# Health Evidence Review Commission's Evidence-based Guideline Subcommittee

## June 13, 2023

**2:00 PM - 5:00 PM**

**Online**

**Join online meeting here**

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# Section 1.0

# Call to Order

# Agenda
# Evidence-based Guidelines Subcommittee (EbGS)
# June 13, 2023

2:00 pm–5:00pm

Online meeting

All agenda items are subject to change and times listed are approximate.

Public comment will be taken on each topic per HERC policy at the time at which that topic is discussed.

| | Time | Topic |
|---|---|---|
| I. | 2:00 PM | Call to Order, Roll Call, Approval of Minutes |
| II. | 2:05 PM | Staff report |
| III. | 2:10 PM | Review Public Comment Disposition: Continuous Glucose Monitoring for Diabetes Mellitus |
| IV. | 4:45 PM | Other Business |
| V. | 4:50 PM | Next Steps<br>• Next meeting September 7, Online |
| VI. | 4:55 PM | Public comment on topics not on the agenda |
| VII. | 5:00 PM | Adjournment |

# Minutes
## Evidence-based Guidelines Subcommittee (EbGS)
## Online meeting
## April 20, 2023

**Members Present**: Devan Kansagara, MD, Chair; Max Kaiser, DO; Lisa Kouzes, DC; Mimi McDonell, MD; Leslie Sutton; Lynnea Lindsey, PhD; Cat Livingston, MD, MPH.

**Members Absent:** Abigail Khan, MD; Ben Hoffman, MD; Leda Garside, RN, MBA.

**Staff Present:** Amy Cantor, MD, MPH; Jason Gingerich; Liz Walker, PhD, MPH; Daphne Peck.

**Also Attending**: Val King MD, MPH, Rita Shiau & Shauna Durbin, MPH (OHSU Center for Evidence-based Policy); Andrea Steoud; Barbara Hettinger; Brian Wilhelmsen; Bruce Wolfe, MD; Carissa Kemp (ADA); Chad Graham; Charlene Lai; Chris Merkle; Cody; Dr. Rogalsky; Elizabeth Potter; Gary Parenteau; Gene Spader; Gillien; Greg Showell; Holly Jo L Hodges, MD (Moda Health/EOCCO; Jennifer Olson; Jessica Castle, MD; Jolene Carter; Jordain Mahr; Kat Wolf Khachatourian, PharmD; Kelsie; Kimberly, RN Certified Diabetes Educator; Laura Briggs; Laura Lacey; Leif Bruce; Sarah Like; Linda Nunes; Lori Landolt; Lynnea Lindsey; Marie Frazzitta; Mathieu in Motion; Mathieu Pitre (Abbott Diabetes Care); Rhonda McGivney; Mean Gene; Melissa Smith; Merrie Kay Alzola; Mohammad Abu Mallou, PharmD; Oana Dumitrescu; Kelly Jamison (OHA); Rafat Fields (Abbott Diabetes Care); Rebecca Knight-Alvarez; Renee Taylor; schoepp; sevketyigit; Sharon McDowell; Siobhan Hess; Stephen Willis PA-C; Tala Bayad; Val Halpin; Robert Vigersky, MD; Walter Lindstrom; YJ Shukla (EOCCO Moda Health).

## Call to Order

Devan Kansagara called the meeting of the Evidence-based Guidelines Subcommittee (EbGS) to order at 2:00 pm. A quorum of members was present at the meeting.

## Minutes Approval

Minutes from the February 2, 2023, meeting were reviewed and approved 5-0 (Livingston and Kaiser abstained).

## Staff Report

Jason Gingerich announced several membership changes, welcoming Cat Livingston, MD, MPH, to the EbGS subcommittee. Livingston gave a brief background. Gingerich also stated that Leslie Sutton's reappointment to HERC has been delayed until the September Senate confirmation, and that Sara Love, ND, has been appointed to the VBBS subcommittee. Gingerich then gave a brief legislative update for several active bills relevant to HERC's purview. He asked all those who attended the retreat to respond to the retreat follow-up survey that was distributed.

## Review Public Comment Disposition: Bariatric Procedures

Gingerich read aloud the biographical statements of the three appointed experts for this topic:

**Derek Rogalsky, MD**, is a general surgeon with expertise in bariatric, laparoscopic and robotic surgeries. He is based in Coos Bay, Oregon and runs the Center of Excellence for Bay Area Hospital's bariatric program. He has received some food/beverage funding (<$20) and has no conflicts of interest to declare.

**Bruce Wolfe, MD**, is a bariatric surgeon and emeritus faculty within OHSU's Division of Bariatrics in Portland, Oregon. Though retired from active practice, he conducts research in the areas of bariatric surgery and metabolomics and is currently a co-investigator of a NIDDK-funded trial studying amino acid supplementation after bariatric surgery. He has received some food/beverage funding (<$70) and has no conflicts of interest to declare.

**Sevket Yigit, MD**, is a board-certified pediatric endocrinologist at Randall Children's Hospital at Legacy Emanuel in Portland. He is the Clinical Director of Legacy's pediatric obesity program called "Fresh Start Wellness Program" since 2013. His specialties include pediatric endocrinology, obesity medicine and diabetes. Dr. Yigit is a member of the Obesity Medicine Association and serves on the editorial board for Obesity Pillars Journal. He has no conflicts of interest to declare.

Valerie King reviewed the public comments received during the comment period and the disposition statements. Kansagara stated that he'd like to discuss the coverage around adolescents and the BMI 30-34.9 group. He invited the group to share comments. Mimi McDonell said that the data are clear around the significant improvement for adults who have type 2 diabetes (T2DM) and undergo bariatric surgery. Lisa Kouzes agreed with McDonell. Max Kaiser said he did not find the data as compelling given the small number of study participants and time periods of the studies. Kansagara stated that the diabetes outcomes could be seen as an intermediate outcome of glycemic control and said he's cautious about interpreting these outcomes as compared to other end outcomes such as cardiac outcomes, mortality, or neuropathies. Kaiser stated that the resource cost of the interventions are large enough to warrant longer-term and more significant outcomes of benefit. Rogalsky stated the outcomes are not inferior to other medical management treatments of diabetes.

Amy Cantor reminded the subcommittee that the initial staff recommendation was to expand coverage to this BMI group, but the subcommittee opted to field comments during the formal comment period. The group continued to discuss the coverage and evidence available for this BMI group.

Kansagara asked if there is a motion for amending the recommendation for this group. McDonell made a motion to reconsider the draft guidance to recommend coverage for this BMI group when a diagnosis of T2DM is present. Kansagara queried the group for additional

indications. Kaiser agreed that narrowing the T2DM population would be helpful; Kansagara suggested adding the requirement of prior trials of diabetes medications, as well as considering an HbA1c threshold of 9%. Lindsey asked if we have enough evidence to set additional parameters or whether staff should perform additional analysis. Kouzes agreed with Lindsey. Kansagara stated these parameters would be practical considerations of how to implement these recommendations. Livingston agreed that these sound like straightforward clinical criteria that would prioritize those who would be an appropriate subset. The vast majority of people tolerate metformin well, which is a $4 a month medication. Those who have an HbA1c of 9% despite two medication trials would likely experience a meaningful benefit.

The group continued discussing parameters around diabetic medication trials, including reviewing the coverage guidance report appendices and professional society guidelines. Kansagara stated that poor control of diabetes could be defined by a HbA1c of 8.0%. Wolfe agreed with that definition. The subcommittee directed staff to incorporate wording to reflect the intent of the discussion.

The group then focused on the recommendation for the adolescent population. McDonell stated that she submitted testimony asking the group to reconsider their recommendation given that the release of the American Academy of Pediatrics (AAP) guideline happened before the meeting and not everyone had the opportunity to review the evidence on which those guidelines were based. She reminded the group that EPSDT would ensure every adolescent would receive an individual determination.

Kansagara stated that the draft recommendation to cover adolescents is a departure from past precedent given the poor state of the evidence on this group. He asked the group for additional thoughts. Kaiser also expressed hesitation of the long-term benefit of surgery in adolescents and expressed strong concerns about coverage for this group. Kansagara asked Dr. Yigit to provide his input. Yigit stated that diabetes remission rates are very high in this group, and there are other beneficial outcomes. He stated the pediatric community sentiment is to not wait to intervene and that this would be a very select group of kids and adolescents who are facing life-threatening levels of obesity who would be offered this option. Kansagara asked the expert to weigh in on wording to define life-threatening obesity and whether the recommendation language captures the sentiment. Yigit expressed agreement and said the language aligns with AAP's recommendation.

McDonell asked whether it'd be appropriate to offer a 13-year-old the option of surgery when the patient is still in a developmental stage. Kansagara asked the CEBP team if they found appropriate age cutoffs. King stated there were not subgroup analyses stratified by age in the adolescent studies. Yigit stated that it should be at the discretion of the pediatrician to determine the maturity level and readiness of the patient before offering the option and that the preoperative workup includes extensive evaluation of the patient before making the final decision. Kansagara stated that if the group moves forward with the recommendation in favor of coverage, then the rationale should be adjusted to reflect that this option is anticipated to be offered to a limited adolescent population experiencing life-threatening obesity.

Kansagara invited those who registered to offer public comment:

Walter Lindstrom, Senior Director for ReShape LifeSciences (manufacturer): Mr. Lindstrom stated he has been a bariatric patient advocate since 1994, a prior gastric bypass patient, and that he works for the manufacturer of the lap band, which is indicated for patients 18 years and older. He stated that the lap band is still among the ASMBS-approved procedures and should be a covered procedure.

Kat Khachatourian, Medical Account Associate for Novo Nordisk (pharmaceutical manufacturer): Ms. Khachatourian stated that anti-obesity medications will be reviewed by OHA's Pharmacy and Therapeutics (P&T) committee in the near future. She summarized obesity statistics nationally and in Oregon and outlined equity disparities in prevalence. She stated that pharmaceuticals should be considered as a treatment modality for obesity, alongside lifestyle modifications and surgical procedures.

Gingerich clarified that weight loss medications are currently excluded from coverage per Oregon's Medicaid state plan and confirmed that the P&T committee will review that class of medications later this year, after which HERC may or may not take action depending on the result.

Kansagara stated that in regard to the adolescent recommendation, the rationale should be revised from relying on the professional guideline to instead offer a pathway to coverage for those adolescents with really life threatening disease who don't have other options. In regard to the BMI 30-34.9 group, the rationale should reflect that for those with T2DM who have exhausted medical treatment options, bariatric surgery may provide a long term clinical benefit. He asked the group for further comments. The subcommittee had no further discussion.

A motion was made to refer the BMI $\geq$ 35 recommendation to the HERC for consideration. **Motion approved 7-0.**

A motion was made to refer the BMI 30-34.9 recommendation, as amended, to the HERC for consideration. **Motion approved 7-0.**

A motion was made to refer the adolescent recommendation, as amended, to the HERC for consideration. **Motion approved 6-0 (Nay: Kaiser).**

## Review Draft Coverage Guidance: Continuous Glucose Monitoring for Diabetes Mellitus

King reviewed the evidence and background information for the coverage guidance report. Cantor reviewed the values and preferences, resource allocation, and other factors considered in staff recommendations.

Gingerich introduced the appointed experts for this topic:

**Barbara Hettinger, MD, PhD**, is an endocrinologist at the Portland Veterans Affairs Medical Center, specializing in diabetes. She is in active practice and prescribes continuous glucose monitors, which are under review today. Dr. Hettinger is also the Associate Program Director OHSU's Endocrinology, Diabetes and Clinical Nutrition Fellowship program, and she serves on local committees to develop criteria for use of continuous glucose monitors. She has no conflicts of interest to declare.

**Laura Lacey, PharmD**, is a clinical pharmacist and diabetes specialist. In 2019 she joined the St. Charles Medical Group in Bend. Dr. Lacey utilizes continuous glucose monitors in her regular practice and works under a collaborative practice agreement to provide specialized diabetes management, including insulin pump and continuous glucose monitor management. She has no conflicts of interest to declare.

**Kimberly Cleveland, RN**, is a diabetes educator at Samaritan Lebanon Community Hospital. Her specialties include diabetes management and diabetes foot care. Ms. Cleveland conducts group classes and individual sessions on diabetes self-management education and provides training on the use of personal continuous glucose monitors. She serves as the Advocacy Co-Chair for the Oregon chapter of Association of Diabetes Specialists. She has submitted legislative testimony in favor of CGM coverage in Oregon's current legislative session.

Kansagara thanked the experts and asked the subcommittee for their thoughts. Kouzes stated that it is understandable to not cover continuous glucose monitoring (CGM) if someone does not use their monitor for at least 50% of the time, but it seems that generally people prefer CGM over finger-sticks.

Hettinger stated that it's important that patients are trained on how to use CGM. She spoke to the HbA1c requirement and that patients could experience a variability of blood sugars. Kaiser stated concern about the strength of the evidence. He stated that some compliance requirements are appropriate, as these are in place for other types of monitors, such as CPAP. CGM is not effective if people are not using it.

Cantor stated that the recommendation aligns with Medicare's recent CGM coverage decision.

Livingston stated that the recommendation does not require either an intensity of insulin taken or frequency. King responded that studies as well as payors are not consolidated around a certain insulin dosage or frequency, and therefore staff relied on recent CMS guidance.

Kansagara moved to hear public testimony.

Marie Frazzitta, Manager at Abbott Diabetes Care (CGM manufacturer): Ms. Frazzitta shared the results of a retrospective cohort study that showed benefit from CGM use. She stated that HbA1c is an average, whereas time in range can account for glucose variability.

Charlene Lai, pediatric endocrinologist at OHSU: Dr. Lai spoke about pediatric type 2 diabetes and her concern about the HbA1c requirement. She also asked if staff had done a review for CGM for cystic fibrosis-related diabetes.

Jessica Castle, adult endocrinologist at OHSU: Dr. Castle supported coverage for patients with type 2 diabetes on basal insulin. She stated that people who transition onto OHP who already use CGM would need to meet the HbA1c requirement. She stated that for patients who are pregnant, although there is limited data, it is a short amount of time so coverage should be considered for those who develop gestational diabetes but are not on insulin.

Robert Vigersky, Chief Medical Officer for Medtronic (CGM manufacturer): Dr. Vigersky disclosed his conflicts of interest. He described his study which showed CGM benefit and stated that CGMs help bring about behavior modification. He expressed concern about the HbA1c cutoff, stating that one of the report's studies showed a benefit from CGM with HbA1c ranges 7.1-11.6%.

Kansagara thanked the testifiers and asked if the subcommittee wanted to put the report out for public comment and discuss comments in detail at the June meeting. No objections were made by the subcommittee.

A motion was made to refer the draft coverage guidance report, as presented, for a 30-day public comment period. **Motion approved 7-0.**

HEALTH EVIDENCE REVIEW COMMISSION (HERC) COVERAGE GUIDANCE

## CONTINUOUS GLUCOSE MONITORING IN DIABETES MELLITUS

**Should continuous glucose monitoring (CGM) be covered for individuals with type 2 diabetes mellitus (T2DM) who use insulin?**

**We recommend coverage for CGM in individuals with T2DM or gestational diabetes who use 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, *AND***
C. **Have one of the following at the time of CGM therapy initiation:**
a. **Baseline HbA1c levels greater than or equal to 8.0%, *OR***
b. **Frequent or severe hypoglycemia, *OR***
c. **Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM).**

**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.**

**Should continuous glucose monitoring (CGM) be covered for individuals with type 2 diabetes mellitus (T2DM) who do not use insulin?**

**We do not recommend coverage for CGM in individuals who do not use insulin, including those with gestational diabetes mellitus (GDM).**

## Adjournment

The meeting was adjourned at 5:00 pm. The next meeting is scheduled for June 13, 2023, from 2:00-5:00 pm, online.

# Section 2.0

# Continuous Glucose Monitors

# 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.<br><br>Further, CGM supplies should not continually be paid for if they are not being used.<br><br>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.<br><br>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.<br><br>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.<br><br>**For EbGS discussion**<br><br>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).<br><br>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).<br><br>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%).<br><br>Severe hypoglycemia was an outcome that was included in the approved scope statement for this draft report.<br><br>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).<br><br>**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.).<br><br>The key questions for this report did not request differential comparative effectiveness by type of insulin regimen.<br><br>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).<br><br>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.<br><br>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 for staff to report outcomes by CGM type (therapeutic/non-adjunctive versus nontherapeutic/adjunctive).*<br><br>*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.*<br><br>*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.<br><br><u>CGM Clinical Criteria</u><br>Initial request:<br>A. Type 1 diabetic OR<br>B.<br>1. Diagnosed with Diabetes Mellitus Type II with A1C 6.5 or higher, and requiring insulin therapy<br>AND<br>2. Is medically complex as defined as <u>ONE</u> of the following:<br>a. Highly-intensive insulin regimen (Tests 4 or more times per day AND uses at least 3 insulin injections per day/insulin pump); OR<br>b. Hx of hypoglycemia with one of the following: OR<br>i. Dawn phenomenon<br>ii. Hypoglycemic unawareness<br>iii. Nocturnal hypoglycemia | *Thank you for your comments. The following comments address specific elements of your proposed coverage criteria:*<br><br>*A: This report excluded people with type 1 diabetes because CGM is already a covered benefit for this population.*<br><br>*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).*<br><br>*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<br>d. Has loss of manual dexterity (such as from dementia, Parkinson's, tremor interfering with ADLs, etc).<br><br>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).<br><br>(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.*<br><br>*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.*<br><br>*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.*<br><br>*Finally, we recognize that plans have exception processes for situations not addressed by coverage recommendations, which apply at the population level.*<br><br>***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.<br><br>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):<br><br>• Option B.: Uses the CGM 50% or more of the time by their first follow-up visit<br>• 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 |
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| C2 | Option B: Medtronic recommends that the criteria of 50% use of CGM be omitted from the coverage statement:<br><br>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.<br><br>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.*<br><br>*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.*<br><br>*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.*<br><br>*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.*<br><br>*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.* |

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| | 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.*<br><br>***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:<br><br>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.*<br><br>*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.* |

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| | 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.<br><br>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%.<br><br>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.*<br><br>*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:<br><br>• 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.<br>• 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:<br>  ○ Convenience<br>  ○ Interest in technology<br>  ○ Massive industry advertising/social media<br>• 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.* |

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| | ○ We think there is potential value for patients with T2DM who are taking short acting insulin to allow for better adjustments in therapy.<br>○ Basal insulin dosing does not require this more intensive monitoring due to the pharmacokinetics of the therapy.<br>○ UHA has been approving CGMs to our members with T2DM on basal+ short-acting insulin for the last year.<br>○ 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:<br><br>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:<br><br>A. Have received or will receive diabetes education specific to the use of CGM, AND<br>B. Have used the device for at least 50% of the time by their first follow-up visit<br><br>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.<br><br>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.*<br><br>*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* |

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| | | *use to any insulin regimen subgroup in the proposed coverage guidance.* |
| D3 | Lastly, UHA is very concerned about the rationale provided for this guideline:<br><br>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.<br><br>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.*<br><br>*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.*<br><br>*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.*<br><br>*See response to C2 regarding the subcommittee's decision to include an adherence requirement.*<br><br>***For EbGS discussion***<br><br>*Consider adding wording in the coverage guidance to address re-initiation of CGM.* |

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| | "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.*<br><br>*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.*<br><br>*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.*<br><br>*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* |

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| | | *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.*<br><br>*See response to B1 regarding the subcommittee's decision to include an HbA1c threshold as one pathway for CGM coverage.* |

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| | 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.<br><br>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.*<br><br>*See response to C2 regarding the utilization requirement.* |

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| | Remove the requirement: Have used the device for at least 50% of the time by their follow-up visit<br><br>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)<br><br>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.*<br><br>*The subcommittee considered TIR and other outcome measures in the initial scoping process, ultimately selecting HbA1c as the outcome in the approved scope* |

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| | 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)<br><br>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* |

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| | 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.*<br>*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.* |

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| | 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).<br><br>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* |

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| | | *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**<br>• 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.<br>• 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.<br>**Excluded from the coverage guidance**<br>• 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]<br>• 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)<br>(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<br>(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)<br>(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 |

## Disposition of Public Comments

| ID | References |
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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<br>(6) American Diabetes Association. Diabetes Technology: Standards of Medical Care in Diabetes – 2023. Diabetes Care (2023). https://doi.org/10.2337/dc22-S007<br>(7) Klimontov, V. et. al. Glucose Variability: How Does It Work? Int. J. Mol. Sci. (2021). DOI: 10.3390/ijms22157783<br>(8) AACE Clinical Practice Guidelines, Volume 28, Issue 10, (2022). https://doi.org/10.1016/j.eprac.2022.08.002.<br>(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<br>(10) Association of Diabetes Care and Education Specialists. Diabetes Care and Education Curriculum 3rd Edition.<br>(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 |

HEALTH EVIDENCE REVIEW COMMISSION (HERC)
COVERAGE GUIDANCE PLAIN LANGUAGE SUMMARY

For complete details, please see the coverage guidance document, "CONTINUOUS GLUCOSE MONITORING IN DIABETES MELLITUS" that follows this summary.

# CONTINUOUS GLUCOSE MONITORS (CGM) FOR TYPE 2 DIABETES

Draft 6/13/2023

## Should a wearable monitor for checking blood sugar (glucose) levels be covered for people who have type 2 diabetes?

Yes, if the person:

- Needs daily insulin injections and
- Receives diabetes education about how to use the CGM and
- Uses the CGM 50% or more of the time by their first follow-up visit and
- If *one* of the following issues at the time a CGM is prescribed is true:
    - A1c (a blood test that measures average blood glucose level) level of 8% or higher or
    - Severe problems with low blood sugar (hypoglycemia) or
    - Not knowing the signs of low blood sugar

Twice a year, the provider should meet with the person to review their use of CGM and diabetes treatment plan.

## Why should we cover the CGM?

We recommend covering the CGM because, for people who need daily insulin injections, the benefit is greater than the small risk of harm. We do not recommend it for other people who do not need insulin since our research didn't show any meaningful benefits to that group.

## What about CGM for people who develop diabetes while pregnant?

We recommend covering CGM for this group, if they use insulin, because it is reasonable to expect a benefit and more research is not likely to happen for this group.

We do not recommend covering CGM for this group if they do not need insulin. Medical studies did not show enough meaningful benefit to justify adding coverage for this group.

HEALTH EVIDENCE REVIEW COMMISSION (HERC) COVERAGE GUIDANCE

# CONTINUOUS GLUCOSE MONITORING IN DIABETES MELLITUS

DRAFT for EbGS Meeting June 13, 2023

QUESTION ONE

## Should continuous glucose monitoring (CGM) be covered for individuals with type 2 diabetes mellitus (T2DM) who use insulin?

**We recommend coverage for CGM in individuals with T2DM or gestational diabetes who use 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, *AND***
C. **Have one of the following at the time of CGM therapy initiation:**
   a. **Baseline HbA1c levels greater than or equal to 8.0%, *OR***
   b. **Frequent or severe hypoglycemia, *OR***
   c. **Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM).**

**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.**

Rationale:
We recommend coverage of CGM because the benefits for individuals using insulin outweigh the minimal risk of harms. 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. A recommendation for conditional coverage was informed by evidence of safety and effectiveness, as well as the importance of reducing disparities in access to care for this population.

QUESTION TWO

## Should continuous glucose monitoring (CGM) be covered for individuals with type 2 diabetes mellitus (T2DM) who do not use insulin?

