Washington State Health Care Authority

Continuous Glucose Monitors: New Populations

Draft Evidence Report

January 9, 2025

Health Technology Assessment Program (HTA)

Washington State Health Care Authority
PO Box 42712
Olympia, WA 98504-2712
(360) 725-5126
www.hca.wa.gov/hta
shtap@hca.wa.gov

Continuous Glucose Monitors: New Populations

Draft Evidence Report

January 9, 2025

Prepared by:

Center for Evidence-based Policy
Oregon Health & Science University
3030 S Moody, Suite 250
Portland, OR 97201
Phone: 503.494.2182
Fax: 503.494.3807
http://centerforevidencebasedpolicy.org/

Center

Authors:

Shauna Durbin, MPH, Beth Shaw, MSc, MPH, Allison Leof, PhD, Andrea Vintro, RD, MPH, Sneha Yeddala, PharmD, MS, Shannon Robalino, MSc, Jennifer Lyon, MS, MLIS, MEd, and Valerie King, MD, MPH

The authors would like to acknowledge [List of subject matter experts - TBD] for their contributions to this report. The authors would also like to acknowledge Courtney Cooper, Jacqui Krawetz, and Firozeh Darabi from the Center for Evidence-based Policy for their contributions to this work.

This health technology assessment report is based on research conducted by the Center for Evidence-based Policy (Center) under contract to the Washington State Health Care Authority (HCA). This report is an independent assessment of the technology question(s) described based on accepted methodological principles. Researchers and authors involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document. The findings and conclusions contained herein are those of the authors, who are responsible for the content. These findings and conclusions do not necessarily represent the views of the Washington HCA and thus, no statement in this report shall be construed as an official position or policy of the Center or of the HCA.

This assessment is for informational purposes only and is intended to assist health care decision makers, clinicians, patients, and policymakers in making evidence-based decisions that may improve the quality and cost-effectiveness of health care services. Information in this report is not a substitute for sound clinical judgment. The document is intended as a reference and does not, and is not intended to, constitute the rendering of any clinical, legal, business, or other professional advice by the Center or the authors. Those making decisions regarding the provision of health care services should consider this report in a manner similar to any other medical reference, integrating the information with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability.

About the Center for Evidence-based Policy

The Center is recognized as a national leader in evidence-based decision making and policy design. The Center understands the needs of policymakers and supports public organizations by providing reliable information to guide decisions, maximize existing resources, improve health outcomes, and reduce unnecessary costs. The Center specializes in ensuring that diverse and relevant perspectives are considered and appropriate resources are leveraged to strategically address complex policy issues with high-quality evidence and collaboration. The Center is based at Oregon Health & Science University in Portland, Oregon.

Conflict of Interest Disclosures: No authors have conflicts of interest to disclose. All authors have completed and submitted the Oregon Health & Science University form for Disclosure of Potential Conflicts of Interest, and none were reported.

Table of Contents

List of Tables

List of Figures

List of Abbreviations

AACE	American Association of Clinical Endocrinology
ADA	American Diabetes Association
Center	Center for Evidence-based Policy
CI	confidence interval
CGM	continuous glucose monitor(ing)
CMS	Centers for Medicare & Medicaid Services
CoE	certainty of evidence
CQ	contextual question
FDA	US Food and Drug Administration
GDM	gestational diabetes
GLP-1	glucagon-like peptide 1
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HbA1c	hemoglobin A1c (i.e., glycated hemoglobin)
isCGM	intermittently scanned continuous glucose monitor(ing)
KQ	key question
OHM	oral hypoglycemic medication(s)
QoL	quality of life
RoB	risk of bias
rtCGM	real-time continuous glucose monitor(ing)
SMBG	self-monitoring blood glucose
T2D	type 2 diabetes

Structured Abstract

Purpose

The objective of the health technology assessment is to evaluate the effectiveness, safety, and cost-effectiveness of continuous glucose monitors (CGM) in adults and children with type 2 diabetes (T2D) and gestational diabetes (GDM).

Methods

We ran a literature search across multiple databases for randomized controlled trials (RCTs), cost-effectiveness studies, and clinical practice guidelines of CGM in the target populations. We conducted dual independent title and abstract screening, and full-text article review for English-language randomized controlled trials and economic evaluations of CGM use in adults and children. We also selected and assessed relevant clinical practice guidelines using a similar process. We used standardized procedures to extract relevant data from each of the included trials and performed dual independent risk-of-bias assessment. We used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to rate the overall certainty of evidence (CoE) of selected measures of outcomes.

Results

- In adults with T2D on nonintensive insulin regimens, CGM use resulted in a small, but statistically significant, reduction in HbA1c from baseline (moderate CoE, based on 7 RCTs).
- In adults with T2D on oral hypoglycemic medications, there was no consistent difference in change in HbA1c from baseline with CGM vs. other non-CGM monitoring methods (low CoE, based on 6 RCTs).
- We did not identify any eligible RCTs evaluating CGMs in adults with T2D not on insulin or oral hypoglycemic medication regimens.
- In adults with T2D on mixed nonintensive hypoglycemic therapies, there was no consistent difference in change in HbA1c from baseline with CGM vs. other non-CGM monitoring methods (very low CoE, based on 5 RCTs).
- In pregnant people with gestational diabetes who are not using insulin, CGM use was not associated with a significantly lower HbA1c at the end of pregnancy (low CoE, based on 3 RCTs).
- We did not identify any eligible RCTs evaluating the effectiveness or safety of CGMs in children with T2D on nonintensive insulin regimens, or in pregnant people with T2D who were not using insulin before or during pregnancy.
- Device-related adverse events were generally sensor insertion site-related problems of mild to moderate intensity (e.g., skin irritation, bruising, pain, swelling), generally treated with topical treatments or by moving the sensor to a different site on the body.

Cost-Effectiveness Outcomes

Based on 1 cost-effectiveness analysis, over a 10-year time horizon, from the Medicaid perspective, CGM (specifically, the FreeStyle Libre system) provides more quality-adjusted life-years and life-years at lower costs for people with T2D using basal insulin, when compared with self-monitoring (moderate CoE).

Clinical Practice Guidelines and Payer Policies

Clinical practice guidelines recommendations and payer coverage policies are varied for adults and children with T2D not on intensive insulin treatment and pregnant people with either T2D or GDM who do not use insulin.

Conclusions

Evidence from RCTs indicates CGM are safe and effective devices to reduce HbA1c levels in adults with T2D on nonintensive insulin regimens compared with daily SMBG testing. Cost-effectiveness analyses suggest CGM are cost-effective for monitoring glucose levels compared with daily SMBG testing in adults with T2D using basal insulin. There was no clear evidence of effectiveness in adults with T2D on OHM therapies or mixed nonintensive hypoglycemic regimens and for pregnant people with GDM not on insulin, although available evidence suggests CGM is not harmful in these populations. We found no eligible RCTs of CGM use for children with T2D not on intensive insulin regimens.

Executive Summary

Background

The objective of the health technology assessment is to evaluate the effectiveness, safety, and cost-effectiveness of continuous glucose monitoring (CGM) in adults and children with diabetes. This evidence review will help inform Washington's independent Health Technology Clinical Committee as it determines coverage regarding the use CGM of in adults and children with type 2 diabetes (T2D) and gestational diabetes (GDM). The scope for this 2025 review focuses on the effectiveness and safety of CGM for populations who do not currently have coverage for CGM.

Technology of Interest

Individuals traditionally used self-monitoring of blood glucose (SMBG) systems to measure glucose in a fingerstick blood sample to understand how effective treatments and interventions are at controlling blood sugar daily. How often individuals are advised to measure glucose through SMBG testing varies by type of diabetes, activity levels, whether they use insulin, and the type of insulin used.

While SMBG gives a moment in time reading of blood glucose levels, CGM estimates blood glucose levels every few minutes and saves the data, providing information about trends in glucose levels. The information is collected by a sensor placed on the skin or implanted. Sensors are disposable and must be replaced depending on the CGM, but sensors placed on the skin are generally replaced every 7 to 14 days and implantable sensors can last up to 180 days. There are 3 types of CGM devices:

- Professional or retrospective CGM devices are managed by clinicians. Patients wear the devices for 7 to 14 days and then return to the clinic to have the blood glucose data downloaded and interpreted by their treating clinician. Professional CGM devices are excluded from this evidence review.
- Real-time CGM (rtCGM) measures glucose levels in interstitial fluid on a regular basis and automatically sends the information to a smartphone application, an insulin pump, or a separate receiver where the information is displayed and shows trends in blood glucose levels. Real-time CGM systems can be programed to send alerts or alarms when blood glucose levels rise above or fall below optimal levels.
- Intermittently scanned (also sometimes called "flash") CGM (isCGM) measures blood glucose levels every few minutes but patients must actively scan their sensor with a separate device to see and store the data.

Policy Context

In 2018, the Health Technology Clinical Committee made the following coverage determination:

- Continuous glucose monitoring is a covered benefit with conditions. This determination does not pertain to closed loop or artificial pancreas systems.

The specified conditions were:

- Continuous glucose monitoring is covered for children and adolescents younger than 19 years old, adults with type 1 diabetes (T1D), and adults with T2D who are:

  - Unable to achieve target HbA1C (hemoglobin A1c) despite adherence to an appropriate glycemic management plan (intensive insulin therapy; testing blood glucose 4 or more times per day), or
  - Suffering from 1 or more severe (blood glucose < 50 mg/dl or symptomatic) episodes of hypoglycemia despite adherence to an appropriate glycemic management plan (intensive insulin therapy, testing blood glucose 4 or more times per day), or
  - Unable to recognize, or communicate about, symptoms of hypoglycemia

- Continuous glucose monitoring is covered for pregnant women with:
  - T1D, or
  - T2D and on insulin before pregnancy, or
  - T2D and blood glucose does not remain well controlled (HbA1C above target or experiencing episodes of hyperglycemia or hypoglycemia) on diet or oral medications during pregnancy and require insulin, or
  - GD whose blood glucose is not well controlled (HbA1C above target or experiencing episodes of hyperglycemia or hypoglycemia) during pregnancy and require insulin

The objective of this health technology assessment is to evaluate the effectiveness, safety, and cost-effectiveness of CGM in adults and children with T2D and GDM. This evidence review will help inform Washington's independent Health Technology Clinical Committee as it determines coverage regarding the use of CGM in adults and children with diabetes. The scope for the 2025 rereview is on the effectiveness and safety of CGM for populations in whom CGM is not currently covered.

Methods

This evidence review is based on the final key questions (KQs) published on September 30, 2024. The draft KQs were available for public comment from September 3, 2024, through September 16, 2024, and appropriate revisions were made to the KQs based on the comments and responses. All public comments received and a table of responses can be found on the Washington Health Technology Assessment website. The PICOS (population, intervention, comparator, outcome, study design) details, along with the setting, sample size, and publication factors that guided development of the KQs and study selection are presented in the Methods section of the Technical Report. Full details of our methods can be found in Appendix A of the Technical Report.

Key Questions

KQ1. What is the comparative effectiveness of CGM in adults and children with T2D vs. other forms of monitoring (e.g., self-monitoring blood glucose or routine clinical monitoring)?

   a. Adults with T2D and using:

      i. Nonintensive insulin therapy (1 to 3 injections per day)

      ii. No insulin but on oral hypoglycemic medication

      iii. No insulin and no oral hypoglycemic medication

   b. Children with T2D

i. Nonintensive insulin therapy (1 to 3 injections per day)
ii. No insulin but on oral hypoglycemic medication
iii. No insulin and no oral hypoglycemic medication

c. Pregnant people with T2D who are not using insulin
d. Pregnant people with GD who are not using insulin

KQ2. What is the device-related safety of CGM in adults and children with T2D?

KQ3. What is the differential efficacy or safety by patient and clinical factors, such as:
a. Age
b. Gender
c. Race and ethnicity
d. Presence of comorbidities (e.g., hypertension)
e. Severity of disease (e.g., baseline HbA1c, number of self-tests per day)
f. Level of adherence to CGM use
g. Type of CGM (rtCGM vs. isCGM)
h. Duration of CGM monitoring
i. Timing of initiation of CGM monitoring relative to baseline level of control measured by A1C (A1C level indicating well-controlled vs. uncontrolled disease at initiation)

KQ4. What are the costs and cost-effectiveness of CGM in adults and children with T2D?
a. Adults with T2D and using:
i. Nonintensive insulin therapy (1 to 3 injections per day)
ii. No insulin but on oral hypoglycemic medication
iii. No insulin and no oral hypoglycemic medication
b. Children with T2D
i. Nonintensive insulin therapy (1 to 3 injections per day)
ii. No insulin but on oral hypoglycemic medication
iii. No insulin and no oral hypoglycemic medication
c. Pregnant people with T2D who are not using insulin
d. Pregnant people with GD who are not using insulin

Data Sources

We ran a literature search using Ovid MEDLINE ALL, PsycINFO, and the Cochrane Central Register of Controlled Trials (CENTRAL) for any randomized controlled trials, cost-effectiveness studies, and clinical practice guidelines of CGM in the target populations. Searches for interventions were limited to January 1, 2000, to September 4 and 5, 2024, to capture relevant published studies.

Study and Guideline Selection

We independently screened titles and abstracts and reached agreement on exclusion through discussion. We performed dual full-text review for any study not excluded by review of title and abstract. Disagreements were managed by discussion; if consensus could not be reached, any remaining disagreements were settled by a third independent researcher. We also selected and assessed relevant clinical practice guidelines using a similar process.

Data Extraction and Risk-of-Bias Assessment

We used standardized procedures to extract relevant data from each of the included trials and fully cross-checked all entered data for accuracy. We evaluated each eligible study for methodological risk of bias (RoB) and held discussions to reach agreement on these assessments. Any remaining disagreement was settled by a third independent researcher. Each trial was assessed using Center for Evidence-based Policy instruments adapted from national and international standards and assessments for RoB. A rating of high, moderate, or low RoB was assigned to each study based on adherence to recommended methods and the potential for internal and external biases.

We also evaluated the methodological quality of eligible clinical practice guidelines. Any remaining disagreement among these assessments was settled by a third independent researcher. We rated the methodological quality of clinical practice guidelines as good, fair, or poor.

Data Synthesis and Analysis

We assigned selected outcomes a summary judgment for the overall certainty of evidence (CoE) using the system developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) Working Group. We assessed the CoE for the following outcomes:

- Change in HbA1c
- Achieving or maintaining target HbA1c levels
- Quality of life (QoL)
- Severe perinatal morbidity and mortality
- Cost-effectiveness outcomes

Results

Our data collection returned a total of 8,154 records. After duplicate records were removed, 4,776 remained for title and abstract screening. Of these, 246 required full-text review to determine eligibility. In total, 22 RCTs (in 35 publications), 2 economic studies, and 13 clinical practice guidelines met the inclusion criteria for key questions (KQs) 1 to 4.

KQ1. Comparative Effectiveness of CGM

Adults with T2D (KQ1a) on Nonintensive Insulin Regimens

We identified 7 RCTs in 15 publications (N = 802; follow-up range, 12 to 52 weeks) that assessed CGM among adults with T2D on nonintensive insulin regimens (1 to 3 injections per day).

- CGM use resulted in a small, but statistically significant, reduction in HbA1c from baseline (moderate CoE, based on 7 RCTs).

  - At final follow-up (range, 12 to 52 weeks), CGM use was associated with a significant reduction in HbA1c compared with no CGM (pooled MD, −0.27%; 95% CI, −0.46 to −0.08; *P* = .005). However, this difference did not meet the threshold for clinical significance ([MCID], 0.5% change).
- There was no difference between CGM and SMBG groups in the proportion of participants who achieved target HbA1c levels (i.e., 7.0%, 7.5%) at 12 or 24 weeks (low CoE, based on 1 RCT).
- There was no clear association between CGM and improved diabetes-related quality of life ([QoL] low CoE, based on 4 RCTs).
- There was no clear association between CGM and improved general QoL (low CoE, based on 2 RCTs).

Adults With T2D (KQ1a) on Oral Hypoglycemic Medications

We identified 6 RCTs in 8 publications (N = 560; follow-up range, 12 to 52 weeks) that assessed CGM among adults with T2D on OHM therapy, but not on insulin.

- There was no consistent difference in change in HbA1c from baseline with CGM vs. other non-CGM monitoring methods (low CoE, based on 6 RCTs).
  - There was no between-group difference for change in HbA1c from baseline in a meta-analysis of 5 RCTs (pooled MD, −0.18%; 95% CI, −0.45 to 0.09; *P* = .20). Findings were significant (favoring CGM) when the GLiMPSE trial was removed during sensitivity testing, but the reasons for this effect are unclear.
  - The single study not included in MA (N = 61) found mixed results between the 2 CGM study arms when compared with SMBG at 24 weeks.
- There was no significant between-group differences in the proportion of individuals randomized to CGM vs. no CGM who achieved an HbA1c level below 7.0% or below 7.5% (very low CoE, based on 1 RCT).
- There was no clear association between CGM and improved diabetes-related QoL (very low CoE, based on 3 RCTs).
- There was no clear association between CGM and improved general QoL (very low CoE, based on 1 RCT).

Adults With T2D (KQ1a) Not on Insulin or Oral Hypoglycemic Therapies

We did not identify any eligible RCTs evaluating CGMs in adults with T2D not on insulin or OHM regimens.

Adults With T2D (KQ1a) on Mixed Nonintensive Hypoglycemic Therapies

We identified 5 RCTs in 7 publications (N = 450; follow-up range, 12 to 52 weeks) that assessed CGM in adults with T2D on mixed nonintensive hypoglycemic treatments.

- There was no consistent difference in change in HbA1c from baseline with CGM vs. other non-CGM monitoring methods (very low CoE, based on 5 RCTs).
  - At final study follow-up (range, 12 to 52 weeks), there were no between-group differences in change in HbA1c from baseline in 4 studies. Comparatively, CGM use was associated with a statistically and clinically greater reduction in HbA1c than SMBG in 1 study with a higher proportion of insulin users (−1.1% vs. −0.4%; *P* = .004).

  - All CGM groups experienced clinically meaningful reductions in HbA1c levels (0.5%) from baseline (range, −0.8% to −5.2%) compared with only 3 of 5 control groups (range, −0.2% to −2.4%).
- No eligible studies reported on the achievement of target HbA1c levels.
- There were no between-group differences at final study assessments (range, 12 to 52 weeks) in perceived diabetes burden, diabetes-related distress, and treatment satisfaction (very low CoE, based on 3 RCTs).
- There was no difference in overall QoL at 12 weeks among individuals using isCGM vs. SMBG for glycemic management (very low CoE, based on 1 RCT).

Children With T2D (KQ1b) Not on Intensive Insulin Treatment

We did not identify any eligible RCTs evaluating the effectiveness or safety of CGMs in children with T2D on nonintensive insulin regimens.

Pregnant People With T2D (KQ1c) Not on Insulin Treatment

We did not identify any eligible RCTs evaluating the effectiveness or safety of CGMs in pregnant people with T2D who were not using insulin before or during pregnancy.

Pregnant People With GDM (KQ1d) Not on Insulin Treatment

We identified 4 eligible RCTs in 4 publications (N = 343; follow-up range, 4 to 16 weeks) that assessed CGM in pregnant people with GDM who are not using insulin.

- CGM use was not associated with a significantly lower HbA1c at the end of pregnancy (4 to 16 weeks of follow-up) compared with non-CGM controls (low CoE, based on 3 RCTs).
- No eligible studies reported on the achievement of target HbA1c levels or QoL.
- No significant between-group differences were observed in the incidence of severe perinatal outcomes (very low CoE, based on 4 RCTs).

KQ2. CGM-Device Related Safety

The incidence of CGM-related adverse events (AE) was reported in 12 of 22 included RCTs. Across the 12 RCTs, 64 device-related AEs were observed that were sensor insertion site-related problems of mild to moderate intensity (e.g., skin irritation, bruising, pain, swelling), generally treated with topical antihistamines or by moving the sensor to a different site on the body. No serious AEs (e.g., hospitalizations, infections, hypoglycemia, diabetic ketoacidosis) were ultimately attributed to CGM use.

Similar reports of device-related AEs were reported in the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database, a registry of medical device reports from manufacturers and users, for CGM-related AE. The device reports largely documented sensor-related issues such as insertion site symptoms (e.g., rash, pain, infection), premature detachment, failure to connect with the receiver, and inaccurate blood glucose readings. Reports of serious AEs (e.g., severe hypoglycemia) were rare; 2 deaths were reported but it was unclear from the database information whether these events were related to CGM use (i.e., records only reported that the patient was deceased, but not how a CGM device was involved).

We also identified open 5 open recalls of CGM systems currently available in US markets. Of these, 4 recalls were categorized as Class 1, the most serious type of recall, indicating reasonable probability of serious injury or death.

KQ3. Differential Efficacy or Safety of CGM

We assessed all comparative effectiveness and safety outcomes for evidence of differential subgroup effects by key demographic and clinical characteristics. We identified several subgroup analyses, all of which assessed differences in change in HbA1c from baseline. We did not identify subgroup analyses for any other outcome of interest (e.g., QoL, severe hypoglycemia).

- Age, gender, race or ethnicity, baseline HbA1c, and CGM adherence did not appear to have a strong or consistent association with the effectiveness of CGM use on changes in HbA1c.
-
- No RCTs reported prespecified subgroup analyses by comorbidity status (e.g., hypertension), type CGM, duration of CGM use, or timing of CGM initiation.

KQ4. Costs and Cost-effectiveness of CGM

We identified 2 eligible studies reporting economic outcomes on the use of CGM from a US perspective. Based on the single cost-effectiveness analysis, we found:

- Over a 10-year time horizon, from the Medicaid perspective, CGM (specifically, the FreeStyle Libre system) was dominant to SMBG, providing more quality-adjusted life-years and life-years at lower costs for people with T2D using basal insulin (moderate CoE).

Ongoing Studies

We identified 37 ongoing RCTs that align with the inclusion criteria for this report topic.

- 23 ongoing trials are assessing adults with T2D not on intensive insulin regimens, 1 is assessing children with T2D not on intensive insulin regimens, and 13 are assessing pregnant people with T2D or GDM who are not on insulin.
- 8 ongoing trials are testing isCGMs, while the remainder are using rtCGMs or do not have detailed information for CGM type.
- Estimated study sample sizes range from 10 to 430 participants.
- Most studies compare CGM with SMBG testing or usual care (at least 3 report the employment of a blinded CGM with the comparator arm.

Clinical Practice Guidelines

We included 11 clinical practice guidelines from 6 professional organizations. The guidelines recommended CGM for all individuals with T1D and for those with T2D or GDM who inject insulin more than 3 times a day or use an insulin pump. The recommendations are more varied for adults and children with T2D not on intensive insulin treatment and pregnant people with either T2D or GDM who do not use insulin.

Select Payer Coverage Determinations

As with the clinical practice guidelines, payer coverage determinations are varied for adults and children with T2D not on intensive insulin treatment and pregnant people with either T2D or GDM who do not use insulin. In 2021, Medicare eliminated the requirement that individuals have a history of 4 daily SMBG tests to qualify for a CGM. The 2023 changes allowed CGMs for individuals who use insulin to treat their diabetes regardless of the type of insulin used or the

type of diabetes; before the change, individuals with diabetes had to take a certain amount of insulin daily to quality for a CGM. The new Medicare policy allows individuals with diabetes who do not take insulin but have a history of problematic hypoglycemia to qualify for a CGM.

Conclusions

Evidence from RCTs indicates CGM are safe and effective devices to reduce HbA1c levels in adults with T2D on nonintensive insulin regimens compared with daily SMBG testing. Cost-effectiveness analyses suggest CGM are cost-effective for monitoring glucose levels compared with daily SMBG testing in adults with T2D using basal insulin. There was no clear evidence of effectiveness in adults with T2D on OHM therapies or mixed nonintensive hypoglycemic regimens and for pregnant people with GDM not on insulin, although available evidence suggests CGM is not harmful in these populations. We found no eligible RCTs of CGM use for children with T2D not on intensive insulin regimens.

Device-related serious AEs and deaths were relatively rare. Clinical guidelines issued by relevant professional organizations commonly recommend CGM coverage for patients with T2D or GDM who require insulin therapy and are at high risk for hypoglycemia. Public and private payer policies follow major clinical guidelines and cover individuals with T2D who are on insulin therapy, although specific criteria for pregnant populations is limited.

Technical Report

Background

Diabetes, also known as high blood glucose or hyperglycemia, is a chronic health condition characterized by harmful high levels of blood sugar.[1,2] Blood sugar is converted into energy to be used by cells through the hormone insulin which is released by the pancreas in normal metabolism.[1,2] In diabetes, the pancreas either does not produce any insulin or does not produce enough insulin to properly regulate blood glucose levels.[1,2] Exposure to high blood glucose levels over time can lead to increased risk of developing serious health conditions such as heart disease, kidney failure, nerve damage, lower-limb amputations, adult onset blindness, and digestive problems such as gastroparesis.[3]

Diabetes affects children and adults and presents primarily in 3 forms:[2]

- Type 1 diabetes (T1D) is considered an autoimmune disease where the pancreas's ability to make insulin is affected.[1,4] Individuals with T1D produce no insulin or very little insulin and need to take insulin every day to prevent damage to the body from high blood glucose levels.[1,4] T1D typically develops in childhood although it can occur at any age.[4]
- Type 2 diabetes (T2D) results when the body does not use insulin properly because the pancreas does not produce enough insulin or because the cells respond poorly to insulin and take in less sugar from blood.[5,6] T2D is a chronic condition that usually develops in adults aged 45 and older, although it is becoming more common in young people, who are usually diagnosed in their early teens.[5,7]
- Gestational diabetes (GDM) develops in some pregnant women between the 24th and 28th weeks of pregnancy and is characterized by high blood sugar due to insufficient insulin production.[8] While GDM usually resolves after pregnancy, about half of women with GDM develop T2D.[8]

Prevalence

According to 2021 data from the Centers for Disease Control and Prevention, approximately 38.4 million people in the US have diabetes, which is 11.6% of the US population.[9] About 20% of US citizens with diabetes are undiagnosed and do not know they have the condition.[2] T1D is less common; about 5% to 10% of individuals diagnosed with diabetes in the US have T1D[4] while the remaining 90% to 95% have T2D.[7] GDM develops in 5% to 9% of US pregnancies annually.[8]

In addition, about 1 in 3 US adults have prediabetes, when blood sugar levels are higher than normal but do not meet the threshold for a T2D diagnosis.[2] Eighty percent of individuals with prediabetes do not know they have the condition.[2]

Diabetes in Washington

In Washington, 2020 data estimates that approximately 521,000 adults in the state, or 8.6% of the adult population, have diagnosed diabetes with an additional 164,000 people having undiagnosed diabetes.[10] Based on 2016 data from the Centers from Disease Control and Prevention showing 90.9% of diagnosed diabetes cases have T2D,[11] we can estimate that in Washington, around 474,000 residents diagnosed with diabetes have T2D and just over 30,000 residents have T1D. Diabetes is more prevalent among Washington residents who are male,

Black, Hispanic, American Indian and Alaska Native, older than 65 years of age, or of lower economic status.[12]

Diabetes is the 7th leading cause of death in Washington; it was associated with 5,700 deaths in the state in 2015.[12,13] Diabetes is also associated with significantly higher rates of outpatient emergency department use and inpatient admissions.[13] Higher health care utilization also leads to increased costs.[13] A 2017 report to the Washington legislature stated diabetes cost approximately $8 billion annually, with $6 billion expended in direct health care costs and $2 billion in indirect costs due to lost productivity.[13] The report projected costs related to diabetes would increase from $8 billion in 2015 to more than $13 billion by 2030.[13]

Continuous Glucose Monitoring

The primary goal of diabetes treatment is to regulate the levels of blood sugar to avoid both high blood sugar (hyperglycemia) and low blood sugar (hypoglycemia).[14] Treatment options include lifestyle modifications (e.g., diet and nutrition, physical activity), oral glucose-regulating medications, or insulin therapy.[14,15] To determine the effectiveness of treatment at regulating blood sugar levels, clinicians assess patient glycemic status by measuring hemoglobin A1C.[16] The A1C test measures average glycemia over approximately 2 to 3 months.[17] However, hemoglobin A1C levels do not offer information about daily glycemic variability or incidents of hypoglycemia.[17-19]

Individuals traditionally used self-monitoring of blood glucose (SMBG) systems to measure glucose in a fingerstick blood sample to gauge how effective treatments and interventions are at controlling blood sugar on a daily basis.[14,15,17] How often individuals measure glucose through SMBG testing varies by type of diabetes, activity levels, whether they use insulin, and the type of insulin used.[14,20] Individuals on insulin therapy for diabetes are often advised to do SMBG testing upon awakening, before meals, 2 hours after a meal, and at bedtime.[14] For people not on insulin therapy, SMGB is often recommended when changing treatment plans.[14]

While SMBG gives a moment in time reading of blood glucose levels, CGM estimates blood glucose levels every few minutes and saves the data, providing information about trends in glucose levels.[21] The information is collected by a sensor placed on the skin or implanted.[21] Sensors are disposable and must be replaced depending on the CGM, but generally sensors placed on the skin are replaced every 7 to 14 days and implantable sensors can last up to 180 days.[21]

There are 3 types of CGM devices:

- Professional or retrospective CGM devices are managed by clinicians. Patients wear the devices for 7 to 14 days and then return to the clinic to have the blood glucose data downloaded and interpreted by their treating clinician.[18,22,23] Professional CGM devices are excluded from this evidence review.
- Real-time CGM (rtCGM) measures glucose levels in interstitial fluid on a regular basis and automatically sends the information to a smartphone application, an insulin pump, or a separate receiver where the information is automatically displayed and shows trends in blood glucose levels.[21] Real-time CGM systems can be programed to send alerts or alarms when blood glucose levels rise above or fall below optimal levels.[21,24]

- Intermittently scanned (also sometimes called "flash") CGM (isCGM) measures blood glucose levels every few minutes but patients must actively scan their sensor with a separate device to see and store the data.[24]

CGM devices vary in how often the sensor has to be replaced, how long it takes the CGM to warm up when a new sensor is inserted, and whether the patient must calibrate the system by using SMBG to ensure the CGM readings are accurate.[21]

Diabetes technologies evolve rapidly and new CGM devices or new versions of devices frequently enter the market.[20,25] In 2024, the FDA cleared Stelo by Dexcom, the first over-the-counter rtCGM intended for use by individuals older than age 18 who do not use insulin and do not have problematic hypoglycemia.[26] According to the FDA, Stelo can also be used by individuals "without diabetes who want to better understand how diet and exercise may impact blood sugar levels."[26] Both the American Diabetes Association[27] and diaTribe,[28] an advocacy organization for individuals with diabetes and prediabetes, maintain websites with information about CGM products. Table 1 lists the CGM currently available and cleared or authorized by the FDA.

Table 1. CGM Devices Available in the US[27,28]

Device	Manufacturer	Fingerstick Calibration	Approved Patient Age and Patient Population	Sensor Wear Duration	Alarms for Low and High Blood Sugar
rtCGM					
Eversense E3	Senseonics	2 per day minimum for first 21 days, then 1 per day	18+ years	180 days	Yes
Freestyle Libre 2	Abbott	Not required	4+ years and in pregnancy	14 days	Yes
Freestyle Libre 2 Plus	Abbott	Not required	2+ years and in pregnancy	15 days	Yes
Freestyle Libre 3	Abbott	Not required	4+ years and in pregnancy	14 days	Yes
Freestyle Libre 3 Plus	Abbott	Not required	2+ years and in pregnancy	15 days	Yes
Guardian 3	Medtronic	2 per day, minimum	3+ years	7 days	Yes
Guardian 4	Medtronic	Not required	7+ years	7 days	Yes
G6	Dexcom	Not required	2+ years	10 days	Yes
G7	Dexcom	Not required	2+ years and in pregnancy	10 days	Yes
isCGM					
Freestyle Libre 14-day System	Abbott	Not required	18+	14 days	No
Over-the-Counter CGM					

Device	Manufacturer	Fingerstick Calibration	Approved Patient Age and Patient Population	Sensor Wear Duration	Alarms for Low and High Blood Sugar
Stelo	Dexcom	Not required	18+ years and not on insulin	15 days	No

Abbreviations: CGM: continuous glucose monitor. isCGM: intermittently scanned continuous glucose monitor; real-time continuous glucose monitor.

Health Equity

Research has shown that access to CGM varies significantly based on patient income, insurance coverage, geographic location, and race and ethnicity.[29-31] Both the American Diabetes Association and the Center for Health Care Strategies published reports showing individuals covered by Medicaid are less likely to have access to CGM, and access within Medicaid is less likely among non-White individuals.[29,30,32] Other research has suggested that access to diabetes technology may be affected by limited availability of endocrinologists or other specialists particularly when coverage requires a specialist to order the technology.[33] Additional studies found providers may be less likely to suggest diabetes technology due to implicit racial bias or bias against public insurance.[34-36] The Center for Health Care Strategies funding from the Leona M. and Harry B. Helmsley Charitable Trust supports improved access to CGM technology for Medicaid beneficiaries.[30,32,37]

Methods

This evidence review is based on the final key questions (KQs) published on September 30, 2024. The draft KQs were available for public comment from September 3, 2024, through September 16, 2024, and appropriate revisions were made to the KQs based on the comments and responses. All public comments received and a table of responses can be found on the Washington Health Technology Assessment website. The PICOS (population, intervention, comparator, outcome, study design) details, along with the setting, sample size, and publication factors that guided development of the KQs and study selection are presented in Table 2.

Key Questions

KQ1. What is the comparative effectiveness of CGM in adults and children with T2D vs. other forms of monitoring (e.g., self-monitoring blood glucose or routine clinical monitoring)?

a. Adults with T2D and using:
   i. Nonintensive insulin therapy (1 to 3 injections per day)
   ii. No insulin but on oral hypoglycemic medication
   iii. No insulin and no oral hypoglycemic medication

b. Children with type 2 diabetes
   i. Nonintensive insulin therapy (1 to 3 injections per day)
   ii. No insulin but on oral hypoglycemic medication

iii. No insulin and no oral hypoglycemic medication

c. Pregnant people with T2D who are not using insulin

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

KQ2. What is the device-related safety of CGM in adults and children with T2D?

KQ3. What is the differential efficacy or safety by patient and clinical factors, such as:

a. Age

b. Gender

c. Race and ethnicity

d. Presence of comorbidities (e.g., hypertension)

e. Severity of disease (e.g., baseline hemoglobin A1c [HbA1c], number of self-tests per day)

f. Level of adherence to CGM use

g. Type of CGM (i.e., rtCGM vs. isCGM)

h. Duration of CGM monitoring

i. Timing of initiation of CGM monitoring relative to baseline level of control measured by A1C (i.e., A1C level indicating well-controlled vs. uncontrolled disease at initiation)

KQ4. What are the costs and cost-effectiveness of CGM in adults and children with T2D

a. Adults with T2D and using:

i. Nonintensive insulin therapy (1 to 3 injections per day)

ii. No insulin but on oral hypoglycemic medication

iii. No insulin and no oral hypoglycemic medication

b. Children with T2D

i. Nonintensive insulin therapy (1 to 3 injections per day)

ii. No insulin but on oral hypoglycemic medication

iii. No insulin and no oral hypoglycemic medication

c. Pregnant people with T2D who are not using insulin

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

PICOS and Eligible Studies

Table 2 details the inclusion and exclusion criteria applied by Center of Evidence-based Policy (Center) researchers to determine the eligibility of studies.

Table 2. Detailed Inclusion and Exclusion Criteria

Study Component	Inclusion	Exclusion
Populations	• Adults with T2D not on intensive insulin treatment[a] • Children with T2D not on intensive insulin treatment[a] • Pregnant people with T2D not using insulin • Pregnant people with gestational diabetes not using insulin	• Populations other than those listed
Interventions	• FDA-approved CGM devices (rtCGM and isCGM) • FDA-approved combination devices integrating CGM with insulin pump or infusion (including sensor-augmented insulin pumps) if effect of CGM component can be isolated	• Interventions other than those listed • Professional CGM
Comparators	• Self-monitoring using conventional blood glucose meters • Attention control • Blinded or sham CGM • Routine lab monitoring • Usual care	• Comparators other than those listed • No comparator • Comparisons of different models of the same device

Outcomes	• Primary intermediate outcomes
	  ○ Achieving target HbA1C level[b]
	  ○ Maintaining target HbA1C level
	  ○ Change in HbA1c[b]
	  ○ Acute episodes of hypoglycemia requiring intervention
	• Secondary intermediate outcomes
	  ○ Quality of life (validated instruments only) [b]
	  ○ Mortality
	  ○ Perinatal mortality[b]
	  ○ Severe perinatal morbidity[b]
	• Safety related to device itself
	• Economic outcomes
	  ○ Cost-effectiveness[b]
	  ○ Health care resource utilization and costs[b]
		• Outcomes other than those listed
		• Economic outcomes from studies performed in non-US countries
		• Economic outcomes from studies performed in US published more than 5 years ago

Timing	• When used for routine monitoring of glucose control in T2D or GDM	• Other uses (e.g., monitoring hyperglycemia during hospitalization for coronary care)
Setting	• Any outpatient or inpatient clinical setting in countries categorized as *very high* on UN Human Development Index	• Emergency settings • Nonclinical settings (e.g., studies in healthy volunteers) • Countries categorized other than *very high* on UN Human Development Index

Study Component	Inclusion	Exclusion

Study Design and Sample Size	• KQ1
	  ○ RCTs with no sample size limitation
	• KQ2
	  ○ RCTs with no sample size limitation
	  ○ FDA documentation on device-related safety concerns
	• KQ3
	  ○ RCTs with no sample size limitation
	• KQ4
	  ○ RCTs with no sample size limitation
	  ○ Formal economic studies with no sample size limitation
		• Studies other that those listed by KQ
		• Studies that do not report outcomes of interest
		• Noncomparative association or correlation studies
		• Proof-of-principle studies (e.g., device modification)

Study Duration	• 12 weeks or longer[c]	• Less than 12 weeks
Publication	• Published, peer-reviewed, English-language articles	• Abstracts, conference proceedings, posters, editorials, letters

Notes. [a] Qualifying regimens for "not on intensive insulin" included nonintensive insulin therapy (i.e., 1 to 3 injections of any insulin type per day), oral antidiabetic medication therapy (e.g., metformin) without insulin, and lifestyle management (i.e., no insulin or oral antidiabetic medications). [b] Outcomes selected for GRADE assessment. [c] Due to the limited nature of the condition, no minimum follow-up required for studies of pregnant people with gestational diabetes.

Abbreviations. CGM: continuous glucose monitoring; FDA: Food and Drug Administration; HbA1c: glycated hemoglobin; isCGM: intermittently scanned continuous glucose monitoring; KQ: key question; RCT: randomized controlled trial; rtCGM: real-time continuous glucose monitoring; T2D: type 2 diabetes; UN: United Nations.

Data Sources and Searches

We ran a literature search using Ovid MEDLINE ALL, PsycINFO, and the Cochrane Central Register of Controlled Trials (CENTRAL) for any RCTs, cost-effectiveness studies, and clinical practice guidelines of CGM in the target populations. We conducted general internet searches in DuckDuckGo and Google Scholar, and reviewed reference lists of included studies and relevant systematic reviews to identify relevant publications not identified through the database searches. Searches for interventions were limited to January 1, 2000, to September 4 and 5, 2024, to capture relevant published studies. We also searched ClinicalTrials.gov and ScanMedicine for ongoing studies of CGM in the listed populations of interest.

Screening, Data Abstraction, and Quality Assessment

Screening of the literature search results, risk-of-bias (RoB) and methodological assessments, and data abstraction were performed in DistillerSR; artificial intelligence was used to aid in title and abstract screening.[38] Two independent researchers reviewed each citation and conducted RoB and methodological assessments; conflicts were handled through discussion, and any disagreements were resolved by a third independent senior researcher. Data was extracted by one researcher and checked by another for accuracy. We performed the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach[39,40] on these select outcomes: change in HbA1c, achieving or maintaining target HbA1c levels, quality of life (QoL), severe perinatal morbidity and mortality, and cost-effectiveness outcomes. Two independent researchers assigned GRADE certainty-of-evidence (CoE) ratings from *very low* to

high; conflicts were handled through discussion and any disagreements were resolved by a third independent senior researcher.

We included RCTs with no sample size limitations that evaluated FDA-approved CGM for the listed populations of interest. Additional eligibility criteria were studies on human participants conducted in countries evaluated as *very high* on the United Nations Human Development Index published between database inception and September 4, 2024. Economic evaluations and clinical practice guidelines published from January 1, 2019, were also included and required to have a US perspective. All included studies were published in the English language. Studies were excluded if data was not extractable or if we were unable to isolate data for populations of interest for this review. We excluded studies of adults, children, and pregnant people with T2D if the sample included 10% or greater participants with T1D. Results reporting was limited to prespecified primary and secondary outcomes; post hoc and exploratory analyses were excluded. Refer to Table 2 for more detailed inclusion and exclusion criteria.

We conducted meta-analyses of the most-reported primary glycemic outcome of change in HbA1c levels using the Cochrane Collaborations Review Manager (RevMan) software, desktop version 5.4.1.[41] For each key subpopulation identified in KQ1, outcomes data from studies with at least 4 weeks of planned CGM use were pooled at final follow-up. Pooled analyses were only conducted when 3 or more studies were eligible. Where possible, mean difference (MD) from baseline to follow-up was the preferred outcome. If the study did not give the mean difference, we included mean HbA1c levels at the final follow-up timepoint as indicated in the Cochrane Handbook.[42]

Overview of Key Outcome Measures

Table 3 summarizes the primary measures used for outcomes in the included RCTs, the interpretation of those measures (with categories or classes used to determine treatment approaches), and change values determined as clinically meaningful. Minimal clinically important difference (MCID) values are defined as the smallest improvement in an outcome in response to treatment in an individual patient identified as important, leading to a change in the patient's management[43] (also known as differences, or improvements, that are clinically meaningful). While these thresholds can offer valuable information about effectiveness beyond statistical significance for responders and nonresponders, there is controversy around methods used and lack of standardization in the derivation of MCIDs.[44] MCIDs should not be applied and interpreted in isolation, but rather with consideration of the wider patient population, the individual patient, and other clinically relevant information.[44,45]

Although HbA1c is an important indicator of glycemic control among individuals with diabetes, there is a lack of consensus regarding what level of change between tests should be accepted as the MCID. 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, accepted change thresholds ranging from 0.3% to 0.5%.[46-48] Randomized controlled trials of CGM have also variably defined a clinically meaningful change in HbA1c as 0.3%,[49] 0.4%,[50,51] or 0.5%.[52] Outside of research environments, surveys indicate diabetes clinicians are most likely to endorse a 0.5% change between HbA1c tests as an indicator that treatment

adjustments are needed.[53] Moreover, laboratory testing standards accepted 0.5% as a statistically and clinically meaningful change in serial HbA1c tests.[54-56] For the purposes of this review, we considered the MCID for HbA1c to be a difference of 0.5% between measurements according to NICE and in wide acceptance in clinical practice and laboratory standards.

For dichotomous outcomes (e.g., severe hypoglycemia, severe perinatal events), we applied a default MCID of a 25% increase or decrease in relative risk (i.e., RR, ≤ 0.75 or ≥ 1.25) when no other threshold could be identified, according to NICE guidelines on T2D in adults.[57]

We searched for MCIDs associated with each validated scale used to measure general or diabetes-related quality of life in the included RCTs. Since measurement scales may have different MCIDs for each population in which these are validated (e.g., T1D vs. T2D vs. GDM), we did not apply a general standard when a threshold could not be identified.

Table 3. Summary of Key Outcomes and Assessment Tools for Studies of CGM

Measure	Description	Interpretation	MCID
Diabetes outcomes			
Change in HbA1c	$((CGM\ baseline\ HbA1c - follow\ up\ HbA1c) - (Control\ baseline\ HbA1c - follow\ up\ HbA1c))$	Assessment of between-group differences in change in HbA1c level from baseline to follow-up, expressed as a percentage • Secondarily accepted between group difference in mean HbA1c levels at follow-up	• Reduction or increase of 0.5%[57]
Achievement of target HbA1c levels	$\left(\frac{N\ with\ HbA1c\ below\ designated\ level}{N\ in\ study\ group}\right) x\ 100$	Proportion of participants in each group who achieved an HbA1c level below a certain percentage threshold (e.g., percentage of participants with an HbA1c < 7.0% at final follow-up timepoint)	• Relative risk reduction or increase of ≥ 25%[57]
Severe hypoglycemia requiring intervention	$\left(\frac{N\ with\ severe\ hypoglycemic\ event}{N\ in\ study\ group}\right) x\ 100$	Proportion of participants in each group who experienced a severe hypoglycemic event requiring third-party assistance (e.g., administration of oral glucose, hospitalization)	• Relative risk reduction or increase of ≥ 25%[57]
Pregnancy outcomes			
Severe perinatal outcomes	$\left(\frac{N\ with\ severe\ perinatal\ outcome}{N\ in\ study\ group}\right) x\ 100$	Proportion of participants (mother or neonate) in each study group who experienced a severe perinatal event associated with poor diabetes control (e.g., macrosomia, shoulder dystocia)	• Relative risk reduction or increase of ≥ 25%[57]
Quality of life			
Diabetes-related quality of life scales			
Audit of Diabetes-Dependent Quality of Life-19 (ADDQoL)[58-61]	• 19-item questionnaire for adults with diabetes • Individualized measure of impact of diabetes on quality of life	• Score range: -9 to +3 points • Higher scores indicate fewer negative impacts of diabetes	• No MCID identified
Appraisal of Diabetes Scale (ADS)[62] (Korean version – ADS-K[63])	• 7-item questionnaire that measures a patient's appraisal of diabetes status across several domains: glycemic control, uncertainty, coping, effect on life goals, predictive and degree of distress	• Score range: 7 to 35 points • Higher scores indicate more negative appraisal of diabetes status	• No MCID identified

Measure	Description	Interpretation	MCID
Diabetes Distress Scale-17 (DDS)[64-66]	• 17 items that measure patients' perceptions in 4 general domains of diabetes distress: interpersonal, physician, regimen, and emotional	• Score range: 1 to 6 points • Lower scores indicate less of a problem or less distress • Interpretive cut points[65]: ○ < 2.0: little or no distress ○ 2.0 to 2.9: moderate distress ○ ≥ 3.0: high distress	• Change of 0.25 points for overall score[64]
Diabetes Management Self-Efficacy Scale (DMSES)[67,68] (Korean version – K-DMSES[69])	• 20-item assessment that measures a patient's efficacy expectations across 4 subscales: nutrition and weight, medical treatment, physical exercise, and blood sugar	• Score range: 0 to 200 points • Higher scores indicate greater diabetes self-management efficacy	• No MCID identified
Diabetes Quality of Life (DQoL)[70-72]	• 46-item measurement tool assessing diabetes-related life satisfaction, impact, worries, and social concern	• Score range: 0 to 100 points • Lower scores indicate better diabetes-related QoL (e.g., fewer problems or less distress from diabetes)	• Change of 3 to 4 points for overall score[71]
Diabetes Treatment Satisfaction Questionnaire (DTSQs[62,73] and DTSQc[74])	• 8-item questionnaire assessing patients' satisfaction with aspects of diabetes treatment, such as respect from providers and convenience of care	DTSQs scoring: • Satisfaction score range: 0 to 36 points • Burden score range: 0 to 12 points • Higher scores indicate more treatment satisfaction and less perceived burden DTSQc scoring • Satisfaction score range: -18 to + 18 points • Burden score range: -6 to +6 points • Higher scores indicate more treatment satisfaction and less perceived burden	• No MCID identified
Hypoglycemia Confidence Survey (HCS)[75]	• 9-item scale assessing patient's general confidence related to managing hypoglycemia • Validated for use in adults with T1D and insulin-using T2D	• Score range: 9 to 36 points ○ Each item has a possible score of 1 to 4 points • Higher scores indicate more confidence	• No MCID identified
Hypoglycemia Fear Survey-II (HFS-II)[76-79] and short-form version[80]	• 33-item questionnaire that assesses specific behaviors people with diabetes engage in to avoid hypoglycemia and manage concerns about hypoglycemia	• Score range: 0 to 132 points ○ Behavior subscale: 0 to 60 points ○ Worry subscale: 0 to 72 points • Lower scores indicate less fear-related behaviors or worry	• No MCID identified • Exploratory study suggests a range between 2.0 and 5.8 points in T2D

Measure	Description	Interpretation	MCID
	• Comprises a Behavior Subscale (15 items) and a Worry Subscale (18 items)	• Score of 3 or 4 on any item indicates fear of hypoglycemia that necessitates further exploration	patients treated with OHM therapy[81]
LMC Skills, Confidence, and Preparedness Index (SCPI)[82,83]	• A 25-item electronic tool to assess 3 dimensions of diabetes self-management: skills, confidence and, preparedness	• Score range: 0 to 10 points (average of all 3 subscales) ○ Each subscale may be graded individually on a 10-point scale • Higher scores indicate higher diabetes self-management efficacy • Tertile cut points[82]: ○ ≥ 7.3: likely good glycemic control ○ 6.8 to 7.2: likely moderate glycemic control ○ ≤ 6.7: likely poor glycemic control	• No MCID identified
Problem Areas in Diabetes (PAID)[66,84,85]	• 20-item assessment of diabetes-specific emotional distress	• Score range: 0 to 100 points • Higher scores indicate greater distress levels ○ 0 to 16: low distress ○ 17 to 39: moderate distress ○ ≥ 40: severe distress	• Change of 5 points
Summary of Diabetes Self-Care Activities Questionnaire (SDSCA)[86] (Korean version – K-SDSCA[87,88])	• 11-item self-report questionnaire of diabetes self-management aspects of the diabetes regimen including general diet, specific diet, exercise, blood-glucose testing, foot care, and smoking	• Score range: could not identify • Higher scores indicate better adherence to recommended diabetes self-management behaviors	• No MCID identified
General quality of life scales			
Euro Quality of Life 5 Dimension (EQ-5D)[89,90]	• General QoL questionnaire on 5 dimensions of a patient's health status: mobility, usual activities, self-care, pain and discomfort, and anxiety and depression	• Score range: 0 to 1 point • Higher scores indicate fewer health problems (i.e., "full health")	• Change of 0.03 to 0.05 points for adults with T2D[90]
EuroQoL-5D Visual Analog Scale (EQ-5D VAS)[89]	• Single-item assessment of patient's overall assessment of their health on a scale from 0 (worst health imaginable) to 100 (best health imaginable)	• Score range: 0 to 100 • Higher scores indicate better perceived health	• No MCID identified

Measure	Description	Interpretation	MCID
5-item World Health Organization Well-being Index (WHO-5)[91]	• 5-item questionnaire on how a patient has been feeling over past 2 weeks	• Score range: 0 to 25 points (can be converted to a 100-point scale) • Higher scores indicate better well-being	• No MCID identified

Abbreviations. BMI: body mass index; CGM: continuous glucose monitoring; DBP: diastolic blood pressure; bs: pounds; LDL: low-density lipoprotein; HbA1c: glycated hemoglobin; MBS: metabolic and bariatric surgery MCID: minimal clinically important difference; OHM: oral hypoglycemic medication; QoL: quality of life; SF36: 36item Short Form Health Survey; T1D: type 1 diabetes; T2D: type 2 diabetes.

Evidence Summary

We identified 8,154 citations through bibliographic database (e.g., MEDLINE) searches and other search methods, such as reference list checking and internet searches. Following the removal of duplicate citations, 4,776 unique records were reviewed. Ultimately, we included 22 RCTs in 35 publications (N = 2,175),[51,92-125] 2 economic studies, and 13 clinical practice guidelines. See Figure 1 for full study flow details.

