirement anyone taking premixed insulin would be denied.

What is even more frustrating is when person does so well because of CGM, that we can reduce doses or stop meal insulin to the point that they are only on long acting, then they no longer qualify for CGM coverage because of the decreased number of injections. So essentially, we are telling people, if you improved your A1C because of CGM, you reduce your risk of complications such as lower extremity amputations by 43%, your medication is reduced, and you are re-engaged, then your CGM won't be covered.

In my practice, I have seen dramatic improvement in A1C, often decreasing 2% or more in just a few months, in people whose diabetes has been uncontrolled for years, who may or may not be injecting insulin. They see what impacts their glucose, they make changes to their breakfast choices, they stop that soda that they have once a week. They get reengaged in the diabetes management.

Why should it be accessible to all people on insulin and not just intensive insulin therapy? Therapy needs to be individualized. People have different lifestyles and challenges. Here are a few examples: I have a person with Type 1 diabetes who sometimes has only one meal a day because of food insecurity, so he may only take 2 injections that day; also some people do only have 2 meals a day; I have used a sample CGM on several people who are not on insulin, but may have experienced lows, they often don't confirm a low with a BG check since they know their symptom and they treat it the low. There is then no documentation on how frequent or serious the low was. People have a tendency to keep their numbers higher because they are scared they won't wake up. I have had people tell me that they are finally sleeping. I work with cancer patients, receiving and taking steroids where they receive chemo every other week, requiring on and off again insulin injections. I had someone who kept bananas in his bathroom because when he would have a low, he had them at hand; he was afraid of falling and he was too weak to get to his kitchen downstairs. He eventually did have a serious low with seizure which he did not recover from. He did not have a CGM.

Prior auths take time, and often must be appealed despite the person being on 4-6 injections, checking BG 4-6 times, having lows in the 50's and highs in the 300's because they didn't have a written log. It has to be transcribed to a form from the meter memory. What if there was a day that they missed because they didn''t have their meter.

Some have argued that checking blood sugars does not improve control. Indeed, there is an article published in the early 2000 that supports this and has been used by insurances to even deny more than

once a day testing. However, while the Standards of Diabetes Care 2024 S127 blood glucose monitoring in non insulin therapies has not consistently shown clinical reduction in A1C, it also states it is of little benefit unless education and training is provided. People who attend diabetes education programs, have a diabetes educator and a team to help them manage diabetes do improve. It is likewise with CGM. Some will use the data very effectively, some less so, but all improved. This year a referral to a diabetes educator/education is now part of the standard at diagnosis.

I believe that having broad coverage for CGM will reduce the costs through prevention of diabetes related complications such as CVD, CHF, CKD, retinopathy, neuropathy, MI, amputations, dementia, hypoglycemia. Because of clinical inertia, delay in putting people on insulin when they need it, then waiting until they go on intensive insulin therapy to cover CGM, putting barriers accessing CGM, after their diabetes has been out of control for 5 years costs all of us thousands of dollars because of need to treat and manage these complication instead of preventing them. I have a friend who has proliferative retinopathy and sees a retinal specialist ever 6 weeks for injections. We calculated that this has cost in well over $200,000 so far. His A1C was in the 9 range for years, with his CGM his A1C is <7%. I believe that all people with diabetes should have access to CGM coverage and especially when they go on insulin even if it is one injection daily.

Diabetes is a disease, not a condition and not about willpower. Having data that CGM provides makes a difference in choices which will not only save money but improves quality of life.

I encourage each of you who are involved in this decision to start checking your own blood sugars at least 4 times a day for the next month. Write down your numbers and what you ate. Go to Walmart, buy a Reli On Meter ($12), a lancing device $6, enough lancets for a month (125), 125 test strips, you will need 2 bottles, one of 100, and another 25 strips in a separate bottle. $18 +$5. Then imagine doing this for years.

CMS Medicare removed the requirements for multiple injections and multiple testing. This should also be part of your policy.

Yours truly

Line Goulet RN, BSN, M.Ed. Certified Diabetes Education and Care Specialist

Diabetes Program Coordinator

WhidbeyHealth Medical Center

[redacted]

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Remove Glucose Monitor Restrictions
Date: Wednesday, February 5, 2025 5:27:40 AM

External Email

Please remove restrictions. I have witnessed people with frail, slender fingers are sore with even two needle tests daily. The monitors are very, very helpful. I have also witnessed caregiver in DSHS program and hospitals use aggressive pen pricks to take the blood. The meteor removed this issue.

Next, please allow hospital staff to use the device. Why is the glucose meter restricted in hospitals? Please remove this restriction also
I would like a follow up on this effort. Thank you for what you do.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: support for more coverage of CGMs
Date: Wednesday, February 5, 2025 4:23:18 PM
Attachments: Outlook-iwpcdbuc.png

External Email

I appreciate the opportunity to provide comments on the Health Technology Clinical Committee's draft report reviewing evidence related to the patient populatiI appreciate the opportunity to provide comments on the Health Technology Clinical Committee's draft report reviewing evidence related to the patient populations who would benefit from using CGMs.

