HERC Coverage Guidance:
Continuous Glucose Monitoring (CGM) in Diabetes Mellitus

Disposition of Public Comments

Table of Contents

Discussion Table

IDs/#s	Summary of Issue	Subcommittee Response
C2, E1, G2, H1	There is concern around requiring CGM use for at least 50% of the time by the first follow up visit due to access issues and potential barriers to care.	CGM therapy is not useful if it is not utilized. Further, CGM supplies should not continually be paid for if they are not being used. The 50% use requirement was included to document minimally acceptable use for continued coverage. Studies included in this report required minimum CGM usage ranging from 50-85%. The subcommittee added this requirement to align coverage with the study population. Further, the (A) requirement for education specific to the use of CGM was included to ensure that patients are trained and confident in their use the device, in order to minimize any barriers to use. The intent of the draft recommendation is not to penalize OHP members who stop using CGMs due to extenuating life circumstances;

Disposition of Public Comments

IDs/#s	Summary of Issue	Subcommittee Response
		the EbGS subcommittee may consider when a member may re-initiate CGM use. **For EbGS discussion** Consider organizing coverage criteria into two sections, Initiation and Renewal of Authorization, OR defining an initiation window (e.g., when HbA1c level is ≥8.0% or a number of documented hypoglycemic events within a time period) OR requiring that prescribers, when requesting re-initiation of CGM, justify medical appropriateness and necessity for a member, including a rationale or plan for how the member will meet adherence requirements.
C3, D1, G1, H2, I2	Requiring an HbA1c threshold for CGM initiation is concerning since HbA1c is an indirect measure and such a threshold is not used by major payers or clinical guidelines. This may add unnecessary barriers to using CGM for patients who have good control of their diabetes.	Coverage of CGM is recommended for people with HbA1c levels lower than 8.0% if they meet any other coverage criteria requirement listed in Criterion C (related to hypoglycemia or hypoglycemia unawareness). HbA1c was the outcome that was included in the approved scope statement for this draft report. A HbA1c threshold was included because it has been linked to end outcomes and is a more proximal measure as compared to time-in-range (a surrogate outcome). The subcommittee included poorly controlled HbA1c as one threshold for CGM to prioritize CGM for those most likely to benefit from the therapy (e.g., those who are unable to achieve a target HbA1c, have hypoglycemic episodes or hypoglycemic unawareness).

Disposition of Public Comments

IDs/#s	Summary of Issue	Subcommittee Response
		For EbGS discussion
H3, I2	The requirement to have experienced frequent or severe hypoglycemia is concerning as it may be a barrier to care for patients with good diabetes control.	Coverage of CGM is recommended for people without severe hypoglycemia if they meet any other coverage criteria requirement listed in Criterion C (e.g., hypoglycemia unawareness or HbA1c ≥8.0%). Severe hypoglycemia was an outcome that was included in the approved scope statement for this draft report. The subcommittee included severe hypoglycemia as one threshold for CGM to prioritize CGM for those most likely to benefit from the therapy (e.g., those who are unable to achieve a target HbA1c, have or hypoglycemic unawareness). **For EbGS discussion**
A1, B1, D1, D2	There is a lack of evidence that CGM improves outcomes, except for those who use short-acting insulin to allow for better adjustments in therapy, such that the requirement for insulin should specify short-acting insulin. HERC should require stronger evidence to add coverage.	Given the variety in insulin use (and frequency of dosing) reported in the included studies, this draft report did not disaggregate results by type of insulin regimen (short- or long-acting, basal or basal plus bolus, etc.). The key questions for this report did not request differential comparative effectiveness by type of insulin regimen. The included studies showed a benefit for patients with a variety of insulin types and frequencies; the studies did not report separate results for each type of insulin regimen.

Disposition of Public Comments

IDs/#s	Summary of Issue	Subcommittee Response
A1, B1	CGMs that do not replace finger sticking are not useful to people with type 2 diabetes, such that only "non-adjunctive" CGMs that replace testing strips should be covered.	The approved scope did request differential comparative effectiveness related to CGM type (therapeutic/non-adjunctive versus nontherapeutic/adjunctive). However, because the draft coverage guidance reported outcomes comparing CGM and control groups across adult, pediatric, and pregnant individuals (6 cohorts), staff elected to not further differentiate between adjunctive and non-adjunctive devices because that would have further fragmented the limited available evidence.
F1, I4	CGM should be covered for all people with diabetes irrespective of insulin use because patients can make daily choices affecting blood glucose levels based on device feedback.	We do not recommend coverage of CGM in people who do not use insulin because the included studies of adults demonstrated a statistical but not clinically meaningful benefit in HbA1c reduction. No other benefits were identified. No eligible studies evaluated the effectiveness of CGM for children, adolescents, or for pregnant individuals with gestational diabetes who do not use insulin. Daily home glucose monitoring (i.e., SMBG) is not recommended for individuals with T2DM who do not use insulin. CGM is more resource-intensive than clinically indicated in the absence of hypoglycemic episodes or inability to achieve target HbA1c.