**We do not recommend coverage for CGM in individuals who do not use insulin, including those with gestational diabetes mellitus (GDM).**

Rationale:
We do not recommend coverage of CGM because 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 GDM. There were insufficient data to determine the balance of benefits and harms for these populations.

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# RATIONALE FOR DEVELOPMENT OF COVERAGE GUIDANCES AND MULTISECTOR INTERVENTION REPORTS

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as plan administrators seek to improve patients' experience of care, population health, and the cost-effectiveness of health care. In the era of public and private sector health system transformation, reaching these goals requires a focus on maximizing the benefits and minimizing the harms and costs of health interventions.

The Health Evidence Review Commission (HERC) uses the following principles in selecting topics for its reports to guide public and private payers:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

HERC bases its reports on a review of the best-available research applicable to the intervention(s) in question. For coverage guidances that focus on diagnostic and clinical interventions, evidence is evaluated using an adaptation of the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. In some cases, HERC has reviewed evidence and identified effective interventions, but has not made formal coverage recommendations when these policies are implemented in settings other than traditional health care delivery systems because effectiveness could depend on the environment in which the intervention is implemented.

## GRADE

HERC develops recommendations by using the concepts of the GRADE approach. GRADE is a transparent and structured process for developing and presenting evidence and for performing the steps involved in developing recommendations. The tables below list the elements that determine the strength of a recommendation. HERC reviews the evidence and assesses each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. Assessments of confidence are from the published systematic reviews and meta-analyses, where available and judged to be reliable. The level of confidence in the estimate is determined by HERC based on the assessment of 2 independent reviewers from the Center for Evidence-based Policy (Center; Figure 1).

In some cases, no systematic reviews or meta-analyses encompass the most current literature. In those cases, HERC may describe the additional evidence or alter the assessments of confidence in light of all

available information. Such assessments are informed by clinical epidemiologists from the Center. Unless otherwise noted, statements regarding resource allocation, values and preferences, and other considerations are the assessments of HERC, as informed by the evidence reviewed, public testimony, and subcommittee discussion.

Figure 1. GRADE Table Key

| Outcomes | Table Key | | | | | |
|---|---|---|---|---|---|---|
| | Confidence in Estimate: | NO DATA | VERY LOW | LOW | MODERATE | HIGH |
| | Direction of Effect: | No Data, Unclear, No Effect, Benefit, Harm, Mixed | | | | |

Notes. Recommendations for coverage are based on the balance of benefit and harms, resource allocation, values and preferences, and other considerations. See Appendix A for more details about the factors that constitute the GRADE table.
Abbreviation. GRADE: Grading of Recommendations, Assessment, Development, and Evaluations approach.

# GRADE TABLES

## GRADE TABLE 1
## POPULATION: INDIVIDUALS WITH T2DM REQUIRING INSULIN

### CRITICAL OUTCOMES

#### Severe hypoglycemia requiring intervention


Across the 3 eligible studies reporting on severe hypoglycemia, very few events occurred (4 events with CGM vs. 2 events with SMBG). Tests of significance were not performed, and studies were likely underpowered to detect true differences among groups. Of the severe hypoglycemic events that did occur, none were judged to be associated with CGM use.

A higher rate of severe hypoglycemic events was reported in 1 study of pregnant individuals with preexisting T2DM (15 events in 5 individuals), but events were not reported by group assignment and the study was not powered to detect differences for this outcome in individuals with T2DM.

4 RCTs; N = 588

Very low confidence due to substantial imprecision, because of the small number of events and lack of statistical power, and RoB concerns because of study attrition and possible funding-related COI.

#### Change in HbA1c


In 2 US-based RCTs of adults (DIAMOND, MOBILE), CGM was associated with a statistically significant reduction in HbA1c compared with SMBG (DIAMOND: MD, −0.30%; *P* = .02; MOBILE: MD, −0.50%; *P* = .02). Additionally, a greater proportion of individuals randomized to CGM in these trials experienced a ≥ 0.5% HbA1c reduction at the final study follow-up (DIAMOND: 79% vs. 51%; *P* = .002; MOBILE: 73% vs. 65%; *P* = .05). There were no statistically significant subgroup differences for change in HbA1c in either trial.

In 1 non-US-based RCT of adults (REPLACE), there was no statistically significant difference in change in HbA1c between the CGM and SMBG groups at the final study follow-up (−0.29% vs. −0.31%; *P* = .82). However, study participants aged < 65 years using CGM experienced a significantly greater reduction in HbA1c compared with SMBG (−0.5% vs. −0.2%; *P* = .03), whereas participants aged ≥ 65 years using CGM did not.

In a staff-conducted pooled analysis of these 3 studies, CGM use was ultimately not associated with a statistically significant HbA1c reduction.

In 1 study of pregnant individuals with preexisting T2DM randomized to CGM or SMBG, mean change in HbA1c was not reported, but there were no significant between-group differences in mean HbA1c at any follow-up timepoint. This study was not powered to detect between-group differences for individuals with T2DM.

# GRADE TABLE 1
## POPULATION: INDIVIDUALS WITH T2DM REQUIRING INSULIN

4 RCTs; N = 588

Low confidence due to inconsistency in findings among studies and indirectness due to use of run-in periods to assess adherence prior to randomization.

### Severe perinatal morbidity


In 1 study of CGM vs. SMBG in pregnant individuals with preexisting T1DM or T2DM, a subgroup analysis of participants with T2DM found no statistically significant between-group differences in the incidence of:

- Miscarriage
- Preterm birth
- Preeclampsia
- Caesarean section
- Perinatal hypoglycemia
- Severe perinatal hypoglycemia
- Large for gestational age

However, this study was underpowered to assess statistical differences in the T2DM subgroup, so the true effect is unknown.

1 RCT; N = 31 (T2DM group only)

Very low confidence due to RoB regarding incomplete outcome reporting, imprecision due to being underpowered to detect between-group differences, and indirectness due to intermittent CGM use (i.e., several 6-day periods) in the intervention group.

### Quality of life


Comparative results regarding QoL were mixed across 3 RCTs. In the study evaluating CGM in a US population treated with multiple daily insulin injections, there were no significant differences in any general or diabetes specific QoL measure. In 2 studies that evaluated CGM in non-US populations, 1 study of individuals on intensive insulin therapy observed higher diabetes-related treatment satisfaction ($P < .001$; DTSQ scale) and diabetes-related QoL ($P = .03$; DQoL scale) with CGM compared with SMBG, whereas 1 study of individuals treated with multiple daily insulin injections found no difference in treatment satisfaction. QoL scores were generally positive across all study groups and scales.

3 RCTs; N = 427

Low confidence due to inconsistent results among studies and indirectness related to heterogeneity of multiple unrelated scales and inclusion of data from non-US health care systems.

# GRADE TABLE 1
## POPULATION: INDIVIDUALS WITH T2DM REQUIRING INSULIN

### IMPORTANT OUTCOMES

### Health resource utilization

NO DATA

There were no eligible studies that reported health resource utilization outcomes.

### Harms

MINIMAL

Across 6 RCTs, AEs were generally more common in CGM groups, but rates of SAEs were nearly equivalent between groups in most studies. SAEs were largely attributed to diabetes events (e.g., hypoglycemia) or hospitalizations surgeries unrelated to diabetes (e.g., hip replacement). Few study discontinuations occurred.

AEs attributed to CGM use were not common and those that occurred were mild to moderate sensor adhesive skin reactions which resolved by the end of the study. No CGM-related AEs resulted in study discontinuation.

6 RCTs; N = 772

Moderate confidence due to consistently low rates of events attributed to study devices or protocol; some indirectness due to use of run-in periods to assess tolerability and adherence prior to randomization.

**Balance of benefits and harms**

There is limited benefit of CGM for adults with T2DM requiring insulin based on studies demonstrating HbA1c reductions (vs. SMBG). There were no studies in children or adolescents who use insulin, and insufficient data for pregnant populations. There are insufficient data for other critical clinical outcomes in any population using insulin, with limited evidence of benefit for QoL. There are few harms related to the use of CGM.

**Resource allocation**

Individuals who require insulin have higher resource needs than those with diet controlled T2DM or who use oral medications; however, there are no data comparing effectiveness among these groups.

CGM requires both an upfront equipment cost for the receiver/monitor as well as a monthly supply cost for batteries, transmitters and sensors. The receiver/monitor is considered DME by federal Medicaid rules (42CFR §440.70) and has a minimum useful lifetime of 3 years, and if functioning, does not require replacement within 3 years of dispensing.

For individuals requiring insulin, CGM may replace the need for lancets and test strips, outside of the need for calibration.

**Values and preferences**

Individuals who require insulin may value monitoring their blood glucose in real time to enable timely response to fluctuating glucose levels or to improve overall glycemic control.

| | |
|---|---|
| | Some individuals may prefer CGM over SMBG, which requires finger sticking. Other individuals may or may not experience discomfort wearing a consumable device that requires routine maintenance and replacement transmitters and sensors.<br><br>Pregnant individuals may want to optimize blood glucose control to minimize the potential negative maternal or neonatal outcomes, given the higher risk for pregnancy complications and neonatal AEs compared with nondiabetic pregnant populations. |
|  | **Other considerations**<br>There is an overall absence of clear evidence of benefit for CGM in adult populations with T2DM other than a reduction in of HbA1c, an intermediate outcome. While the evidence is unclear for the benefit of CGM for specific populations with T2DM, lack of coverage for CGM may be a perceived barrier to prescribing among specific racial or ethnic groups. |

Notes. GRADE table elements are described in Appendix A; a corresponding GRADE Evidence Profile is in Appendix B.
Abbreviations. AE: adverse events; CGM: continuous glucose monitoring; COI: conflict of interest; DIAMOND: multiple Daily Injections And continuous glucose MONnitoring in Diabetes; DME: durable medical equipment; DQoL: Diabetes Quality of Life; DTSQ: Diabetes Treatment Satisfaction Questionnaire; HbA1c: glycated hemoglobin; MD: mean difference; MOBILE: Continuous Glucose MOnitoring in T2D Basal InsuLin UsErs; QoL: quality of life; RCT: randomized controlled trial; REPLACE: Novel Glucose-sensing Technology as a REPLACEment for Blood Glucose Monitoring for the Management of Insulin-treated Type 2 Diabetes; RoB: risk of bias; SMBG: self-monitoring of blood glucose; T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus; US: United States; vs.: versus.

# GRADE TABLE 2
## POPULATION: INDIVIDUALS WITH T2DM NOT REQUIRING INSULIN

### CRITICAL OUTCOMES

#### Severe hypoglycemia requiring intervention

NO DATA

There were no eligible studies that reported the incidence of severe hypoglycemic events.

#### Change in HbA1c

BENEFIT

Among the 4 RCTs that reported on mean change in HbA1c, 2 studies observed significant reductions in HbA1c ranging from –0.30% to –0.70% with CGM compared with SMBG (P < .001) whereas 2 studies observed no differences between study groups. In a staff-led pooled analysis of these 4 RCTs, CGM was associated with a statistically significant mean HbA1c reduction of −0.35% (95% CI, −0.54 to −0.16; *P* < .001) compared with SMBG.

Two RCTs reported on other related outcomes: 1 study observed a greater median reduction in HbA1c compared with SMBG (−0.6% vs. −0.1%; *P* < .001) and 1 study found that a significantly greater proportion of participants in the CGM group achieved a clinically meaningful HbA1c reduction of ≥ 0.5% compared with the SMBG group (51.7% vs. 21.0%; *P* < .001).

Trial-reported subgroup analyses demonstrated greater HbA1c reductions among those with high CGM adherence than those with lower CGM adherence compared with SMBG groups.

6 RCTs; N = 609

Low certainty due to RoB from study attrition and COI-related funding concerns and indirectness from inclusion of studies conducted in health systems that may not be generalizable to US contexts.

#### Severe perinatal morbidity

NO DATA

There were no eligible studies reporting the incidence of severe perinatal morbidity in pregnant populations.

#### Quality of life

MIXED

Comparative results regarding diabetes-related QoL were mixed across 3 RCTs with relevant outcomes. In 1 US-based study of CGM use in adults, there were no between-group differences in the reported level of diabetes-related problems (PAID scale) at 12 or 52 weeks of follow-up (*P* = .96). Comparatively, 2 studies assessing CGM in non-US populations found that participants randomized to CGM reported significantly higher diabetes-related treatment satisfaction at 24 weeks (*P* < .001; DTSQ scale) and improved ability to perform diabetes self-care activities (*P* = .003; SDSCA-K survey), such as foot care and glucose monitoring, compared with SMBG.

# GRADE TABLE 2
## POPULATION: INDIVIDUALS WITH T2DM NOT REQUIRING INSULIN

3 RCTs; N = 326

Very low confidence due to inconsistent results among studies, RoB due to study attrition and COI-related funding concerns, and indirectness related to heterogeneity of multiple unrelated scales and studies conducted in non-US health care systems.

## IMPORTANT OUTCOMES

### Health resource utilization

●○○○ UNCLEAR

Compared with SMBG, adults with T2DM randomized to CGM had significantly fewer mean diabetes-related total health care visits (5.6 vs. 7.0; *P* = .009), emergency department or urgent care visits (0.2 vs. 0.5; *P* = .02), and lab tests (7.7 vs. 11.9; *P* < .001). Study groups did not differ with respect to diabetes-related primary care clinic visits (*P* = .28) or visits with specialty diabetes clinicians (*P* = .06).

1 RCT; N = 99

Very low confidence due to RoB related to high control group attrition, imprecision due to small sample size, and indirectness due to inclusion of some participants with T1DM.

### Harms

●●●○ MINIMAL

Across 6 RCTs, AEs were generally more common in CGM groups, but rates of SAEs were nearly equivalent between groups in most studies. SAEs were largely attributed to diabetes events (e.g., hypoglycemia) or hospitalizations surgeries unrelated to diabetes (e.g., hip replacement). Few study discontinuations occurred.

AEs attributed to CGM use were not common and those that occurred were mild to moderate sensor adhesive skin reactions which resolved by the end of the study. No CGM-related AEs resulted in study discontinuation.

6 RCTs; N = 772

Moderate confidence due to consistently low rates of events attributed to study devices or protocol; some indirectness due to use of run-in periods to assess tolerability and adherence prior to randomization.

**Balance of benefits and harms**

Among adults with T2DM who do not require insulin, there is very little evidence of benefit, and reductions in HbA1c are not clinically meaningful. There were no studies in children, adolescents, or pregnant individuals who do not require insulin. There are insufficient data to evaluate the balance of benefits and harms of CGM in populations who do not require insulin.

| | |
|---|---|
| | **Resource Allocation**<br>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. |
| | **Values and Preferences**<br>There may be children, adolescents and their families who would prefer CGM over alternative methods of monitoring T2DM due to factors of convenience or surveillance, despite recommendations against daily monitoring of blood glucose levels for this population. |
| | **Other considerations**<br>There is an overall absence of clear evidence for benefit for CGM in adult populations with T2DM other than a small reduction of HbA1c, an intermediate outcome. There are no studies of effectiveness of CGM in children and adolescents with T2DM. |

Notes. GRADE table elements are described in Appendix A; a corresponding GRADE Evidence Profile is in Appendix B.
Abbreviations. AE: adverse event; CGM: continuous glucose monitoring; CI: confidence interval; COI: conflict of interest; DTSQ: Diabetes Treatment Satisfaction Questionnaire; HbA1c: glycated hemoglobin; MD: mean difference; PAID: Problem Areas In Diabetes; QoL: quality of life; RCT: randomized controlled trial; RoB: risk of bias; SAE: serious adverse event; SDSCA-K: Summary of Diabetes Self-Care Activities–Korean Version; SMBG: self-monitoring of blood glucose; T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus; US: United States; vs.: versus.

# BACKGROUND

This section includes contextual information regarding diabetes and continuous glucose monitoring (CGM) including the prevalence of diabetes in Oregon, CGM modalities and devices, the relationship between glucose monitoring and glycated hemoglobin (HbA1c), barriers to CGM access and utilization, and potential direct and indirect costs of CGM use.

Diabetes mellitus ("diabetes") is a chronic metabolic condition that occurs when an individual's blood sugar (i.e., blood glucose) is too high.[1] Blood sugar is regulated by the pancreas, which releases a hormone called insulin to facilitate the transfer of blood sugar into energy within the body's cells.[1] Diabetes occurs when the pancreas does not produce enough, or any, insulin to keep blood sugar at an optimal level.[1] In the long-term, exposure to elevated blood sugar is associated with increased risk of developing severe health complications such as heart disease, stroke, kidney disease, eye conditions, dental disease, nerve damage, or skin ulcer problems.[1]

Diabetes affects children and adults and primarily occurs in 3 forms[1]:

- Type 1 diabetes mellitus (T1DM), in which the pancreas produces little or no insulin
- Type 2 diabetes mellitus (T2DM), in which the pancreas produces insufficient amounts of insulin or the body does not use insulin effectively
- Gestational diabetes mellitus (GDM), which develops during pregnancy and typically resolves after pregnancy, although it is associated with an increased risk for eventually developing T2DM[2]

## Diabetes in Oregon

In 2015, the Oregon Health Authority estimated that about 12% of Oregon adults aged 18 years and older had diabetes, including 287,000 individuals with diagnosed diabetes and 110,000 living with undiagnosed diabetes.[3] These estimates corresponded with a more than two-fold increase in diabetes prevalence from 1990, when fewer than 5% of adults had diagnosed diabetes of any type.[3] The majority of the increase in diabetes prevalence is attributable to T2DM, which accounts for 90% to 95% of adults diagnosed with diabetes.[3] The prevalence of GDM in Oregon has also been steadily increasing: in 2013, 10% of all births in Oregon were to mothers with GDM, compared with less than 5% in 1990.[3] Among Oregon children, the estimated 2017 prevalence of obesity (a major risk-factor for T2DM) was 11.4%, a more than 50% increase from 2001.[4]

Diabetes in Oregon is more prevalent among women and adults older than 65 years, and disproportionately affects communities of color.[3] In 2015, Black, Latino, or American Indian and Alaska Native populations were more than twice as likely to have diagnosed diabetes compared with White individuals.[3] Oregon Medicaid enrollees are also disproportionately affected by diabetes: in 2013, nearly 19% of Oregon Health Plan beneficiaries had diabetes, compared with 7% on employer-sponsored health plans.[3]

The cost impact of T2DM in Oregon is substantial. According to the Oregon Health Authority, costs for health care and lost productivity from untreated or poorly-controlled T2DM total an estimated $3 billion per year.[3] Annual medical expenditures for T2DM in Oregon are estimated at $2.2 billion, while reduced or lost productivity from T2DM is estimated at around $840 million per year.[3] In 2012, the Oregon Health

Plan paid an estimated $106 million in T2DM-related claims, including costs for complications such as cardiovascular events, peripheral artery disease, and retinopathy.[3]

## Continuous Glucose Monitoring

Most individuals with diabetes need to regularly measure their blood glucose levels to effectively manage their condition and make treatment adjustments, which may include behavioral lifestyle modifications, oral glucose-regulating medications, or insulin therapy.[5] Several techniques and devices may be used to measure blood glucose levels.

Self-monitoring of blood glucose (SMBG) is the most widely used technique and involves taking manual, point-in-time glucose measurements throughout the day.[5] SMBG is typically performed with devices called glucometers that measure blood glucose in capillary blood obtained from finger needle sticks, and display the percentage glucose concentration on a screen; many glucometers can also store and download finger-stick readings that can be reviewed by the individual or their clinician.[5,6] When performed regularly, SMBG can help individuals and their clinicians better understand their blood glucose and make adjustments to their diabetes regimen. The recommended number of daily glucose measurements varies by the intensity of an individual's treatment needs: individuals with diabetes who require multiple daily insulin injections are advised to measure their blood at least 4 times per day, usually prior to eating or sleeping, whereas individuals with T2DM not treated with insulin are advised to limit daily SMBG to periods of change in their treatment regimen.[5-8]

Continuous glucose monitoring (CGM) uses a device, called a continuous glucose monitor, with an interchangeable sensor inserted in the skin to automatically measure interstitial glucose (i.e., glucose in the fluid between cells) every few minutes, generating as many as 288 measurements in a 24-hour period.[9,10] Measurements taken by the sensor are transferred to a receiver for viewing and storage; the receiver may be a standalone device or an app on a smartphone or tablet.[9,10] In addition to continuous measurement, many CGM models also include features such as alarms that sound when a user may be at risk for low or high blood sugar and allow users to download and share their information with their clinicians or family members.[9] Most CGM are used on their own, but they may also be integrated with an insulin pump to automatically adjust the amount of insulin a patient receives throughout the day.[6,9]

There are 2 primary CGM modalities: retrospective or real-time.[5,6] Retrospective CGM record an individual's glucose measurements over a short period of time, during which patients are blinded to the glucose readings; the data are then downloaded by a clinician and reviewed with the patient.[5,6] This type of CGM is sometimes referred to as "professional CGM," as it is typically used by clinicians for diagnostic or management-adjustment purposes. In contrast, real-time CGM (rtCGM) are for long-term individual use and have monitoring components that allow users to view their glucose measurements and make in-the-moment adjustments to their daily eating, activities, and medications.[6,11] Several types of rtCGM have been approved by the US Food and Drug Administration (FDA)[10,11]:

- Therapeutic, or nonadjunctive, rtCGM are factory-calibrated and do not require users to confirm readings with finger-stick tests before making management adjustments
- Nontherapeutic, or adjunctive, rtCGM require users to perform 2 or more finger-stick calibration measurements daily to ensure accuracy

- Intermittently scanned CGM (isCGM) are a type of therapeutic rtCGM that requires users to scan their sensor with a device to see their glucose values instead of the device automatically pushing all values to a monitor

Table 1 describes the rtCGM that are currently commercially available and approved by the FDA.

Table 1. FDA-Approved Real-time Continuous Glucose Monitors[10]

| DEVICE | MANUFACTURER | FINGER-STICK CALIBRATION | APPROVED PATIENT AGE | SENSOR WEAR DURATION |
|---|---|---|---|---|
| **THERAPEUTIC REAL-TIME CGM** | | | | |
| FreeStyle Libre 3 | Abbott | Not required | 4+ years | 14 days |
| G6 | Dexcom | Not required | 2+ years | 10 days |
| G7 | Dexcom | Not required | 2+ years | 10 days |
| **NONTHERAPEUTIC REAL-TIME CGM** | | | | |
| G4 PLATINUM[a] | Dexcom | 2 per day, minimum | 2+ years | 7 days |
| G5[a] | Dexcom | 2 per day, minimum | 2+ years | 7 days |
| Guardian Connect | Medtronic | 2 per day, minimum | 14+ years | 7 days |
| Eversense CGM System | Senseonics | 2 per day, minimum | 18+ years | 90 days |
| **INTERMITTENTLY SCANNED CGM** | | | | |
| FreeStyle Libre 2 | Abbott | Not required | 4+ years | 14 days |

Notes. [a] Dexcom discontinued the G4 PLATINUM and G5 models in US markets in 2020.[12]
Abbreviations. CGM: continuous glucose monitoring; FDA: US Food and Drug Administration.