I understand that the draft report concludes:
●CGMs are safe and effective devices to reduce HbA1c levels in adults with T2D on non-intensive insulin regimens compared with daily self-monitoring blood glucose (SMBG) testing.
●CGMs are cost-effective for monitoring glucose levels compared with daily SMBG testing in adults with T2D using basal insulin

As a doctor in a community health center I want to share my personal/professional experiences that support these findings. Further, I urge the HTCC to view these findings as evidence of the benefits of further enhancing CGM access.

Specifically, I am advocating for elimination of coverage requirements that limit access and clinical benefit to only people with diabetes who are on intensive insulin and who check their blood glucose levels four or more times a day. The findings support eliminating such requirements, given the clinical benefit that can be gained through the use of CGMs by others with diabetes. In alignment with these conclusions, I hope you will expand access to all people with diabetes who are on insulin so that we can help more Washingtonians manage their diabetes through the utilization of a continuous glucose monitor.
I have personally helped several people bring their diabetes from completely out of control to well controlled using CGM data.
Thank you for taking the time to read and consider my comments.
Sincerely,
Jane King, M.D.

Jane King, she/her
Family Physician and Clinical IT Consultant
[redacted]

[redacted]

Serving our community for more than 50 years.

Country Doctor Community Health Centers is now:

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: CGM access for Medicaid participants
Date: Thursday, January 30, 2025 12:27:32 PM

External Email

To whom it may concern.

The Evolution of Diabetes Management: A Diabetes Educator's Perspective

As a diabetes educator with nearly 40 years of experience, I've witnessed the remarkable evolution of blood glucose monitoring technology. This progression has significantly improved diabetes management and patient outcomes.

Early Methods

- Initially, patients used urine test strips, which indicated if blood glucose present and described simply as Negative, 100, 250, 500, >2,000 mg/dl
- This method was imprecise and often led to complications due to inadequate information.

First-Generation Glucometers

- Required a large blood sample and a 60-120 second wait time.
- The deep finger prick needed was often painful and discouraged regular testing.

Improved Glucometers

- While more advanced, these still required blood samples through skin puncture.
- The ongoing need for blood draws remained a barrier for many patients.

Current Technology: Continuous Glucose Monitoring (CGM)

- Painless and provides continuous data.
- Benefits:
    1. Clinicians receive accurate, real-time data for better decision-making.
    2. Patients experience both short-term and long-term health improvements.
    3. Encourages positive behavior change, which is crucial for managing chronic diseases.

Request for Medicaid Coverage

CGM technology has been a game-changer in diabetes management. I strongly urge consideration for Medicaid coverage of CGM devices, as they have the potential to significantly improve the lives of many patients with diabetes.

Pam Kramer, RDN, CDCES | Manager of Diabetes and Nutrition Services
Ambulatory Pharmacy Services | MultiCare Health System
[redacted]
Office: Remote
Work hours: Monday-Friday 8:00 AM – 5:00 PM

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: mytype2diabetescoach@gmail.com
Subject: Response re: Prescribing CGMs
Date: Friday, January 31, 2025 11:01:36 PM
Attachments: Letter to the HTCC re CGMs.docx

External Email

Dear Sir/Madame,

Thank you for requesting input from the community as you study, review, and decide on the prescribing recommendations of CGMs for patients enrolled in the Medicaid program. My response is lengthy, so I've attached it to this email. If opening an attachment is contrary to your guidelines, don't hesitate to contact me and I will send it to you as part of the body of the email.

Thank you,

[redacted]

Dear Sir/Madame.

Thank you for the extensive work involved in the review of available research regarding the effectiveness of using CGM on people with Type 2 Diabetes (T2D). I submitted a letter/opinion earlier last year and upon reviewing the results of your research continue to feel that the use of CGMs do have a niche in the treatment of people with T2D who also take insulin.
My comments are based on reviews of the literature as well as my own clinical experience.

I recently retired after functioning as an ARNP in WA for the past 23 years, having focused on internal medicine and diabetes. In 2005 I earned my CDCES (Certified Diabetes Care and Education Specialist). Prior to retiring, I worked in the Endocrinology Department at MAMC, and for 3 years conducted research to justify my position. During that time, 249 patients were referred to me for intensive management of their Type 2 Diabetes (T2D) 235 showed up for the initial visit. Despite assertive efforts, a significant percentage of patients were lost to follow-up, resulting in a study cohort of 150. Of the retained group, only three (3) used CGMs. Patients were taking either oral medications and/or insulin. Fifty-eight (58%) were on Lantus and 27% were also taking meal-time insulin.

The equivalent information labeled as Time in Range (TIR) for CGMs is also attainable from a glucometer report. It is labeled as the Standard Deviation (SD) and the 'variance'.

Admittedly, effectively managing people with Type 2 Diabetes is labor intensive. After an average of 7 visits, the average A1c dropped from 9.838 (at their initial visit) to 7.001 upon discharge from the clinic.