We identified the following RCTs evaluating the effectiveness of CGM, as compared with no CGM, for people with diabetes who are not currently eligible for CGM coverage under the 2018 Washington coverage determination:

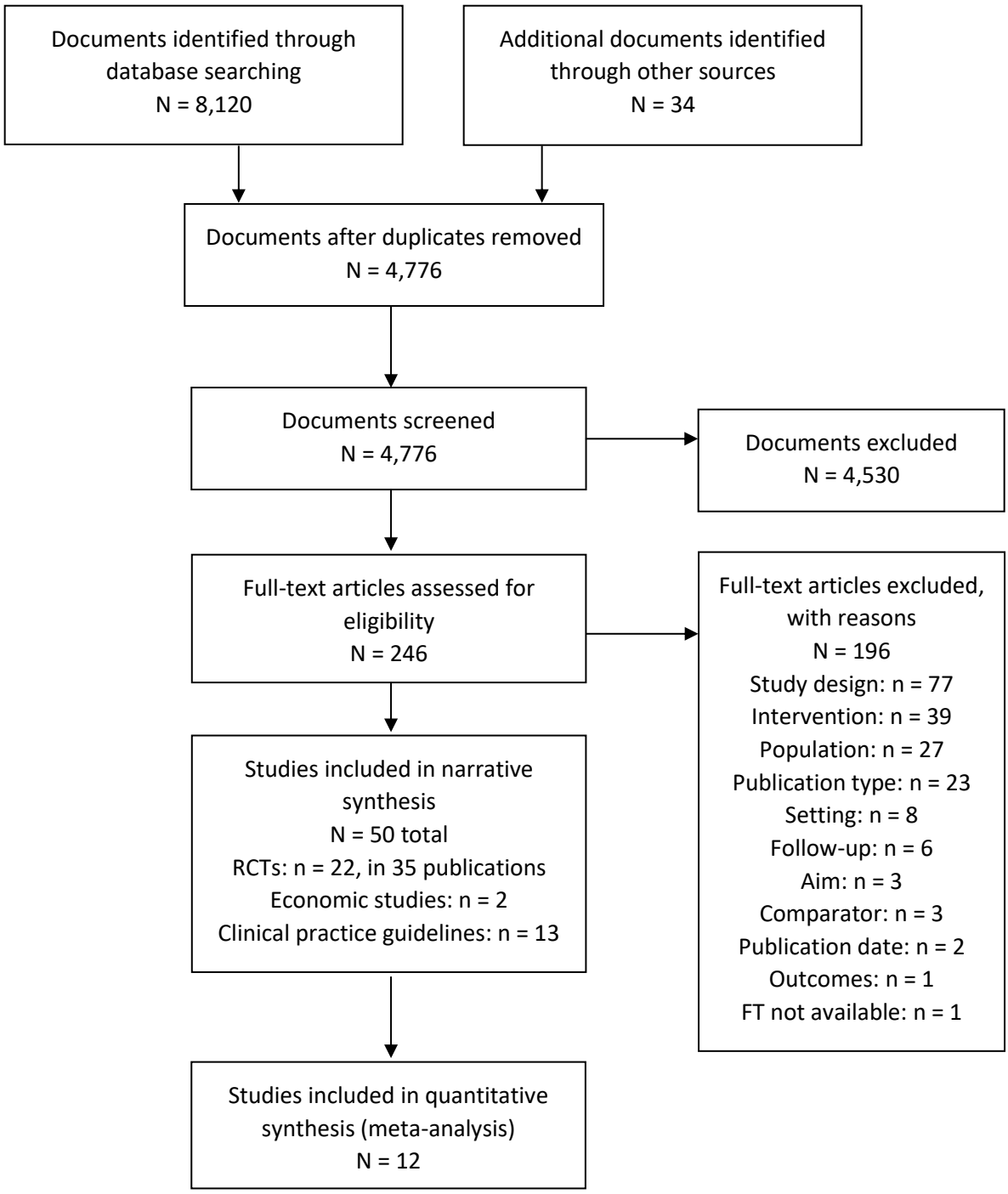
- 18 RCTs (N = 1,832) conducted in adults with T2D who were not on intensive insulin regimens[51,92,93,95,97,103,109,110,113-115,117,118,120,122-125]
  - 7 studied CGM in participants on nonintensive insulin regimens (i.e., 1 to 3 insulin injections of any type per day)[51,92,103,109,110,113,122]
  - 6 studied CGM in participants on oral hypoglycemic medication (OHM) therapy (e.g., metformin), but not on insulin[95,114,117,118,120,124]
  - 5 studied CGM in participants on mixed nonintensive hypoglycemic regimens[93,97,115,123,125]
- 4 RCTs (N = 343) conducted in pregnant people with gestational diabetes (GDM) who were not on insulin therapy[94,106,107,112]

We did not identify any eligible RCTs for the following populations of interest not currently eligible for CGM coverage under the 2018 Washington coverage determination:

- Adults with T2D not on insulin or OHM therapy
- Children or adolescents with T2D not on intensive insulin therapy
- Pregnant people with T2D not on insulin therapy

Included economic studies and clinical practice guideline findings are presented in subsequent report sections.

Figure 1. Study Flow Diagram



Abbreviations. RCT: randomized controlled trial.

Table 4 details key study and participant characteristics from the 22 included RCTs (see Appendix B for information about study and baseline characteristics, enrollment criteria, and CGM use). Sample sizes ranged from 20 to 224 participants and study duration ranged from 4 to 52 weeks (2 studies of pregnant people with GDM had fewer than 12 weeks of follow-up[106,107]). Five RCTs were conducted exclusively in US populations[97,107,113,115,123] and 2 were multisite international studies with participants from the US [51,117]; the remaining 15 RCTs were international studies that did not include US participants. Most studies were conducted in specialty care clinics (e.g., endocrinology, obstetrics and gynecology) or in outpatient and hospital clinic settings following a diabetes-related emergency department visit or hospitalization.

In studies of adults with T2D, participants were generally required to be aged 18 years or older at enrollment, with few upper limit age restrictions, and have a minimum HbA1c level of 7.0% to 8.0%. Additionally, most RCTs of adults (i.e., 12 of 18) included a prerandomization run-in period when all participants wore a blinded CGM for up to 2 weeks to gauge tolerability and adherence; 5 of these studies required participants to demonstrate a certain level of adherence to be randomized.[51,92,103,113,118] Participants in the pregnancy studies typically were enrolled after they received a new GDM diagnosis based on a 1- or 2-hour oral glucose tolerance test (OGTT) conducted between 22 to 34 weeks of gestation and limited to people aged 18 years and older with singleton pregnancies.

Studies varied in terms of CGM type and modalities. Fifteen RCTs evaluated the effectiveness of rtCGM[51,92,94,97,106,107,109,110,113,114,117,120,122,123,125] and 7 evaluated isCCM.[93,95,103,112,115,118,124] While most RCTs assessed therapeutic CGM devices that are factory calibrated and do not require concurrent SMBG testing, 6 studies assessed nontherapeutic CGM devices[51,92,120,122,123,125] that need intermittent SMBG calibration and are no longer commercially available in US markets. Studies also varied in intended CGM use. Eleven RCTs evaluated uninterrupted CGM use,[51,93,95,97,103,107,109,110,113,120,122] and 11 RCTs evaluated the effect of CGM devices when used at periodic intervals or for a single, limited session.[92,94,106,112,114,115,117,118,123-125] All but 4 RCTs compared CGM with daily SMBG testing. Two studies had blinded CGM control groups,[107,120] 1 compared CGM with low-intensity self-monitoring education (i.e., attention control)[95] and 1 compared CGM with usual diabetes care at their providers' discretion.[115]

Eight RCTs were assessed as having a low RoB,[51,92,93,109,110,112,120,124] 7 were assessed as moderate,[94,95,97,103,113,118,122] and 7 as high.[106,107,114,115,117,123,125] Moderate and high RoB ratings were due primarily to lack of information on randomization procedures, high or differential losses to follow-up (i.e., > 20%), lack of intention-to-treat analyses, and potential industry-related author conflicts of interest.[94,95,97,103,106,107,113-115,117,118,122,123,125] See Appendix F for full RoB information by individual study.

The results of this review are presented by key question with subsections by the key population categories and relevant outcomes. Study details include additional information about baseline characteristics, CGM use, and treatment regimens in the relevant sections.

Table 4. Summary of Key Study and Participant Characteristics for Included RCTs

Study Details						Eligibility Criteria		Baseline Characteristics (CGM vs. Control)				
Author, Year Study Name	Includes US participants	N Randomized	CGM Type	Comparator	Study duration [CGM use], weeks	Age criteria, years	Min. HbA1c criteria	Mean Age, years	Mean HbA1c, %	Mean Diabetes Duration, years	% Female	Risk of Bias
Adults With T2D Not on Intensive Insulin Regimens (18 RCTs)												
Nonintensive insulin therapy (7 RCTs)												
Ajjan, 2016[92]	X	45	RT	SMBG	12[a] [12]	≥ 18	7.5%	57.8 vs. 55.5	9.2 vs. 9.2	13.9 vs. 15.8	37 vs. 27	Low
Beck, 2017[51] DIAMOND	✓	158	RT	SMBG	24 [24]	≥ 25	7.5%	60 vs. 60	8.5 vs. 8.5	17 vs. 18	62 vs. 51	Low
Haak, 2017[103] REPLACE	X	224	IS	SMBG	24 [24]	≥ 18	7.5%	59.0 vs. 59.5	8.7 vs. 8.9	17 vs. 18	37 vs. 25	Mod
Lever, 2024[109] 2GO-CGM	X	67	RT	SMBG	12 [12]	≥ 16	8.0%	51 vs. 56	9.2 vs. 9.7	13.0 vs. 13.0	61 vs. 53	Low
Lind, 2024[110] Steno2tech	X	76	RT	SMBG	52 [52]	≥ 18	7.5%	61.1 vs. 61.3	8.2 vs. 8.4	18.8 vs. 17.4	38 vs. 39	Low
Martens, 2021[113] MOBILE	✓	175	RT	SMBG	32 [32]	≥ 30	7.8%	56 vs. 59	9.1 vs. 9.0	14 vs. 15	53 vs. 46	Mod
Tildesley, 2013[122]	X	57	RT	SMBG	24 [24]	≥ 18	7.0%	58 vs. 59.5	8.8 vs. 8.8	17.4 vs. 17.0	36 vs. 36	Mod
Oral hypoglycemic medications regimens, but not insulin (6 RCTs)												
Aronson, 2023[95] IMMEDIATE	X	116	IS	AC[b]	16 [16]	≥ 18	7.5%	59.2 vs. 57.6	8.5 vs. 8.7	9.2 vs. 10.9	36 vs. 36	Mod
Moon, 2022[114]	X	61	RT-1 RT-2	SMBG	24 [1-2]	30 to 65	7.5%	55.6 vs. 50.7 53.9 vs. 50.7	8.3 vs. 8.1 8.2 vs. 8.1	10.4 vs. 10.0 13.1 vs. 10.0	39 vs. 47 53 vs. 47	High
Price, 2021[117] COMMITTED	✓	70	RT	SMBG	12 [4[c]]	≥ 30	7.8%	58.9 vs. 60.9	8.4 vs. 8.5	13.9 vs. 12.3	41 vs. 58	High
Rama Chandran, 2024[118]	X	193	IS	SMBG	24 [7]	21 to 75	7.5%	54.9 vs. 55.1	8.0 vs. 8.1	11.3 vs. 10.6	49 vs. 35	Mod

Study Details						Eligibility Criteria		Baseline Characteristics (CGM vs. Control)				Risk of Bias
Author, Year Study Name	Includes US participants	N Randomized	CGM Type	Comparator	Study duration [CGM use], weeks	Age criteria, years	Min. HbA1c criteria	Mean Age, years	Mean HbA1c, %	Mean Diabetes Duration, years	% Female	
GLiMPSE												
Taylor, 2019[120]	X	20	RT	Blinded CGM	12 [12]	20 to 75	Unclear	60.2 vs. 60.9	6.6 vs. 7.1	10.5 vs. 11.0	50 vs. 50	Low
Wada, 2020[124]	X	100	IS	SMBG	24 [12]	20 to 70	7.5%	58.1 vs. 58.7	7.8 vs. 7.8	NR	31 vs. 33	Low
Mixed nonintensive hypoglycemic regimens (5 RCTs)												
Ajjan, 2023[93] LIBERATES	X	141	IS	SMBG	12/52 [12]	≥ 18	NR	62 vs. 63	9.0 vs. 8.8	14.5 vs. 11.0	26 vs. 28	Low
Bergenstal, 2022[97]	✓	114	RT	SMBG	16 [16]	18 to 75	7.0%	59.3 vs. 58.8	8.2 vs. 7.8	NR	49 vs. 58	Mod
O'Connor, 2024[115] GOOD-ER	✓	30	IS	Usual care	12 [2]	≥ 18	NR	56 vs. 60	11.5 vs. 10.6	NR	44 vs. 36	High
Vigersky, 2012[123] Walter Reed	✓	100	RT	SMBG	52 [8]	≥ 18	7.0%	55.5 vs. 60	8.4 vs. 8.2	NR	34 vs. 56	High
Yoo, 2008[125]	X	65	RT	SMBG	12 [9d]	20 to 80	8.0%	54.6 vs. 57.5	9.1 vs. 8.7	11.7 vs. 13.3	66 vs. 50	High
Pregnant People With GDM Not on Insulin (4 RCTs)												
Alfadhli, 2016[94]	X	130	RT	SMBG	12-16 [3-7d]	GA: NR	NA[d]	32.9 vs. 34.2	5.6 vs. 5.9	NR	100	Mod
Kestila, 2007[106]	X	73	RT	SMBG	10 [1]	GA: 22 to 34w	NA[d]	32.6 vs. 32.2	5.4 vs. 5.3	NR	100	High
Lane, 2019[107]	✓	40	RT	Blinded CGM	4 [4]	GA: 24 to 32w	NA[d]	29.9 vs. 30.8	5.3 vs. 5.3	NR	100	High

Study Details						Eligibility Criteria		Baseline Characteristics (CGM vs. Control)				Risk of Bias
Author, Year Study Name	Includes US participants	N Randomized	CGM Type	Comparator	Study duration [CGM use], weeks	Age criteria, years	Min. HbA1c criteria	Mean Age, years	Mean HbA1c, %	Mean Diabetes Duration, years	% Female	
Majewska, 2023[112] FLAMINGO	X	100	IS	SMBG	12-16 [4]	GA: 24 to 28w	NA[d]	33 vs. 32	4.9 vs. 4.9	NA	100	Low

Notes. Populations, CGM use and treatment regimens were highly varied; see Appendix B for further details. [a] Total listed study length was 100 days (i.e., 14.2 weeks), which included a 15-day run-in period with blinded CGM. Excluding the run-in, the randomized study period was 85 days (i.e., 12.1 weeks). [b] Attention control consisted of an educational program on glucose self-monitoring. [c] Total duration of CGM use was 4 weeks, distributed over three 10-day periods during the 3-month study period. [d] Participants were enrolled after confirmation of GDM by a positive 1- or 2-hour oral glucose tolerance test (i.e., blood sugar value ≥ 140 mg/dL).

Abbreviations. AC: attention control; CGM: continuous glucose monitor(ing); GA: gestational age; GDM: gestational diabetes; HbA1c: glycated hemoglobin; IS: intermittently scanned; Mod: moderate; NA: not applicable; NR: not reported; RCT: randomized controlled trial; RT: real-time; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes; w: weeks.

Comparative Effectiveness (KQ1)

The following section compares the effectiveness of CGM versus other forms of glucose monitoring (e.g., self-monitoring of blood glucose or routine clinical monitoring) in adults and children with T2D or pregnant people with GDM who are not currently eligible for CGM therapy under the 2018 Washington coverage determination.

Results in this section are presented by major noncovered populations of interest and then by treatment category (as outlined in the Methods section) when evidence was available.

Adults With T2D (KQ1a) Not on Intensive Insulin Treatment

The following section includes those who are:

- On nonintensive insulin regimens (1 to 3 injections per day)
- On OHM therapy (e.g., metformin), but not on insulin
- Not on insulin or OHM therapy

When possible, we stratified our analysis of effectiveness evidence by these key treatment categories. However, several relevant studies enrolled participants on any nonintensive hypoglycemic intervention that either did not stratify results by treatment regimen or did not have sufficient proportions of participants on a single regimen type to be attributed to a prespecified categories. We present the results of these studies in a hybrid analytic category called mixed nonintensive treatment regimens.

Adults With T2D on Nonintensive Insulin Regimens

We identified 7 RCTs in 15 publications (N = 802; follow-up range, 12 to 52 weeks) that assessed CGM among adults with T2D on nonintensive insulin regimens (1 to 3 injections per day).[51,92,96,98,99,103,104,108-111,113,116,119,122] As shown in Table 5, mean baseline ages across study groups ranged from 51 to 61.5 years, mean HbA1c levels ranged from 8.2% to 9.7%, and mean diabetes duration ranged from 13.0 to 18.8 years.[51,92,103,109,110,113,122] Only 2 studies included participants from the US (N = 333).[51,113] Four studies were assessed as low risk of bias,[51,92,109,110] and 3 studies were assessed as moderate.[103,113,122]

Six studies assessed rtCGM[51,92,109,110,113,122] and 1 study (REPLACE) assessed isCGM.[103] Notably, 3 of the studies that assessed rtCGM used nontherapeutic models (i.e., those that require regular SMBG calibration), which are no longer commercially available.[51,92,122] All 7 studies instructed participants to use their CGM devices for the full length of the study period (range, 12 to 52 weeks) and all studies compared CGM with SMBG testing.[51,92,103,109,110,113,122]

Insulin regimens varied between studies, ranging from 1 to 2 daily injections of basal insulin[110,113,122] to multiple daily injections of basal and prandial (bolus) insulin.[51,92,103,109] Although the number of baseline daily insulin injections was not always assessable, included study participants all reported conducting fewer than 4 SMBG tests per day at enrollment.[51,92,103,109,110,113,122] In addition to insulin, most participants were concomitantly using glucose-lowering oral medications (e.g., metformin) or injectable glucagon-like peptide-1 (GLP-1) agonists (e.g. semaglutide).[51,92,103,109,110,113,122]

See Appendix B for more information regarding specific study and treatment characteristics.

Table 5. GRADE Summary of Findings of CGM vs. No CGM in Adults With T2D on Nonintensive Insulin Regimens

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Change in HbA1c			
N = 802 7 RCTs[51,92,103,109,110,113,122]	CGM use resulted in a small, but statistically significant, reduction in HbA1c from baseline. At final follow-up (range, 12 to 52 weeks), CGM use was associated with a significant reduction in HbA1c compared with no CGM (pooled MD, −0.27%; 95% CI, −0.46 to −0.08; *P* = .005). However, this difference did not meet the threshold for clinical significance (MCID, 0.5% change).	●●●○ Moderate	Downgraded 1 level • 1 for risk of bias (increased risk of selection bias; funding-related COI concerns)
Achievement of Target Hb1c Level			
N = 158 1 RCT[51]	There was no difference between CGM and SMBG groups in the proportion of participants who achieved target HbA1c levels (i.e., 7.0%, 7.5%) at 12 or 24 weeks.	●●○○ Low	Downgraded 2 levels[a] • 1 for imprecision (i.e., small sample size, wide CIs) • 1 for indirectness (i.e., use of nontherapeutic CGM)
Quality of Life			
Diabetes-related QoL N = 503 4 RCTs[51,92,103,110]	There was no clear association between CGM and improved diabetes-related QoL. There were mixed diabetes-related QoL findings, indicating either no difference between study groups or improved QoL with CGM vs. no CGM (i.e., SMBG), across a range of validated measurement scales and follow-up timepoints (range, 12 to 52 weeks). Where statistically significant differences were reported, it was generally unclear whether the differences were clinically meaningful due to a lack of established MCIDs. Across all study groups, mean follow-up scores where indicative of low diabetes distress levels and high treatment-related satisfaction.	●●○○ Low	Downgraded 2 levels • 1 for risk of bias (i.e., increased risk of selection bias, funding-related COI concerns) • 1 for inconsistency (i.e., inconsistent direction of effect across and within studies)
General QoL N = 234 2 RCTs[51,110]	There was no clear association between CGM and improved general QoL. There were mixed general QoL findings, indicating either no difference or improved QoL with CGM across multiple	●●○○ Low	Downgraded 2 levels • 1 for inconsistency (i.e., inconsistent direction of effect across and within studies)

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
	validated measurement scales. One study found no between-group differences at 24 weeks on 2 validated general QoL scales. Comparatively, 1 study observed no between-group difference in general QoL at 24 weeks but reported significantly higher QoL with CGM vs. SMBG at 52 weeks (*P* =.04); however, it was unclear whether this difference was clinically meaningful due to lack of an established MCID. All study groups had mean follow-up scores indicating overall high perceived well-being.		• 1 for indirectness (i.e., use of nontherapeutic CGM)

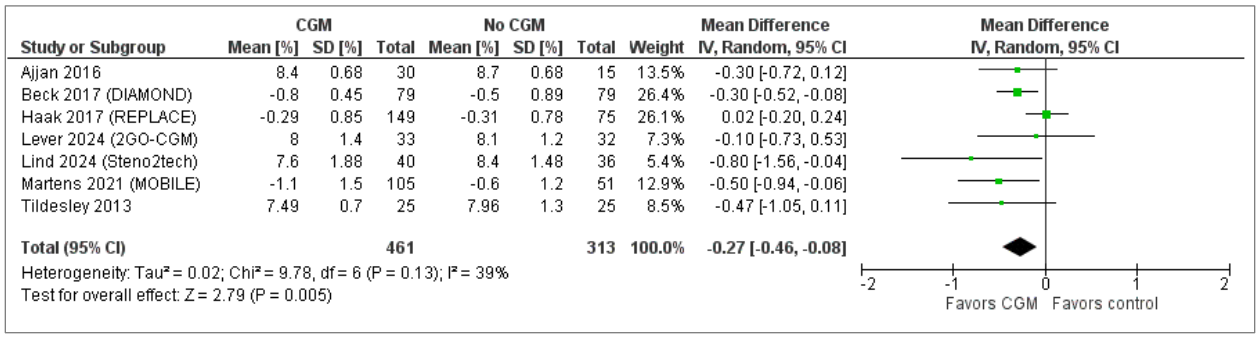
Notes. See Appendix G, Table G1 for the complete GRADE profile. [a] *Inconsistency not assessed as only a single study reported this outcome.*

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; COI: conflict of interest; GRADE: Grading of Recommendations, Assessment, Development, and Evaluations; HbA1c: glycated hemoglobin; MCID: minimal clinically important difference; MD: mean difference; QoL: quality of life; RCT: randomized controlled trial; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Change in HbA1c

Seven RCTs of adults with T2D on nonintensive insulin (N = 802) reported change in HbA1c outcomes at final follow-up.[51,92,103,109,110,113,122] All 7 studies had sufficient planned CGM use (i.e., ≥ 4 weeks) to be included in a pooled analysis comparing CGM with no CGM at final follow-up (Figure 2).

Figure 2. Change in HbA1c[a]: CGM vs. No CGM at Final Follow-up in Adults with T2D on Nonintensive Insulin Regimens[41,42]



Notes. Meta-analysis and corresponding forest plot prepared using Review Manager, version 5.4.1. [a] *Mean HbA1c values at follow-up were compared when mean change from baseline by study group was not available.*

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; IV: inverse variance; SD: standard deviation.

Among these studies, mean baseline HbA1c levels ranged from 8.2% to 10.0% in the CGM groups and from 8.5% to 9.7% in the no-CGM control groups. At the final follow-up (range, 12 to 52 weeks) the CGM groups experienced mean HbA1c reductions ranging from 1.8% to 0.6% compared with a 1.6% reduction to no change in the control groups (note: change values calculated by Center staff when not directly reported). When these results were pooled in a meta-analysis (Figure 2), CGM use was associated with a significant 0.27% reduction (95% CI, −0.46 to −0.08; *P* = .005) in HbA1c compared with no CGM.[51,92,103,109,110,113,122] Although the pooled difference was statistically significant, it did not meet the accepted threshold for a clinically meaningful change in HbA1c (i.e., an increase or decrease of 0.5%).

There was moderate heterogeneity for the pooled finding (i.e., I^2 = 39%), but no differences in direction of effect were observed during sensitivity testing in which each study was systematically removed and added back into the meta-analysis.

Achieving or Maintaining Target HbA1c Level

One RCT, the DIAMOND trial (N = 158),[51] compared the proportion of participants who achieved clinically meaningful HbA1c thresholds using CGM or SMBG. After adjusting for baseline HbA1c levels, there were no differences in proportion of individuals randomized to CGM or SMBG who achieved prespecified HbA1c targets (i.e., < 7.0% or < 7.5%) at 12 or 24 weeks of follow-up (Appendix C, Table C1).[51]

Hypoglycemia Requiring Intervention

Five RCTs (N = 700; follow-up range, 12 to 52 weeks)[51,103,109,110,113] reported the comparative incidence of severe hypoglycemic events requiring medical intervention (e.g., oral glucose

administration from a third party). Three studies (DIAMOND, 2GO-CGM, Steno2tech) reported no incidence of severe hypoglycemia.[51,109,110] Two studies (REPLACE, MOBILE) reported a total of 6 events occurring across 399 participants (i.e., ≤ 2% with a qualifying event in any study group) and none of the events were deemed related to CGM use.[103,113] No between-group tests of significance were reported.

Quality of Life

Four RCTs comparing CGM with SMBG in adults with T2D on nonintensive insulin reported quality of life (QoL) outcomes using validated assessment tools.[51,92,103,110] Reported QoL assessment scales measured diabetes-related wellness and functioning (e.g., Diabetes Distress Scale) and general well-being (e.g., World Health Organization well-being index). See Table 3 for more information about QoL measurement scale interpretation, and see Appendix C, Table C3 for complete QoL outcomes data in this population.

Diabetes-Related QoL

Four RCTs (N = 503; follow-up range, 12 to 52 weeks) reported mixed diabetes-related QoL findings across a range of validated measurement scales.[51,92,103,110]

Two studies (N = 203) found no between-group differences in any reported diabetes-related QoL measure.[51,92] The DIAMOND trial (N = 158) observed no significant between-group differences at the final 24-week follow-up in the Diabetes Distress Scale (DDS), the Hypoglycemia Fear Survey (HFS), and the Hypoglycemia Confidence Survey (HCS). While there were no differences between groups, participants in each group (rtCGM and SMBG) reported low levels of diabetes distress, low levels of hypoglycemia-related fear, and generally high levels of confidence in ability to prevent and manage hypoglycemia (Appendix C, Table C3).[51] Ajjan and colleagues (N = 45) observed no difference between the isCGM and SMBG study groups on the Diabetes Treatment Satisfaction Questionnaire (DTSQc) at 12 weeks, although scores indicated overall treatment satisfaction was high in both groups (13.4 vs. 13.5 points; *P* = .94).[92]

The REPLACE trial (N = 242) reported better diabetes-related QoL with CGM across all assessed measures at 24 weeks.[103] Compared with SMBG, participants randomized to isCGM reported reduced worry related to diabetes as indicated by DQoL scores (−0.2 vs. 0.0 points; *P* = .026) and significantly higher treatment satisfaction as indicated by mean DTSQc scores (13.1 vs. 9.0 points; *P* < .001). Although the observed between-group differences were statistically significant, the difference in DQoL scores did not meet the MCID (i.e., 3 to 4 points) and it is unclear whether the difference in DTSQc scores was clinically significant as no established MCID was identified.[103]

Steno2tech (N = 76) found mixed diabetes-related QoL outcomes at 52 weeks.[110] Compared with SMBG, participants randomized to rtCGM were significantly more satisfied with their diabetes treatment, as indicated by follow-up DTSQc scores (14.4 vs. 6.4 points; MD, 8.0 points; 95% CI, 4.7 to 11.4; *P* < .001), but it is unclear whether this difference also was clinically significant due to lack of an established MCID.[110] Comparatively, there was no significant between group difference in diabetes-related distress, as indicated by DDS scores (1.8 vs. 2.2; *P* = .06), or fear of hypoglycemia on the HFS-II scale (5.6 vs. 5.3 points; *P* = .86); scores in both study groups indicated generally low levels of distress and fear.[110]

General QoL

Two RCTs (N = 234) reported mixed general QoL findings.[51,110] In the DIAMOND trial (N = 158), participants in both study groups reported low burden of health problems and high overall well-being as evidenced by high scores on the Euro Quality of Life 5 Dimension ([EQ-5D]; 0.82 points in each group) and 5-item World Health Organization Well-being Index ([WHO-5]; 16 vs. 17 points) at 24 weeks; however, there were no between group differences in scores for either measure (as indicated by authors; *P* values were not reported).[51] In contrast, rtCGM participants in the Steno2tech trial (N = 76) had significantly higher WHO-5 scores (indicating increased well-being) compared with SMBG participants at 52 weeks (MD, +7.6 points; 95% CI, 0.3 to 14.9; *P* = .04), although it is unclear whether this difference was clinically significant as no MCID was identified.[51,110]

Mortality

Very few events occurred in the 2 RCTs (N = 333) that reported on mortality.[51,113] In the 24-week DIAMOND trial (N = 158), 1 participant in the rtCGM group died after experiencing a myocardial infarction, which investigators deemed unrelated to CGM use, and no deaths were reported among the SMBG group.[51] In the MOBILE trial (N = 175), no deaths were reported in either study group (rtCGM vs. SMBG) during the 32-week follow-up.[113]

Adults With T2D on Oral Hypoglycemic Medications

We identified 6 RCTs in 8 publications (N = 560; follow-up range, 12 to 52 weeks) that assessed CGM among adults with T2D on OHM therapy, but not on insulin.[95,105,114,117,118,120,121,124] Table 6 shows mean baseline ages across study groups ranged from 50.7 to 60.9 years, mean HbA1c levels ranged from 6.6% to 8.7%, and mean diabetes duration ranged from 9.2 to 13.9 years. Only 1 study included participants from the US (N = 70).[117] Two studies were assessed as low-risk of bias,[120,124] 2 were moderate,[95,118] and 2 were high.[114,117]

Three of the OHM studies assessed rtCGM[114,117,120] and 3 assessed isCGM[95,118,124]; only 1 study of rtCGM used a nontherapeutic device.[120] The intensity of CGM use was varied. Two studies instructed participants to use CGM for the full length of the study period,[95,120] and 4 studies assessed episodic or tapering CGM use of less than half the study period (range, 1 to 12 weeks).[114,117,118,124] All but 2 studies compared CGM with standard SMBG. One study compared CGM with a brief self-monitoring education intervention (i.e., attention control)[95] and 1 used blinded CGM as the comparator.[120]

The intensity and type of OHM regimens varied across studies. Most studies in this cohort required participants to be using at least 1 noninsulin OHM at enrollment,[95,118,120] and 2 studies required participants to be using 2 or more classes of OHM.[114,117] One study required only that participants were not being treated with insulin but was included in this category as 97% of participants were on some form of OHM therapy (type unspecified).[124] When specified, the most common types of OHM were biguanides (e.g., metformin), sulfonylureas, sodium-glucose cotransporter-2 (SGLT-2) inhibitors, and dipeptidyl peptidase 4 (DPP-4) inhibitors. Notably, in 2 recently published studies, some participants were also using injectable GLP-1 agonists.[95,118]

Table 6. GRADE Summary of Findings: CGM vs. No CGM in Adults With T2D on Oral Hypoglycemic Medication

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Change in HbA1c			
N = 560 6 RCTs[95,114,117,118,120,124]	There was no consistent difference in change in HbA1c from baseline with CGM versus other non-CGM monitoring methods. There was no between-group difference for change in HbA1c from baseline in a meta-analysis of 5 RCTs (pooled MD, −0.18%; 95% CI, −0.45 to 0.09; *P* = .20). Findings were significant (favoring CGM) when the GLiMPSE trial was removed during sensitivity testing, but the reasons for this effect are unclear. The single study not included in MA (N = 61) found mixed results between the 2 CGM study arms when compared with SMBG at 24 weeks.	●●○○ Low	Downgraded 2 levels • 1 for risk of bias (i.e., lack of reporting on study group allocation procedures, funding-related COI concerns, differential losses to follow-up, possible selection bias due to use of run-in periods) • 1 for inconsistency (i.e., unexplained heterogeneity)
Achievement of Target Hb1c Level			
N = 70 1 RCT[117]	There was no significant between-group differences in the proportion of individuals randomized to CGM versus no CGM who achieved an HbA1c level below 7.0% or below 7.5%.	●○○○ Very low	Downgraded 3 levels • 1 for risk of bias (i.e., lack of reporting on study group allocation procedures, funding-related COI concerns) • 1 for indirectness (i.e., limited CGM use relative to length of study follow-up) • 1 for imprecision (i.e., small study size)
Quality of Life			
Diabetes-related QoL N = 277 3 RCTs[95,114,124]	There was no clear association between CGM and improved diabetes-related QoL. There were mixed diabetes-related QoL results reported across 6 validated measurement scales at final follow-up (range, 16 to 52 weeks); each scale was used only by a single study. Two studies found no-between group differences in any reported QoL construct and scale including diabetes distress, perceived diabetes status, and diabetes self-management efficacy. In comparison, 1 study reported	●○○○ Very low	Downgraded 3 levels • 1 for risk of bias (i.e., lack of reporting on study group allocation procedures, high and differential LTFU, funding-related COI concerns)

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
	improved diabetes treatment satisfaction with CGM vs. SMBG. All study groups generally reported within-group improvements on all QoL scales, but MCIDs were not widely available so clinical significance was not assessable.		• 1 for indirectness (i.e., limited overlap in QoL outcomes and scales, limited CGM use) • 1 for imprecision (i.e., wide confidence intervals, lack of MCIDs)
General QoL N = 193 1 RCT[118]	No clear association between CGM and improved diabetes-related QoL. There were mixed results on 2 measures of general QoL at 52 weeks in the GLiMPSE trial. Due to decreases in QoL scores in the SMBG group, the CGM had higher overall well-being on the EQ-5D scale, despite no change in scores (0.00 vs. −0.07 points; *P* = .01). Comparatively, there was no difference in on the EQ-VAS scale, although both groups reported improvements from baseline (+3.7 vs. +4.1 points; *P* = .85)	●○○○ Very low	Downgraded 3 levels • 1 for risk of bias (i.e., possible imbalances in key baseline characteristics, potential selection bias, author-related COI concerns) • 1 for imprecision (i.e., single study) • 1 for other reasons (i.e., mixed results on 2 related scales measuring overall well-being)

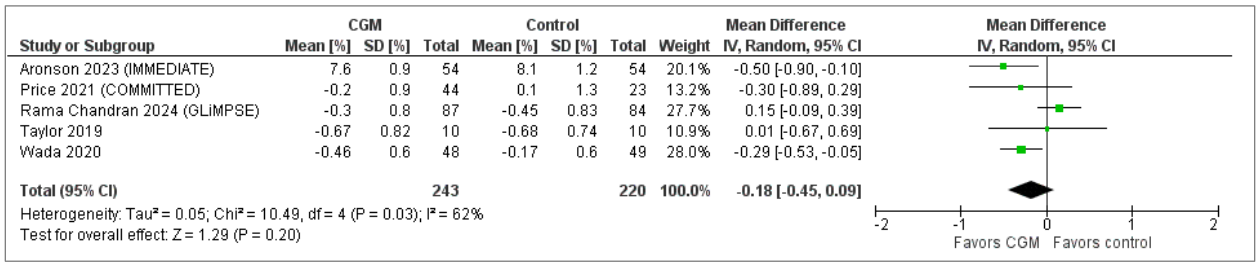
Notes. See Appendix G, Table G2 for the complete GRADE profile.

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; COI: conflict of interest; EQ-5D: EuroQol 5-Dimension Scale; EQ-VAS: EuroQol Visual Analogue Scale; HbA1c: glycated hemoglobin; LTFU: long-term follow-up; MA: meta-analysis; MCID: minimal clinically important difference; MD: mean difference; OHM: oral hypoglycemic medications; QoL: quality of life; RCT: randomized controlled trial; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Change in HbA1c

Six RCTs of adults with T2D on OHM (N = 560) reported change in HbA1c outcomes.[95,114,117,118,120,124] Five of these had sufficient planned CGM use (i.e., ≥ 4 weeks) to be included in a pooled analysis comparing CGM with no CGM at final follow-up (Figure 3)[95,117,118,120,124]; results from the single study not included in the pooled estimate are reported narratively.[114]

Figure 3. Change in HbA1c: CGM vs. No CGM at Final Follow-up in Adults With T2D on Oral Hypoglycemic Medications, but Not on Insulin[41,42]



Notes. Meta-analysis and corresponding forest plot prepared using Review Manager, version 5.4.1. [a] Mean HbA1c values at follow-up were compared when mean change from baseline by study group was not available.

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; IV: inverse variance; SD: standard deviation; T2D: type 2 diabetes.

Among the studies eligible for meta-analysis, mean baseline HbA1c levels ranged from 6.6% to 8.5% in the CGM groups and from 7.1% to 8.7% in the no-CGM control groups.[95,117,118,120,124] At the final follow-up (range, 12 to 24 weeks) the CGM groups experienced mean HbA1c reductions ranging from 0.9% to 0.2% compared with a 0.7% reduction to a 0.1% increase in the control groups.[95,117,118,120,124] When these results were meta-analyzed (Figure 3), there was ultimately no statistically significant difference between CGM and no CGM for change in HbA1c (pooled MD, −0.18%; 95% CI, −0.45 to 0.09; *P* = .20).[95,117,118,120,124]

There was a high level of heterogeneity for the pooled analysis (I^2 = 62%) and the overall result was significant (favoring CGM) when the GLiMPSE trial[118] was removed during sensitivity testing. Although the reasons for this effect are unclear, factors in the GLiMPSE trial such as use of a run-in period to test for likely adherence, combination and intensity of included diabetes medication regimens, study location (Singapore), enhanced diabetes self-management education in both study groups, and a mixed-use CGM protocol (i.e., continuous use for the first 6 weeks followed by intermittent use for 18 weeks) may have contributed to the high heterogeneity.[118]

In the study excluded from the meta-analysis due to insufficient CGM use, Moon and colleagues (N = 61; follow-up, 24 weeks) randomized participants to rtCGM for 1 week (rtCGM-1), CGM for 2 weeks separated by 3 months (rtCGM-2), or an SMBG control group.[114] Baseline HbA1c levels were 8.3%, 8.2%, and 8.1% respectively; at the final 24-week follow-up, both rtCGM groups experienced a 0.6% reduction in HbA1c but the SMBG group did not exhibit any change.[114] As compared with SMBG after adjustment (i.e., age, gender, BMI, waist circumference and baseline time-in-range), the between-group difference for the rtCGM-1 group was not significant (adjusted MD, −0.67%; 95% CI, −1.43 to 0.09; *P* = .08), but the between group difference for the rtCGM-2 group was statistically significant (adjusted MD, −0.68; 95% CI, −1.23 to −0.13; *P* = .02)

and exceeded the 0.5% MCID. These findings align with the mixed results observed in the meta-analysis.

Achieving or Maintaining Target HbA1c Level

The COMMITTED trial (N = 70)[117] compared the proportion of participants who achieved clinically meaningful HbA1c thresholds using episodic rtCGM (i.e., 10 days per month) versus SMBG (Appendix C, Table C5). At 12 weeks of follow-up, there were no statistically significant between-group differences in the proportion of individuals randomized to episodic rtCGM versus SMBG who achieved an HbA1c level below 7.0% (18.2% vs. 8.7%; *P* = .26) or below 7.5% (34.1% vs. 17.4%; *P* = .12).[117]

Hypoglycemia Requiring Intervention

Four RCTs (N = 440)[95,114,117,118] reported the incidence of severe hypoglycemia requiring third-party intervention (Appendix C, Table C6). In the COMMITTED and GLiMPSE trials, no severe hypoglycemic events occurred in either study group.[117,118] In the 16-week IMMEDIATE trial, 1 event occurred in the control group,[95] and in the 24-week study conducted by Moon and colleagues, a single event occurred in 1 of the CGM intervention arms and was not attributed to use of the CGM device.[114] No tests of significance were reported.

QoL

Four RCTs of adults with T2D on OHM therapy reported QoL outcomes using a range of validated measurement scales.[95,114,118,124] See Table 3 for more information about QoL measurement scale interpretation and see Appendix C, Table C7 for complete QoL outcomes data in this population.

Diabetes-Related QoL

Three RCTs (N = 277; follow-up range, 16 to 52 weeks)[95,114,124] reported mixed results on 6 measures of diabetes-related QoL. There was no measurement scale overlap between studies.

Two studies observed no differences (CGM vs. no CGM) in diabetes-related QoL at the final study assessment.[95,114]

- 16-week IMMEDIATE trial (N = 116) had no significant between-group differences (isCGM vs. brief education) in diabetes-related distress or diabetes self-management efficacy as indicated by change scores on the DDS and LMC Skills, Confidence, and Preparedness Index (SCPI), respectively.[95] However, both study groups reported clinically meaningful reductions in diabetes distress (−0.3 vs. −0.4 points; MCID, 0.25 points) and improved self-management efficacy (an increase of 0.8 points in each group; MCID not identified).[95] Mean follow-up scores indicated both study groups were experiencing low to moderate distress (2.1 vs. 1.9 points) and had moderate perceived self-management efficacy (6.1 points in each group).[95]
- 24-week trial conducted by Moon and colleagues (N = 61) showed no significant between-group differences (rtCGM [1 or 2 weeks of CGM use] vs. SMBG) in perceived diabetes status as measured by the Korean version of the Appraisal of Diabetes Scale (ADS-K) or in diabetes self-management efficacy as measured by Korean versions of the Diabetes Management Self-Efficacy Scale (K-DMSES) and Summary of Diabetes Self-Care Activities (SDSCA-K).[114] All study groups reported improved QoL for each of the 3 measures as indicated by change scores, but it is unknown whether these improvements were clinically meaningful since we

did not identify corresponding MCIDs.[114] Mean baseline and follow-up scores were not reported, so participants' QoL levels could not be assessed.

Comparatively, 1 study reported improved diabetes-related QoL with CGM, versus no CGM, at the final study assessment.[124]

- CGM participants in the 24-week RCT conducted by Wada and colleagues (N = 100) reported greater diabetes treatment satisfaction compared with SMBG controls as indicated by significantly higher follow-up scores on the DTSQs (MD, 3.4 points; 95% CI, 1.9 to 5.0; $P < .001$)[124]; it is unclear whether this difference was clinically meaningful due to lack of an identified MCID. Scores were balanced at baseline and the observed difference at follow-up appeared to be driven by increasing satisfaction with treatment convenience and flexibility in the CGM group and decreasing satisfaction with the frequency of hyperglycemia in the SMBG group.[124] However, follow-up scores in both groups indicated high levels of treatment satisfaction overall (34.9 vs. 31.4 points).[124]

General QoL

The GLiMPSE trial (N = 193) reported mixed results on 2 measures of general QoL at the final study assessment.[118] The isCGM group reported no change in overall QoL on the provider-delivered EQ-5D questionnaire at 52 weeks, compared with a reported decrease in the SMBG group (+0.001 vs. −0.07 points; $P = .01$). Comparatively, study groups did not differ when asked to rate their overall health on the self-reported EQ Visual Acuity Scale (EQ-VAS), although both groups reported improvements from baseline (+3.7 vs. +4.1 points; $P = .85$).[118] Mean baseline and follow-up scores were not reported, so participants' QoL levels could not be assessed.

Mortality

No included RCT reported mortality outcomes.

Adults With T2D Not on Insulin or Oral Hypoglycemic Therapies

We did not identify any eligible RCTs evaluating CGMs in adults with T2D not on insulin or OHM regimens.

Adults With T2D on Mixed Nonintensive Hypoglycemic Therapies

We identified 5 RCTs in 7 publications (N = 450; follow-up range, 12 to 52 weeks) that assessed CGM in adults with T2D on mixed nonintensive hypoglycemic treatments.[92,93,97,100,115,123,125] As shown in Table 7, mean baseline ages across study groups ranged from 54.6 to 63 years and mean HbA1c levels ranged from 7.8% to 11.5%; mean diabetes duration was not consistently reported. Three studies included participants from the US (N = 244).[97,115,123] One study was rated low risk of bias,[93] 1 was moderate,[97] and 3 were high.[115,123,125]

Among the mixed-regimen studies, 3 assessed rtCGM[97,123,125] and 2 assessed isCGM[93,115]; 2 of the rtCGM studies used nontherapeutic devices.[123,125] The intensity of CGM use was varied with 2 studies instructing participants to use CGM for the full length of the primary study assessment period,[93,97] and 4 studies assessed episodic or tapering CGM use that amounted to less than half of the study period (range, 9 days to 8 weeks).[115,123,125] All studies compared CGM with standard SMBG, except for the GOOD-ER trial which randomized control participants to "usual care" in the community setting after discharge from the emergency department.[115]

All mixed-regimen studies enrolled participants on any nonintensive hypoglycemic intervention. Three studies had nearly equivalent proportions of participants on insulin or OHM therapies[93,97,125]; 1 study included participants using basal insulin (33%), OHM (60%), or lifestyle management (7%) regimens[123]; and 1 study did not report sufficient information to understand the full profile of hypoglycemic therapies being used by study participants at baseline.[115] None of the studies in this category stratified outcome results by treatment regimen.

Table 7. GRADE Summary of Findings: CGM vs. No CGM in Adults With T2D on Mixed Nonintensive Hypoglycemic Regimens

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Change in HbA1c			
N = 450 5 RCTs[93,97,115,123,125]	There was no consistent difference in change in HbA1c from baseline with CGM versus other non-CGM monitoring methods. At final study follow-up (range, 12 to 52 weeks), there were no between-group differences in change in HbA1c from baseline in 4 studies. Comparatively, CGM use was associated with a statistically and clinically greater reduction in HbA1c than SMBG in 1 study with a higher proportion of insulin users (−1.1% vs. −0.4%; *P* = .004). All CGM groups experienced clinically meaningful reductions in HbA1c levels (i.e., 0.5%) from baseline (range, −0.8% to −5.2%) compared with only 3 of 5 control groups (range, −0.2% to −2.4%).	●○○○ Very low	Downgraded 3 levels • 1 for risk of bias (i.e., insufficient information about study group allocation procedures, high losses to follow-up, industry related funding concerns) • 2 for indirectness (i.e., high heterogeneity in terms of treatment regimen types, limited CGM use in most studies, higher-risk study populations)
Achievement of Target Hb1c Level			
No studies – not assessable			
Quality of Life			
Diabetes-related QoL N = 271 3 RCTs[93,115,123]	There were no between-group differences at final study assessments (range, 12 to 52 weeks) in perceived diabetes burden, diabetes-related distress, and treatment satisfaction.	●○○○ Very low	Downgraded 3 levels • 1 for risk of bias (i.e., insufficient information about study group allocation procedures, high LTFU) • 2 for indirectness (populations mostly high risk, limited overlap in QoL scales, limited CGM use across studies)
General QoL N = 141 1 RCT[93]	There was no difference in overall QoL at 12 weeks among individuals using isCGM vs. SMBG for glycemic management.	●○○○ Very low	Downgraded 3 levels • 1 for indirectness (i.e., limited to patients with recent acute MI) • 1 for imprecision (i.e., small sample size, wide CI)

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
			• 1 for other reasons (i.e., short-term data only, no within-group scores reported)

Notes. See Appendix G, Table G3 for the complete GRADE profile.

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; HbA1c: glycated hemoglobin; isCGM: intermittently scanned continuous glucose monitor(ing); LTFU: long-term follow-up; MI: myocardial infarction; QoL: quality of life; RCT: randomized controlled trial; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Change in HbA1c

Five RCTs (N = 450) reported change in HbA1c levels at the final study assessment (Table 8).[93,97,115,123,125] We did not meta-analyze results for this population group as only 4 studies reported sufficient data for inclusion and, of these, only 2 had planned CGM use of 4 weeks or greater; all results are summarized narratively.

Table 8. Change in HbA1c at Final Study Follow-up in RCTs of Adults With T2D on Mixed Nonintensive Hypoglycemic Regimens

Author, Year Study Name	Time point	CGM Group			Control Group			Between-group Difference	*P* Value
		Group Name	N	Mean (SD)	Group Name	N	Mean (SD)		
Ajjan, 2023[93] LIBERATES	12 weeks[a]	isCGM	69	−2.8% (NR)	SMBG	72	−2.8% (NR)	Adj. MD, 2.5% (95% CI, -2.2 to 2.8)	NR[b]
Bergenstal, 2022[97]	16 weeks	rtCGM	59	-1.1% (1.1)	SMBG	55	-0.8% (0.9)	NR	*P* = .11
O'Connor, 2024[115] GOOD-ER	12 weeks	isCGM	10	-5.2% (3.5)	Usual care	11	-2.4% (3.5)	NR	*P* = .08
Vigersky, 2012[123]	52 weeks	rtCGM	50	-0.8% (1.5)	SMBG	50	-0.2% (1.3)	NR	NR[b]
Yoo, 2008[125]	12 weeks	rtCGM	29	-1.1% (1.2)	SMBG	28	-0.4% (1.1)	NR	*P* = .004

Notes. [a] The LIBERATES trial had a 12-week follow-up for all glycemic outcomes and a 52-week follow-up for long-term health outcomes (e.g., cardiac events). [b] P value not reported, but authors indicated the between-group comparison was not significant.

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; isCGM: intermittently scanned continuous glucose monitor(ing); MD: mean difference; NR: not reported; rtCGM: real-time continuous glucose monitor(ing); SD: standard deviation; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Across the 5 studies mean baseline HbA1c levels ranged from 8.2% to 11.5% in the CGM groups and from 7.9% to 10.6% in the control groups (Appendix B, Table B3).[93,97,115,123,125] As shown in Table 8, all CGM groups experienced clinically meaningful HbA1c reductions (≥ 0.5%) at the final study assessment (range, 12 to 52 weeks) comparatively, and although all control groups (SMBG or usual care) experienced HbA1c reductions, only 3 had clinically meaningful reductions.[93,97,115,123,125]

When compared at final follow-up, there were no significant between-group HbA1c differences in 4 RCTs (Table 8).[93,97,115,123] In comparison, Yoo and colleagues observed a statistically greater reduction in HbA1c at 12 weeks in the rtCGM group compared with the SMBG controls (−1.1% vs. −0.4%; *P* = .004); the unadjusted between-group difference of −0.7% was also clinically significant (≥ 0.5% change).[125] It should be noted that participants in this study had the highest rate of insulin use (59.7%) out of the 5 mixed-regimen studies included in this review.[125]

Achieving or Maintaining Target HbA1c Level

No studies of adults with T2D on mixed nonintensive diabetes treatment regimens reported on the proportion of participants who achieved or maintained a target HbA1c level.

Hypoglycemia Requiring Intervention

Two RCTs reported the incidence of severe hypoglycemia requiring third-party intervention (Appendix C, Table C8).[93,125] The 12-week study conducted by Yoo and colleagues compared a nontherapeutic rtCGM with SMBG, and no severe hypoglycemic events were reported in either group.[125] In the LIBERATES trial (N = 141), 2 participants experienced a hypoglycemic emergency requiring third-party assistance during the 12-week isCGM assessment period (both in the SMBG group); 2 more events occurred (1 in the isCGM group and 1 in the SMBG group) during the follow-up period when the isCGM was no longer being used (study weeks 13 to 52).[93] Between-group tests of significance were not reported.

QoL

Three RCTs of adults with T2D on mixed nonintensive hypoglycemic therapies reported QoL outcomes using a range of validated measurement scales.[93,115,123] See Table 3 for more information about QoL measurement scale interpretation, and see Appendix C, Table C9 for complete QoL outcomes data in this population.

Diabetes-related QoL

Three studies (N = 271) reported diabetes-related QoL in 4 measurement scales.[93,115,123] At the final study assessments (range, 12 to 52 weeks), there were no between-group (CGM vs. no CGM) differences in:

- Perceived diabetes burden, as assessed by the Audit of Diabetes-Dependent Quality of Life (ADDQoL)[93] and Problem Areas in Diabetes (PAID) scales[115,123]
- Diabetes-related stress, as assessed by the DDS[93]
- Diabetes treatment satisfaction, as assessed by the DTSQ[93]

Individual group change scores and mean follow-up scores were largely not reported, so an evaluation of the magnitude of change or overall level of QoL was not assessable.

General QoL

One RCT, the LIBERATES trial (N = 141) assessed overall quality of life with 1 measurement tool, the EQ-5D scale.[93] At the 12-week primary outcome study assessment, there was no between-group difference in EQ-5D scores (MD, -0.004; 95% CI, -0.076 to 0.068).[93] Individual group change scores and mean follow-up scores were not reported, so an evaluation of the magnitude of change or overall level of QoL was not assessable.

Mortality

One RCT, the LIBERATES trial (N = 141), reported on mortality (Appendix C, Table C10).[93] In total, 5 participants died (2 in the isCGM group and 3 in the SMBG group) over the 52-week long-term health outcome follow-up period[93]; between-group tests of significance were not reported for this outcome. Importantly, although the causes of death were not reported, none of the deaths occurred during the initial 12-week study period when the isCGM devices were in use.[93]

Children With T2D (KQ1b) Not on Intensive Insulin Treatment

Children and adolescents younger than age 18 years with T2D not on intensive insulin regimens include individuals who are:

- On nonintensive insulin regimens (i.e., 1 to 3 injections per day)
- On OHMs (e.g., metformin), but not on insulin
- Not on insulin or OHMs

We did not identify any eligible RCTs evaluating the effectiveness or safety of CGMs in children with T2D on nonintensive insulin regimens.

Pregnant People with T2D (KQ1c) Not on Insulin

We did not identify any eligible RCTs evaluating the effectiveness or safety of CGMs in pregnant people with T2D who were not using insulin before or during pregnancy.

Pregnant People with GDM (KQ1d) Not on Insulin

We identified 4 eligible RCTs in 4 publications (N = 343; follow-up range, 4 to 16 weeks) that assessed CGM in pregnant people with GDM who are not using insulin.[94,106,107,112] As shown in Table 9, participants in these studies were newly diagnosed with GDM between 22 and 34 weeks of gestation and had mean baseline maternal ages ranging from 29.9 to 34.5 years.[94,106,107,112] According to GDM standards, baseline HbA1c levels were lower than the adult T2D populations and ranged from 4.9% to 5.9%.[94,106,107,112] Only 1 small study included participants from the US (N = 40).[107] One study was rated as low risk of bias,[112] 1 was rated moderate,[94] and 2 were rated high.[106,107]

Three studies assessed rtCGM[94,106,107] and 1 assessed isCGM[112]; 1 study of rtCGM used a now-discontinued nontherapeutic device.[94] Only 1 of the included GDM studies instructed participants to use their CGM devices for the full length of the study period (4 of 4 weeks),[107] while the other 3 studies assessed episodic or tapering CGM use was less than half of the study period (range, 3 to 7 days to 4 weeks).[94,106,112] Three studies compared CGM with standard SMBG[94,106,112] and 1 used blinded CGM as the comparator.[107]

Although participants in the GDM studies were not using insulin at baseline, some participants in each study received insulin during the study period in response to increasing blood glucose levels or risk of hyperglycemia. In 3 studies, the rate of new insulin use ranged from 17.4% to 31.3% at the final follow-up,[94,106,112] while in the remaining study, 43% of participants were newly using hypoglycemic medications, including insulin, by the final assessment.[107]

Table 9. GRADE Summary of Findings: CGM vs. No CGM in Pregnant People With GDM Not on Insulin Therapy

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
Change in HbA1c			
N = 270 3 RCTs[94,107,112]	CGM use was not associated with a significantly lower HbA1c at the end of pregnancy (4 to 16 weeks of follow-up) compared with non-CGM controls.	●●○○ Low	Downgraded 2 levels • 1 for risk of bias (i.e., unclear group allocation procedures and reliance on completers-only analyses) • 1 for indirectness (i.e., nontherapeutic CGM models and limited CGM use)
Achievement of Target Hb1c Level			
No studies – not assessable			
QoL			
No studies – not assessable			
Severe Perinatal Morbidity and Mortality			
N = 343 4 RCTs[94,106,107,112]	No significant between-group differences in the incidence of severe perinatal outcomes. At the end of pregnancy (follow-up range, 4 to 16 weeks), very few severe perinatal events occurred and there were no statistically significant between-group differences in most reported outcomes, including: • Large for gestational age • Low birth weight • NICU admission • Perinatal death • Preeclampsia • Preterm birth • Shoulder dystocia • Unplanned cesarean delivery Results for macrosomia were mixed: 3 of 4 RCTs (N = 243) found no difference in incidence between the CGM groups and no-CGM controls, whereas 1 study (N = 100) found reduced incidence of macrosomia in the CGM	●○○○ Very low	Downgraded 3 levels • 1 for risk of bias (i.e., unclear randomization and group allocation procedures, unclear or high losses to follow-up) • 1 for indirectness (i.e., nontherapeutic CGM models, limited CGM use) • 1 for imprecision (i.e., few events, small sample sizes for rare events, wide CIs)

Number of Participants (N) Number of RCTs	Findings	Certainty of Evidence	Rationale
	group. However, no studies were powered to detect clinically meaningful differences in perinatal outcomes.		