Although SMBG has been linked to improved glycemic control, performing the multiple daily finger sticks necessary to understand an individual's glycemic response can be painful and difficult to maintain; in contrast, CGM sensors are inserted once every couple of weeks and, depending on the device, may not require calibration with finger sticks.[6] To that end, studies of rtCGM in adult and pediatric populations have observed high rates of treatment satisfaction among device users, largely driven by perceived convenience and flexibility compared with SMBG.[13-15] In qualitative studies, adults and caregivers of children with diabetes have also reported that having access to frequent, real-time glycemic data resulted in improved confidence in managing hypoglycemia and led to better engagement with their diabetes clinicians.[16-18]

## Important Glycemic Outcomes and Management Considerations

Other types of testing can be used to assist in the long-term management of diabetes, such as periodic laboratory testing of glycated hemoglobin (HbA1c). This value represents the percentage of hemoglobin molecules with attached glucose molecules, and also provides an average level of the percentage of hemoglobin molecules with attached glucose molecules over the past 10 to 12 weeks (the lifespan of a hemoglobin molecule).[19] Although it is an indirect measure of glycemic control and can underestimate or overestimate actual blood glucose levels, HbA1c is commonly used to assess whether an individual is meeting glycemic goals over time.[5] Studies have shown a high correlation between HbA1c levels and

blood glucose levels as measured by SMBG or CGM, although the correlation may be slightly less accurate in specific subpopulations (e.g., children).[5,19] Between HbA1c laboratory tests, home blood glucose readings from SMBG or CGM can be used to aid in daily management of diabetes.[5]

Although HbA1c is an important indicator of glycemic control among individuals with diabetes, there is a lack of consensus regarding what constitutes a clinically meaningful change in HbA1c between tests. Professional guideline organizations, such as National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK), accept 0.5% as a clinically meaningful change in HbA1c, whereas other regulatory organizations, including the FDA and European Medicines Agency, have accepted change thresholds ranging from 0.3% to 0.5%.[20-22] Randomized controlled trials of CGM have also variably defined a clinically meaningful change in HbA1c as 0.3%,[23] 0.4%,[24,25] or 0.5%.[26] Outside of research environments, surveys indicate that diabetes clinicians are most likely to endorse a 0.5% change between HbA1c tests as an indicator that treatment adjustments are needed.[27] Moreover, laboratory testing standards have accepted a 0.5% change as a statistically and clinically meaningful change in serial HbA1c tests.[5,28,29] For the purposes of this coverage guidance, we defined a clinically significant change in HbA1c as a difference of 0.5% from baseline, according to the NICE guideline, wide acceptance in clinical practice, and laboratory standards.

In addition to changes in blood sugar levels over time as measured by HbA1c, low blood sugar (i.e., hypoglycemia) is an important outcome for people with diabetes.[5] The American Diabetes Association (ADA) defines Level 1 hypoglycemia as a blood glucose concentration between 54 mg/dL (3.0 mmol/L) and 70 mg/dL (3.9 mmol/L); Level 2 hypoglycemia as a blood glucose concentration of less than 54 mg/dL (3.0 mmol/L); and Level 3 hypoglycemia as a severe event that causes altered mental or physical functioning and which requires assistance from another person for recovery, such as administration of oral or injectable glucose.[5] Individuals with hypoglycemia may experience shakiness, irritability, confusion, tachycardia, or hunger; if left untreated, hypoglycemia can lead to loss of consciousness, seizure, coma, or death.[5] Certain individuals with diabetes experience higher rates of severe hypoglycemic events, including older adults, young children, and Black individuals.[5]

Prolonged high blood sugar (i.e., hyperglycemia) is also a concern for individuals with diabetes and, when persistent, can lead to severe microvascular complications such as retinopathy, neuropathy, and diabetic kidney disease.[5] Individuals with hyperglycemia are at risk of developing diabetic ketoacidosis, the buildup of acid in the blood which can cause hypoglycemia, low potassium levels, brain swelling, loss of consciousness, or death.[5,30]

Individuals with diabetes who are pregnant face additional disease management challenges as diabetes can affect maternal and neonatal outcomes.[5,31] The range of "normal" HbA1c levels are slightly lower for individuals with diabetes during pregnancy, and can require changes to an individual's normal regimen to manage blood glucose levels.[31] Individuals with diabetes who are pregnant are at higher risk for pregnancy complications and adverse events (AEs) such as spontaneous abortion, fetal anomalies, stillbirth, retinopathy, hypertension, and infants with macrosomia or hypoglycemia.[31]

## Access and Equity

Disparities in access to and utilization of CGM have been consistently documented for historically marginalized groups.[32,33] Despite having proportionally higher rates of diabetes compared with other

racial and ethnic groups, Black adults and children have been observed to have the lowest rates of CGM access and subsequent use, even after adjusting for factors such as age, sex, income, and insurance status.[32-37] In a single-center study of children and adolescents with T1DM, White children were more than twice as likely to start using a CGM compared with Black or Hispanic children; among those who starting using a CGM, White children were also more than 4 times as likely as Black children to still be using their CGM 1 year after initiation.[37] Notably, the differences observed in this study persisted across insurance types, despite being conducted in a state in which all study participants were eligible for CGM coverage under Medicaid.[37] Similarly, a national study conducted by the ADA found that states with higher proportions of Black adults with diabetes had significantly lower rates of CGM access and use compared with states with greater proportions of White adults with diabetes.[35] Disparities in CGM utilization based on racial and ethnic identity were particularly pronounced in states with higher proportions of older adults and Medicaid enrollees.[35]

A growing body of literature attributes inequitable CGM prescribing patterns to implicit bias among clinicians.[38-41] In qualitative studies, Black and Hispanic individuals with diabetes have reported a perceived lack of information from clinicians regarding diabetes technology and limited opportunities for shared decision making regarding CGM use.[39,40] Moreover, few participants in these studies received diabetes care from specialists likely to be comfortable with CGM technology, such as endocrinologists and certified diabetes educators.[40] Supporting these lived experience accounts from patients, implicit bias assessments of diabetes clinicians in the US have shown that racial-related, ethnic-related, and public insurance-related biases in recommending diabetes technologies (such as CGM) are common across clinician types.[38,41] In 1 study, 85% of surveyed clinicians were more likely to recommend CGM or insulin pump systems to patients with private versus public insurance; clinicians were also more likely to rank insurance type as a primary reason for their decision to offer CGM.[38]

In addition to socioeconomic barriers, insurance eligibility requirements for CGM coverage often pose a significant obstacle to access.[33,42-44] Current prescribing guidance for most national Medicare and Medicaid plans requires clinical documentation of 4 or more SMBG tests and 3 or more insulin injections daily, despite limited or no evidence of necessity for these requirements in clinical studies of individuals with T1DM and T2DM.[42,43] Documentation of these and other requirements poses a substantial burden to diabetes providers, particularly for primary care providers who may have limited administrative resources.[33] Additionally, Medicaid enrollees are often required to be treated by an endocrinologist to qualify for CGM, regardless of whether they meet other clinical criteria.[43,44] Because most lower-income individuals are treated for their diabetes in primary care settings,[40] these requirements may result in substantially lower utilization of CGM than would otherwise be clinically indicated.

## Cost Impacts of CGM

Studies conducted among individuals with T1DM suggest that CGM may offer cost savings relative to SMBG over time and may reduce overall health care costs associated with diabetes.[45-50] A systematic review of 35 comparative economic studies found that any CGM use was associated with a cost savings of $1,025 to $1,458 over a 1-year period compared with SMBG, but this estimate was based on several international economic assessments that use different health care systems and cost values than the US.[46] Clinical studies of patients with T1DM in the US have shown that individuals using therapeutic rtCGM experienced significantly fewer severe hypoglycemic or ketoacidosis events and related hospital

admissions compared with those using SMBG[47-50]; subsequently, rtCGM participants were found to have lower total health care costs (about $4,200 less over a year).[49] Evidence regarding the cost impacts of CGM in individuals with T2DM is limited, but a 2022 study of adults with either T1DM and T2DM found that 6 months of rtCGM use resulted in a total average cost savings of $417 per member per month on non-Medicare health plans and $426 on Medicare plans, compared with SMBG.[45]

In terms of direct costs, CGM are generally more expensive than SMBG. Without insurance coverage, out-of-pocket costs for CGM have been estimated to range from $2,500 to $6,000 per year, including sensors, transmitters, receivers, and test strips for calibration, compared with about $1,600 per year for test strips with SMBG.[44,47] Among insured populations, yearly out-of-pocket CGM expenditures may range from the hundreds to the low thousands.[44] Data from the 2017 DIAMOND trial of rtCGM versus SMBG in individuals with T1DM on a regimen of multiple daily insulin injections estimated the daily cost of rtCGM supplies to be about $15 compared to around $3 for SMBG test strips (standardized to 2015 US dollars).[24,47] Accordingly, 61% of adults surveyed in 2017 by the T1D Exchange group listed "cost of supplies" as a major barrier to CGM use.[51] Of note, DIAMOND trial participants randomized to rtCGM used a now-discontinued, nontherapeutic CGM unit and were instructed to calibrate with test strips twice daily; SMBG confirmation is no longer required with newer factory-calibrated models, so current estimated daily CGM costs may be lower.[24]

# METHODS

The following section summarizes the overall scope of the evidence review, including Key Questions (KQs) and Contextual Questions (CQs), inclusion and exclusion criteria, and a brief overview of the methods used to conduct the review. Additional information regarding methods can be found in Appendix C.

## Key Questions

KQ1. What is the effectiveness of CGM in idmproving outcomes compared to self-monitoring of blood glucose in:
   a. people with type 2 diabetes who use insulin
   b. People with type 2 diabetes who do not use insulin

KQ2. Is there evidence of differential comparative effectiveness of CGM in people with diabetes based on:
   a. Age
   b. Sex
   c. Identity-related factors (for example race and ethnicity, gender)
   d. Diabetes type (T2DM, GDM)
   e. Baseline glycemic control
   f. Type of diabetes medication (if any)
   g. CGM adherence
   h. CGM type (therapeutic rtCGM vs. nontherapeutic rtCGM vs. isCGM)

## Contextual Questions (addressed in Background section)

CQ1. What minimum level of HbA1c change is considered clinically significant by various professional and regulatory groups?

CQ2. What is the overall impact on health care costs associated with rtCGM vs. isCGM vs. SMBG in the United States?

CQ3. How do the costs of monitoring with CGM compare to self-monitoring with test strips?

## Study Eligibility Criteria

Table 2 summarizes the criteria used to inform study selection for the evidence review. See Appendix C for more detailed selection criteria.

Table 2. Evidence Review Criteria Overview

| CATEGORY | INCLUDED | EXCLUDED |
|---|---|---|
| POPULATION | Children, adolescents, and adults with T2DM (including individuals who are pregnant) who use insulin<br>Children, adolescents, and adults with T2DM (including individuals who are pregnant) who do not use insulin<br>Individuals with GDM | Individuals with T1DM[a] |
| INTERVENTIONS | rtCGM (therapeutic and nontherapeutic)<br>isCGM | Retrospective (i.e., professional) CGM |
| COMPARATORS | SMBG<br>Routine HbA1c monitoring | Other CGM |
| OUTCOMES | **Critical:** Severe hypoglycemia requiring intervention; change in HbA1c; severe perinatal morbidity[b]; QoL<br>**Important:** Health resource utilization[c] | **Considered but not selected for review:** Myocardial infarction, cerebrovascular accident, amputations, neuropathy, retinopathy, nephropathy, time-in-range, time-below-range, adherence to CGM, mortality |
| STUDY DESIGNS | RCTs | Cohort studies, case series |
| FOLLOW-UP | ≥ 12 weeks | < 12 weeks |

Notes. [a] CGM are already covered for Oregon Health Plan enrollees with T1DM. [b] For example, life-threatening perinatal hypoglycemia or shoulder dystocia. [c] Limited to hospitalizations, ED visits, and unscheduled clinic visits.
Abbreviations. CGM: continuous glucose monitoring; ED: emergency department; GDM: gestational diabetes mellitus; HbA1c: glycated hemoglobin; isCGM: intermittently scanned CGM; QoL: quality of life; RCT: randomized controlled trial; rtCGM: real-time CGM; SMBG: self-monitoring of blood glucose; T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus.

## Methods Overview

To answer the KQs, we searched multiple clinical evidence databases (e.g., Ovid MEDLINE, Cochrane Library) for published randomized controlled trials (RCTs) evaluating the effectiveness and harms of rtCGM as compared with SMBG for eligible populations with T2DM or GDM. To meet eligibility criteria, primary studies had to be available in English, include follow-up of at least 12 weeks, and be published in

2012 or later. Two reviewers independently examined abstracts and full-text articles for inclusion and assessed the risk of bias of included studies. Disagreements were resolved through consensus or by a third reviewer. We assessed the overall strength of evidence by outcome using the previously described GRADE table.

We summarized findings from eligible studies based on participants' insulin-use status. Studies that limited enrollment to participants on insulin therapy or those that included a majority (i.e., ≥ 50%) of insulin users were classified as 'requiring insulin,' whereas studies that limited enrollment to individuals not on insulin therapy or those where insulin users comprised less than half of the study sample were classified as 'not requiring insulin.'

To better visualize the comparative glycemic impact of rtCGM versus SMBG, pooled analyses of change in HbA1c from RCTs of adults with T2DM were conducted using Review Manager 5.4, Cochrane's systematic review software.[52] Outcomes data were pooled when 3 or more trials reported the same outcome based on comparable criteria.

We identified evidence for CQs by using results of the KQ database searches, auditing reference lists of relevant systematic reviews, and performing targeted searches of relevant sources as needed. We included any study design or other type of publication if it was relevant to answering the CQ and was published in English. Evidence regarding the CQs is summarized in the Background section; specifically, CQ1 is addressed in the Important Glycemic Outcomes subsection, whereas CQ2 and CQ3 are addressed in the Cost Impact of CGM subsection.

For the Policy Landscape section, we conducted targeted searches in Ovid MEDLINE, websites of relevant professional societies and guideline groups, and DuckDuckGo to identify relevant clinical practice guidelines published since 2018 and key payer policies regarding CGM use in populations with T2DM or GDM. Two reviewers independently assessed the quality of the included clinical practice guidelines; disagreements were resolved through consensus or by a third reviewer.

# EVIDENCE REVIEW

**The following results section organizes findings by 2 key population groups:**

- **Individuals with T2DM who use insulin**
- **Individuals with T2DM who do not use insulin**

**Within each population, results are summarized for each relevant critical and important outcome.**

We identified 11 eligible RCTs reported in 16 publications comparing the effectiveness of CGM and SMBG in individuals with T2DM with or without insulin use (Table 3; Appendix D, Table D1).[25,45,53-65] In 5 studies, all or most of the participants were on insulin therapy, which included regimens of once or twice daily injections of basal insulin,[62] multiple daily injections of short-acting prandial insulin,[25,53] and intensive insulin therapies combining insulin types.[61,66] Three studies included participants with or without insulin therapy; among those using insulin, regimens ranged from minimal (e.g., single daily doses of long-acting insulin) to high-intensity (e.g., multiple daily injections, combination therapy) insulin

use.[45,55,57] The remaining 3 studies limited participation to individuals who were not being treated with insulin therapy. [63-65]

Of the 11 included studies, 10 were conducted in nonpregnant adults with T2DM and 1 study was conducted in pregnant individuals with preexisting diabetes (T1DM or T2DM), with selected results stratified by diabetes type. As the focus of this coverage guidance is CGM use in populations with T2DM, we limited our results reporting for the pregnancy trial to the T2DM subgroup. However, this study was not powered to detect meaningful differences in the T2DM subgroup, which limits the generalizability of the results.[66] We did not identify any eligible studies of pregnant individuals with GDM or children and adolescents with T2DM.

Across the included studies, sample sizes ranged from 31 to 224 participants and study duration ranged from 12 to 52 weeks. Four studies were conducted solely in US-based populations, 2 were conducted in North American populations (i.e., Canada, Mexico, the US), and 5 were conducted in non-North American populations including Denmark, France, Germany, Japan, South Korea, and the United Kingdom. Study participants were generally recruited from primary care or endocrinology practices or from hospital-based diabetes care clinics. In terms of CGM type, 7 studies evaluated rtCGM[25,45,55,62-64] and 4 evaluated isCGM[53,57,61,65]; notably, 4 RCTs evaluated nontherapeutic CGM models that are no longer commercially available in US markets (i.e., Dexcom SEVEN and G4, Abbot FreeStyle Navigator, Medtronic Guardian Connect).[25,53,64] Prior to randomization, most studies included a run-in period wherein all participants wore a blinded CGM for up to 2 weeks to gauge adherence.

In studies of nonpregnant adults, mean age was 55 years or greater for all study groups and the percentage of female participants ranged from 25% to 62%. On average, study participants had T2DM for 13 years or more at baseline and had mean HbA1c levels ranging from 7.8% to 9.2%. In studies of insulin users, participants were conducting and average of 1 to 4 blood glucose finger sticks per day. Participants in the included pregnancy study had a mean baseline age of 31.5 years, a mean gestational age of 58.5 days, and a mean diabetes duration of 11 years with a lower mean HbA1c (i.e., 6.7%) than participant cohorts in the adult studies. Socioeconomic demographics were not commonly reported. See Appendix D, Table D1 for additional study details including complete inclusion and exclusion criteria.

Table 3. Characteristics of Included Studies of CGM Use in Individuals with T2DM by Insulin Use Status

| AUTHOR, YEAR<br>STUDY NAME<br>RISK OF BIAS | TOTAL N<br>FOLLOW-UP<br>COUNTRY | INSULIN USE<br>CGM TYPE | STUDY GROUP | N, GROUP | MEAN AGE | MEAN T2DM DURATION | MEAN HbA1c (%) |
|---|---|---|---|---|---|---|---|
| **T2DM REQUIRING INSULIN[a]** | | | | | | | |
| Haak, 2017[61]<br>REPLACE<br>Moderate | N = 224<br>24 weeks<br>France, UK, Germany | All participants on intensive insulin therapies[b]<br>isCGM | CGM | N = 149 | 59.0 years | 17 years | 8.7% |
| | | | SMBG | N = 75 | 59.5 years | 18 years | 8.9% |
| Secher, 2013[66]<br>Moderate | N = 31[c]<br>36 weeks<br>Denmark | Most participants (97%) using intensive insulin therapies[b]<br>rtCGM[d] | CGM | N = 16 | 32 years<br>GA: 59 days | 10 years | 6.6% |
| | | | SMBG | N = 14 | 31 years<br>GA: 58 days | 12 years | 6.8% |

| AUTHOR, YEAR STUDY NAME RISK OF BIAS | TOTAL N FOLLOW-UP COUNTRY | INSULIN USE CGM TYPE | STUDY GROUP | N, GROUP | MEAN AGE | MEAN T2DM DURATION | MEAN HbA1c (%) |
|---|---|---|---|---|---|---|---|
| Ajjan, 2016[53] Low | N = 45 36 weeks UK | All participants on multiple daily insulin injections isCGM[d] | CGM | N = 30 | 57.8 years | 14 years | 9.2% |
| | | | SMBG | N = 15 | 55.5 years | 16 years | 9.2% |
| Beck, 2017[25] DIAMOND Low | N = 158 24 weeks US, Canada | All participants on multiple daily insulin injections rtCGM[d] | CGM | N = 79 | 60 years | 17 years | 8.5% |
| | | | SMBG | N = 79 | 60 years | 18 years | 8.5% |
| Martens, 2021[62] MOBILE Moderate | N = 175 32 weeks US | All participants on basal insulin only[e] rtCGM | CGM | N = 116 | 56 years | 14 years | 9.1% |
| | | | SMBG | N = 59 | 59 years | 15 years | 9.0% |
| **T2DM NOT REQUIRING INSULIN[f]** | | | | | | | |
| Bergenstal, 2022[55] Moderate | N = 114 16 weeks US | Some participants (47%) using insulin with metformin rtCGM | CGM | N = 59 | 59.3 years | NR | 8.2% |
| | | | SMBG | N = 55 | 58.8 years | NR | 7.9% |
| Vigersky, 2012[64] Walter Reed High | N = 100 12 weeks US | Some participants using basal insulin (33%) rtCGM[d] | CGM | N = 50 | 55.5 years | NR | 8.4% |
| | | | SMBG | N = 50 | 60.0 years | NR | 8.2% |
| Choe, 2022[57] PDF Moderate | N = 126 12 weeks South Korea | Some participants (27%) using basal insulin isCGM | CGM | N = 63 | 58.6 years | 13 years | 7.9% |
| | | | SMBG | N = 63 | 57.5 years | 13 years | 7.9% |
| Isaacson, 2022[45] Moderate | N = 99 24 weeks US | Some participants (% NR) using insulin rtCGM | CGM | N = 50 | NR | NR | NR |
| | | | SMBG | N = 49 | NR | NR | NR |
| Price, 2021[63] COMMITTED High | N = 70 12 weeks US, Canada, Mexico | Not using insulin rtCGM | CGM | N = 46 | 58.9 years | 14 years | 8.4% |
| | | | SMBG | N = 24 | 60.9 years | 12 years | 8.5% |
| Wada, 2020[65] Low | N = 100 24 weeks Japan | Not using insulin isCGM | CGM | N = 49 | 58.1 years | NR | 7.8% |
| | | | SMBG | N = 51 | 58.7 years | NR | 7.8% |

Notes. [a] Studies that limited enrollment to participants on insulin therapy or those that included ≥ 50% insulin users. [b] Intensive insulin regimens included multiple daily injections of prandial only or prandial and basal insulin or CSII therapy. [c] The reported sample size corresponds to the number of participants with T2DM included in the study; including the 123 participants with T1DM, the total number of randomized participants was 154. [d] The CGM device was a nontherapeutic model that required finger-stick calibration. [e] Participants received up to 2 daily injections of basal insulin. [f] Studies that limited enrollment to participants not on insulin therapy or those that included < 50% insulin users

Abbreviations. CGM: continuous glucose monitoring; CSII: continuous subcutaneous insulin infusion; GA: gestational age; HbA1c: glycated hemoglobin; isCGM: intermittently scanned CGM; NR: not reported; rtCGM: real-time CGM; SMBG: self-monitoring of blood glucose; T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus; UK: United Kingdom; US: United States.

It is important to note that we excluded the majority of published RCTs of CGM use in pregnant individuals with diabetes from this evidence review as they did not meet the scoped eligibility criteria. In pregnant individuals with preexisting diabetes, most trials of CGM use have been limited to T1DM populations or evaluated retrospective CGM devices.[67-72] In pregnant individuals with GDM, all available RCTs were excluded due to either limited study duration (i.e., follow-up < 12 weeks) or use of retrospective CGM.[73-78] However, systematic reviews of CGM use in individuals with diabetes during pregnancy that include these studies suggest that CGM use generally improves glycemic control relative to SMBG, but has limited impact on diabetes-related perinatal outcomes, such as caesarean birth and macrosomia.[79,80] A list of excluded RCTs of CGM use in pregnancy and the primary reasons for exclusion are presented in Appendix D, Table D2.

Additionally, we did not identify any eligible RCTs assessing the effectiveness of CGM compared with SMBG in children and adolescents with T2DM. A subsequent audit of relevant systematic reviews and clinical practice guidelines showed that to date, no clinical trials or interventional studies of CGM use in pediatric populations with T2DM have been published.[81-83] Currently, the evidence informing CGM use in this population is extrapolated from studies conducted among children and adolescents with T1DM, who account for the majority of children with diabetes.[84] See the Ongoing Studies section for information about relevant studies in progress.