Summary of the HTCC Findings

* CGM is safe and effective in reducing A1C in adults with T2D on non-intensive insulin regimens, compared with SBMG

The terms "safe" and "effective" need a bit more clarification. Was there a number at which device recalls, local skin reaction, or need to use an additional sensor determined? Being a sterile device, once a sensor has been inserted it cannot be reinserted elsewhere on the body.
In most studies, a reduction of A1c was noted but not clearly statistically better than with SBMG.

* CGM is cost-effective in adults with T2D using basal insulin, as compared with SMBG

Regarding the cost comparison between using a CGM vs. SMBG, the practice of testing one's blood sugar 4 times per day can be both burdensome and not necessary. Patients often cannot afford to purchase extra supplies to test 4x day, because if they are not on insulin, insurance usually only coveres supplies for twice daily testing.

Testing two times per day can reveal enough useful information to manage non-insulin blood sugars effectively.
Let me explain further. As a provider I consider the A1c, which reflects the average between the fasting blood sugar and the post meal blood sugars (the lowest and highest). If a person tests before breakfast and after breakfast i.e. the first day of the week, and then every third day, a pattern can be charted for the fasting blood sugar. On the second day and then every third day thereafter, s/he tests before and after lunch, another pattern can be studied. Finally, on the third day and every third day thereafter, the before and after dinner values are charted, within a week, both the pt. and the provider have much data on which to make changes. Limiting use of the SMBG would minimize any cost differences between using the CGM vs SMBG.

* There was **NO** evidence for effectiveness in adults with T2D on oral meds or mixed non-intensive hypoglycemia regimens
* There was **NO** evidence for effectiveness for pregnant people with GDM not on insulin
* There were **NO** RCTs of CGM use in children with T2D who were not on intensive insulin regimens

The current coverage requirements:
*Limit access to CGMs to only people with diabetes who are on intensive insulin,

The word "intensive" should be omitted from the requirements for CGM coverage. All patients taking insulin are at risk of hypoglycemia. Having a hypoglycemic reaction causes extreme stress to the body.

*Limit access to CGMs to those who check their blood glucose levels 4 or more times a day. (see previous comment re: frequency of testing)

I would recommend the following measures be taken when the use of any CGM is considered/prescribed.

CGMs should not be dispensed to individuals without active involvement by the health care provider/team. Diabetes education should be incorporated into managing all persons with diabetes. The rate of compliance in self-management is significantly improved when patients understand the disease and treatment process. I recall an adage, "If you prescribe it, you manage it".

Prior to prescribing the use of a CGM, the provider would:

- Complete an assessment of
    - the motives of the person with T2D,

    - the history of following through on recommendations given by the provider
- Have the person with T2D wear a “professional CGM” during which time, the pt. would keep a diet diary.
- Conduct an analysis of the CGM results alongside the diet diary
- Discuss the findings during a follow-up appointment. Often this discussion alone is insufficient to alert the pt. where improvements need to be made.
- Understand that if a CGM reading is below 70 or above 250 a SMBG reading should be taken.

If at that point, both the provider and pt. agree that a CGM would be useful, then a prescription would be given.
There would be a follow-up visit in 3 months to determine,

- If the pt was changing their lifestyle to improve their condition
- There was compliance with medication AEB some improvement in the A1C.

If use of the CGM is continued, prescriptions should be limited to 12 months after which the patient returns for re-evaluation of progress, and other diabetes related care needs, i.e. referral for annual eye exam as well as immunizations, foot exam, and medication review.

In the report by the HTCC (p. 8), it was noted that, “adults with poorly controlled T2D on oral glucose-lowering medications, no statistically significant subgroup interaction was found according to CGM or SMBG adherence level”.

In my experience following such patients over 3 years, I found that, those persons whose diabetes is poorly controlled must develop a desire to manage their diabetes and establish a therapeutic relationship with a provider before meaningful improvement is consistent (regardless of the monitoring method).

Summary

- CGMs do have a valid and important niche in the treatment of people with T2D especially those persons taking insulin.
- Providers need to first consider using a short term professional CGM coupled with a dietary report before prescribing the long-term use of a CGM.
- The use and cost of SMBGs can be minimal if testing measures both fasting and post-meal glucose levels.
- Efforts need to be made so that prescribed CGMs are used by the intended patient and not become a saleable commodity as has been seen with glucose test strips.
- When a medication or device is prescribed it needs to be managed by the prescriber.
- As stewards of this planet, we need to be aware of the potential waste and long-term consequences of adding to the use plastic.

Thank you for being open to comments from the community, and for reading this to the end. 😊

I am asking that you please hold my name in confidence, as my opinions are contrary to many of my peers as well as the device reps with whom I interact.

Thank you again,

[redacted], PhD, ARNP, CDCES

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: approve access to continuous glucose monitors for WAshington state residents
Date: Thursday, February 6, 2025 6:39:43 AM

External Email

Hello,

I have been a manager working in outpatient diabetes care for 7 years. Current criteria for Washington State Medicaid patients for getting a Continuous glucose monitor (CGM) covered requires injecting insulin 3 times a day and checking blood sugars 4 times a day. I am asking the WA Health care authority to change that to allow more patients access to this technology.