HERC Coverage Guidance:
Continuous Glucose Monitoring (CGM) in Diabetes Mellitus

Disposition of Public Comments

Commenters

Identification	Stakeholder
A	Tim Kelly – Medical Director, Samaritan Health Services *[Submitted April 25, 2023]*
B	Mary Beth Engrav, MD – Medical Director, Care Oregon *[Submitted April 25, 2023]*
C	Robert Vigersky, MD – Chief Medical Officer, Medtronic Diabetes *[Submitted May 8, 2023]*
D	F. Douglas Carr, MD – Medical Director, Umpqua Health Alliance *[Submitted May 9, 2023]*
E	Kelsie Bostwick, PharmD – Clinical Pharmacist Primary Care Manager, St. Charles Healthcare System *[Submitted May 17, 2023]*
F	Laura Like, RD – Diabetes Educator, PeaceHealth *[Submitted May 19, 2023]*
G	Carissa Kemp – Director of State Government Affairs, American Diabetes Association *[Submitted May 22, 2023]*
H	Marie Frazzitta, DNP – Senior Medical Outcomes Manager, Abbott Diabetes Care *[Submitted May 25, 2023]*
I	Kimberly Cleveland, RN – Diabetes Educator, Samaritan Lebanon Community Hospital, Oregon *[Submitted May 22, 2023]*

Public Comments

ID/#	Comment	Disposition
A1	Please note that CGM are more complicated in the fact that there are adjunctive and non-adjunctive CGM. At no point would an adjunctive CGM be the best medical chose for a type 2 diabetic. There are benefits to non-adjunctive CGM for type 2 diabetics who are insulin dependent. However, an adjunctive not attached to a pump would have no benefit and one attached to a pump rarely have value to a type 2 diabetic. For this reason, could I recommend that non-adjunctive be added to the guideline note. This would mean only CGM that replace testing strips would be covered.	*Thank you for your comments. At the initial scoping for this report, the subcommittee requested that staff report outcomes by CGM type (therapeutic/non-adjunctive versus nontherapeutic/adjunctive).* *However, available evidence to inform decisions by CGM type was limited. Staff included a total of 11 RCTs for evidence review after completing the literature search. Of these, 8 RCTs evaluated therapeutic CGM (4 real-time and 4 intermittently scanned) and 3 RCTs evaluated nontherapeutic CGM.*

Disposition of Public Comments

ID/#	Comment	Disposition
		Overall, most studies had moderate or high risk of bias. *Given the small number of studies with high quality evidence and the number of subgroups that needed to be examined as required by the project scope, staff elected not to further differentiate between therapeutic and non-therapeutic devices within these subgroups.*
B1	We have had many meetings over this issue over the last few years to be sure we are consistent between Medical and Pharmacy benefit, and with reviews of the literature. Agree with the prior statement that the literature that shows no improvement for DM 2 is not great, which especially would seem to make sense with Medicaid populations due to churn/intermittent coverage/risk factors etc. <u>CGM Clinical Criteria</u> Initial request: A. Type 1 diabetic OR B. 1. Diagnosed with Diabetes Mellitus Type II with A1C 6.5 or higher, and requiring insulin therapy AND 2. Is medically complex as defined as <u>ONE</u> of the following: a. Highly-intensive insulin regimen (Tests 4 or more times per day AND uses at least 3 insulin injections per day/insulin pump); OR b. Hx of hypoglycemia with one of the following: OR i. Dawn phenomenon ii. Hypoglycemic unawareness iii. Nocturnal hypoglycemia	*Thank you for your comments. The following comments address specific elements of your proposed coverage criteria:* *A: This report excluded people with type 1 diabetes because CGM is already a covered benefit for this population.* *B.1 and 2. Because glucose control goals and strategies differ among people with Type 2 diabetes requiring insulin, rather than uniformly specifying a HbA1c threshold that all patients must meet for obtaining CGM, the subcommittee elected to specify an elevated HbA1c level as one of a few potential pathways to obtain CGM (as specified by Criterion C). For the same reason, the draft recommendation also does not specify medical complexity beyond requiring at least one criterion to be met within (C).* *2a. Regarding the requirement for people with Type 2 diabetes to have a highly intensive insulin regimen, 9 of*

Disposition of Public Comments

ID/#	Comment	Disposition
	c. Pregnant; OR d. Has loss of manual dexterity (such as from dementia, Parkinson's, tremor interfering with ADLs, etc). If approved: Authorization for 6 months at which time CGM download to document compliance of at least 50% of the time must be received for continued Authorization. (We have had a lot of discussion on compliance testing with regards to removing this as a potential barrier). (We also continue to make Exceptions if patient is uncontrolled, with DM complications such as foot ulcers, severe PAD, nonhealing wounds, etc, so that may be a consideration to add)	*the 11 RCTs included in the evidence review included any insulin users and differed on inclusion criteria, with 3 studies requiring basal insulin use but not prandial insulin, 4 studies requiring prandial insulin use, and 2 studies with no specification on insulin regimen at study inclusion. Because of the lack of uniformity regarding insulin regimens in these RCT study populations, staff were unable to directly evaluate CGM effectiveness in this subgroup.* *2c. Only 1 study of CGM use in pregnant people was included in this evidence review. This study included people with both Type 1 and Type 2 diabetes, and the Type 2 diabetes subgroup was not adequately powered to detect meaningful differences in key outcomes by CGM usage. Therefore, due to very low-quality evidence regarding CGM use in pregnant people, the subcommittee did not include this as a criterion for CGM coverage. However, the draft recommendation includes coverage for women with gestational diabetes, as long as they require insulin.* *2d. While loss of manual dexterity may be a practical consideration for obtaining CGM, most RCTs included in the evidence review excluded people with any physical or cognitive issues that made it difficult for them to use*