## Individuals With T2DM Requiring Insulin

### Severe Hypoglycemia Requiring Intervention

Four included RCTs of CGM use reported the incidence of level 3 hypoglycemia (as defined by the ADA,[5] severe hypoglycemia requiring intervention [e.g., administration of oral glucose] by another person) among individuals with T2DM requiring insulin (Table 4).[5]

Table 4. Incidence of Severe Hypoglycemia Requiring Intervention in Included RCTs of Adults With T2DM

| AUTHOR, YEAR STUDY NAME | CGM TYPE INSULIN REGIMEN | TIMEPOINT | OUTCOME | CGM | SMBG |
|---|---|---|---|---|---|
| Beck, 2017[25] DIAMOND | rtCGM Prandial (MDI) | 24 weeks | Number of events | 0 | 0 |
| Haak, 2017[61] REPLACE | isCGM Basal or prandial (IIT) | 24 weeks | Number of events | 3 | 1 |
| | | | Number of participants | 3 of 149 (2%) | 1 of 75 (1%) |
| Martens, 2021[62] MOBILE | rtCGM Basal only | 32 weeks | Number of events | 1 | 1 |
| | | | Number of participants | 1 of 116 (1%) | 1 of 59 (2%) |
| Secher, 2014[66] | rtCGM Basal or prandial (IIT) | 36 weeks | Number of events | 15 | |
| | | | Number of participants | 5 of 31 (16%) | |

Note. Severe hypoglycemic events defined as those that cause impaired mental and physical function and require intervention by another person.[5]
Abbreviations. CGM: continuous glucose monitor; IIT: intensive insulin therapy; isCGM: intermittently scanned CGM; MDI: multiple daily injections; RCT: randomized controlled trial; rtCGM: real-time CGM; SMBG: self-monitoring of blood glucose; T2DM: type 2 diabetes mellitus.

As shown in Table 4, an equivalent number of rare events occurred in each study group in the DIAMOND and MOBILE trials (0 events and 1 event, respectively).[25,62] These RCTs evaluated rtCGM in US-based T2DM populations over 24-week to 32-week follow-up periods and defined severe hypoglycemic events as those requiring assistance from another person to administer oral carbohydrates or other resuscitative action.[25,62] In the 24-week REPLACE trial, evaluating isCGM in adult T2DM populations in multiple European centers, 3 severe hypoglycemic events occurred among 3 participants (2%) in the isCGM group compared with 1 event in 1 participant (1%) in the SMBG group[61]; no additional severe hypoglycemic events occurred in the in the REPLACE 52-week open-label extension.[60] In the trial of CGM use in pregnant individuals conducted by Secher and colleagues, 5 participants (16%) with T2DM experienced 15 severe hypoglycemic events (defined as those requiring help from another person) during the 36-week trial period.[66] Although severe hypoglycemic events were not reported by study group in this trial, investigators stated that there were no statistically significant differences in the rate of events between those randomized to rtCGM versus SMBG.[66] In the 3 studies with reported severe hypoglycemic events, none were judged to be associated with CGM use.[61,62]

No subgroup analyses evaluating differential rates of severe hypoglycemic events by participant demographic or clinical characteristics were reported.

### Change in HbA1c

Three RCTs of insulin-treated individuals with T2DM evaluated some measure of change in HbA1c at 12 weeks of follow-up or later.[25,61,62] All 3 studies were conducted in adults and evaluated mean change in HbA1c,[25,55,59,61-63,65] and 2 studies also evaluated the comparative proportion of participants who achieved a clinically meaningful mean HbA1c reduction (i.e., ≥ 0.5%).[57]

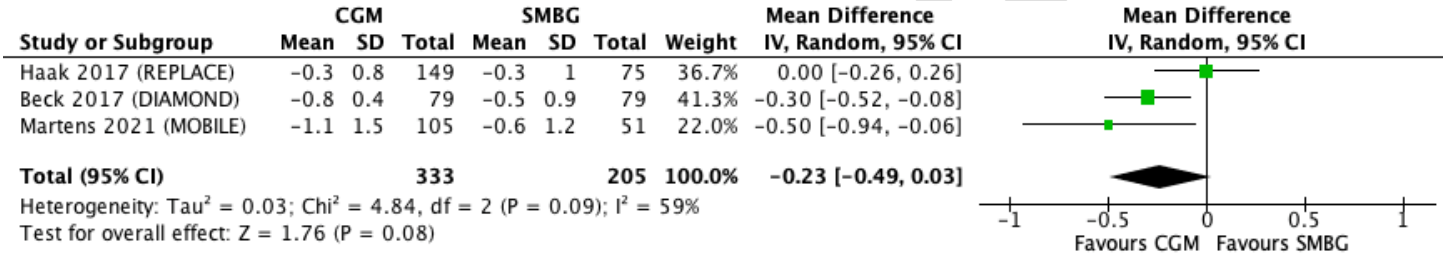
Two studies, the DIAMOND and MOBILE trials,[25,62] were conducted among US populations and observed significantly greater reductions in HbA1c from baseline in the CGM groups compared with the SMBG groups. In the DIAMOND trial of CGM use in adults treated with multiple daily injections of prandial insulin (N = 158), there was a significantly greater reduction in mean HbA1c with a nontherapeutic rtCGM compared with SMBG at 24 weeks (mean difference [MD], −0.30; 95% confidence interval [CI], −0.52 to −0.08; *P* = .02).[25] Although the absolute between-group difference in mean HbA1c change did not meet the clinically meaningful threshold of 0.5% in this study, a responder analysis by group showed that compared with the SMBG group, a significantly greater proportion of participants in the CGM group experienced a reduction of 0.5% or greater (79% vs. 51%; *P* = .002) as well as a reduction of 1.0% or greater (52% vs. 33%; *P* = .04).[25] In the MOBILE trial of CGM use in adults treated with once-daily or twice-daily basal insulin injections (N = 175), therapeutic rtCGM use was associated with a statistically significant and clinically meaningful reduction in HbA1c compared with SMBG at 32 weeks (MD, −0.50; 95% CI, −0.94 to −0.06; *P* = .02).[62] Accordingly, a responder analysis showed that more participants randomized to CGM experienced an HbA1c reduction of 0.5% or greater compared with those randomized to SMBG (73% vs. 65%; *P* = .05), but there was no difference in the proportion achieving a reduction of 1.0% or greater (54% vs. 39%; *P* = .07).[62] Notably, more than half of study participants in the MOBILE trial were non-White and more than half were enrolled in some form of public insurance.[62]

In the European-based (i.e., UK, France, Germany) REPLACE trial assessing isCGM use in adults treated with intensive insulin therapies (N = 224), there was no difference between the isCGM and SMBG groups

with respect to change in HbA1c at 24 weeks (MD, 0.0; 95% CI, −0.26 to 0.26; *P* = .82); both study groups experienced around a 0.3% reduction at the final study follow-up (−0.29% vs. −0.31%, respectively).[61] No responder analysis assessing the proportion of participants who achieved a clinically meaningful HbA1c reduction was reported.[61]

As presented in Figure 2, a staff-led pooled analysis of change in HbA1c outcomes from these 3 studies ultimately showed that compared with SMBG, CGM use did not result in a statistically significant difference at 24 weeks or later (MD, −0.23%; 95% CI, −0.49 to 0.03; *P* = .09). Studies are presented in descending order of insulin regimen intensity.

Figure 2. Mean Change in HbA1c at Final Study Follow-up in Included RCTs of Adults with T2DM Requiring Insulin




Note. Pooled analyses were conducted with Review Manager 5.4
Abbreviations. CGM: continuous glucose monitor; CI: confidence interval; HbA1c: glycated hemoglobin; IV: inverse variance; RCT: randomized controlled trial; SD: standard deviation; SMBG: self-monitoring of blood glucose; T2DM: type 2 diabetes mellitus.

Change in HbA1c from baseline was not reported in the trial of pregnant individuals with preexisting T2DM conducted by Secher and colleagues (the majority of whom were treated with intensive insulin regimens), although a comparative analysis of mean HbA1c level found that there were no significant between-group differences at any follow-up timepoint.[66] Importantly, this study was not powered to detect between-group differences for individuals with T2DM.[66]

### Subgroups

All studies evaluated change in HbA1c across a range of predefined subgroups (Appendix D, Table D3).

- In the 32-week MOBILE trial of rtCGM use in US adults with T2DM on once-daily or twice-daily basal insulin injections, no statistically significant subgroup interaction was found according to baseline age, HbA1c level, diabetes duration, noninsulin diabetes medication use, or racial and ethnic identity.[54,58,62]
- In the 24-week DIAMOND trial of rtCGM use in US adults with T2DM on multiple daily prandial insulin injections, there were no statistically significant subgroup differences according to age or baseline HbA1c level.[25,56]
- In the 24-week REPLACE trial of isCGM use in European (i.e., UK, France, Germany) adults with T2DM on intensive insulin therapy, participants younger than 65 years randomized to isCGM experienced a significantly greater reduction in mean HbA1c at 24 weeks compared to those randomized to SMBG (−0.5% vs. −0.2%; *P* = .03); conversely, participants aged 65 years or older in the isCGM group experienced significantly less mean HbA1c reduction compared with the SMBG group (−0.05% vs. −0.49%; *P* = .008).

## Severe Perinatal Morbidity

Secher and colleagues compared the incidence of a range of perinatal (maternal and neonatal) outcomes among pregnant individuals with T2DM requiring insulin, randomized to rtCGM or SMBG (Table 5).[66] At the final study follow-up, there were no statistically significant between-group differences in any reported perinatal event including incidence of large-for-gestational-age newborns, preeclampsia, preterm birth, neonatal hypoglycemia (severe or not), delivery by caesarean section, or miscarriage.[66] However, it is important to note that given the small sample size of participants with T2DM (N = 31), this study was not powered to detect clinically meaningful differences in perinatal outcomes for this group.

Table 5. Perinatal Outcomes for Participants With T2DM Reported in Secher, 2013[66]

| AUTHOR, YEAR SAMPLE SIZE | PERINATAL OUTCOME | rtCGM | SMBG | *P* VALUE |
|---|---|---|---|---|
| Secher, 2013 N = 31 | Large for gestational age[a] | 4 of 16 (25%) | 4 of 15 (29%) | *P* = 1.0 |
| | Preeclampsia[b] | 2 of 16 (13%) | 1 of 15 (7%) | *P* = 1.0 |
| | Preterm birth[c] | 3 of 16 (19%) | 0 of 15 (0%) | *P* = .23 |
| | Neonatal hypoglycemia[d] | 4 of 13 (31%) | 2 of 15 (14%) | *P* = .39 |
| | Severe neonatal hypoglycemia[e] | 0 of 13 (0%) | 0 of 15 (0%) | NR |
| | Caesarean delivery | 8 of 16 (50%) | 6 of 15 (43%) | *P* = .70 |
| | Miscarriage[f] | 0 of 16 (0%) | 1 of 15 (7%) | *P* = .48 |

Notes. [a] Defined as infant birth weight ≥ 90th percentile adjusted for sex and gestational age. [b] Defined as blood pressure ≥ 140/90 and proteinuria. [c] Defined as birth prior to 37 weeks of gestation. [d] Defined as having a 2-hour plasma glucose < 2.5 mmol/L. [e] Defined as having a 2-hour plasma glucose < 2.5 mmol/L and requiring intravenous glucose infusion. [f] Defined as fetal loss before 22 weeks gestation.
Abbreviations: NR: not reported; rtCGM: real-time continuous glucose monitor; SMBG: self-monitoring of blood glucose; T2DM: type 2 diabetes mellitus.

## Quality of Life

Three included RCTs of CGM use in insulin-treated individuals with T2DM reported comparative quality of life (QoL) measures on validated assessment scales.[25,53,57,59,61,65] Reported QoL scales included those measuring general well-being (e.g., World Health Organization well-being index) and those measuring diabetes-related wellness and functioning (e.g., Diabetes Distress Scale). Table 6 presents QoL outcomes by treatment group at follow-up; for a detailed description of reported QoL scales see Appendix D, Table D4.

Table 6. QoL Outcomes Reported in Included RCTs of CGM use in Individuals With T2DM Requiring Insulin

| STUDY CGM TYPE | QoL MEASURE[A] | TIMEPOINT | CGM GROUP | | SMBG GROUP | | *P* VALUE |
|---|---|---|---|---|---|---|---|
| | | | N | MEAN (SD) | N | MEAN (SD) | |
| Ajjan, 2016[53] isCGM | DTSQ: total score | 12 weeks | 30 | 13.4 (NR) | 15 | 13.5 (NR) | *P* = .94 |
| Beck, 2017[25] DIAMOND rtCGM | EQ-5D: overall index | 24 weeks | 77 | 0.82 (0.14) | 73 | 0.82 (0.16) | NR[b] |
| | WHO-5: total score | 24 weeks | 77 | 16 (5) | 73 | 17 (4) | NR[b] |

| STUDY CGM TYPE | QoL MEASURE[A] | TIMEPOINT | CGM GROUP | | SMBG GROUP | | *P* VALUE |
|---|---|---|---|---|---|---|---|
| | | | N | MEAN (SD) | N | MEAN (SD) | |
| | DDS: overall score | 24 weeks | 77 | 1.8 (0.9) | 73 | 1.8 (0.6) | NR[b] |
| | HFS: worry subscale | 24 weeks | 77 | 0.8 (0.6) | 73 | 0.7 (0.5) | NR[b] |
| | HCS: total score | 24 weeks | 77 | 3.3 (0.6) | 73 | 3.4 (0.6) | NR[b] |
| Haak, 2017[61] REPLACE isCGM | DQoL: total score | 24 weeks | 149 | -0.2 (0.04) | 75 | 0.0 (0.06) | *P* = .03 |
| | DTSQ: total score | 24 weeks | 149 | 13.1 (0.50) | 75 | 9.0 (0.72) | *P* < .001 |

Notes. [a] See Appendix D, Table D4 for descriptions of individual scale ranges and scoring. [b] *P* value not reported, but study authors noted that between-group effects were not significant.
Abbreviations. CGM: continuous glucose monitor; DDS: Diabetes Distress Scale; DQoL: Diabetes QoL; DTSQ: Diabetes Treatment Satisfaction Questionnaire; EQ-5D: EuroQoL-5D; HCS: Hypoglycemia Confidence Survey; HFS: Hypoglycemia Fear Survey; isCGM: intermittently scanned CGM; NR: not reported; QoL: quality of life; RCT: randomized controlled trial; rtCGM: real-time CGM; SD: standard deviation; SMBG: self-monitoring of blood glucose; T2DM: type 2 diabetes mellitus; WHO-5: 5-item World Health Organization Well-being Scale.

As shown in Table 6, comparative results regarding QoL were mixed across the 3 studies with relevant outcomes.[25,53,57,59,61,65]

- In the 24-week REPLACE trial of European adults with T2DM on intensive insulin therapy, participants in the isCGM group had significantly higher overall Diabetes Treatment Satisfaction Questionnaire (DTSQ) scores (13.1 vs. 9.0 points; *P* < .001) and Diabetes QoL Survey (DQoL) scores (P = .03, scores not reported) indicating higher treatment satisfaction.[25] Comparatively, study groups did not differ on DTSQ subscores regarding their perceived fear of hypoglycemia or hyperglycemia or DQoL sub scales over the same follow-up period.[25]
- In the 24-week DIAMOND trial of US adults on multiple daily prandial insulin injections: there were no significant between-group differences in general QoL on the EuroQoL-5D (EQ-5D) or the 5-item World Health Organization Well-being (WHO-5) scales, although scores in both study groups indicated high levels of overall well-being.[59,64] Similarly, there were no statistically significant between-group differences on the Diabetes Distress Scale (DDS), including for the emotional, regimen, clinician, and diabetes worry sub scales, or the Hypoglycemia Fear Survey (HFS) and Hypoglycemia Confidence Survey (HCS); scores in both study groups indicated that participants did not feel high levels of diabetes distress or hypoglycemia-related fear and were mostly confident about their ability to prevent and manage hypoglycemia.[53,57,61,65] Notably, the CGM group used a now-discontinued nontherapeutic rtCGM model, which required confirming blood glucose with a glucometer reading prior to any treatment action.
- In the 12-week study conducted by Ajjan and colleagues of adults in the UK with T2DM on multiple daily prandial insulin injections (N = 99), there were no significant differences in DTSQ scores between the isCGM and SMBG groups, although the positive scores indicated that treatment satisfaction was high in both groups (13.4 vs. 13.5 points; *P* = .94).[53]

## Health Resource Utilization

No studies of CGM use in individuals with T2DM requiring insulin assessed health resource utilization (e.g., hospitalizations, emergency department or urgent care visits, unscheduled clinic visits).

## Harms

Six RCTs of CGM use in adults with T2DM reported harms.[25,53,61,62] Harms data varied in both reported outcomes and recorded event types. Commonly reported outcomes across studies included AEs, serious adverse events (SAEs), and device-related harms. Since CGM procedures do not differ by insulin use status, we analyzed harms across all eligible studies of CGM use in individuals with T2DM.

Table 7. Harms Outcomes Reported in Eligible RCTs of CGM Use in Individuals With T2DM

| AUTHOR, YEAR STUDY NAME | TIMEPOINT | CGM GROUP | SMBG GROUP |
|---|---|---|---|
| **TOTAL ADVERSE EVENTS[a]** | | | |
| Ajjan, 2016[53] | 12 weeks | 19 of 30 participants (63%) | 8 of 15 participants (53%) |
| Haak, 2017[61] REPLACE | 24 weeks | 336 events,<br>114 of 149 participants (77%) | 179 events,<br>47 of 75 participants (63%) |
| Martens, 2021[62] MOBILE | 32 weeks | 45 events,<br>30 of 116 participants (26%) | 16 events,<br>12 of 59 participants (20%) |
| Price, 2021[63] COMMITTED | 12 weeks | 2 events,<br>2 of 46 participants (4%) | 6 events,<br>4 of 24 participants (17%) |
| Wada, 2020[65] | 24 weeks | 10 events,<br>10 of 49 participants (20%) | 3 events,<br>3 of 51 participants (6%) |
| **SERIOUS ADVERSE EVENTS[b]** | | | |
| Ajjan, 2016[53] | 12 weeks | 0 events | 0 events |
| Beck, 2017[25] DIAMOND | 24 weeks | 3 events<br>3 of 79 participants (4%) | 0 events |
| Haak, 2017[61] REPLACE | 24 weeks | 20 events<br>16 of 149 participants (11%) | 22 events,<br>12 of 75 participants (16%) |
| Martens, 2021[62] MOBILE | 32 weeks | 14 events<br>10 of 116 participants (9%) | 7 events,<br>5 of 59 participants (9%) |
| Price, 2021[63] COMMITTED | 12 weeks | 0 events | 0 events |
| Wada, 2020[65] | 24 weeks | 1 event<br>1 of 49 participants (2%) | 1 event,<br>1 of 51 participants (2%) |
| **DEVICE-RELATED ADVERSE EVENTS[c]** | | | |
| Beck, 2017[25] DIAMOND | 24 weeks | 0 events | NA |
| Haak, 2017[61] REPLACE | 24 weeks | 9 sensor adhesive skin rashes<br>6 of 149 participants (4%) | NA |
| Price, 2021[63] COMMITTED | 12 weeks | 1 sensor adhesive skin rash<br>1 of 46 participants (2%) | NA |
| Wada, 2020[65] | 24 weeks | 7 sensor adhesive skin rashes<br>7 of 49 participants (14%) | NA |

Notes. [a] This category is inclusive of all severity levels (i.e., mild, moderate, severe). [b] Events requiring additional medical intervention including hospitalizations or emergency department visits. [c] Events directly related to CGM use.

Abbreviations. CGM: continuous glucose monitor; NA: not applicable; RCT: randomized controlled trial; SMBG: self-monitoring of blood glucose; T2DM: type 2 diabetes mellitus.

As shown in Table 7, more AEs occurred in the CGM groups compared with the SMBG groups, but the proportion of participants with AEs was nearly equivalent between groups. The majority of AEs were categorized as mild or moderate and generally resolved before study completion. Reported AEs included a wide variety of outcomes ranging from minor events like mild itching to severe outcomes like sepsis.[62,63,65] Common AEs (i.e., those that occurred in more than 10% of participants with an AE) included heartburn, gallstones, urinary tract infections, wheezing, and diarrhea.[62] Very few events were judged to be related to CGM use.[53,61-63,65]

As with total AEs, SAEs were nearly evenly distributed between study groups (Table 7).[25,53,61,62] The majority of reported SAEs were hospitalizations for surgeries unrelated to diabetes or glycemia control (e.g., knee and hip replacements) or other unrelated conditions (e.g., COVID-19, pneumonia).[25,53,61,62] Diabetes-related SAE, such as severe hypoglycemia and diabetic ketoacidosis, were rare and not attributed to CGM use or any study procedure.[25,61,62]

CGM device-related AEs occurred infrequently (Table 7). Reported device-related events ranged among studies from 0 to 9 events and were attributed solely to sensor adhesive reactions.[25,61,63,65] Reactions were treated topically and were of mild to moderate intensity. No device-related events resulted in study or device discontinuation.[25,61,63,65]

## Individuals With T2DM Not Requiring Insulin

### Severe Hypoglycemia Requiring Intervention

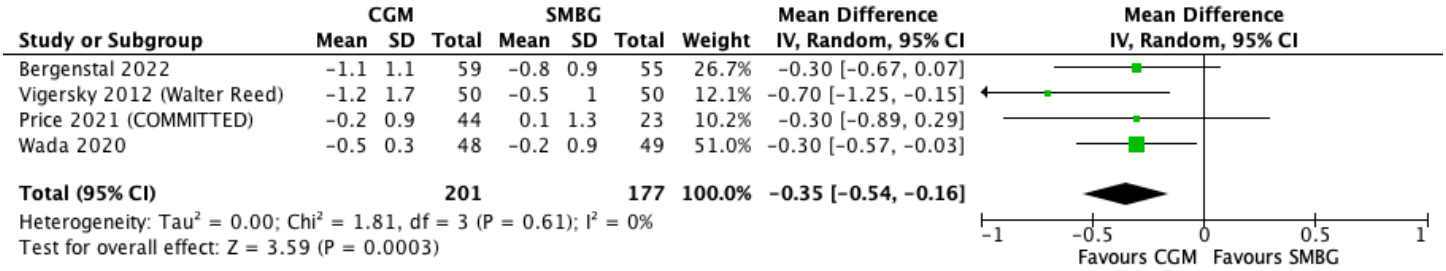
No studies of CGM use in individuals with T2DM not requiring insulin reported the incidence of severe hypoglycemia.

### Change in HbA1c

Six included RCTs of individuals with T2DM not requiring insulin evaluated some measure of change in HbA1c at 12 weeks of follow-up or greater.[45,55,57,63-65] Of these, 4 studies evaluated mean change in HbA1c,[55,63-65] 1 study reported median change,[45] and 1 study evaluated the comparative proportion of participants achieving a clinically meaningful mean HbA1c reduction (i.e., ≥ 0.5%).[57]

As presented in Figure 3, pooled analyses of the 4 studies evaluating mean change found that use of CGM resulted in significantly greater mean HbA1c reduction compared with SMBG at 12 weeks follow-up or later (MD, −0.35%; 95% CI, −0.54 to −0.16; $P < .001$). Although insulin use was not required in any of the studies included in the pooled analysis, 2 RCTs[55,64] enrolled some participants who were using insulin (< 50% of total enrollment) whereas 2 studies[63,65] did not enroll any individuals on insulin therapy. To that end, studies in the figure are arranged in descending order of insulin use.

Figure 3. Mean Change in HbA1c at Final Study Follow-up in Included RCTs of Adults with T2DM Not Requiring Insulin




Note. Pooled analyses were conducted with Review Manager 5.4.
Abbreviations. CGM: continuous glucose monitor; CI: confidence interval; HbA1c: glycated hemoglobin; IV: inverse variance; RCT: randomized controlled trial; SD: standard deviation; SMBG: self-monitoring of blood glucose; T2DM: type 2 diabetes mellitus.