The ask is to change the criteria so that patients on once daily insulin, similar to Medicare criteria, will get access to this technology. Liberalizing the criteria will allow more patients access to this technology.

CGM technology is CRUCIAL for managing patients' diabetes and preventing fluctuations in blood glucose levels which cause long term damage to the body.

-Cricket McCleary
UW Medicine

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: CGM Provider Comments
Date: Wednesday, February 5, 2025 9:22:35 AM

External Email

Hello,

My name is Tammy Ninh, I am currently a PGY1 Pharmacy Resident working in a community/ambulatory care setting. As a student and current resident that works closely with diabetic patients, I would like to share my experiences, and my patients experiences about CGM's and their importance in their care.

CGM's have been important for the patients I help manage get a better sense of how their sugars are throughout the day. It has been essential to help identify and prevent further complications from their diabetes.

One example is an older patient I have with type 2 diabetes in her mid-70's. She lives by herself and manages her own diabetes; the alarm alerts have been essential in helping her identify lows that occur overnight. These have alerted her to wake up and treat lows if needed and has also helped me identify that her basal insulin needed adjusting to prevent overnight hypoglycemia from occurring. Her A1c was within her goal of less than 7% and her morning FBG's were always within goal. Had we not seen the CGM data we would not have known that this was a recuring trend that was happening to her. There are several patients that also have hypoglycemia unawareness during the day, having a CGM that is able to alert patients when their blood sugar is low has also been helpful for the people around them to be aware and help the patients if needed.

CGM's have also been helpful in identifying trends and patterns in patients. They also keep track of how many units of insulin they give at a certain time in day and what they eat which is helpful and easy to read and assess. This has also been helpful in identifying what adjustments to their insulin are needed, for example some patients overcorrect with their prandial insulin causing drops in their sugars.

Overall, I think CGM's have been very beneficial for my diabetes patients.

Thanks,
Tammy Ninh

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Washington State Health Care Authority Public Comment
Date: Monday, February 3, 2025 7:52:06 AM
Attachments: Washington Medicaid Testimony_Final.pdf
Washington Medicaid Testimony_Final.docx

External Email

Hello,

Attached are my public comments on the draft evidence report on CGMs. Please reach out with any questions.

Best regards,

Abbott

Qaashif Panjwani
PharmD, MPH, RPH, AHEOR
Medical Outcomes Manager

Abbott Diabetes Care
[redacted]
[redacted]

For Medical Information Inquiries for HCPs, submit to: https://adc-north-america.irmscare.com/

February 17, 2025

To whom it may concern.

Thank you for allowing us the opportunity to provide additional comments on the Washington CGM Policy that is currently in revision.

We would like to respectfully provide the most updated National guidelines recommendations that are pertinent information for this policy, as well as clinical data to support the removal of the hypoglycemia and fingerstick requirements, change the hypoglycemia definition of 50mg/dL to 54 mg/dL and expansion to support CGM use in pregnancy.[1]

ADA defines Level 2 hypoglycemia as a blood glucose concentration < 54 mg/dL, which is the threshold at which neuroglycopenic symptoms being to occur and requires immediate action to resolve the hypoglycemic event.[1]

National Guideline Recommendations Summary:

- Diabetes devices should be offered to people with diabetes.[1]
- CGM is recommended for all insulin using patients (pediatrics and adults) and those at risk for hypoglycemia. [1,2,3]
- Consideration of CGM use for adults with type 2 diabetes on glucose-lowering agents other than insulin.[1]
- Based on ADA 2025 guidelines, the ADA recommends that CGM can help achieve glycemic goals (time in range, time above range) and A1c goal in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy.[1]
- Choice of the device should be individualized based on the person's needs.[1]
- AACE states that use CGM metrics can be used as a surrogate to HbA1c.[2]
- ADA cautions providers that if they use HbA1c alone to assess glycemic control they should do so with caution- they advise on the use of CGM metrics for comprehensive assessment.[1]
- Lifestyle intervention and on- going glucose monitoring with CGM is preferred.[3]
- CGM is highly recommended for all patients to reach glycemic goals safely.[3]

Removal of hypoglycemia* / adverse event requirement for coverage of CGM**

a. Requiring an adverse event such as Hypoglycemia or DKA prior to coverage poses a serious health threat to the patient as both conditions are life threating, as well as hypoglycemia can cause cognitive decline. CGM is a patient safety tool where studies have demonstrated statistically significant outcomes in the reduction of hypoglycemia and DKA. [4,5]
b. Being proactive regarding prevention of these life altering events improves quality of life as well as have a positive impact of reducing cost of care by preventing avoidable utilization.
c. the National Organizations recommend CGM for those at risk for hypoglycemia which CMS aligned to. The reason being is that hypoglycemia is an acute event that can lead to loss of consciousness, coma, seizures and even death if left untreated[1].People using insulin or oral

hypoglycemic agents (e.g. sulfonylureas, meglitinides) to manage their diabetes are at risk for this complication and can experience detrimental outcomes with the first hypoglycemic episode. Requiring a person that is utilizing a high- risk medication to first experience a hypoglycemic episode to quality for CGM, could put the person at risk for severe adverse outcomes.

d. The American Diabetes Care and Education Specialists (ADCES) Diabetes Education Core Curriculum recommends teaching patients the signs, symptoms, and treatment of hypoglycemia at the time insulin or a hypoglycemic agent is initiated, rather than after the first event because of the associated risk of hypoglycemia[5].
e. There is also evidence that people with diabetes may be less adherent to hypoglycemia-causing medications due to fear of hypoglycemia. CGM may be a tool to help them detect potential risk for hypoglycemia or intervene even before the hypoglycemic event occurs, reducing the risk of ED or hospital admission[6].