Disposition of Public Comments

ID/#	Comment	Disposition
		CGM. Therefore, this issue is beyond the scope of what this report can address based on the evidence review. *Finally, we recognize that plans have exception processes for situations not addressed by coverage recommendations, which apply at the population level.* ***For EbGS discussion***
C1	I am the Chief Medical Officer of Medtronic Diabetes with a long academic background (Walter Reed National Military Medical Center where I founded its Diabetes Institute in 2001) prior to joining Medtronic. I spent 27 years on Active Duty in the US Army Medical Corps and retired 8 years ago at the rank Colonel. I was also the founder of the Endocrine Society's Clinical Practice Guideline Committee (using the GRADE method of Gordon Guyott and Victor Montori) about 20 years ago and was President of the Endocrine Society in 2009-10. I am Professor of Medicine at the Uniformed Services University of the Health Sciences and still see patients, teach Residents and Fellows, and mentor junior staff as a Red Cross Volunteer in the Endocrine Clinic at Walter Reed. On behalf of Medtronic, I am writing to respectfully recommend the omission of two listed criteria on the expanded continuous glucose monitoring (CGM) coverage scope statement for people who have type 2 diabetes (question 1, page 28 of EbGS Meeting Materials): • Option B.: Uses the CGM 50% or more of the time by their first follow-up visit • Option C.a.: Baseline HbA1c levels greater than or equal to 8%	*Thank you for your comments. We have addressed specific points in the rows that follow.*

Disposition of Public Comments

ID/#	Comment	Disposition
C2	Option B: Medtronic recommends that the criteria of 50% use of CGM be omitted from the coverage statement: There is both a clinical and an administrative reason for this recommendation. Clinically, it is clear that CGM is a powerful behavior modification tool. In the RCT done by my group at Walter Reed Army Medical Center (Vigersky RA et al. Diabetes Care 2012; 35: 32-38) which is cited by the Committee, two-thirds of the subjects were on oral agents and one-third were with orals plus basal insulin. The study protocol specified that subjects wear real-time CGM for four sequential periods of 2 weeks on and 1 week off, and then not wear CGM for the next nine months. The study participants achieved clinically and statistically significant improvement in HbA1c at three (-0.5%) and twelve months (-0.6%) compared to the control group suggesting that continuous use of CGM is not necessary to improve glycemic outcomes. Of note is that these subjects were followed by their primary care providers and not the study staff or endocrinologists. A recent RCT by Moon SJ et al. (Diab Obes Metab 2022; https://doi.org/10.1111/dom.14852) in non-insulin treated subjects with type 2 diabetes demonstrated that there was a 0.6% improvement in HbA1c at 3 and 6 months after either one or two one-week use of real-time CGM. There is an additional study (not captured in your review because it was beyond the limits of your search) that speaks to the duration of use of real-time CGM to achieve reduction in HbA1c. Yoo et al. (Diab Res Clin Pract 2008, 82: 73-79) did an RCT in 65 subjects (A1C 8-10%) with T2D on orals +/- insulin (evenly divided) comparing CGM used for three consecutive days a week once a month to SMBG four times weekly (fasting and 2 hour post-prandial) over a 3 month. A1C improved from 9.1 to 8.0% in the CGM group and 8.7 to 8.3% in the SMBG group (p=0.004).	*Thank you for bringing Vigersky et al., 2012, Moon et al., 2022, and Yoo et al., 2008 to the Subcommittee's attention.* *Evaluation of intermittent CGM use on outcomes of interest is out of scope of our current report. As stated in Key Question 1, our intent was to evaluate the effectiveness of CGM in improving key glycemic control outcomes compared to SMBG. Thus, we focused on including studies where CGM was being used for the majority of the time so that SMBG use could be minimized or replaced as a glycemic control tool.* *Given this scope, we already cite Vigersky et al., 2012 (reference #64 in the report) because study protocol instructed participants to use their CGM for two-thirds of the study period.* *Moon et al., 2022 was excluded because participants were instructed to use CGM for only 1 or 2 weeks in a 3-month period; and Yoo et al., 2008 was excluded because participants used CGM 3 days out of each month.* *While intermittent CGM use may change patient behavior toward better glycemic control, this evidence review did not seek to answer this question on behavior modification.*