Median change in HbA1c at 24 weeks in the RCT of individuals with or without insulin use conducted by Isaacson and colleagues was consistent with the pooled results, with the rtCGM group experiencing a significantly greater reduction in median HbA1c compared with the SMBG group (−0.6% vs. −0.1%; $P < .001$).[45] In addition, a significantly greater proportion of participants randomized to isCGM in the PDF trial achieved a clinically meaningful HbA1c reduction of 0.5% or greater from baseline compared with the SMBG group over the 12-week study period (51.7% vs. 21.0%; $P < .001$).[57] Notably, this study limited enrollment to participants not on intensive diabetes treatment regimens, resulting in a relatively small proportion of insulin users among participants (27%; basal insulin only).

### Subgroups

Two studies evaluated change in HbA1c for a range of predefined subgroups (Appendix D, Table D3):

- In the 12-week PDF trial of isCGM use in Korean adults with T2DM who were not on intensive insulin regimens, no statistically significant subgroup interaction was found for the achievement of a reduction in HbA1c of 0.5% or greater with respect to baseline age, sex, BMI, duration of diabetes, use of insulin, or HbA1c level.[57]
- In the 52-week Walter Reed study of rtCGM use in US adults with T2DM not on prandial insulin (33% on basal insulin), participants who used their CGM for 48 days or more (per study protocol) during the initial 12-week study period had significantly greater mean reduction in HbA1c at 52 weeks compared with the SMBG group (−1.3% vs. −0.2%; $P < .001$), whereas those who used their CGM for fewer than 48 days did not experience a significant change in HbA1c compared to SMBG.[59,64]

## Severe Perinatal Morbidity

No studies of CGM use in individuals with T2DM not requiring insulin reported the incidence of severe perinatal morbidity.

## Quality of Life

Three included RCTs of CGM use in primarily non-insulin-requiring individuals with T2DM reported comparative QoL measures on validated assessment scales at or beyond 12 weeks of follow-up.[57,64,65] Table 8 presents QoL outcomes by treatment group at follow-up; for a detailed description of reported QoL scales see Appendix D, Table D4.

Table 8. QoL Outcomes Reported in Included RCTs of CGM use in Individuals With T2DM Not Requiring Insulin

| AUTHOR, YEAR STUDY NAME CGM TYPE | QoL MEASURE | TIMEPOINT | CGM GROUP | | SMBG GROUP | | *P* VALUE |
|---|---|---|---|---|---|---|---|
| | | | N | MEAN (SD) | N | MEAN (SD) | |
| Choe, 2022[57] PDF isCGM | SDSCA: total score | 12 weeks | 58 | 44.4 (9.2) | 62 | 39.2 (10.1) | *P* = .003 |
| Vigersky, 2012[64] Walter Reed rtCGM | PAID: overall score | 12 weeks | 50 | 19.9 (17.1) | 50 | 17.1 (18.0) | *P* = .96 |
| | | 52 weeks | 50 | 19.6 (20.5) | 50 | 18.4 (20.5) | *P* = .96 |
| Wada, 2020[65] isCGM | DTSQ: total score | 24 weeks | 45 | 34.9 (5.2) | 45 | 31.4 (6.6) | *P* < .001 |

Abbreviations. CGM: continuous glucose monitor; DTSQ: Diabetes Treatment Satisfaction Questionnaire; isCGM: intermittently scanned CGM; PAID: Problem Areas in Diabetes; QoL: quality of life; RCT: randomized controlled trial; rtCGM: real-time CGM; SD: standard deviation; SDSCA: Summary of Diabetes Self-Care Activities; SMBG: self-monitoring of blood glucose; T2DM: type 2 diabetes mellitus.

As shown in Table 8, comparative results regarding diabetes-related QoL were mixed among studies:

- In the 52-week Walter Reed study (N = 100), participants in the rtCGM and SMBG groups did not report significantly different Problem Areas in Diabetes (PAID) scores at either the 12-week or 52-week follow-up visits. However, scores indicated that participants in both groups were experiencing moderate diabetes distress (i.e., 17 to 39 points) associated with factors such as food and eating, family support, relationships with treating clinicians, and hypoglycemia.[59,64]
- In the 24-week study conducted by Wada and colleagues, in Japanese adults with T2DM not using insulin (N = 100), participants in the isCGM group reported significantly higher overall treatment satisfaction compared with the SMBG group on the Japanese version of the DTSQ (34.9 vs. 31.4 points; *P* < .001).[65] The higher overall score in the isCGM group was attributed to higher individual survey item scores regarding the frequency of hyperglycemia as well as the convenience and flexibility of their glucose monitoring modality.[65]
- In the 12-week PDF trial of adults in Korea with T2DM with mixed insulin-use status (N = 126), participants randomized to isCGM had significantly higher overall scores on the Korean version of the Summary of Diabetes Self-Care Activities (SDCSA) survey compared with the SMBG group (44.4 vs. 39.2 points; *P* = .003), indicating higher self-efficacy performing diabetes care tasks such as diet, exercise, foot care, and glucose monitoring.[57]

## Health Resource Utilization

One included 24-week RCT of rtCGM (Dexcom G6) use in US adults with primarily T2DM with mixed insulin use status, conducted by Isaacson and colleagues, reported health resource utilization outcomes including emergency department and clinic visits.[45] Compared with the SMBG group, participants randomized to rtCGM had significantly fewer mean diabetes-related total health care visits (5.6 vs. 7.0; *P* = .009), emergency department visits (0.2 vs. 0.5; *P* = .02), and lab tests (7.7 vs. 11.9; *P* < .001).[45] However, study groups did not differ with respect to mean diabetes-related primary care clinic visits (1.8 vs. 3.3; *P* = .28) or visits with specialty diabetes clinicians (2.6 vs. 3.2; *P* = .06).[45]

### Harms

See section on Harms for Individuals with T2DM Requiring Insulin.

## Evidence Summary and Limitations

There is a substantial evidence base from multiple RCTs regarding the use of CGM in individuals with T2DM with or without insulin therapy. However, direct evidence regarding the effectiveness and harms of CGM in pregnant populations with T2DM or GDM is extremely limited and there is a lack of direct evidence regarding CGM use in children and adolescents with T2DM. In the following summaries, low and very-low levels of confidence indicate that if new information from additional studies were published, our understanding of the effectiveness and harms of CGM for those populations would likely change.

### Individuals With T2DM Requiring Insulin

- We identified 5 eligible RCTs comparing the effectiveness of CGM and SMBG among individuals with T2DM requiring insulin. Four studies were conducted in adults, and 1 study was conducted among pregnant individuals with preexisting T2DM; there were no eligible studies conducted in children and adolescents or individuals with GDM.
- We have very low confidence regarding the impact of CGM on the incidence of severe hypoglycemia requiring intervention, due primarily to very low rates of reported events in all study groups.
- We have low confidence that CGM are associated with greater reductions in HbA1c over time compared with SMBG. This rating is based on statistically significant findings in 2 US-based RCTs of rtCGM and 1 non-US-based RCT of isCGM that found no between-group differences.
- We have very low confidence regarding the impact of CGM use on severe perinatal outcomes (e.g., preterm birth, preeclampsia, macrosomia) among pregnant individuals with T2DM, because the single eligible study reporting these outcomes was underpowered to detect differences in this population.
- We have low confidence regarding the comparative impact of CGM on QoL due to mixed results across multiple general and diabetes-specific scales. QoL scores were generally indicative of positive feelings about diabetes treatment and daily functioning across all study groups and scales.
- There were no eligible studies that reported health resource utilization outcomes.
- We have moderate confidence that AEs attributed to CGM use are infrequent, mostly mild intensity (e.g., skin rash reactions to sensor adhesives), and treatable. Reported events generally do not lead to study or device discontinuation.

### Individuals With T2DM Not Requiring Insulin

- We identified 6 eligible RCTs comparing the effectiveness of CGM and SMBG among individuals with T2DM not requiring insulin. All studies were conducted in adults; there were no eligible studies conducted in children and adolescents, or pregnant individuals with either GDM or preexisting T2DM.
- There were no eligible studies that reported the incidence of severe hypoglycemic events.
- We have low confidence that CGM are associated with greater reductions in HbA1c over time compared with SMBG.
- There were no eligible studies that reported the incidence of severe perinatal morbidity.

- We have very low confidence regarding the comparative impact of CGM on QoL due primarily to mixed results across multiple general and diabetes-specific scales. QoL scores were generally indicative of positive feelings about diabetes treatment and daily functioning across all study groups and scales.
- We have very low confidence that CGM use may reduce overall health care visits, emergency department visits, and the number of glycemic laboratory assays, while not impacting the number of regularly scheduled primary or specialty care visits for diabetes care.
- We have moderate confidence that AEs attributed to CGM use are infrequent, mostly mild intensity (e.g., skin rash reactions to sensor adhesives), and treatable. Reported events generally do not lead to study or device discontinuation.

## Review Limitations

Although our evidence reviews are conducted using rigorous and systematic methods, we often encounter limitations in the literature or in the review design that are important to acknowledge.

- Several included studies of adults with T2DM evaluated nontherapeutic rtCGM models. These studies required participants to perform several daily SMBG finger-stick tests to calibrate their CGM devices, which may have had an impact on comparative QoL assesasments.
- Several studies required participants to complete a run-in period to gauge device tolerability and adherence prior to randomization. Participants who had trouble wearing a CGM or who exhibited less than optimal adherence during these screening periods were generally excluded from randomization, which may have limited the generalizability of study results to general T2DM populations.
- Participants randomized to SMBG may have been exhibiting optimal use. Several included studies required control participants to record 5 or more daily finger-stick glucose tests; however, baseline study data indicated that most participants were conducting between 1 to 3 tests per day on average. Therefore, it is possible that study participation resulted in better than average glucose self-management in these groups than would be observed in non-study settings.
- The availability of long-term data in eligible RCTs of CGM use was limited. The longest follow-up reported by any trial was 52 weeks, which may be sufficient to demonstrate the comparative impact of CGM use on glycemic control targets but may not be long enough to assess rare but important intermediate outcomes, such as severe hypoglycemia. Moreover, the paucity of long-term comparative follow-up limits our ability to understand the impact of CGM use regarding important diabetes-related health outcomes, such as heart disease or retinopathy.
- Few available studies of CGM use during pregnancy met our review criteria. In the case of GDM, most trials evaluated retrospective CGM and had a follow-up period of less than 12 weeks. In the case of pregnant individuals with preexisting diabetes, most trials have been conducted in individuals with T1DM or mixed diabetes type without stratified results.
- No RCTs of CGM use in children and adolescents with T2DM have been published. Currently, the evidence informing CGM use in this population is extrapolated from studies conducted among children and adolescents with T1DM, who account for the majority of children with diabetes.

## Ongoing Studies

We identified ongoing studies with searches of the ClinicalTrials.gov registry conducted in March 2023. Results of the ongoing studies search are summarized in the sections below by population group. See Appendix D, Table D5 for individual study characteristics.

### Adults With T2DM

We identified 9 ongoing RCTs comparing rtCGM to SMBG in adults with T2DM.[85-93] Most eligible adult trials (5 studies) are examining isCGM models (e.g., FreeStyle Libre 2), whereas 2 studies are looking at contemporary rtCGM devices,[90,93] and 2 do not specify the CGM type.[89,92] All studies include an SMBG control group with or without periods of blinded CGM use. Estimated study enrollment ranges from 100 to 254 participants and planned study durations range from 12 to 52 weeks. Of the 9 eligible studies, 3 are being conducted in the US,[90-92] 2 each are being conducted in Canada or South Korea,[85-88] 1 study is being conducted in the UK,[93] and 1 in Denmark.[89] Study populations are mostly limited to adults between the ages of 18 to 64 with stable diabetes or health status, but several studies include older adults (i.e., ≥ 65 years) and 1 study is examining CGM use in adults and older adults with T2DM and a history of myocardial infarction.[93] Studies also include populations with differing T2DM treatment regimens, ranging from intensive insulin therapy with multiple daily injections or insulin pumps, to noninsulin medication therapy or diet-based management alone. All identified ongoing trials are assessing change in HbA1c; other reported relevant outcomes include incidence of severe hypoglycemia, QoL, and health resource use. Estimated primary completion dates range from January 2022 to August 2024, with 3 RCTs[85-87] likely to publish in the next year on the basis of having achieved primary study completion in 2022.

### Children and Adolescents With T2DM

We identified 2 ongoing single-arm studies evaluating rtCGM use in children and adolescents with T2DM, both being conducted in the US.[94,95] In 1 study,[94] investigators are assessing the effect of 10-day periods of rtCGM (Dexcom G6) use on glycemic control measures such as change in HbA1c and time in range at 12-weeks and 24-weeks of follow-up in 41 children and adolescents (ages 5 to 21 years) with a T2DM duration of at least 3 months.

In the second study,[95] investigators are assessing the impact of 52 weeks of rtCGM use (device not specified) on various glycemic outcomes, including change in HbA1c and diabetes-related QoL, in an estimated 30 publicly insured children and adolescents (ages 4 to 19 years) with a recent T2DM diagnosis. Both studies have reported primary completion dates prior to the release of this coverage guidance and 1 study[94] may be likely to publish in the next year as it achieved final completion in July 2022.

### Individuals Who Are Pregnant With Preexisting T2DM or GDM

We identified 4 ongoing RCTs of CGM use in pregnant individuals with T2DM or GDM, all being conducted in US populations.[96-99] Two studies[97,99] are evaluating CGM use among individuals with preexisting T2DM and 2 studies[96,98] are looking at individuals with GDM. Estimated study enrollments range from 40 to 162 participants with intended enrollment between 20 to 24 weeks of gestation in all 4 studies, with follow-up continuing several days after delivery. All identified studies are assessing rtCGM use compared with SMBG, with the outcomes of diabetes-related severe perinatal morbidity (e.g., preeclampsia, preterm

birth, large-for-gestational-age infants); other outcomes include change in HbA1c, and QoL. Given that estimated primary completion dates range from December 2023 to July of 2025 it is unlikely that any of these trials will be published in 2023.

# POLICY LANDSCAPE

In the following section, we summarize evidence-based clinical guildelines from professional societies and governmental health agencies about continuous glucose monitoring (CGM), and report on payer policies from select public and private organizations about these devices.

Table 9 presents a high-level summary of recommendations and coverage criteria across these materials. In the text portion of this section, we report in more detail to highlight differences among the published guidelines, within the select coverage policies, and between the policies and guidance documents, as well as other relevant details for the use of CGM in the management of T2DM and GDM diabetes.

## Evidence-based Recommendations

We assessed the methodological quality of 8 clinical practice guidelines from 5 professional organizations for this report[100-107]; we cite 1 additional guideline focused on the pediatric population, but did not perform risk of bias as it did not make recommendations regarding CGM use, and we report it only for interest in this age group.[108] These guidelines are commonly used to guide treatment selection and to determine type of care for persons with diabetes, and each was prepared after the guideline panel reviewed the published literature for the use of CGM in T2DM and GDM.

- 6 guidelines had good methodological quality[100-104,107]
- 2 guidelines had fair methodolgical quality[105,106]
- No guidelines had poor methodological quality

See Appendix C for guideline methodologic quality assessment criteria. We grouped the recommendations by the following population categories: adults with T2DM, children and adolescents with T2DM, and pregnant populations with T2DM or GDM.

Two guidelines provide recommendations for all 3 population groups explicitly,[6,31,81,101,103,104,107,109] while 1 provides recommendations for "all persons" and during pregnancy,[100] 1 provides recommendations for "persons at risk for hypoglycemia" which includes children,[102] and 1 provides general recommedations for "people with diabetes" only.[106] Three organizations that prepared the included guidelines included language for both rtCGM and isGCMs,[100,101,103,104,107] 1 guideline recommended only rtCGM for the included populations and conditions,[102] and 1 guideline (in collaboration with CADTH) included only isGCM in their recommendations[106,110,111]; the AAP guideline for T2DM in children only mentions CGM as a general term.[108]

Table 9. Clinical Recommendations and Coverage Criteria From Clinical Practice Guidelines and Payer Coverage Policies

| PATIENT CHARACTERISTICS | AACE | ADA | ENDOCRINE SOCIETY | HEALTH QUALITY ONTARIO | NICE | MEDICARE LCD | WASHINGTON MEDICAID | NEW YORK MEDICAID | AETNA, CIGNA, MODA, RBCBS |
|---|---|---|---|---|---|---|---|---|---|
| **ADULT POPULATIONS** | | | | | | | | | |
| T2DM on multiple daily insulin injections or continuous insulin infusion | ✓ | ✓ | ✓ [a] | ✓ [a] | ✓ [a] | ✓ [a] | ✓ [a] | ✓ [a] | ✓ [a,j] |
| T2DM on basal insulin | ✓ | ✓ | ✓ [a] | X | ✓ [a] | ✓ [a] | ✓ [a] | ✓ [a] | X [k] |
| T2DM using noninsulin diabetes medications (e.g., sulfonylureas) | ✓ [a] | X [d] | ✓ [a] | X | X | ✓ [a] | ✓ [a] | X [i] | X [k] |
| T2DM not using any diabetes medications | ✓ [a] | X | X | X | X | ✓ [a] | ✓ [a] | X [i] | X [k] |
| **PEDIATRIC POPULATIONS** | | | | | | | | | |
| T2DM on multiple daily insulin injections or continuous insulin infusion | ✓ [b] | ✓ | ✓ [a,f] | ✓ [a,b] | X [g] | ✓ [a,b,h] | ✓ | ✓ [a,b] | ✓ [l] |
| T2DM on basal insulin | ✓ [b] | X [e] | ✓ [a,f] | X | X [g] | ✓ [a,b,h] | ✓ | ✓ [a,b] | X [k] |
| T2DM using noninsulin diabetes medications (e.g., sulfonylureas) | ✓ [a,b] | X [e] | ✓ [a,f] | X | X [g] | ✓ [a,b,h] | ✓ | X [b,i] | X [k] |
| T2DM not using any diabetes medications | ✓ [a,b] | X [e] | X | X | X [g] | ✓ [a,b,h] | ✓ | X [b,i] | X [k] |
| **PREGNANT POPULATIONS** | | | | | | | | | |
| Preexisting T2DM | ✓ [c] | ✓ | ✓ [a,b,c] | ✓ [a,b] | ✓ [a,c] | ✓ [a,b,h] | ✓ [a,c] | ✓ [a,b] | ✓ [m] |
| Gestational diabetes | ✓ | ✓ | NA | NA | ✓ [a,c] | ✓ [a,b,h] | ✓ [a,c] | ✓ | X [k] |

Table Key. ✓ indicates the criterion is endorsed; X indicates the criterion is not or not fully endorsed; NA indicates the population is not considered in the document.
Notes. [a] Conditional (e.g., recurrent, severe, or at risk for hypoglycemia, impaired hypoglycemia awareness, caregiver responsible for managing blood glucose, unstable blood glucose despite efforts to optimize, in-person or other regular visits with knowledgeable provider). [b] Population broadly included in recommendations for all individuals. [c] On insulin therapy. [d] Not recommended in general but can be considered if at high risk for hypoglycemia in older adults on insulin or sulfonylureas. [e] Not a primary recommendation but may be considered if frequent blood glucose monitoring required. [f] Includes all preschool-age children irrespective of whether with or without additional condition. [g] No recommendation because of lack of evidence. [h] Small population of youth and pregnant individuals may be eligible for Medicare. [i] May be considered after prior authorization form review. [j] All require condition be met except Cigna. [k] None except RBCBS covers, with conditions. [l] All cover except Moda, RBCBS with conditions. [m] All require insulin therapy except RBCBS which requires other conditions be met for coverage.
Abbreviations. AACE: American Association of Clinical Endocrinology; ADA: American Diabetes Association; LCD: local coverage determination; NA: not applicable (see Table Key); NICE: National Institute for Health and Care Excellence (UK); RBCBS: Regence BlueCross BlueShield; T2DM: type 2 diabetes mellitus.

## Adult Populations With T2DM

All included guidelines for adult populations with T2DM recommended the use of CGM in persons taking insulin, irrespective of regimen,[100-103] except for the 2019 Healthy Quality Ontario (HQO) guidelines that only recommended isCGM for adults with T2DM diabetes if they require intensive insulin therapy including mutlple daily injections or use of an insulin pump.[106] The HQO, Endocrine Society, and UK National Institute for Health and Care Excellence (NICE) guidelines require additional conditions to be met, detailed below, in order for CGM to be recommended.

In addition to the requirement of being on insulin, conditions for coverage include the following.

- Endocrine Society (recommendations for rtCGM only)[102]:
  - Persons at risk for hypoglycemia, including older-age patients and individuals with (any):
    - Impaired kidney or liver function, or untreated pituitary, adrenal, or thyroid insufficiency
    - A history of severe hypoglycemia or impaired awareness of hypoglycemia
    - Cognitive impairment or intellectual disability that may reduce ability to respond to low blood glucose
    - A longer duration of diabetes (including those using insulin for ≥ 5 years)
    - History of frequent alcohol use or eating disorders
    - Irregular eating schedules, or fasting for religious or cultural reasons
- Health Quality Ontario (recommendations for isCGM only)[106]:
  - Individuals experiencing recurrent hypoglycemia despite other efforts to optimize glucose targets
- NICE (recommendations for isCGM unless rtCGM are available for the same or lower cost)[103]:
  - For individuals on intensive insulin therapy (any)
    - With recurrent or severe hypoglycemia
    - Having a condition or disability that precludes other methods of blood glucose self-monitoring
    - Recommended to self-measure 8 or more times daily
  - For individuals using any insulin therapy
    - Requiring a care worker or other professional to monitor their blood glucose

The 2023 ADA guidelines require no condition other than being on any insulin regimen to prescribe CGM, and state that the type of device (rtCGM or isCGM) prescribed should depend on patient circumstances, preferences, and diabetes treatment plan.[6] Moreover, the ADA highlights in key recommendations that people who use CGM should have consistent device access, citing that interruptions to access could result in negative consequences to health outcomes.[6] The 2022 Endocrine Society guidelines also recommend rtCGM for people who are taking sulfonylureas or meglitinides to lower blood sugar, and who may or may not be on insulin, but are otherwise at risk for hypoglycemia (see list above).[102]

Only the 2020 American Association of Clinical Endocrinology (AACE) guidelines recommended CGM for all indivudals with diabetes (including T2DM) who are experiencing problematic hypoglycemia, which includes people not using any medications for diabetes.[100] The AACE also recommends rtCGM over isCGM for most situations and conditions, unless the individual is relcutant or unable to commit to routine

rtCGM use, or may not have any serious risk for hypoglycemia, but is motivated to to gather more data to support their diabetes treatment.[100]

The Canadian Agency for Drugs and Technologies in Health (CADTH) prepared evidence reviews for isCGM generally for individuals with diabetes in 2018[110] and specifically for children and adolescents in 2021.[111] These reviews helped inform the HOQ recommendations for isCGM, along with a health technology assessment completed internally by HOQ. CADTH also prepared a review in 2022 on rtCGM for people living with T2DM.[112] In general, this review reported that rtCGM may be preferred over SMBG in some adult populations with T2DM, but that exisiting evidence was mostly of poor quality.[112]

### Pediatric Populations

The ADA, Endocrine Society, and NICE organizations explicitly include children and adolescents in their guildelines.[81,102,107] The 2023 ADA Standards of Care guidelines for Children and Adolescents recommended rtCGM or isCGM be offered to children with T2DM on intenisve insulin therapy.[81] Athough not a primary recommendation because of limited data, the ADA reported that CGM *may be* considered for any youth with T2DM requiring frequent blood glucose monitoring.[81] The Endocrine Society recommended rtCGM for any individual, including youth, who take insulin or sulfonylureas and are at risk of hypoglycemia (see list above); preschool-age children were also designated "at risk" for hypoglyemia irrespective of any other condition or risk.[102]

In contrast, the NICE recommendation for CGM for youth with T2DM was for more research only.[107] The NICE guidelines reported a lack of studies in this area, and the need for adequately powered RCTs to assess the effectiveness and cost-effectivenes of rtCGM and isCGM in this population.[107] This lack of evidence (precluding any CGM recommendations) was also reported in a 2022 health technology review prepared by CADTH,[112] and by the American Academy of Pediatrics (AAP) in a 2013 clinical practice guildelines for the management of newly disagnosed T2DM in children and adolescents.[108] We identified no further guideline updates for this topic, even within the recently published 2023 AAP guidelines for the evaluation and treatment of children and adolescents with obesity.[113]

The AACE[100] and HQO[106] guidelines broadly include children and adolescents in their recommendations for "all persons with diabetes" and "people with T2DM," respectively. See the criteria for the AACE and HQO recommendations in section above (Adult Populations).