SMBG requirement (4 test-strips/day) to be eliminated in alignment with CMS's CGM criteria.

f. Requirement removed from CMS as of July 2021
g. As reported in the DIAMOND study, only 48% of the rtCGM users (T1D and T2D) were preforming fingerstick testing ≥4 times per day at baseline; however, there was no association between Hb1c reductions at study end and baseline fingerstick frequency. [7]
h. In a study of adult T2D patients, the mean self-reported fingerstick frequency at baseline for the BGM and rtCGM and BGM groups was 3.2 and 3.3, respectively. 2 The mean change in HbA1c at 6 months, was significantly greater in the rtCGM group (−1.0) compared with BGM users (−0.6%), P = 0.005. [8]
i. A post hoc analysis of the REPLACE study shows no association between baseline BGM frequency and rtCGM outcomes. [9]
j. Findings from a recent retrospective claims data analysis have also shown no association between prior BGM frequency and reductions in acute diabetes events (ADE) associated with CGM use. A cohort of 12,521 individuals with T1D and T2D experienced reductions in ADE from 0.245 to 0.132 events/patient-year (P < 0.001), with similar reductions observed in patients testing <4 and ≥4 times per day. [10]
k. Only 1 out of 3 patients adhere to BGM as recommended by their HCP. [11]
l. <1 out of 4 patients using insulin achieve their HbA1c target (<7%). [12]

Expansion to CGM use in pregnancy.

m. CGM indication is now expanded to include pregnancy, which will enhance care in this population.[1]
n. Based on ADA 2025 guidelines, the ADA recommends that CGM can help achieve glycemic goals (time in range, time above range) and A1c goal in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy.[1]
o. A randomized controlled trial found the use of CGM during pregnancy in patients with type 1 diabetes is associated with reduction in maternal hyperglycemia, more pregnancy-specific time in range, reduction in large-for-gestational-age births, infant hospital length of stay, and severe neonatal hypoglycemia. [13]

Thank you for your consideration in allowing us to provide additional comments to the Washington CGM

policy in current revision.

Sincerely,

Qaashif Panjwani, PharmD, RPh, MPH, AHEOR

***Recurrent level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L) that persist despite multiple (2 or more) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or; a history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

References:

1. American Diabetes Association. Diabetes Care (2025) https://doi.org/10.2337/dc25-S007
2. AACE Clinical Practice Guidelines, (2022): https://doi.org/10.1016/j.eprac.2022.08.002
3. AACE American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm – 2023 Update(2023): https://doi.org/10.1016/j.eprac.2023.02.001
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5. Association of Diabetes Care and Education Specialists. Diabetes Care and Education Curriculum 3rd Edition.]
6. Trief, P. et. al. Psychosocial factors predict medication adherence in young adults with youth-onset type 2 diabetes: Longitudinal results from the TODAY2 iCount study. Wiley Online Library(2023). https://doi.org/10.1111/dme.15062]
7. Ruedy KJ, Parkin CG, Riddlesworth TD, Graham C; for the DIAMOND Study Group. Continuous glucose monitoring in older adults with type 1 and type 2 diabetes using multiple daily injections of insulin: results from the DIAMOND trial. J Diabetes Sci Technol. 2017;11(6):1138-1146. DOI: 10.1177/1932296817704445
8. Beck RW, Riddlesworth TD, Ruedy K, et al. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections: a randomized trial. Ann Intern Med. 2017;167:365-374. DOI: 10.7326/M16-2855
9. 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;8:573-586. DOI: 10.1007/s13300-017-0255-6
10. Hirsch IB, Kerr MSD, Roberts GJ, et al. Utilization of continuous glucose monitors is associated with reduction in inpatient and outpatient emergency acute diabetes events regardless of prior blood test strip usage. Diabetes. 2020;69(suppl 1):875- P.
11. Vincze G, et al. Diabetes Educ. 2004;30(1):112-25. https://doi.org/10.1177/014572170403000119;
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13. 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 [published correction appears in Lancet. 2017 Nov 25;390(10110):2346. doi: 10.1016/S0140-6736(17)32712-5]. *Lancet*. 2017;390(10110):2347-2359. doi:10.1016/S0140-6736(17)32400-5.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Comment Letter on Draft Report For HTCC Continuous Glucose Monitoring Review
Date: Thursday, February 6, 2025 3:46:22 PM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
image006.png
image007.png
ADA Comments on HTCC Draft Report Final February 6.pdf

External Email

Good afternoon,

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

Matt Prokop

Director, State Government Affairs
(Northwest and North Central: AK, ID, KS, MN, MT, ND, NE, OR, SD, WA, and WY)

Central Time Zone

[redacted]

American Diabetes Association®

February 6, 2025

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

Re: Comments on draft report related to review of coverage for continuous glucose monitors

Dear Health Technology Clinical Committee Members,

On behalf of the American Diabetes Association (ADA), we respectfully submit the following comments and recommendations for your consideration regarding the release of your draft report.