Disposition of Public Comments

ID/#	Comment	Disposition
	From an administrative standpoint, patients are seen roughly every three months to evaluate their treatment plans and assess changes, if needed. If the intent of HERC/EbGS including this requirement is to decrease the risk of overutilization and/or fraudulent use with Medicaid funds, please reference CMS LCD L33822 which states "every six (6) months following the initial prescription of the CGM, the treating practitioner conducts an in-person or Medicare-approved telehealth visit with the beneficiary to document adherence to their CGM regimen and diabetes treatment plan." CMS does not require a percentage of utilization be documented to provide continued medical authorization. The timing of a patient's 1st follow-up visit post-CGM implementation and training requires starting date and assessing the number of viable CGM wear days. This adds additional burden to the healthcare provider and may divert attention from more clinically related matters during the follow-up visit. Medtronic recommends adopting CMS's LCD policy.	*Regarding the removal of utilization criteria, our evidence review found that 2 RCTs required minimum CGM usage of 50% during the lead-in period to be included in their studies, 1 RCT required 70% and 1 RCT required 85%. The Subcommittee selected 50% to represent minimally acceptable use in order to align coverage with the study populations, and to ensure that CGM supplies would not be continually paid for if they were not being used.* ***For EbGS discussion***
C3	Option C.a. Medtronic recommends that an HbA1c levels greater than or equal to 8% be omitted from the coverage statement: The minutes from the HERC/EbGS report of February 2, 2023, comprehensively document the recommendations for CGM use in people with type 2 diabetes from professional societies and criteria from other payers in Table 9 and related text. The American Diabetes Association, the American Association of Clinical Endocrinology, and Endocrine Society do not recommend an HbA1c threshold below which CGM use in persons with type 2 diabetes. In addition, CMS, two Medicaid programs, other most commercial U.S. payers, and NICE have not established HbA1c criteria for use of CGM in type 2 diabetes in those on intensive insulin therapy or on basal insulin. All these organizations have done exhaustive evaluations of the risks vs. benefits of CGM	*While the Subcommittee is aware that various guidelines do not have an HbA1c threshold for CGM use in people with Type 2 diabetes, we are including an HbA1c threshold to prioritize providing CGM for those most likely to benefit from the therapy – for example, those who are unable to achieve a target HbA1c or are having hypoglycemic episodes.* *Further, Criterion C describes 3 conditions, only 1 of which needs to be met, in order to obtain CGM; for people with HbA1c levels lower than 8.0%, they will still be able to obtain CGM if they are experiencing hypoglycemia.*

Disposition of Public Comments

ID/#	Comment	Disposition
	in the type 2 diabetes population so it is unclear why the EbGS is proposing to institute an HbA1c threshold while these others have not. Finally, please note a recently published exploratory sub-analysis of the MOBILE study (an RCT in PWD's with type 2 diabetes on basal insulin) demonstrating a clinically significant improvement in HbA1c regardless of baseline HbA1c and age (Davis G et al. Diab Tech Ther 2023; 24: DOI: 10.1089/dia.2021.0489. The HbA1c level improved in the CGM group compared with SMBG across the age range of 33 to 79 years and the baseline HbA1c range of 7.1%-11.6%. We appreciate the opportunity to provide these recommendations to help you more closely align the proposed policy with the current universe of coverage for CGM in the population of people with type 2 diabetes.	*Thank you for bringing Davis et al., 2022 to our attention; we already cite this study and referenced the subgroup analysis results on page 25 of our report.* *While HbA1c levels did decrease both in the CGM and SMBG group (–1.08 ± 1.48 and –0.64 ± 1.17, respectively), no between-group mean difference was presented to evaluate whether the decrease statistically differed between the CGM and SMBG users.*

D1	Umpqua Health Alliance (UHA) has looked at the evidence concerning CGM utilization and Type 2 Diabetes and has made the following conclusions:
	
	• There is no good evidence that CGM use results in better outcomes. This is the summary in the latest issue of the American Diabetes Association Guidelines for 2023.
	• Based on actual office visit documentation by PCPS in the Prior Authorization requests we receive, the use of CGMs by (most) patients with T2DM appears to be motivated by:
	  ○ Convenience
	  ○ Interest in technology
	  ○ Massive industry advertising/social media
	• There is a practical consideration when determining CGM coverage: Does providing real-time data assist clinical decision-making by the patient?
		Thank you for your comments. We have addressed specific points in the rows that follow.