Notes. See Appendix G, Table G4 for the complete GRADE profile.

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; GDM: gestational diabetes; HbA1c: glycated hemoglobin; NICU: neonatal intensive care unit; RCT: randomized controlled trial.

Change in HbA1c

Three studies (N = 270)[94,107,112] reported relevant change in HbA1c outcomes (Appendix C, Table C11). Study groups were balanced in baseline HbA1c levels across the 3 studies and there were no significant between-group differences in mean or median HbA1c at the final follow-up assessments (range, 4 to 16 weeks).[94,107,112]

Notably, participants in the 2 largest studies (N = 230)[94,112] were instructed to use their CGM devices intermittently and had total use durations ranging from 3 days to 4 weeks out of 12- to 16-weeks of follow-up.

Achieving or Maintaining Target HbA1c Level

No studies of pregnant people with CGM not on insulin regimens reported on the proportion of participants who achieved or maintained a target HbA1c level.

Hypoglycemia Requiring Intervention

No studies of pregnant people with CGM not on insulin regimens reported the incidence of severe hypoglycemic events that required intervention from another person.

QoL

No studies of pregnant people with CGM not on insulin regimens reported QoL outcomes from validated scales.

Mortality

No studies of pregnant people with CGM not on insulin regimens reported the incidence of maternal deaths.

Severe Perinatal Morbidity and Mortality

Four RCTs (N = 343)[94,106,107,112] looked at the incidence of selected severe perinatal outcomes among pregnant people with GDM who were randomized to CGM or no-CGM comparators (Appendix C, Table C12). At the end of pregnancy (follow-up range, 4 to 16 weeks), very few severe perinatal events occurred and there were no statistically significant between-group differences in most reported outcomes, including:

- Large for gestational age[107,112]
- Low birth weight[94]
- NICU admission[94,106,107]
- Perinatal death (i.e., intrauterine fetal death or neonatal death before hospital discharge)[94,106]
- Preeclampsia[107]
- Preterm birth[94,106,107]
- Shoulder dystocia[94,107]
- Unplanned cesarean delivery[94,106,107,112]

Results for macrosomia were mixed. One low-RoB study, the FLAMINGO trial (N = 100; 12 to 16 weeks follow-up), observed significantly higher incidence of macrosomia in the SMBG controls compared with participants randomized to isCGM (20% vs. 4%; OR, 5.6 [95% CI, 1.2 to 27.2]; $P = .03$).[112] Comparatively, 3 RCTs (N = 243; 4 to 16 weeks of follow-up) found no difference in the incidence of macrosomia between the CGM groups and no-CGM controls.[94,106,107] However,

considering none of the studies were powered to detect clinically meaningful differences in perinatal outcomes (including macrosomia), limited CGM exposure in the intervention groups (range, 3 days to 4 weeks), and an apparent lack of corresponding increases in deleterious end outcomes (e.g., unplanned cesarean deliveries) in the FLAMINGO study, we assessed macrosomia as having the same certainty level and direction of effect as the other perinatal outcomes (i.e., very-low confidence of no difference).

Device-Related Safety (KQ2)

Safety Outcomes Reported in RCTs

Since CGM device mechanics do not vary by treatment regimen or diabetes type, we analyzed device-related safety across all RCTs included in this review. Qualifying adverse events (AE) were those explicitly assessed by study investigators as reasonably resulting from use of a CGM and included events experienced during any prestudy assessment periods in which all participants wore a CGM device.

The incidence of CGM-related AE was reported in 12 of 22 included RCTs (Appendix D, Table D1).[92-94,103,107,109,110,114,117,124,125] All reported device-related AEs (N = 64; range, 0 to 17 per study arm) were sensor insertion site-related problems of mild to moderate intensity (e.g., skin irritation, bruising, pain, swelling), which generally were treated with topical antihistamines or by moving the sensor to a different site on the body.[92-94,103,107,109,110,114,117,124,125] In contrast, no reported serious AEs (e.g., hospitalizations, infections, hypoglycemia, diabetic ketoacidosis) were ultimately attributed to CGM use.[92-94,103,107,109,110,114,117,124,125] Only 1 study, a pilot RCT of rtCGM use in pregnant individuals with GDM (N = 40),[107] reported study discontinuations due to device-related AE. After randomization, 7 participants (3 in the rtCGM group and 4 in the blinded CGM group) dropped out due to sensor-related skin irritation, while 6 participants who also reported skin irritation continued to the end of the assessment period after the sensor was inserted in a different part of the body.[107]

CGM-Related Events Reported in the FDA MAUDE Registry

We queried the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database, a registry of medical device reports from manufacturers and users, for CGM-related AE reported from January 2019 through November 2024 (see Appendix M). We excluded reports from devices currently unavailable in US markets (e.g., Dexcom G5), those associated with an insulin pump malfunction, and those with an active product recall (reported below).

Our query of MAUDE returned 649 results and included reports for the following devices:

- Dexcom G6, G7, and Stelo
- Abbot FreeStyle Libre 2 Plus and 3 Plus
- Medtronic MiniMed Guardian 3 and 4
- Senseonics Eversense

The device reports largely documented sensor-related issues such as insertion site symptoms (e.g., rash, pain, infection), premature detachment, failure to connect with the receiver, and inaccurate blood glucose readings. Reports of serious AEs (e.g., severe hypoglycemia) were rare; 2 deaths were reported but it was unclear from the database information whether these events

were related to CGM use (i.e., records only reported that the patient was deceased, but not how a CGM device was involved).

Device Recalls

We searched the FDA Medical Device Recalls database for open CGM-related recalls. Open recalls for discontinued devices or those posted more than 2 years ago without resolution were excluded. Using these criteria, we identified open 5 eligible open recalls of CGM systems currently available in US markets.

Four recalls were categorized as Class 1, the most serious type of recall, indicating reasonable probability of serious injury or death.

- In April 2023, the FDA issued Class 1 recalls of handheld reader devices for the Abbott FreeStyle Libre,[126] FreeStyle Libre 14 day,[127] and FreeStyle Libre 2 Flash Glucose Management Systems[128] due to risk of extreme heat and fire from rechargeable lithium-ion batteries when not properly stored or charged. At the time of the recall, 88 events including 7 fires and 1 nondeath injury has been reported.[126-128] Abbott Diabetes Care, Inc. estimates this recall affects nearly 3 million readers issued since 2017.[126-128]
- In July 2024, the FDA issued a Class 1 recall of Abbott FreeStyle Libre 3 sensors due to reported events of inaccurately high glucose values.[129] These sensor errors could increase the risk of hypoglycemia by causing users to take higher doses of insulin than needed or could delay recognition of existing hypoglycemia.[129] Abbott Diabetes Care, Inc. estimates this recall affects approximately 8,000 sensors.[129] Users of FreeStyle Libre 3 systems were issued notices of the recall in July with instructions to check sensor serial numbers.[129]

One recall was categorized as Class 2, indicating an increased possibility of temporary or medically reversible adverse events.

- In February 2024, the FDA issued a Class 2 recall of Medtronic MiniMed Guardian 4 sensors due to a lot manufactured with overly thick glucose oxidase layers, which could cause incorrect sensor glucose readings.[130] The FDA estimates use of these sensors could result in potential effects from user inconvenience to hyperglycemia or hypoglycemia due to over- or under-delivery of insulin.[130] Medtronic MiniMed estimates this recall affects approximately 115,000 sensors.[130] Recall notices were sent to users with instructions to check the lot numbers and discard affected sensors.[130]

Subgroups (KQ3)

We assessed all comparative effectiveness and safety outcomes for evidence of differential subgroup effects by key demographic and clinical characteristics. We identified several subgroup analyses, all of which assessed differences in change in HbA1c from baseline; we did not identify subgroup analyses for any other outcome of interest (e.g., QoL, severe hypoglycemia).

Subgroup evidence is reported by the demographic or clinical variables enumerated in KQ 3 (see the Methods section) and then by relevant subpopulation.

Age (KQ3a)

Four RCTs reported subgroup analyses of change in HbA1c by baseline age (Appendix E, Table E1). Overall, age did not appear to have a strong or consistent association with the effectiveness of CGM use on changes in HbA1c; findings were mixed.

Three RCTs were conducted in adults with T2D on nonintensive insulin regimens.[51,103,113]

- In the 24-week DIAMOND trial of rtCGM use in US adults with T2D on prandial insulin, there were no statistically significant subgroup differences according to baseline age (44 years vs. 45 to 59 years vs. ≥ 60 years).[51,98]
- In the 32-week MOBILE trial of rtCGM use in US adults with T2D on once-daily or twice-daily basal insulin injections, no statistically significant subgroup interaction was found according to baseline age (< 65 years vs. ≥ 65 years).[96,99,113]
- In the 24-week REPLACE trial of isCGM use in European (i.e., UK, France, Germany) adults with T2D on insulin therapy, participants aged younger than 65 years randomized to isCGM experienced a significantly greater reduction in mean HbA1c at 24 weeks compared with 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).

One RCT was conducted in adults with T2D on OHM therapy.[118]

- In the 24-week GLiMPSE trial of isCGM vs. SMBG conducted among a multiethnic cohort of Singapore adults with poorly controlled T2D on oral glucose-lowering medications, no statistically significant subgroup interaction was found according to baseline age (< 60 years vs. ≥ 60 years).

No age-related subgroups were reported for any other outcome or review population.

Gender (KQ3b)

One RCT, conducted among adults with T2D on OHM therapy, reported change in HbA1c subgroups by gender (Appendix E, Table E2).[118] Overall, gender did not appear to have a strong or consistent association with the effectiveness of CGM use on changes in HbA1c.

- In the 24-week GLiMPSE trial of isCGM vs. SMBG conducted among a multiethnic cohort of Singapore adults with poorly controlled T2D on oral glucose-lowering medications, no statistically significant subgroup interaction was found according to sex or gender (male vs. female).

No sex or gender-related subgroups were reported for any other outcome or review population.

Race and Ethnicity (KQ3c)

Two RCTs reported subgroup analyses of change in HbA1c by race and ethnicity (Appendix E, Table E3).[113,118] Overall, race or ethnicity did not appear to have a strong or consistent association with the effectiveness of CGM use on changes in HbA1c.

One RCT was conducted in adults with T2D on nonintensive insulin regimens.[113]

- In the 32-week MOBILE trial of rtCGM use in US adults with T2D on once-daily or twice-daily basal insulin injections, no statistically significant subgroup interaction was found according to racial or ethnic identity (White vs. non-White).[96,99,113]

One RCT was conducted among adults with T2D on OHM therapy.

- In the 24-week GLiMPSE trial of isCGM vs. SMBG conducted among a multiethnic cohort of Singapore adults with poorly controlled T2D on oral glucose-lowering medications, no statistically significant subgroup interaction was found according to racial or ethnic identity (Chinese vs. non-Chinese).

No race and ethnicity-related subgroups were reported for any other review population.

Comorbidities (KQ3d)

No RCTs reported prespecified subgroup analyses by comorbidity status (e.g., hypertension).

Severity of Diabetes (KQ3e)

Four RCTs reported subgroup analyses of change in HbA1c by baseline diabetes severity (Appendix E, Table E4).[51,113,118,124] Overall, baseline HbA1c did not appear to have a strong or consistent association with the effectiveness of CGM use on changes in HbA1c.

Two RCTs were conducted in adults with T2D on nonintensive insulin regimens.[51,113]

- In the 24-week DIAMOND trial of rtCGM use in US adults with T2D on prandial insulin, there were no statistically significant subgroup differences by baseline HbA1c level (< 8.5% vs. ≥ 8.5%) or by baseline frequency of SMBG testing (< 4 vs. ≥ 4 tests per day).[51,98]
- In the 32-week MOBILE trial of rtCGM use in US adults with T2D on once-daily or twice-daily basal insulin injections, no statistically significant subgroup interaction was found according to baseline HbA1c level (< 9.0% vs. ≥ 9.0%), baseline diabetes duration (< 5 years vs. 5 to 17 years vs. 18 to 29 years vs. ≥ 30 years), or noninsulin diabetes medication use (use vs no use of GLP1 or SGLT2 meds at baseline).[96,99,113]

Two RCTs were conducted in adults with T2D on OHM therapy.[118,124]

- In the 24-week GLiMPSE trial of isCGM vs. SMBG conducted among a multiethnic cohort of Singapore adults with poorly controlled T2D on oral glucose-lowering medications, no statistically significant subgroup interaction was found according to baseline HbA1c level (< 7.0% vs. ≥ 7.0%) or baseline diabetes duration (< 10 years vs. ≥ 10 years).[118]
- In the 24-week trial of isCGM use in Japanese adults on any noninsulin hypoglycemic medication, Wada and colleagues observed a statistically significant reduction in HbA1c from baseline with CGM compared with SMBG among adults who did not receive a medication adjustment during the study period (MD, −0.14%; 95% CI, −0.27 to 0.00; *P* = .04).[124] However, this subgroup finding aligned with the primary cohort results, and subgroup findings for participants with medication adjustments were not reported.[124]

No subgroups by baseline diabetes severity were reported for the other review populations.

Adherence to CGM Use (KQ3f)

Two RCTs reported change in HbA1c by CGM adherence level (Appendix E, Table E5).[118,123] Overall, CGM adherence did not appear to have a strong or consistent association with the effectiveness of CGM use on changes in HbA1c; findings were mixed.

One RCT was conducted in adults with T2D on OHM therapy.[118]

- In the 24-week GLiMPSE trial of isCGM vs. SMBG conducted among a multiethnic cohort of Singapore adults with poorly controlled T2D on oral glucose-lowering medications, no statistically significant subgroup interaction was found according to CGM or SMBG adherence level (< 7 scans or < 1 SMBG test per day vs. ≥ 7 scans or ≥ 1 SMBG test per day).[118]

One RCT was conducted in adults with T2D on mixed nonintensive hypoglycemic regimens.[123]

- In the 52-week study of rtCGM use in US adults with T2D not on prandial insulin therapy conducted by Vigersky and colleagues, participants who used their CGM for 48 days or more or who conducted 1 or more SMBG tests per day during the initial 12-week study period (per study protocol) had significantly greater mean reduction in HbA1c at 52 weeks compared with the SMBG group (−1.0% vs. −0.3%; *P* < .001), while those who used their CGM for fewer than 48 days or conducted less than 1 SMBG test per day did not experience a significant change in HbA1c compared with SMBG.[100,123] Based on these findings, the authors estimated that each day of rtCGM use resulted in a 0.02% decrease in HbA1c level.[123]

No subgroups by CGM adherence were reported for the other review populations.

Type of CGM (KQ3g)

No RCTs reported prespecified subgroup analyses by CGM type (rtCGM vs. isCGM). Although we included RCTs assessing both CGM modalities, none looked at mixed modalities or included parallel study arms of both CGM types, and we were therefore unable to directly compare outcomes by type of CGM.

Duration of CGM Monitoring (KQ3h)

No RCTs reported prespecified subgroup analyses by duration of CGM monitoring.

However, we included 1 RCT in the primary analysis (Moon and colleagues, 2022[114]) that randomized participants to either 1 or 2 (nonconsecutive) weeks of CGM use compared with an SMBG control group. The results of this study are reported in the Comparative Effectiveness section under the Adults with T2D on Oral Hypoglycemic Medications header and in the Device-Related Safety outcomes section.

Timing of CGM Initiation Relative to Baseline Diabetes Control (KQ3i)

No RCTs reported prespecified subgroup analyses by timing of CGM initiation relative to baseline diabetes control as measured by HbA1c.

Economic Outcomes (KQ4)

We identified 2 eligible studies reporting economic outcomes on the use of CGM from a US perspective (Table 10).[131]

Table 10. Summary Study Characteristics for Economic Studies

Citation Perspective Risk of bias	Design Intervention Comparator(s)	Population
Frank et al., 2024[132] US perspective, specifically Medicaid Moderate RoB	Patient-level microsimulation model • FreeStyle Libre • SMBG • N = 10,000 simulated patients	Adults with T2D using basal insulin • Mean age at model entry, 56.0 years (SD, 10.2) • Female, 48.0% • Race/ethnicity, 13.6% Black, 17.0% Hispanic • Mean HbA1c, 9.2% (SD, 1.0) • Current smokers, 12.0% • Comorbid CVD, 35.7% • OAD medications, 83.0% • No details of insulin use intensity reported Pregnancy not reported
Kerr et al., 2023[131] US, commercial and Medicare claims High RoB	Retrospective analysis • CGM (N = 3,498) • SMBG (N = 3,498)	Adults with nonintensively managed T2D • Mean age in years, 52.8 (SD, 8.9) vs. 52.8 (SD, 8.9) • Female, 48.2% vs. 47.8% • CVD, 11.2% vs. 12.3% • Microvascular and macrovascular complications, 30.5% vs. 30.2% • Mean frequency of SMBG tests per day, 1.34 (SD, 1.58) vs. 1.35 (SD, 1.62) • OAD medications only, 41.4% vs. 41.6% • Insulin only, 13.6% vs. 12.9% Nonintensive management was defined as not using rapid-acting prandial insulin Pregnancy, gestational or secondary diabetes at any time during the study period was excluded

Abbreviations. CGM. continuous glucose monitor; CVD. cardiovascular diseases; HbA1c: glycated hemoglobin; OAD. oral antidiabetics medication; RoB. risk of bias; SD: standard deviation; SMBG. self-monitoring of blood glucose; T2D. type 2 diabetes; US: United States.

Adults With T2D on Nonintensive Insulin Regimens

We identified 1 eligible cost-effectiveness study of CGM in US individuals with T2D using basal insulin.[132]

Table 11. GRADE Summary of Findings of CGM vs. SBMG in Adults With T2D on Nonintensive Insulin Regimens

Number of Studies	Findings	Certainty of Evidence	Rationale
CGM vs. SMBG			
1 cost-effective analysis[132]	Over a 10-year time horizon, from the Medicaid perspective • CGM (specifically, FreeStyle Libre systems) was dominant to SMBG, providing more QALYs and LYs at lower costs for people with T2D on basal insulin	●●●○ Moderate	Downgraded 1 level • 1 for RoB (i.e, role of funder in study publication)

Notes. See Appendix G, Table G5 for the complete GRADE profile of economic outcomes.

Abbreviations. CGM: continuous glucose monitor(ing); GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HbA1c: glycated hemoglobin; LY: life-year; QALY: quality-adjusted life year; RoB: risk of bias; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Frank and colleagues used a patient-specific microsimulation model and assigned costs and utilities for diabetes complications.[132] The study was conducted from a US Medicaid payer perspective with a 10-year time horizon. Costs and utilities were discounted at 3% and all costs were adjusted to April 2023 US dollars.[132] The study compared glucose monitoring costs, and costs and disutilities associated with acute diabetic events and diabetes-related complication for FreeStyle Libre CGM and SMBG users.[132] We assessed this study as having a moderate risk of bias due to funding from the manufacturer (Abbott) and conflicts of interest among the authors.

The key model assumptions for the study population of 10,000 simulated patients and HbA1c reductions were based on published clinical trials and real-world studies[132]:

- Baseline risk factors (e.g., blood pressure, smoking status) from an RCT conducted in the US and Canada[132,133]
- Reduction in HbA1c based on a retrospective chart review conducted in the US and Canada[132,133]
- Reductions in acute diabetes events from a French reimbursement claim study due to a lack of evidence among the US population[132,134]
- Diabetic ketoacidosis mortality data based on an Israeli study because of limited data in the US[132,135]
- Rate of nonsevere hypoglycemic events from a meta-analysis of 46 population-based studies[132,136]
- Frequency of nonsevere hypoglycemic events among CGM users calculated from the SMBG rate by applying a 29% reduction reported in a US claims database study[132,137]

The costs of glucose monitoring were calculated based on the use of[132]:

- 1 test strip and lancet per day for SMBG users
- 1 test strip and lancet per week for CGM users, 26 sensors per year, and 1 isCGM reader every 3 years

Costs associated with diabetes complications and severe hypoglycemic events were from a US study using data from the Optum deidentified Normative Health Information database, and the costs of treating diabetic ketoacidosis was based on hospitalization costs from a review of the US National Inpatient Sample database.[132]

Utilities at the baseline and disutilities associated with complications and severe hypoglycemic events were taken from a published RCT conducted in the US and Canada.[132] In the absence of US data, treatment disutility was based on a study conducted in the UK.[132]

A total of 10,000 patients were simulated over a 10-year period, using the Determination of Diabetes Utilities, Costs, and Effects (DEDUCE) model (a Microsoft Excel-based tool for evaluating diabetes interventions for T1D and T2D).[132] The base case analysis[132] showed CGM was dominant to SMBG, with more quality-adjusted life years ([QALYs] 6.18 vs. 5.97) and lower costs ($70,137 vs. $71,809). [132] Although CGM had higher costs associated with glucose

monitoring when compared with SMBG ($14,842 vs. $4,385 over the 10-year time period), these were offset by reductions in costs for treating acute diabetic events and diabetes-related complications (a reduction of $12,127 when compared with SMBG; Appendix I, Tables I1 and I2).[132]

Similarly, CGM was associated with more life-years than SMBG (8.08 vs. 7.98 years) and lower costs ($70,137 vs. $71,809).[132]

A probabilistic sensitivity analysis was conducted to explore uncertainties in the model inputs.[132] The study varied factors such as discount rates, treatment effects, complications, utilities, and costs, using relevant data sources to define parameter uncertainty.[132] When variability was unknown, the standard error (SE) was estimated as 10% of the parameter value.[132] The analysis found that CGM was 100% likely to be dominant to SMBG (i.e., to result in more QALYS at a lower cost).[132] In effect, even if the willingness-to-pay threshold was $0, CGM would be cost-effective relative to SMBG.[132] Scenario analyses were also conducted, varying time horizon, discounting, glucose monitoring cost, acute diabetic event frequency, and the effect of SMBG on HbA1c as key parameters.[132] In each scenario, CGM would likely be considered cost-effective, with incremental cost-effectiveness ratios (ICERs) of less than $20,000 per QALY.[132] Over longer time horizons (20 and 30 years), both QALY gains and cost savings increased, compared with the base case analysis, meaning that even greater cost savings and utility gains would be likely beyond the 10-year time horizon.[132]

Adults With T2D on Mixed Nonintensive Hypoglycemic Treatment Regimens

We identified 1 eligible study reporting on all-cause health care resource utilization (HCRU) and costs among adults with nonintensively managed T2D.[131] We did not assess CoE for these outcomes as no formal economic analysis was undertaken.

Kerr and colleagues conducted a retrospective observational analysis using Merative Marketscan commercial and Medicare databases comparing HCRU and costs of CGM and SMBG in patients with T2D.[131] The study included adult patients (aged 18 years or older) with primary or secondary T2D with at least 1 pharmacy claim for an SMBG strip or CGM sensor and 1 OHM between January 2018 and March 2019.[131] Patients were excluded if they had any claims for rapid-acting insulin or glucagon medication.[131] We assessed this study as having a moderate risk of bias due to the retrospective, observational design (although propensity matching was conducted), the source of funding (Roche Diabetes Care), and author conflicts of interest.

After propensity score matching, 6996 patients were included, 3,498 in each group[131]:

- Mean age was 52.8 years
- 41% of patients were on oral antidiabetic medications
- 37% of CGM users and 34% of SMBG users were on insulin regimens during the study period
- 30% of CGM users also used SMBG strips

Over the 12-month study period, when compared with patients in the SMBG groups, patients in the CGM group had[131]:

- Similar proportions of patients with an inpatient stay (6.7% vs. 7.1%; *P* = .54)
- Similar numbers of inpatient admissions (mean, 0.09 vs. 0.10; *P* = .33)

- A statistically significant higher proportion of patients with an emergency department (ED) visit (23.2% vs. 20.9%; *P* = .02)
- Similar numbers of ED visits (mean, 0.41 in each group; *P* = .75)
- Similar proportions of patients with an outpatient visit (98.9% vs. 98.5%; *P* = .12)
- A statistically significantly higher number of outpatient visits (mean, 13.98 vs. 12.77; *P* < .001)
- A statistically significant higher proportion of outpatient endocrinologist visits (35.9% vs. 22.6%, *P* < .001)
- A statistically significantly higher number of outpatient endocrinologist visits (mean, 1.04 vs. 0.64; *P* < .001)

Per-patient per-year (PPPY) all-cause cost was statistically significantly lower in the SMBG group compared with the CGM group ($19,349 vs. $20,542; *P* < .001).[131] This difference was primarily driven by lower pharmacy costs ($8,974 vs. $10,629; *P* < .001) and outpatient office visit costs ($1,882 vs. $2,292; *P* < .001) in the SMBG group.[131] Although CGM users had more all-cause outpatient visits and office visits with an endocrinologist, there were no significant differences in the PPPY costs of ED visits or hospitalizations between the 2 groups.[131] The authors concluded that SMBG appears to be less costly than CGM in adults with nonintensively managed T2D.[131]

Ongoing Studies

We identified 37 ongoing studies that align with the inclusion criteria for this report topic; all are RCTs (see Appendix H, Table H1 for study characteristics of ongoing studies).[138-173] Eight ongoing trials are testing isCGMs,[140,143,144,149,153,158,168,173] while the remainder are using rtCGMs or do not have detailed information for CGM type. Estimated study sample sizes range from 10[165] to 430[156] participants. Most studies compare CGM with self-monitoring blood glucose testing or usual care (at least 3 report the employment of a blinded CGM with the comparator arm[145,146,152]).

Adults With T2D Not on Intensive Insulin Regimes

- In adults, we identified 23 ongoing RCTs[139,142-144,147,149,151-157,159,161,162,165-170,174] with primary completion dates from September 2022 to December 2027, of which 6[144,149,151,153,154,161] are reported as completed
  - 13 RCTs on rtCGMs,[139,142,151,152,156,157,159,161,162,165,167,169,174] 5 on isCGMs,[143,144,149,153,168] and 5 do not specify the type of CGM being evaluated
  - 13 studies are being conducted in the US,[142,147,151,153-155,157,159,161,162,165,167,170] 5 in Europe,[139,152,156,166,169] 1 in Canada,[149] and none are multinational
  - Target sample sizes range from 10 to 430, and 11 RCTs[139,142,143,154,157,159,161,165,169,170,174] plan to include less than 100 participants
  - 5 studies are 12 weeks in duration,[143,149,153,165,174] and 4 are at least 52 weeks[142,147,157,166]
  - 8 studies require participants to be on insulin,[143,144,147,156,161,167,170] 7 exclude individuals on insulin,[149,155,162,165,166,168,169,174] 2 require any pharmacologic diabetes intervention,[152,153] 3 include any individual with T2D not on intensive insulin treatments,[139,151,157] and 3 have no details around diabetes treatment requirements

Children and Adolescents With T2D Not on Intensive Insulin Regimens

- We identified 1 ongoing RCT of youths located in the US with an expected completion date in December 2027[160]
  - The estimated trial duration is 24 weeks, with a planned sample size of 30 youth aged 8 to 20 years on nonintensive insulin regimens; rtCGM is compared with usual care[160]

Pregnant Individuals With T2D Not on Insulin

- 3 ongoing RCTs in pregnant individuals with T2D not on insulin[138,148,150] with estimated primary completion dates from December 2024 to April 2027
  - 2 RCTs report using rtCGMs,[138,150] 1 study does not indicate CGM-type,[148] and all compare the intervention with self-monitoring of blood glucose
  - 2 studies are being conducted in the US,[148,150] and 1 in the UK
  - Target sample sizes include 16,[150] 180,[148] and 422[138] participants across the 3 RCTs
  - All studies enroll participants in early pregnancy, and then follow-up individuals through delivery[138,148,150]

Pregnant Individuals With CGM Not on Insulin

- 10 ongoing RCTs in pregnant individuals with GDM not on insulin[140,141,145,146,158,163,164,171-173] with primary completion dates from September 2023 to December 2027, of which 2[145,173] are reported as completed
  - 6 RCTs use rtCGMs,[145,146,163,164,171,172] 3 use isCGMs,[140,158,173] and 1 does not indicate CGM-type[141]
  - 2 studies are being conducted in the US,[141,145] 5 in Europe,[140,146,163,172,173] 2 in Taiwan,[164,171] and 1 in South Korea[158]
  - Target sample sizes range from 40 to 386, and 3[140,141,173] include fewer than 100 participants
  - 5 studies plan to continue to follow individuals postpartum (at least 12 weeks[140,158,164,171] to more than 52 weeks[146] postpartum). The 5 other studies follow individuals to delivery,[141,163,172,173] and at 32-weeks gestation[145]

Clinical Practice Guidelines

We assessed the methodological quality of 11 clinical practice guidelines from 6 professional organizations.[19,175-185] Five of the guidelines addressed diabetes care in general.[19,175-177,185] The American Diabetes Association's *Standards of Care in Diabetes* includes chapters on diabetes technology,[25] diabetes care in children and young people,[186] and diabetes care in pregnancy.[187] We identified 2 additional guidelines on diabetes care in pregnancy,[178,180] 1 additional guideline on children and adolescents,[182] 2 guidelines on management of T2D in adults,[181,184] and 1 on management of diabetes in older adults.[179]

The guidelines recommended CGM for all individuals with T1D[19,25,175,176] and for those who inject insulin more than 3 times a day or use an insulin pump.[19,25,175,176] The recommendations are more varied for adults and children with T2D not on intensive insulin treatment and pregnant people with either T2D or GDM who do not use insulin. This section of the report describes guideline recommendations for CGM use in the targeted populations.

Guideline Recommendations for Adults With T2D

Seven of the guidelines addressed CGM use in adults with T2D.[19,25,175-177,181,184] In general, guidelines recommended CGM use for adults who have multiple daily injections of insulin, use an insulin pump, or have problematic hyperglycemia.

Table 12. Guideline Recommendations for CGM Use in Adults With T2D

Guideline Publication Year Methodological Quality	Guideline Recommendation
American Diabetes Association *Standards of Care in Diabetes: Chapter 7 Diabetes Technology*[25] 2024 Fair	CGM should be offered to adults with diabetes who: • Use multiple daily injections of insulin (number of injections not specified) or have an insulin pump OR • Use basal insulin
Blonde et al. American Association of Clinical Endocrinology *Developing a Diabetes Mellitus Comprehensive Care Plan*[19] 2022 Poor	CGM recommended for adults with T2D who: • Are treated with insulin therapy OR • Have high risk for hypoglycemia and/or with hypoglycemia unawareness
Grunberger et al. American Association of Clinical Endocrinology *The Use of Advanced Technology in the Management of Persons with Diabetes Mellitus*[175] 2021 Poor	CGM recommended for: • All persons who take 3 or more insulin injections daily or have an insulin pump OR • Individuals with problematic hypoglycemia CGM may be recommended for individuals with T2D who are treated with less intensive insulin therapy
McCall et al. Endocrine Society *Management of Individuals with Diabetes at High Risk for Hypoglycemia*[176] 2023 Good	CGM is suggested for people with T2D who take insulin and/or sulfonylureas and are at risk for hypoglycemia
NICE *Type 2 Diabetes in Adults: Management*[181] 2022 Good	Offer CGM to adults with T2D who have multiple daily insulin injections if 1 of the following apply: • Recurrent hypoglycemia or severe hypoglycemia • Impaired hypoglycemia awareness • Learning disability or cognitive impairment impeding SMBG • Would otherwise have to self-measure at least 8 times a day
Ontario Health Quality *Flash Glucose Monitoring System for People with Type 1 or Type 2 Diabetes: Recommendations*[177] 2019 Good	CGM recommended for people with T2D who use multiple daily injections of insulin or an insulin pump, and who experience recurrent hypoglycemia despite frequent self-monitoring of blood glucose and efforts to optimize insulin management
Veterans Administration/Department of Defense *Management of Type 2 Diabetes Mellitus*[184] 2023 Good	CGM is suggested for adults with T2D who are treated with insulin but are not achieving glycemic goals

Abbreviations. CGM: continuous glucose monitoring; NICE: National Institute for Health and Care Excellence; SMBG: self-monitored blood glucose; T2D: type 2 diabetes.

In addition to the guidelines in Table 12 above, the 2019 Endocrine Society's *Treatment of Diabetes in Older Adults* briefly mentions CGM recommending that individuals aged 65 years and older who treat their diabetes with insulin should use "frequent fingerstick glucose monitoring and/or continuous glucose monitoring … in addition to HbA1c."[179, p. 1522] We rated this guideline as having poor methodological quality.

Guideline Recommendations for Children With T2D

We identified recommendations on CGM use for children and adolescents with T2D in 2 chapters of the American Diabetes Association's *Standards of Care in Diabetes*[25,186] and in a NICE guideline for management of diabetes in youth.[182] As with adults with T2D, recommendations for CGM use in children with T2D were limited to individuals who have multiple daily injections of insulin or use an insulin pump[185,186]; the NICE guideline also recommends offering CGM to children with conditions that would impede SMBG or have severe hypoglycemia.[182]

Table 13. Guideline Recommendations for CGM Use in Children and Adolescents With T2D

Guideline Publication Year Methodological Quality	Guideline Recommendation
American Diabetes Association *Standards of Care in Diabetes: Chapter 7 Diabetes Technology*[25] 2024 Fair	CGM should be offered to youth with T2D who use multiple daily injections of insulin (number of injections not specified) or have an insulin pump
American Diabetes Association *Standards of Care in Diabetes: Chapter 14 Children and Adolescents*[186] 2024 Fair	CGM should be offered to youth with T2D who use multiple daily injections of insulin or have an insulin pump
NICE *Diabetes (Type 1 and Type 2) in Children and Young People: Diagnosis and Management*[182] 2023 Good	Offer CGM to children and youth with T2D if any of the following apply: • Have a need, condition or disability that impedes SMBG • Would otherwise have to self-measure at least 8 times a day • Have recurrent or severe hypoglycemia Consider CGM for children and youth with T2D who are on insulin therapy

Abbreviations. CGM: continuous glucose monitoring; NICE: National Institute for Health and Care Excellence; SMBG: self-monitored blood glucose; T2D: type 2 diabetes.

Guideline Recommendations for Pregnant People With T2D or GDM

We identified 6 guidelines with recommendations on CGM use in pregnant people with T2D.[19,25,175,178,180,186] Three of the guidelines commented on CGM use in pregnant individuals but did not make a specific recommendation.[19,25,187] In the remaining 3 guidelines, 2 limited recommendations for CGM use in pregnant people to those taking insulin,[175,180] and the Healthcare Improvement Scotland guideline said clinicians could consider CGM in pregnant people with T2D not on insulin.[178]

Guideline recommendations for CGM use in pregnant people with GDM were similar to recommendations for pregnant people with T2D. Only the American Association of Clinical Endocrinology guideline specifically recommended CGM for individuals with GDM who use insulin and that CGM may be recommended for women with GDM who do not use insulin.[175]

Table 14. Guideline Recommendations for CGM Use in Pregnant People With T2D or GDM

Guideline Publication Year Methodological Quality	Guideline Recommendation
American Diabetes Association *Standards of Care in Diabetes: Chapter 7 Diabetes Technology*[25] 2024 Fair	When used as an adjunct to pre-prandial and postprandial BGM, CGM can help to achieve A1C targets in diabetes and pregnancy.
American Diabetes Association *Standards of Care in Diabetes: Chapter 15 Management of Diabetes in Pregnancy*[187] 2024 Fair	There are insufficient data to support the use of CGM in all people with **T2D** or **GDM**. The decision of whether to use CGM in pregnant individuals with **T2D** or **GDM** should be individualized based on treatment regimen, circumstances, preferences, and needs.
Blonde et al. American Association of Clinical Endocrinology *Developing a Diabetes Mellitus Comprehensive Care Plan*[19] 2022 Poor	Although the available evidence is not strong to support use of GCM in pregnant women with **T2D** and **GDM** for maternal or neonatal benefits, it may be used in select persons who are at risk for hypoglycemia, especially those treated with insulin.
Grunberger et al. American Association of Clinical Endocrinology *The Use of Advanced Technology in the Management of Persons with Diabetes Mellitus*[175] 2021 Poor	CGM recommended for pregnant women with T1D and **T2D** treated with intensive insulin therapy. CGM recommended for women with **GDM** on insulin therapy. GCM may be recommended for women with **GDM** who are not on insulin therapy.
NICE *Diabetes in Pregnancy: Management from Preconception to the Postnatal Period*[180] 2020 Good	Consider CGM for pregnant women who are on insulin therapy **but do not have T1D** if they have: • Problematic severe hypoglycemia (with or without impaired hypoglycemia awareness) OR • Unstable blood glucose levels despite efforts to optimize glycemic control.
Healthcare Improvement Scotland *SIGN 171: Management of Diabetes in Pregnancy*[178] 2024 Good	In Scotland, CGM is offered to all pregnant women with insulin treated **T2D**. The guideline recommends that CGM is considered for pregnant women with **T2D** not on insulin. Insufficient evidence to support a recommendation for the routine use of CGM in women with **GDM**.

Abbreviations. A1c: glycated hemoglobin; BGM: blood glucose monitoring; CGM: continuous glucose monitoring; GDM: gestational diabetes; NICE: National Institute for Health and Care Excellence; T1D: type 1 diabetes; T2D: type 2 diabetes.

Selected Payer Coverage Determinations

We searched our standard WA-HTA sources for payer policies. We identified 1 local coverage determination (LCD) for Medicare,[188] 4 policies from 3 private payers,[189-192] and the Medicaid coverage determination from the Oregon Health Evidence Review Commission.[193] We identified a news release from Regence BlueShield of Washington announcing coverage for CGM would move from the medical benefit to the pharmacy benefit in 2023 but were unable to identify a coverage policy for CGMs.[194] We identified 2 coverage policies for Cigna[191,192]; we report details on the Cigna coverage policy with the effective date of January 15, 2025, in this analysis.[192] Complete coverage policies are included in Appendix J, Table J1.

Following advocacy efforts by the American Diabetes Association and others, Medicare expanded coverage for CGMs on March 2, 2023, effective April 16, 2023.[195-198] In 2021, Medicare eliminated the requirement that individuals have a history of 4 daily SMBG fingersticks to qualify for a CGM.[198] The 2023 changes allowed CGMs for individuals who use insulin to treat their diabetes regardless of the type of insulin used or the type of diabetes; before the change, individuals with diabetes had to take a certain amount of insulin daily to quality for a CGM.[188,196] The new Medicare policy allows individuals with diabetes who do not take insulin but have a history of problematic hypoglycemia to qualify for a CGM.[188,196] All FDA-approved CGM devices are included.[196] Ordering clinicians must certify the recipient or the recipient's caregiver has sufficient training in using the CGM and recipients must have a follow-up appointment (in person or by telehealth) with the prescribing clinician within 6 months of beginning use of the device.[188,196]

For the 3 private payers and Oregon Medicaid, CGM coverage for adults and children with T2D requires use of insulin, although the type of insulin routine required for eligibility varies; see Table 15. Only Aetna and Oregon Medicaid address pregnant people with GDM.[189,193] Aetna's policy excludes pregnant people with GDM for CGM eligibility.[189] The Oregon policy applies the same criteria for adults with T2D to pregnant people with GDM.[193]

Table 15. Summary of Payer Policy Language

Payer	Adults T2D	Children T2D	Pregnant People T2D	Pregnant People GDM
Medicare[188]	• Covered if taking insulin of any kind or any amount OR • History of problematic hypoglycemia	NA	NA	NA
Aetna[189]	• Covered if using intensive insulin therapy defined as 3 or more daily injections or use of insulin pump AND member is not meeting glycemic targets, experiencing hypoglycemia or	• Covered if using intensive insulin therapy defined as 3 or more daily injections or use of insulin pump	• Not specified (adult T2D conditions likely apply)	Not covered

Payer	Adults T2D	Children T2D	Pregnant People T2D	Pregnant People GDM
	hypoglycemia unawareness			
Anthem[190]	• Covered if insulin injections are required multiple times daily or use of an insulin pump AND inadequate glycemic control	• Not specified (Adult T2D conditions likely apply)	• Not specified (adult T2D conditions likely apply)	Not specified
Cigna[192]	• Covered for the following insulin routines: ○ Multiple daily injections ○ Long-acting basal insulin ○ Insulin pump	• Covered for the following insulin routines: ○ Multiple daily injections ○ Long-acting basal insulin ○ Insulin pump	• Not specified (adult T2D conditions likely apply)	Not specified
Oregon Medicaid[193]	• Covered when using short- or intermediate- acting insulin injections AND have 1 of the following: ○ Baseline HbA1c levels ≥8.0% ○ Frequent or severe hypoglycemia ○ Impaired awareness of hypoglycemia ○ Diabetes-related complications	• Covered when using short- or intermediate-acting insulin injections AND have one of the following: ○ Baseline HbA1c levels ≥8.0% ○ Frequent or severe hypoglycemia ○ Impaired awareness of hypoglycemia ○ Diabetes-related complications	• Not specified (adult T2D conditions likely apply)	• Covered when using short- or intermediate-acting insulin injections AND have 1 of the following: ○ Baseline HbA1c levels ≥8.0% ○ Frequent or severe hypoglycemia ○ Impaired awareness of hypoglycemia ○ Diabetes-related complications

Abbreviations. GDM: gestational diabetes; HbA1c: glycated hemoglobin; NA; not applicable; T2D: type 2 diabetes.

Our research also identified a website hosted by the Association of Diabetes Care & Education Specialists that compiles publicly available CGM coverage policies.[199] Intended as a tool for clinicians, the website allows users to search for CGM coverage policies by state, payer, and plan type.[199]

Discussion

Summary

The clinical effectiveness analysis in this report found moderate-confidence evidence that CGM in adults with T2D on nonintensive insulin regimens resulted in a small, but statistically significant reduction in HbA1c level from baseline compared with non-CGM glucose monitoring methods (e.g., SMBG). However, the observed difference did not exceed the predetermined threshold for clinical significance (MCID, ≥ 0.5% change). There were no clear differences in other outcomes (i.e., achievement of target HbA1c levels, quality of life, severe hypoglycemia, mortality). Comparatively, there were no clear differences in these outcomes for adults with T2D on OHM therapies or mixed nonintensive hypoglycemic regimens, and for pregnant people with GDM not on insulin (including no difference in severe perinatal outcomes). Mortality and severe hypoglycemia requiring intervention were rarely reported, and few instances occurred in studies that assessed these outcomes.

We did not identify clinical evidence that assessed CGM use in these populations not currently covered by the 2018 Washington HTCC coverage decision:

- Adults with T2D not on insulin or OHM
- Children with T2D not using intensive insulin
- Pregnant people with T2D not on insulin

While device-related AEs were not uncommon, most were mild or moderate sensor-related skin irritation and resolved with minimal intervention. Few study drop-outs due to device-related AEs occurred; deaths were also infrequent and not attributed to CGM. A survey of device incident reports in the FDA MAUDE database suggests while serious AEs are rare, mild to moderate sensor-related CGM issues (e.g., skin irritation at the sensor placement site, loss of connection with the CGM receiver) are not infrequent. There are 2 ongoing recalls of select CGM devices associated with potentially serious sensor malfunctions and 1 associated with increased risk of battery fires in handheld receiver devices.

Few studies conducted subgroups analyses assessing differential effectiveness and safety by key demographic and clinical characteristics. When reported, subgroup data was available only for change in HbA1c levels from baseline. We found mixed evidence suggesting possible differential HbA1c effects by age in adults with T2D on nonintensive insulin regimens and by CGM adherence in adults with T2D on mixed nonintensive hypoglycemic regimens. There were no reported differential effects by gender, race and ethnicity, or baseline diabetes severity. We did not identify subgroup analyses that assessed outcomes by baseline comorbidities, type of CGM, duration of CGM monitoring, or timing of CGM initiation.

The cost-effectiveness analysis in this report found CGM (specifically, FreeStyle Libre systems) is cost-effective for monitoring glucose levels compared with SMBG for patients with T2D using basal insulin. These findings are based on a patient-level microsimulation model of US patients with T2D on basal insulin.[132] Overall, we had moderate CoE in this finding.

In contrast, a real-world data study using claims data to compare health care costs between CGM and SMBG users in adults with nonintensively managed T2D found significantly lower total

all-cause costs in the SMBG group, primarily due to fewer outpatient office visits and lower pharmacy costs.[131]

Professional organizations commonly recommend CGM for use in adults and children with T2D who are on insulin therapy, particularly for those on intensive insulin regimens or at high risk for hypoglycemia. Recommendations for pregnant people with T2D or GDM were of limited specificity, but CGM was consistently recommended for those on insulin therapy. CGM coverage policies among public and commercial payers generally align with professional society guidelines, although few policies include specific coverage criteria for pregnant people with T2D or GDM.

Limitations

We encountered several limitations although we conducted this health technology assessment using rigorous and systematic methods.

The availability of long-term data in RCTs of CGM use was limited. The longest follow-up reported by any included 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 concerning outcomes, such as severe hypoglycemia or severe perinatal events.

Participants in the RCTs may have exhibited better adherence than would be expected in nonresearch settings. Several studies required participants to complete a run-in period to gauge device tolerability and adherence before randomization. Participants who had trouble wearing a CGM or exhibited less than optimal adherence during these screening periods were generally excluded from randomization. Additionally, several studies required control participants to record 4 or more daily SMBG tests; however, baseline study data indicated that most participants were conducting between 1 to 3 tests per day on average. It is possible that study participation resulted in better than average glucose self-management in these groups than would be observed in nonstudy settings.

The number and functionality of available CGM devices is changing rapidly. Several RCTs evaluated nontherapeutic rtCGM models, which must be calibrated with daily SMBG fingerstick tests and are no longer commercially available in US markets. Use of these devices may have tempered differential QoL effects when compared with SMBG alone. A few studies used therapeutic CGM device models that have been discontinued. The body of evidence available for assessment may not reflect the capabilities of more recent models. We also did not identify any RCTs assessing the effectiveness of newly approved over-the-counter models that can be purchased without a prescription (e.g., Dexcom Stelo).

There was substantial heterogeneity in treatment regimens. Due to limitations in reporting, it was not always possible to cleanly parse studies into the nonintensive hypoglycemic treatment categories specified in the scope, and many participants experienced changes in treatment regimen during the study period. For example, although all participants in the GDM trials were not on insulin at baseline, as specified in the scope, many participants were being treated with insulin by the final assessment. The landscape surrounding pharmacotherapies for diabetes has rapidly changed in the past few years. While newer injectable therapies (e.g., GLP-1 agonists) were not the focus of this review, several recent studies included participants on these regimens that may have affected the magnitude of clinical response relative to older studies.

Finally, although there are known CGM access and use inequities in the US with respect to income (as described in the Background section), insurance type, geographic location, provider type, and race and ethnicity, our review included few US-based studies, and none were designed to assess interventions to increase CGM uptake or prescribing habits.

Conclusions

Evidence from RCTs indicates CGM are safe and effective devices to reduce HbA1c levels in adults with T2D on nonintensive insulin regimens compared with daily SMBG testing. Cost-effectiveness analyses suggest CGM are cost-effective for monitoring glucose levels compared with daily SMBG testing in adults with T2D using basal insulin. There was no clear evidence of effectiveness in adults with T2D on OHM therapies or mixed nonintensive hypoglycemic regimens and for pregnant people with GDM not on insulin, although available evidence suggests CGM is not harmful in these populations. Device-related serious AEs and deaths were relatively rare. Clinical guidelines issued by relevant professional organizations commonly recommend CGM coverage for patients with T2D or GDM who require insulin therapy or are at high risk for hypoglycemia. Public and private payer policies follow major clinical guidelines and cover individuals with T2D who are on insulin therapy, although specific criteria for pregnant populations is limited.

References

1. National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health. What is diabetes? National Institues of Health; 2023; https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes. Accessed November 4, 2024.

2. Centers for Disease Control and Prevention. Diabetes basics. 2024; https://www.cdc.gov/diabetes/about/index.html. Accessed November 4, 2024.

3. Centers for Disease Control and Prevention. Diabetes complications. 2024; https://www.cdc.gov/diabetes/complications/index.html. Accessed November 4, 2024.

4. Centers for Disease Control and Prevention. About type 1 diabetes. 2024; https://www.cdc.gov/diabetes/about/about-type-1-diabetes.html. Accessed November 11, 2024.

5. American Diabetes Association. Understanding type 2 diabetes. 2024; https://diabetes.org/about-diabetes/type-2. Accessed November 11, 2024.

6. Mayo Clinic. Type 2 diabetes. 2024; https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/symptoms-causes/syc-20351193. Accessed November 11, 2024.

7. Centers for Disease Control and Prevention. Type 2 diabetes. 2024; https://www.cdc.gov/diabetes/about/about-type-2-diabetes.html. Accessed November 11, 2024.

8. Centers for Disease Control and Prevention. About gestational diabetes. 2024; https://www.cdc.gov/diabetes/about/gestational-diabetes.html. Accessed November 11, 2024.

9. Centers for Disease Control and Prevention. National diabetes statistics report. 2024; https://www.cdc.gov/diabetes/php/data-research/index.html. Accessed November 4, 2024.

10. American Diabetes Association. The burden of diabetes in Washington. 2023; https://diabetes.org/sites/default/files/2023-09/ADV_2023_State_Fact_sheets_all_rev_Washington.pdf. Accessed November 4, 2024.

11. Bullard KM, Cowie CC, Lessem SE, et al. Prevalence of diagnosed diabetes in adults by diabetes type - United States, 2016. *MMWR Morb Mortal Wkly Rep*. 2018;67(12):359-361. doi: 10.15585/mmwr.mm6712a2.

12. Washington State Department of Health. Washington state health assessment: diabetes and prediabetes. 2018; https://doh.wa.gov/sites/default/files/legacy/Documents/1000/SHA-DiabetesandPrediabetes.pdf. Accessed November 4, 2024.

13. Washington State Department of Health, Washington State Department of Social and Health Services, Washington State Health Care Authority. Diabetes epidemic and action report. 2017; https://doh.wa.gov/sites/default/files/legacy/Documents/Pubs//345-349-DiabetesEpidemicActionReport.pdf. Accessed November 4, 2024.

14. Centers for Disease Control and Prevention. Manage blood sugar. 2024; https://www.cdc.gov/diabetes/treatment/index.html. Accessed November 11, 2024.

15. Mayo Clinic. Diabetes: diagnosis and treatment. 2024; https://www.mayoclinic.org/diseases-conditions/diabetes/diagnosis-treatment/drc-20371451. Accessed November 12, 2024.

16. National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health. The A1C test and diabetes. 2018; https://www.niddk.nih.gov/health-information/diagnostic-tests/a1c-test. Accessed November 12, 2024.

17. American Diabetes Association Professional Practice Committee. 6. Glycemic goals and hypoglycemia: Standards of Care in Diabetes-2024. *Diabetes Care*. 2024;47(Suppl 1):S111-S125. doi: 10.2337/dc24-S006.

18. American Diabetes Association. About diabetes: CGM and time in range. https://diabetes.org/about-diabetes/devices-technology/cgm-time-in-range. Accessed October 21, 2024.

19. Blonde L, Umpierrez GE, Reddy SS, et al. American Association of Clinical Endocrinology clinical practice guideline: developing a diabetes mellitus comprehensive care plan—2022 update. *Endocr Pract*. 2022;28(10):923-1049. doi: 10.1016/j.eprac.2022.08.002.

20. Didyuk O, Econom N, Guardia A, Livingston K, Klueh U. Continuous glucose monitoring devices: Past, present, and future focus on the history and evolution of technological innovation. *J Diabetes Sci Technol.* 2021;15(3):676-683. doi: 10.1177/1932296819899394.

21. National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health. Continuous glucose monitoring. 2023; https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/continuous-glucose-monitoring. Accessed October 21, 2024.

22. Miller EM. Using continuous glucose monitoring in clinical practice. *Clin Diabetes*. 2020;38(5):429-438. doi: 10.2337/cd20-0043.

23. Society for Maternal-Fetal Medicine. Coding tips: ambulatory continuous glucose monitoring. 2024; https://www.smfm.org/news/ambulatory-continuous-glucose-monitoring. Accessed October 21, 2024.

24. American Diabetes Association. About diabetes: choosing a CGM. 2024; https://diabetes.org/about-diabetes/devices-technology/choosing-cgm. Accessed October 21, 2024.

25. American Diabetes Association Professional Practice Committee. 7. Diabetes technology: Standards of Care in Diabetes—2024. *Diabetes Care.* 2024;47(Suppl 1):S126-S144. doi: 10.2337/dc24-S007.

26. US Food and Drug Administration. FDA clears first over-the-counter continuous glucose monitor. 2024; https://www.fda.gov/news-events/press-announcements/fda-clears-first-over-counter-continuous-glucose-monitor. Accessed December 6,2024.