Our objective in asking for this review was to improve access to continuous glucose monitors (CGM) for those that would clinically benefit in accordance with the current clinical evidence.

We were encouraged to see the following conclusions in the report.

Draft Report Conclusion #1: "CGMs are safe and effective devices to reduce HbA1c levels in adults with T2D on non-intensive insulin regimens compared with daily self-monitoring blood glucose (SMBG) testing."

The ADA's Standards of Care in Diabetes - 2025 recommends "real-time CGM (rtCGM) or intermittently scanned CGM (isCGM) for diabetes management to youth and adults with diabetes on any type of insulin therapy." Randomized control trial (RCT) data from rtCGM use in individuals with type 2 diabetes on MDI, mixed therapies, and basal insulin have consistently shown reductions in A1C levels and increases in time in range. Based on the report's conclusion and the revised recommendations in ADA's Standards of Care, we respectfully ask the committee to recommend changes in coverage guidelines to support patients who are on any type of insulin therapy, not just intensive insulin therapy.

We also wanted to provide information from our Standards of Care relative to your examination of CGMs for pregnant people and other adults with type 2 diabetes who do not use insulin, ADA's 2025 Standards recommend the following: "Consider using rtCGM and isCGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals."

Draft Report Conclusion #2: "CGMs are cost-effective for monitoring glucose levels compared with daily SMBG testing in adults with T2D using basal insulin."

Based on this conclusion, we respectfully ask the committee to change the coverage guidelines to remove the 4 times a day blood glucose checking requirements in the coverage criteria. This will align both with the ADA's Standards of Care, as well as the Medicare local coverage determination (LCD) (DL33822) for blood glucose monitors, which removed the coverage criterion for 4 times a day blood glucose testing requirement for CGM coverage on July 18, 2021. In its proposed LCD, the Centers for Medicare and Medicaid Services (CMS) stated that "CGM can be particularly useful for improving safety in patients with nocturnal hypoglycemia, hypoglycemia unawareness, and/or frequent episodes of hypoglycemia. However, there is no evidence to support that frequent self-monitoring of blood glucose ≥4 times per day as a prerequisite for initiating CGM use is predictive of improved health outcomes."[1]

We thank the committee for considering removal of coverage barriers. Our comments and proposed recommendations reflects the American Diabetes Association's clinical evidence and aligns with CMS coverage policy in Medicare. As we mentioned previously, we would appreciate the committee's consideration to cover CGMs for non-insulin using people living with Type 2 diabetes, which would further align with ADA's most recent recommendations for 2025. People with diabetes in Washington would now be one step closer to having access to this important device, which is central to managing their diabetes.

Sincerely,

Matt Prokop
Director of State Government Affairs
[redacted]

[1] Proposed Local Coverage Determination (LCD): Glucose Monitors (DL33822), p. 13

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Letter of Support
Date: Thursday, February 6, 2025 11:58:42 AM
Attachments: _Washington_State_CGM_DR_Feb_2025.docx

External Email

Please accept this letter of support from DiabetesSister to expand CGM coverage for people in Washington.

Thank you!

Donna Rice
COO, DiabetesSisters

diabetessisters

Donna Rice MBA, BSN, RN, CDCES, FADCES
DiabetesSisters,Inc
[redacted]
February 4, 2025

Dear Committee Members,

On behalf of DiabetesSisters, I appreciate the opportunity to provide comments on the draft report reviewing the clinical benefits of continuous glucose monitors (CGMs). As a strong advocate for those living with diabetes, I urge you to support expanded access to this life-changing technology, ensuring that all individuals—regardless of their medication regimen—can benefit from CGM use.

The draft report clearly outlines the significant advantages of CGMs, including:

- Their safety and effectiveness in reducing HbA1c levels in adults with type 2 diabetes (T2D) on non-intensive insulin regimens compared to self-monitoring blood glucose (SMBG) testing.
- Their cost-effectiveness as a glucose-monitoring tool for adults with T2D using basal insulin.

As a **Certified Diabetes Care and Education Specialist**, I have witnessed firsthand how CGMs transform diabetes management, improving glycemic control and overall quality of life. These benefits extend beyond those on intensive insulin therapy to many individuals who could better manage their condition with real-time glucose data.

Given these findings, I strongly urge the Health Technology Clinical Committee to remove restrictive coverage requirements that limit CGM access solely to individuals on intensive insulin therapy who check their blood glucose four or more times daily. The evidence clearly supports expanding eligibility to all individuals with diabetes who are on insulin, as broader access would lead to improved health outcomes and a reduced burden on the healthcare system.