### Pregnant Populations

The ADA, AACE, and NICE organizations have CGM recommendations specifically for pregnant individuals experiencing diabetes.[31,100,104] The 2023 ADA guidelines report broadly states that CGM can be considered to help achieve glycemic targets with diabetes during pregnancy, but recognizes that there is insufficent data to strongly support their use in pregnant individuals with T2DM or GDM.[31] The ADA also emphasizes that CGM should be used in addition to, and not as a substitute for, self-monitoring of blood glucose levels before and after meals.[31] The AACE guidelines strongly recommends CGM for pregnant individuals with diabetes (T2DM or GDM) on any insulin theapy, and that they may be recommended for individuals with GDM who are not on insulin therapy.[100] NICE also recommends rtCGM for pregnant individuals with diabetes (T2DM or GDM) on any insulin regimen, but only if they also have challenges with hypoglycemia or maintaining glycemic targets despite other efforts to optimize.[104]

The Endocrine Society[102] and HQO[106] guidelines broadly include pregnant women with T2DM in their recommendations for "outpatients with T2DM" and "people with T2DM," respectively (see recommendations and criteria for these organizations are in the Adult Populations section above). Neither the Endocrine Society or HQO guidelines explicitly mention the population of individuals with GDM.

## Payer Coverage Policies

We identified 7 policies related to coverage of CGM, from Aetna, Cigna, Moda, Regence Blue Cross BlueShield (Regence BCBS), the New York and Washington Medicaid programs, and the Medicare local coverage determination (LCD).[114-120] All payers we included cover CGM for adults with T2DM who are on intensive insulin therapy, although some required additional criteria for coverage. Medicare recently updated their policy to allow CGM coverage for persons who are not on insulin, but who have problems with hypoglycemia, as long as other conditions are followed. In general, public payers cover more populations than private payers, although some unclear language made it difficult to fully confirm coverage from the cited policy documents alone for particular populations.

CGM type (isCGM, rtCGM) was not mentioned in policy documents for Medicare,[115] Washington Medicaid,[117] and Regence BCBS,[119] while New York Medicaid,[120,121] Aetna,[118] and Cigna[116] listed both CGM types as options. The Moda policy did not mention CGM type within the body of the policy document, but did not include any isCGM products as examples offered.[114]

### Medicare

We identified 1 coverage determination document for Medicare that included information about CGM.[115] This LCD included nearly all US states and territories and was revised with an effective date of April 2023.[115] Beneficiaries diagnosed with diabetes (including T2DM and GDM) are initially eligible for CGM coverage if **all** of these criteria are met[115]:

- The CGM is prescribed according to FDA indications; *AND*
- The treating practitioner concludes that the individual (or caregiver of the individual) has had sufficient training to use the CGM; *AND*
- The individual has an in-person visit with the treating practitioner within 6 months prior to ordering the device, to confirm criteria are met; *AND*
- If either of these criteria are met[115]:
  - Treated with insulin; *OR*
  - History of documented recurrent or severe hypoglycemia.

For continued coverage of CGM by Medicare, individuals must experience in-person or telehealth visits with the treating practitioner every 6 months to document adherence to treatment plans for diabetes.[115]

While the majority of Medicare beneficiaries are adults over 65 years of age, younger persons can qualify for Medicare in certain situations.[122] For younger individuals who qualify for Medicare, coverage for CGM can be extrapolated to pediatric populations and pregnant individuals, as long as all the same criteria are met.[115]

## Medicaid Programs

### Adult Populations

The Washington State Health Care Authority adopted a Medicaid coverage policy for CGM in 2018.[117] Washington Medicaid covers CGM for adults with T2DM on intensive insulin therapy *OR* requiring frequent blood sugar monitoring of 4 or more times daily, with **at least 1** of the 2 following conditions[117]:

- One or more episodes of severe hypoglycemia; *OR*
- Challenges with maintaining glycemic targets despite other efforts to optimize.

Washington Medicaid coverage may also be considered in adults with T2DM not on insulin or taking other drugs that lower blood sugar, if their awareness of symptoms of hypoglycemia is impaired.[117]

New York Medicaid covers CGM for adults with T2DM if **all** of these criteria are met[120]:

- On insulin therapy that requires frequent dosing adjustments; *AND*
- Under care of an enrolled Medicaid provider with experience treating diabetes; *AND*
- Compliant with regular visits to review CGM data with the experienced Medicaid provider; *AND*
- Member or caregiver can hear and view CGM alerts and respond appropriately.

However, New York Medicaid providers can submit a prior authorization form to request CGM coverage for patients who do not meet all of the listed criteria, although approval is not guaranteed.[120]

### Pediatric Populations

Washington Medicaid appears to cover CGM for all children and adolescents (under 19 years of age) with diabetes without any additional criteria or conditions.[117]

The New York Medicaid policy for CGM[120] broadly includes children and adolescents for CGM coverage as "…members who are diagnosed with T2DM"; see the criteria for coverage listed the section above (Medicaid Programs: Adult Populations).

### Pregnant Populations

Washington Medicaid covers CGM for individuals with pregestational T2DM who are on insulin, as well as for individuals with T2DM or GDM during pregnancy who are on insulin and are having problems with achieving blood glucose targets or hypoglycemia.[117]

New York Medicaid covers CGM for all individuals with GDM, without any additional criteria requirements listed.[120] CGM coverage can also be extrapolated from the general New York Medicaid adult "member" population to individuals with pregestational T2DM[120]; see the 4 criteria needed for coverage above (Medicaid Programs: Adult Populations).

## Private Payers (Aetna, Cigna, Moda, Regence Blue Cross BlueShield)

### Adult Populations

Private payers Aetna, Cigna, and Moda cover CGM for adults with T2DM using intensive insulin regimens[114,116,118]; only Cigna does not require additional criteria for CGM coverage in this adult population.[116] The additional criteria for coverage by Aetna and Moda are:

- Aetna[118]:
  - Not meeting glycemic targets; *OR*
  - Experiencing hypoglycemia, including hypoglycemic unawareness

- Moda[114]:
  - Not meeting glycemic targets

Regence BCBS uses the Medicare LCD policy to determine CGM coverage, so individuals must be either on any insulin regimen, or have a history of documented problems with hypoglycemia, to have access to CGM, as long as these additional criteria are met[119]:

- The CGM is prescribed according to FDA indications; *AND*
- The treating practitioner concludes that the individual (or caregiver of the individual) has had sufficient training to use the CGM; *AND*
- The individual has an in-person visit with the treating practitioner within 6 months prior to ordering the device, to confirm criteria are met.

Aetna and Regence BCBS also include different coverage criteria for continued use of CGM in adults with T2DM.[118,119] For Aetna, individuals must be experiencing improved glycemic control or decreased hypoglycemia episodes while using a CGM, or are being assessed every 6 months by their prescriber for adherence to the diabetes treatment plan.[118] For continued CGM coverage by Regence BCBS (again, based on Medicare LCD coverage), members with diabetes must visit with their treating practioner every 6 months to document adherence to treatment plans.[119]

### Pediatric Populations

Aetna and Cigna cover CGM for children and adolescents with T2DM who are also on intensive insulin regimens.[116,118] Regence BCBS may cover CGM for youth who are not on insulin if they are experiencing problems with hypoglycemia; additional coverage criteria must also be met, including sufficient CGM use training and an in-person visit with the treating practitioner prior to ordering the CGM (similar to criteria for the adult population).[119]

Moda does not cover CGM for youth with T2DM (coverage is only for youth with T1DM).[114]

### Pregnant Populations

Coverage of CGM for pregestational and pregnant individuals with T2DM can be extrapolated from the more general adult coverage policies across all included private payers.[114,116,118,119] See additional population criteria above (Private Payers: Adult Populations).

GDM is not mentioned as a specific population in any of the included private payer coverage populations for CGM. However, because Regence BCBS uses the Medicare LCD policy for CGM coverage, CGM for people with GDM may be covered since the policy requires only broadly that "the beneficiary has diabetes," rather than specific diabetes types (i.e., T1DM, T2DM, GDM).[119]

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# APPENDIX A. GRADE TABLE ELEMENT DESCRIPTIONS

Table A1. GRADE Table Elements

| Element | Description |
|---|---|
| Balance of benefits and harms | The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded. |
| Quality of evidence | The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted. |
| Resource allocation | The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted. |
| Values and preferences | The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted. |
| Other considerations | Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon. |

Abbreviation. GRADE: Grading of Recommendations, Assessment, Development, and Evaluations approach.

## Confidence in Estimate Rating Across Studies for the Intervention and Outcome

Assessment of confidence in estimate includes factors such as risk of bias, precision, directness, consistency, and publication bias.

***High:*** The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are randomized controlled trials (RCTs) with few or no limitations, and the estimate of effect is likely stable.

***Moderate:*** The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

***Low:*** The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

***Very low:*** The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

# APPENDIX B. GRADE EVIDENCE PROFILES

Table B1. Certainty Assessment (Confidence in Estimate of Effect) for Individuals With T2DM Requiring Insulin

| NO. OF STUDIES | RISK OF BIAS | INCONSISTENCY | INDIRECTNESS | IMPRECISION | OTHER FACTORS | LEVEL OF CONFIDENCE |
|---|---|---|---|---|---|---|
| **SEVERE HYPOGLYCEMIA** | | | | | | |
| 4 RCTs<br>N = 588 | **Serious:** downgraded 1 level for some COI- related funding concerns (manufacturer involvement) and high differential attrition in at least 1 RCT | Not easily assessable due to very low event rates and lack of significance testing | **Not serious:** outcome of interest was reported in large trials of high-HDI countries | **Serious:** downgraded 2 levels for very low event rates and sample sizes underpowered to detect differences | None | Very low |
| **CHANGE IN HbA1c** | | | | | | |
| 4 RCTs<br>N = 588 | **Not serious:** potential COI (manufacturer involvement) | **Serious:** downgraded 1 level as 2 trials found significantly lower HbA1c, 2 trials found no difference | **Serious:** downgraded 1 level as use of run-in periods to screen out low-adherence candidates prior to randomization may have limited generalizability | **Not serious:** large sample size and fairly tight CIs in the pooled analyses of CGM vs. SMBG | Several studies were conducted in non-US settings (e.g., UK, Denmark) that have substantially different health care systems | Low |
| **SEVERE PERINATAL MORBIDITY** | | | | | | |

| NO. OF STUDIES | RISK OF BIAS | INCONSISTENCY | INDIRECTNESS | IMPRECISION | OTHER FACTORS | LEVEL OF CONFIDENCE |
|---|---|---|---|---|---|---|
| 1 RCT<br>N = 31 | **Serious:** downgraded 1 level for incomplete outcome reporting | Not assessable | **Serious:** downgraded 1 level for use of an older CGM model in a non-US population | **Serious:** downgraded 1 level for small sample size | Use of CGM was episodic, not continuous throughout the study | Very low |
| **QUALITY OF LIFE** | | | | | | |
| 3 RCTs<br>N = 427 | **Not serious:** possible funding-related COI (manufacturer involvement) | **Serious:** downgraded 1 level; differing results across studies even for the same time period of use | **Serious:** downgraded 1 level; comparing different scales between varying populations; some studies evaluating nontherapeutic CGM models | **Not serious:** some larger SDs, but respondent sample size seems adequate | Almost all study groups reported high treatment satisfaction on at least 1 scale | Low |
| **HEALTH CARE RESOURCE USE** | | | | | | |
| No eligible studies | | | | | | |
| **HARMS** | | | | | | |
| 6 RCTs<br>N = 772 | **Not serious:** possible funding-related COI (manufacturer involvement) | **Not serious:** similar patterns of adverse events reported across studies | **Serious:** downgraded 1 level as several of the contributing studies used run-in periods to eliminate people who could not | **Not serious:** reasonable sample size and volume of reported events for comparison | None | Moderate |

| NO. OF STUDIES | RISK OF BIAS | INCONSISTENCY | INDIRECTNESS | IMPRECISION | OTHER FACTORS | LEVEL OF CONFIDENCE |
|---|---|---|---|---|---|---|
| | | | tolerate or adhere to CGM use | | | |

Abbreviations. CGM: continuous glucose monitor; CI: confidence interval; COI: conflict of interest; HbA1c: glycated hemoglobin; HDI: high development index; No.: number; RCT: randomized controlled trial; SD: standard deviation; SMBG: self-management of blood glucose; T2DM: type 2 diabetes mellitus; UK: United Kingdom; US: United States; vs.: versus.

Table B2. Certainty Assessment (Confidence in Estimate of Effect) for Individuals With T2DM **Not** Requiring Insulin

| NO. OF STUDIES | RISK OF BIAS | INCONSISTENCY | INDIRECTNESS | IMPRECISION | OTHER FACTORS | LEVEL OF CONFIDENCE |
|---|---|---|---|---|---|---|
| **SEVERE HYPOGLYCEMIA** | | | | | | |
| No eligible studies | | | | | | |
| **CHANGE IN HbA1c** | | | | | | |
| 6 RCTs<br>N = 609 | **Serious:** high downgraded 1 level for high attrition in some studies and potential COI (manufacturer involvement) | **Not serious:** reasonable alignment across studies | **Serious:** downgraded 1 level as several studies were conducted in non-US settings | **Not serious:** large sample size and fairly tight CIs in the pooled analyses of CGM vs. SMBG | None | Low |
| **SEVERE PERINATAL MORBIDITY** | | | | | | |
| No eligible studies | | | | | | |
| **QUALITY OF LIFE** | | | | | | |
| 3 RCTs<br>N = 326 | **Serious:** downgraded 1 level for high attrition in some studies and potential COI from manufacturer involvement | **Serious:** downgraded 1 level for differing results across studies even for the same time period of use | **Serious:** downgraded 1 level for comparing different scales between varying populations; some studies evaluating nontherapeutic CGM models | **Not serious:** some wider SDs, but respondent sample size seems adequate | Almost all study groups reported high treatment satisfaction on at least 1 scale | Very low |
| **HEALTH CARE RESOURCE USE** | | | | | | |
| 1 RCT<br>N = 99 | **Serious:** downgraded 1 level for high differential attrition in the control group | Not assessable | **Serious:** downgraded 1 level for some T1DM users included (6%) | **Serious:** downgraded 1 level for small sample size | Study was conducted at 4 sites in a single health care system in Utah | Very low |

| NO. OF STUDIES | RISK OF BIAS | INCONSISTENCY | INDIRECTNESS | IMPRECISION | OTHER FACTORS | LEVEL OF CONFIDENCE |
|---|---|---|---|---|---|---|
| **HARMS** | | | | | | |
| 6 RCTs<br>N = 772 | **Not serious:** possible funding-related COI (manufacturer involvement) | **Not serious:** similar patterns of adverse events reported across studies | **Serious:** downgraded 1 level as several of the contributing studies used run-in periods to eliminate people who could not tolerate or adhere to CGM use | **Not serious:** reasonable sample size and volume of reported events for comparison | None | Moderate |

Abbreviations. CGM: continuous glucose monitor; CI: confidence interval; COI: conflict of interest; HbA1c: glycated hemoglobin; No.: number; RCT: randomized controlled trial; SD: standard deviation; SMBG: self-management of blood glucose; T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus; US: United States; vs.: versus.

# APPENDIX C. METHODS

## Scope Statement

### Populations

Children, adolescents, and adults with type 2 diabetes mellitus (T2DM; including those who are pregnant); individuals with gestational diabetes mellitus (GDM)

*Population exclusions: People with type 1 diabetes (no coverage change proposed)*

### Interventions

Real-time continuous glucose monitor (CGM) use

*Intervention exclusions: Retrospective (physician-owned) continuous glucose monitoring*

### Comparators

Self-monitoring of blood glucose (SMBG); routine HbA1c (glycated hemoglobin) monitoring

### Outcomes

**Critical:** Severe hypoglycemia requiring intervention; change in HbA1c; severe perinatal morbidity (e.g., life-threatening or disabling neonatal hypoglycemia or shoulder dystocia); quality of life

**Important:** Health resource utilization (limited to hospitalizations, emergency department visits, clinic visits)

*Considered, but not selected for GRADE table: myocardial infarction, cerebrovascular accident, amputations, neuropathy, retinopathy, nephropathy (we chose to generalize these into "severe morbidity" to simplify consideration); time in range, time below range, adherence to CGM use, mortality*

### Study Designs

Randomized controlled trials (RCTs), clinical practice guidelines (CPGs

*Study design exclusions: systematic reviews were removed from the list of eligible study designs following a decision to exclude studies of T1DM from the evidence review; nonrandomized study designs excluded*

### Follow-up

**RCTs:** 12 weeks or greater
**CPGs:** not applicable

### Key Questions

The following key questions (KQs) guided our research for the present report:

KQ1. What is the effectiveness of CGM in improving outcomes compared to SMBG in:
   a. people with T2DM who use insulin
   b. People with T2DM who do not use insulin

KQ2. Is there evidence of differential comparative effectiveness of CGM in people with diabetes based on:
   a. Age
   b. Sex

c. Identity-related factors (e.g., race/ethnicity, gender)
d. Diabetes type (T2DM, GDM)
e. Baseline glycemic control
f. Type of diabetes medication (if any)
g. CGM use adherence
h. CGM type (therapeutic vs. nontherapeutic real-time continuous glucose monitors [rtCGM] vs. intermittently scanned continuous glucose monitors [isCGM])

### Contextual Questions

CQ1. What minimum level of HbA1c change is considered clinically significant by various professional and regulatory groups?

CQ2. What is the overall impact on health care costs associated with rtCGM vs. isCGM vs. SMBG in the United States?

CQ3. How do the costs of monitoring with CGM compare to self-monitoring with test strips?

## Key Question Methods

### Search Strategy

We conducted a full search of the core sources to identify RCTs and related systematic reviews (for reference purposes only) that meet the criteria for the scope described above. Searches of core sources were limited to citations published after 2012.

We searched the following core sources:

- Agency for Healthcare Research and Quality (AHRQ)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Cochrane Library (Wiley Online Library)
- Institute for Clinical and Economic Review (ICER)
- National Institute for Health and Care Excellence (NICE)
- Veterans Administration Evidence-based Synthesis Program (ESP)
- Washington State Health Technology Assessment Program

We also conducted a MEDLINE search to identify RCTs and health technology assessments. For systematic reviews and meta-analyses, we limited the search to publications in English published since 2019. For RCTs and cohort studies, we limited the search to publications in English published since 2012.

Database(s): **Ovid MEDLINE ALL** 1946 to March 23, 2023
Search Strategy:

| # | Searches | Results |
|---|---|---|
| 1 | ((realtime or real-time or real time or rt or continu* or constant) adj3 glucose adj2 (monitor* or sensor* or sensing)).ti,ab,kf. | 7314 |
| 2 | ((rtcgm or rt-cgm or (realtime or real-time or real time or continu* or constant)) adj3 cgm).ti,ab,kf. | 2783 |
| 3 | (ambulatory adj2 (glucose or insulin or glycam* or glycaem*) adj1 (monitor* or sensor*)).ti,ab,kf. | 26 |
| 4 | cgm.ti,ab. and (diabetes or insulin).mp. | 2937 |
| 5 | Eversense*.ti,ab,kf. | 24 |
| 6 | dexcom*.ti,ab,kf. | 326 |

| | | |
|---|---|---|
| 7 | (FreeStyle or SmartGuard or Omnipod or T-slimX2 or TslimX2).ti,ab,kf. | 1752 |
| 8 | (Medtronic adj2 (Enlite* or Guardian* or Minimed*)).ti,ab,kf. | 242 |
| 9 | or/1-8 | 8980 |
| 10 | limit 9 to english language | 8710 |
| 11 | (exp Animals/ not Humans/) or (animal$1 or bovine$1 or canine$1 or cat$1 or chimpanzee$1 or cow$1 or dog$1 or feline$1 or goat$1 or hens or mice or monkey$1 or mouse or murine$1 or ovine or pig$1 or porcine or primate$1 or sheep or rabbit$1 or rat or rats or rattus or rhesus or rodent*).ti. | 5575319 |
| 12 | 10 not 11 | 8402 |
| 13 | (harm$1 or adverse event$1 or adverse effect$1 or safe*).ti,ab,kf. or ae.fs. | 3086888 |
| 14 | (random* adj3 assign*).ab. | 137876 |
| 15 | ("clinical trial" or "clinical trial, phase i" or "clinical trial, phase ii" or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or "multicenter study" or "randomized controlled trial").pt. or double-blind method/ or clinical trials as topic/ or clinical trials, phase i as topic/ or clinical trials, phase ii as topic/ or clinical trials, phase iii as topic/ or clinical trials, phase iv as topic/ or controlled clinical trials as topic/ or randomized controlled trials as topic/ or early termination of clinical trials as topic/ or multicenter studies as topic/ or ((randomi?ed adj7 trial*) or (controlled adj3 trial*) or (clinical adj2 trial*) or ((single* or doubl* or tripl* or treb* or quad*) adj1 (blind* or mask*))).ti,ab,kw. or ("2 arm" or "two arm" or "3 arm" or "three arm" or "4 arm" or "four arm" or "5 arm" or "five arm").ti,ab,kw. or quasi*.ti,ab. | 1971621 |
| 16 | (phase 2$1 or phase ii or phase 3$1 or phase iii or phase 4 or phase iv).ti,ab,kw. | 139842 |
| 17 | (placebo* or head-to-head or (compar* adj3 (effectiveness or efficacy))).ti,ab,kw. or Comparative Effectiveness Research/ | 343909 |
| 18 | (active adj1 (comparator* or control$1 or treatment*)).ti,ab. | 20900 |
| 19 | or/14-18 | 2146162 |
| 20 | (((comprehensive* or integrative or systematic*) adj3 (bibliographic* or review* or literature)) or (meta-analy* or metaanaly* or "research synthesis" or ((information or data) adj3 synthesis) or (data adj2 extract*))).ti,ab. or (cinahl or (cochrane adj3 trial*) or embase or medline or psyclit or (psycinfo not "psycinfo database") or pubmed or scopus or "sociological abstracts" or "web of science").ab. or ("cochrane database of systematic reviews" or evidence report technology assessment or evidence report technology assessment summary).jn. or Evidence Report: Technology Assessment*.jn. or ((review adj5 (rationale or evidence)).ti,ab. and review.pt.) or meta-analysis as topic/ or Meta-Analysis.pt. | 674309 |
| 21 | psychinfo.ab. or heath technology assessment.ti,ab. or ((review or umbrella or evidence) adj2 (review* or synthesis)).ti,ab. | 2095579 |
| 22 | or/20-21 | 2291585 |
| 23 | 12 and 19 | 2255 |
| 24 | 12 and 22 | 929 |
| 25 | 12 and 13 | 1718 |
| 26 | 23 or 24 or 25 | 3806 |
| 27 | limit 26 to yr="2012 -Current" | 3115 |
| 28 | limit 27 to yr="2017 -Current" | 2344 |
| 29 | (202204* or 202205* or 202206* or 202207* or 202208* or 202209* or 20221*).dp,dt,ep. | 1268588 |
| 30 | 23 and 29 | 201 |
| 31 | 24 and 29 | 125 |
| 32 | 25 and 29 | 163 |

### Inclusion/Exclusion Criteria

We excluded studies if they were not published in English, did not address the scope statement, or were study designs other than RCTs. We required that studies have a minimum of 12 weeks of follow-up.