27. American Diabetes Association. Consumer guide: CGMs. 2024; https://consumerguide.diabetes.org/collections/cgm. Accessed November 14, 2024.

28. diaTribe Learn. Continuous glucose monitors. 2024; https://diatribe.org/diabetes-technology/continuous-glucose-monitors. Accessed October 22, 2024.

29. American Diabetes Association. Health equity and diabetes technology: a study of access to continuous glucose monitors by payer, geography and race. 2024; https://diabetes.org/sites/default/files/2023-09/ADA-CGM-Utilization-White-Paper-Oct-2022.pdf. Accessed October 21, 2024.

30. Center for Health Care Strategies. Accelerating access to continuous glucose monitors in Medicaid to improve diabetes care. 2022; https://www.chcs.org/project/accelerating-access-to-continuous-glucose-monitors-in-medicaid-to-improve-diabetes-care/. Accessed October 22, 2024.

31. Galindo RJ, Aleppo G, Parkin CG, et al. Increase access, reduce disparities: Recommendations for modifying Medicaid CGM coverage eligibility criteria. *J Diabetes Sci Technol.* 2024;18(4):974-987. doi: 10.1177/19322968221144052.

32. Center for Health Care Strategies. Continuous glucose monitors for Medicaid beneficiaries living with diabetes: state-by-state coverage. 2023; https://www.chcs.org/resource/continuous-glucose-monitor-access-for-medicaid-beneficiaries-living-with-diabetes-state-by-state-coverage/. Accessed October 22, 2024.

33. Howe G, Chavis J. Expanding Medicaid access to continuous glucose monitors. Center for Health Care Strategies; 2022; https://www.chcs.org/resource/expanding-medicaid-access-to-continuous-glucose-monitors/. Accessed October 22, 2024.

34. Addala A, Hanes S, Naranjo D, Maahs DM, Hood KK. Provider implicit bias impacts pediatric type 1 diabetes technology recommendations in the United States: findings from the Gatekeeper study. *J Diabetes Sci Technol.* 2021;15(5):1027-1033. doi: 10.1177/19322968211006476.

35. Odugbesan O, Addala A, Nelson G, et al. Implicit racial-ethnic and insurance-mediated bias to recommending diabetes technology: insights from T1D exchange multicenter pediatric and adult diabetes provider cohort. *Diabetes Technol Ther.* 2022;24(9):619-627. doi: 10.1089/dia.2022.0042.

36. Walker AF, Hood KK, Gurka MJ, et al. Barriers to technology use and endocrinology care for underserved communities with type 1 diabetes. *Diabetes Care.* 2021;44(7):1480-1490. doi: 10.2337/dc20-2753.

37. Center for Health Care Strategies. Accelerating access to continuous glucose monitors in Medicaid resource center. 2024; https://www.chcs.org/resource-center/accelerating-access-to-continuous-glucose-monitors-in-medicaid-resource-center/. Accessed October 22, 2024.

38. DistillerSR, Inc. DistillerSR [cloud-based systematic review software]. 2024; https://www.distillersr.com/.

39. Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ.* 2008;336(7650):924-926. doi: 10.1136/bmj.39489.470347.AD.

40. Schünemann H, Brozek J, Guyatt G, Oxman A, (editors). GRADE handbook: a handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach. Updated October 2013. The GRADE Working Group; 2014; http://gdt.guidelinedevelopment.org/app/handbook/handbook.html. Accessed December 6, 2023.

41. The Cochrane Collaboration. Review Manager (RevMan) [computer program], version 5.4. 2020.

42. Higgins J, Thomas J, Chandler J, et al. Cochrane handbook for systematic reviews of interventions version 6.5 (updated August 2024). 2024; https://training.cochrane.org/handbook/current. Accessed December 16, 2024.

43. McGlothlin AE, Lewis RJ. Minimal clinically important difference: defining what really matters to patients. *JAMA.* 2014;312(13):1342-1343. doi: 10.1001/jama.2014.13128.

44. Cook CE. Clinimetrics corner: the Minimal Clinically Important Change score (MCID): a necessary pretense. *J Man Manip Ther.* 2008;16(4):E82-83. doi: 10.1179/jmt.2008.16.4.82E.

45. Sedaghat AR. Understanding the minimal clinically important difference (MCID) of patient-reported outcome measures. *Otolaryngol Head Neck Surg.* 2019;161(4):551-560. doi: 10.1177/0194599819852604.

46. National Institute for Health and Care Excellence. Type 2 diabetes in adults: management (NG28). NICE; 2015; https://www.nice.org.uk/guidance/ng28/evidence/full-guideline-pdf-78671532569. Accessed May 12, 2022.

47. European Medicines Agency. Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus. 2012; https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-clinical-investigation-medicinal-products-treatment-prevention-diabetes-mellitus-revision_en.pdf. Accessed May 12, 2022.

48. United States Food and Drug Administration. Draft guidance for industry on diabetes mellitus: developing drugs and therapeutic biologics for treatment and prevention - guidance document. 2008; https://www.regulations.gov/document/FDA-2008-D-0118-0003. Accessed May 12, 2022.

49. Lind M, Polonsky W, Hirsch IB, et al. Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: the GOLD randomized clinical trial. *JAMA.* 2017;317(4):379-387. doi: 10.1001/jama.2016.19976.

50. Beck RW, Riddlesworth T, Ruedy K, et al. Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: the DIAMOND randomized clinical trial. *JAMA.* 2017;317(4):371-378. doi: 10.1001/jama.2016.19975.

51. Beck RW, Riddlesworth TD, Ruedy K, et al. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections: a randomized trial. *Ann Intern Med.* 2017;167(6):365-374. doi: 10.7326/M16-2855.

52. Laffel LM, Kanapka LG, Beck RW, et al. Effect of continuous glucose monitoring on glycemic control in adolescents and young adults with type 1 diabetes: a randomized clinical trial. *JAMA.* 2020;323(23):2388-2396. doi: 10.1001/jama.2020.6940.

53. Lenters-Westra E, Schindhelm RK, Bilo HJ, Groenier KH, Slingerland RJ. Differences in interpretation of haemoglobin A1c values among diabetes care professionals. *Neth J Med.* 2014;72(9):462-466.

54. ElSayed NA, Aleppo G, Aroda VR, et al. 6. Glycemic targets: Standards of Care in Diabetes-2023. *Diabetes Care.* 2023;46(Suppl 1):S97-S110. doi: 10.2337/dc23-S006.

55. Kaiafa G, Veneti S, Polychronopoulos G, et al. Is HbA1c an ideal biomarker of well-controlled diabetes? *Postgrad Med J.* 2021;97(1148):380-383. doi: 10.1136/postgradmedj-2020-138756.

56. Penttila I, Penttila K, Holm P, et al. Methods, units and quality requirements for the analysis of haemoglobin A1c in diabetes mellitus. *World J Methodol.* 2016;6(2):133-142. doi: 10.5662/wjm.v6.i2.133.

57. National Institute for Health and Care Excellence. Type 2 diabetes in adults: management (NG28). 2022; https://www.nice.org.uk/guidance/ng28/resources/type-2-diabetes-in-adults-management-pdf-1837338615493. Accessed February 10, 2023.

58. Health Psychology Research. ADDQoL19: audit of diabetes dependent quality of life. 2009; https://healthpsychologyresearch.com/guidelines/addqol19-audit-diabetes-dependent-quality-life-0/. Accessed November 27, 2024.

59. Bradley C, Todd C, Gorton T, Symonds E, Martin A, Plowright R. The development of an individualized questionnaire measure of perceived impact of diabetes on quality of life: the ADDQoL. *Qual Life Res.* 1999;8(1-2):79-91. doi: 10.1023/a:1026485130100.

60. Bradley C, Speight J. Patient perceptions of diabetes and diabetes therapy: assessing quality of life. *Diabetes Metab Res Rev.* 2002;18 Suppl 3:S64-69. doi: 10.1002/dmrr.279.

61. Wee HL, Tan CE, Goh SY, Li SC. Usefulness of the Audit of Diabetes-Dependent Quality-of-Life (ADDQoL) questionnaire in patients with diabetes in a multi-ethnic Asian country. *Pharmacoeconomics.* 2006;24(7):673-682. doi: 10.2165/00019053-200624070-00006.

62. Carey MP, Jorgensen RS, Weinstock RS, et al. Reliability and validity of the Appraisal of Diabetes scale. *J Behav Med.* 1991;14(1):43-51. doi: 10.1007/BF00844767.

63. Lee EH, Lee YW, Lee KW, Nam M, Kim YS, Han SJ. A Korean version of the Appraisal of Diabetes Scale (ADS-K): psychometric evaluation with a population of Koreans with type 2 diabetes. *J Transcult Nurs.* 2015;26(3):270-278. doi: 10.1177/1043659614524793.

64. Banks J, Amspoker AB, Vaughan EM, Woodard L, Naik AD. Ascertainment of minimal clinically important differences in the diabetes distress scale-17: a secondary analysis of a randomized clinical trial. *JAMA Netw Open.* 2023;6(11):e2342950. doi: 10.1001/jamanetworkopen.2023.42950.

65. Fisher L, Hessler DM, Polonsky WH, Mullan J. When is diabetes distress clinically meaningful? Establishing cut points for the Diabetes Distress Scale. *Diabetes Care.* 2012;35(2):259-264. doi: 10.2337/dc11-1572.

66. American Diabetes Association. Behavioral health toolkit, resources for supporting people with type 1 and type 2 diabetes: behavioral health toolkit questionnaires. 2024;

https://professional.diabetes.org/professional-development/behavioral-mental-health/behavioral-health-toolkit. Accessed November 27, 2024.

67. Sturt J, Hearnshaw H, Wakelin M. Validity and reliability of the DMSES UK: a measure of self-efficacy for type 2 diabetes self-management. *Prim Health Care Res Dev.* 2010;11(04):374-381. doi: 10.1017/s1463423610000101.

68. Bijl JV, Poelgeest-Eeltink AV, Shortridge-Baggett L. The psychometric properties of the diabetes management self-efficacy scale for patients with type 2 diabetes mellitus. *J Adv Nurs.* 1999;30(2):352-359. doi: 10.1046/j.1365-2648.1999.01077.x.

69. Lee EH, van der Bijl J, Shortridge-Baggett LM, Han SJ, Moon SH. Psychometric properties of the Diabetes Management Self-Efficacy Scale in Korean patients with type 2 diabetes. *Int.* 2015;2015:780701. doi: 10.1155/2015/780701.

70. Bujang MA, Adnan TH, Mohd Hatta NKB, Ismail M, Lim CJ. A revised version of diabetes quality of life instrument maintaining domains for satisfaction, impact, and worry. *J Diabetes Res.* 2018;2018:5804687. doi: 10.1155/2018/5804687.

71. Huang IC, Liu JH, Wu AW, Wu MY, Leite W, Hwang CC. Evaluating the reliability, validity and minimally important difference of the Taiwanese version of the diabetes quality of life (DQOL) measurement. *Health Qual Life Outcomes.* 2008;6:87. doi: 10.1186/1477-7525-6-87.

72. Diabetes Control and Complications Trial (DCCT) Research Group. Reliability and validity of a diabetes quality-of-life measure for the diabetes control and complications trial (DCCT). The DCCT Research Group. *Diabetes Care.* 1988;11(9):725-732. doi: 10.2337/diacare.11.9.725.

73. Saisho Y. Use of Diabetes Treatment Satisfaction Questionnaire in diabetes care: Importance of patient-reported outcomes. *Int J Environ Res Public Health.* 2018;15(5). doi: 10.3390/ijerph15050947.

74. Bradley C, Plowright R, Stewart J, Valentine J, Witthaus E. The Diabetes Treatment Satisfaction Questionnaire change version (DTSQc) evaluated in insulin glargine trials shows greater responsiveness to improvements than the original DTSQ. *Health Qual Life Outcomes.* 2007;5:57. doi: 10.1186/1477-7525-5-57.

75. Polonsky WH, Fisher L, Hessler D, Edelman SV. Investigating hypoglycemic confidence in type 1 and type 2 diabetes. *Diabetes Technol Ther.* 2017;19(2):131-136. doi: 10.1089/dia.2016.0366.

76. Gonder-Frederick LA, Schmidt KM, Vajda KA, et al. Psychometric properties of the Hypoglycemia Fear Survey-Ii for adults with type 1 diabetes. *Diabetes Care.* 2011;34(4):801-806. doi: 10.2337/dc10-1343.

77. Gonder-Frederick LA, Vajda KA, Schmidt KM, et al. Examining the behaviour subscale of the Hypoglycaemia Fear Survey: an international study. *Diabet Med.* 2013;30(5):603-609. doi: 10.1111/dme.12129.

78. Hajos TR, Polonsky WH, Pouwer F, Gonder-Frederick L, Snoek FJ. Toward defining a cutoff score for elevated fear of hypoglycemia on the hypoglycemia fear survey worry subscale in patients with type 2 diabetes. *Diabetes Care.* 2014;37(1):102-108. doi: 10.2337/dc13-0971.

79. American Diabetes Association. Diabetes and emotional health workbook, chapter 4: fear of hypoglycemia (and other diabetes-specific fears). 2024; https://professional.diabetes.org/sites/default/files/media/ada_mental_health_workbook_chapter_4.pdf. Accessed November 27, 2024.

80. Grabman J, Vajda Bailey K, Schmidt K, et al. An empirically derived short form of the Hypoglycaemia Fear Survey II. *Diabet Med.* 2017;34(4):500-504. doi: 10.1111/dme.13162.

81. Stargardt T, Gonder-Frederick L, Krobot KJ, Alexander CM. Fear of hypoglycaemia: defining a minimum clinically important difference in patients with type 2 diabetes. *Health Qual Life Outcomes.* 2009;7:91. doi: 10.1186/1477-7525-7-91.

82. Aronson R, Brown RE, Jiandani D, Walker A, Orzech N, Mbuagbaw L. Assessment of self-management in patients with diabetes using the novel LMC Skills, Confidence and Preparedness Index (SCPI). *Diabetes Res Clin Pract.* 2018;137:128-136. doi: 10.1016/j.diabres.2017.10.028.

83. Mbuagbaw L, Aronson R, Walker A, Brown RE, Orzech N. The LMC Skills, Confidence & Preparedness Index (SCPI): development and evaluation of a novel tool for assessing self-management in patients with diabetes. *Health Qual Life Outcomes.* 2017;15(1):27. doi: 10.1186/s12955-017-0606-z.

84. Polonsky WH, Anderson BJ, Lohrer PA, et al. Assessment of diabetes-related distress. *Diabetes Care.* 1995;18(6):754-760. doi: 10.2337/diacare.18.6.754.

85. McGuire BE, Morrison TG, Hermanns N, et al. Short-form measures of diabetes-related emotional distress: the Problem Areas in Diabetes Scale (PAID)-5 and PAID-1. *Diabetologia.* 2010;53(1):66-69. doi: 10.1007/s00125-009-1559-5.

86. Toobert DJ, Hampson SE, Glasgow RE. The Summary Of Diabetes Self-Care Activities measure: results from 7 studies and a revised scale. *Diabetes Care.* 2000;23(7):943-950. doi: 10.2337/diacare.23.7.943.

87. Chang SJ, Song MS. The validity and reliability of a Korean version of the summary of diabetes self-care activities questionnaire for older patients with type 2 diabetes. *Korean J Adult Nurs.* 2009;21(2):235-244.

88. Choi EJ, Nam M, Kim SH, et al. Psychometric properties of a Korean version of the summary of diabetes self-care activities measure. *Int J Nurs Stud.* 2011;48(3):333-337. doi: 10.1016/j.ijnurstu.2010.08.007.

89. Devlin N, Parkin D, Janssen B. Methods for analysing and reporting EQ-5D data [internet]: chapter 1, an introduction to EQ-5D instruments and their applications. Springer; 2020; https://www.ncbi.nlm.nih.gov/books/NBK565680/. Accessed November 27, 2024.

90. McClure NS, Sayah FA, Ohinmaa A, Johnson JA. Minimally important difference of the EQ-5D-5L index score in adults with type 2 diabetes. *Value Health.* 2018;21(9):1090-1097. doi: 10.1016/j.jval.2018.02.007.

91. Topp CW, Ostergaard SD, Sondergaard S, Bech P. The WHO-5 Well-Being Index: a systematic review of the literature. *Psychother Psychosom.* 2015;84(3):167-176. doi: 10.1159/000376585.

92. Ajjan RA, Abougila K, Bellary S, et al. Sensor and software use for the glycaemic management of insulin-treated type 1 and type 2 diabetes patients. *Diab Vasc Dis Res.* 2016;13(3):211-219. doi: 10.1177/1479164115624680.

93. Ajjan RA, Heller SR, Everett CC, et al. Multicenter randomized trial of intermittently scanned continuous glucose monitoring versus self-monitoring of blood glucose in individuals with type 2 diabetes and recent-onset acute myocardial infarction: results of the LIBERATES trial. *Diabetes Care.* 2023;46(2):441-449. doi: 10.2337/dc22-1219.

94. 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.

95. Aronson R, Brown RE, Chu L, et al. IMpact of flash glucose Monitoring in pEople with type 2 Diabetes Inadequately controlled with non-insulin Antihyperglycaemic ThErapy (IMMEDIATE): a randomized controlled trial. *Diabetes Obes Metab.* 2023;25(4):1024-1031. doi: 10.1111/dom.14949.

96. Bao S, Bailey R, Calhoun P, Beck RW. Effectiveness of continuous glucose monitoring in older adults with type 2 diabetes treated with basal insulin. *Diabetes Technol Ther.* 2022;24(5):299-306. doi: 10.1089/dia.2021.0494.

97. Bergenstal RM, Mullen DM, Strock E, Johnson ML, Xi MX. Randomized comparison of self-monitored blood glucose (BGM) versus continuous glucose monitoring (CGM) data to

optimize glucose control in type 2 diabetes. *J Diabetes Complications.* 2022;36(3):108106. doi: 10.1016/j.jdiacomp.2021.108106.

98. Billings LK, Parkin CG, Price D. Baseline glycated hemoglobin values predict the magnitude of glycemic improvement in patients with type 1 and type 2 diabetes: Subgroup analyses from the DIAMOND study program. *Diabetes Technol Ther.* 2018;20(8):561-565. doi: 10.1089/dia.2018.0163.

99. 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.

100. Ehrhardt NM, Chellappa M, Walker MS, Fonda SJ, Vigersky RA. The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. *J Diabetes Sci Technol.* 2011;5(3):668-675. doi: 10.1177/193229681100500320.

101. Everett CC, Reynolds C, Fernandez C, et al. Rationale and design of the LIBERATES trial: protocol for a randomised controlled trial of flash glucose monitoring for optimisation of glycaemia in individuals with type 2 diabetes and recent myocardial infarction. *Diab Vasc Dis Res.* 2020;17(5):1479164120957934. doi: 10.1177/1479164120957934.

102. Fonda SJ, Salkind SJ, Walker MS, Chellappa M, Ehrhardt N, Vigersky RA. Heterogeneity of responses to real-time continuous glucose monitoring (RT-CGM) in patients with type 2 diabetes and its implications for application. *Diabetes Care.* 2013;36(4):786-792. doi: 10.2337/dc12-1225.

103. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Use of flash glucose-sensing technology for 12 months as a replacement for blood glucose monitoring in insulin-treated type 2 diabetes. *Diabetes Ther.* 2017;8(3):573-586. doi: 10.1007/s13300-017-0255-6.

104. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Flash glucose-sensing technology as a replacement for blood glucose monitoring for the management of insulin-treated type 2 diabetes: a multicenter, open-label randomized controlled trial. *Diabetes Ther.* 2017;8(1):55-73. doi: 10.1007/s13300-016-0223-6.

105. Hayase A, Onoue T, Kobayashi T, et al. Improved glycemic control after the use of flash glucose monitoring accompanied by improved treatment satisfaction in patients with non-insulin-treated type 2 diabetes: a post-hoc analysis of a randomized controlled trial. *Prim Care Diabetes.* 2023;17(6):575-580. doi: 10.1016/j.pcd.2023.09.009.

106. 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.

107. 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.

108. Lever CS, Williman JA, Boucsein A, et al. Study protocol: glycaemic outcomes in people with type 2 diabetes initiating continuous glucose monitoring: the 2GO-CGM study. *J Diabetes Metab Disord.* 2023;22(2):1779-1792. doi: 10.1007/s40200-023-01244-y.

109. Lever CS, Williman JA, Boucsein A, et al. Real time continuous glucose monitoring in high-risk people with insulin-requiring type 2 diabetes: a randomised controlled trial. *Diabet Med.* 2024;41(8):e15348. doi: 10.1111/dme.15348.

110. Lind N, Christensen MB, Hansen DL, Norgaard K. Comparing continuous glucose monitoring and blood glucose monitoring in adults with inadequately controlled, insulin-treated type 2 diabetes (Steno2tech Study): a 12-month, single-center, randomized controlled trial. *Diabetes Care.* 2024;47(5):881-889. doi: 10.2337/dc23-2194.

111. Lind N, Lindqvist Hansen D, Saetre Rasmussen S, Norgaard K. Real-time continuous glucose monitoring versus self-monitoring of blood glucose in adults with insulin-treated type 2 diabetes: a protocol for a randomised controlled single-centre trial. *BMJ Open.* 2021;11(1):e040648. doi: 10.1136/bmjopen-2020-040648.

112. Majewska A, Stanirowski PJ, Tatur J, et al. Flash glucose monitoring in gestational diabetes mellitus (FLAMINGO): a randomised controlled trial. *Acta Diabetol.* 2023;60(9):1171-1177. doi: 10.1007/s00592-023-02091-2.

113. Martens T, Beck RW, Bailey R, et al. Effect of continuous glucose monitoring on glycemic control in patients with type 2 diabetes treated with basal insulin: a randomized clinical trial. *JAMA.* 2021;325(22):2262-2272. doi: 10.1001/jama.2021.7444.

114. 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 Obes Metab.* 2023;25(1):110-120. doi: 10.1111/dom.14852.

115. O'Connor MJ, Ding X, Hernandez C, Hubacz L, Church RJ, O'Connor L. A pilot trial of continuous glucose monitoring upon emergency department discharge among people with diabetes mellitus. *Endocr Pract.* 2024;30(2):122-127. doi: 10.1016/j.eprac.2023.11.001.

116. Peters A, Cohen N, Calhoun P, et al. Glycaemic profiles of diverse patients with type 2 diabetes using basal insulin: MOBILE study baseline data. *Diabetes Obes Metab.* 2021;23(2):631-636. doi: 10.1111/dom.14238.

117. Price DA, Deng Q, Kipnes M, Beck SE. Episodic real-time CGM use in adults with type 2 diabetes: results of a pilot randomized controlled trial. *Diabetes Ther*. 2021;12(7):2089-2099. doi: 10.1007/s13300-021-01086-y.

118. Rama Chandran S, Rahman N, Gandhi M, et al. Intermittently scanned continuous glucose monitoring provides no benefit over structured self-monitoring of blood glucose in type 2 diabetes not on prandial insulin, in the context of diabetes self-management education: GLucose monitoring programme SingaporE (GLiMPSE). *Diabetes Res Clin Pract*. 2024;211:111678. doi: 10.1016/j.diabres.2024.111678.

119. Tang TS, Digby EM, Wright AM, et al. Real-time continuous glucose monitoring versus internet-based blood glucose monitoring in adults with type 2 diabetes: a study of treatment satisfaction. *Diabetes Res Clin Pract*. 2014;106(3):481-486. doi: 10.1016/j.diabres.2014.09.050.

120. Taylor PJ, Thompson CH, Luscombe-Marsh ND, Wycherley TP, Wittert G, Brinkworth GDM. Efficacy of real-time continuous glucose monitoring to improve effects of a prescriptive lifestyle intervention in type 2 diabetes: a pilot study. *Diabetes Ther*. 2019;10(2):509-522. doi: 10.1007/s13300-019-0572-z.

121. Taylor PJ, Thompson CH, Luscombe-Marsh ND, et al. Tolerability and acceptability of real-time continuous glucose monitoring and its impact on diabetes management behaviours in individuals with Type 2 Diabetes - A pilot study. *Diabetes Res Clin Pract*. 2019;155:107814. doi: 10.1016/j.diabres.2019.107814.

122. Tildesley HD, Wright AM, Chan JH, et al. A comparison of internet monitoring with continuous glucose monitoring in insulin-requiring type 2 diabetes mellitus. *Can J Diabetes*. 2013;37(5):305-308. doi: 10.1016/j.jcjd.2013.05.006.

123. 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.

124. Wada E, Onoue T, Kobayashi T, et al. Flash glucose monitoring helps achieve better glycemic control than conventional self-monitoring of blood glucose in non-insulin-treated type 2 diabetes: a randomized controlled trial. *BMJ Open Diabetes Res Care*. 2020;8(1). doi: 10.1136/bmjdrc-2019-001115.

125. 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.

126. US Food and Drug Administration. Class 1 device recall the FreeStyle Libre flash glucose monitoring system. 2023;

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=198772. Accessed December 12, 2024.

127. US Food and Drug Administration. Class 1 device recall FreeStyle Libre 14 day flash glucose monitoring system. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=198773. Accessed December 12, 2024.

128. US Food and Drug Administration. Class 1 device recall FreeStyle Libre 2 flash glucose monitoring system. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=198813. Accessed December 12, 2024.

129. US Food and Drug Administration. Class 1 device recall FreeStyle Libre 3 sensor, a component of the FreeStyle Libre 3 continuous glucose monitoring system. 2024; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=209214. Accessed December 12, 2024.

130. US Food and Drug Administration. Class 2 device recall Guardian 4 sensor. 2024; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=205092. Accessed December 12, 2024.

131. Kerr D, Duncan I, Repetto E, et al. Cost analysis of self-monitoring blood glucose in nonintensively managed type 2 diabetes. *Am J Manag Care.* 2023;29(12):670-675. doi: 10.37765/ajmc.2023.89422.

132. Frank J, Son D, Szafranski K, Poon Y. Continuous glucose monitoring for self-management of diabetes in people living with type 2 diabetes mellitus on basal insulin therapy: A microsimulation model and cost-effectiveness analysis from a US perspective with relevance to Medicaid. *J Manag Care Spec Pharm.* 2024;30(9):917-928. doi: 10.18553/jmcp.2024.24025.

133. Carlson AL, Daniel TD, DeSantis A, et al. Flash glucose monitoring in type 2 diabetes managed with basal insulin in the USA: a retrospective real-world chart review study and meta-analysis. *BMJ Open Diabetes Res Care.* 2022;10(1):e002590. doi: 10.1136/bmjdrc-2021-002590.

134. Guerci B, Roussel R, Levrat-Guillen F, et al. Important decrease in hospitalizations for acute diabetes events following FreeStyle Libre system initiation in people with type 2 diabetes on basal insulin therapy in France. *Diabetes Technol Ther.* 2023;25(1):20-30. doi: 10.1089/dia.2022.0271.

135. Sagy I, Zimhony-Nissim N, Brandstaetter E, et al. Outcomes of diabetic ketoacidosis in a tertiary centre with restricted intensive care unit bed capacity. *Intern Med J.* 2021;51(6):948-954. doi: 10.1111/imj.14842.

136. Edridge CL, Dunkley AJ, Bodicoat DH, et al. Prevalence and incidence of hypoglycaemia in 532,542 people with type 2 diabetes on oral therapies and insulin: a systematic review and meta-analysis of population based studies. *PLoS One.* 2015;10(6):e0126427. doi: 10.1371/journal.pone.0126427.

137. Bergenstal RM, Kerr MSD, Roberts GJ, Souto D, Nabutovsky Y, Hirsch IB. Flash CGM is associated with reduced diabetes events and hospitalizations in insulin-treated type 2 diabetes. *J Endocr Soc.* 2021;5(4):bvab013. doi: 10.1210/jendso/bvab013.

138. ISRCTN Registry. ISRCTN12804317. Continuous glucose monitoring amongst pregnant women with early-onset type 2 diabetes. https://www.isrctn.com/ISRCTN12804317. Accessed November 15, 2024.

139. ISRCTN Registry. ISRCTN17386990. Type 2 diabetes self-management using continuous glucose monitoring. https://www.isrctn.com/ISRCTN17386990. Accessed November 15, 2024.

140. ISRCTN Registry. ISRCTN92877235. Comparing continuous glucose monitoring with self-monitoring of blood glucose in gestational diabetes. https://www.isrctn.com/ISRCTN92877235. Accessed November 15, 2024.

141. ClinicalTrials.gov. NCT04219085. Continuous glucose monitoring in A2 gestational diabetes and pregnancy outcomes (CAPO). https://clinicaltrials.gov/study/NCT04219085. Accessed November 15, 2024.

142. ClinicalTrials.gov. NCT04663061. Diabetes data-assisted remission trial (DDART). https://clinicaltrials.gov/study/NCT04663061. Accessed November 15, 2024.

143. ClinicalTrials.gov. NCT04871438. Flash continous glucose monitoring in transition to outpatient: libre for type 2 diabetes mellitus (CONTROL-DM). https://clinicaltrials.gov/study/NCT04871438. Accessed November 15, 2024.

144. ClinicalTrials.gov. NCT04926623. FreeStyle Libre-based education on MDI in T2DM (FreEdoM-2). https://clinicaltrials.gov/study/NCT04926623. Accessed November 15, 2024.

145. ClinicalTrials.gov. NCT04948112. Effectiveness of CGMS vs. self-monitoring blood glucose (SMBG) in woman with gestational diabetes (STEADYSUGAR). https://clinicaltrials.gov/study/NCT04948112. Accessed November 15, 2024.

146. ClinicalTrials.gov. NCT05037526. Utility of real time continuous glucose monitoring in the care of gestational diabetes versus standard care in pregnancy outcomes (DiP GlucoMo). https://clinicaltrials.gov/study/NCT05037526. Accessed November 15, 2024.

147. ClinicalTrials.gov. NCT05222815. Glucose monitoring comparison in primary care (GluCoCare). https://clinicaltrials.gov/study/NCT05222815. Accessed November 15, 2024.

148. ClinicalTrials.gov. NCT05317585. Continuous glucose monitor use in pregnancy. https://clinicaltrials.gov/study/NCT05317585. Accessed November 15, 2024.

149. ClinicalTrials.gov. NCT05319496. isCGM with education and feedback for non-insulin dependent type 2 diabetes (iCUDE). https://clinicaltrials.gov/study/NCT05319496. Accessed November 15, 2024.

150. ClinicalTrials.gov. NCT05370612. AT GOAL: adopting technology for glucose optimization and lifestyle in pregnancy. https://clinicaltrials.gov/study/NCT05370612. Accessed November 15, 2024.

151. ClinicalTrials.gov. NCT05394844. Diabetes education with real-time continuous glucose monitoring (CUTDM). https://clinicaltrials.gov/study/NCT05394844. Accessed November 15, 2024.

152. ClinicalTrials.gov. NCT05431296. Glucose monitoring after acute myocardial infarct in people with diabetes (GLAM). https://clinicaltrials.gov/study/NCT05431296. Accessed November 15, 2024.

153. ClinicalTrials.gov. NCT05516797. Impact of glucose monitoring and nutrition on time in range (IGNITE). https://clinicaltrials.gov/study/NCT05516797. Accessed November 15, 2024.

154. ClinicalTrials.gov. NCT05826678. Trial to assess continuous glucose monitoring in asian americans with type 2 diabetes. https://clinicaltrials.gov/study/NCT05826678. Accessed November 15, 2024.

155. ClinicalTrials.gov. NCT05911256. A community health worker/pharmacist team to improve blood sugars in diabetes care using continuous glucose monitoring (TEAM-CGM). https://clinicaltrials.gov/study/NCT05911256. Accessed November 15, 2024.

156. ClinicalTrials.gov. NCT05944432. CGM use in adults with type 2 diabetes on basal insulin. https://clinicaltrials.gov/study/NCT05944432. Accessed November 15, 2024.

157. ClinicalTrials.gov. NCT06028503. ACT intervention for type 2 diabetes management for rural and underserved community. https://clinicaltrials.gov/study/NCT06028503. Accessed November 15, 2024.

158. ClinicalTrials.gov. NCT06031987. Long-term effects of flash glucose monitoring system in patients with gestational diabetes (GDMLIBRE). https://clinicaltrials.gov/study/NCT06031987. Accessed November 15, 2024.

159. ClinicalTrials.gov. NCT06054659. CGM and DFU healing post-discharge. https://clinicaltrials.gov/study/NCT06054659. Accessed November 15, 2024.

160. ClinicalTrials.gov. NCT06089070. Continuous glucose monitoring system feasibility in youth with T2D (FREE_CGM). https://clinicaltrials.gov/study/NCT06089070. Accessed November 15, 2024.

161. ClinicalTrials.gov. NCT06111508. The effect and safety of a novel CGM-based titration algorithm for basal insulin in T2DM participants. (CGM-DTx). https://clinicaltrials.gov/study/NCT06111508. Accessed November 15, 2024.

162. ClinicalTrials.gov. NCT06296550. Enhancing digitally delivered diabetes education with real-time CGM. https://clinicaltrials.gov/study/NCT06296550. Accessed November 15, 2024.

163. ClinicalTrials.gov. NCT06310356. Continuous glucose monitoring for women with gestational diabetes (CORDELIA). https://clinicaltrials.gov/study/NCT06310356. Accessed November 15, 2024.

164. ClinicalTrials.gov. NCT06436326. The impact of continuous glucose monitoring on maternal and infant's outcomes in gestational diabetes. https://clinicaltrials.gov/study/NCT06436326. Accessed November 15, 2024.

165. ClinicalTrials.gov. NCT06465693. Personalized nutrition therapy using continuous glucose monitoring to improve outcomes in type 2 diabetes mellitus. https://clinicaltrials.gov/study/NCT06465693. Accessed November 15, 2024.

166. ClinicalTrials.gov. NCT06471699. The effect of continuous glucose monitoring in individuals with newly diagnosed type 2 diabetes (CHANGE-diab). https://clinicaltrials.gov/study/NCT06471699. Accessed November 15, 2024.

167. ClinicalTrials.gov. NCT06517576. Using remote monitoring to address health disparities in type 2 diabetes. https://clinicaltrials.gov/study/NCT06517576. Accessed November 15, 2024.

168. ClinicalTrials.gov. NCT06594055. Periodic use of continuous glucose monitoring with personalized diet interventions using AI camera among non-insulin treated type 2 diabetes. https://clinicaltrials.gov/study/NCT06594055. Accessed November 15, 2024.

169. ClinicalTrials.gov. NCT06641765. Continuous glucose monitoring in dialysis patients with diabetes. https://clinicaltrials.gov/study/NCT06641765. Accessed November 15, 2024.

170. ClinicalTrials.gov. NCT06643611. Addressing disparities in diabetes care. https://clinicaltrials.gov/study/NCT06643611. Accessed November 15, 2024.

171. ClinicalTrials.gov. NCT06648174. The project for managing cardiometabolic risk in women diagnosed with gestational diabetes mellitus. https://clinicaltrials.gov/study/NCT06648174. Accessed November 15, 2024.

172. ClinicalTrials.gov. NCT03981328. The effectiveness of rt-CGM to improve glycemic control and pregnancy outcome in patients with GDM. https://clinicaltrials.gov/study/NCT03981328. Accessed November 18, 2024.

173. ISRCTN Registry. ISRCTN42125256. Intermittent glucose monitoring for the management of gestational diabetes mellitus. https://www.isrctn.com/ISRCTN42125256. Accessed November 18, 2024.

174. ANZCTR Registry. ACTRN12621000889853. Glycaemic outcomes in people with type 2 diabetes initiating continuous glucose monitoring (2GO-CGM). https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=381981&isReview=true. Accessed November 18, 2024.

175. Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology clinical practice guideline: The use of advanced technology in the management of persons with diabetes mellitus. *Endocr Pract*. 2021;27(6):505-537. doi: 10.1016/j.eprac.2021.04.008.

176. McCall AL, Lieb DC, Gianchandani R, et al. Management of individuals with diabetes at high risk for hypoglycemia: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2023;108(3):529-562. doi: 10.1210/clinem/dgac596.

177. Ontario Health (Quality). Flash glucose monitoring system for people with type 1 or type 2 diabetes: recommendation. 2019; https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/flash-glucose-monitoring-system-for-people-with-type-1-or-type-2-diabetes. Accessed October 28, 2024.

178. Healthcare Improvement Scotland. SIGN 171: management of diabetes in pregnancy. 2024; https://www.sign.ac.uk/media/2205/sign-171-management-of-diabetes-in-pregnancy.pdf. Accessed October 25, 2024.

179. LeRoith D, Biessels GJ, Braithwaite SS, et al. Treatment of diabetes in older adults: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2019;104(5):1520-1574. doi: 10.1210/jc.2019-00198.

180. National Institute for Health and Care Excellence. Diabetes in pregnancy: management from preconception to the postnatal period (NG3). 2020; https://www.nice.org.uk/guidance/ng3/resources/diabetes-in-pregnancy-management-from-preconception-to-the-postnatal-period-pdf-51038446021. Accessed October 25, 2024.

181. National Institute for Health and Care Excellence. Type 2 diabetes in adults: management (NG28). 2022; https://www.nice.org.uk/guidance/ng28/resources/type-2-diabetes-in-adults-management-pdf-1837338615493. Accessed October 25, 2024.

182. National Institute for Health and Care Excellence. Diabetes (type 1 and type 2) in children and young people: diagnosis and management (NG18). 2023; https://www.nice.org.uk/guidance/ng18. Accessed October 25, 2024.

183. Ontario H. Flash glucose monitoring system for people with type 1 or type 2 diabetes: A health technology assessment. *Ont Health Technol Assess Ser.* 2019;19(8):1-108.

184. VA/DOD Clinical Practice Guideline. Management of type 2 diabetes mellitus. 2023; https://www.healthquality.va.gov/guidelines/CD/diabetes/VADOD-Diabetes-CPG_Final_508.pdf. Accessed October 25, 2024.

185. American Diabetes Association. Standards of care in diabetes. 2024; https://professional.diabetes.org/standards-of-care. Accessed October 28, 2024.

186. American Diabetes Association Professional Practice C. 14. Children and adolescents: Standards of Care in Diabetes-2024. *Diabetes Care.* 2024;47(Suppl 1):S258-S281. doi: 10.2337/dc24-S014.

187. American Diabetes Association Professional Practice C. 15. Management of diabetes in pregnancy: Standards of Care in Diabetes-2024. *Diabetes Care.* 2024;47(Suppl 1):S282-S294. doi: 10.2337/dc24-S015.

188. Medicare Coverage Database. Local coverage determination glucose monitors: L33822. 2024; https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822. Accessed October 24, 2024.

189. Aetna. Diabetes tests, programs and supplies. 2024; https://www.aetna.com/cpb/medical/data/1_99/0070.html. Accessed October 24, 2024.

190. Anthem. Continuous glucose monitoring devices. 2024; https://www.anthembluecross.com/dam/medpolicies/abcny/active/guidelines/gl_pw_d073854.html. Accessed October 24, 2024.

191. Cigna. Prior authorization policy: diabetes, continuous glucose monitoring systems prior authorization policy. 2024; https://static.cigna.com/assets/chcp/pdf/coveragePolicies/cnf/cnf_676_coveragepositioncriteria_diabetes_continuous_glucose_monitoring_systems_pa.pdf. Accessed October 24, 2024.

192. Cigna. Diabetes equipment and supplies. 2025; https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_Future/mm_0106_coveragepositioncriteria_blood_glucose_monitors.pdf. Accessed October 24, 2024.

193. Oregon Health Evidence Review Commission. Coverage guidance: continuous glucose monitoring in diabetes mellitus. 2023; https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/CG%20for%20CGM%202023_final.pdf. Accessed October 25, 2024.

194. Regence. Coverage for continuous glucose monitors moving to pharmacy benefit in 2023. 2022; https://www.regence.com/producer/knowledge-center/producer-update/continuous-glucose-monitors. Accessed November 13, 2024.

195. American Diabetes Association. Advocacy: continuous glucose monitors. 2024; https://diabetes.org/advocacy/cgm-continuous-glucose-monitors. Accessed October 21, 2024.

196. American Diabetes Association. Advocacy: FAQs on CGM coverage criteria changes in Medicare. 2024; https://diabetes.org/advocacy/cgm-continuous-glucose-monitors/faqs-medicare-coverage. Accessed October 21, 2024.

197. Oser SM, Oser TK. Medicare coverage of continuous glucose monitoring: 2023 updates. *Fam Pract Manag*. 2024;31(1):17-18.

198. Schaffer R. We have to make it easy: barriers hinder CGM access for some people with diabetes. Healio News; 2023; https://www.healio.com/news/endocrinology/20230524/we-have-to-make-it-easy-barriers-hinder-cgm-access-for-some-people-with-diabetes. Accessed October 22, 2024.

199. Association of Diabetes Care and Education Specialists. CGM insurance coverage tool from Danatech. 2022; https://danatech.policyacumen.health/. Accessed October 22, 2024.

200. Drummond MF, Jefferson TO. Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. *BMJ*. 1996;313(7052):275-283. doi: 10.1136/bmj.313.7052.275.

201. Husereau D, Drummond M, Petrou S, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. *BMJ*. 2013;346:f1049. doi: 10.1136/bmj.f1049.

202. Canadian Agency for Drugs and Technologies in Health. Guidelines for the economic evaluation of health technologies: Canada. 2017; https://www.cadth.ca/sites/default/files/pdf/guidelines_for_the_economic_evaluation_of_health_technologies_canada_4th_ed.pdf. Accessed August 28, 2018.

203. Evers S, Goossens M, de Vet H, van Tulder M, Ament A. Criteria list for assessment of methodological quality of economic evaluations: Consensus on Health Economic Criteria. *International journal of technology assessment in health care.* 2005;21(2):240-245.

204. National Institute for Health and Care Excellence. Developing NICE guidelines: the manual. NICE; 2014; https://www.nice.org.uk/media/default/about/what-we-do/our-programmes/developing-nice-guidelines-the-manual.pdf. Accessed December 15, 2015.

205. Brouwers MC, Kho ME, Browman GP, et al. AGREE II: advancing guideline development, reporting and evaluation in health care. *CMAJ.* 2010;182(18):E839-842. doi: 10.1503/cmaj.090449.

206. Brouwers MC, Kho ME, Browman GP, et al. Development of the AGREE II, part 2: assessment of validity of items and tools to support application. *CMAJ.* 2010;182(10):E472-478. doi: 10.1503/cmaj.091716.

207. Ontario Health (Quality). Flash glucose monitoring system for people with type 1 or type 2 diabetes: recommendation. 2019; https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/flash-glucose-monitoring-system-for-people-with-type-1-or-type-2-diabetes. Accessed February 15, 2023.

208. National Institute for Health and Care Excellence. Diabetes in pregnancy: management from preconception to the postnatal period: [a] evidence review for continuous glucose monitoring in pregnancy. 2020; https://www.nice.org.uk/guidance/ng3/evidence/a-continuous-glucose-monitoring-pdf-8955770797. Accessed February 08, 2023.

209. Oregon Health Authority, Health Evidence Review Commission. Continuous glucose monitoring in diabetes mellitus. 2023; https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports-Blog.aspx?View={DE654D2C-76D6-4607-B754-C7862C05B54F}&SelectedID=5. Accessed October 25, 2024.

Appendix A. Clinical Evidence Methods

Search Strategy

We searched select clinical bibliographic databases (Table A1) and gray literature clinical evidence sources to identify randomized controlled trials (RCTs), cost-effectiveness studies, and clinical practice guidelines analyzing CGM in listed populations of interest including the terms: *continuous glucose monitor*, *real-time CGM*, *flash or intermittent CGM*, *glycemic monitoring*, *glycemic sensor*, *diabetes*, and *insulin* (see below for full search strategies). We limited records retrieved to those studies on human subjects and published in the English language. We also used study design and publication type (e.g., RCT, economic evaluation) filters to limit records retrieved. Systematic reviews were used for reference list searching and not as evidence sources. Clinical evidence searches for this report were based on those conducted for a previous evidence review of this topic that assessed literature published through March 23, 2023; searches for this review were conducted on September 4 and 5, 2024, and included clinical references published since January 1, 2017, 1 year before the 2018 Wahington HTA coverage decision on CGM, and a new search for economic studies of cost-effectiveness limited to references published in the past 5 years (January 01, 2019, to September 05, 2024).

Table A1. Bibliographic Databases Searched

Database	Platform	Issue/Version	Total Number of Records Retrieved
Previous searches			
MEDLINE ALL	Ovid	1946 to March 23, 2023	4,659 • RCTs: 2,159 • Harms: 1,617 • Systematic reviews: 883
Current searches			
CENTRAL	Wiley	Issue 9 of 12, September 2024	1,329
MEDLINE ALL	Ovid	1946 to September 04, 2024	2,040 • RCTs: 1,778 • Economic studies: 262
APA PsycINFO	Ovid	1806 to August 2024 Week 5	92

Abbreviations. APA: American Psychological Association; CENTRAL: Cochrane Central Register of Controlled Trials; RCT: randomized controlled trial.

Ovid MEDLINE ALL Search Strategy

1	(continu* adj3 glucose monitor*).mp.	8530
2	(continu* adj3 glyc?emic monitor*).mp.	16
3	(continu* adj3 glucose sens*).mp.	277
4	(continu* adj3 glyc?emic sens*).mp.	1
5	(constant* adj3 glucose monitor*).mp.	10
6	(constant* adj3 glyc?emic monitor*).mp.	0

7 (constant* adj3 glucose sens*).mp. 1

8 (constant* adj3 glyc?emic sens*).mp. 0

9 (flash* adj3 glucose monitor*).mp. 684

10 (flash* adj3 glyc?emic monitor*).mp. 1

11 (flash* adj3 glucose sens*).mp. 10

12 (flash* adj3 glyc?emic sens*).mp. 0

13 flash cgm*.mp. 26

14 ((realtime or real-time or real time or rt) adj3 glucose adj2 monitor*).mp. 649

15 ((realtime or real-time or real time or rt) adj3 glyc?em* adj2 monitor*).mp. 5

16 ((realtime or real-time or real time or rt) adj3 glucose adj2 sens*).mp. 63

17 ((realtime or real-time or real time or rt) adj3 glyc?em* adj2 sens*).mp. 3

18 cgm$1.ti,ab. and (diabetes or insulin).mp. 5384

19 isCGM*.mp. 197

20 (intermittent* adj4 glucose adj2 monitor*).mp. 320

21 (intermittent* adj4 glyc?em* adj2 monitor*).mp. 4

22 (intermittent* adj4 glucose adj2 sens*).mp. 6

23 (intermittent* adj4 glyc?em* adj2 sens*).mp. 0

24 (ambulatory adj3 glucose adj2 monitor*).mp. 42

25 (ambulatory adj3 glyc?em* adj2 monitor*).mp. 0

26 (ambulatory adj3 glucose adj2 sens*).mp. 6

27 (ambulatory adj3 glyc?em* adj2 sens*).mp. 0

28 ((sensor-augmented or sensor augmented) adj4 pump*).mp. 476

29 (hybrid adj5 (closed-loop or closed loop)).mp. 729

30 Senseonics*.mp. 15

31 Eversense*.mp. 27

32 animas vibe*.mp. 4

33 dexcom*.mp. 419

34 (abbott* and (freestyle* or libre* or navigator* or lingo*)).mp. 192

35 (freestyle* and (glucose or diabetes or CGM$1)).mp. 689

36 (libre* and (glucose or diabetes or CGM$1)).mp. 731

37 (navigator* and (glucose or diabetes or CGM$1)).mp. 197

38 (Medtronic* and (guardian* or minimed* or IPRO2* or Paradigm* or Enlite*)).mp. 421

39 (minimed* and (glucose or diabetes or CGM$1)).mp. 476

40 (enlite* and (glucose or diabetes or CGM$1)).mp. 58

41 IPRO2*.mp. 60

42 omnipod*.mp. 89

43 ("t:slim*" or t-slim*).mp. 74

44 SmartGuard*.mp. 32

45 or/1-44 11769

46 (baboon$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 macque$1 or mice or monkey$1 or (mouse adj2 model$1) or murine$1 or ovine or pig$1 or porcine or (non-human adj2 primate$1) or sheep or rabbit$1 or rat or rats or rattus or rhesus or rodent$1 or zebrafish).ti. 2218812

47 45 not 46 11272

48 limit 47 to english language 10856

49 Randomized Controlled Trial/ 620768

50 Random Allocation/ 107556

51 Control Groups/ 2131

52 Placebos/ 35992

53 (random* or sham or placebo* or head-to-head).ti,ab,kf. 1724910

54 Single-Blind Method/ 33947

55 Double-Blind Method/ 180192

56 ((singl* or doubl*) adj (blind* or dumm* or mask*)).ti,ab,kf. 206364

57 ((tripl* or trebl*) adj (blind* or dumm* or mask*)).ti,ab,kf. 1909

58 Controlled Clinical Trial/ 95599

59 exp "Controlled Clinical Trials as Topic"/ 183445

60 (control* adj3 (study or studies or trial* or group*)).ti,ab,kf. 1324180

61 (non random* or non-random* or quasi-random*).ti,ab,kf. 34415

62 allocated.ti,ab,kf. 90940

63 ((open label or open-label) adj5 (study or studies or trial*)).ti,ab,kf. 48970

64 ((equivalence or superiority or non-inferiority or noninferiority) adj3 (study or studies or trial*)).ti,ab,kf. 13168

65 (pragmatic study or pragmatic studies).ti,ab,kf. 670

66 ((pragmatic or practical) adj3 trial*).ti,ab,kf. 6843

67 (quasi-experimental adj3 (study or studies or trial*)).ti,ab,kf. 13813

68 "Clinical Trials, Phase II as Topic"/ 9516

69 ((phase adj3 (II or "2") adj3 (study or studies or trial*)) or phase2).ti,ab,kf. 68482

70 "Clinical Trials, Phase III as Topic"/ 11572

71 ((phase adj3 (III or "3") adj3 (study or studies or trial*)) or phase3).ti,ab,kf. 55131

72 "Clinical Trials, Phase IV as Topic"/ 404

73 ((phase adj3 (IV or "4") adj3 (study or studies or trial*)) or phase4).ti,ab,kf. 3120

74 Comparative Effectiveness Research/ 4064

75 (compar* adj3 (effectiveness or efficacy)).ti,ab,kf. 109865

76 (active adj1 (comparator* or control$1 or treatment* or intervention*)).ti,ab,kf. 25649

77 (Randomized Controlled Trial or Controlled Clinical Trial or Pragmatic Clinical Trial or Equivalence Trial or clinical trial, phase ii or Clinical Trial, Phase III or clinical trial, phase iv).pt. 743920

78 or/49-77 2893640

79 48 and 78 2661

80 limit 79 to yr="2017 -Current" 1778

81 Economics/ 27539

82 exp "Costs and Cost Analysis"/ 272881

83 Economics, Nursing/ 4013

84 Economics, Medical/ 9291

85 Economics, Pharmaceutical/ 3146

86 exp Economics, Hospital/ 25962

87 Economics, Dental/ 1922

88 exp "Fees and Charges"/ 31509

89 exp Budgets/ 14254

90 budget*.ti,kf. 9571

91 (economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed).ti,kf. 301176

92 (cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ti,ab,kf. 246418

93 (value adj2 (money or monetary)).ti,ab,kf. 3269

94 exp models, economic/ 16492

95 economic model*.ti,ab,kf. 4943

96 markov chains/ 16406

97 markov.ti,ab,kf. 31411

98 monte carlo method/ 33259

99 monte carlo.ti,ab,kf. 64246

100 exp Decision Theory/ 13812

101 (decision* adj2 (tree* or analy* or model*)).ti,ab,kf. 44737

102 or/81-101 782394

103 48 and 102 430

104 limit 103 to yr="2019 -Current" 262

APA PsycINFO Search Strategy

1 (continu* adj3 glucose monitor*).mp. 130

2 (continu* adj3 glyc?emic monitor*).mp. 0

3 (continu* adj3 glucose sens*).mp. 2

4 (continu* adj3 glyc?emic sens*).mp. 0

5 (constant* adj3 glucose monitor*).mp. 0

6 (constant* adj3 glyc?emic monitor*).mp. 0

7 (constant* adj3 glucose sens*).mp. 0

8 (constant* adj3 glyc?emic sens*).mp. 0

9 (flash* adj3 glucose monitor*).mp. 2

10 (flash* adj3 glyc?emic monitor*).mp. 0

11 (flash* adj3 glucose sens*).mp. 0

12 (flash* adj3 glyc?emic sens*).mp. 0

13 flash cgm*.mp. 0

14 ((realtime or real-time or real time or rt) adj3 glucose adj2 monitor*).mp. 7

15 ((realtime or real-time or real time or rt) adj3 glyc?em* adj2 monitor*).mp. 0

16 ((realtime or real-time or real time or rt) adj3 glucose adj2 sens*).mp. 0

17 ((realtime or real-time or real time or rt) adj3 glyc?em* adj2 sens*).mp. 0

18 cgm$1.ti,ab. and (diabetes or insulin).mp. 89

19 isCGM*.mp. 1

20 (intermittent* adj4 glucose adj2 monitor*).mp. 1

21 (intermittent* adj4 glyc?em* adj2 monitor*).mp. 0

22 (intermittent* adj4 glucose adj2 sens*).mp. 0

23 (intermittent* adj4 glyc?em* adj2 sens*).mp. 0

24 (ambulatory adj3 glucose adj2 monitor*).mp. 0

25 (ambulatory adj3 glyc?em* adj2 monitor*).mp. 0

26 (ambulatory adj3 glucose adj2 sens*).mp. 0

27 (ambulatory adj3 glyc?em* adj2 sens*).mp. 0

28 ((sensor-augmented or sensor augmented) adj4 pump*).mp. 2

29 (hybrid adj5 (closed-loop or closed loop)).mp. 8

30 Senseonics*.mp. 0

31 Eversense*.mp. 0

32 animas vibe*.mp. 0

33 dexcom*.mp. 4

34 (abbott* and (freestyle* or libre* or navigator* or lingo*)).mp. 0

35 (freestyle* and (glucose or diabetes or CGM$1)).mp. 5

36 (libre* and (glucose or diabetes or CGM$1)).mp. 9

37 (navigator* and (glucose or diabetes or CGM$1)).mp. 14

38 (Medtronic* and (guardian* or minimed* or IPRO2* or Paradigm* or Enlite*)).mp. 3

39 (minimed* and (glucose or diabetes or CGM$1)).mp. 0

40 (enlite* and (glucose or diabetes or CGM$1)).mp. 1

41 IPRO2*.mp. 0

42 omnipod*.mp. 0

43 ("t:slim*" or t-slim*).mp. 2

44 SmartGuard*.mp. 0

45 or/1-44 211

46 (baboon$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 macque$1 or mice or monkey$1 or (mouse adj2 model$1) or murine$1 or ovine or pig$1 or porcine or (non-human adj2 primate$1) or sheep or rabbit$1 or rat or rats or rattus or rhesus or rodent$1 or zebrafish).ti. 166629

47 45 not 46 189

48 limit 47 to english language 183

49 limit 48 to yr="2017 -Current" 114

50 limit 49 to "0400 dissertation abstract" 22

51 49 not 50 92

Cochrane CENTRAL Search Strategy

1 (continu* near/3 glucose monitor*) 4084

2 (continu* near/3 glyc?emic monitor*) 186

3 (continu* near/3 glucose sensor*) 861

4	(continu* near/3 glyc?emic sensor*)	27
5	(constant* near/3 glucose monitor*)	18
6	(constant* near/3 glyc?emic monitor*)	5
7	(constant* near/3 glucose sensor*)	8
8	(constant* near/3 glyc?emic sensor*)	2
9	(flash* near/3 glucose monitor*)	332
10	(flash* near/3 glyc?emic monitor*)	12
11	(flash* near/3 glucose sensor*)	122
12	(flash* near/3 glyc?emic sensor*)	3
13	flash cgm*	108
14	((realtime or real-time or real time or rt) near/3 glucose near/2 monitor*)	429
15	((realtime or real-time or real time or rt) near/3 glyc?em* near/2 monitor*)	14
16	((realtime or real-time or real time or rt) near/3 glucose near/2 sensor*)	92
17	((realtime or real-time or real time or rt) near/3 glyc?em* near/2 sensor*)	0
18	cgm*:ti,ab and (diabetes or insulin)	2981
19	isCGM*	97
20	(intermittent* near/4 glucose near/2 monitor*)	133
21	(intermittent* near/4 glyc?em* near/2 monitor*)	3
22	(intermittent* near/4 glucose near/2 sensor*)	6
23	(intermittent* near/4 glyc?em* near/2 sensor*)	0
24	(ambulatory near/3 glucose near/2 monitor*)	27
25	(ambulatory near/3 glyc?em* near/2 monitor*)	0
26	(ambulatory near/3 glucose near/2 senor*)	0
27	(ambulatory near/3 glyc?em* near/2 senor*)	0
28	Senseonics*	8
29	Eversense*	13
30	animas vibe*	3

31	dexcom*	441
32	(abbott* and (freestyle* or libre* or navigator*))	148
33	(freestyle* and (glucose or diabetes or CGM*))	389
34	(libre* and (glucose or diabetes or CGM*))	431
35	(navigator* and (glucose or diabetes or CGM*))	149
36	(Medtronic* and (guardian* or minimed* or IPRO2* or Paradigm* or Enlite*))	282
37	(minimed* and (glucose or diabetes or CGM*))	248
38	(enlite* and (glucose or diabetes or CGM*))	64
39	IPRO2*	86
40	omnipod*	48
41	t-slim*	53
42	SmartGuard*	26
43	or 1-42	5558
44	dissertation:so or trial:pt or conference:pt	782385
45	43 not 44 with Cochrane Library publication date Between Jul 2019 and Aug 2024, in Cochrane Reviews	24
46	43 not 44 with Publication Year from 2017 to 2024, in Trials	1348
47	46 and english:la	1329

Gray Literature

Search Terms

- Continuous glucose monitoring
- Flash CGM
- Gestational diabetes
- Intermittent or intermittently scanned CGM
- Real-time CGM
- Glycemic monitoring
- Glycemic sensor
- Type 2 diabetes

Sources

We searched the following gray literature sources for relevant literature using the search terms outlined above:

- Agency for Healthcare Research and Quality (AHRQ)
  - Effective Health Care (EHC) Program
  - Evidence-based Practice Centers (EPC) Reports
- American Diabetes Association (ADA)
- American Association of Clinical Endocrinology (AACE)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Oregon Health Evidence Review Commission (HERC)
- Institute for Clinical and Economic Review (ICER)/California Technology Assessment Forum (CTAF)
- International Health Technology Assessment (HTA) Database
- National Institute for Health and Care Excellence (NICE)
- Veterans Administration Evidence-based Synthesis Program (VA-ESP)

We searched Medicare, Oregon Medicaid, Aetna, Cigna, and Regence BlueCross BlueShield (Regence) for current CGM policies and used general internet searches in DuckDuckGo and Google Scholar for background and gray literature searches.