Disposition of Public Comments

ID/#	Comment	Disposition
	○ We think there is potential value for patients with T2DM who are taking short acting insulin to allow for better adjustments in therapy. ○ Basal insulin dosing does not require this more intensive monitoring due to the pharmacokinetics of the therapy. ○ UHA has been approving CGMs to our members with T2DM on basal+ short-acting insulin for the last year. ○ The A1c level is not an entry criterion for CGM approval on multidose insulin regimens because it unjustly penalizes patients who are already successfully managing their condition with finger-stick glucose monitoring.	
D2	We propose changing the guideline to read: We recommend coverage for CGM in individuals with T2DM or gestational diabetes who use regimens that include short-acting insulin when all of the following criteria are met: A. Have received or will receive diabetes education specific to the use of CGM, AND B. Have used the device for at least 50% of the time by their first follow-up visit Every 6 months following the initial prescription for CGM, the prescriber must conduct an in-person or telehealth visit with the member to document adherence to their CGM regimen and diabetes treatment plan. Retrospective (physician-owned) CGM is not recommended for coverage.	*Regarding your recommendation to restrict CGM coverage to those using short-acting insulin, the Subcommittee did not include this requirement in the draft recommendation because staff were unable to disaggregate the study results by insulin regimen in our evidence review.* *9 of the 11 RCTs in the evidence review included any insulin users and differed on inclusion criteria, with 3 requiring insulin users to using basal but not prandial insulin, 4 requiring prandial insulin use, and 2 with no specification on insulin regimen at study inclusion. Because of the lack of uniformity regarding insulin regimens in these RCT study populations, staff were unable to directly evaluate CGM effectiveness in this subgroup and thus did not recommend restricting CGM*

Disposition of Public Comments

ID/#	Comment	Disposition
		use to any insulin regimen subgroup in the proposed coverage guidance.
D3	Lastly, UHA is very concerned about the rationale provided for this guideline: We have low confidence in the evidence of benefit that CGM demonstrates a small reduction in HbA1c for adults with T2DM who use insulin. While no other benefits were identified, few harms were reported. The Health Evidence Review Commission cannot allow their decision making to degrade to this level of evidence, or they risk applying this criterion to a multitude of popular and prescribed but unproven treatments.	*Thank you for your comment and your involvement in ensuring that OHP members receive evidence-based care.* *Though the evidence included in our review have mostly moderate to high risk of bias, the subcommittee has decided to conditionally recommend coverage based on the few harms reported, the potential to reduce HbA1c in people with Type 2 diabetes who require insulin, and to reduce differential barriers to care.*
E1	My name is Dr. Kelsie Bostwick and I am an Ambulatory Care PharmD and the Ambulatory Care Pharmacy Services Manager for St. Charles Healthcare System in Central Oregon. My team and I work under CDTM to manage chronic disease states as a part of a multidisciplinary team within our 8 Family Care and Internal Medicine clinics here at St. Charles. Due to the prevalence of diabetes, we work with this population regularly and intimately understand the challenges our patients encounter. After reviewing the current CGM coverage guidelines I am concern about the "adherence" factor. Though our goal is for 100% adherence for all patients, regardless of testing type, this may not be realistic. I have several patients that scan as instructed for months and then, for whatever reason, skip a few days or weeks before resetting. Placing adherence as a requirement is adding another barrier to success for these patients. As DM is a overwhelming diagnosis and chronic disease state for most, at least the folks who would benefit the most from a CGM, this adds another "goal" they are fearful they will not be able to meet. Then they will be	*Thank you for your comment.* *The subcommittee understands that adherence criteria may be perceived as a barrier for people with Type 2 diabetes who feel overwhelmed by managing a chronic disease, potential co-morbidities, and other life circumstances.* *See response to C2 regarding the subcommittee's decision to include an adherence requirement.* ***For EbGS discussion*** *Consider adding wording in the coverage guidance to address re-initiation of CGM.*

Disposition of Public Comments

ID/#	Comment	Disposition
	"punished" for not being able to meet it consistently. I do not agree with this type of practice style. I'd imaging that if a patient is filling enough test strips for 4 checks per day (#120 for 30 days), then the cost may be getting close to the price of the CGM. The results I have seen in my challenging patient with the switch from manual finger sticks to CGM has been remarkable and believe all patients should have this opportunity without the added pressure of another barrier to success. My suggestion is following the lead of other insurers (Medicare and Commercial) and remove the PA for adherence, as it is a major barrier for patients and providers (lots of unnecessary paperwork) alike, to allow for CGMs to be treated equally to manual test strips/devices.	
F1	Please consider coverage of Continuous Glucose Monitoring systems for all people with diabetes. These systems offer massive safety benefits to all patients on insulin (type 1 or type 2 alike) in alerting to hypoglycemia, which is potentially life-saving. In addition, CGM is enormously useful to both patients and clinicians who are working on insulin dose adjustment and assessment thereafter, and facilitates a deeper understanding for the patient to make better decisions regarding the timing and amount of each insulin dose. Please also consider CGM for those patients not on insulin, as CGM is a proactive tool that empowers patients to gain valuable feedback on how the daily choices they make affect their glucose outcomes, especially related to their food choices. I firmly believe that the early implementation of CGM after initial DM diagnosis would likely lead to more cases of remission and less overall lifetime expense and burdens associated with diabetes.	*Thank you for your comment.* *The subcommittee does not recommend CGM for people who do not require insulin because even daily home glucose monitoring is not recommended in this population.* *Since CGM requires more resources than daily home glucose monitoring, its use is not indicated in people not using insulin in the absence of other clinically relevant conditions, such as hypoglycemia.* *Additionally, we do not recommend coverage of CGM in people who do not use insulin because while a pooled analysis of studies from our evidence review showed a statistically significant decrease in HbA1c reduction in CGM users compared with daily glucose self-monitoring*