## Contextual Question Methods

We identified evidence for CQs by using results of the KQ database searches, auditing reference lists of relevant systematic reviews, and performing targeted searches of relevant sources as needed. We included any study design or other type of publication if it was relevant to answering the CQ and was

published in English. Evidence regarding the CQs is summarized in the Background section; specifically, CQ1 is addressed in the Important Glycemic Outcomes and Management Considerations subsection, whereas CQ2 and CQ3 are addressed in the Cost Impact of CGM subsection.

## Policy Landscape Methods

For the Policy Landscape section, we conducted targeted searches in Ovid MEDLINE, websites of relevant professional societies and guideline groups, and DuckDuckGo to identify relevant CPGs and key payer policies regarding CGM use in populations with T2DM or GGM. Two reviewers independently assessed the quality of the included CPGs; disagreements were resolved through consensus or by a third reviewer.

We limited searches for CPGs to those published since 2018. We conducted a search for relevant clinical practice guidelines using MEDLINE and the following sources:

- American Association of Clinical Endocrinology (AACE)
- American Academy of Pediatrics (AAP)
- American College of Obstetricians and Gynecologists (ACOG)
- American Diabetes Association (ADA)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Centers for Disease Control and Prevention (CDC)
- Community Preventive Services
- Endocrine Society
- Health Quality Ontario
- National Institute for Health and Care Excellence (NICE)
- Scottish Intercollegiate Guidelines Network (SIGN)
- United States Preventive Services Task Force (USPSTF)
- Veterans Administration/Department of Defense (VA/DoD) Clinical Practice Guidelines

We additionally sought CGM coverage policies from select public and commercial payers, including:

- Medicare
- Medicaid (Washington state and New York state)
- Aetna
- Cigna
- Moda
- Regence BlueCross BlueShield of Oregon

## Risk of Bias and Methodologic Quality of Included Studies

We assessed the risk of bias of the included RCTs and methodologic quality of clinical practice guidelines using standard instruments developed and adapted by the Center for Evidence-based Policy (Center) based on a instruments used by the other reputable organizations.[123] One experienced researcher independently rated the risk of bias of included studies. A second experienced researcher reviewed each assessment. Disagreement was managed by discussion.

### Randomized Controlled Trials

Low-risk-of-bias RCTs include a clear description of the population, setting, intervention, and comparison groups; a random and concealed allocation of patients to study groups; low dropout rates; and intention-

to-treat analyses. Low-risk-of-bias RCTs also have low potential for bias from conflicts of interest and funding source(s). Moderate-risk-of-bias RCTs have incomplete information about methods that might mask important limitations or a meaningful conflict of interest. High-risk-of-bias RCTs have clear flaws that could introduce significant bias.

### Clinical Practice Guidelines

We assessed the methodological quality of the guidelines using an instrument adapted from the Appraisal of Guidelines Research and Evaluation (AGREE) Collaboration.[124-126] Each rater assigned the study a rating of good, fair, or poor based on its adherence to recommended methods and potential for biases. A good-quality guideline fulfills all or most of the criteria outlined in the instrument. A fair-quality guideline fulfills some of the criteria, and its unfulfilled criteria are not likely to alter the recommendations. A poor-quality guideline met few or none of the criteria.

# APPENDIX D. ADDITIONAL EVIDENCE TABLES

Table D1. Adults With T2DM: Study and Participant Characteristics From Included RCTs

| AUTHOR, YEAR STUDY NAME RISK OF BIAS | SAMPLE SIZE FOLLOW-UP LOCATION | INCLUSION/EXCLUSION CRITERIA | BASELINE CHARACTERISTICS (CGM VS. SMBG) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | MEAN AGE (YRS) | MEAN T2DM LENGTH (YRS) | MEAN SMBG (TESTS/ DAY) | MEAN HbA1c | % FEMALE | % NON-WHITE |
| Ajjan, 2016[53]<br>Low | N = 45<br>36 weeks<br>UK | INCLUSION<br>Treatment with MDI of prandial insulin for > 6 months prior to study enrollment, HbA1c between 7.5% and 12.0% (58 and 108 mmol/mol) obtained within 6 months of enrollment, and individuals who were judged by the investigators to be technically capable of using the FreeStyle Navigator<br>EXCLUSION<br>1) Had concomitant disease or any condition that could compromise patient safety (including unstable coronary heart disease, cystic fibrosis, serious psychiatric disorder or any uncontrolled chronic medical condition); (2) Were pregnant or planning to become pregnant within the study duration; (3) Were currently using/had previously used a CGM device within the last 6 months, or were using CSII or basal insulin only; (4) Were participating in another study of a glucose-monitoring device/drug that could affect glucose measurements/ management; (5) Had a known allergy to medical-grade adhesives; (6) Were judged by the investigators as unsuitable to participate due to any other cause/reason | 57.8 vs. 55.5 | 13.9 vs. 15.8 | NR | 9.2% vs. 9.2% | 37% vs. 27% | NR |
| Beck, 2017[25]<br>DIAMOND<br>Low | N = 158<br>24 weeks<br>US, Canada | INCLUSION<br>(1) Age at least 25 years; (2) T2DM treated with multiple daily injections of insulin for at least 1 year; (3) Central laboratory measured HbA1c levels of 7.5% to 10.0%; (4) Stable diabetes medication regimen and weight over the | 60 vs. 60 | 17 vs. 18 | 3.3 vs. 3.2 | 8.5% vs. 8.5% | 62% vs. 51% | 46% vs. 27% |

| AUTHOR, YEAR STUDY NAME RISK OF BIAS | SAMPLE SIZE FOLLOW-UP LOCATION | INCLUSION/EXCLUSION CRITERIA | BASELINE CHARACTERISTICS (CGM VS. SMBG) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | MEAN AGE (YRS) | MEAN T2DM LENGTH (YRS) | MEAN SMBG (TESTS/ DAY) | MEAN HbA1c | % FEMALE | % NON-WHITE |
| | | prior 3 months; (5) Self-reported blood glucose meter testing averaging 2 or more times per day; and (6) Estimated glomerular filtration rate of at least 45 mL/min/1.73 $m^2$<br><br>EXCLUSION<br>(1) Use of personal real-time CGM ≤ 3 months before study entry; (2) use of CSII ≤ 3 months before study entry (including patch pumps); (3) addition of any new oral or injectable hypoglycemic agents < 3 months before study entry; (4) For GLP-1 medications, must be on stable dose and the medication will be maintained throughout the study; (5) use of premixed insulin ≤ 6 months before study entry; (6) current or anticipated short-term uses of glucocorticoids that will affect glycemic control and HbA1c levels; (7) pregnancy at time of screening or plan to become pregnant during study; (8) Medical conditions that make it inappropriate or unsafe to target an HbA1c level of < 7; (9) history of psychiatric, psychological, or psychosocial issues that could limit adherence to required study tasks; (10) renal disease; (11) skin changes/disease that preclude wearing the sensor on normal skin; (12) known allergy to medical-grade adhesives; (13) current participation in another study; (14) hospitalization or emergency department visit ≤ 6 months before screening resulting in a primary diagnosis of uncontrolled diabetes; (15) current SUD; (16) any condition that can impact reliability of an HbA1c test | | | | | | |
| Bergenstal, 2022[55]<br>Moderate | N = 114<br>16 weeks<br>US | INCLUSION<br>Subjects with uncontrolled T2DM defined as those with an HbA1c ≥ 7.0% (53 mmol/mol) aged 18–75 years being treated with one of the following three common therapies: (1) sulfonylurea (SU) ± metformin (SU group), (2) incretin | 59.3 vs. 58.8 | NR | NR | 8.2% vs. 7.6% | 49% vs. 58% | NR |

| AUTHOR, YEAR STUDY NAME RISK OF BIAS | SAMPLE SIZE FOLLOW-UP LOCATION | INCLUSION/EXCLUSION CRITERIA | BASELINE CHARACTERISTICS (CGM VS. SMBG) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | MEAN AGE (YRS) | MEAN T2DM LENGTH (YRS) | MEAN SMBG (TESTS/ DAY) | MEAN HbA1c | % FEMALE | % NON-WHITE |
| | | (DPP4 inhibitor or GLP-1 agonist) ± metformin (incretin group), or (3) insulin± metformin (insulin group)<br>EXCLUSION<br>Subjects were excluded if they had been treated with T2DM or a maltose metabolizing agent, had taken steroids in the past 30 days, were physically, cognitively, or psychologically unable to participate, were pregnant or planned to be, had inherited galactosemia, or were not English fluent | | | | | | |
| Choe, 2022[57]<br>PDF<br>Moderate | N = 126<br>12 weeks<br>South Korea | INCLUSION<br>(1) Age between 19–80; (2) Able to understand instructions in Korean language; (3) Diagnosed with type 2 diabetes treated with antidiabetic medications of lifestyle modifications; (4) HbA1c of 7.0%–10.0% within 3 months; (5) Stable medication regimen during the 3 months prior to entry visit; (6) Naïve to intermittent CGM use and willing to participate in the study<br>EXCLUSION<br>(1) Type 1 diabetes patients; (2) Use of short acting insulin in the 3 months prior to entry visit or planning to initiate prandial insulin or short acting insulin; (3) Pregnancy at time of screening or are planning to become pregnant during the study; (4) Alcoholics or addicted to drugs; (5) Heavy smokers of nicotinic acid ≥ 1500 mg/day; (6) Use of glucocorticoid or other medications that will affect glycemic control ; (7) Taking obesity drugs; (8) Severe liver disease that may compromise patient safety; (9) End-stage renal disease on dialysis; (10) Acute perioperative period or planning to go through surgery with general anesthesia during the study period; (11) Known allergy to medical grade adhesives or any other skin problems that | 58.6 vs. 57.5 | 13.3 vs. 13.4 | NR | 7.9% vs. 7.9% | 36% vs. 44% | NR |

| AUTHOR, YEAR STUDY NAME RISK OF BIAS | SAMPLE SIZE FOLLOW-UP LOCATION | INCLUSION/EXCLUSION CRITERIA | BASELINE CHARACTERISTICS (CGM VS. SMBG) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | MEAN AGE (YRS) | MEAN T2DM LENGTH (YRS) | MEAN SMBG (TESTS/ DAY) | MEAN HbA1c | % FEMALE | % NON-WHITE |
| | | may interfere with CGM sensor insertion; (12) Inapt to participate in the study made at the investigator's discretion | | | | | | |
| Vigersky, 2012[64] High | N = 100 12 weeks US | INCLUSION Aged 18 years or older, who had T2DM for at least 3 months and an initial HbA1c ≥ 7% but ≤ 12%. Eligible participants were treated with diet/exercise alone or other glucose lowering therapies except prandial insulin, were able to independently measure and read finger-stick blood glucose levels and were willing to perform SMBG four times daily. They had all attended an American Diabetes Association-recognized diabetes self-management education program EXCLUSION Individuals who were pregnant, lactating, or attempting pregnancy and those on glucocorticoids, amphetamines, anabolic, or weight reducing medications were excluded | 55.5 vs. 60.0 | NR | 2.9 vs. 2.4 | 8.4% vs. 8.2% | 34% vs. 56% | NR |
| Haak, 2017[61] REPLACE Moderate | N = 224 24 weeks France, Germany, UK | INCLUSION ≥ 18 years of age with T2DM treated with insulin for at least 6 months and on their current regimen (prandial only or prandial and basal multi-dose-insulin therapy or CSII therapy) for 3 months; had an HbA1c level of 58–108 mmol/mol (7.5%–12.0%); had self-reported regular blood glucose testing data (more than 10/week for at least 2 months prior to study entry); were considered by the investigator to be technically capable of using the flash sensor-based glucose monitoring system EXCLUSION Other insulin regimens to that described above; had a total daily dose of insulin 1.75 U/kg on study entry; had severe hypoglycemia (requiring third-party assistance), diabetic ketoacidosis or hyperosmolar– hyperglycemic state in the | 59.0 vs. 59.5 | 17 vs. 18 | 3.6 vs. 3.9 | 8.7% vs. 8.9% | 37% vs. 25% | 5% vs. 7% |

| AUTHOR, YEAR STUDY NAME RISK OF BIAS | SAMPLE SIZE FOLLOW-UP LOCATION | INCLUSION/EXCLUSION CRITERIA | BASELINE CHARACTERISTICS (CGM VS. SMBG) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | MEAN AGE (YRS) | MEAN T2DM LENGTH (YRS) | MEAN SMBG (TESTS/ DAY) | MEAN HbA1c | % FEMALE | % NON-WHITE |
| | | preceding 6 months; had a known allergy to medical-grade adhesives; used continuous glucose monitoring within the previous 4 months; were pregnant or planning pregnancy; were receiving steroid therapy for any condition; were considered by the investigator to be unsuitable to participate | | | | | | |
| Isaacson, 2022[45] Moderate | N = 99 24 weeks US | INCLUSION<br>Patients between the ages of 18 and 80, having been diagnosed with T1DM or T2DM, not currently using a CGM device<br>EXCLUSION<br>Patients who are not pregnant or planning to become pregnant for the duration of the study | NR | NR | NR | NR | 57% | NR |
| Martens, 2021[62] MOBILE Moderate | N = 175 32 weeks US | INCLUSION<br>1) Age ≥ 30 years old; 2) T2DM; 3) Comprehends written and spoken English; 4) Using 1-2 injections of basal or intermediate acting insulin daily for ≥ 6 months prior to screening; 5) HbA1c between 7.8% to 11.5% inclusive at enrollment; 6) Patient is able and willing to wear a CGM device; 7) No use of a personal real-time CGM within 3 months of study entry; 8) SMBG on average ≥ 3 times per week during the month prior to screening; 9) Stable medication regimen during the 3 months prior to screening; 10) Has a smart phone compatible with CGM and BGM systems; 11) Diabetes managed by a primary care physician or nurse practitioner/ physician assistant<br>EXCLUSION<br>1) Regular use of short acting insulin in the 3 months prior to entry visit or planning to initiate prandial insulin or short acting insulin; 2) Pregnancy or planning to become pregnant during the study; 3) Weight reduction | 56 vs. 59 | 14 vs. 15 | 1 vs. 2 | 9.1% vs. 9.0% | 53% vs. 46% | 57% vs. 44% |

| AUTHOR, YEAR STUDY NAME RISK OF BIAS | SAMPLE SIZE FOLLOW-UP LOCATION | INCLUSION/EXCLUSION CRITERIA | BASELINE CHARACTERISTICS (CGM VS. SMBG) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | MEAN AGE (YRS) | MEAN T2DM LENGTH (YRS) | MEAN SMBG (TESTS/ DAY) | MEAN HbA1c | % FEMALE | % NON-WHITE |
| | | medications, programs or surgery; 4) Concomitant disease or condition that may compromise patient safety (e.g., SMI); 5) Known or significant allergy to medical grade adhesives; 6) Renal disease; 7) Anticipated use of glucocorticoids that could affect glycemic control; 8) Acute conditions that could impact the stability of a HbA1c measurement; 9) Diabetes management by a study PI or sub-investigator; 10) Diabetes management in the prior 6 months by a diabetes specialist; 11) Concurrent participation in another clinical trial | | | | | | |
| Price, 2021[63] COMMITTED High | N = 70 12 weeks US, Canada, Mexico | INCLUSION (1) Age 30+ years; (2) Diagnosis of T2DM; treated with two or more noninsulin antidiabetic drugs; (3) HbA1c ≥ 7.8% and ≤ 10.5% by local laboratory or point of care; (4) Stable body weight over the past 3 months; (5) English speaking; and (6) Owner of a compatible smart device for CGM data display (receivers were not used) EXCLUSION (1) Use of insulin; (2) Prior CGM use (past professional CGM use was acceptable); (3) Pregnancy; and (4) Estimated glomerular filtration rate < 30 mL/min/1.73 $m^2$ | 58.9 vs. 60.9 | 13.9 vs. 12.3 | NR | 8.4% vs. 8.5% | 41% vs. 58% | 33% vs. 13% |
| Secher, 2013[66] Moderate | N = 154 T2DM = 31 36 weeks Denmark | INCLUSION 1) Pregestational T1DM or T2DM; 2) Singleton pregnancy; 2) Length of gestation < 14 weeks at recruitment; 4) Referral to specialty obstetrical diabetes center EXCLUSION 1) Present use of real-time CGM; 2) Severe mental or psychiatric barriers; 3) Diabetic nephropathy; 4) Severe concurrent comorbidity; 5) Fetal multiples or multiple singleton pregnancies during the study period | 32 vs. 31 | 10 vs. 12 | 7 vs. 7 | 6.6% vs. 6.8 | 100% | NR |

| AUTHOR, YEAR STUDY NAME RISK OF BIAS | SAMPLE SIZE FOLLOW-UP LOCATION | INCLUSION/EXCLUSION CRITERIA | BASELINE CHARACTERISTICS (CGM VS. SMBG) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | MEAN AGE (YRS) | MEAN T2DM LENGTH (YRS) | MEAN SMBG (TESTS/ DAY) | MEAN HbA1c | % FEMALE | % NON-WHITE |
| Wada, 2020[65]<br>Low | N = 100<br>24 weeks<br>Japan | INCLUSION<br>(1) T2DM; (2) HbA1c ≥ 7.5% (59 mmol/mol) and < 8.5% (69 mmol/mol); (3) aged ≥ 20 years and < 70 years<br>EXCLUSION<br>(1) Treated with insulin; (2) Had been using SMBG or flash glucose monitoring ; (3) Were on dialysis; (4) Had severe renal failure; (6) Could not properly operate the devices or; (7) Were judged by their physicians to be unsuitable for participation in the study | 58.1 vs. 58.7 | NR | NR | 7.8% vs. 7.8% | 31% vs. 33% | NR |

Abbreviations. BGM: blood glucose monitoring; CGM: continuous glucose monitor; CSII: continuous subcutaneous insulin infusion; DPP4: dipeptidyl peptidase-4; FGM: ;GLP-1: glucagon-like peptide; HbA1c: glycated hemoglobin; MDI: multiple daily injections; NR: not reported; PI: principal investigator; RCT: randomized controlled trial; SMBG: self-monitoring of blood glucose; SU: sulfonylurea; SUD: substance use disorder; T2DM: type 2 diabetes mellitus; UK: United Kingdom; US: United States; vs.: versus; yrs: years.

Table D2. Excluded Studies of CGM Use in Pregnancy

| STUDY CITATION | RESULTS SUMMARY | REASON FOR EXCLUSION |
|---|---|---|
| **PREGNANT INDIVIDUALS WITH PREEXISTING T2DM** | | |
| Feig DS, Donovan LE, Corcoy R, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. *Lancet.* 2017;390(10110):2347-2359. doi: 10.1016/s0140-6736(17)32400-5. | Significantly lower HbA1c and lower incidence of neonatal outcomes (LGA, NICU admissions, neonatal hypoglycemia) in the CGM group | All participants had T1DM |
| Perea V, Picon MJ, Megia A, et al. Addition of intermittently scanned continuous glucose monitoring to standard care in a cohort of pregnant women with type 1 diabetes: effect on glycaemic control and pregnancy outcomes. *Diabetologia.* 2022;65(8):1302-1314. doi: 10.1007/s00125-022-05717-2. | No difference between groups for HbA1c or neonatal outcomes (macrosomia) | All participants had T1DM |
| Murphy HR, Rayman G, Lewis K, et al. Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomised clinical trial. *BMJ.* 2008;337:a1680. doi: 10.1136/bmj.a1680. | Significantly lower HbA1c and lower incidence of neonatal outcomes (LBW, macrosomia) in the CGM group | Published prior to 2012 |
| Voormolen DN, DeVries JH, Sanson RME, et al. Continuous glucose monitoring during diabetic pregnancy (GlucoMOMS): a multicentre randomized controlled trial. *Diabetes Obes Metab.* 2018;20(8):1894-1902. doi: 10.1111/dom.13310. | No difference between groups for HbA1c or neonatal outcomes (macrosomia) | Use of professional (retrospective) CGM |
| **PREGNANT INDIVIDUALS WITH GDM** | | |
| Alfadhli E, Osman E, Basri T. Use of a real time continuous glucose monitoring system as an educational tool for patients with gestational diabetes. *Diabetol Metab Syndr.* 2016;8:48. doi: 10.1186/s13098-016-0161-5. | No difference between groups for HbA1c or neonatal outcomes | < 12 weeks of follow-up |
| Kestila KK, Ekblad UU, Ronnemaa T. Continuous glucose monitoring versus self-monitoring of blood glucose in the treatment of gestational diabetes mellitus. *Diabetes Res Clin Pract.* 2007;77(2):174-179. doi: 10.1016/j.diabres.2006.12.012. | No difference in maternal and neonatal outcomes between study groups | Published prior to 2012 |
| Lane AS, Mlynarczyk MA, de Veciana M, Green LM, Baraki DI, Abuhamad AZ. Real-time continuous glucose monitoring in gestational diabetes: a randomized controlled trial. *Am J Perinatol.* 2019;36(9):891-897. doi: 10.1055/s-0039-1678733. | No difference between groups for HbA1c, hypoglycemia, or neonatal outcomes | Use of professional (retrospective) CGM |

| STUDY CITATION | RESULTS SUMMARY | REASON FOR EXCLUSION |
|---|---|---|
| Paramasivam SS, Chinna K, Singh AKK, et al. Continuous glucose monitoring results in lower HbA1c in Malaysian women with insulin-treated gestational diabetes: a randomized controlled trial. *Diabet Med.* 2018;35(8):1118-1129. doi: 10.1111/dme.13649. | Significantly higher incidence of hypoglycemia in CGM group; no difference in neonatal outcomes between groups | Use of professional (retrospective) CGM |
| Wei Q, Sun Z, Yang Y, Yu H, Ding H, Wang S. Effect of a CGM and SMBG on maternal and neonatal outcomes in gestational diabetes mellitus: a randomized controlled trial. *Sci Rep.* 2016;6:19920. doi: 10.1038/srep19920. | No difference between groups for HbA1c or neonatal outcomes | Not conducted in a Very High HDI country (i.e., China) and follow-up is unclear; participants only wore CGM for 48 to 72 hours in any given week |
| Zhang X, Jiang D, Wang X. The effects of the instantaneous scanning glucose monitoring system on hypoglycemia, weight gain, and health behaviors in patients with gestational diabetes: a randomised trial. *Annals of palliative medicine.* 2021;10(5):5714-5720. doi: 10.21037/apm-21-439. | Significantly lower incidence of hypoglycemia in CGM group | < 12 weeks of follow-up |

Abbreviations. CGM: continuous glucose monitor; GDM: gestational diabetes mellitus; HbA1c: glycated hemoglobin; HDI: human development index; LBW: low birth weight; LGA: large for gestational age; NICU: neonatal intensive care unit; T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus.