Ongoing Studies

We searched the following sources for ongoing studies using the search terms: *continuous glucose monitor*, *real-time CGM*, *flash or intermittent CGM*, *glycemic monitoring*, *glycemic sensor*, *type 2 diabetes*, *gestational diabetes* and *insulin*.

- ClinicalTrials.gov
- ScanMedicine

Clinical Practice Guidelines

We searched clinical practice guideline sources and performed general internet searches using DuckDuckGo to identify guidelines using the search terms: *continuous glucose monitor*, *real-time CGM*, *flash or intermittent CGM*, *glycemic monitoring*, *glycemic sensor*, *type 2 diabetes*, *gestational diabetes* and *insulin*. We searched the following sources for clinical practice guidelines published in the past 5 years:

- Agency for Healthcare Research and Quality (AHRQ)
- American Diabetes Association (ADA)
- American Association of Clinical Endocrinology (AACE)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Oregon Health Evidence Review Commission (HERC)
- Institute for Clinical and Economic Review (ICER)/California Technology Assessment Forum (CTAF)
- International Health Technology Assessment (HTA) Database
- National Institute for Health and Care Excellence (NICE)
- Veterans Administration Evidence-based Synthesis Program (VA-ESP)

Screening

Two researchers independently screened all titles and abstracts of identified documents using the inclusion and exclusion criteria (Table A2). When there was disagreement about eligibility, a

third senior researcher resolved the disagreement. This method was repeated for full-text review of documents that could not be excluded by title and abstract screening.

Inclusion and Exclusion Criteria

Table A2. Detailed Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Populations	

• Adults with T2D who are:
  ○ On nonintensive insulin regimens (1 to 3 injections per day)
  ○ On oral hypoglycemic medications, but not on insulin
  ○ Not on insulin or oral medications
• Children with T2D who are:
  ○ On nonintensive insulin regimens (1 to 3 injections per day)
  ○ On oral hypoglycemic medications, but not on insulin
  ○ Not on insulin or oral medications
• Pregnant people with T2D who are not using insulin
• Pregnant people with GDM who are not using insulin
	• Populations other than those listed

Interventions	
• FDA-approved CGM devices • FDA-approved combination devices integrating CGM with insulin pump or infusion (including sensor-augmented insulin pumps) if the effect of the CGM component can be isolated	• Interventions other than those listed • Professional (retrospective) CGM
Comparators	
• Self-monitoring using conventional blood glucose meters (SMBG) • Attention control • Blinded or sham CGM • Routine lab monitoring • Usual care	• Comparators other than those listed • No comparator • Comparisons of different models of the same device
Outcomes	

• Primary intermediate outcomes
  ○ Achieving target HbA1C level[a]
  ○ Maintaining target HbA1C level
  ○ Change in HbA1c[a]
  ○ Acute episodes of hypoglycemia requiring intervention
• Secondary intermediate outcomes
  ○ Quality of life (validated instruments only) [a]
  ○ Mortality
  ○ Perinatal mortality[a]
  ○ Severe perinatal morbidity[a]
• Safety related to the device itself
• Economic outcomes
  ○ Cost-effectiveness
  ○ Health care resource utilization and costs
	• Outcomes other than those listed
	• Economic outcomes from studies:
	  ○ Performed in non-US countries
	  ○ Published more than 5 years ago

Inclusion Criteria	Exclusion Criteria
Timing	
• When used for routine monitoring of glucose control in T2D	• Other uses (e.g., monitoring hyperglycemia during hospitalization for coronary care)
Setting	
• KQs 1-3: Any outpatient or inpatient clinical setting in countries categorized as *very high* on the UN Human Development Index • KQ4: US settings only	• Emergency settings • Nonclinical settings (e.g., studies in healthy volunteers) • Countries categorized other than *very high* on the UN Human Development Index
Study design and sample size	

• KQ1
  ○ RCTs with no sample size limitation
• KQ2
  ○ RCTs with no sample size limitation
  ○ FDA documentation on device-related safety concerns
• KQ3
  ○ RCTs with no sample size limitation
• KQ4
  ○ RCTs with no sample size limitation
  ○ Formal economic studies with no sample size limitation
	• Studies other that those listed by KQ (including SRs)
	• Studies that do not report outcomes of interest
	• Noncomparative association or correlation studies
	• Proof-of-principle studies (e.g., device modification)
	• Position papers

Publication	
• Studies of adults and children: 12 weeks or longer • Studies of pregnant people: no follow-up limit	• Follow-up other than specified

Notes. [a] These outcomes were assessed using the GRADE method.
Abbreviations. CGM: continuous glucose monitor(ing); FDA: Food and Drug Administration; GDM: gestational diabetes; HbA1c: glycated hemoglobin; KQ: key question; RCT: randomized controlled trial; SR: systematic review; T2D: type 2 diabetes; UN: United Nations; US: United States.

Risk-of-Bias Assessment

All included studies were independently rated by 2 experienced raters. If disagreement could not be settled between the 2 reviewers, a third reviewer resolved the dispute.

Randomized Controlled Trials

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

Table A3. Risk-of-Bias Assessment: Randomized Controlled Trials

Domain	Domain Elements[a]
Randomization	• An appropriate method of randomization is used to allocate participants or clusters to groups, such as a computer random number generator • Baseline characteristics between groups or clusters are similar
Allocation concealment	• An adequate concealment method is used to prevent investigators and participants from influencing enrollment or intervention allocation
Intervention	• Intervention and comparator intervention applied equally to groups • Co-interventions appropriate and applied equally to groups • Control selected is an appropriate intervention
Outcomes	• Outcomes are measured using valid and reliable measures • Investigators use single outcome measures and do not rely on composite outcomes, or outcome of interest can be calculated from composite outcome • The trial has an appropriate length of follow-up and groups are assessed at same time points • Outcome reporting of entire group or subgroups is not selective
Masking (blinding) of investigators and participants	• Investigators and participants are unaware (masked or blinded) of intervention status
Masking (blinding) of outcome assessors	• Outcome assessors are unaware (masked or blinded) of intervention status
Intention-to-treat analysis	• Participants are analyzed based on random assignment (intention-to-treat analysis)
Statistical analysis	• Participants lost to follow-up unlikely to significantly bias results (i.e., complete follow-up of ≥ 80% of participants overall and nondifferential, ≤ 10% difference between groups) • The most appropriate summary estimate (e.g., risk ratio, hazard ratio) is used • Paired or conditional analysis used for crossover RCT • Clustering appropriately accounted for in a cluster-randomized trial (e.g., use of an intraclass correlation coefficient)
Other biases (as appropriate)	• List others in table footnote and describe, such as: • Sample size adequacy • Interim analysis or early stopping • Recruitment bias, including run-in period used inappropriately • Use of unsuitable crossover intervention in a crossover RCT
Interest disclosure	• Disclosures of interest are provided for authors/funders/commissioners of study • Interests are unlikely to significantly affect study validity
Funding	• There is a description of source(s) of funding • Funding source is unlikely to have a significant impact on study validity

Note. [a] The elements included in each domain are assessed and rated as Yes, No, Unclear, or Not Applicable based on performance and documentation of individual elements in each domain. The overall risk of bias for study is assessed as High, Moderate, or Low based on assessment of how well overall study methods and processes were performed to limit bias and ensure validity.
Abbreviation. RCT: randomized controlled trial.

Economic Modeling Studies

Raters assessed the risk of bias of the economic studies using a standard instrument developed and adapted by the Center. This instrument is a modification of checklists in *BMJ*,[200,201] the CADTH economic evaluation guidelines,[202] the Consensus on Health Economic Criteria,[203] and the NICE economic evaluation checklist.[204]

Each study was assigned a rating of low, moderate, or high based on its adherence to recommended methods and potential for biases.

In brief, low-risk-of-bias economic evaluations include a well-described research question with economic importance and detailed methods to estimate the effectiveness and costs of the intervention. These studies provided a sensitivity analysis for all important variables, and the researchers justified the choice and values of variables. Low-risk-of-bias economic evaluations also have low potential for bias from conflicts of interest and funding source(s). Moderate-risk-of-bias economic evaluations have incomplete information about methods to estimate the effectiveness and costs of the intervention. The studies' sensitivity analyses might not consider 1 or more important variables, and the researchers did not completely justify the choice and values of variables. These factors might mask important study limitations. High-risk-of-bias economic evaluations have clear flaws that could introduce significant bias. These could include significant conflict of interest, lack of sensitivity analysis, or lack of justification for the choice of values and variables.

Table A4. Risk-of-Bias Assessment: Economic Modeling Studies

Domain	Domain Elements[a]
Target population	• Target population and care setting described • Describe and justify basis for any target population stratification, identify any previously identifiable subgroups • If no subgroup analyses were performed, justify why these were not required
Perspective	• State and justify analytic perspective (e.g., societal, payer, etc.)
Time horizon	• Describe and justify time horizon(s) used in analysis
Discount rate	• State and justify discount rate used for costs and outcomes
Comparators	• Describe and justify selected comparators • Competing alternatives appropriate and clearly described
Modeling	• Model structure (e.g., scope, assumptions made) is described and justified • Model diagram provided, if appropriate • Model validation is described (may involve validation of different aspects such as structure, data, assumptions, and coding and different validation models such as comparison with other models) • Data sources listed and assumptions for use justified • Statistical analyses are described
Effectiveness	• Estimates of efficacy/effectiveness of interventions are described and justified • Factors likely to have an impact on effectiveness (e.g., adherence, diagnostic accuracy, values, and preferences) are described and an explanation of how these were factored into analysis is included • Quality of evidence for relationship between intervention and outcomes, and any necessary links, is described

Domain	Domain Elements[a]
Outcomes	• All relevant outcomes are identified, measured, and valued appropriately (including harms/adverse events) for each intervention, and justification for information/assumptions is given • Any QoL measures used in modeling are described and use justified • Any other outcomes that were considered but rejected are described with rationale for rejection • Ethical and equity-related outcomes are considered and included when appropriate
Resource use/costs	• All resources used are identified, valued appropriately, and included in analyses • Methods for costing are reporting (e.g., patient level) • Resource quantities and unit costs are both reported • Methods for costing time (e.g., lost time, productivity losses) are appropriate and a justification is given if time costs are not considered
Uncertainty	• Sources of uncertainty in analyses are identified and justification for probability distributions used in probabilistic analyses are given • For scenario analyses, values and assumptions tested are given and justified
Results	• All results are presented in a disaggregated fashion, by component, in addition to an aggregated manner • All results are presented with undiscounted totals before discounting and aggregation • Natural units are presented along with alternative units (e.g., QALYs) • The components of incremental cost-effectiveness ratio (ICER) are shown (e.g., mean costs of each intervention in numerator and mean outcomes of each intervention in denominator) • Results of scenario analyses, including variability in factors such as practice patterns and costs, are reported and described in relation to reference (base) case
Interest disclosure	• Disclosures of interest are given for authors/funders/commissioners of study • Interests are unlikely to significantly affect study validity
Funding source	• There is a description of source(s) of funding • Funding source is unlikely to have a significant impact on study validity

Note. [a] The elements included in each domain are assessed and rated as Yes, No, Unclear, or Not Applicable based on performance and documentation of individual elements in each domain. The overall risk of bias for study is assessed as High, Moderate, or Low based on assessment of how well overall study methods and processes were performed to limit bias and ensure validity.
Abbreviation. QALY: quality-adjusted life year QoL: quality of life.

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.[205,206] 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.

Table A5. Methodological Quality Assessment: Clinical Practice Guidelines

Domain	Domain Elements[a]
Rigor of development: Evidence	• Systematic literature search meets quality standards for a systematic review (i.e., comprehensive search strategy with, at a minimum, 2 or more electronic databases) • Criteria used to select evidence for inclusion is clear and appropriate • Strengths and limitations of individual evidence sources and overall quality of body of evidence is assessed
Rigor of development: Recommendations	• Methods for developing recommendations clearly described and appropriate • There is an explicit link between recommendations and supporting evidence • Balance of benefits and harms is considered in formulating recommendations • Guideline has been reviewed by external expert peer reviewers • Updating procedure is specified in guideline or related materials (e.g., specialty society website)
Editorial independence	• There is a description of source(s) of funding and views of funder(s) are unlikely to have influenced content or validity of guideline • Disclosures of interests for guideline panel members are given and are unlikely to have a significant impact on overall validity of guideline (e.g., a process for members to recuse themselves from participating on recommendations for which a significant conflict is given)
Scope and purpose	• Objectives described • Health question(s) described • Target population(s) for guideline recommendations (e.g., patients in primary care) and target users for guideline (e.g., primary care clinicians) are specified
Stakeholder involvement	• Relevant professional groups represented • Views and preferences of target population(s) sought (e.g., clinicians and patients)
Clarity and presentation	• Recommendations are specific and unambiguous • Different management options are clearly presented • Key recommendations are easily identifiable
Applicability	• Shares advice and/or tools on how recommendation(s) can be put into practice • Description of catalysts and barriers to its application • Potential resource implications considered • Criteria for monitoring, audit, and/or performance measures based on guideline are presented

Note. [a] Assessment indicates how well guideline methodology and development process were performed to limit bias and ensure validity for elements in domain (each domain rated as Good, Fair, or Poor overall based on performance and documentation of elements).

Data Abstraction

One researcher abstracted and entered data from eligible studies in a standardized way using DistillerSR.[38] A second researcher reviewed all the data entered. We attempted to resolve discrepancies through discussion. When discussion did not resolve the issue, a third researcher settled disagreements.

Participant Characteristics and Association with Outcomes

When discussing risk and protective factors or variables in statistical models in Center research products, in almost all cases, we are referring to associations of participant characteristics with outcomes, and not causation of outcomes. This is important because participant characteristics, such as race and ethnicity, serve as proxy or surrogate measures for underlying etiological factors not measured or evaluated in analyses. Etiological factors that might cause differences in outcomes for subgroups of participants could include systemic racism or other forms of systemic discrimination, stress, poverty, housing instability, or epigenetics. For example, by describing any differences in outcomes by race and ethnic groups, we are noting observed associations; these associations are not caused by biological determinants of being Black, White, or Hispanic.

Meta-analysis

We conducted meta-analyses using the Cochrane Collaborations Review Manager (RevMan) software, desktop version 5.4.1.[41] For each key subpopulation identified in KQ1, outcomes data from studies with at least 4 weeks of planned CGM use were pooled at final follow-up. Pooled analyses were only conducted when 3 or more studies were eligible.

Certainty of Evidence Assessment

We assigned each outcome a summary judgment for the overall certainty of evidence based on the system developed by the Grading of Recommendations, Assessment, Development, and Evaluation Working Group (GRADE).[39,40] Two independent researchers assigned ratings, with disagreements resolved by a third rater. The GRADE system defines the overall certainty of a body of evidence for an outcome in the following manner:

- **High**: Raters are very confident that the estimate of the effect of the intervention on the outcome lies close to the true effect. Typical sets of studies are randomized controlled trials with few or no limitations, and the estimate of effect is likely stable.
- **Moderate**: Raters are moderately confident in the estimate of the effect of the intervention on the outcome. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is different. Typical sets of studies are randomized controlled trials with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.
- **Low**: Raters have little confidence in the estimate of the effect of the intervention on the outcome. The true effect may be substantially different from the estimate of the effect. Typical sets of studies are randomized controlled trials with serious limitations or nonrandomized studies without special strengths.
- **Very low**: Raters have no confidence in the estimate of the effect of the intervention on the outcome. 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.
- **Not applicable**: Researchers did not identify any eligible articles.

Appendix B. Detailed Study Characteristics for Included RCTs

Table B1. Study Details, All RCTs

Author, Year Study Name	Population Description	CGM Type Control Group	N Randomized Study Duration	Setting Care Context	Diabetes Treatment (hypoglycemic) Regimen(s)
Adults With T2D on Nonintensive Insulin Regimens					
Ajjan, 2016[92]	Insulin-treated adult patients with T1D or T2D	rtCGM SMBG	N = 45 36 weeks	International (no US) Outpatient	• 100% on MDI insulin • # of daily injections not specified • < 4 SMBG sticks/day
Beck, 2017[51] DIAMOND	Adults with T2D receiving multiple daily injections of insulin	rtCGM SMBG	N = 158 24 weeks	International (includes US) Specialty clinics	• 99% were on 1-2 long-acting injections/day • 93% were on 3+ short-acting injections/day • < 4 SMBG sticks/day
Haak, 2017[103] REPLACE	T2D on intensive insulin therapy or continuous subcutaneous insulin infusion	isCGM SMBG	N = 224 24 weeks	International (no US) Specialty clinics	• 100% on prandial only or prandial and basal or CSII therapy • <4 SMBG sticks/day
Lever, 2024[109] 2GO-CGM	Predominantly indigenous (Māori) population of adults (and adolescents) with insulin-requiring T2D	rtCGM SMBG	N = 67 12 weeks	International (no US) Specialty clinics	• 100% on basal insulin • 51% using bolus insulin • < 4 SMBG sticks/day
Lind, 2024[110] Steno2tech	Adults with inadequately controlled, insulin-treated (at least 1 daily injection) T2D	rtCGM SMBG	N = 96 (randomized) N = 76 (analytic sample) 52 weeks	International (no US) Outpatient	• 83% on basal insulin alone • 17.1% were on MDI
Martens, 2021[113] MOBILE	Adults T2D treated with basal insulin without prandial insulin (with or without OHMs) in primary care practices	rtCGM SMBG	N = 175 32 weeks	US-based Specialty clinics	• 100% on 1 or 2 daily injections of long- or intermediate-acting basal insulin
Tildesley, 2013[122]	Patients with T2D treated with insulin, either alone	rtCGM SMBG	N = 57 24 weeks	International (no US) Specialty clinic	• 76% were receiving 2 or fewer daily insulin doses

Author, Year Study Name	Population Description	CGM Type Control Group	N Randomized Study Duration	Setting Care Context	Diabetes Treatment (hypoglycemic) Regimen(s)
	or in combination with OHMs				• 24% were on ≥3 injections/day
Adults With T2D on Oral Hypoglycemic Medications, but Not Insulin					
Aronson, 2023[95] IMMEDIATE	Adults with T2D and using at least 1 noninsulin antihyperglycemic therapy	isCGM Attention control	N = 116 16 weeks	International (no US) Specialty clinics	• 100% on 1 or more OHMs (mostly metformin and SU therapy) • Mean number of OHMs, 2.6 - 2.7
Moon, 2022[114]	Noninsulin-treated patients with T2D uncontrolled with OHMs	rtCGM SMBG	N = 61 24 weeks	International (no US) Specialty clinics	• All patients treated with 3 or more classes of OHMs
Price, 2021[117] COMMITTED	Noninsulin-using adults with poorly controlled T2D treated with 2 or more noninsulin antidiabetic drugs	rtCGM SMBG	N = 70 12 weeks	International (includes US) Specialty clinics	• 100% treated with 2 or more OHMs (mainly sulfonylureas, SGLT-2 inhibitors, and biguanides)
Rama Chandran, 2024[118] GLiMPSE	Suboptimally controlled T2D on OHM with or without basal insulin in a multiethnic setting	isCGM SMBG	N = 193 24 weeks	International (no US) NR	• 100% on at least 1 OHM (93% on metformin)
Taylor, 2019[120]	Adults with overweight or obesity and T2D	rtCGM Blinded CGM	N = 20 12 weeks	International (no US) NR	• 90% on OHMs • 10% on insulin (1 per study group)
Wada, 2020[124]	Patients with non-insulin-treated T2D	isCGM SMBG	N = 100 24 weeks	International (no US) Outpatient	• 97% using OHMs but types not specified.
Adults With T2D on Mixed Nonintensive Hypoglycemic Regimens					
Ajjan, 2023[93] LIBERATES	Adults with T2D and recent acute MI treated with insulin and/or a sulphonylurea (with or without other OHMs) before hospital admission	isCGM SMBG	N = 141 12 weeks (primary outcomes) 52 months (LT health outcomes)	International (no US) Outpatient	• 49.6% on insulin (intensity NR) • 50.4% on SU therapy without insulin

Author, Year Study Name	Population Description	CGM Type Control Group	N Randomized Study Duration	Setting Care Context	Diabetes Treatment (hypoglycemic) Regimen(s)
Bergenstal, 2022[97]	Adults with uncontrolled T2D being treated with 1 of 3 common therapies: 1) sulfonylurea (SU) 2) incretin (DPP4 inhibitor or GLP-1 agonist) or 3) insulin (insulin group) All groups were ± metformin	rtCGM SMBG	N = 114 16 weeks	US-based Specialty clinics	• 44.7% were on insulin [intensity NR]
O'Connor, 2024[115] GOOD-ER	Adults with T1D or T2D who were seen in the ED for glycemic events • T2D: 97% • T1D: 3%	isCGM Usual Care	N = 30 12 weeks	US-based Primary care or specialty clinics[a]	• 27% on insulin only • 20% on insulin and other meds • 20% on OHMs only
Vigersky, 2012[123]	People with T2D not using prandial insulin	rtCGM SMBG	N = 100 52 weeks	US-based Primary care	• 33% basal insulin alone, or in combination • 51% OHMs only • 9% OHMs/GLP-1 • 7% diet + exercise only
Yoo, 2008[125]	Adults with poorly controlled T2D treated with use of oral hypoglycemic agents (OHA) or insulin for at least 1 year	rtCGM SMBG	N = 65 12 weeks	International (no US) Outpatient	• 15.8% using insulin alone [intensity NR] • 40.4% using insulin + OHMs • 40.3% using OHMs alone
Pregnant People With GDM Not on Insulin Therapy					
Alfadhli, 2016[94]	Pregnant women with GDM	rtCGM SMBG	N = 130 12 to 16 weeks	International (no US) Primary care	Insulin was prescribed if SMBG values were persistently above the glycemic target 3 or more times during the study period • 28% were using insulin at the final follow-up
Kestila, 2007[106]	Pregnant people with GDM at 24 to 34 gestational weeks not	rtCGM SMBG	N = 73 10 weeks	International (no US) NR	Participants were not on antidiabetic meds at baseline, but goal of the study was to

Author, Year Study Name	Population Description	CGM Type Control Group	N Randomized Study Duration	Setting Care Context	Diabetes Treatment (hypoglycemic) Regimen(s)
	treated with antidiabetic agents at enrollment				identify those who needed additional therapy • 11 (17.4%) participants were on insulin final follow-up ○ rtCGM: 10 (26%) ○ SMBG: 1 (2.7%)
Lane, 2019[107]	Patients with GDM	rtCGM Blinded CGM	N = 40 4 weeks	US-based NR	Any GDM level enrolled Patients who required insulin received subcutaneous injections, but it is unclear how many patients were on insulin therapy • 10 (43%) participants were on hypoglycemic medication (any kind) at follow-up ○ rtCGM: 4 (36.4%) ○ Blinded CGM: 6 (50%)
Majewska, 2023[112] FLAMINGO	Pregnant women diagnosed with GDM between 24 and 28 weeks of gestation	isCGM SMBG	N = 100 12 to 16 weeks	International (no US) Primary care	Patients were not on insulin therapy at enrollment, but some received insulin based on their risk of hyperglycemia during the study • 31 (31.3%) participants were on insulin by final follow-up ○ isCGM: 15 (30.6%) ○ SMBG: 16 (32%)

Notes. [a] *Participants in this study were identified in the emergency department but were discharged to receive care in community settings with their regular provider (primary care or endocrinology) for the duration of study follow-up.*

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; CSII: continuous subcutaneous insulin infusion; DPP4: Dipeptidyl Peptidase-4; ED: emergency department; GDM: gestational diabetes; GLP-1: glucagon-like peptide-1 agonist; isCGM: intermittently scanned continuous glucose monitor(ing); MD: mean difference; MDI: multiple daily injections; MI: myocardial infarction; NR: not reported; OHM: oral hypoglycemic medication; NR: not reported; RCT: randomized controlled trial; rtCGM: real-time continuous glucose monitor(ing); SD: standard deviation; SGLT-2: sodium-glucose cotransporter 2; SMBG: self-monitoring of blood glucose; SU: sulfonylurea; T1D: type 1 diabetes; T2D: type 2 diabetes; US: United States.

Table B2. Detailed RCT Enrollment Criteria

Author, Year Study Name	Inclusion Criteria	Exclusion Criteria
Adults With T2D on Nonintensive Insulin Regimens		
Ajjan, 2016[92]	• Treatment with MDI for > 6 months before study enrolment • HbA1c between 7.5% and 12.0% (58 and 108 mmol/mol) obtained within 6 months of enrollment • Individuals judged by the investigators to be technically capable of using the FreeStyle Navigator	• 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) • Pregnant or planning to become pregnant within the study duration • Currently using or had previously used a CGM device within the past 6 months, or were using CSII or basal insulin only • Participating in another study of a glucose-monitoring device/drug that could affect glucose measurements/management • Known allergy to medical-grade adhesives • Judged by the investigators as unsuitable to participate due to any other cause/reason
Beck, 2017[51] DIAMOND	• Aged at least 25 years • T2D treated with multiple daily injections of insulin for at least 1 year • Central laboratory–measured HbA1c levels of 7.5% to 10.0% • Stable diabetes medication regimen and weight over the previous 3 months • Self-reported blood glucose meter testing averaging 2 or more times per day • eGFR of at least 45 mL/min/1.73 m^2	• Use of personal rtCGM ≤3 months before study entry • Use of CSII ≤3 months before study entry (including patch pumps) • Addition of any new oral or injectable hypoglycemic agents <3 months before study entry • For GLP-1 medications, must be on stable dose and the medication will be maintained throughout the study • Use of premixed insulin ≤6 months before study entry • Current or anticipated short-term uses of glucocorticoids that will affect glycemic control and HbA1c levels • Pregnancy at time of screening or plan to become pregnant during study • Medical conditions that make it inappropriate or unsafe to target an HbA1c level of <7% • History of psychiatric, psychological, or psychosocial issues that could limit adherence to required study tasks • Renal disease

Author, Year Study Name	Inclusion Criteria	Exclusion Criteria
		• Skin changes and/or disease that preclude wearing the sensor on normal skin • Known allergy to medical-grade adhesives • Current participation in another investigational study • Hospitalization or ED visit ≤6 months before screening resulting in a primary diagnosis of uncontrolled diabetes • Current SUD • Any condition that can affect reliability of HbA1c measurement, such as hemoglobinopathy, hemolytic anemia, etc.
Haak, 2017[103] REPLACE	• Aged 18 years or older • T2D treated with insulin for at least 6 months • On current regimen (prandial only or prandial and basal intensive insulin therapy or CSII therapy) for 3 months or more • HbA1c level 7.5 to 12.0% (58 to 108 mmol/mol) • Self-reported regular blood glucose testing (more than 10/week for at least 2 months before study entry), • Considered by the investigator to be technically capable of using isCGM	• Any other insulin regimen to the specified inclusions • Total daily dose of insulin C1.75 units/kg on study entry; had severe hypoglycemia (requiring third-party assistance) • Diabetic ketoacidosis, or hyperosmolar-hyperglycemic state in the preceding 6 months • 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, or were considered by the investigator to be unsuitable to participate
Lever, 2024[109] 2GO-CGM	• T2D as per American Diabetes Association classification • HbA1c > 8.0% or 64 mmol/mol • Minimum daily insulin use of ≥ 0.2 units of insulin/kg/day for > 3 months • Aged 16 years and older • Be willing and able to conform to the study protocol • Have access to a smartphone or computer with internet connection	• History of T1D • History of other types of diabetes such as diabetes secondary to pancreatitis • Hospital admission for hyperglycemia in past 6 months • Use of systemic corticosteroids > 14 days, or repeated pharmacologic systemic courses of corticosteroids • Recurrent or chronic systemic infections that, in the view of the investigator, would significantly affect glycemia • Major cardiovascular event or major surgery in past 3 months • Active malignancy requiring ongoing treatment • Previous or planned bariatric surgery • Pregnancy, or plan to become pregnant while participating in study

Author, Year Study Name	Inclusion Criteria	Exclusion Criteria
		• Any other reason that investigator feels may not be in best interest of patient to participate
Lind, 2024[110] Steno2tech	• ≥ 18 years of age • Clinically diagnosed T2D more than 1 year ago • Treatment with insulin injections at least once daily for more than 1 year • HbA1c ≥ 7.5% (58 mmol/mol) • Attending the outpatient clinic for more than 1 year	• Comorbidity that did not allow lowering of HbA1c to 7.0% (53 mmol/mol) • Conditions with nonglycemic factors altering HbA1c levels • Previous experience with the use of CGM
Martens, 2021[113] MOBILE	• Age ≥ 30 years old • T2D • Comprehends written and spoken English • Using 1 to 2 injections of basal or intermediate acting insulin daily for ≥ 6 months before screening • HbA1c between 7.8% to 11.5% inclusive at enrollment • Patient is able and willing to wear a CGM device • No use of a personal rtCGM within 3 months of study entry • SMBG on average ≥ 3 times per week during the month before screening • Stable medication regimen during the 3 months before screening • Has a smart phone compatible with CGM and BGM systems • Diabetes managed by a primary care physician or nurse practitioner/physician assistant	• Regular use of short acting insulin in the 3 months before entry visit or planning to initiate prandial insulin or short acting insulin • Pregnancy or planning to become pregnant during the study • Weight reduction medications, programs, or surgery • Concomitant disease or condition that may compromise patient safety (e.g., severe mental illness) • Known or significant allergy to medical-grade adhesives • Renal disease • Anticipated use of glucocorticoids that could affect glycemic control • Acute conditions that could impact the stability of a HbA1c measurement (e.g., GI blood loss) • Diabetes management by a study PI or subinvestigator • Diabetes management in the previous 6 months by a diabetes specialist • Concurrent participation in another clinical trial
Tildesley, 2013[122]	• Recent HbA1c level greater than 7.0% • Internet access and previous training in SMBG • T2D	NR
Adults With T2D on Oral Hypoglycemic Medications, but Not Insulin		
Aronson, 2023[95] IMMEDIATE	• Adults with T2D for 6 months or longer • HbA1c of 7.5% or higher (≥ 58 mmol/mol) • Using at least 1 noninsulin antihyperglycemic therapy • No prior use of a rtCGM/isCGM device	• Previous insulin use (> 3 months) • Advanced diabetes complications • Severe hypoglycemia within the previous 6 months

Author, Year Study Name	Inclusion Criteria	Exclusion Criteria
Moon, 2022[114]	• Male and female patients aged between 30 and 65 years • Type 2 diabetes • Taking 3 types of oral hypoglycemic agents for at least 12 weeks • HbA1c of 7.5 to 10.0% • Willing to use the rtCGM system • Signed letter of consent	• T1D • GDM patients; undergone continuous or intermittent insulin treatments for more than 7 days within 12 weeks from the selection test date • Corticosteroid treatment for more than 7 consecutive days within 1 month before the selection test date • History of hyperplastic diabetic retinosis • Serious infection, scheduled for surgery, history of recent surgery, or severe injury • History of malignant tumor in the preceding 5 years • Medical reports and past treatment reports show history of drug abuse or alcoholism within 12 weeks from the questionnaire completion • Pregnant or breastfeeding • Participating in clinical research other than the current clinical research or who have taken other clinical test drugs within the preceding 4 weeks • Unfit to take part in clinical research as determined by the researcher
Price, 2021[117] COMMITTED	• Aged ≥ 30 years • Diagnosis of T2D • Treated with 2 or more noninsulin OHMs • HbA1c ≥ 7.8% and ≤ 10.5% by local laboratory or point of care • Stable body weight over the past 3 months • English speaking • Owner of a compatible smart device for CGM data display (receivers were not used)	• Use of insulin • Previous CGM use (past professional CGM use was acceptable) • Pregnancy • eGFR <30 mL/min/1.73 m2.
Rama Chandran, 2024[118] GLiMPSE	• Adults (age ≥ 21 years to ≤ 75 years) with suboptimally controlled T2D (HbA1c ≥ 7.5% to ≤ 10% on 2 consecutive readings over the preceding 9 months) • On OHMs, including metformin, sulphonylureas, alpha-glucosidase inhibitors, incretin therapy (DPP4 inhibitors or GLP-1 agonist), SGLT2 inhibitors with or without basal insulin • Doing at least 3 SMBG readings per week (self-reported)	• Pregnant women • Children • Using prandial insulin • Current steroid or cancer therapy, • Haemolytic anaemia or haemoglobinopathies, • Previous bariatric surgery • Use of > 3 isCGM

Author, Year Study Name	Inclusion Criteria	Exclusion Criteria
Taylor, 2019[120]	• Adults who were overweight or obese (BMI 26 to 45 kg/m^2, aged 20 to 75 years) with T2D • HbA1c 5.9 to 6.9%	• T1D • Proteinuria, abnormal liver, impaired renal function, any abnormal or significant clinical history including current malignancy, liver, respiratory, gastrointestinal, cardiovascular disease or pregnancy/lactation, eating disorder or clinical depression; any significant endocrinopathy • Have taken/or taking glucocorticoids (oral/inhaled or topical) within past 3 months, psychotropics other than a stable dose of a selective serotonin reuptake inhibitor • Illicit drugs, medications that affect gastrointestinal motility or hunger, or past history of gastrointestinal surgery which may affect study outcomes
Wada, 2020[124]	• T2D • HbA1c ≥ 7.5% (59 mmol/mol) and < 8.5% (69 mmol/mol) • Aged ≥ 20 years and < 70 years	• Treated with insulin • Had been using SMBG or isCGM • On dialysis • Severe renal failure (estimated glomerular filtration rate < 30 mL/min/1.73 m^2 • Preproliferative diabetic retinopathy or proliferative diabetic retinopathy • Could not properly operate the devices • Judged by their physician to be unsuitable for participation in the study
Adults With T2D on Mixed Nonintensive Hypoglycemic Regimens		
Ajjan, 2023[93] LIBERATES	• Adult patients aged ≥ 18 years, with preadmission diagnosis of T2D receiving treatment with a sulphonylurea and/or insulin (in addition to or without other hypoglycemic agents) • MI was defined as symptoms of cardiac ischemia associated with a typical rise in troponin levels using the 99th percentile threshold (individuals with ST-elevation MI and non–ST-elevation MI were eligible)	• Active malignancy, other than localized squamous cell or basal cell skin carcinoma • Known pregnancy • Renal dialysis • Inability to follow study instructions or considered unsuitable for trial participation • Patients with a permanent pacemaker were initially excluded but were subsequently allowed to participate after an ethics amendment (April 2019)
Bergenstal, 2022[97]	• Uncontrolled T2D (i.e., HbA1c ≥ 7.0%) • Aged 18 to 75 years	• Treated with TZD or a maltose metabolizing agent • Taken steroids in the past 30 days

Author, Year Study Name	Inclusion Criteria	Exclusion Criteria

	• Treated with 1 of the following 3 common therapies:
	  ○ Sulfonylurea (SU) ± metformin (SU group),
	  ○ Incretin (DPP4 inhibitor or GLP-1 agonist) ± metformin (incretin group)
	  ○ Insulin ± metformin (insulin group)
		• Physically, cognitively, or psychologically unable to participate
		• Pregnant or planned to be
		• Inherited galactosemia
		• Not English-fluent

O'Connor, 2024[115] GOOD-ER	• Adults aged ≥ 18 years • Diagnosed with either T1D or T2D • Presented to the ED for a diabetes-related complaint such as hyper- or hypoglycemia • Suitable for follow up in the medical center's diabetes subspecialty clinic • Fluent in either English or Spanish	• Altered mental status • Incarceration • Preexisting CGM use • Hospital admission • Discharge to a rehab facility • Pregnant patients • Those with an upcoming computed tomography or magnetic resonance imaging scan
Vigersky, 2012[123]	• Military health care beneficiaries • Aged ≥ 18 years • Had T2D for at least 3 months • Initial A1c ≥ 7% but ≤ 12% • Eligible participants were treated with diet and/or exercise alone or other glucose lowering therapies except prandial insulin, were able to independently measure and read fingerstick blood glucose levels • Willing to perform SMBG 4 times daily • Attended an American Diabetes Association (ADA)-recognized diabetes self-management education program	• Pregnant, lactating, or attempting pregnancy • On glucocorticoids, amphetamines, anabolic, or weight reducing medications
Yoo, 2008[125]	• Aged 20 to 80 years • T2D with use of OHM or insulin for at least 1 year • HbA1c between 8.0% and 10% • Stable insulin or OHM regimen for the previous 2 months • Stable dose of antihypertensive or lipid-lowering drugs for at least 4 weeks	• Severe diabetic complications (e.g., diabetic foot or severe diabetic retinopathy) • Corticosteroid use in the previous 3 months • Liver disease • Renal insufficiency • Other medical problems that affected study results or trial participation
Pregnant People With GDM Not on Insulin Therapy		
Alfadhli, 2016[94]	• Diagnosed with GDM in the current pregnancy • Singleton pregnancy • Planned to give birth at the study hospital	• Preexisting diabetes • Multiple pregnancies • Chronic diseases

Author, Year Study Name	Inclusion Criteria	Exclusion Criteria
		• Taking drugs that might affect pregnancy outcome

Kestila, 2007[106]	• Women in high-risk group according to the evaluation system used in Finland:
	  ○ BMI above 25 kg/m2
	  ○ Aged > 40 years
	  ○ Previous child more than 4500 g
	  ○ Glucosuria during pregnancy
	  ○ Weight gain during pregnancy > 20 kg
	  ○ Previous gestational diabetes or suspected fetal macrosomia in the current pregnancy
	• At least 2 abnormal high plasma glucose values out of 3 measurements in 75 g OGTT
	• Singleton pregnancies
		NR

Lane, 2019[107]	• Maternal age of 18 to 45 years • Singleton gestation • Gestational age ≥ 24 weeks and < 32 weeks at enrollment	• Maternal age < 18 or > 45 years • Multifetal gestations • < 24 or ≥ 32 weeks gestational age at enrollment • Known fetal structural or chromosomal anomalies • Chronic use of medications associated with hyperglycemia (hydroxyprogesterone caproate, antiviral HIV medications, oral steroids, asthma inhalers) • Planned preterm delivery
Majewska, 2023[112] FLAMINGO	• Aged > 18 years • Singleton pregnancy • Diagnosed with GDM between 24 and 28 weeks of gestation (fasting plasma glucose 92–125 mg/dl, 1-h glucose ≥ 180 mg/dl, or 2-h glucose 153–199 mg/dl)	• Multiple pregnancy • Fetal malformations • Pregestational diabetes • Chronic or pregnancy-induced hypertension • Chronic renal or hepatic disease diagnosed before study entry • In vitro fertilization • Premature rupture of membranes • Placenta previa • Smoking in pregnancy • Intake of medications including ethyldopa, tetracyclin, acetylosalicylic acid, acetaminofen, ibuprofen, L-dopa, tolazamide or tolbutamide

Abbreviations. BGM: blood glucose monitor(ing); BMI: body mass index; CGM: continuous glucose monitor(ing); CI: confidence interval; CSII: continuous subcutaneous insulin infusion; dl: deciliter; DPP4: dipeptidyl peptidase-4; ED: emergency department; eGFR: estimated glomerular filtration rate; FGM: flash glucose monitor(ing); GA: gestational age; GDM: gestational diabetes; GI: gastrointestinal; GLP-1: glucagon-like peptide-1; HIV: human immunodeficiency virus; isCGM: intermittently scanned continuous glucose monitor; kg: kilogram; MD: mean difference; MDI: multiple daily injections; mg: milligram; mL: milliliter; MI: myocardial infarction; min: minute(s); mo: month(s); mmol: millimoles; mol: mole; NR: not reported; OGTT: oral glucose tolerance test ; OHA: oral hypoglycemic agent; OHM: oral hypoglycemic medication; PI: principal investigator; rtCGM: real-time continuous glucose monitor; RCT: randomized controlled trial; SD: standard deviation; SGLT-2: sodium-glucose cotransporter 2; SMBG: self-monitoring of blood glucose; T1D: type 1 diabetes; T2D: type 2 diabetes; TZD: thiazolidinedione; US: United States; w: week(s).

Table B3. Full Baseline Characteristics

Author, Year Study Name	Mean Age, years	MeanT2D duration, years	Mean SMBG, number of tests per day	Mean HbA1c, %	% Female	% Non-White
Adults With T2D on Nonintensive Insulin Regimens						
Ajjan, 2016[92]	CGM: 57.8 Control: 55.5	CGM: 13.9 Control: 15.8	CGM: 3.0 Control: 2.0	CGM: 9.2 Control: 9.2	CGM: 36.7 Control: 26.7	NR
Beck, 2017[51] DIAMOND	CGM: 60 Control: 60	CGM: 17 Control: 18	CGM: 3.3 Control: 3.2	CGM: 8.5 Control: 8.5	CGM: 62 Control: 51	CGM: 46 Control: 27
Haak, 2017[103] REPLACE	CGM: 59.0 Control: 59.5	CGM: 17 Control: 18	CGM: 3.6 Control: 3.9	CGM: 8.7 Control: 8.9	CGM: 37 Control: 25	CGM: 5 Control: 7
Lever, 2024[109] 2GO-CGM	Median CGM: 51 Control: 56	Median CGM: 13.0 Control: 13.0	NR	Median CGM: 9.2 Control: 9.7	CGM: 61 Control: 53	CGM: 54.5 Control: 68
Lind, 2024[110] Steno2tech	CGM: 61.1 Control: 61.3	CGM: 18.8 Control: 17.4	CGM: 1.6 Control: 1.6	CGM: 8.2 Control: 8.4	CGM: 37.5 Control: 38.9	CGM: 10 Control: 8
Martens, 2021[113] MOBILE	CGM: 56 Control: 59	CGM: 14 Control: 15	Median CGM: 1 Control: 2	CGM: 9.1 Control: 9.0	CGM: 53 Control: 46	CGM: 57 Control: 44
Tildesley, 2013[122]	CGM: 58 Control: 59.5	CGM: 17.4 Control: 17.0	NR	CGM: 8.80 Control: 8.79	CGM: 36 Control: 36	NR
Adults With T2D on Oral Hypoglycemic Medications, but Not Insulin						
Aronson, 2023[95] IMMEDIATE	CGM: 59.2 Control: 57.6	CGM: 9.2 Control: 10.9	NR	CGM: 8.5 Control: 8.7	CGM: 36.2 Control: 36.2	NR
Moon, 2022[114]	CGM-1: 55.6 CGM-2: 53.9 Control: 50.7	CGM-1: 10.4 CGM-2: 13.1 Control: 10.0	CGM-1: 1.9 CGM-2: 1.7 Control: 1.3	CGM-1: 8.3 CGM-2: 8.2 Control: 8.1	CGM-1: 38.9 CGM-2: 53.3 Control: 46.7	CGM-1: 100 CGM-2: 100 Control: 100
Price, 2021[117] COMMITTED	CGM: 58.9 Control: 60.9	CGM: 13.9 Control: 12.3	NR	CGM: 8.4 Control: 8.5	CGM: 41.3 Control: 58.3	CGM: 32.6 Control: 12.5
Rama Chandran, 2024[118]	CGM: 54.9 Control: 55.1	CGM: 11.3 Control: 10.6	NR	CGM: 8.0 Control: 8.1	CGM: 48.9 Control: 34.9	CGM: 100 Control: 100

Author, Year Study Name	Mean Age, years	MeanT2D duration, years	Mean SMBG, number of tests per day	Mean HbA1c, %	% Female	% Non-White
GLiMPSE						
Taylor, 2019[120]	CGM: 60.2 Control: 60.9	CGM: 10.5 Control: 11.0	NR	CGM: 6.6 Control: 7.1	Full cohort: 50	NR
Wada, 2020[124]	CGM: 58.1 Control: 58.7	NR	NR	CGM: 7.8 Control: 7.8	CGM: 31 Control: 33	NR
Adults With T2D on Mixed Nonintensive Hypoglycemic Regimens						
Ajjan, 2023[93] LIBERATES	CGM: 62 Control: 63	CGM: 14.5 Control: 11.0	CGM: NR Control: NR	CGM: 9.0 Control: 8.8	CGM: 26.1 Control: 27.8	CGM: 5.8 Control: 13.9
Bergenstal, 2022[97]	CGM: 59.3 Control: 58.8	NR	NR	CGM: 8.2 Control: 7.9	CGM: 49 Control: 58	NR
O'Connor, 2024[115] GOOD-ER	CGM: 56 Control: 60	NR	NR	CGM: 11.5 Control: 10.6	CGM: 44 Control: 36	CGM: 44 Control: 36
Vigersky, 2012[123]	CGM: 55.5 Control: 60.0	All participants had T2D for at least 3 months[a]	CGM: 2.9 Control: 2.4	CGM: 8.4 Control: 8.2	CGM: 34 Control: 56	NR
Yoo, 2008[125]	CGM: 54.6 Control: 57.5	CGM: 11.7 Control: 13.3	NR	CGM: 9.1 Control: 8.7	CGM: 65.5 Control: 50	CGM: 100 Control: 100
Pregnant People With GDM Not on Insulin Therapy						
Alfadhli, 2016[94]	CGM: 32.93 Control: 34.15	History of GDM CGM: 14 (25.0) Control: 14 (23.3)	2-hr OGTT, mmol/L: CGM: 9.2 Control: 8.7	CGM: 5.6 Control: 5.9	CGM: 100 Control: 100	NR
Kestila, 2007[106]	CGM: 32.6 Control: 32.2	NA	2-hr OGTT, mmol/L: CGM: 8.1 Control: 7.8	CGM: 5.4 Control: 5.3	CGM: 100 Control: 100	NR
Lane, 2019[107]	CGM: 29.9 Control: 30.8	History of GDM CGM: 4 (36.4) Control: 4 (33.3)	NR	CGM: 5.3 Control: 5.3	CGM: 100 Control: 100	CGM: 36.4 Control: 50.0

Author, Year Study Name	Mean Age, years	MeanT2D duration, years	Mean SMBG, number of tests per day	Mean HbA1c, %	% Female	% Non-White
Majewska, 2023[112] FLAMINGO	Median CGM: 33 Control: 32	NA	2-hr OGTT, mg/dL: CGM: 143 Control: 138.5	Median CGM: 4.9 Control: 4.9	CGM: 100 Control: 100	NR

Notes. [a] *As per the study protocol.*

Abbreviations. CGM: continuous glucose monitor(ing); GDM: gestational diabetes; NA: not applicable; NR: not reported; OGTT: oral glucose tolerance test; RCT: randomized controlled trial; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table B4. RCT Study Group Protocols

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
Adults With T2D on Nonintensive Insulin Regimens					
Ajjan, 2016[92]	rtCGM	30	NR	• Participants in the CGM group wore an unblinded device (Abbott FreeStyle Navigator) with high, low, and projected alarms switched off to avoid interference.	• All participants wore a blinded CGM device (Abbott FreeStyle Navigator) for 15 days at baseline. • All participants were allowed to make changes to their insulin doses using their existing diabetes doses. • Study-related adjustments to insulin doses were made on days 30 and 45 only in the presence of the health care practitioner and could include re-education on carbohydrate counting and assessing the effects of exercise.
	SMBG	15	NR	• Participants in the control group managed blood glucose with a standard SMBG device (Abbott FreeStyle Freedom Lite). • Participants wore a blinded CGM device (Abbott FreeStyle Navigator) the final 15 days of the study review, during which a health care practitioner reviewed data and made recommendations.	
Beck, 2017[51] DIAMOND	rtCGM	79	As needed	• Participants in the CGM group wore a Dexcom G4 Platinum CGM System with an enhanced algorithm.	• All participants used a blinded CGM device (Dexcom G4 Platinum CGM System) 2 weeks before randomization.

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
				• CGM was used as an adjunct to blood glucose monitoring (Countour Next USB meter) according to US FDA labeling. • Participants received general guidelines as well as individual recommendations from their clinicians on incorporating CGM trends into diabetes management.	• All participants were given a Countour Next USB meter (Ascensia Diabetes Care) and test strips. • Specific insulin adjustments were made at the discretion of clinicians.
	SMBG	79	At least 4	• Participants in the control group were instructed to self-monitor their blood glucose (Countour Next USB meter). • Participants in the control group had additional visits 1 week before the 12- and 24- week visits to initiate blinded CGM use (Dexcom G4 Platinum CGM System) for 1 week.	
Haak, 2017[103] REPLACE	isCGM	149	As needed	• Participants in the CGM group wore an unblinded device (Abbott FreeStyle Libre) for 6 months to use for self-management including insulin dose decisions according to product labeling. • No training was given to interpret sensor data. • Participants were able to complete an additional 6-month, open access study phase.	• All participants wore a blinded CGM device (Abbott FreeStyle Libre) for 14 days at baseline and were asked to scan their sensor every 8 hours.
	SMBG	75	NR	• Participants in the control group self-managed glucose levels using a standard blood glucose device (Abbott Diabetes Care) and a glucose diary. • Participants wore the blinded CGM again (Abbott FreeStyle Libre) for the final 2 weeks of the study.	
Lever, 2024[109] 2GO-CGM	rtCGM	33	None	• Participants in the CGM group received training on the Dexcom G6 rtCGM system.	• All participants wore a blinded CGM device (Dexcom G6 rtCGM system) for 2 weeks at baseline.