I appreciate your time and consideration of these comments and hope you will prioritize policies that ensure more Washingtonians can manage their diabetes effectively with the help of CGM technology.

Sincerely,
Donna Rice

Chief Operations Officer
DiabetesSisters

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: CGM coverage for Medicaid
Date: Thursday, January 30, 2025 1:11:06 PM

External Email

Hello,

I am a diabetes educator and every day I see continuous glucose monitors change patient behaviors for the better. I believe that mor access to continuous glucose monitors for people with diabetes will ultimately save money. The sooner people change their behaviors, the less likely they are to have a costly hospital stay. When people can see what different foods do to their blood sugars with immediate feedback, they make changes. When they can see that taking their medications or exercising brings blood glucose control, they adhere to their plans.

I strongly urge consideration for Medicaid coverage of CGM devices, as they have the potential to significantly improve the lives of many patients with diabetes.

Sincerely,
Amber Robbins-Ghormley, RN
Diabetes Educator

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: continuous glucose monitoring comment
Date: Monday, February 10, 2025 10:17:13 AM
Attachments: image001.png
WSMA Support for Medicaid Coverage of CGM.pdf
Importance: High

External Email

Good afternoon,

Please see attached letter in support of Medicaid coverage for CGM. Apologies for not getting this in before Friday's deadline and we hope the letter will be shared with the HTCC before its March meeting.

Best,
Jeb

Jeb Shepard
Director of Policy
Washington State Medical Association (WSMA)
[redacted]
[redacted]

WSMA Washington State Medical Association
Physician Driven, Patient Focused

Washington State Medical Association
Physician Driven, Patient Focused

February 6, 2025

Dear HTCC,

On behalf of the Washington State Medical Association (WSMA) and our nearly 13,000 physician members across the state, I am writing to express support for Medicaid coverage of glucose monitoring devices for beneficiaries in our state.

Apple Health has historically committed to ensuring that all beneficiaries receive necessary care, as evidenced by policies designed to expand access and reduce disparities in healthcare delivery. We applaud your efforts and offer our support per the 2024 WSMA House of Delegates Resolution as stated below:

RESOLVED, that the WSMA advocate for Medicaid to establish uniform coverage for all Medicaid beneficiaries with diabetes per current Medicare guidelines (New HOD Policy); and BE IT FURTHER

RESOLVED, that the WSMA supports legislative efforts to ensure consistent and comprehensive coverage of Continuous Glucose Monitors for all diabetes patients across different insurance plans, including Medicaid (New HOD Policy).

Should you have any further questions on our policy, please contact our policy department anytime at [redacted].

Sincerely,

Jeb Shepard
WSMA
Director of Policy

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: re approval of cgms for Medicaid pts
Date: Tuesday, February 4, 2025 1:08:07 PM

External Email

I am a nurse and diabetes educator with Providence in Lewis County. I strongly support the use of cgms in our Medicaid population. They are safe, result in improved A1C's and are cost effective. Over and over again, we see improved outcomes with our Medicare patients who inject insulin daily and have coverage for cgms. It is an empowering tool, spurring patients to take more control of their diabetes in terms of lifestyle change and often they end up requiring less insulin. Our Medicaid patients who inject insulin once daily should have this same access!

I have worked with several elderly Medicare patients who live many miles away in small rural towns, but because they use insulin, have cgms and are able to connect their data with our clinic, we are able to do telehealth visits and help them with adjustments for their diabetes care with improved outcomes. I want the same for my patients with Medicaid coverage. I am certain they would have improved outcomes and would also be cost effective.

Thank you for your time.
Sarah Skidmore, RN, CDCES

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Comments about coverage for CGM
Date: Friday, January 31, 2025 9:53:32 PM

External Email

As a certified diabetes care and education specialist (CDCES), registered dietitian nutritionist (RDN) and certified dietitian (CD), practicing in Richland, WA, I've seen firsthand how CGMs have benefitted people with type 2 diabetes. I frequently hear from people that they don't want to stick their finger to check blood glucose (BG), many of them, with T2D wait until their next primary care visit, to get their lab work done rather than checking BG. Then 3 to 6 months later, they have found out their BG is elevated – contributing to diabetes complications, and increased healthcare costs.

Key points from the Washington Health Care Authority (HCA) report – in support of covering CGMs:

- Continuous glucose monitoring (CGM) is safe and effective to reduce hemoglobin A1C (A1C) in adults with type 2 diabetes (T2D) on non-intensive insulin regimens, compared with self-monitoring of blood glucose (SMBG) with traditional blood glucose monitoring (BGM).
- CGM is cost-effective in adults with T2D using basal insulin, as compared with SMBG.

Recommendations for the request to Washington Health Care Authority (HCA):

1. **Remove the requirement to be on multiple daily injections of insulin for coverage of CGM. The current CMS (Medicare) guidelines don't include the requirement of multiple daily insulin injections for coverage of CGMs for people with T2D. Therefore, the HCA should not make this a requirement.**
2. **Remove the requirement for HCA members to be checking their blood glucose (BG) 4 times a day as this is not cost effective, or a recommended standard for BGM for people with T2D.**

I ask that you follow through with the requested changes to support increased coverage of cost-effective diabetes management for people with T2D in Washington State by supporting expanded coverage of CGMs.