Disposition of Public Comments

ID/#	Comment	Disposition
		users (−0.35% [95% CI, −0.54 to −0.16]; P < .001), this decrease did not meet the Subcommittee's definition of a −0.5% clinically relevant reduction (see Grade Table 2, pp. 10-12 in the report). The studies also lacked evidence on whether people not using insulin had fewer severe hypoglycemic and other health care use episodes or better diabetes-related quality of life when using CGM compared to self-monitoring.
G1	I am writing on behalf of the American Diabetes Association (ADA), the nation's largest voluntary health organization concerned with the health of people with diabetes. An estimated 37 million Americans and nearly 306,000 individuals in Oregon have diabetes (1). Advances in treatments, including continuous glucose monitoring (CGM), have been shown to be effective tools in diabetes management and the prevention of tragic and costly complications associated with the disease. Unfortunately, there continue to be gaps in access to CGM and other technologies among under-served populations, including – and perhaps most acutely – in the Medicaid population. ADA recommends the implementation of measures to expand access for people with diabetes to these technologies that will enable them to better manage their diabetes, which may result in fewer adverse health outcomes, disability, or premature deaths. The ADA appreciates the work that the committee has done to review access to CGM devices. We support the recommendation to	*Thank you for your comment.* *See response to B1 regarding the subcommittee's decision to include an HbA1c threshold as one pathway for CGM coverage.*

Disposition of Public Comments

ID/#	Comment	Disposition
	expand access for CGMs to people with type 2 and gestational diabetes who are on insulin. However, we do have concerns about the additional criteria that has been included. 1. We respectfully urge the committee to remove the coverage requirement that a person with diabetes would need to have an HbA1c of greater than or equal to 8.0%, in order to receive a CGM under Medicaid. The ADA believes that the use of CGMs should be individualized based on the patient's specific needs and the inclusion of this criteria limits the ability for a patient and their provider to determine what is the best treatment option for managing their diabetes. This proposed requirement would preclude efforts to further improve glucose management for people with diabetes who already maintain glucose control below 8% and prevent them from using a CGM, the ADA would not want to see that improvement rolled back.	
G2	2. We respectfully urge the committee to remove the requirement that the person with diabetes must have used the device for at least 50% of the time by their first follow-up visit. This requirement takes away the opportunity for providers and patients to work together to identify solutions to increase use, address barriers for use, and for providers to work with their patients to help them improve their diabetes management. Given the critical role that CGMs play in improving long-term diabetes management and the reduction of complications, as well as in addressing immediate issues like severe hypoglycemia, we encourage the committee to take extra care to avoid inclusion of criteria that may hinder access.	*See response to C2 regarding the utilization requirement.*
H1	Thank you for the opportunity to provide feedback on the proposed Continuous Glucose Monitoring (CGM) Policy criteria. After review of the criteria, we propose the following for your consideration:	*Thank you for your comment.* *See response to C2 regarding the utilization requirement.*

Disposition of Public Comments

ID/#	Comment	Disposition
	Remove the requirement: Have used the device for at least 50% of the time by their follow-up visit Removal of "Have used the device for at least 50% of the time by their follow-up visit" justification: Currently, there are no clinical recommendations or evidence that supports using CGM for at least 50% of the time prior to follow up as a beneficial indicator for long-term patient engagement or improved outcomes. The literature suggests that CGM provides patient centered data that can be used in shared decision-making discussions with the person's diabetes health care team.(1) Although barriers to CGM utilization exist, the literature supports motivational interview techniques and interventions that can improve adherence.(2,3) Recent evidence shows that as people with diabetes become more comfortable with CGM utilization, their adherence increases over time, accompanied by an increase in time in range (TIR). Low initial adherence can improve with continued CGM use and was not found to be a strong predictor of poor glycemic outcomes. (4) There is also evidence to show that when CGM is discontinued after 8 months of use, the initial gains in glycemic improvement are partially lost. (5) American Diabetes Association (ADA) Standards of Care 2023 also state that people with diabetes should have uninterrupted access to CGM to minimize gaps.(6)	
H2	Remove the requirement: Have one of the following at the time of CGM therapy initiation: Baseline HbA1c levels greater than or equal to 8.0%, OR Frequent or severe hypoglycemia, OR Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM) Removal of Baseline HbA1c levels greater than or equal to 8.0% justification: HbA1c test is an indirect measure of average glucose and is subject to limitations.(6) The accuracy of HbA1c results can be impacted by conditions such as anemias, glucose-6-	*See response to B1 regarding the subcommittee's decision to include an HbA1c threshold as one pathway for CGM coverage.* *The subcommittee considered TIR and other outcome measures in the initial scoping process, ultimately selecting HbA1c as the outcome in the approved scope*