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
				• Dexcom G6 rtCGM system app was installed on a compatible smartphone or participants were given a receiver device. • Participants used the Dexcom Clarity (glucose depository software) to review data. • Following the 12-week RCT phase, participants could be followed for a total of 78 weeks.	• All participants had cardiovascular risk and noninsulin glucose-lowering medications maximized by prescribing diabetes nurse specialists supervised by an endocrinologist at baseline or during the run-in period. • Prescribing diabetes nurse advised all participants on their insulin dosing/regimen at baseline, week 2, and week 8. • All participants were encouraged to self-titrate their insulin between study contacts using the same algorithm as the prescribing diabetes nurse. • Noninsulin medications were not adjusted unless required for safety.
	SMBG	34	4 to 7 times	• Participants in the control group were issued a CareSens Premier glucometer with Bluetooth capacity and used SmartLog software to view and export their glucose results to the prescribing diabetes nurse. • Participants received training on the CareSens and SmartLog software. • During weeks 10-12, participants wore the CGM device (Dexcom G6 rtCGM system) for 14 days. • Following the 12-week RCT phase, participants in the control group could crossover to the CGM group (Dexcom G6 rtCGM system) for an additional 12 weeks and, subsequently, followed for an additional 12 months.	
Lind, 2024[110] Steno2tech	rtCGM	40	NR	• Participants in the CGM group used the CGM device (Dexcom G6 CGM System) for the duration of the study.	• All participants wore a blinded CGM (Dexcom G6 CGM System) for 10 days at baseline, after 6 months, and after 12 months. • All participants received the same 3-hour diabetes self-management course at baseline, including a unique glucose monitoring education component
	SMBG	36	As needed	• Participants in the control group used their own blood glucose monitor throughout the study.	

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
				• Participants measured their blood glucose as agreed with their usual health care provider.	depending on their randomization group. • All participants were followed for 12 months with standard clinical visits with their usual health care providers. • Treatment adjustments were made by participants and their health care providers during the study, following current treatment guidelines.
Martens, 2021[113] MOBILE	rtCGM	116	As needed	• Participants in the CGM group were given a Dexcom G6 CGM System which they were instructed to use continuously.	• All participants wore a blinded CGM (Dexcom G6 CGM System) for up to 10 days before randomization. • All participants were given a Bluetooth-enabled BGM (OneTouch Verio Flex; LifeScan) and test strips. • All participants received general diabetes education. • Diabetes therapy changes were made by the participants' clinician unless deemed imperative for safety by the study investigator.
	SMBG	59	1 to 3 times	• Participants in the control group were asked to perform BGM testing fasting and postprandial. • Participants had a blinded CGM sensor (Dexcom G6 CGM System) placed at the 3-month visit and before the 8-month visit.	
Tildesley, 2013[122]	rtCGM	25	3 times	• Participants in the CGM group were trained to use the Guardian REAL-Time CGM System. • Participants were asked to save reports from the CGM to send to their endocrinologist every 2 weeks.	• All participants were given a blood glucose meter (Abbott Freestyle) and test strips. • All participants were required to perform a laboratory blood test combined with a visit to their endocrinologist at 3- and 6-month intervals. • All participants received comprehensive diabetes education. • All participants were given standard office-based care when visiting their endocrinologist.
	SMBG	25	3 times	• Participants in the control group were trained to upload their glucose readings every 2 weeks to a secure, commercially available website where they could view summaries and contact their endocrinologist who could review the readings to send feedback.	

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
					• Endocrinologist recommendations to all participants could include changes in therapy, suggestions on testing frequency, lifestyle modifications, and/or encouragement to continue with no changes.
Adults With T2D on Oral Hypoglycemic Medications, but Not Insulin					
Aronson, 2023[95] IMMEDIATE	isCGM	58	At least 4 times	• Participants wore the CGM device (Abott FreeStyle Libre) and received diabetes education.	• All participants received the same visit schedule and educational materials. • All participants were instructed to self-monitor their blood glucose, supported by both scheduled learning exercises and unscheduled reminders focusing on glucose self-monitoring. • All participants wore a blinded CGM device (Abbott FreeStyle Libre Pro) for 14 days at baseline and again at week 14.
	Attention control	58	At least 4 times	• Participants received diabetes education.	
Moon, 2022[114]	rtCGM-1	18	Freely (no frequency guide)	• Participants wore a CGM device (Guardian Connect system with a Guardian 3 sensor) for 1 week, immediately after randomization.	• All participants wore a blinded CGM device (iPro2 with Enlite sensor) for 6 days at baseline and for up to 6 days, 1 week before the study ended. • All participants received a single session of education on lifestyle modification. • All participants received Bluetooth glucometers (Caresens N Premier, i-SENS, Korea). • All participants were instructed to use the Switch mobile application (Huray positive, Korea) to monitor SMBG. • After randomization, none of the participants received additional education beyond device use and were
	rtCGM-2	15	Freely (no frequency guide)	• Participants wore a CGM device (Guardian Connect system with a Guardian 3 sensor) for 1 week, immediately after randomization. • Participants wore a CGM device for an additional week at 12 weeks.	
	SMBG	15	Freely (no frequency guide)	• Participants in the control group were allowed to perform self-monitoring of blood glucose.	

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
					instructed to control glucose on their own. • Oral antidiabetic drugs were changed during study periods.
Price, 2021[117] COMMITTED	rtCGM	46	NR	• Participants in the CGM group used unblinded CGM (Dexcom G6 CGM) for 10 days each at weeks 0, 4, and 8. • Participants received learning modules at each CGM wear period to facilitate experiential learning.	• All participants wore a blinded CGM device (Dexcom G6 CGM) for 10 days at baseline. • Medication changes were not allowed unless required for safety. • A study-site clinician reviewed data with all participants at weeks 2, 6, and 10 to conduct structured discussions about what participants were learning from their glucose monitoring, what changes were made in response to the data, and what the study clinician observed. • After week 12, participants were followed through usual care by their clinician (medication changes were allowed) and returned for a follow-up visit at month 9.
	SMBG	24	NR	• Participants in the control group conducted daily SMBG. • Participants wore a blinded (Dexcom G6 CGM) again at week 8.	
Rama Chandran, 2024[118] GLiMPSE	isCGM	90	As needed	• Participants in the CGM group received device-specific education. • Participants wore the Abbott Freestyle Libre continuously for the first 6 weeks followed by intermittent use of 1 sensor every 4 weeks (each sensor lasting 2 weeks). • Participants had a physician visit at week 38, but there were no further educational touchpoints or specific instructions on glucose monitoring.	• All participants wore a blinded CGM (FreeStyle Libre Pro) and were asked to test capillary blood glucose readings at least once daily for 2 weeks at baseline. • All participants wore a blinded CGM at weeks 24 to 26. • All participants received baseline diabetes education. • All participants were taught how to interpret their glucose profiles at 2 weeks and given guidance on how to

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
	SMBG	86	At least twice, preferably 4 times	• Participants in the control group received the Abbott Optium Neo glucose meter.	adjust the macronutrient composition or meal portions to achieve glucose targets. • In total, both groups received 6 education sessions from diabetes nurse educators and dietitians at weeks 0, 2, 8, and 16 and had physician consults at weeks 0, 8, 16, 24, 38, 52. • Medication titration at weeks 8 or 16 were left to the discretion of the physician.
Taylor, 2019[120]	rtCGM	10	Before and after each meal, and at bedtime	• Participants wore a CGM (Medtronic Guardian Connect device with the Harmony glucose sensor). • Participants received an iPod device that was Bluetooth-connected to the CGM (Medtronic Guardian Connect device with the Harmony glucose sensor) to provide real-time blood glucose level displays throughout the 12-week intervention period.	• All participants received an exercise and diet plan at week 0 and additional education materials on diet at week 3. • All participants were instructed to perform usual SMBG readings. • All participants were given AccuChek glucometers and testing strips. • At commencement of the study, participants were trained on the glucose sensor (Medtronic Guardian Connect device with the Harmony glucose sensor). • Participants visited the clinic every 3 weeks for the research nurse to download sensor glucose data, check on glucose sensor insertion and initiation technique, review morning fasting glucose logs, and to replenish devices supplies. • All participants were blinded to the CGM (Medtronic Guardian Connect device with the Harmony glucose sensor) a week before commencement of the lifestyle intervention.
	Blinded CGM	10	Before and after each meal, and at bedtime	• Participants in the control group wore a blinded CGM (Medtronic Guardian Connect device with the Harmony glucose sensor).	

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
					• At baseline and throughout the study, blood sugar-lowering medication type, dosage and changes were monitored and documented.
Wada, 2020[124]	isCGM	49	NR	• Participants in the CGM group were given an CGM device (FreeStyle Libre; Abbott Diabetes Care) for 12 weeks.	• All participants wore a blinded CGM (FreeStyle Libre Pro) for > 7 days at baseline. • All participants were given instructions on how to operate each device and how to adjust their diet and lifestyle based on the blood glucose levels. • All participants were followed for 12 additional weeks for the open-label portion of the study.
	SMBG	51	3 times	• Participants in the control group were given an SMBG device (FreeStyle Precision Neo; Abbott Diabetes Care) for 12 weeks, with enough supplies to test 3 times a day. • Participants in the SMBG groups were also given a blinded sensor (Free Style Libre Pro) for the final 2 weeks of the 12-week period.	
Adults With T2D on Mixed Nonintensive Hypoglycemic Regimens					
Ajjan, 2023[93] LIBERATES	isCGM	69	NR	• Participants in the CGM group wore the Freestyle Libre sensor and received a handheld reader to display current glucose levels and download data. • Participants scanned the sensor with their handheld reader at least 3 times a day. • The treating clinician could alter the patient's glucose-lowering therapy at their own discretion and/or according to relevant guidelines based on the reported data. • Participants were instructed to monitor the sensor for 90 days and replace it every 14 days.	• All participants had access to capillary glucose testing (Freestyle glucose meter) and testing strips (Optium glucose testing) provided by the study and were asked to stop using any other glucose meters for the duration of the study period.
	SMBG	72	NR	• Participants in the control group self-monitored using capillary glucose testing	

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
				(Freestyle glucose meter) on a regular basis. • Participants used their own lancing device to draw blood. • Site research nurses updated knowledge on glucose testing and familiarized patients with the new glucose meter. • At follow-up visits, data from the glucose meter was downloaded and used by the attending team to adjust glycemic therapy in line with local management policies. • Participants wore a blinded CGM device (Freestyle Libre pro sensor) in the first month and on days 76 to 90.	
Bergenstal, 2022[97]	rtCGM	59	NR	• Participants in the CGM group wore a DexCom SevenPlus CGM. • Participants received a glucose profile report (IDC's Ambulatory Glucose Profile) every 4 weeks during each clinic visit. • Participants using rtCGM had basic education on CGM data usage for making dietary or medication adjustments.	• A run-in period of 2–4 weeks before the baseline visit was used to add incretins, titrate metformin, or both as tolerated up to 2,000 mg. • All participants were taught how to use the Aviva BGM study meter for calibration measurements 4 times daily and a blinded DexCom SevenPlus CGM at baseline. • All participants wore a blinded CGM device for 14 days (DexCom SevenPlus CGM) at baseline. • All participants could wear a blinded CGM for an additional 7 days if insufficient data was obtained at baseline.
	SMBG	55	4 times	• Participants in the control group were asked to perform structured BGM with a Aviva glucose meter. • Data from the control group using the blood glucose monitor (Aviva BGM study meter) were downloaded at each visit. • Participants received a glucose profile to support diabetes management. • Clinician instructions were given, and participants were expected to follow	

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
				clinical pathways to alter diet, exercise, and medications to reach and maintain near normal glucose levels. • 2 weeks before the 8- and 16- week visits, participants wore blinded CGM (DexCom SevenPlus CGM). Participants could wear a blinded CGM for an additional 7 days if insufficient data was obtained. • CGM data was not seen by the participant or clinician in this group.	
O'Connor, 2024[115] GOOD-ER	rtCGM	16	NR	• All participants wore a CGM (Freestyle Libre 2 CGM system) and received a reader device. • Participants received basic education on how to use the device. • Each participant in the CGM arm received 1 CGM sensor capable of lasting 14 days and were told that additional CGM would be at the discretion of their longitudinal care team. • Participants were instructed to follow the recommendations of the ED care team and use a glucometer if there was any doubt as to CGM accuracy. • Participants were instructed to use the CGM in conjunction with the diabetes management plan upon ED discharge.	• All participants were given 1-page educational handouts related to hyper- and hypoglycemia
	Usual care	14	NR	• Participants in the control group received care coordination alone.	
Vigersky, 2012[123]	rtCGM	50	Before meals, at bedtime, and at the time of symptoms of	• Participants wore a CGM device (DexCom SEVEN) that was calibrated according to manufacturer recommendations for 4 cycles (2 weeks/1 week off) for 3 months.	• All participants were given the AccuChek Aviva glucometer and instructions on use. • No care management was given by study staff.

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
			hypo- or hyperglycemia	• Alarms were set to activate at < 70 and > 180 mg/dL. • After the initial 12 weeks, participants continued with SPMG for the duration of the study.	• All participants continued usual care for T2D and were instructed to contact their primary care provider for treatment decisions.
	SMBG	50	Before meals, at bedtime, and at the time of symptoms of hypo- or hyperglycemia	• Participants in the control group used the AccuChek Aviva glucometer.	
Yoo, 2008[125]	rtCGM	29	At least 3 times (during CGM application); otherwise, at participant's convenience	• Participants in the CGM group underwent rtCGM (Guardian RT) monitoring once a month for 3 days. • Sensor placement was done by certified diabetes educator nurses and the alarm thresholds were set for hyperglycemia (> 300 mg/dL) and hypoglycemia (< 60 mg/dL). • When hyperglycemic alarms sounded, participants were instructed to increase movement and take in little amounts of foods • When hypoglycemic alarms sounded, participants were instructed to perform confirmatory SMBG before acting. • Data collected from the CGM informed diabetes educator nurse consultation on participant lifestyle.	• Adjustment of oral hypoglycemic agents or insulin dosage was not permitted in either group, except for recurrent episodes of hypoglycemia.
	SMBG	28	At least 4 times a week	• Participants in the control group checked fasting blood glucose and postprandial 2 hour blood glucose levels for 3 months continuously (Accu-Check Complete meter and Comfort Curve glucose strips).	

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
				• Participants received standard diabetes education. • Participants received instruction on diet and exercise every month based on SMBG values.	
Pregnant People With GDM Not on Insulin Therapy					
Alfadhli, 2016[94]	rtCGM	60	4 times	• Participants in the CGM group wore a CGM device (Guardian REAL-Time CGM System) once for 3-7 days within 2 weeks of GDM diagnosis (in addition to SMBG). • Participants were instructed to enter all blood glucose values into the CGM for calibration and record glucose values, time and contents of meals, insulin injections, exercise periods, and symptomatic hypoglycemic events in a logbook. • Participants could view glucose values and were encouraged to react appropriately. • Glucose profiles were reviewed by researchers who updated glucose profiles accordingly.	• The glucose values from all participants were evaluated weekly from SMBG using a glucometer (Easy max). • Insulin was prescribed to participants if glucose levels were persistently above the glycemic target based on ADA recommendations. • All participants were followed until delivery; however, the frequency of follow up was dependent on blood sugar control and week of gestation.
	SMBG	62	4 times	• Participants in the control group used SMBG alone (Easy max).	
Kestila, 2007[106]	rtCGM	36	At least 5 times	• Participants wore a CGM device (CGMS Medtronic MiniMed) after diagnosis of GDM. • Participants were given instructions on how to use the device. • At least 4 daily plasma glucose calibration values were introduced to the device.	• All participants were instructed to measure plasma glucose with either the Ascensia Elite meter or Super Glucocard II meter. • All participants were asked to keep a diary on glucose measurement days when exercise was also reported.

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
				• Participants were advised to not shower during the monitoring period.	• Treatment mode was determined based on results within a week after monitoring began and could include metformin, insulin, or diet.
	SMBG	37	At least 5 times	• Participants in the control group measured measure plasma glucose (Ascensia Elite meter or Super Glucocard II meter).	
Lane, 2019[107]	rtCGM	20	4 times	• Participants in the intervention group wore a CGM (Medtronic MiniMed 530G system) that connected wirelessly to an insulin pump and displayed data.	• All participants received a half-day of education led by a certified diabetes educator that included a meal plan, exercise program, proper nutrition, and information on SMBG. • All participants were followed by a team of maternal-fetal medicine specialists and a certified diabetes educator. • All participants who required insulin received subcutaneous injections. • All participants were instructed to record SMBG values and dietary intake. • All participants had the CGM sensor replaced at each study visit. • All management decisions were based on patient-recorded SMBG values.
	Blinded CGM	20	4 times	• Participants in the control group wore a blinded CGM (Medtronic iPro 2 professional CGM system with Enlite sensor).	
Majewska, 2023[112] FLAMINGO	isCGM	50	After breakfast, lunch, and dinner	• Participants in the CGM group measured glucose concentrations using Freestyle Libre 1 during the first 4 weeks following GDM diagnosis.	• All participants measured glucose concentrations using SMBG after the first 4 weeks following GDM diagnosis. • All participants were given information on glycemic control, diet, and physical activity at the first study visit. • All participants had physical activity monitored through a step counter app • Clinical and laboratory results were assessed at the 3 follow-up visits. • The qualification to insulin therapy was decided in case of hyperglycemia
	SMBG	50	After breakfast, lunch, and dinner	• Participants in the control group measured glucose concentrations (iXell; Genexo sp) during the first 4 weeks following GDM diagnosis.	

Author, Year Study Name	Group Name	Group Size	Daily SMBG Testing Protocol	Study Group Protocol	Protocol for All Study Participants
					(fasting glycemia ≥90 mg/dl or 1 h-postprandial glycemia ≥ 140 m g/d). • Dietary habits and modifications were monitored using an Eating Assessment Test.

Abbreviations. BGM: blood glucose meter; CGM: continuous glucose monitor(ing); dL: deciliter; ED: emergency department; FDA: Food and Drug Administration; GDM: gestational diabetes; hr: hour; isCGM: Intermittently-scanned continuous glucose monitor(ing); mg: milligram; NR: not reported; RCT: randomized controlled trial; rtCGM: real-time continuous glucose monitor(ing); SMBG: self-monitoring blood glucose; T2D: type 2 diabetes; US: United States.

Table B5. Additional CGM Details

Author, Year Study Name	CGM Brand and Model	Type Modality	Total CGM Use/ Study Duration	Run-in Period?	Length of Run-in	Run-in Used to Exclude Candidates?	Run-in Description
Adults With T2D on Nonintensive Insulin Regimens							
Ajjan, 2016[92]	FreeStyle Navigator (FSN)	rtCGM Therapeutic	85/100 days	Yes	2 weeks	Yes	Patients self-managed their BG with the FSN meter built into the FSN receiver. They wore a FSN transmitter to collect continuous glucose data. The receiver was in masked mode and glucose data were not visible to patients. In addition, patients were asked to log insulin, food, exercise, state of health and hypoglycemic episodes while using the FSN. Only patients who had CGM data for 50% of the 15-day masked period (or at least 1000 individual CGM readings) were randomized.

Author, Year Study Name	CGM Brand and Model	Type Modality	Total CGM Use/ Study Duration	Run-in Period?	Length of Run-in	Run-in Used to Exclude Candidates?	Run-in Description
Beck, 2017[51] DIAMOND	Dexcom G series (any model)	rtCGM Nontherapeutic	24/24 weeks	Yes	2 weeks	Yes	For 2 weeks before randomization, each participant used a CGM device that recorded glucose concentrations that were not visible to the participant (called a blinded CGM device). Eligibility, which was discussed on the consent form, required participants to wear the blinded CGM device on at least 85% of possible days, calibrate it at least twice per day, and do blood glucose meter testing at least twice per day on average.
Haak, 2017[103] REPLACE	FreeStyle Libre (any model)	isCGM Nontherapeutic	6/6 months	Yes	2 weeks	Yes	All participants wore a system locked into masked mode for the 14-day baseline period and were asked to scan their sensor every 8 hours. Sensor glucose measurements were blinded while patients continued SMBG with a glucose diary. Two subjects who failed to have sensor data for at least 50% of this period withdrew from the study. This is before randomization.
Lever, 2024[109] 2GO-CGM	Dexcom G series (any model)	rtCGM Therapeutic	12 weeks	Yes	2 weeks	No	Participants had blinded CGM fitted for data collection over a 2-week run-in phase.
Lind, 2024[110] Steno2tech	Dexcom G series (any model)	rtCGM Therapeutic	12 months	Yes	10 days	No	All participants wore a blinded Dexcom G6 for 10 days
Martens, 2021[113] MOBILE	Dexcom G series (any model)	rtCGM Therapeutic	8 months	Yes	10 days	Yes	Each participant used a CGM system that recorded glucose concentrations not visible to the participant (blinded version of the CGM device used by the CGM group) for up to 10 days.

Author, Year Study Name	CGM Brand and Model	Type Modality	Total CGM Use/ Study Duration	Run-in Period?	Length of Run-in	Run-in Used to Exclude Candidates?	Run-in Description
							Eligibility required a minimum of 168 hours of glucose values.
Tildesley, 2013[122]	Medtronic Guardian Connect system	rtCGM Nontherapeutic	6 months	No	NA	NA	NA
Adults With T2D on Oral Hypoglycemic Medications, but Not Insulin							
Aronson, 2023[95] IMMEDIATE	FreeStyle Libre	isCGM Therapeutic	16/16 weeks	No	NA	NA	NA
Moon, 2022[114]	Medtronic MiniMed system	rtCGM Nontherapeutic	rtCGM-1: 1/12 wk rtCGM-2: 2/12 wk	Yes	<1 week (6 days)	No	An iPro2 with Enlite sensor (Medtronic MiniMed, USA), a blinded CGM (retrospective CGM), was applied to the subjects for up to 6 days with lifestyle coaching
Price, 2021[117] COMMITTED	Dexcom G series	rtCGM Therapeutic	4 weeks (i.e., 3, 10-day periods over 3 months)	Yes	10 days	No	All participants completed quality-of-life questionnaires and wore Dexcom G6 CGM (Dexcom Inc, San Diego, CA) in a blinded, study mode for one 10-day wear session to collect baseline CGM data.
Rama Chandran, 2024[118] GLiMPSE	FreeStyle Libre	isCGM Nontherapeutic	7/24 weeks	Yes	2 weeks	Yes	Prerandomized use of isCGM and self-monitoring of capillary blood glucose (CBG) for 2 weeks; patients who did not adhere to is-CGM wear or/and < 10 CBG over 2 weeks were excluded before randomization (n = 10)
Taylor, 2019[120]	Medtronic Guardian Connect system	rtCGM Nontherapeutic	12 weeks	Yes	1 week	No	All participants were blinded CGM for 1 week before commencement of the lifestyle intervention for baseline data collection, then randomization revealed at baseline (week 0) for 12 weeks while following the lifestyle intervention.

Author, Year Study Name	CGM Brand and Model	Type Modality	Total CGM Use/ Study Duration	Run-in Period?	Length of Run-in	Run-in Used to Exclude Candidates?	Run-in Description
Wada, 2020[124]	FreeStyle Libre	isCGM Therapeutic	12/24 weeks	Yes	> 1 week	No	All participants wore a sensor (Free Style Libre Pro; Abbott Diabetes Care, Alameda, California, USA) for a baseline period of > 7 days; the sensor glucose measurements obtained during this period were blinded (not visible) to the participants and investigators.
Adults With T2D on Mixed Nonintensive Hypoglycemic Regimens							
Ajjan, 2023[93] LIBERATES	FreeStyle Libre	isCGM Therapeutic	3/10 months	No	NA	NA	NA
Bergenstal, 2022[97]	Dexcom SEVEN system	rtCGM Therapeutic	16 weeks	Yes	2 to 4 weeks	No	A run-in period of 2–4 weeks before the baseline visit was used to add incretins and/or to titrate metformin as tolerated up to 2000 mg
O'Connor, 2024[115] GOOD-ER	FreeStyle Libre	isCGM Therapeutic	2/12 weeks (additional CGM at the discretion of patient's care team)	No	NA	NA	NA
Vigersky, 2012[123]	Dexcom SEVEN system	rtCGM Nontherapeutic	8 of the first 12 weeks, then standard care for 40 weeks	No	NA	NA	NA
Yoo, 2008[125]	Medtronic Guardian Connect system (any model)	rtCGM Nontherapeutic	9 days/12 weeks (3 days a month for the duration of study)	No	NA	NA	NA

Author, Year Study Name	CGM Brand and Model	Type Modality	Total CGM Use/ Study Duration	Run-in Period?	Length of Run-in	Run-in Used to Exclude Candidates?	Run-in Description
Pregnant People With GDM Not on Insulin Therapy							
Alfadhli, 2016[94]	Medtronic Guardian Connect system	rtCGM Nontherapeutic	3 to 7 days	No	NA	NA	NA
Kestila, 2007[106]	Medtronic MiniMed system	rtCGM Nontherapeutic	4 weeks	No	NA	NA	NA
Lane, 2019[107]	Medtronic MiniMed system	rtCGM Nontherapeutic	4 weeks	No	NA	NA	NA
Majewska, 2023[112] FLAMINGO	FreeStyle Libre 1	isCGM Therapeutic	4 weeks	No	NA	NA	NA

Abbreviations. BGM: blood glucose meter; CGM: continuous glucose monitor(ing); isCGM: Intermittently scanned continuous glucose monitor(ing); mg: milligram; NA: not applicable; NR: not reported; RCT: randomized controlled trial; rtCGM: real-time continuous glucose monitor(ing); SMBG: self-monitoring blood glucose; T2D: type 2 diabetes.

Appendix C. Outcomes Tables for RCTs of Noncovered Populations (KQ1)

Adults with T2D on Nonintensive Insulin Regimens

Table C1. Target HbA1c Outcomes, Adults With T2D on Nonintensive Insulin Regimens

Author, Year Study Name	Outcome Measure	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
			Group Name	Group N	N (%)	Group Name	Group N	N (%)		
Beck, 2017[51] DIAMOND	HbA1c level < 7.0%	12 weeks	rtCGM	77	17 (22%)	SMBG	75	9 (12%)	MD, 10% (95% CI, −2% to 23%)	*P* = .26
		24 weeks	rtCGM	77	11 (14%)	SMBG	75	9 (12%)	MD, 3% (95% CI, −9% to 14%)	*P* = .88
	HbA1c level < 7.5%	12 weeks	rtCGM	77	35 (45%)	SMBG	75	22 (29%)	MD, 17% (95% CI, −3% to 37%)	*P* = .054
		24 weeks	rtCGM	77	27 (35%)	SMBG	75	21 (28%)	MD, 8% (95% CI, −11% to 26%)	*P* = .63

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; HbA1c: glycated hemoglobin; MD: mean difference; rtCGM: real-time continuous glucose monitor(ing); SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table C2. Severe Hypoglycemia Requiring Intervention, Adults With T2D on Nonintensive Insulin Regimens

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	N (%)	Group Name	Group N	N (%)		
Beck, 2017[51] DIAMOND	24 weeks	rtCGM	74	0 (0)	SMBG	72	0 (0)	NA	NA
Haak, 2017[103] REPLACE	24 weeks	isCGM	149	3 (2)	SMBG	75	1 (1)	NR	NR
Lever, 2024[109] 2GO-CGM	12 weeks	rtCGM	33	0 (0)	SMBG	32	0 (0)	NA	NA
Lind, 2024[110] Steno2tech	52 weeks	rtCGM	40	0 (0)	SMBG	36	0 (0)	NA	NA
Martens, 2021[113] MOBILE	32 weeks	rtCGM	116	1 (0.9)	SMBG	59	1 (1.7)	NR	NR

Abbreviations. CGM: continuous glucose monitor(ing); NA: not applicable; NR: not reported; rtCGM: real-time continuous glucose monitor(ing); SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table C3. QoL Outcomes, Adults With T2D on Nonintensive Insulin Regimens

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
Diabetes Distress Scale (DDS)									
Beck, 2017[51] DIAMOND	24 weeks	rtCGM	77	1.8 (SD, 0.9)	SMBG	73	1.8 (SD, 0.6)	NR	NR[a]
Lind, 2024[110] Steno2tech	24 weeks	rtCGM	40	1.9 (95% CI, 1.6 to 2.1)	SMBG	36	2.3 (95% CI, 2.0 to 2.5)	MD, -0.4 (95% CI, -0.7 to -0.1)	*P* = .01
	52 weeks	rtCGM	40	1.8 (95% CI, 1.5 to 2.1)	SMBG	36	2.2 (95% CI, 1.9 to 2.5)	MD, -0.4 (95% CI, -0.7 to 0.0)	*P* = .06
Diabetes Quality of Life (DQoL)									
Haak, 2017[103] REPLACE	24 weeks	isCGM	149	-0.2 (SE, 0.04)	SMBG	75	0.0 (SE, 0.06)	NR	*P* = .026
Diabetes Treatment Satisfaction Questionnaire (DTSQ)									
Ajjan, 2016[92]	12 weeks	rtCGM	30	13.39 (NR)	SMBG	15	13.52 (NR)	NR	*P* = .94
Haak, 2017[103] REPLACE	24 weeks	isCGM	149	13.1 (SE, 0.50)	SMBG	75	9.0 (SE, 0.72)	NR	*P* < .001
Lind, 2024[110] Steno2tech	52 weeks	rtCGM	40	14.4 (95% CI, 13.1 to 15.6)	SMBG	36	6.4 (3.2, 9.5)	MD, 8.0 (95% CI, 4.7 to 11.4)	*P* < .001
Euro Quality of Life 5 Dimension (EQ-5D)									
Beck, 2017[51] DIAMOND	24 weeks	rtCGM	77	0.82 (SD, 0.14)	SMBG	73	0.82 (SD, 0.16)	NR	NR[a]
Hypoglycemia Confidence Scale (HCS)									
Beck, 2017[51] DIAMOND	24 weeks	rtCGM	77	3.3 (SD, 0.6)	SMBG	73	3.4 (SD, 0.6)	NR	NR[a]
Hypoglycemia Fear Survey (HFS)									
Lind, 2024[110] Steno2tech	24 weeks	rtCGM	40	5.7 (95% CI, 3.9 to 7.4)	SMBG	36	6.4 (95% CI, 4.4 to 8.3)	MD, -0.7 (95% CI, -2.9 to 1.5)	*P* = .53
	52 weeks	rtCGM	40	5.6 (95% CI, 3.5 to 7.6)	SMBG	36	5.3 (95% CI, 3.0 to 7.6)	MD, 0.2 (95% CI, -2.4 to 2.9)	*P* = .86

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
5-item World Health Organization Well-being Index (WHO-5)									
Beck, 2017[51] DIAMOND	24 weeks	rtCGM	77	16 (SD, 5)	SMBG	73	17 (SD, 4)	NR	NR[a]
Lind, 2024[110] Steno2tech	24 weeks	rtCGM	40	64.1 (95% CI, 58.4 to 69.8)	SMBG	36	58.2 (95% CI, 51.9 to 64.5)	MD, 5.9 (95% CI, -0.6 to 12.5)	*P* = .07
	52 weeks	rtCGM	40	67.4 (95% CI, 61.4 to 73.4)	SMBG	36	59.8 (95% CI, 53.1 to 66.5)	MD, 7.6 (95% CI, 0.3 to 14.9)	*P* = .04

Notes. [a] *P value not reported, but DIAMOND study authors noted that between-group effects were not significant for all reported quality of life measures.*
Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; HbA1c: glycated hemoglobin; isCGM: intermittently scanned continuous glucose monitor(ing); MD: mean difference; NR: not reported; rtCGM: real-time continuous glucose monitor(ing); SD: standard deviation; SE: standard error; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table C4. Mortality Outcomes, Adults With T2D on Nonintensive Insulin Regimens

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	Events	Group Name	Group N	Events		
Beck, 2017[51] DIAMOND	24 weeks	rtCGM	74	1 death (myocardial infarction)	SMBG	72	0 deaths	NR	NR
Martens, 2021[113] MOBILE	32 weeks	rtCGM	116	0 deaths	SMBG	59	0 deaths	NR	NR

Abbreviations. CGM: continuous glucose monitor(ing); NR: not reported; rtCGM: real-time continuous glucose monitor(ing); SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Adults with T2D on Oral Hypoglycemic Medications, but not on Insulin

Table C5. Target HbA1c Level Outcomes, Adults With T2D on Oral Hypoglycemic Medications and Not on Insulin

Author, Year Study Name	Outcome Measure	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
			Group Name	Group N	N (%)	Group Name	Group N	N (%)		
Price, 2021[117] COMMITTED	HbA1c level < 7.0%	12 weeks	rtCGM	44	8 (18.2%)	SMBG	23	2 (8.7%)	NR	*P* = .26
	HbA1c level < 7.5%	12 weeks	rtCGM	44	15 (34.1%)	SMBG	23	4 (17.4%)	NR	*P* = .12

Abbreviations. CGM: continuous glucose monitor(ing); HbA1c: glycated hemoglobin; NR: not reported; rtCGM: real-time continuous glucose monitor(ing); SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table C6. Severe Hypoglycemia Requiring Intervention, Adults With T2D on Oral Hypoglycemic Medications and Not on Insulin

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	N (%)	Group Name	Group N	N (%)		
Aronson, 2023[95] IMMEDIATE	16 weeks	isCGM	53	0 (0)	Attention control	52	1 (2)	NR	NR
Moon, 2022[114]	24 weeks	rtCGM-1	18	1 (5.6)	SMBG	15	0 (0)	NR	NR
		rtCGM-2	15	0 (0)	SMBG	15	0 (0)	NA	NA
Price, 2021[117] COMMITTED	12 weeks	rtCGM	44	0 (0)	SMBG	23	0 (0)	NA	NA
Rama Chandran, 2024[118] GLiMPSE	24 weeks	isCGM	90	0 (0)	SMBG	86	0 (0)	NA	NA

Abbreviations. CGM: continuous glucose monitor(ing); isCGM: intermittently scanned continuous glucose monitor(ing); NA: not applicable; NR: not reported; rtCGM: real-time continuous glucose monitor(ing); SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table C7. Quality of Life Outcomes, Adults With T2D on Oral Hypoglycemic Medications and Not on Insulin

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
Appraisal of Diabetes Scale-Korean (ADS-K)									
Moon, 2022[114]	24 weeks	rtCGM-1	18	-0.8 (SD, 3.6)	SMBG	15	-0.5 (SD, 2.9)	Adj. MD, 0.07 (95% CI, -2.33 to 2.47)	*P* = .95
		rtCGM-2	15	-1.5 (SD, 2.7)	SMBG	15	-0.5 (SD, 2.9)	Adj. MD, -1.00 (95% CI, -3.60 to 1.60)	*P* = .44
Diabetes Distress Scale									
Aronson, 2023[95] IMMEDIATE	16 weeks	isCGM	53	2.1 -0.3 (SD, 1.1)	Attention control	52	1.9 -0.4 (SD, 1.2)	Adj. MD, −0.2 (95% CI, −0.5 to 0.2)	NR
Diabetes Treatment Satisfaction Questionnaire									
Wada, 2020[124]	24 weeks	isCGM	45	34.9 (SD, 5.2)	SMBG	45	31.4 (SD, 6.6)	MD, 3.4 (95% CI, 1.9 to 5.0)	*P* < .001
Euro Quality of Life 5 Dimension (EuroQoL-5D)									
Rama Chandran, 2024[118] GLiMPSE	24 weeks	isCGM	89	−0.02 (95% CI, −0.06 to 0.01)	SMBG	84	−0.05 (95% CI, −0.09 to −0.02)	MD, 0.03 (95% CI, −0.02 to 0.08)	*P* = .21
	52 weeks	isCGM	88	0.001 (95% CI, − 0.03 to 0.04)	SMBG	82	−0.07 (95% CI, −0.10 to −0.03)	MD, 0.07 (95% CI, 0.02 to 0.12)	*P* = .01
EuroQoL-5D Visual Acuity Scale (EuroQoL-VAS)									
Rama Chandran, 2024[118] GLiMPSE	24 weeks	isCGM	89	+5.50 (95% CI, 3.00 to 8.00)	SMBG	84	+5.59 (95% CI, 3.01 to 8.18)	MD, −0.09 (95% CI, −3.62 to 3.44)	*P* = .96
	52 weeks	isCGM	88	+3.70 (95% CI, 0.94 to 6.45)	SMBG	82	+4.08 (95% CI, 1.22 to 6.93)	MD, −0.38 (95% CI, −4.29 to 3.53)	*P* = .85
Korean Diabetes Management Self-Efficacy Scale (K-DMSES)									
Moon, 2022[114]	24 weeks	rtCGM-1	18	+3.6 (SD, 23.0)	SMBG	15	+1.2 (SD, 10.3)	Adj. MD, 8.97 (95% CI, -4.72 to 22.66)	*P* = .19
		rtCGM-2	15	+14.5 (SD, 19.9)	SMBG	15	+1.2 (SD, 10.3)	Adj. MD, 11.96 (95% CI, -1.19 to 25.12)	*P* = .07
LMC Skills, Confidence, and Preparedness Index (SCPI)									
Aronson, 2023[95] IMMEDIATE	16 weeks	isCGM	53	6.1 +0.8 (SD, 0.8)	Attention control	52	6.1 +0.8 (SD, 0.8)	Adj. MD, −0.2 (95% CI, −0.3 to 0.2)	NR

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
Summary of Diabetes Self-Care Activities measure-Korean (SDSCA-K)									
Moon, 2022[114]	24 weeks	rtCGM-1	18	+13.9 (SD, 9.9)	SMBG	15	+10.1 (SD, 8.9)	Adj. MD, 5.11 (95% CI, -2.56 to 12.78)	*P* = .18
		rtCGM-2	15	+9.9 (SD, 6.0)	SMBG	15	+10.1 (SD, 8.9)	Adj. MD, 0.69 (95% CI, -5.20 to 6.57)	*P* = .81

Abbreviations. Adj: adjusted; CGM: continuous glucose monitor(ing); CI: confidence interval; isCGM: intermittently scanned continuous glucose monitor(ing); MD: mean difference; NR: not reported; rtCGM: real-time continuous glucose monitor(ing); SCPI: LMC Skills, Confidence, and Preparedness Index; SD: standard deviation; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Adults with T2D on Mixed Nonintensive Hypoglycemic Treatment Regimens

Table C8. Severe Hypoglycemia Requiring Intervention, Adults With T2D on Mixed Nonintensive Hypoglycemic Regimens

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	N (%)	Group Name	Group N	N (%)		
Ajjan, 2023[93] LIBERATES	12 weeks	isCGM	69	0 (0)	SMBG	72	2 (3)	NR	NR
Yoo, 2008[125]	12 weeks	rtCGM	29	0 (0)	SMBG	28	0 (0)	NA	NA

Abbreviations. CGM: continuous glucose monitor(ing); isCGM: intermittently scanned continuous glucose monitor(ing); NA: not applicable; NR: not reported; rtCGM: real-time continuous glucose monitor(ing); SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table C9. Quality of Life Outcomes, Adults With T2D on Mixed Nonintensive Hypoglycemic Regimens

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	N (%)	Group Name	Group N	N (%)		
Audit of Diabetes-Dependent Quality of Life (ADDQoL)									
Ajjan, 2023[93] LIBERATES	12 weeks	isCGM	69	NR	SMBG	72	NR	MD, -0.02 (95% CI, -0.24 to 0.20)	NR
Diabetes Distress Scale (DDS)									
O'Connor, 2024[115] GOOD-ER	12 weeks	isCGM	16	0.0 (SD, 1.1)	Usual care	14	0.5 (SD, 1.0)	NR	*P* = .29
Diabetes Treatment Satisfaction Questionnaire (DTSQ)									
Ajjan, 2023[93] LIBERATES	12 weeks	isCGM	69	NR	SMBG	72	NR	MD, 1.1 (95% CI, -0.7 to 2.9)	NR
Euro Quality of Life 5 Dimension (EQ-5D)									
Ajjan, 2023[93] LIBERATES	12 weeks	isCGM	69	NR	SMBG	72	NR	MD, -0.004 (95% CI, -0.076 to 0.068)	NR
Problem Areas in Diabetes (PAID)									
O'Connor, 2024[115] GOOD-ER	12 weeks	isCGM	16	0.0 (SD, 5.8)	Usual care	14	2.3 (SD, 3.2)	NR	*P* = .26
Vigersky, 2012[123]	12 weeks	rtCGM	50	19.9 (SD, 17.1)	SMBG	50	17.1 (SD, 18.0)	NR	NR
	52 weeks	rtCGM	50	19.6 (SD, 20.5)	SMBG	50	18.4 (SD, 20.5)	NR	NR

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; HbA1c: glycated hemoglobin; isCGM: intermittently scanned continuous glucose monitor(ing); MD: mean difference; NR: not reported; rtCGM: real-time continuous glucose monitor(ing); SD: standard deviation; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table C10. Mortality, Adults With T2D on Mixed Nonintensive Hypoglycemic Regimens

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	N (%)	Group Name	Group N	N (%)		
Ajjan, 2023[93] LIBERATES	52 weeks	isCGM	69	2 (3)	SMBG	72	3 (4)	NR	NR

Abbreviations. CGM: continuous glucose monitor(ing); isCGM: intermittently scanned continuous glucose monitor(ing); NR: not reported; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Pregnant People with GDM

Table C11. Change in HbA1c Outcomes, Pregnant People With GDM Not on Insulin Therapy

Author, Year Study Name	Outcome Measure	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
			Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
Alfadhli, 2016[94]	Mean HbA1c at follow-up	End of pregnancy (16 weeks follow-up)	rtCGM	60	5.7 (SD, 0.7)	SMBG	62	6.1 (SD, 0.4)	MD, NR (95% CI, −0.20 to 1.01)	*P* = .17
Lane, 2019[107]	Mean HbA1c at follow-up	End of pregnancy (4 weeks follow-up)	rtCGM	11	5.3 (SD, 0.03)	Blinded CGM	12	5.3 (SD, 0.04)	NR	*P* = .90
Majewska, 2023[112] FLAMINGO	Mean HbA1c at follow-up	End of pregnancy (16 weeks follow-up)	isCGM	49	Median, 5.1 (IQR, 4.8 to 5.4)	SMBG	50	Median, 5.1 (IQR, 4.9 to 5.3)	NR	*P* = .80

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; HbA1c: glycated hemoglobin; IQR: interquartile range; isCGM: intermittently scanned continuous glucose monitor(ing); MD: mean difference; NR: not reported; rtCGM: real-time continuous glucose monitor(ing); SD: standard deviation; SMBG: self-monitoring of blood glucose.

Table C12. Perinatal Morbidity and Mortality Outcomes, Pregnant People With GDM Not on Insulin Therapy

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	N (%)	Group Name	Group N	N (%)		
Large for Gestational Age (> 90th percentile)									
Lane, 2019[107]	End of pregnancy	rtCGM	11	2 (18.2)	Blinded CGM	12	0 (0)	NR	*P* = .20
Majewska, 2023[112] FLAMINGO	End of pregnancy	isCGM	49	10 (20.4)	SMBG	50	15 (30.0)	OR, 2.38 (95% CI 0.69 to 8.22)	*P* = .64
Low Birth Weight									
Alfadhli, 2016[94]	End of pregnancy	rtCGM	60	NR (22.2)	SMBG	62	NR (9.5)	OR, 2.7 (95% CI, 0.78 to 9.45)	*P* = .15
Macrosomia (birth weight ≥ 4000 g)									
Alfadhli, 2016[94]	End of pregnancy	rtCGM	60	NR (2.4)	SMBG	62	0 (0)	OR, 0.48 (95% CI, 0.39 to 0.60)	*P* = .49
Kestila, 2007[106]	End of pregnancy	rtCGM	36	4 (11.1)	SMBG	37	3 (8.1)	NR	*P* = .33
Lane, 2019[107]	End of pregnancy	rtCGM	11	2 (18.2)	Blinded CGM	12	0 (0)	NR	*P* = .20
Majewska, 2023[112] FLAMINGO	End of pregnancy	isCGM	49	2 (4.08)	SMBG	50	10 (20.0)	OR 5.62 (95% CI, 1.16 to 27.22)	*P* = .028
NICU Admission									
Alfadhli, 2016[94]	End of pregnancy	rtCGM	60	NR (34.8)	SMBG	62	NR (30.0)	OR, 1.2 (95% CI, 0.50 to 3.09)	*P* = .65
Kestila, 2007[106]	End of pregnancy	rtCGM	36	7 (19.4)	SMBG	37	11 (30.8)	NR	*P* = .11
Lane, 2019[107]	End of pregnancy	rtCGM	11	0 (0)	Blinded CGM	12	1 (8.3)	NR	*P* = 1.0

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	N (%)	Group Name	Group N	N (%)		
Perinatal Death (intrauterine fetal death or neonatal death before hospital discharge)									
Alfadhli, 2016[94]	End of pregnancy	rtCGM	60	NR (3.4)[a]	SMBG	62	NR (3.7)[a]	NR	NR
Kestila, 2007[106]	End of pregnancy	rtCGM	36	0 (0)	SMBG	37	0 (0)	NA	NA
Preeclampsia									
Lane, 2019[107]	End of pregnancy	rtCGM	11	1 (9.1)	Blinded CGM	12	2 (16.7)	NR	*P* = 1.0
Preterm Birth[a]									
Alfadhli, 2016[94]	End of pregnancy	rtCGM	60	16.3%	SMBG	62	9.5%	OR, 1.85 (95% CI, 0.52 to 6.66)	NR
Kestila, 2007[106]	End of pregnancy	rtCGM	36	2 (5.5)	SMBG	37	2 (5.4)	NR	NR
Lane, 2019[107]	End of pregnancy	rtCGM	11	1 (9.1)	Blinded CGM	12	2 (16.7)	NR	*P* = 1.0
Shoulder Dystocia									
Alfadhli, 2016[94]	End of pregnancy	rtCGM	60	0 (0)	SMBG	62	0 (0)	NA	NA
Lane, 2019[107]	End of pregnancy	rtCGM	11	0 (0)	Blinded CGM	12	0 (0)	NA	NA
Unplanned Cesarean Delivery									
Alfadhli, 2016[94]	End of pregnancy	rtCGM	60	55.1%	SMBG	62	49.1%	OR, 1.27 (95% CI, 0.59 to 2.76)	*P* = .56
Kestila, 2007[106]	End of pregnancy	rtCGM	36	8 (22.2)	SMBG	37	8 (21.6)	NR	*P* = .47
Lane, 2019[107]	End of pregnancy	rtCGM	11	4 (36.3)	Blinded CGM	12	4 (33.3)	NR	*P* = 1.0

Author, Year Study Name	Timepoint	CGM Group			Control Group			Between-group Differences	P Value
		Group Name	Group N	N (%)	Group Name	Group N	N (%)		
Majewska, 2023[112] FLAMINGO	End of pregnancy	isCGM	49	25 (51.0)	SMBG	50	25 (50.0)	NR	*P* = .68

Notes: [a] Defined as delivery before 37 weeks of gestation.

Abbreviations. CGM: continuous glucose monitor(ing); GDM: gestational diabetes; isCGM: intermittently scanned continuous glucose monitor(ing); NA: not applicable; NR: not reported; OR: odds ratio; rtCGM: real-time continuous glucose monitor; SMBG: self-monitoring of blood glucose.