Table D3. Change in HbA1c Outcomes and Subgroups in RCTs of Individuals With T2DM

| AUTHOR, YEAR<br>STUDY NAME<br>RISK OF BIAS<br>SAMPLE SIZE | CGM TYPE<br>CGM MODEL<br>INSULIN USE | ANALYSIS GROUP | SUBGROUP DEFINITION | TIMEPOINT | CGM | | SMBG | | BETWEEN-GROUP DIFFERENCE | *P* VALUE |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | N | MEAN | N | MEAN | | |
| Beck, 2017[25]<br>DIAMOND<br>Low<br>N = 158 | Nontherapeutic rtCGM<br>Dexcom G4 PLATINUM<br>Prandial insulin (MDI) | Primary analysis | NA | 12 weeks | 77 | −1.0% (95% CI, −1.2 to −0.8) | 75 | −0.6% (95% CI, −0.8 to −0.4) | Adjusted MD, −0.3% (95% CI, −0.6 to −0.1) | *P* = .005 |
| | | | | 24 weeks | 79 | −0.8% (95% CI, −1.0 to −0.7) | 79 | −0.5% (95% CI, −0.7 to −0.3) | Adjusted MD, −0.3% (95% CI, −0.5 to 0.0) | *P* = .02 |
| | | Age | ≤ 44 years | 24 weeks | 9 | −1.0% (SD, 0.6) | 4 | −0.3% (SD, 1.2) | NR | NR |
| | | | 45 to 59 years | 24 weeks | 26 | −0.7% (SD, 0.7) | 32 | −0.5% (SD, 0.9) | NR | NR |
| | | | ≥ 60 years | 24 weeks | 42 | −0.9% (SD, 0.7) | 39 | −0.5% (SD, 0.8) | NR | NR |
| | | Baseline HbA1c | < 8.5% | 24 weeks | 38 | −0.6% (SD, 0.7) | 36 | −0.3% (SD, 0.8) | NR | NR |
| | | | ≥ 8.5% | 24 weeks | 39 | −1.1% (SD, 0.6) | 39 | −0.7% (SD, 0.9) | NR | NR |
| Bergenstal, 2022[55]<br>Moderate<br>N = 114 | Therapeutic rtCGM<br>Dexcom G7<br>Some insulin use | Primary analysis | NA | 16 weeks | 59 | −1.12% (SD, 1.1) | 55 | −0.82% (SD, 0.9) | NR | *P* = .11 |
| Vidersky, 2012[64]<br>High<br>N = 100 | Nontherapeutic rtCGM<br>Dexcom SEVEN | Primary analysis | NA | 12 weeks | 50 | −1.0% (SD, 1.1) | 50 | −0.5% (SD, 0.8) | NR | *P* = .006 |
| | | | | 24 weeks | 50 | −1.2% (SD 1.7) | 50 | −0.5% (SD, 1.0) | NR | NR |

| AUTHOR, YEAR<br>STUDY NAME<br>RISK OF BIAS<br>SAMPLE SIZE | CGM TYPE<br>CGM MODEL<br>INSULIN USE | ANALYSIS GROUP | SUBGROUP DEFINITION | TIMEPOINT | CGM | | SMBG | | BETWEEN-GROUP DIFFERENCE | *P* VALUE |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | N | MEAN | N | MEAN | | |
| | Not on insulin | | | 38 weeks | 50 | −0.8% (SD 1.7) | 50 | −0.5% (SD, 1.1) | NR | NR |
| | | | | 52 weeks | 50 | −0.8% (SD 1.5) | 50 | −0.2% (SD, 1.3) | NR | NR |
| | | CGM adherence | ≥ 48 days vs. < 48 days | 12 weeks | 34 | 1.2% (SD, 1.1) | 16 | 0.6% (SD, 1.1) | NR | NR |
| | | | | 24 weeks | 34 | 1.5% (SD, 1.5) | 16 | 0.6% (SD, 1.5) | NR | NR |
| | | | | 38 weeks | 34 | 1.1% (SD, 1.7) | 16 | 0.2% (SD, 1.5) | NR | NR |
| | | | | 52 weeks | 34 | 1.0% (SD, 1.5) | 16 | 0.3% (SD, 1.3) | NR | NR |
| | | | ≥ 48 days | 52 weeks | 34 | −1.3% (SD, NR) | 50 | −0.2% (SD, 1.5) | Adjusted MD, −0.60% | *P* < .001 |
| | | | < 48 days | 52 weeks | 16 | −0.7% (SD, NR) | 50 | −0.2% (SD, 1.5) | NR | NR |
| Haak, 2017[61]<br>REPLACE<br>Moderate<br>N = 224 | isCGM<br>FreeStyle Libre<br>Prandial insulin (MDI), basal insulin, CSII therapy | Primary analysis | NA | 24 weeks | 149 | −0.29% (SE, 0.07) | 75 | −0.31% (SE, 0.09) | NR | *P* = .82 |
| | | Age | < 65 years | 24 weeks | NA | −0.53% (SE, 0.09) | NA | −0.20% (SE, 0.12) | NR | *P* = .03 |
| | | | ≥ 65 years | 24 weeks | NA | −0.05% (SE, 0.10) | NA | −0.49% (SE, 0.13) | NR | *P* = .008 |
| Isaacson, 2022[45]<br>Moderate<br>N = 175 | Therapeutic rtCGM<br>Dexcom G6<br>Some insulin use | Primary analysis | NA | 24 weeks | NR | Median, −0.6% (IQI, −1.4 to 0.1) | NR | Median, −0.1% (IQI, −0.7 to 0.1) | NR | *P* < .001 |

| AUTHOR, YEAR<br>STUDY NAME<br>RISK OF BIAS<br>SAMPLE SIZE | CGM TYPE<br>CGM MODEL<br>INSULIN USE | ANALYSIS GROUP | SUBGROUP DEFINITION | TIMEPOINT | CGM | | SMBG | | BETWEEN-GROUP DIFFERENCE | *P* VALUE |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | N | MEAN | N | MEAN | | |
| Martens, 2021[62]<br>MOBILE<br>Moderate<br>N = 175 | Therapeutic rtCGM<br>Dexcom G6<br>Basal insulin (1-2 daily injections) | Primary analysis | NA | 32 weeks | 105 | −1.1% (SD, 1.5) | 51 | −0.6% (SD, 1.2) | −0.4% (95% CI, −0.8% to −0.1%) | *P* = .02 |
| | | Age | 30 to 39 years | 32 weeks | 5 | −3.0% (SD, 0.9) | 1 | 0.8% (SD, 0.0) | NR | NR |
| | | | 40 to 49 years | 32 weeks | 19 | −0.9% (SD, 2.1) | 7 | −0.4% (SD, 1.3) | NR | NR |
| | | | 50 to 59 years | 32 weeks | 40 | −1.0% (SD, 1.4) | 18 | −0.9% (SD, 1.2) | NR | NR |
| | | | ≥ 60 years | 32 weeks | 40 | −1.0% (SD, 1.1) | 25 | 0.6% (SD, 1.1) | NR | NR |
| | | Race and ethnicity | White | 32 weeks | 47 | −1.4% (SD, 1.3) | 31 | −0.7% (SD, 1.0) | NR | NR |
| | | | Non-White | 32 weeks | 57 | −0.8% (SD, 1.6) | 20 | −0.6% (SD, 1.4) | NR | NR |
| | | Baseline HbA1c | < 9.0% | 32 weeks | 51 | −0.7% (SD, 1.3) | 24 | −0.2% (SD, 1.0) | NR | NR |
| | | | ≥ 9.0% | 32 weeks | 53 | −1.4% (SD, 1.6) | 27 | −1.0% (SD, 1.2) | NR | NR |
| | | Diabetes medication use | Not using diabetes meds at baseline | 32 weeks | 71 | −1.0% (SD, 1.6) | 40 | −0.7% (SD, 1.2) | NR | NR |
| | | | Using diabetes meds at baseline | 32 weeks | 33 | −1.2% (SD, 1.2) | 11 | −0.6% (SD, 0.9) | NR | NR |

| AUTHOR, YEAR<br>STUDY NAME<br>RISK OF BIAS<br>SAMPLE SIZE | CGM TYPE<br>CGM MODEL<br>INSULIN USE | ANALYSIS GROUP | SUBGROUP DEFINITION | TIMEPOINT | CGM | | SMBG | | BETWEEN-GROUP DIFFERENCE | *P* VALUE |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | N | MEAN | N | MEAN | | |
| | | Baseline HbA1c | ≥ 8.5% | 32 weeks | 74 | −1.4% (SD, 1.4) | 35 | −0.9% (SD, 1.1) | MD, −0.4% (95% CI, −0.8 to 0.1) | *P* = .10 |
| | | | ≥ 9.0% | 32 weeks | 53 | −1.4% (SD, 1.6) | 27 | −1.0% (SD, 1.2) | MD, −0.2% (95% CI, −0.8 to 0.3) | NR |
| | | | ≥ 9.5% | 32 weeks | 39 | −1.7% (SD, 1.6) | 13 | −0.9% (SD, 1.5) | MD, −0.8% (95% CI, −1.6 to 0.1) | NR |
| | | | ≥ 10.0% | 32 weeks | 22 | −2.1% (SD, 1.5) | 8 | −0.4% (SD, 1.5) | MD, −1.5% (95% CI, −2.6 to −0.5) | NR |
| | | Age | ≥ 65 years | 32 weeks | 25 | −1.08% (SD, 1.23) | 13 | −0.38% (SD, 0.92) | Adjusted MD, −0.65% (95% CI, −1.49 to 0.19) | *P* = .13 |
| | | | < 65 years | 32 weeks | 79 | −1.08% (SD, 1.55) | 38 | −0.73% (SD, 1.24) | Adjusted MD, −0.35% (95% CI, −0.77 to 0.07) | *P* = .10 |
| Price, 2021[63]<br>COMMITTED<br>High<br>N = 70 | Therapeutic rtCGM<br>Dexcom G6<br>Not on insulin | Primary analysis | NA | 12 weeks | 44 | −0.5% (SD, 0.9) | 23 | −0.3% (SD, 0.7) | NR | *P* = .74 |
| | | | | 36 weeks | 44 | −0.2% (SD, 0.9) | 23 | +0.1% (SD, 1.3) | NR | *P* = .79 |
| Secher, 2013[66]<br>Moderate<br>N = 31 | Nontherapeutic rtCGM | Primary analysis (T2DM group only) | NA | 36 weeks[a] | NR | 6.0% (95% CI, 5.1 to 6.5) | NR | 5.9% (95% CI, 5.2 to 6.7) | NR | *P* = .31 |

| AUTHOR, YEAR<br>STUDY NAME<br>RISK OF BIAS<br>SAMPLE SIZE | CGM TYPE<br>CGM MODEL<br>INSULIN USE | ANALYSIS GROUP | SUBGROUP DEFINITION | TIMEPOINT | CGM | | SMBG | | BETWEEN-GROUP DIFFERENCE | *P* VALUE |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | N | MEAN | N | MEAN | | |
| | Most participants on intensive insulin regimens | | | | | | | | | |
| Wada, 2020[65]<br>Low<br>N = 100 | isCGM<br>FreeStyle Libre<br>Not on insulin | Primary analysis | NA | 12 weeks | 49 | −0.43% (95% CI, −0.57 to −0.28) | 51 | −0.30% (95% CI, −0.48 to −0.013) | MD, −0.13% (95% CI, −0.35 to 0.09) | *P* = .24 |
| | | | | 24 weeks | 48 | −0.46% (95% CI, −0.59 to −0.32) | 49 | −0.17% (95% CI, −0.05 to 0.11) | MD, −0.29% (95% CI, −0.54 to −0.05) | *P* = .02 |
| | | Diabetes medication use | No change in diabetic meds over study | 24 weeks | 41 | −0.46% (95% CI, −0.60 to −0.31) | 41 | −0.18% (95% CI, −0.41 to 0.05) | Adjusted MD, −0.14% (95% CI, −0.27 to −0.00) | *P* = .04 |

Note. [a] Results are mean HbA1c levels; change in HbA1c was not reported for this trial.

Abbreviations. CGM: continuous glucose monitor; CI: confidence interval; CSII: continuous subcutaneous insulin infusion; HbA1c: glycated hemoglobin; IQI: interquartile interval; isCGM: intermittently scanned CGM; MD: mean difference; MDI: multiple daily injections; NA: not applicable; NR: not reported; RCT: randomized controlled trial; rtCGM: real-time CGM; SD: standard deviation; SE: standard error; SMBG: self-monitoring of blood glucose; T2DM: type 2 diabetes mellitus; vs: versus.

Table D4. QoL Scales in Included RCTs of CGM Use in Adults With T2DM

| QoL SCALE | SCORE RANGE | INTERPRETATION |
|---|---|---|
| **GENERAL SCALES** | | |
| EuroQoL-5D (EQ-5D) | 0 to 1 point | Higher scores indicate fewer health problems |
| 5-item World Health Organization Well-being Index (WHO-5) | 0 to 25 points | Higher scores indicate better well-being |
| **DIABETES-SPECIFIC SCALES** | | |
| Diabetes Distress Scale (DDS) | 1 to 6 points | Lower scores indicate fewer problems or less distress |
| Diabetes Quality of Life (DQoL) | 1 to 5 points | Higher scores indicate dissatisfaction or frequent worry |
| Diabetes Treatment Satisfaction Questionnaire (DTSQ) | −18 to +18 points | Higher scores indicate more treatment satisfaction |
| Hypoglycemia Confidence Survey (HCS) | 1 to 4 points; scores for each of 9 items | Higher scores indicate more confidence |
| Hypoglycemia Fear Survey (HFS) | 0 to 4 points; scores for each of 18 items | Lower scores indicate less fear |
| Problem Areas in Diabetes (PAID) | 0 to 100 points | 0 to 16: low distress<br>17 to 39: moderate distress<br>≥ 40: severe distress |
| Summary of Diabetes Self-Care Activities Questionnaire (SDSCA) | Korean Version of Revised Summary of Diabetes Self-Care Activities (SDSCA-K). Scoring scale not described. | NR |

Abbreviations. CGM: continuous glucose monitor; QoL: quality of life; RCT: randomized controlled trial; T2DM: type 2 diabetes mellitus.

Table D5. Potentially Eligible Ongoing Studies of CGM Use in Populations with T2DM

| STUDY NUMBER<br>STUDY TITLE | ENROLLMENT<br>FOLLOW-UP<br>LOCATION | CONDITIONS | CGM VS. CONTROL | RELEVANT OUTCOMES | STUDY DESIGN | PRIMARY COMPLETION DATE |
|---|---|---|---|---|---|---|
| **ADULTS WITH T2DM** | | | | | | |
| **NCT04926623**[85]<br>Multicenter, Open-label, Randomized Trial to Compare the Effectiveness of Structured Education and Safety of FreeStyle Libre or Self-Monitoring of Blood Glucose (SMBG) in Patients With Type 2 Diabetes Mellitus Using Multiple Daily Injections or Insulin Pumps (FreEdoM-2) | NR<br>24 weeks<br>South Korea | T2DM treated with insulin | FreeStyle Libre vs. SMBG | • Change in HbA1c | RCT | January 2022 |
| **NCT04562714**[86]<br>Impact of Flash Glucose Monitoring in People With Type 2 Diabetes Using Non-Insulin Antihyperglycemic Therapy (IMMEDIATE) | N = 116<br>16 weeks<br>Canada | T2DM not using insulin | FreeStyle Libre vs. SMBG | • Severe hypoglycemia<br>• Change in HbA1c<br>• QoL | RCT | April 2022 |
| **NCT04932928**[87]<br>Patient-Driven Lifestyle Modification Using FreeStyle Libre in Type 2 Diabetes Patients | N = 126<br>12 weeks<br>South Korea | T2DM | FreeStyle Libre vs. SMBG | • Change in HbA1c<br>• QoL | RCT | September 2022 |
| **NCT05319496**[88]<br>Intermittently Scanned CGM Versus Usual Care With Diabetes Education and Feedback, in Adults With Non-Insulin Dependent Type 2 Diabetes (iCUDE): A Randomized Trial | N = 120<br>12 weeks<br>Canada | T2DM | FreeStyle Libre 2 vs. SMBG | • Change in HbA1c<br>• QoL<br>• Health resource use | RCT | June 2023 |
| **NCT04331444**[89]<br>The Effect of Real-time Continuous Glucose Monitoring vs. Self-monitoring of Blood Glucose on Glycemic Variables and Patient Reported Outcomes in Adults With Type 2 Diabetes Treated With Insulin-A | N = 100<br>52 weeks<br>Denmark | T2DM treated with insulin | CGM (not specified) vs. SMBG | • Severe hypoglycemia<br>• Change in HbA1c<br>• QoL | RCT | July 2023 |

| STUDY NUMBER<br>STUDY TITLE | ENROLLMENT<br>FOLLOW-UP<br>LOCATION | CONDITIONS | CGM VS. CONTROL | RELEVANT OUTCOMES | STUDY DESIGN | PRIMARY COMPLETION DATE |
|---|---|---|---|---|---|---|
| Randomized Controlled Trial (Steno2tech CGM) | | | | | | |
| **NCT05394844**[90]<br>Diabetes Education With Real-time Continuous Glucose Monitoring | N = 100<br>24 weeks<br>United States | T2DM with or without medication use | Dexcom G6 vs. SMBG | • Change in HbA1c | RCT | June 2024 |
| **NCT05516797**[91]<br>Continuous Glucose Monitoring Versus Blood Glucose Monitoring to Optimize Glycemic Outcomes in People With Type 2 Diabetes Following the Virta Treatment Program (IGNITE: Impact of Glucose moNitoring and nutrItion on Time in rangE Study) | N = 150<br>12 weeks<br>United States | T2DM | FreeStyle Libre 2 vs. SMBG | • Change in HbA1c | RCT | July 2024 |
| **NCT05222815**[92]<br>Comparing Finger-Stick Blood Glucose Monitoring Versus Continuous Glucose Monitoring in Primary Care | N = 354<br>52 weeks<br>United States | T2DM | CGM (not specified) vs. SMBG | • Change in HbA1c<br>• QoL | RCT | July 2024 |
| **NCT05431296**[93]<br>Glucose Control Using Continuous Glucose Monitoring in People With Type 2 Diabetes Who Have Had Acute Myocardial Infarction | N = 160<br>26 weeks<br>United Kingdom | T2DM with history of acute MI | Dexcom ONE vs. blinded CGM | • Severe hypoglycemia<br>• Change in HbA1c<br>• QoL | RCT | August 2024 |
| **CHILDREN OR ADOLESCENTS WITH T2DM** | | | | | | |
| **NCT04721158**[94]<br>IMPlementation of Continuous Glucose Monitoring in Children With Type 2 Diabetes (IMPaCT2) | N = 41<br>24 weeks<br>United States | T2DM, duration > 3 months | Dexcom G6 | • Change in HbA1c | Single group | July 2022 |

| STUDY NUMBER<br>STUDY TITLE | ENROLLMENT<br>FOLLOW-UP<br>LOCATION | CONDITIONS | CGM VS.<br>CONTROL | RELEVANT OUTCOMES | STUDY DESIGN | PRIMARY COMPLETION DATE |
|---|---|---|---|---|---|---|
| **NCT05074667**[95]<br>Use of Continuous Glucose Monitors in Publicly-Insured Youth With Type 2 Diabetes - A Pilot and Feasibility Study | N = 30<br>52 weeks<br>United States | T2DM | CGM (not specified) | • Change in HbA1c<br>• QoL | Single group | February 2023 |
| **PREGNANT POPULATIONS WITH T2DM OR GDM** | | | | | | |
| **NCT04219085**[96]<br>CAPO: Continuous Glucose Monitoring in A2 Gestational Diabetes and Pregnancy Outcomes | N = 80<br>~16 weeks<br>United States | GDM | CGM (not specified) vs. SMBG | • Severe perinatal morbidity | RCT | December 2023 |
| **NCT05370612**[97]<br>AT GOAL: Adopting Technology for Glucose Optimization and Lifestyle in Pregnancy | N = 40<br>26 weeks<br>United States | T2DM | Dexcom G6 vs. SMBG | • Change in HbA1c<br>• Severe perinatal morbidity<br>• QoL | RCT | June 2024 |
| **NCT04605497**[98]<br>A Single Center Open-label Randomized Control Pilot Study to Assess the Efficacy of Real-time Continuous Glucose Monitoring in Subjects with Gestational Diabetes to Increase Glucose Time-in-range | N = 110<br>~22 weeks<br>United States | GDM | Dexcom G6 vs. SMBG | • Change in HbA1c<br>• Severe perinatal morbidity | RCT | December 2024 |
| **NCT05317585**[99]<br>Continuous Glucose Monitor Use and Perinatal Outcomes Among Pregnant Women with Type 2 Diabetes Mellitus: A Randomized Controlled Trial | N = 162<br>NR<br>United States | T2DM treated with insulin | CGM (not specified) vs. SMBG | • Severe perinatal morbidity<br>• QoL | RCT | July 2025 |

Note. Table reflects studies registered on ClinicalTrials.gov as of March 2023.
Abbreviations. CGM: continuous glucose monitor; GDM: gestational diabetes mellitus; HbA1c: glycated hemoglobin; NR: not reported; QoL: quality of life; RCT: randomized controlled trial; SMBG: self-monitoring of blood glucose; T2DM: type 2 diabetes mellitus; US: United States; vs.: versus.

# APPENDIX E. APPLICABLE CODES

Table E1. Applicable Codes for Continuous Glucose Monitoring in Diabetes Mellitus

| Code | Description |
|---|---|
| **ICD-10-CM Codes** | |
| E08.00-E13.9 | Diabetes mellitus |
| O24.011-O24.93 | Diabetes mellitus in pregnancy, childbirth, and the puerperium |
| **CPT Codes** | |
| 95249 | Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording |
| 95250 | Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording |
| 95251 | Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report |
| 99091 | Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days |
| 0446T | Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training |
| 0448T | Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation |
| **HCPCS Codes** | |
| A4238 | Supply allowance for adjunctive nonimplanted CGM, includes all supplies and accessories, 1-month supply = 1 unit of service |
| A4239 | Supply allowance for nonadjunctive, nonimplanted CGM, includes all supplies and accessories, 1-month supply = 1 unit of service |
| A9276 | Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial CGM system, 1 unit = 1-day supply |
| A9277 | Transmitter; external, for use with nondurable medical equipment interstitial CGM system |

| Code | Description |
|---|---|
| A9278 | Receiver (monitor); external, for use with non-durable medical equipment interstitial CGM system |
| A9279 | Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified |
| E2102 | Adjunctive, nonimplanted CGM or receiver |
| E2103 | Nonadjunctive, nonimplanted CGM or receiver [that is, a device that does not require a finger stick, e.g., Dexcom G5] |
| G0308 | Creation of subcutaneous pocket with insertion of 180-day implantable interstitial glucose sensor, including system activation and patient training |
| G0309 | Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180-day implantable sensor, including system activation |
| S1030 | Continuous noninvasive glucose monitoring device, purchase |
| S1031 | Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor |

Abbreviations. CGM: continuous glucose monitor; CPT: Current Procedural Terminology; ECG: electrocardiogram; HCPCS: Healthcare Common Procedure Coding System; ICD-10-CM: International Classification of Diseases, Tenth Revision, Clinical Modification.