Disposition of Public Comments

ID/#	Comment	Disposition
	phosphate dehydrogenase deficiency, recent blood transfusions, end stage kidney disease and pregnancy.(6) The American Diabetes Association Standards of Care states "clinicians should exercise judgement when using HbA1c as the sole basis for assessing glycemic control, particularly If the result is close to the threshold that might prompt a change in medication therapy."(6) Additional HbA1c limitations include the inability to detect glucose variability and hypoglycemia.(6) A growing body of evidence points to the role of glucose variability (GV) in the development of microvascular and macrovascular complications of diabetes including cardiovascular disease.(7) Both the ADA and American Association of Clinical Endocrinology (AACE) recommend the inclusion of CGM metrics, GV and Time In Range (TIR) as important metrics to evaluate a person's glycemic control.(7-9) Lastly, the National Organization Associations do not utilize HbA1c levels as an indicator for determining eligibility recommendations for CGM utilization. Instead, they recommend CGM for all insulin using patients and those at risk for hypoglycemia.(7,8)	*statement because it is associated with important end outcomes.*
H3	Removal of Frequent or severe hypoglycemia or Impaired awareness of hypoglycemia justification: Hypoglycemia is an acute event that can lead to loss of consciousness, coma, seizures and even death if left untreated.(7) 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 qualify for CGM could put the person at risk for severe adverse outcomes. 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	*Because the subcommittee recognizes hypoglycemia as serious and life-threatening in people with diabetes, it prioritized severe hypoglycemia as a critical outcome in the approved scope statement for this report in order to evaluate the effectiveness of CGM on decreasing these events. While 3 RCTs reported on this outcome, they were likely underpowered to detect true differences in frequency of these events comparing CGM and self-monitoring, thus we were unable to conclude whether*

Disposition of Public Comments

ID/#	Comment	Disposition
	hypoglycemic agents are initiated rather than after the first event because of the associated risk of hypoglycemia.(10) There is also evidence that people with diabetes may be less adherent to hypoglycemia-causing medications due to hypoglycemia risk.(11) CGM may be a tool to help them detect potential risk for hypoglycemia or intervene even before the hypoglycemic event occurs. The AACE 2023 Consensus statement highly recommends the use of CGM for patients to get to their goals safely. (9)	*CGM users had fewer hypoglycemic events in the studies under review.* *The intention of including severe hypoglycemia in Criterion C of the coverage guidance is not to require patients to experience the condition before approving CGM use; rather, it encompasses 2 of 3 conditions in patients with potential poor glycemic control who may benefit from CGM use. Under the current coverage guidance, if patients have elevated HbA1c, they do not need to have experienced hypoglycemia to qualify for CGM use. The subcommittee included severe hypoglycemia in Criterion C in order to prioritize CGM for those most likely to benefit from the therapy.*
I1	As one of the HERC appointed ad-hoc experts on the topic of continuous glucose monitoring (CGM), I recommend coverage of CGM for people with T2DM or gestational diabetes using insulin for the following reasons: 1. It would increase access and equity. As addressed in the document for the evidence-based guidelines subcommittee (EBGS) 4/20/2023, (section 3, page 17), insurance coverage often governs if CGM is offered. Clinicians were 85% more likely to offer CGM to individuals with private pay over public insurance. As a compassionate and caring certified diabetes educator, I hesitate to discuss CGM with individuals with T2DM who have Oregon Medicaid even if this would be the best intervention based on their clinical needs. I hesitate to offer an intervention that is out of reach as, in my experience, I have never had a person who qualifies for Oregon Medicaid say they can afford to pay out of pocket for CGM, an intervention that costs 70-140$ monthly. Providing	*Thank you for your comments. We have addressed specific points in the rows that follow.*

Disposition of Public Comments

ID/#	Comment	Disposition
	coverage of CGM for people with T2DM using insulin would relieve this unfair financial burden and increase equity to the same level as CMS (Medicare). 2. It is cost effective. Referring once again to the document for EBGS 4/20/2023 (section 3, page 18) it is estimated the cost savings for people with diabetes T1 or T2 using CGM for non-Medicare members is 417$ per month compared with those using SMBG. CGM therapy is preventative, like a vaccine it reduces incredibly expensive personal and population health issues.	
I2	I have concerns about additional criteria to coverage of CGM, especially those included in part C for the following reasons: 1. There does not appear to be evidence of a health benefit to requiring poor outcomes such as hyperglycemia (high blood sugar), hypoglycemia (low blood sugar) or impaired awareness of hypoglycemia prior to initiation of CGM. On the contrary, avoiding these crises are foundational to diabetes management using best practices, including CGM for individuals using insulin. Every time a person experiences hypoglycemia, they are at greater risk for impaired awareness the next time their blood sugar goes low. I cannot recommend the guidelines in section C as beneficial or "evidence based."	*Please see response to H3 regarding the subcommittee's decision to include hypoglycemia as one pathway to CGM coverage.*
I3	2. There does not appear to be evidence of cost savings. It is cost effective for our population to keep their blood sugars in target range as hyperglycemia is directly correlated with cardiovascular disease, strokes, kidney disease, amputations and infections that lead to expensive interventions including emergency department visits and hospitalizations. Likewise, hypoglycemia is also responsible for emergency department visits and hospitalizations. 1. Adding these additional requirements reduces access and equity.	*Recognizing the importance of healthcare cost-effectiveness, the subcommittee identified health resource utilization as an important outcome in this evidence review. However, in our evidence review, only one very low quality study (Isaacson et al, 2022 on page 31 of the report) reported on this outcome and thus the committee was unable to conclude whether CGM use*