Appendix D. Full Evidence Tables for Device-Related Safety Outcomes from RCTs (KQ2)

Table D1. Device-related Adverse Events Reported in All Included RCTs of Target Populations Without CGM Coverage

Author, Year Study Name	Study Duration [CGM use]	CGM Group			Control Group			Event Details
		Group Name	Group N	Event Rate	Group Name	Group N	Event Rate	
Device-Related AE								
Ajjan, 2016[92]	12 weeks [12 weeks]	isCGM	56[a]	6 events	NA	NA	NA	5 AE were related to the study device and 1 AE was possibly related to the study device. All events were sensor site insertion events including bleeding, bruising, erythema, induration, edema, rash and pain. None of these were rated as serious.
Ajjan, 2023[93] LIBERATES	52 weeks [12 weeks]	isCGM	69	17 events in 14 participants	SMBG	72	7 events in 4 participants [a]	Complaints included mild/ moderate erythema, itching, bruising, and pain, but none was severe enough to warrant discontinuation of the sensor.
Alfadhli, 2016[94]	12-16 weeks [3-7 days]	rtCGM	68	NR – see details	NA	NA	NA	No major side effects aside from mild erythema and skin irritation around the sensor's insertion site
Haak, 2017[103] REPLACE	24 weeks [24 weeks]	isCGM	149	9 events in 6 participants	SMBG	75	0 events [a]	9 sensor adhesive reactions (2 severe, 6 moderate, and 1 mild) occurred in the CGM group. Reactions were primarily treated with topical preparations; all were resolved at study exit.
Lane, 2019[107]	4 weeks [4 weeks]	rtCGM	20	3 (15%) participants	Blinded CGM	20	4 (20%) participants	Reported events are dropouts due to sensor irritation. Overall, 13 (34%) of participants experienced redness, pain, tenderness, or swelling at the sensor insertion site; however,

Author, Year Study Name	Study Duration [CGM use]	CGM Group			Control Group			Event Details
		Group Name	Group N	Event Rate	Group Name	Group N	Event Rate	
								this was usually remedied by replacement at a different site.
Lever, 2024[109] 2GO-CGM	12 weeks [12 weeks]	rtCGM	33	1 event in 1 participant	NA	NA	NA	Minor skin reaction to sensor adhesive requiring antihistamine treatment.
Lind, 2024[110] Steno2tech	52 weeks [52 weeks]	rtCGM	40	1 event in 1 participant	SMBG	36	1 event in 1 participant[a]	Skin reactions (rashes) after removal of the first blinded CGM during the run-in period
Moon, 2022[114]	24 weeks [1-2 weeks]	rtCGM-1	18	0 events	SMBG	N/A	NA	A single case of skin rash was observed in the second CGM group.
		rtCGM-2	18	1 event in 1 participant	NA	N/A	NA	
Price, 2021[117] COMMITTED	12 weeks [4 weeks]	rtCGM	44	1 event in 1 participant	SMBG	23	1 event in 1 participant[a]	Excessive skin irritation from sensor adhesives. Other AE occurred, but were not determined to be device related.
Rama Chandran, 2024[118] GLiMPSE	24 weeks [7 weeks]	isCGM	90	0 events	NA	NA	NA	Sensor wear-related symptoms throughout the intervention period
Wada, 2020[124]	24 weeks [12 weeks]	isCGM	49	7 events in 7 participants	SMBG	51	1 event in 1 participant[a]	All device-related AE involved skin problems related to physical contact with the sensor. None of these were serious AEs. All were resolved at study exit.
Yoo, 2008[125]	12 weeks [9 days]	rtCGM	29	0 events	NA	NA	NA	No reports of skin reactions (irritation and allergies)

Notes. [a] *Includes device-related AE experienced during the pre-study run-in period during which all participants wore a CGM.* [c] *In the REPLACE trial, the CGM was used for 6 months by intervention participants and worn (blinded) for 4 weeks by control participants.* [c] *In the LIBERATES trial, participants in the SMBG control group wore a blinded CGM during the first study month and on study days 79 to 90.*

Abbreviations. AE: adverse event(s); CGM: continuous glucose monitor(ing); isCGM: intermittently scanned continuous glucose monitor(ing); NA: not applicable; NR: not reported; RCT: randomized controlled trial; rtCGM: real-time continuous glucose monitor(ing); SAE: serious adverse event; SMBG: self-monitoring of blood glucose

Appendix E. Evidence Tables for Subgroup Analyses (KQ3)

Table E1. Age Subgroups: Change in HbA1c Outcomes

Author, Year Study Name	Timepoint	Subgroup	CGM Group			Control Group			Between-group Differences	P Value
			Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
Adults With T2D on Nonintensive Insulin Regimens										
Beck, 2017[51] DIAMOND	24 weeks	≤ 44 years	rtCGM	9	−1.0% (SD, 0.6)	SMBG	4	−0.3% (SD, 1.2)	NR	*P* = .89
		45 to 59 years	rtCGM	26	−0.7% (SD, 0.7)	SMBG	32	−0.5% (SD, 0.9)	NR	
		≥ 60 years	rtCGM	42	−0.9% (SD, 0.7)	SMBG	39	−0.5% (SD, 0.8)	NR	
Haak, 2017[103] REPLACE	24 weeks	< 65 years	isCGM	149	-0.53% (SE, 0.09)	SMBG	75	-0.20% (SE, 0.12)	MD, -0.33 (SE, 0.149)	*P* = .03
		≥ 65 years	isCGM	149	-0.05% (SE, 0.10)	SMBG	75	-0.49% (SE, 0.13)	MD, 0.44 (SE, 0.161)	*P* = .008
Martens, 2021[113] MOBILE	32 weeks	30 to 39 years	rtCGM	5	-3.0% (SD, 0.9)	SMBG	1	0.8% (SD, 0.0)	NR	*P* = .76
		40 to 49 years	rtCGM	19	-0.9% (SD, 2.1)	SMBG	7	-0.4% (SD, 1.3)	NR	
		50 to 59 years	rtCGM	40	-1.0% (SD, 1.4)	SMBG	18	-0.9% (SD, 1.2)	NR	
		≥ 60 years	rtCGM	40	-1.0% (SD, 1.1)	SMBG	25	0.6% (SD, 1.1)	NR	
	32 weeks	< 65 years	rtCGM	79	-1.08% (SD, 1.55)	SMBG	38	-0.73% (SD, 1.24)	MD, -0.35% (95% CI, -0.77 to 0.07)	*P* = .10
		≥ 65 years	rtCGM	25	-1.08% (SD, 1.23)	SMBG	13	-0.38% (SD, 0.92)	MD, -0.65% (95% CI, -1.49 to 0.19)	*P* = .13

Author, Year Study Name	Timepoint	Subgroup	CGM Group			Control Group			Between-group Differences	P Value
			Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
Adults With T2D on OHM Therapy										
Rama Chandran, 2024[118] GLiMPSE	24 weeks	< 60 years	isCGM	NR	NR	SMBG	NR	NR	MD, −0.003% (95% CI, −0.29 to 0.28)	*P* = .78
		≥ 60 years	isCGM	NR	NR	SMBG	NR	NR	MD, 0.13% (95% CI, −0.20 to 0.47)	

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; HbA1c: glycated hemoglobin; isCGM: intermittently scanned continuous glucose monitor(ing); MD: mean difference; NR: not reported; OHM: oral hypoglycemic medication; rtCGM: real-time continuous glucose monitor(ing); SD: standard deviation; SE: standard error; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table E2. Sex and Gender Subgroups: Change in HbA1c Outcomes

Author, Year Study Name	Timepoint	Outcome Measure	CGM Group			Control Group			Between-group Differences	P Value
			Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
Adults With T2D on OHM Therapy										
Rama Chandran, 2024[118] GLiMPSE	24 weeks	Male	isCGM	NR	NR	SMBG	NR	NR	MD, −0.06% (95% CI, −0.34 to 0.23)	*P* = .55
		Female	isCGM	NR	NR	SMBG	NR	NR	MD, 0.18% (95% CI, −0.16 to 0.52)	

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; HbA1c: glycated hemoglobin; isCGM: intermittently scanned continuous glucose monitor(ing); NR: not reported; OHM: oral hypoglycemic medication; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table E3. Race and Ethnicity Subgroups: Change in HbA1c Outcomes

Author, Year Study Name	Timepoint	Outcome Measure	CGM Group			Control Group			Between-group Differences	P Value
			Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
Adults With T2D on Nonintensive Insulin Regimens										
Martens, 2021[113] MOBILE	32 weeks	White	rtCGM	47	-1.4% (SD, 1.3)	SMBG	31	-0.7% (SD, 1.0)	NR	NR
		Non-White	rtCGM	57	-0.8% (SD, 1.6)	SMBG	20	-0.6% (SD, 1.4)	NR	NR
Adults With T2D on OHM Therapy										
Rama Chandran, 2024[118] GLiMPSE	24 weeks	Chinese	isCGM	NR	NR	SMBG	NR	NR	MD, 0.14% (95% CI, –0.15 to 0.42)	*P* = .67
		Non-Chinese	isCGM	NR	NR	SMBG	NR	NR	MD, –0.05% (95% CI, –0.39 to 0.28)	

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; HbA1c: glycated hemoglobin; isCGM: intermittently scanned continuous glucose monitor(ing); MD: mean difference; NR: not reported; OHM: oral hypoglycemic medication; rtCGM: real-time continuous glucose monitor(ing); SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table E4. Severity of Disease Subgroups: Change in HbA1c Outcomes

Author, Year Study Name	Timepoint	Outcome Measure	CGM Group			Control Group			Between-group Differences	P Value
			Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
Baseline HbA1c Level										
Adults With T2D on Nonintensive Insulin Regimens										
Beck, 2017[51] DIAMOND	24 weeks	< 8.5%	rtCGM	38	−0.6% (SD, 0.7)	SMBG	36	−0.3% (SD, 0.8)	NR	*P* = .35
		≥ 8.5%	rtCGM	39	−1.1% (SD, 0.6)	SMBG	39	−0.7% (SD, 0.9)	NR	
Martens, 2021[113] MOBILE	32 weeks	<9.0%	rtCGM	51	-0.7% (SD, 1.3)	SMBG	24	-0.2% (SD, 1.0)	NR	*P* = .76
		≥ 9.0%	rtCGM	53	-1.4% (SD, 1.6)	SMBG	27	-1.0% (SD, 1.2)	NR	
	32 weeks	≥ 8.5%	rtCGM	74	-1.4% (SD, 1.4)	SMBG	35	-0.9% (SD, 1.1)	MD, -0.4% (95% CI, -0.8 to 0.1)	*P* = .10
		≥ 9.0%	rtCGM	53	-1.4% (SD, 1.6)	SMBG	27	-1.0% (SD, 1.2)	MD, -0.2% (95% CI, -0.8 to 0.3)	NR
		≥ 9.5%	rtCGM	39	-1.7% (SD, 1.6)	SMBG	13	-0.9% (SD, 1.5)	MD, -0.8% (95% CI, -1.6 to 0.1)	NR
		≥ 10.0%	rtCGM	22	-2.1% (SD, 1.5)	SMBG	8	-0.4% (SD, 1.5)	MD, -1.5% (95% CI, -2.6 to -0.5)	NR
Adults With T2D on OHM Therapy										
Rama Chandran, 2024[118] GLiMPSE	24 weeks	< 7.0%	isCGM	NR	NR	SMBG	NR	NR	MD, 0.20% (95% CI, −1.34 to 1.73)	*P* = .97
		≥ 7.0%	isCGM	NR	NR	SMBG	NR	NR	MD, 0.05% (95% CI, −0.17 to 0.27)	

Author, Year Study Name	Timepoint	Outcome Measure	CGM Group			Control Group			Between-group Differences	P Value
			Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
Baseline Diabetes Duration										
Adults With T2D on Nonintensive Insulin Regimens										
Martens, 2021[113] MOBILE	32 weeks	< 5 years	rtCGM	16	−1.4% (SD, 1.6)	SMBG	8	−0.7% (SD, 1.7)	NR	*P* = .76
		5 to 17 years	rtCGM	52	−0.9% (SD, 1.6)	SMBG	29	−0.7% (SD, 1.1)	NR	
		18 to 29 years	rtCGM	31	−1.3% (SD, 1.1)	SMBG	9	−0.6% (SD, 1.1)	NR	
		≥ 30 years	rtCGM	5	−0.7% (SD, 0.7)	SMBG	5	−0.3% (SD, 1.0)	NR	
Adults With T2D on OHM Therapy										
Rama Chandran, 2024[118] GLiMPSE	24 weeks	< 10 years	isCGM	NR	NR	SMBG	NR	NR	MD, 0.04% (95% CI, −0.27 to 0.35)	*P* = .38
		≥ 10 years	isCGM	NR	NR	SMBG	NR	NR	MD, −0.08% (95% CI, −0.23 to 0.38)	
Frequency of SMBG Testing at Baseline										
Adults With T2D on Nonintensive Insulin Regimens										
Beck, 2017[51] DIAMOND	24 weeks	< 4 times/day	rtCGM	51	−0.9% (SD, 0.7)	SMBG	52	−0.6% (SD, 0.8)	NR	*P* = .78
		≥ 4 times/day	rtCGM	26	−0.7% (SD, 0.6)	SMBG	23	−0.3% (SD, 0.9)	NR	
Noninsulin Medication Use										
Adults With T2D on Nonintensive Insulin Regimens										
Martens, 2021[113] MOBILE	32 weeks	Not using GLP1 or SGLT2 meds at baseline	rtCGM	71	-1.0% (SD, 1.6)	SMBG	40	-0.7% (SD, 1.2)	NR	*P* = .76

Author, Year Study Name	Timepoint	Outcome Measure	CGM Group			Control Group			Between-group Differences	P Value
			Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
		Using GLP1 or SGLT2 meds at baseline	rtCGM	33	-1.2% (SD, 1.2)	SMBG	11	-0.6% (SD, 0.9)	NR	
Adults With T2D on Oral Hypoglycemic Medications but Not on Insulin										
Wada, 2020[124]	24 weeks	No change in hypoglycemic medication use during study period	isCGM	41	−0.46% (95% CI, −0.60 to −0.31)	SMBG	41	−0.18% (95% CI, −0.41 to 0.05)	MD, −0.14% (95% CI, −0.27 to −0.00)	*P* = .04

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; GLP1: glucagon-like-peptide 1 agonist; HbA1c: glycated hemoglobin; isCGM: intermittently scanned continuous glucose monitor(ing); MD: mean difference; NR: not reported; OHM: oral hypoglycemic medication; rtCGM: real-time continuous glucose monitor(ing); SD: standard deviation; SGLT2: sodium-glucose cotransporter-2 inhibitor; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table E5. Adherence Subgroups: Change in HbA1c Outcomes

Author, Year Study Name	Timepoint	Outcome Measure	CGM Group			Control Group			Between-group Differences	P Value
			Group Name	Group N	Mean (Variance)	Group Name	Group N	Mean (Variance)		
Adults With T2D on OHM Therapy										
Rama Chandran, 2024[118] GLiMPSE	24 weeks	< 7 scans/day or < 1 SMBG test/day	isCGM	NR	NR	SMBG	NR	NR	MD, 0.35% (95% CI, –0.04 to 0.74)	*P* = .20
		≥ 7 scans/day or ≥ 1 SMBG test/day	isCGM	NR	NR	SMBG	NR	NR	MD, −0.04% (95% CI, −0.31 to 0.23)	
Adults With T2D on Mixed Nonintensive Hypoglycemic Regimens										
Vigersky, 2012[123]	52 weeks	< 48 days of use or < 1 SMBG test/day	rtCGM	NR	−0.3% (SD, 1.3)	SMBG	NR	0.0% (SD, 1.1)	NR	NR[a]
		≥ 48 days of use (per protocol) or ≥ 1 SMBG test/day	rtCGM	NR	−1.0% (SD, 1.5)	SMBG	NR	−0.3% (SD, 1.4)	NR	*P* < .001

Notes. [a] *P value was not reported, but study authors indicated that the difference was not significant.*
Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; HbA1c: glycated hemoglobin; isCGM: intermittently scanned continuous glucose monitor(ing); MD: mean difference; NR: not reported; OHM: oral hypoglycemic medication; rtCGM: real-time continuous glucose monitor(ing); SD: standard deviation; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Appendix F. Full Risk-of-Bias and Methodological Quality Assessment Tables

Table F1. Risk-of-Bias Assessments for Included RCTs of CGM

Author, Year Study Name	Randomization	Allocation Concealment	Masking	Follow-Up	Outcome Measures	Intention to Treat Analysis	Statistical Analysis	Sample Baseline Characteristic	Attrition < 20%	Interest Disclosure	Funding	Applicability	Overall RoB Assessment
Adults With T2D on Nonintensive Insulin Regimens													
Ajjan, 2016[92]	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Low
Beck, 2017[51] DIAMOND	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Low
Haak, 2017[103] REPLACE	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Mod
Lever, 2024[109] 2GO-CGM	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Unclear	Yes	Yes	Low
Lind, 2024[110] Steno2tech	Yes	Yes	No	Yes	Yes	Yes	Yes	Unclear	Yes	Unclear	Yes	Yes	Low
Martens, 2021[113] MOBILE	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	Mod
Tildesley, 2013[122]	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Mod
Adults With T2D on Oral Hypoglycemic Medications													
Aronson, 2023[95] IMMEDIATE	Yes	Unclear	No	Yes	Yes	No	Yes	Unclear	Yes	Unclear	Unclear	Yes	Mod
Moon, 2022[114]	Yes	Yes	No	Yes	Yes	Unclear	Yes	Yes	No	Unclear	No	Yes	High
Price, 2021[117]	Unclear	Unclear	No	Yes	Yes	No	Yes	Unclear	Yes	Unclear	Unclear	Yes	High
Rama Chandran, 2024[118] GLiMPSE	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Unclear	Yes	Unclear	Yes	Yes	Mod

Author, Year Study Name	Randomization	Allocation Concealment	Masking	Follow-Up	Outcome Measures	Intention to Treat Analysis	Statistical Analysis	Sample Baseline Characteristic	Attrition < 20%	Interest Disclosure	Funding	Applicability	Overall RoB Assessment
Taylor, 2019[120]	Yes	Unclear	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low
Wada, 2020[124]	Yes	Yes	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Low
Adults With T2D on Mixed Nonintensive Hypoglycemic Regimens													
Ajjan, 2023[93] LIBERATES	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low
Bergenstal, 2022[97]	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Mod
O'Connor, 2024[115] GOOD-ER	Unclear	Unclear	Unclear	No	Yes	Yes	Yes	No	No	Yes	Yes	Unclear	High
Vigersky, 2012[123]	Unclear	Unclear	No	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes	High
Yoo, 2008[125]	Yes	Unclear	No	Yes	Yes	No	Yes	Yes	Unclear	Yes	Unclear	Yes	High
Pregnant People With GDM Not on Insulin Therapy													
Alfadhli, 2016[94]	Yes	Unclear	No	Unclear	Yes	No	Yes	Yes	Unclear	Yes	Yes	Yes	Mod
Kestila, 2007[106]	Unclear	Unclear	Unclear	Yes	Yes	Unclear	Yes	Yes	Unclear	Unclear	Yes	Yes	High
Lane, 2019[107]	No	No	No	Yes	Yes	No	Unclear	Yes	No	Yes	Unclear	Yes	High
Majewska, 2023[112] FLAMINGO	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Low

Abbreviations. CGM: continuous glucose monitor(ing); GDM: gestational diabetes; Mod: moderate; RCT: randomized controlled trial; RoB: risk of bias; T2D: type 2 diabetes.

Table F2. Risk of Bias: Economic Modeling Studies of CGMs

Author, Year	Target Population	Perspective	Time Horizon	Discount Rate	Comparators	Modeling	Effectiveness	Outcomes	Resource Use/Costs	Uncertainty	Results	Interest Disclosure	Funding Source	Overall RoB Assessment
Frank, 2024[132]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Mod
Kerr, 2023[131]	Yes	NA	NA	NA	Yes	NA	NA	NA	Yes	NA	Yes	No	No	Mod

Abbreviations.; Mod: moderate; NA: not applicable; RoB: risk of bias.

Table F3. Methodological Quality of Included Clinical Practice Guidelines for CGM

Guideline Developer, Year Guideline Title	Rigor of Development: Evidence	Rigor of Development: Recommendations	Editorial Independence	Scope & Purpose	Stakeholder Involvement	Clarity and Presentation	Applicability	Overall Assessment
General Diabetes Guidelines								
American Association of Clinical Endocrinology, 2021[175] *The Use of Advanced Technology in the Management of Persons With Diabetes*	No	Yes	Unclear	Yes	No	Yes	Unclear	Poor
American Association of Clinical Endocrinology, 2022[19] *Developing a Diabetes Comprehensive Care Plan 2022 Update*	No	Yes	Unclear	Yes	Unclear	Yes	Yes	Poor
American Diabetes Association, 2024[25] *Diabetes Technology: Standards of Care in Diabetes 2024*	Unclear	Yes	Yes	No	Yes	Yes	Unclear	Fair
Endocrine Society, 2019[179] *Treatment of Diabetes in Older Adults*	No	No	Yes	Yes	Yes	Yes	Unclear	Poor
Endocrine Society, 2022[176] *Management of Individuals With Diabetes at High Risk for Hypoglycemia*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good

Guideline Developer, Year Guideline Title	Rigor of Development: Evidence	Rigor of Development: Recommendations	Editorial Independence	Scope & Purpose	Stakeholder Involvement	Clarity and Presentation	Applicability	Overall Assessment
T2D Guidelines								
National Institute for Health and Care Excellence, 2022[57] *T2D in Adults: Management (NG28)*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Ontario Health (Quality), 2019[207] *Flash Glucose Monitoring System for People With T1D or T2D: Recommendation*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
US Veterans Affairs/ Department of Defense, 2023[184] *Management of T2D*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Pregnancy Guidelines								
American Diabetes Association, 2024[187] *Management of Diabetes in Pregnancy: Standards of Care in Diabetes 2024*	Unclear	Yes	Yes	No	Yes	Yes	Unclear	Fair
Healthcare Improvement Scotland, 2024[178] *SIGN 171: Management of Diabetes in Pregnancy*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good

Guideline Developer, Year Guideline Title	Rigor of Development: Evidence	Rigor of Development: Recommendations	Editorial Independence	Scope & Purpose	Stakeholder Involvement	Clarity and Presentation	Applicability	Overall Assessment
National Institute for Health and Care Excellence, 2020[208] *Diabetes in Pregnancy: Management From Preconception to the Postnatal Period*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Pediatric Guidelines								
American Diabetes Association, 2024[186] *Children And Adolescents: Standards of Care in Diabetes 2024*	Unclear	Yes	Yes	No	Yes	Yes	Yes	Fair
National Institute for Health and Care Excellence, 2023[182] *T1D and T2D in Children and Young People: Diagnosis and Management*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good

Abbreviations. CGM: continuous glucose monitor(ing); T1D: type 1 diabetes; T2D: type 2 diabetes.

Appendix G. Full GRADE Certainty of Evidence Tables

Table G1. GRADE Profile: CGM vs. No CGM in Adults With T2D on Nonintensive Insulin Regimens

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
Change in HbA1c							
N = 802 7 RCTs[51,92,103,109,110,113,122]	Serious (downgraded 1 level) • High likelihood of selection bias due to use of run-in periods to screen for adherence before randomization in 4 studies (including 3 largest) • Funding related COI concerns	Not serious • Moderate heterogeneity as indicated by I^2 (39%), but results of the MA did not vary during sensitivity testing by individual trial removal	Not serious • Reasonably direct despite some use of nonthera-peutic CGMs • Most studies looked at CGM use across entire study period • Same comparator (SMBG)	Not serious	Not assessed	At final follow-up (range 12 to 52 weeks), CGM use was associated with a pooled 0.27% (95% CI, −0.46 to −0.08; *P* = .005) reduction in HbA1c compared with no CGM (i.e., SMBG). However, this difference did not meet the threshold for clinical significance (MCID, 0.5% change).	●●●○ Moderate
Achievement of Target HbA1c Level							
N = 158 1 RCT	Not serious	Not assessable (single study)	Serious (downgraded 1 level) • Use of nonthera-peutic CGM in	Serious (downgraded 1 level) • Small sample size	Not assessed	After adjusting for baseline HbA1c level, there were no significant differences between CGM and SMBG groups in the proportion of	●●○○ Low

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
			intervention group (these models are no longer available)	• wide confidence intervals		participants who achieved an HbA1c level of ≤ 7.0% or ≤ 7.5% at the 12 or 24 weeks.	
Quality of Life							
Diabetes-related QoL N = 503 4 RCTs[51,92,103,110]	Serious (downgraded 1 level) • Increased potential for selection bias due to use of run-in periods to screen for adherence (3 of 4 studies) • Funding related COI concerns	Serious (downgraded 1 level) • Inconsistent direction of effect on similar scales across studies • Mixed findings within at least 1 study	Not serious	Not serious	Limited overlap of QoL scales, some of which may be comparing difference constructs	There were mixed diabetes-related QoL findings, indicating either no difference or improved QoL with CGM, across a range of validated measurement scales and follow-up timepoints (range 12 to 52 weeks). All study groups reported low diabetes distress levels and high treatment-related satisfaction.	●●○○ Low
General QoL N = 234 2 RCTs[51,110]	Not serious	Serious (downgraded 1 level) • Inconsistent direction of effect on similar scales across studies	Serious (downgraded 1 level) • Largest study used a nonthera-peutic CGM which of which the modality and model	Not serious	Not assessed	There were mixed general QoL findings, indicating either no difference or improved QoL with CGM, across multiple validated measurement scales. One study found no between-group differences at 24 weeks in either the EQ-5D or WHO-5	

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
			are currently discontinued • Comparison at different timepoints			scales, although both study groups had scores indicating overall high well-being. One study found no between group difference in WHO-5 scores at 24 weeks but reported significantly higher scores with CGM vs. SMBG at 52 weeks (67.4 vs. 59.8 points; *P* =.04). This difference did/did not meet the threshold for clinical significance.	

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; COI: conflict of interest; EQ-5D: EuroQol 5-Dimension; GRADE: Grading of Recommendations, Assessment, Development, and Evaluations; HbA1c: glycated hemoglobin; MA: meta-analysis; MCID: minimal clinically important difference; MD: mean difference; QoL: quality of life; RCT: randomized controlled trial; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes; WHO: World Health Organization.

Table G2. GRADE Profile: CGM vs. No CGM in Adults With T2D on Oral Hypoglycemic Medications

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
Change in HbA1c							
N = 560 6 RCTs[95,114,117,118,120,124]	Serious (downgraded 1 level) • Most studies had high or moderate RoB • Lack of information regarding study group allocation procedures • Funding-related COI concerns • Differential LTFU in several studies • Potential for selection bias due to run-in periods	Serious (downgraded 1 level) • High I^2 in MA • Pooled results were significant when GLiMPSE trial was removed for sensitivity testing, but the reasons for this difference are unclear	Not serious • Half the studies had low levels of planned CGM use (i.e., ≤ 50% the length of follow-up)	Not serious	Not assessed	No difference in HbA1c change from baseline in pooled analysis (5 RCTs; pooled MD, −0.18%; 95% CI, −0.45 to 0.09; *P* = .20). Single study not included in MA due to minimal CGM use found mixed results at 24 weeks.	●●○○ Low

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
Achievement of Target HbA1c Level							
N = 70 1 RCT[117]	Serious (downgraded 1 level) • High RoB study • Lack of information about study group allocation procedures • Funding-related COI concerns	Not assessable (single study)	Serious (downgraded 1 level) • Episodic use of CGM (only 30% of total study follow-up)	Serious (downgraded 1 level) • Small sample size (< 100)	Data only from a single short-term timepoint (12 weeks)	At 12 weeks of follow-up, there were no significant between-group differences in the proportion of individuals randomized to CGM versus no CGM (i.e., SMBG who achieved an HbA1c level below 7.0% (18.2% vs. 8.7%; *P* = .26) or below 7.5% (34.1% vs. 17.4%; *P* = .12).	●○○○ Very low
Quality of Life							
Diabetes-related QoL N = 277 3 RCTs[95,114,124]	Serious (downgraded 1 level) • 2 of 3 studies had RoB issues • Lack of information about study group allocation procedures • High and differential LTFU in 1 study	Not serious • Inconsistent between-group results across studies, but not all scales were measuring the same concepts (i.e., treatment satisfaction vs. self-efficacy)	Serious (downgraded 1 level) • Indirect outcome comparisons only ○ No overlap in QoL scales ○ Limited overlap in QoL constructs • 2 studies had CGM use	Serious (downgraded 1 level) • Wide confidence intervals for between-group comparisons in 1 study (Moon, 2022) • Lack of MCIDs to gauge	All groups generally reported within-group improvements from baseline	There were mixed diabetes-related QoL results reported across 6 validated measurement scales at final follow-up (range, 16 to 52 weeks); each scale was only used by a single study. Two studies found no-between group differences in any reported QoL construct and scale including diabetes distress, perceived	●○○○ Very low

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
	• Funding related author COI and concern regarding funder involvement		< 50% of total follow-up	clinical significance		diabetes status, and diabetes self-management efficacy. In comparison, 1 study reported improved diabetes treatment satisfaction with CGM vs. SMBG. All study groups generally reported within-group improvements on all QoL scales, but MCIDs were not widely available so clinical significance was not assessable.	
General QoL N = 193 1 RCT[118]	Serious (downgraded 1 level) • Single moderate-RoB study • Possible imbalance of OHM use at baseline with no explicit method of control • Possible selection bias due to	Not assessable (single study)	Not serious • Episodic use of CGM < 60% of total study follow-up (i.e., continuous use for the first 6 weeks followed by intermittent use of one sensor every 4 weeks (each sensor lasting 2 weeks).	Serious (downgraded 1 level) Single study, small sample size	Serious (downgraded 1 level) • Mixed results within 1 study across 2 related scales of overall QoL	Mixed results on 2 measures of general QoL at 52 weeks in the GLiMPSE trial. Due to decreases in QoL scores in the SMBG group the CGM had higher overall well-being on the EQ-5D scale, despite no change in scores (0.00 vs. −0.07 points; *P* = .01). There was no difference in on the EQ-VAS scale at 52 weeks, although both groups reported	●○○○ Very low

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
	pre-allocation screening with run-in • Author-related COI concerns					improvements (+3.7 vs. +4.1 points; *P* = .85)	

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; COI: conflict of interest; EQ-5D: EuroQol 5-Dimension; EQ-VAS: EuroQol Visual Analogue Scale; GRADE: Grading of Recommendations, Assessment, Development, and Evaluations; HbA1c: glycated hemoglobin; LTFU: long-term follow-up; MA: meta-analysis; MCID: minimal clinically important difference; MD: mean difference; OHM: oral hypoglycemic medication; QoL: quality of life; RCT: randomized controlled trial; RoB: risk of bias; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes; WHO: World Health Organization.

Table G3. GRADE Profile: CGM vs. No CGM in Adults With T2D on Mixed Nonintensive Hypoglycemic Therapy

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
Change in HbA1c							
N = 450 5 RCTs[93,97,115,123,125]	Serious (downgraded 1 level) 4 of 5 studies had moderate or high RoB due to: • Insufficient information about study group allocation procedures • High losses to follow-up • Mostly per protocol analyses • Industry-related funding concerns	Not serious • Results are mostly consistent. • Single study with a difference (Yoo) had the highest rate of insulin use across the studies, which seems like a reasonable explanation for the heterogeneity	Serious (downgraded 2 levels) • Studies varied widely in terms of mix and degree of use of diabetes medications, such as insulin • 3 of 5 studies had very limited CGM use (< 20% of total study duration) • 2 studies were limited to higher-risk patients (e.g., recent MI and recent ED admission)	Not serious	Not assessed	At final study follow-up (range, 12 to 52 weeks), there were no between-group differences in change in HbA1c from baseline in 4 studies. Comparatively CGM use was associated with a statistically and clinically greater HbA1c reduction (–1.1% vs. –0.4%; *P* = .004) in 1 study with a higher proportion of insulin users. All CGM groups experienced clinically meaningful reductions in HbA1c levels (i.e., 0.5%) from baseline	●○○○ Very low

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
						compared with only 3 of 5 control groups.	
Achievement of Target HbA1c Level							
No studies – not assessable							
Quality of Life							
Diabetes-related QoL N = 271 3 RCTs[93,115,123]	Serious (downgraded 1 level) High risk of bias in 2 of 3 studies due to: • Insufficient information about study group allocation procedures • High losses to follow-up	Not serious	Serious (downgraded 2 levels) • 2 of 3 studies limited to higher-risk individuals (i.e., recent MI and recent diabetes related ED admission) • Limited overlap in QoL outcomes and scales • 2 of 3 studies assessed limited CGM use (i.e., < 33% of total study duration)	Not serious	Not serious • Lack of within-group scores for some scales precludes assessment of magnitude of changes or level of QoL	No between-group differences at final study assessments (range 12 to 52 weeks) in perceived diabetes burden, diabetes-related distress, and treatment satisfaction.	●○○○ Very low
General QoL N = 141 1 RCT[93]	Not serious	Not assessed (single study)	Serious (downgraded 1 level)	Serious (downgraded 1 level)	Serious (downgraded 1 level)	No difference in overall QoL on a single validated scale.	●○○○ Very low

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
			• Limited to participants with recent myocardial infarction • Study only assessed isCGM	• Small sample size • Wide confidence interval	• Short term data – 12 weeks only • Lack of within-group scores precludes assessment of magnitude of changes or level of QoL		

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; COI: conflict of interest; ED: emergency department; GRADE: Grading of Recommendations, Assessment, Development, and Evaluations; HbA1c: glycated hemoglobin; isCGM: intermittently scanned continuous glucose monitor(ing); LTFU: long-term follow-up; MA: meta-analysis; MCID: minimal clinically important difference; MD: mean difference; OHM: oral hypoglycemic medication; QoL: quality of life; RCT: randomized controlled trial; RoB: risk of bias; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table G4. GRADE Profile: CGM vs. No CGM in Pregnant People With GDM Not on Insulin Therapy

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
Change in HbA1c							
N = 270 3 RCTs	Serious (downgraded 1 level) • Only 1 study with low RoB • Unclear allocation procedures and per protocol analyses in 2 of 3 studies	Not serious	Serious (downgraded 1 level) • Use of nonthera-peutic CGM 2 RCTs (these models are no longer available) • Intermittent CGM use < 33% of total follow-up in the 2 largest RCTs	Not serious	Note that insulin was administered as needed to an unknown number of study participants as a standard part of study procedures	CGM use (any type) was not associated with a significantly lower HbA1c at delivery (4 to 16 weeks of follow-up) compared with non-CGM controls.	●●○○ Low
Achievement of Target HbA1c Level							
No studies – not assessable							
QoL							
No studies – not assessable							
Severe Perinatal Morbidity and Mortality							
N = 343 4 RCTs	Serious (downgraded 1 level) • 2 high and 1 moderate RoB • Unclear randomization	Not serious	Serious (downgraded 1 level) • Use of nonthera-peutic CGM 2 RCTs (these	Serious (downgraded 1 level) • Low event rates • Small sample sizes for rare	Note that insulin was administered as needed to an unknown number of study	At the end of pregnancy (follow-up range, 4 to 16 weeks), very few severe perinatal events occurred and there were no statistically	●○○○ Very low

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
	and allocation procedures • unclear or high LTFU		models are no longer available) • Intermittent CGM use < 33% of total follow-up in the 3 largest RCTs	events (studies not powered to detect differences) • Wide CIs when reported	participants as a standard part of study procedures	significant between-group differences in most reported outcomes, including: • Large for gestational age • Low birth weight • NICU admission • Perinatal death • Preeclampsia • Preterm birth • Shoulder dystocia • Unplanned cesarean delivery Additionally, 3 of 4 RCTs found no difference in the incidence of macrosomia between the CGM groups and no-CGM controls. Whereas in the FLAMINGO trial (N = 100; 12 to 16 weeks follow-up), there was a significantly higher incidence of macrosomia in the control group compared with those using CGM (20% vs.	

Number of Participants (N) and Number of RCTs	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
						4%; OR, 5.6 [95% CI, 1.2 to 27.2]; *P* = .028).	

Abbreviations. CGM: continuous glucose monitor(ing); CI: confidence interval; COI: conflict of interest; GDM: gestational diabetes; GRADE: Grading of Recommendations, Assessment, Development, and Evaluations; HbA1c: glycated hemoglobin; LTFU: long-term follow-up; MA: meta-analysis; MCID: minimal clinically important difference; MD: mean difference; NICU: neonatal intensive care unit; OHM: oral hypoglycemic medication; QoL: quality of life; RCT: randomized controlled trial; RoB: risk of bias; SMBG: self-monitoring of blood glucose; T2D: type 2 diabetes.

Table G5. GRADE Profile: Cost Effectiveness of CGM vs. SMBG in Adults With T2D on Nonintensive Insulin Regimens

Number of Participants (N) and Number of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias or Other	Effect	Overall Certainty of Evidence Rating
Cost-Effectiveness							
1 cost-effectiveness analysis[132]	Serious (downgraded 1 level) • Funding-related COI concerns	Not serious	Not serious	Not serious	Not assessed	Over a 10-year time horizon, from a Medicaid perspective • CGM (specifically, FreeStyle Libre systems) was dominant to SMBG, providing more QALYs and LYs at lower costs for people with T2D on basal insulin	●●●○ Moderate

Abbreviations. CGM: continuous glucose monitoring; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HbA1c: glycated hemoglobin; LY: life-year; QALY: quality-adjusted life year; SMBG: self-monitoring blood glucose; T2D: type 2 diabetes.

Appendix H. Full Details of Ongoing Studies

Table H1. RCTs of CGM in Currently Uncovered Populations

Study Characteristics				Inclusion Criteria		GRADE Outcomes				
Study Name Trial Number	Expected Enrollment Follow-up Location	CGM Type	Control Group(s)	Treatment Regimen(s)	Min. HbA1c Level	Change in HbA1c	Target HbA1c level	QoL	Perinatal morbidity	Primary Completion Date
Adults With T2D Not on Intensive Insulin Regimens										
CONTROL-DM NCT04871438[143]	N = 34 12 weeks Singapore	IS	• SMBG	• Nonintensive insulin	9%	✓	X	✓	X	September 2022
FreEdoM-2 NCT04926623[144]	N = 159 (actual) 24 weeks South Korea	IS	• SMBG	• Nonintensive insulin	7.5%	✓	X	✓	X	October 2022 (actual)
DISCO GM ISRCTN17386990[139]	N = 62 (actual) 36 weeks UK	RT	• Usual care	• Nonintensive insulin • OHM therapy • No insulin or OHMs	9%	✓	X	✓	X	March 2023
iCUDE NCT05319496[149]	N = 105 (actual) 12 weeks Canada	IS	• Usual care	• OHM therapy • No insulin or OHMs	7.0%	✓	X	✓	X	January 2024 (actual)
IGNITE NCT05516797[153]	N = 178 (actual) 12 weeks United States	IS	• SMBG	• Nonintensive insulin • OHM therapy	7.5%	✓	X	X	X	March 2024 (actual)
CUTDM NCT05394844[151]	N = 120 (actual) 24 weeks United States	RT	• Usual care	• Nonintensive insulin • OHM therapy • No insulin or OHMs	8.0%	✓	X	✓	X	April 2024 (actual)
2GO-CGM [a] ACTRN 12621000889853[174]	N = 80 12 weeks intervention (crossover design) New Zealand	RT	• Blinded CGM	• Nonintensive insulin	8.0%	✓	X	✓	X	April 2024

Study Characteristics				Inclusion Criteria		GRADE Outcomes				
Study Name Trial Number	Expected Enrollment Follow-up Location	CGM Type	Control Group(s)	Treatment Regimen(s)	Min. HbA1c Level	Change in HbA1c	Target HbA1c level	QoL	Perinatal morbidity	Primary Completion Date
NCT05826678[154]	N = 30 24 weeks United States	NR	• SMBG	• NR	7.5%	✓	X	✓	X	May 2024 (actual)
GLAM NCT05431296[152]	N = 160 26 weeks UK	RT	• Blinded CGM	• Nonintensive insulin • OHM therapy	6.5%	✓	X	✓	X	August 2024
CGM-DTx NCT06111508[161]	N = 30 (actual) 16 weeks United States	RT	• SMBG	• Nonintensive insulin	7.0%	✓	X	X	X	September 2024 (actual)
NCT06594055[168]	N = 120 24 weeks South Korea	IS	• SMBG	• OHM therapy • No insulin or OHMs	6.5%	✓	X	✓	X	October 2024
DDART NCT04663061[142]	N = 65 (actual) 52 weeks United States	RT	• Usual care	• NR	6.5%	✓	X	X	X	November 2024
NCT05944432[156]	N = 430 32 weeks UK	RT	• SMBG	• Nonintensive insulin	7.5%	✓	X	X	X	December 2024
NCT06517576[167]	N = 150 16 weeks United States	RT	• Usual care	• Nonintensive insulin	8.0%	✓	X	✓	X	June 2025
NCT06054659[159]	N = 92 16 weeks United States	RT	• SMBG	• NR	8.0%	X	X	✓	X	July 2025
NCT06465693[165]	N = 10 12 weeks United States	RT	• Usual care	• OHM therapy • No insulin or OHMs	7.0%	✓	X	✓	X	July 2025

Study Characteristics				Inclusion Criteria		GRADE Outcomes				
Study Name Trial Number	Expected Enrollment Follow-up Location	CGM Type	Control Group(s)	Treatment Regimen(s)	Min. HbA1c Level	Change in HbA1c	Target HbA1c level	QoL	Perinatal morbidity	Primary Completion Date
NCT06028503[157]	N = 60 52 weeks United States	RT	• Usual care	• Nonintensive insulin • OHM therapy • No insulin or OHMs	6.0%	✓	X	✓	X	August 2025
NCT06643611[170]	N = 60 24 weeks United States	NR	• HbA1c testing	• Nonintensive insulin	8%	✓	✓	✓	X	December 2025
NCT06296550[162]	N = 140 24 weeks United States	RT	• Usual care	• OHM therapy • No insulin or OHMs	7.5%	✓	X	✓	X	April 2026
NCT06641765[169]	N = 96 36 weeks Denmark	RT	• SMBG	• OHM therapy • No insulin or OHMs	NR	✓	X	✓	X	September 2026
GluCoCare NCT05222815[147]	N = 359 52 weeks United States	NR	• SMBG	• Nonintensive insulin	7.5%	✓	X	✓	X	October 2026
TEAM-CGM NCT05911256[155]	N = 318 24 weeks United States	NR	• Usual care	• OHM therapy • No insulin or OHMs	9%	✓	X	✓	X	September 2027
CHANGE-diab NCT06471699[166]	N = 250 70 weeks Sweden	NR	• SMBG	• OHM therapy • No insulin or OHMs	7.5%	✓	X	✓	X	December 2027
Youth With T2D Not on Intensive Insulin Regimens										
FREE_CGM NCT06089070[160]	N = 30 24 weeks United States	RT	• Usual care	• Nonintensive insulin	6.5%	✓	X	✓	X	December 2027

Study Characteristics				Inclusion Criteria		GRADE Outcomes				
Study Name Trial Number	Expected Enrollment Follow-up Location	CGM Type	Control Group(s)	Treatment Regimen(s)	Min. HbA1c Level	Change in HbA1c	Target HbA1c level	QoL	Perinatal morbidity	Primary Completion Date
Pregnant People With T2D Not on Insulin										
AT GOAL NCT05370612[150]	N = 16 (actual) At delivery United States	RT	• SMBG	• Not on insulin	NR	✓	X	✓	✓	December 2024
NCT05317585[148]	N = 180 At delivery United States	NR	• SMBG	• Not on insulin	6.5%	X	X	✓	✓	July 2026
PROTECT ISRCTN12804317[138]	N = 422 At delivery UK	RT	• SMBG	• Not on insulin	6.1%	✓	X	✓	✓	April 2027
Pregnant People With GDM Not on Insulin										
DiP GlucoMo NCT05037526[146]	N = 302 Up to 2 years Switzerland	RT	• Blinded CGM	• Not on insulin	NA	✓	X	X	✓	September 2023
NCT03981328[172]	N = 372 At delivery Austria	RT	• SMBG	• Not on insulin	NA	✓	X	✓	✓	December 2023
STEADYSUGAR NCT04948112[145]	N = 128 (actual) Up to 32 weeks United States	RT	• Blinded CGM	• Not on insulin	NA	✓	X	✓	✓	May 2024 (actual)
RECOGNISE[173] ISRCTN42125256	N = 60 (actual) At delivery UK	IS	• SMBG	• On metformin [b]	NA	✓	X	✓	✓	July 2024 (actual)
GDLIBRE NCT06031987[158]	N = 100 Up to 12 weeks postpartum South Korea	IS	• SMBG	• Not on insulin	NA	✓	X	✓	✓	December 2024

Study Characteristics				Inclusion Criteria		GRADE Outcomes				
Study Name Trial Number	Expected Enrollment Follow-up Location	CGM Type	Control Group(s)	Treatment Regimen(s)	Min. HbA1c Level	Change in HbA1c	Target HbA1c level	QoL	Perinatal morbidity	Primary Completion Date
CORDELIA NCT06310356[163]	N = 386 At delivery Belgium	RT	• SMBG	Not on insulin	NA	✓	X	✓	✓	September 2025
CAPO NCT04219085[141]	N = 80 Delivery (40 weeks) United States	NR	• SMBG	• Not on insulin	NA	X	X	X	✓	December 2025
NCT06436326[164]	N = 120 Up to 12 weeks postpartum Taiwan	RT	• SMBG	• Not on insulin	NA	X	X	✓	✓	June 2026
ISRCTN92877235[140]	N = 40 (actual) Up to 12 weeks postpartum UK	IS	• SMBG	• Not on insulin	NA	X	X	✓	✓	April 2027
NCT06648174[171]	N = 120 Up to 12 weeks postpartum Taiwan	RT	• SMBG • Perinatal nursing care	• Not on insulin	NA	X	X	✓	✓	December 2027

Notes. ✓denotes yes; X denotes no; [a] Ages 16 and older; [b] Inclusion criteria indicate on insulin or metformin so study will be eligible if results stratified.

Abbreviations. CGM: continuous glucose monitor(ing); GDM: gestational diabetes; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HbA1c: hemoglobin A1c; IS: intermittently scanned continuous glucose monitor(ing); NA: not applicable; NR: not reported; OHM: oral hypoglycemic medication; QoL: quality of life; RT: real-time continuous glucose monitor(ing); SMBG: self-monitoring blood glucose; T2D: type 2 diabetes; UK: United Kingdom.

Appendix I. Full Evidence Tables for Economic Studies (KQ4)

Table I1. Study Characteristics and Evidence Tables for Economic Studies[a]

Citation Perspective Risk of Bias	Design Intervention Comparator(s)	Population	Analytic Assumptions or Methods	Main Findings
Adults With T2D on Nonintensive Insulin Regimens				
Frank, 2024[132] US perspective, specifically Medicaid Moderate RoB	Patient-level microsimulation model • FreeStyle Libre • SMBG • N = 10,000 simulated patients	Adults with T2D using basal insulin • Mean age at model entry, 56.0 years (SD, 10.2) • Female, 48.0% • Race/ethnicity, 13.6% Black, 17.0% Hispanic • Mean HbA1c, 9.2% (SD, 1.0) • Current smokers, 12.0% • Comorbid CVD, 35.7% • OAD medications, 83.0% No details of insulin use intensity reported Pregnancy not reported	• Perspective, Medicaid • Time horizon, 10 years • Costs and utility discount, 3.0% • Model, Determination of Diabetes Utilities, Costs, and Effects (DEDUCE) • Key model inputs • Reduction in HbA1c (one-time), 1.1% CGM vs. 0% SMBG • Severe hypoglycemic event (annual probability), 0.41% CGM vs. 0.73% SMBG • Nonsevere hypoglycemic event (events per year), 16.50 CGM vs. 23.31 SMBG • Severe DKA event (annual probability), 0.34% CGM vs. 1.37% SMBG • DKA mortality (probability per event), 4.7% CGM vs. 4.7% SMBG • Baseline health utility, 0.8 • Fingerstick disutility, 0.03 • Severe hypoglycemic event disutility, 0.036 per event • Nonsevere hypoglycemic event disutility, 0.00163 per event • DKA disutility, 0.0091 per event • Blindness disutility, 0.057 in year 1 then 0.057 in subsequent years	In the base case analysis, CGM was dominant to SMBG, providing more QALYs (6.18 vs. 5.97) at a lower cost ($70,137 vs. $71,809) over the 10-year time horizon. Similarly, the use of CGM resulted in greater LYs (8.08 vs. 7.98) at a lower cost ($70,137 vs. $71,809) over the 10-year time horizon. Scenario analyses were consistent with the base case results, and the ICER for CGM vs. SMBG ranged from cost-effective to dominant. In probabilistic analysis, CGM was 100% likely to be cost-effective relative to SMBG at a willingness-to-pay threshold of $50,000/QALY. See also Table I2.

Citation Perspective Risk of Bias	Design Intervention Comparator(s)	Population	Analytic Assumptions or Methods	Main Findings
			• Congestive heart failure disutility, 0.089 in year 1 then 0.041 in subsequent years • MI disutility, 0.042 in year 1 then 0.011 in subsequent years • Renal failure disutility, 0.024 in year 1 then 0.024 in subsequent years • Stroke disutility, 0.204 in year 1 then 0.101 in subsequent years	
Adults With T2D on Mixed Nonintensive Hypoglycemic Treatment Regimens				
Kerr, 2023[131] US, commercial and Medicare claims Moderate RoB	Retrospective analysis • CGM (N = 3,498) • SMBG (N = 3,498)	Adults with nonintensively managed primary or secondary T2D • Mean age in years, 52.8 (SD, 8.9) vs. 52.8 (SD, 8.9) • Female, 48.2% vs. 47.8% • CVD, 11.2% vs. 12.3% • Microvascular and macrovascular complications, 30.5% vs. 30.2% • Mean frequency of SMBG tests per day, 1.34 (SD, 1.58) vs. 1.35 (SD, 1.62) • Injectables only, 0.8% vs. 0.8% • OHM plus injectables, 19.0% vs. 19.2% • OHM only, 41.4% vs. 41.6%	Propensity score matching, then logistic regression analysis with multiple covariates[a] Costs adjusted as per the 2020 US dollar Follow-up, 12 months pre and post HCRU and costs reported as annualized means	After propensity score matching, HCRU PPPY, CGM vs. SMBG • Patients with an IP stay, 6.7% vs. 7.1%; *P* = .54 • Mean number of IP admissions, 0.09 (SD, 0.4) vs. 0.1 (SD, 0.4); *P* = .33 • Patients with an ED visit, 23.2% vs. 20.9%; *P* = .02 • Mean number of ED visits, 0.41 (SD, 1.0) vs. 0.41 (SD, 1.2); *P* = .75 • Patients with an OP visit, 98.9% vs. 98.5%; *P* = .12 • Mean number of OP visits, 13.98 (SD 13.0) vs. 12.77 (SD 12.1); *P* < .001 • Patients with an OP endocrinologist visit, 35.9% vs. 22.6%; *P* < .001 • Mean number of OP endocrinologist visits, 1.04 (SD 1.7) vs. 0.64 (SD 1.5); *P* < .001

Citation Perspective Risk of Bias	Design Intervention Comparator(s)	Population	Analytic Assumptions or Methods	Main Findings
		• OHM plus insulin, 29.8% vs. 29.4% • Injectables plus insulin, 14.8% vs.14.2% • Insulin only, 13.6% vs. 12.9% • No treatment, 2.1% vs. 2.2% Nonintensive management was defined as not using rapid-acting prandial insulin or using glucagon medication Use of CGM during the pre-index period, pregnancy, gestational or secondary diabetes at any time during the study period were excluded		All-cause health care mean costs PPPY, CGM vs. SMBG • Total all-cause costs, $20,542 vs. $19,349; *P* < .001 • OP office visit costs, $2,292 vs. $1,882; *P* < .001 • ED visit costs, $705 vs. $668; *P* ≤ .05 • Other OP care, $4,353 vs. $4,646; *P* > .05 • IP costs, $2,562 vs. $3,179; *P* > .05 Pharmacy mean costs, CGM vs. SMBG • Total pharmacy costs, $10,629 vs. $8,974; *P* < .001 • Glucose-lowering medications, $6,312 vs. $5,605; *P* < .001 • CGM devices, $928 vs. 0; *P* < .001 • Blood glucose monitoring devices, $95 vs. $411; *P* < .001 • Other pharmacy costs, $3,294 vs. $2,957; *P* < .001

Note. [a] Covariates for the logistic regression included age, gender, geographical region, health plan coverage, baseline comorbidity, CCI score, presence of certain comorbidities and complications, OHM types, frequency of SMBG testing in the pre-period index, baseline all-cause cost, and baseline HCRU. Bold text indicates statistically significant findings.

Abbreviations. CCI: Charlson Comorbidity Index; CGM: continuous glucose monitor(ing); CVD: cardiovascular disease; DKA: diabetic ketoacidosis; ED: emergency department; HbA1c: glycated hemoglobin; HCRU: health care resource utilization; ICER: incremental cost-effectiveness ratio; IP: inpatient; LY: life year; NR: not reported; OAD: oral antidiabetic; OHM: oral hypoglycemic medication; OP: outpatient; PPPY: per-patient per-year; QALY: quality-adjusted life year; RoB: risk of bias; SD: standard deviation; SMBG: self-monitoring blood glucose; T2D: type 2 diabetes.

Table I2. Complications and Costs Over a 10-Year Time Horizon From Frank et al., 2024[132]

Complications and Costs	CGM	SMBG	Difference (CGM – SMBG)
Cumulative Incidence of Complications			
Blindness	6.7%	7.9%	-1.2%
Congestive heart failure	7.9%	9.5%	-1.6%
Myocardial infarction	12.1%	14.4%	--2.2%
Renal failure	6.5%	7.5%	--0.9%
Stroke	3.6%	5.0%	-1.4%
Treatment Costs			
Glucose monitoring costs	$14,842	$4,385	$10,456
Acute Diabetic Event Costs			
Severe hypoglycemic event	$353	$624	-$271
Nonsevere hypoglycemic event	$0	$0	$0
Diabetic ketoacidosis	$766	$2,926	-$2,159
Costs of Complications			
Blindness	$4,555	$5,291	--$736
Congestive heart failure	$4,890	$5,952	-$1,061
Myocardial infarction	$10,224	$12,220	-$1,996
Renal failure	$32,951	$38,243	-$5,292
Stroke	$1,556	$2,168	-$612
Total Costs			
Total costs	$70,137	$71,809	-$1,671

Abbreviations. CGM: continuous glucose monitor(ing); SMBG: self-monitoring blood glucose.