Please let me know if you have any additional questions.

Warm regards,
Carrie

Carrie S. Swift, MS, RDN, CD, BC-ADM, CDCES, FADCES
DDPG Print Communications Chair 2023-2025

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: sensor stories!
Date: Thursday, January 30, 2025 1:34:30 PM

External Email

When I started working at the Elwha clinic no one was testing their blood sugars. With a small amount of money from my diabetes grant, I started patients with A1C > 10 on the Libre sensors. I only had enough money for 8 patients. Some patients had aic >12.

MY Quality assurance data for my grant is this :

Patients with A1c< 8:

2019 – 30%
2020 – 60%
2021 – 54% (Covid)
2022 – 65%
2023 – 61%
2024 – 68%

I even had 3 patients in 2024 newly dx with type 2 and aic >10; by being on the Libre all with improved their aic <8, 2 even low 6.

So ,please consider allowing **ALL** diabetic patients, oral and insulin controlled to have the opportunity to use these.

If you would like more information about my success, please let me know. I would be happy to share!

Dawn Travelstead MS,RD,CDCES
Diabetes Educator and Dietitian
Lower Elwha Health Clinic
[redacted]

Those who take medicine and neglect their diet waste the skill of the physician.
Chinese Proverb

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: HTCC CGM Comments
Date: Friday, February 7, 2025 8:42:54 AM

External Email

To the HCA HTCC,

My name is Nicole Treanor, MS, RD, CD, CDCES, and I am a diabetes care and education specialist and program coordinator for outpatient diabetes education at Virginia Mason Franciscan Health. Over the past eight years, I have worked in endocrinology and primary care, treating patients with type 1 diabetes (including LADA), type 2 diabetes, gestational diabetes, and pre-existing diabetes during pregnancy. I have worked with newly diagnosed individuals and those managing diabetes for decades, from highly proactive patients to those facing social or cognitive barriers to self-management. My experience also includes both early adopters of diabetes technology and those hesitant due to cost or uncertainty.

The majority of my patients use some form of continuous glucose monitoring (CGM), along with health apps, smart pens, or insulin pump therapy. I am often their first introduction to this technology, providing education and troubleshooting. This firsthand experience has reinforced my belief in the benefits of CGM for diabetes management.

Beyond my clinical role, I have volunteered with the Washington Coordinating Body for the Association of Diabetes Care and Education Specialists since 2020, serving as a local networking group lead and, since 2022, as chair. I have also led or co-chaired the last three state education conferences and partnered with the Washington State Pharmacy Association to provide virtual diabetes education events. My focus has been on equipping healthcare professionals with the confidence and knowledge to support CGM use.

I have also participated in the Foundation for Quality Health Care's Bree Collaborative committee which created a report and guidelines for Best Practices in Diabetes Care. https://www.qualityhealth.org/bree/diabetes-care/

With the above as my background, I did not come to this profession with a personal connection to diabetes. But in the past 10+ years, I have now developed personal connections to many people living with diabetes and have become very passionate about supporting people with diabetes. I have absorbed their experiences and emotions and feel deeply for anyone living with a chronic illness such as diabetes, that requires all-day attention and the complexity of making medical decisions several times a day.

The HTCC draft report supports CGM use for individuals on insulin therapy, a recommendation I strongly agree with. Regardless of insulin regimen - once-daily, mixed, multiple daily injections, or pump therapy- patients face hypoglycemia risk and benefit from CGM's continuous monitoring and alerts.

However, I encourage the committee to expand CGM access to patients not on insulin, including those with type 2 diabetes on oral or non-insulin injectable medications, as well as individuals with gestational diabetes and pre-existing type 2 diabetes during pregnancy.

Many patients have struggled for years to implement behavioral changes despite repeated counseling. When given the opportunity to use CGM, they gain immediate, personal insight into how food, activity, and medication impact their glucose levels. This leads to meaningful behavior change, resulting in lower glucose levels, improved A1C, increased Time in Range, and weight loss. CGM empowers individuals to take control of their health.

Patients with physical or intellectual disabilities may struggle with traditional glucose monitoring methods. For those not yet on insulin, this lack of monitoring can lead to poor disease management and progression. CGM offers an accessible alternative to help them maintain better health. Additionally, caregivers play a critical role in diabetes management, often juggling work and other responsibilities. CGM allows them to remotely monitor their loved one's glucose data, improving safety and peace of mind.

CGM drives behavior change and improves clinical outcomes. I urge the HTCC to remove barriers to CGM eligibility and include it on the HCA preferred drug list. Expanding access will improve individual health and contribute to better public health outcomes in diabetes care.

Thank you for your consideration,

Nicole Treanor, MS, RD, CD, CDCES

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Nicole Treanor MS, RD, CD, CDCES

Certified Diabetes Care and Education Specialist

Diabetes Education Program Coordinator

Franciscan Endocrine Associates – Tacoma

[redacted]

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