Disposition of Public Comments

ID/#	Comment	Disposition
		significantly decreased resource use such as hospitalizations and other interventions.
I4	For future discussion, I recommend investigating when CGM therapy is most effective for people not using insulin. As a professional who spends 30-60 minutes appointments collaboratively managing diabetes with individuals and their families, I have noticed key moments in the progression of diabetes when people are highly motivated to make healthy changes. These moments include: 1. At the time the initial diagnosis. 2. When trying to delay the use of insulin or injectables. People are highly motivated to avoid or delay this transition. In addition to a major lifestyle shift, insulin therapy is costly. 3. With a spike in A1c or other changes in clinical conditions accompanying life transitions like retirement, grief or surgery. Providing continuous glucose monitoring during these critical times, even temporarily, has tremendous value for the individual and aids in the prevention of expensive therapies and costly long-term complications. I support access to CGM for individuals with T2DM and gestational diabetes who use insulin and are covered by Oregon Medicaid, without additional requirements, especially those covered in part C. Thank you so much for all you are doing for Oregonians. It is very much appreciated.	*Please see response to F1 regarding the subcommittee's decision to not recommend CGM coverage for people who do not require insulin.*

Disposition of Public Comments

References Provided by Commenters

ID	References
A	None provided
B	None provided
C	**Already included in the coverage guidance** • Vigersky RA, Fonda SJ, Chellappa M, Walker MS, Ehrhardt NM. Short- and long-term effects of real-time continuous glucose monitoring in patients with type 2 diabetes. *Diabetes Care*. 2012;35(1):32-38. Doi: 10.2337/dc11-1438. • Davis G, Bailey R, Calhoun P, Price D, Beck RW. Magnitude of glycemic improvement in patients with type 2 diabetes treated with basal insulin: subgroup analyses from the MOBILE study. *Diabetes Technol Ther*. 2022;24(5):324-331. Doi: 10.1089/dia.2021.0489. **Excluded from the coverage guidance** • Yoo HJ, An HG, Park SY, et al. Use of a real time continuous glucose monitoring system as a motivational device for poorly controlled type 2 diabetes. *Diabetes Res Clin Pract*. 2008;82(1):73-79. Doi: 10.1016/j.diabres.2008.06.015. [published prior to 2012] • Moon SJ, Kim KS, Lee WJ, Lee MY, Vigersky R, Park CY. Efficacy of intermittent short-term use of a real-time continuous glucose monitoring system in non-insulin–treated patients with type 2 diabetes: A randomized controlled trial. Diabetes, Obesity and Metabolism. 2022. Doi: 10.1111/dom.14852. [Intermittent use of CGM]
D	None provided
E	None provided
F	None provided
G	(1) http://main.diabetes.org/dorg/docs/state-fact-sheets/ADV_2020_State_Fact_sheets_OR.pdf
H	(1) AACE's Guide to Continuous Glucose Monitoring (2023). A Tool for Persons with Diabetes (PWD) and Caregivers | American Association of Clinical Endocrinology (aace.com) (2) Patton, S. Adherence to Glycemic Monitoring in Diabetes. Journal of Diabetes Science and Technology Volume 9. Issue 3, (2015). https://doi.org/10.1177/1932296814567709 (3) Gabbay,R., Durdock,K. Strategies to increase Adherence through Diabetes Technology. Journal of Diabetes Science and Technology Volume 4, Issue 3,(2010). Strategies to Increase Adherence through Diabetes Technology (sagepub.com) (4) Soupal,J. et. al. Low Initial Adherence with Flash Glucose Monitoring is Not a Predictor of Long-Term Glycemic Outcomes: Longitudinal Analysis of the Association Between Experience, Adherence, and Glucose Control for FreeStyle Libre Users. Diabetes Therapy (2023). https://doi.org/10.1007/s13300-023-01422-4

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	(5) Aleppo,G. et.al. The Effect of Discontinuing Continuous Glucose Monitoring in Adult with Type 2 Diabetes Treated with Basal Insulin. Diabetes Care (2021). https://doi.org/10.2337/dc21-1304 (6) American Diabetes Association. Diabetes Technology: Standards of Medical Care in Diabetes – 2023. Diabetes Care (2023). https://doi.org/10.2337/dc22-S007 (7) Klimontov, V. et. al. Glucose Variability: How Does It Work? Int. J. Mol. Sci. (2021). DOI: 10.3390/ijms22157783 (8) AACE Clinical Practice Guidelines, Volume 28, Issue 10, (2022). https://doi.org/10.1016/j.eprac.2022.08.002. (9) AACE Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm-2023 Update. Endocrine Practice 29 (2023). https://doi.org/10.1016/j.eprac.2023.02.001 (10) Association of Diabetes Care and Education Specialists. Diabetes Care and Education Curriculum 3rd Edition. (11) 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
I	None provided