Appendix J. Payer Coverage Policies

Table J1. Payer Policies

Payer	Policy Language
Medicare	
Medicare LCD glucose monitors L33822[188] Last review: October 1, 2024	CONTINUOUS GLUCOSE MONITORS (CGMs) A non-adjunctive CGM can be used to make treatment decisions without the need for a stand-alone BGM to confirm testing results. An adjunctive CGM requires the user verify their glucose levels or trends displayed on a CGM with a BGM prior to making treatment decisions. On February 28, 2022, CMS determined that both non-adjunctive and adjunctive CGMs may be classified as DME. Refer to the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES and CODING GUIDELINES sections in the LCD-related Policy Article for additional information regarding classification of CGMs as DME. To be eligible for coverage of a CGM and related supplies, the beneficiary must meet all of the following initial coverage criteria (1)-(5): 1. The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and, 2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; and, 3. The CGM is prescribed in accordance with its FDA indications for use; and, 4. The beneficiary for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below: 5. A. The beneficiary is insulin-treated; or, B. The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section of the LCD-related Policy Article (A52464)): ▪ Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or, ▪ A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

Payer	Policy Language
	5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the beneficiary to evaluate their diabetes control and determined that criteria (1)-(4) above are met. **CGM Continued Coverage** 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. When a CGM (code E2102 or E2103) is covered, the related supply allowance (code A4238 or A4239) is also covered. Supplies (code A4238) for an adjunctive CGM integrated into an external insulin infusion pump are covered when the beneficiary meets both the CGM coverage criteria and the coverage criteria for an external insulin infusion pump. Refer to the External Infusion Pumps LCD (L33794) for additional information regarding billing a CGM receiver incorporated into an insulin infusion pump. If any of the initial coverage criteria (1)-(5), or the continued coverage criterion are not met, the CGM and related supply allowance will be denied as not reasonable and necessary. The supply allowance (code A4238 or A4239) is a monthly allowance that may be billed up to a maximum of three (3) units of service (UOS) per ninety (90) days at a time. Billing more than three (3) UOS per ninety (90) days of code A4238 or A4239 will be denied as not reasonable and necessary. Refer to the CODING GUIDELINES section in the LCD-related Policy Article for additional billing instructions. Non-adjunctive CGM devices replace standard home BGMs (HCPCS codes E0607, E2100, E2101) and related supplies (HCPCS codes A4233, A4234, A4235, A4236, A4244, A4245, A4246, A4247, A4250, A4253, A4255, A4256, A4257, A4258, A4259). Claims for a BGM and related supplies, billed in addition to a non-adjunctive CGM device (code E2103) and associated supply allowance (code A4239), will be denied. Adjunctive CGM devices do not replace a standard home BGM. The supply allowance for an adjunctive CGM (A4238) encompasses all items necessary for the use of the device and includes but is not limited to, CGM sensors and transmitters. Code A4238 does not include a home BGM and related BGM testing supplies. These items may be billed separately, in addition to code A4238. Refer to the CODING GUIDELINES section in the LCD-related Policy Article for additional information. All CGM devices billed to Medicare using HCPCS code E2103 must be reviewed for correct coding by the Pricing, Data Analysis and Coding (PDAC) contractor and be listed on the Product Classification List (PCL). Effective July 1, 2022, all CGMs billed to Medicare using HCPCS code E2102 must be reviewed for correct coding by the PDAC contractor and be listed on the PCL. If a CGM system is billed using HCPCS code E2102 or E2103 but the CGM system is not on the

Payer	Policy Language
	PCL for that particular HCPCS code, then the claim will be denied as incorrect coding. Refer to the CODING GUIDELINES section in the LCD-related Policy Article for additional information.
Private Payers	
Aetna Diabetes tests, programs and supplies[189] Last review: October 10, 2024	*A. Continuous Glucose Monitoring (CGM) Devices* 1. Short-term (72 hours to 1 week) *diagnostic use* of continuous glucose monitoring (CGM) devices for the following indications: a. For members with diabetes who have *either* of the following problems in controlling blood glucose level, unresponsive to conventional insulin dose adjustment: i. Hypoglycemia unawareness; or ii. Repeated hypoglycemia (less than 50 mg/dL) and hyperglycemia (greater than 150 mg/dL) at the same time each day; *or* b. To diagnose primary islet cell hypertrophy (nesidioblastosis) or persistent hyperinsulinemic hypoglycemia of infancy (PHHI) (congenital hypoglycemia) in members with symptoms suggestive of recurrent hypoglycemia. For short-term (72 hours to 1 week) diagnostic use, no more than 2 continuous glucose monitoring periods within a 12-month period; 2. Long-term (greater than 1 week) therapeutic use of continuous glucose monitoring (CGM) devices (e.g., Dexcom, Eversense, Freestyle Libre, Guardian) for the following indications: a. Criteria for Initial Approval i.Member has a diagnosis of diabetes mellitus (type 1 or type 2) and meets either of the following: i.Member meets *all* of the following criteria: i.Member is 18 years of age or older; *and* ii.Member is using an intensive insulin regimen (defined as multiple daily injections [i.e., 3 or more injections per day] or insulin pump therapy); *and* iii.Member is not meeting glycemic targets or member is experiencing hypoglycemia (including hypoglycemia unawareness); *or* ii.Member is less than 18 years of age and using an intensive insulin regimen (as defined above); *or* ii.Member has a diagnosis of glycogen storage disease; b. Continuation of Therapy Member meets *either* of the following: i.Member has experienced improved glycemic control or decreased hypoglycemia episodes while using a CGM; *or*

Payer	Policy Language
	ii. Member is being assessed every 6 months by the prescriber for adherence to their CGM regimen and diabetes treatment plan. Long-term therapeutic use of a CGM device is considered experimental, investigational, or unproven for all other indications, including the following (not an all-inclusive list), because there is insufficient evidence of the clinical benefits of this approach for these indications: a. Gestational diabetes b. Member with type 2 diabetes not using intensive insulin regimens; c. Monitoring blood glucose in non-diabetic members following gastric bypass surgery d. Neonatal hypoglycemia e. Nesidioblastosis (primary islet cell hypertrophy).
Anthem Continuous glucose monitoring devices #CG-DME-42[190] Last review: August 8, 2024	**Medically Necessary:** I. *Non-Implanted* Continuous Interstitial Glucose Monitoring Devices for Personal Use Use of a *non-implanted* continuous interstitial glucose monitoring device for personal use is considered **medically necessary** for individuals who meet the following criteria: A. Individual has been diagnosed with diabetes mellitus (any type); **and** B. Insulin injections are required multiple times daily or an insulin pump is used for maintenance of blood sugar control; **and** C. Both of the following (1 and 2): 1. The individual or caregiver(s) demonstrates the following: a. An understanding of the technology, including use of the device to recognize alerts and alarms; **and** b. Motivation to use the device correctly and consistently; **and** c. Continued participation in a comprehensive diabetes treatment plan; d. **and** 2. *Any* of the following are present, despite ongoing management using self-monitoring and insulin administration regimens to optimize care: a. Inadequate glycemic control, demonstrated by HbA1c measurements above target; **or** b. Persistent fasting hyperglycemia; **or** c. Recurring episodes of hypoglycemia (blood glucose <54 mg/dL); **or** d. Hypoglycemia unawareness that puts the individual or others at risk; **or** e. In children and adolescents with type 1 diabetes who have achieved HbA1c levels below 7.0%, when treatment is intended to maintain target HbA1c levels and limit the risk of hypoglycemia. *Continued use* of a non-implanted continuous interstitial glucose monitoring device for personal use is considered **medically necessary** when there is documentation that the device has

Payer	Policy Language
	resulted in clinical benefit (for example, improved or stabilized HbA1c control or fewer episodes of symptomatic hypoglycemia or hyperglycemia). *Replacement* of a non-implanted continuous interstitial glucose monitoring device for personal use is considered **medically necessary** when the following criteria have been met: A. The device is out of warranty; **and** B. The device is malfunctioning; **and** C. The device cannot be refurbished. II. *Implanted* Continuous Interstitial Glucose Monitoring Devices for Personal Use Use of an *implanted* continuous interstitial glucose monitoring device for personal use is considered **medically necessary** when the criteria below have been met: A. The individual is 18 years of age or older; **and** B. The individual meets the medical necessity criteria above for a non-implanted continuous interstitial glucose monitoring device for personal use. *Continued use* of an implanted continuous interstitial glucose monitoring device for personal use is considered **medically necessary** when there is documentation that the device has resulted in clinical benefit (for example, improved or stabilized HbA1c control or fewer episodes of symptomatic hypoglycemia or hyperglycemia). *Replacement* of an implantable continuous interstitial glucose monitoring device for personal use is considered **medically necessary** in accordance with FDA approved indications for use. III. Professional, Intermittent, Short-Term Continuous Interstitial Glucose Monitoring Devices *Use of a* continuous interstitial glucose monitoring device for professional, intermittent, short-term use is considered **medically necessary** when **all** of the following criteria are met: A. Individual meets medically necessary criteria for a non-implanted continuous interstitial glucose monitoring devices above; **and** B. Monitoring and interpretation are under the supervision of a physician; **and** C. The device is only used for a maximum of 14 consecutive days on an appropriate, periodic basis. **Not Medically Necessary:** Use of continuous interstitial glucose monitoring devices is considered **not medically necessary** when the criteria above have not been met. *Continued use* of a continuous interstitial glucose monitoring device is considered **not medically necessary** when continued use criteria above have not been met. *Replacement* of currently functional and warrantied continuous interstitial glucose monitoring devices is considered **not medically necessary** when the replacement criteria above have not been met**.**
Cigna (1 of 2) Diabetes equipment and supplies[192]	Continuous Glucose Monitoring System (CGMS)

Payer	Policy Language
Effective date: January 15, 2025[a] *Policy likely replaces policy below in 2025.*	A minimally invasive, continuous glucose monitoring system (CGMS) is considered medically necessary for the management of difficult to control insulin-treated diabetes mellitus (e.g., hypo- or hyperglycemic episodes unresponsive to adjustments in therapy, asymptomatic nocturnal hypoglycemia) for up to 14 days under the core medical benefits of the plan, for up to six separate sessions in any given 12-month period (CPT® code 95249, 95250, 95251). Therapeutic/non-adjunctive Continuous Glucose-Monitoring Systems A minimally invasive, therapeutic/non-adjunctive continuous glucose monitoring system (CGMS) (HCPCS A4238, A4239, E2102, E2103), which may include sensors (HCPCS A4238, A4239, A9276), transmitters (HCPCS A4238, A4239, A9277) and reader/receiver (HCPCS A9278, E2102, E2103), is considered medically necessary for the management of type 1 or type 2 diabetes mellitus: • Freestyle Libre and Freestyle Libre 14 day for an individual age 18 years and older • Freestyle Libre 2 and Freestyle Libre 3 for an individual age 4 years and older • Freestyle Libre 2 Plus, Freestyle Libre 3 Plus, Dexcom G6® and Dexcom G7 for an individual age 2 years and older WHEN the individual is on ANY of the following insulin regimens: • multiple daily injections • long-acting basal insulin (e.g. glargine, detemir, degludec, NPH) • continuous subcutaneous external insulin pump When the above criteria for a minimally invasive, therapeutic/non-adjunctive continuous glucose monitoring system are met, the following quantities for supplies apply: • sensors (HCPCS A4238, A4239, A9276): ○ Freestyle Libre 10-day system: three sensors every 30 days ○ Freestyle Libre 14-day system, Freestyle Libre 2, Freestyle Libre 3, Freestyle Libre 2 Plus, and Freestyle Libre 3 Plus: two sensors every 28 days ○ Dexcom G6 and Dexcom G7: three sensors every 30 days • transmitters (HCPCS A4238, A4239, A9277): ○ Dexcom G6: one transmitter every 90 days • reader/receiver (HCPCS A9278, E2102, E2103): ○ Freestyle Libre 10 day and Freestyle Libre 14 day: one reader every 720 days ○ Freestyle Libre 2 and Freestyle Libre 3: one reader every 720 days ○ Dexcom G6 and Dexcom G7: one receiver every 365 days Non- therapeutic/adjunctive Continuous Glucose-Monitoring Systems A minimally invasive non-therapeutic/adjunctive continuous glucose monitoring system (CGMS) including sensors (HCPCS A4238, A4239, A9276), transmitters (HCPCS A4238, A4239, A9277)

Payer	Policy Language
	and reader/receiver (HCPCS A9278, E2102, E2103) (e.g., Guardian Sensor 3 [HCPCS A4238, A4239, A9276], Guardian Sensor 4 [HCPCS A4238, A9276, A9277], Guardian® REAL-Time [HCPCS code A4238, A4239, A9277, A9278, E2102, E2103]) used with a fingerstick blood glucose monitor is considered medically necessary for the management of type 1 or type 2 diabetes mellitus when used according to the U.S. Food and Drug Administration (FDA) approved indications and ALL of the following criteria have been met: WHEN the individual is on ANY of the following insulin regimens: • multiple daily injections • long-acting basal insulin (e.g. glargine, detemir, degludec, NPH) • continuous subcutaneous external insulin pump When the above criteria for a minimally invasive, non-therapeutic/adjunctive continuous glucose monitoring system are met, the following quantities for supplies apply: • transmitters (HCPCS A4238, A4239, A9277): ○ Medtronic transmitter: one transmitter every 365 days <u>Continuous Glucose Monitoring System with an Implantable Interstitial Glucose Sensor</u> A continuous glucose monitoring system with an implantable interstitial glucose sensor (i.e., Eversense®) (CPT® codes 0446T, 0447T, 0448T) is considered medically necessary for the management of type 1 or type 2 diabetes mellitus for an individual age 18 years or older who is on ANY of the following insulin regimens: • multiple daily injections • long-acting basal insulin (e.g. glargine, detemir, degludec, NPH) • continuous subcutaneous external insulin pump <u>Replacement of a Continuous Glucose Monitoring System and Components</u> Replacement of an existing continuous glucose monitoring system or component is considered medically necessary for an individual managing type 1 or type 2 diabetes mellitus on a continuous glucose monitor when BOTH of the following criteria are met: • documentation confirming that the monitor/component is malfunctioning, is no longer under warranty and cannot be repaired • evidence of an evaluation by the health care provider managing the diabetes within the last six months that includes a recommendation supporting continued use of a continuous glucose monitor <u>Glucose Monitoring Not Covered</u>

Payer	Policy Language
	Each of the following has not demonstrated an improvement to health outcomes and is therefore, considered not medically necessary and/or a convenience item. • additional software or hardware required for downloading data to a device such as personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus • combination devices that include a home blood glucose monitor combined with a cellular telephone or other device not specifically indicated for the management of diabetes mellitus (e.g., blood pressure monitor, cholesterol screening analyzer) • remote glucose monitoring device (e.g., mySentry) • hypoglycemic wristband alarm (e.g., Diabetes Sentry™)
Cigna Prior authorization policy: diabetes, continuous glucose monitoring systems[191] Last review: February 7, 2024	**OVERVIEW** The products targeted in this policy are continuous glucose monitoring (CGM) systems. Freestyle Libre and Freestyle Libre 2 are considered intermittently scanned CGM (isCGM) systems, whereas the other devices are considered real-time CGM (rtCGM) systems. Of note, throughout the policy, the term CGM "system" refers to all applicable components, including sensor, transmitter/reader, and receiver. Of note, the Dexcom G5 CGM System was discontinued by the manufacturer as of June 2020. Per the manufacturer, sensor supply for this system, as well as technical support, would not be guaranteed after December 31, 2020. **POLICY STATEMENT** Prior Authorization is recommended for prescription benefit coverage of the targeted continuous glucose monitoring systems in this policy. All approvals are provided for the duration noted below. • Dexcom G5 CGM System – Dexcom [obsolete 01/01/2022] • Dexcom G6 CGM System – Dexcom • Dexcom G7 CGM System – Dexcom • Eversense CGM System – Ascensia/Senseonics [obsolete 01/04/2022] • Eversense E3 CGM System – Ascensia/Senseonics • Freestyle Libre CGM System – Abbott • Freestyle Libre 2 CGM System – Abbott • Freestyle Libre 3 CGM System – Abbott • Guardian Connect CGM System – Medtronic • Guardian 4 CGM System – Medtronic is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

Payer	Policy Language
	FDA-Approved Indication 1. Diabetes. Approve for 1 year if the patient is using an insulin regimen. Note: This includes patients on a basal insulin regimen, basal and prandial insulin regimen, prandial insulin regimen, or continuous subcutaneous insulin infusion (insulin pump). **CONDITIONS NOT COVERED** • Dexcom G5 CGM System – Dexcom [obsolete 01/01/2022] • Dexcom G6 CGM System – Dexcom • Dexcom G7 CGM System – Dexcom • Eversense CGM System – Ascensia/Senseonics [obsolete 01/04/2022] • Eversense E3 CGM System – Ascensia/Senseonics • Freestyle Libre CGM System – Abbott • Freestyle Libre 2 CGM System – Abbott • Freestyle Libre 3 CGM System – Abbott • Guardian Connect CGM System – Medtronic • Guardian 4 CGM System – Medtronic is(are) considered experimental, investigational, or unproven for ANY other use(s); criteria will be updated as new published data are available.
Medicaid	
Oregon Health Authority Continuous glucose monitoring in diabetes mellitus[209] Coverage guidance[193] Last review: September 28, 2023	QUESTION ONE: Should continuous glucose monitoring (CGM) be covered for individuals with type 2 diabetes mellitus (T2D) who use insulin? We recommend coverage for therapeutic CGM in individuals with T2D or gestational diabetes who use short- or intermediate-acting insulin injections 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 for a 90-day period by their first follow-up visit (within 3-6 months), 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), OR d. Diabetes-related complications (for instance, peripheral neuropathy, end-organ damage)

Payer	Policy Language
	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 to ensure that CGM is used for diabetes treatment planning. Two trials per year of CGM are allowed to meet adherence for continuation of coverage. 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 T2D who use insulin. While no other benefits were identified, few harms were reported. A recommendation for conditional coverage was informed by low confidence in 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 (T2D) 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.

Notes: [a] This policy is effective Jan 1, 2025. The prior authorization policy was last revised on February 7, 2024.

Abbreviations: BGM: blood glucose monitor(ing); CGM: continuous glucose monitor(ing); DME: durable medical equipment; FDA: Food and Drug Administration; GDM: gestational diabetes; HbA1c: glycated hemoglobin; HCPCS: Healthcare Common Procedure Coding System; ICD: International Classification of Diseases; LCD: local coverage determination; mg/dl: milligram per deciliter; mmol/L: millimole per liter; NPH: Neutral Protamine Hagedorn insulin. T2D: type 2 diabetes.

Appendix K. Bibliography of Included Studies

The following is a list of the primary publications (along with any ancillary publications) for the randomized controlled trials presented in this review. They are arranged alphabetically by study name (or first author, when no study name was given).

2GO-CGM

Lever CS, Williman JA, Boucsein A, et al. Real time continuous glucose monitoring in high-risk people with insulin-requiring type 2 diabetes: A randomised controlled trial. *Diabet Med.* 2024;41(8):e15348. doi: 10.1111/dme.15348.

Lever CS, Williman JA, Boucsein A, et al. Study protocol: glycaemic outcomes in people with type 2 diabetes initiating continuous glucose monitoring: the 2GO-CGM study. *J Diabetes Metab Disord.* 2023;22(2):1779-1792. doi: 10.1007/s40200-023-01244-y.

Ajjan, 2016

Ajjan RA, Abougila K, Bellary S, et al. Sensor and software use for the glycaemic management of insulin-treated type 1 and type 2 diabetes patients. *Diab Vasc Dis Res.* 2016;13(3):211-219. doi: 10.1177/1479164115624680.

Alfadhli, 2016

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.

Bergenstal, 2022

Bergenstal RM, Mullen DM, Strock E, Johnson ML, Xi MX. Randomized comparison of self-monitored blood glucose (BGM) versus continuous glucose monitoring (CGM) data to optimize glucose control in type 2 diabetes. *J Diabetes Complications.* 2022;36(3):108106. doi: 10.1016/j.jdiacomp.2021.108106.

COMMITTED

Price DA, Deng Q, Kipnes M, Beck SE. Episodic Real-Time CGM Use in Adults with Type 2 Diabetes: Results of a Pilot Randomized Controlled Trial. *Diabetes Ther.* 2021;12(7):2089-2099. doi: 10.1007/s13300-021-01086-y.

DIAMOND

Beck RW, Riddlesworth TD, Ruedy K, et al. Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial. *Ann Intern Med.* 2017;167(6):365-374. doi: 10.7326/M16-2855.

Billings LK, Parkin CG, Price D. Baseline Glycated Hemoglobin Values Predict the Magnitude of Glycemic Improvement in Patients with Type 1 and Type 2 Diabetes: Subgroup Analyses from the DIAMOND Study Program. *Diabetes Technol Ther.* 2018;20(8):561-565. doi: 10.1089/dia.2018.0163.

FLAMINGO

Majewska A, Stanirowski PJ, Tatur J, et al. Flash glucose monitoring in gestational diabetes mellitus (FLAMINGO): a randomised controlled trial. *Acta Diabetol.* 2023;60(9):1171-1177. doi: 10.1007/s00592-023-02091-2.

GLiMPSE

Rama Chandran S, Rahman N, Gandhi M, et al. Intermittently scanned continuous glucose monitoring provides no benefit over structured self-monitoring of blood glucose in type 2 diabetes not on prandial insulin, in the context of diabetes self-management education: GLucose monitoring programme SingaporE (GLiMPSE). *Diabetes Res Clin Pract.* 2024;211:111678. doi: 10.1016/j.diabres.2024.111678.

GOOD-ER

O'Connor MJ, Ding X, Hernandez C, Hubacz L, Church RJ, O'Connor L. A Pilot Trial of Continuous Glucose Monitoring Upon Emergency Department Discharge Among People With Diabetes Mellitus. *Endocr Pract.* 2024;30(2):122-127. doi: 10.1016/j.eprac.2023.11.001.

IMMEDIATE

Aronson R, Brown RE, Chu L, et al. IMpact of flash glucose Monitoring in pEople with type 2 Diabetes Inadequately controlled with non-insulin Antihyperglycaemic ThErapy (IMMEDIATE): A randomized controlled trial. *Diabetes Obes Metab.* 2023;25(4):1024-1031. doi: 10.1111/dom.14949.

Kestila, 2007

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.

Lane, 2019

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.

LIBERATES

Ajjan RA, Heller SR, Everett CC, et al. Multicenter Randomized Trial of Intermittently Scanned Continuous Glucose Monitoring Versus Self-Monitoring of Blood Glucose in Individuals With Type 2 Diabetes and Recent-Onset Acute Myocardial Infarction: Results of the LIBERATES Trial. *Diabetes Care.* 2023;46(2):441-449. doi: 10.2337/dc22-1219.

> Everett CC, Reynolds C, Fernandez C, et al. Rationale and design of the LIBERATES trial: Protocol for a randomised controlled trial of flash glucose monitoring for optimisation of glycaemia in individuals with type 2 diabetes and recent myocardial infarction. *Diab Vasc Dis Res.* 2020;17(5):1479164120957934. doi: 10.1177/1479164120957934.

MOBILE

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

Bao S, Bailey R, Calhoun P, Beck RW. Effectiveness of Continuous Glucose Monitoring in Older Adults with Type 2 Diabetes Treated with Basal Insulin. *Diabetes Technol Ther*. 2022;24(5):299-306. doi: 10.1089/dia.2021.0494.

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.

Peters A, Cohen N, Calhoun P, et al. Glycaemic profiles of diverse patients with type 2 diabetes using basal insulin: MOBILE study baseline data. *Diabetes Obes Metab*. 2021;23(2):631-636. doi: 10.1111/dom.14238.

Moon, 2023

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 Obes Metab*. 2023;25(1):110-120. doi: 10.1111/dom.14852.

REPLACE

Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Use of Flash Glucose-Sensing Technology for 12 months as a Replacement for Blood Glucose Monitoring in Insulin-treated Type 2 Diabetes. *Diabetes Ther*. 2017;8(3):573-586. doi: 10.1007/s13300-017-0255-6.

Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G. Flash Glucose-Sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-Treated Type 2 Diabetes: a Multicenter, Open-Label Randomized Controlled Trial. *Diabetes Ther*. 2017;8(1):55-73. doi: 10.1007/s13300-016-0223-6.

STENO2TECH

Lind N, Christensen MB, Hansen DL, Norgaard K. Comparing Continuous Glucose Monitoring and Blood Glucose Monitoring in Adults With Inadequately Controlled, Insulin-Treated Type 2 Diabetes (Steno2tech Study): A 12-Month, Single-Center, Randomized Controlled Trial. *Diabetes Care*. 2024;47(5):881-889. doi: 10.2337/dc23-2194.

Lind N, Lindqvist Hansen D, Saetre Rasmussen S, Norgaard K. Real-time continuous glucose monitoring versus self-monitoring of blood glucose in adults with insulin-treated type 2 diabetes: a protocol for a randomised controlled single-centre trial. *BMJ Open*. 2021;11(1):e040648. doi: 10.1136/bmjopen-2020-040648.

Taylor, 2019

Taylor PJ, Thompson CH, Luscombe-Marsh ND, Wycherley TP, Wittert G, Brinkworth GDM. Efficacy of Real-Time Continuous Glucose Monitoring to Improve Effects of a Prescriptive

Lifestyle Intervention in Type 2 Diabetes: A Pilot Study. *Diabetes Ther.* 2019;10(2):509-522. doi: 10.1007/s13300-019-0572-z.

Taylor PJ, Thompson CH, Luscombe-Marsh ND, et al. Tolerability and acceptability of real-time continuous glucose monitoring and its impact on diabetes management behaviours in individuals with Type 2 Diabetes - A pilot study. *Diabetes Res Clin Pract.* 2019;155:107814. doi: 10.1016/j.diabres.2019.107814.

Tildesley, 2013

Tildesley HD, Wright AM, Chan JH, et al. A comparison of internet monitoring with continuous glucose monitoring in insulin-requiring type 2 diabetes mellitus. *Can J Diabetes.* 2013;37(5):305-308. doi: 10.1016/j.jcjd.2013.05.006.

Tang TS, Digby EM, Wright AM, et al. Real-time continuous glucose monitoring versus internet-based blood glucose monitoring in adults with type 2 diabetes: a study of treatment satisfaction. *Diabetes Res Clin Pract.* 2014;106(3):481-486. doi: 10.1016/j.diabres.2014.09.050.

Vigersky, 2012

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.

Ehrhardt NM, Chellappa M, Walker MS, Fonda SJ, Vigersky RA. The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. *J Diabetes Sci Technol.* 2011;5(3):668-675. doi: 10.1177/193229681100500320.

Fonda SJ, Salkind SJ, Walker MS, Chellappa M, Ehrhardt N, Vigersky RA. Heterogeneity of responses to real-time continuous glucose monitoring (RT-CGM) in patients with type 2 diabetes and its implications for application. *Diabetes Care.* 2013;36(4):786-792. doi: 10.2337/dc12-1225.

Wada, 2020

Wada E, Onoue T, Kobayashi T, et al. Flash glucose monitoring helps achieve better glycemic control than conventional self-monitoring of blood glucose in non-insulin-treated type 2 diabetes: a randomized controlled trial. *BMJ Open Diabetes Res Care.* 2020;8(1). doi: 10.1136/bmjdrc-2019-001115.

Hayase A, Onoue T, Kobayashi T, et al. Improved glycemic control after the use of flash glucose monitoring accompanied by improved treatment satisfaction in patients with non-insulin-treated type 2 diabetes: A post-hoc analysis of a randomized controlled trial. *Prim Care Diabetes.* 2023;17(6):575-580. doi: 10.1016/j.pcd.2023.09.009.

Yoo, 2008

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.

Appendix L. Bibliography of Excluded Studies, With Reasons

Table L1. Bibliography of Excluded Studies, With Reasons

Bibliography	Reason for Exclusion
Acciaroli, G, Welsh, JB, Akturk, HK. Mitigation of rebound hyperglycemia with real-time continuous glucose monitoring data and predictive alerts. *J Diabetes Sci Technol*. 2022. 16:677-682 doi: 10.1177/1932296820982584	Population
Aggarwal, A, Pathak, S, Goyal, R. Clinical and economic outcomes of continuous glucose monitoring system (CGMS) in patients with diabetes mellitus: a systematic literature review. *Diabetes Res Clin Pract*. 2022. 186:109825 doi: 10.1016/j.diabres.2022.109825	Study Design
Ajjan, R, Bilir, SP, Hellmund, R, et al. Cost-effectiveness analysis of flash glucose monitoring system for people with type 2 diabetes receiving intensive insulin treatment. *Diabetes Ther*. 2022. 13:1933-1945 doi: 10.1007/s13300-022-01325-w	Setting
Ajjan, RA, Jackson, N, Thomson, SA. Reduction in HbA1c using professional flash glucose monitoring in insulin-treated type 2 diabetes patients managed in primary and secondary care settings: a pilot, multicentre, randomised controlled trial. *Diab Vasc Dis Res*. 2019. 16:385-395 doi: 10.1177/1479164119827456	Intervention
Allen, N, Whittemore, R, Melkus, G. A continuous glucose monitoring and problem-solving intervention to change physical activity behavior in women with type 2 diabetes: a pilot study. *Diabetes Technol Ther*. 2011. 13:1091-9 doi: 10.1089/dia.2011.0088	Comparator
Allen, NA, Fain, JA, Braun, B, et al. Continuous glucose monitoring counseling improves physical activity behaviors of individuals with type 2 diabetes: A randomized clinical trial. *Diabetes Res Clin Pract*. 2008. 80:371-9 doi: 10.1016/j.diabres.2008.01.006	Intervention
Allen, NA, Fain, JA, Braun, B, et al. Continuous glucose monitoring in non-insulin-using individuals with type 2 diabetes: acceptability, feasibility, and teaching opportunities. *Diabetes Technol Ther*. 2009. 11:151-8 doi: 10.1089/dia.2008.0053	Study Design
Alothman, S, Yahya, A, Rucker, J, et al. Effectiveness of interventions for promoting objectively measured physical activity of adults with type 2 diabetes: a systematic review. *J Phys Act Health*. 2017. 14:408-415 doi: 10.1123/jpah.2016-0528	Study Design
Amadou, C, Melki, V, Allain, J, et al. Performance and patients' satisfaction with the A7+TouchCare insulin patch pump system: a randomized controlled non-inferiority study. *PLoS One*. 2023. 18:e0289684 doi: 10.1371/journal.pone.0289684	Intervention
Anonymous. Evidence reviews for continuous glucose monitoring in children and young people with type 1 diabetes: type 1 diabetes in children and young people: diagnosis and management: Evidence review B. 2022.	Population
Asarani, NAM, Reynolds, AN, Boucher, SE, et al. Cutaneous complications with continuous or flash glucose monitoring use: systematic review of trials and observational studies. *J Diabetes Sci Technol*. 2020. 14:328-337 doi: 10.1177/1932296819870849	Study Design
Azhar, A, Gillani, SW, Mohiuddin, G, et al. A systematic review on clinical implication of continuous glucose monitoring in diabetes management. *J Pharm Bioallied Sci*. 2020. 12:102-111 doi: 10.4103/jpbs.JPBS_7_20	Study Design

Bailey, KJ, Little, JP, Jung, ME. Self-monitoring using continuous glucose monitors with real-time feedback improves exercise adherence in individuals with impaired blood glucose: a pilot study. *Diabetes Technol Ther*. 2016. 18:185-93 doi: 10.1089/dia.2015.0285	Study Design
Bally, L, Thabit, H, Hartnell, S, et al. Closed-loop insulin delivery for glycemic control in noncritical care. *N Engl J Med*. 2018. 379:547-556 doi: 10.1056/NEJMoa1805233	Intervention
Bano, A, Kunzler, J, Wehrli, F, et al. Clinical evidence for high-risk CE-marked medical devices for glucose management: a systematic review and meta-analysis. *Diabetes Obes Metab*. 2024. 26:4753-4766 doi: 10.1111/dom.15849	Publication Type
Bertini, A, Garate, B, Pardo, F, et al. Impact of remote monitoring technologies for assisting patients with gestational diabetes mellitus: a systematic review. *Front Bioeng Biotechnol*. 2022. 10:819697 doi: 10.3389/fbioe.2022.819697	Publication Type
Bertini, A, Garate, B, Pardo, F, et al. Impact of remote monitoring technologies for assisting patients with gestational diabetes mellitus: a systematic review. *Front Bioeng Biotechnol*. 2022. 10:819697 doi: 10.3389/fbioe.2022.819697	Study Design
Bidonde, Julia, Fagerlund, Beate Charlotte, Fronsdal, KatrineB, et al. FreeStyle Libre flash glucose self-monitoring system: a single-technology assessment. . 2017.	Study Design
Bomholt, T, Rix, M, Almdal, T, et al. The accuracy of hemoglobin A1c and fructosamine evaluated by long-term continuous glucose monitoring in patients with type 2 diabetes undergoing hemodialysis. *Blood Purif*. 2022. 51:608-616 doi: 10.1159/000519050	Study Design
Boom, DT, Sechterberger, MK, Rijkenberg, S, et al. Insulin treatment guided by subcutaneous continuous glucose monitoring compared to frequent point-of-care measurement in critically ill patients: a randomized controlled trial. *Crit Care*. 2014. 18:453 doi: 10.1186/s13054-014-0453-9	Population
Borel, AL, Lablanche, S, Waterlot, C, et al. Closed-loop insulin therapy for people with type 2 diabetes treated with an insulin pump: a 12-week multicenter, open-label randomized, controlled, crossover trial. *Diabetes Care*. 2024. 47:1778-1786 doi: 10.2337/dc24-0623	Intervention
Borges, LP, de Jesus, PC, de Souza, JB, et al. The impact of diabetes education on continuous glucose monitoring in sus-dependent patients in a northeastern Brazilian city. *Life (Basel)*. 2024. 14:28 doi: 10.3390/life14030320	Setting
Boughton, CK, Tripyla, A, Hartnell, S, et al. Fully automated closed-loop glucose control compared with standard insulin therapy in adults with type 2 diabetes requiring dialysis: an open-label, randomized crossover trial. *Nat Med*. 2021. 27:1471-1476 doi: 10.1038/s41591-021-01453-z	Intervention
CADTH Health Technology Review, Young, C, Grobelna, A. Flash glucose monitoring systems in pediatric populations with diabetes. . 2021.	Study Design
Canada's Drug and Health Technology Agency. Flash glucose monitoring system for diabetes. . 2018.	Study Design
Chamberlain, JJ, Doyle-Delgado, K, Peterson, L, et al. Diabetes technology: review of the 2019 American Diabetes Association standards of medical care in diabetes. *Ann Intern Med*. 2019. 171:415-420 doi: 10.7326/M19-1638	Publication Type
Chang, N, Barber, ROB, Llovido Alula, J, et al. Continuous glucose monitoring versus standard of care in adolescents with type 2 diabetes: a pilot randomized cross-over trial. *J Diabetes Sci Technol*. 2023. 17:1419-1420 doi: 10.1177/19322968231178284	Publication Type

Chang, VYX, Tan, YL, Ang, WHD, et al. Effects of continuous glucose monitoring on maternal and neonatal outcomes in perinatal women with diabetes: a systematic review and meta-analysis of randomized controlled trials. *Diabetes Res Clin Pract*. 2022. 184:109192 doi: 10.1016/j.diabres.2022.109192	Study Design
Chen, R, Yogev, Y, Ben-Haroush, A, et al. Continuous glucose monitoring for the evaluation and improved control of gestational diabetes mellitus. *J Matern Fetal Neonatal Med*. 2003. 14:256-60 doi: 10.1080/jmf.14.4.256.260	Intervention
Choe, HJ, Rhee, EJ, Won, JC, et al. Effects of patient-driven lifestyle modification using intermittently scanned continuous glucose monitoring in patients with type 2 diabetes: results from the randomized open-label PDF study. *Diabetes Care*. 2022. 45:2224-2230 doi: 10.2337/dc22-0764	Intervention
Chu, C, Li, J, Yang, X, et al. Continuous glucose monitoring versus conventional glucose monitoring in the ICU: a randomized controlled trial. *J Crit Care*. 2024. 84:154894 doi: 10.1016/j.jcrc.2024.154894	Population
Clubbs Coldron, B, Coates, V, Khamis, A, et al. Use of continuous glucose monitoring in non-icu hospital settings for people with diabetes: a scoping review of emerging benefits and issues. *J Diabetes Sci Technol*. 2023. 17:467-473 doi: 10.1177/19322968211053652	Publication Type
Cooke, D, Hurel, SJ, Casbard, A, et al. Randomized controlled trial to assess the impact of continuous glucose monitoring on HbA(1c) in insulin-treated diabetes (MITRE Study). *Diabet Med*. 2009. 26:540-7 doi: 10.1111/j.1464-5491.2009.02723.x	Intervention
Cosson, E, Hamo-Tchatchouang, E, Dufaitre-Patouraux, L, et al. Multicentre, randomised, controlled study of the impact of continuous sub-cutaneous glucose monitoring (GlucoDay) on glycaemic control in type 1 and type 2 diabetes patients. *Diabetes Metab*. 2009. 35:312-8 doi: 10.1016/j.diabet.2009.02.006	Intervention
Cowart, K, Updike, W, Bullers, K. Systematic review of randomized controlled trials evaluating glycemic efficacy and patient satisfaction of intermittent-scanned continuous glucose monitoring in patients with diabetes. *Diabetes Technol Ther*. 2020. 22:337-345 doi: 10.1089/dia.2019.0345	Study Design
Cowart, K. A Review of the First Long-term implantable continuous glucose monitoring system available in the United States. *J Diabetes Sci Technol*. 2021. 15:160-166 doi: 10.1177/1932296819890865	Study Design
Cox, DJ, Banton, T, Moncrief, M, et al. Glycemic excursion minimization in the management of type 2 diabetes: a novel intervention tested in a randomized clinical trial. *BMJ Open Diabetes Res Care*. 2020. 8:doi: 10.1136/bmjdrc-2020-001795	Comparator
Cox, DJ, Banton, T, Moncrief, M, et al. Minimizing glucose excursions (GEM) with continuous glucose monitoring in type 2 diabetes: a randomized clinical trial. *J Endocr Soc*. 2020. 4:bvaa118 doi: 10.1210/jendso/bvaa118	Intervention
Danne, T, Nimri, R, Battelino, T, et al. International consensus on use of continuous glucose monitoring. *Diabetes Care*. 2017. 40:1631-1640 doi: 10.2337/dc17-1600	Publication Type
Dashora, U, Levy, N, Dhatariya, K, et al. Managing hyperglycaemia during antenatal steroid administration, labour and birth in pregnant women with diabetes - an updated guideline from the Joint British Diabetes Society for Inpatient Care. *Diabet Med*. 2022. 39:e14744 doi: 10.1111/dme.14744	Publication Type

Davis, GM, Hughes, MS, Brown, SA, et al. Automated insulin delivery with remote real-time continuous glucose monitoring for hospitalized patients with diabetes: a multicenter, single-arm, feasibility trial. *Diabetes Technol Ther*. 2023. 25:677-688 doi: 10.1089/dia.2023.0304	Study Design
Davis, TME, Dwyer, P, England, M, et al. Efficacy of intermittently scanned continuous glucose monitoring in the prevention of recurrent severe hypoglycemia. *Diabetes Technol Ther*. 2020. 22:367-373 doi: 10.1089/dia.2019.0331	Population
De Block, CE, Gios, J, Verheyen, N, et al. Randomized evaluation of glycemic control in the medical intensive care unit using real-time continuous glucose monitoring (REGIMEN Trial). *Diabetes Technol Ther*. 2015. 17:889-98 doi: 10.1089/dia.2015.0151	Intervention
Dehghani Zahedani, A, Shariat Torbaghan, S, Rahili, S, et al. Improvement in glucose regulation using a digital tracker and continuous glucose monitoring in healthy adults and those with type 2 diabetes. *Diabetes Ther*. 2021. 12:1871-1886 doi: 10.1007/s13300-021-01081-3	Study Design
Depczynski, B, Poynten, A. Acceptance and effect of continuous glucose monitoring on discharge from hospital in patients with type 2 diabetes: open-label, prospective, controlled study. *JMIR Diabetes*. 2022. 7:e35163 doi: 10.2196/35163	Study Design
Dicembrini, I, Mannucci, E, Monami, M, et al. Impact of technology on glycaemic control in type 2 diabetes: A meta-analysis of randomized trials on continuous glucose monitoring and continuous subcutaneous insulin infusion. *Diabetes Obes Metab*. 2019. 21:2619-2625 doi: 10.1111/dom.13845	Study Design
Ehrhardt, N, Cedeno, B, Montour, L, et al. Effectiveness of a culturally tailored diabetes education curriculum with real-time continuous glucose monitoring in a Latinx population with type 2 diabetes: the CUT-DM with CGM for Latinx randomised controlled trial study protocol. *BMJ Open*. 2023. 13:e082005 doi: 10.1136/bmjopen-2023-082005	Publication Type
Ehrmann, D, Heinemann, L, Freckmann, G, et al. The effects and effect sizes of real-time continuous glucose monitoring on patient-reported outcomes: a secondary analysis of the HypoDE study. *Diabetes Technol Ther*. 2019. 21:86-93 doi: 10.1089/dia.2018.0332	Population
Ellis, SL, Bookout, T, Garg, SK, et al. Use of continuous glucose monitoring to improve diabetes mellitus management. *Endocrinol Metab Clin North Am*. 2007. 36 Suppl 2:46-68 doi: 10.1016/s0889-8529(07)80011-9	Publication Type
ElSayed, NA, Aleppo, G, Aroda, VR, et al. Introduction and methodology: standards of care in diabetes-2023. *Diabetes Care*. 2023. 46:S1-S4 doi: 10.2337/dc23-Sint	Publication Type
Engler, Solangia, Fields, Sherecce, Leach, Walker, et al. Real-time continuous glucose monitoring as a behavioral intervention tool for T2D: a systematic review. *Journal of Technology in Behavioral Science*. 2022. 7:252-263 doi: 10.1007/s41347-022-00247-5	Study Design
Evans, M, Welsh, Z, Ells, S, et al. The impact of flash glucose monitoring on glycaemic control as measured by hba1c: a meta-analysis of clinical trials and real-world observational studies. *Diabetes Ther*. 2020. 11:83-95 doi: 10.1007/s13300-019-00720-0	Study Design
Fabricatore, AN, Ebbeling, CB, Wadden, TA, et al. Continuous glucose monitoring to assess the ecologic validity of dietary glycemic index and glycemic load. *Am J Clin Nutr*. 2011. 94:1519-24 doi: 10.3945/ajcn.111.020354	Aim
Ferreira, ROM, Trevisan, T, Pasqualotto, E, et al. Continuous glucose monitoring systems in noninsulin-treated people with type 2 diabetes: a systematic review and meta-analysis of	Study Design

randomized controlled trials. *Diabetes Technol Ther*. 2024. 26:252-262 doi: 10.1089/dia.2023.0390	
Fishel Bartal, M, Ashby Cornthwaite, J, Ghafir, D, et al. Continuous glucose monitoring in individuals undergoing gestational diabetes screening. *Am J Obstet Gynecol*. 2023. 229:441 e1-441 e14 doi: 10.1016/j.ajog.2023.04.021	Study Design
Fleming, GA, Petrie, JR, Bergenstal, RM, et al. Diabetes digital app technology: benefits, challenges, and recommendations. a consensus report by the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group. *Diabetes Care*. 2020. 43:250-260 doi: 10.2337/dci19-0062	Publication Type
Fonda, SJ, Graham, C, Munakata, J, et al. The cost-effectiveness of real-time continuous glucose monitoring (rt-cgm) in type 2 diabetes. *J Diabetes Sci Technol*. 2016. 10:898-904 doi: 10.1177/1932296816628547	Publication Date
Fortmann, AL, Spierling Bagsic, SR, Talavera, L, et al. Glucose as the fifth vital sign: a randomized controlled trial of continuous glucose monitoring in a non-ICU hospital setting. *Diabetes Care*. 2020. 43:2873-2877 doi: 10.2337/dc20-1016	Intervention
Franceschi, R, Micheli, F, Mozzillo, E, et al. Intermittently scanned and continuous glucose monitor systems: a systematic review on psychological outcomes in pediatric patients. *Front Pediatr*. 2021. 9:660173 doi: 10.3389/fped.2021.660173	Study Design
Gaborova, M, Donicova, V, Bacova, I, et al. Glycaemic variability and risk factors of pregnant women with and without gestational diabetes mellitus measured by continuous glucose monitoring. *Int J Environ Res Public Health*. 2021. 18:25 doi: 10.3390/ijerph18073402	Study Design
Galindo, RJ, Umpierrez, GE, Rushakoff, RJ, et al. Continuous glucose monitors and automated insulin dosing systems in the hospital consensus guideline. *J Diabetes Sci Technol*. 2020. 14:1035-1064 doi: 10.1177/1932296820954163	Publication Type
Gandhi, GY, Kovalaske, M, Kudva, Y, et al. Efficacy of continuous glucose monitoring in improving glycemic control and reducing hypoglycemia: a systematic review and meta-analysis of randomized trials. *J Diabetes Sci Technol*. 2011. 5:952-65 doi: 10.1177/193229681100500419	Study Design
Gao, Y, Zhou, M, Xu, X, et al. Effects of flash glucose monitoring on glycemic control in participants with diabetes mellitus: a meta-analysis of randomized controlled trials. *J Diabetes Complications*. 2022. 36:108314 doi: 10.1016/j.jdiacomp.2022.108314	Study Design
Garcia-Moreno, RM, Benitez-Valderrama, P, Barquiel, B, et al. Efficacy of continuous glucose monitoring on maternal and neonatal outcomes in gestational diabetes mellitus: a systematic review and meta-analysis of randomized clinical trials. *Diabet Med*. 2022. 39:e14703 doi: 10.1111/dme.14703	Study Design
Garg, S, Zisser, H, Schwartz, S, et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care*. 2006. 29:44-50 doi: 10.2337/diacare.29.01.06.dc05-1686	Population
Garg, SK, Hirsch, IB, Repetto, E, et al. Impact of continuous glucose monitoring on hospitalizations and glucose control in people with type 2 diabetes: real-world analysis. *Diabetes Obes Metab*. 2024. 26:5202-5210 doi: 10.1111/dom.15866	Publication Date
Golden, SH, Sapir, T. Methods for insulin delivery and glucose monitoring in diabetes: summary of a comparative effectiveness review. *J Manag Care Pharm*. 2012. 18:S1-17 doi: 10.18553/jmcp.2012.18.s6-a.1	Study Design

Golden, Sherita Hill, Brown, Todd, Yeh, Hsin-Chieh, et al. Methods for insulin delivery and glucose monitoring: comparative effectiveness. . 2012.	Study Design
Griauzde, DH, Ling, G, Wray, D, et al. continuous glucose monitoring with low-carbohydrate nutritional coaching to improve type 2 diabetes control: randomized quality improvement program. *J Med Internet Res*. 2022. 24:e31184 doi: 10.2196/31184	Intervention
Gross, TM, Mastrototaro, JJ. Efficacy and reliability of the continuous glucose monitoring system. *Diabetes Technol Ther*. 2000. 2 Suppl 1:S19-26 doi: 10.1089/15209150050214087	Population
Grunberger, G, Handelsman, Y, Bloomgarden, ZT, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2018 position statement on integration of insulin pumps and continuous glucose monitoring in patients with diabetes mellitus. *Endocr Pract*. 2018. 24:302-308 doi: 10.4158/PS-2017-0155	Publication Type
Hachem, M, Hearn, T, Kelly, R, et al. Can flash glucose monitoring improve glucose management for Aboriginal and Torres Strait Islander peoples with type 2 diabetes? A protocol for a randomised controlled trial. *Trials*. 2024. 25:493 doi: 10.1186/s13063-024-08267-7	Publication Type
Hallstrom, S, Hirsch, IB, Ekelund, M, et al. Characteristics of continuous glucose monitoring metrics in persons with type 1 and type 2 diabetes treated with multiple daily insulin injections. *Diabetes Technol Ther*. 2021. 23:425-433 doi: 10.1089/dia.2020.0577	Study Design
Hangaard, S, Kronborg, T, Hejlesen, O, et al. The Diabetes teleMonitoring of patients in insulin Therapy (DiaMonT) trial: study protocol for a randomized controlled trial. *Trials*. 2022. 23:985 doi: 10.1186/s13063-022-06921-6	Intervention
Hermanns, N, Ehrmann, D, Schipfer, M, et al. The impact of a structured education and treatment programme (FLASH) for people with diabetes using a flash sensor-based glucose monitoring system: Results of a randomized controlled trial. *Diabetes Res Clin Pract*. 2019. 150:111-121 doi: 10.1016/j.diabres.2019.03.003	Intervention
Herzig, D, Suhner, S, Roos, J, et al. Perioperative fully closed-loop insulin delivery in patients undergoing elective surgery: an open-label, randomized controlled trial. *Diabetes Care*. 2022. 45:2076-2083 doi: 10.2337/dc22-0438	Intervention
Hirsch, IB, Welsh, JB, Calhoun, P, et al. Associations between HbA(1c) and continuous glucose monitoring-derived glycaemic variables. *Diabet Med*. 2019. 36:1637-1642 doi: 10.1111/dme.14065	Aim
Hoeks, LB, Greven, WL, de Valk, HW. Real-time continuous glucose monitoring system for treatment of diabetes: a systematic review. *Diabet Med*. 2011. 28:386-94 doi: 10.1111/j.1464-5491.2010.03177.x	Study Design
Holzinger, U, Warszawska, J, Kitzberger, R, et al. Real-time continuous glucose monitoring in critically ill patients: a prospective randomized trial. *Diabetes Care*. 2010. 33:467-72 doi: 10.2337/dc09-1352	Population
Huhn, EA, Linder, T, Eppel, D, et al. Effectiveness of real-time continuous glucose monitoring to improve glycaemic control and pregnancy outcome in patients with gestational diabetes mellitus: a study protocol for a randomised controlled trial. *BMJ Open*. 2020. 10:e040498 doi: 10.1136/bmjopen-2020-040498	Publication Type

Ida, S, Kaneko, R, Murata, K. Utility of real-time and retrospective continuous glucose monitoring in patients with type 2 diabetes mellitus: a meta-analysis of randomized controlled trials. *J Diabetes Res*. 2019. 2019:4684815 doi: 10.1155/2019/4684815	Study Design
Idrees, T, Castro-Revoredo, IA, Oh, HD, et al. Continuous glucose monitoring-guided insulin administration in long-term care facilities: a randomized clinical trial. *J Am Med Dir Assoc*. 2024. 25:884-888 doi: 10.1016/j.jamda.2024.01.031	Follow-up
Ilany, J, Bhandari, H, Nabriski, D, et al. Effect of prandial treatment timing adjustment, based on continuous glucose monitoring, in patients with type 2 diabetes uncontrolled with once-daily basal insulin: A randomized, phase IV study. *Diabetes Obes Metab*. 2018. 20:1186-1192 doi: 10.1111/dom.13214	Intervention
Isaacson, B, Kaufusi, S, Sorensen, J, et al. Demonstrating the clinical impact of continuous glucose monitoring within an integrated healthcare delivery system. *J Diabetes Sci Technol*. 2022. 16:383-389 doi: 10.1177/1932296820955228	Population
Janapala, RN, Jayaraj, JS, Fathima, N, et al. Continuous glucose monitoring versus self-monitoring of blood glucose in type 2 diabetes mellitus: a systematic review with meta-analysis. *Cureus*. 2019. 11:e5634 doi: 10.7759/cureus.5634	Study Design
Jancev, M, Vissers, Tacm, Visseren, FLJ, et al. Continuous glucose monitoring in adults with type 2 diabetes: a systematic review and meta-analysis. *Diabetologia*. 2024. 67:798-810 doi: 10.1007/s00125-024-06107-6	Study Design
Jones, LV, Ray, A, Moy, FM, et al. Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes. *Cochrane Database Syst Rev*. 2019. 5:CD009613 doi: 10.1002/14651858.CD009613.pub4	Study Design
Jospe, MR, Richardson, KM, Saleh, AA, et al. Leveraging continuous glucose monitoring as a catalyst for behaviour change: a scoping review. *Int J Behav Nutr Phys Act*. 2024. 21:74 doi: 10.1186/s12966-024-01622-6	Study Design
Jovanovic, L. The role of continuous glucose monitoring in gestational diabetes mellitus. *Diabetes Technol Ther*. 2000. 2 Suppl 1:S67-71 doi: 10.1089/15209150050214159	Study Design
Kamusheva, M, Tachkov, K, Dimitrova, M, et al. A systematic review of collective evidences investigating the effect of diabetes monitoring systems and their application in health care. *Front Endocrinol (Lausanne)*. 2021. 12:636959 doi: 10.3389/fendo.2021.636959	Study Design
Kataoka, Y, Hosoda, K, Makino, H, et al. The efficacy of glycemic control with continuous glucose monitoring on atheroma progression: rationale and design of the Observation of Coronary Atheroma Progression under Continuous Glucose Monitoring Guidance in Patients with Type 2 Diabetes Mellitus (OPTIMAL). *Cardiovasc Diagn Ther*. 2019. 9:431-438 doi: 10.21037/cdt.2019.09.02	Intervention
Kataoka, Y, Kitahara, S, Funabashi, S, et al. The effect of continuous glucose monitoring-guided glycemic control on progression of coronary atherosclerosis in type 2 diabetic patients with coronary artery disease: The OPTIMAL randomized clinical trial. *J Diabetes Complications*. 2023. 37:108592 doi: 10.1016/j.jdiacomp.2023.108592	Intervention
Kieu, A, King, J, Govender, RD, et al. The benefits of utilizing continuous glucose monitoring of diabetes mellitus in primary care: a systematic review. *J Diabetes Sci Technol*. 2023. 17:762-774 doi: 10.1177/19322968211070855	Study Design
Kim, JY, Jin, SM, Sim, KH, et al. Continuous glucose monitoring with structured education in adults with type 2 diabetes managed by multiple daily insulin injections: a multicentre	Intervention

randomised controlled trial. *Diabetologia*. 2024. 67:1223-1234 doi: 10.1007/s00125-024-06152-1	
Klarskov, CK, Lindegaard, B, Pedersen-Bjergaard, U, et al. Remote continuous glucose monitoring during the COVID-19 pandemic in quarantined hospitalized patients in Denmark: A structured summary of a study protocol for a randomized controlled trial. *Trials*. 2020. 21:968 doi: 10.1186/s13063-020-04872-4	Publication Type
Klarskov, CK, Windum, NA, Olsen, MT, et al. Telemetric continuous glucose monitoring during the covid-19 pandemic in isolated hospitalized patients in Denmark: a randomized controlled exploratory trial. *Diabetes Technol Ther*. 2022. 24:102-112 doi: 10.1089/dia.2021.0291	Population
Korytkowski, MT, Muniyappa, R, Antinori-Lent, K, et al. Management of hyperglycemia in hospitalized adult patients in non-critical care settings: an Endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2022. 107:2101-2128 doi: 10.1210/clinem/dgac278	Publication Type
Krakauer, M, Botero, JF, Lavalle-Gonzalez, FJ, et al. A review of flash glucose monitoring in type 2 diabetes. *Diabetol Metab Syndr*. 2021. 13:42 doi: 10.1186/s13098-021-00654-3	Study Design
Kudva, YC, Laffel, LM, Brown, SA, et al. Patient-reported outcomes in a randomized trial of closed-loop control: the pivotal international diabetes closed-loop trial. *Diabetes Technol Ther*. 2021. 23:673-683 doi: 10.1089/dia.2021.0089	Population
Kyto, M, Hotta, S, Niinisto, S, et al. Periodic mobile application (eMOM) with self-tracking of glucose and lifestyle improves treatment of diet-controlled gestational diabetes without human guidance: a randomized controlled trial. *Am J Obstet Gynecol*. 2024. 231:541 e1-541 e16 doi: 10.1016/j.ajog.2024.02.303	Intervention
Lai, M, Weng, J, Yang, J, et al. Effect of continuous glucose monitoring compared with self-monitoring of blood glucose in gestational diabetes patients with HbA1c<6%: a randomized controlled trial. *Front Endocrinol (Lausanne)*. 2023. 14:1174239 doi: 10.3389/fendo.2023.1174239	Setting
Law, GR, Ellison, GT, Secher, AL, et al. Analysis of continuous glucose monitoring in pregnant women with diabetes: distinct temporal patterns of glucose associated with large-for-gestational-age infants. *Diabetes Care*. 2015. 38:1319-25 doi: 10.2337/dc15-0070	Study Design
Lee, YB, Kim, G, Jun, JE, et al. An integrated digital health care platform for diabetes management with ai-based dietary management: 48-week results from a randomized controlled trial. *Diabetes Care*. 2023. 46:959-966 doi: 10.2337/dc22-1929	Intervention
Levitt, DL, Spanakis, EK, Ryan, KA, et al. Insulin pump and continuous glucose monitor initiation in hospitalized patients with type 2 diabetes mellitus. *Diabetes Technol Ther*. 2018. 20:32-38 doi: 10.1089/dia.2017.0250	Follow-up
Li, SY, Guo, H, Zhang, Y, et al. Effects of intermittently scanned continuous glucose monitoring on blood glucose control and the production of urinary ketone bodies in pregestational diabetes mellitus. *Diabetol Metab Syndr*. 2021. 13:39 doi: 10.1186/s13098-021-00657-0	Setting
Liang, B, Koye, DN, Hachem, M, et al. Efficacy of flash glucose monitoring in type 1 and type 2 diabetes: a systematic review and meta-analysis of randomised controlled trials. *Front Clin Diabetes Healthc*. 2022. 3:849725 doi: 10.3389/fcdhc.2022.849725	Study Design
Lin, R, Brown, F, James, S, et al. Continuous glucose monitoring: a review of the evidence in type 1 and 2 diabetes mellitus. *Diabet Med*. 2021. 38:e14528 doi: 10.1111/dme.14528	Study Design

Lu, J, Ying, Z, Wang, P, et al. Effects of continuous glucose monitoring on glycaemic control in type 2 diabetes: A systematic review and network meta-analysis of randomized controlled trials. *Diabetes Obes Metab*. 2024. 26:362-372 doi: 10.1111/dom.15328	Study Design
Lu, M, Zuo, Y, Guo, J, et al. Continuous glucose monitoring system can improve the quality of glucose control and glucose variability compared with point-of-care measurement in critically ill patients: A randomized controlled trial. *Medicine (Baltimore)*. 2018. 97:e12138 doi: 10.1097/MD.0000000000012138	Follow-up
Maiorino, MI, Signoriello, S, Maio, A, et al. Effects of continuous glucose monitoring on metrics of glycemic control in diabetes: a systematic review with meta-analysis of randomized controlled trials. *Diabetes Care*. 2020. 43:1146-1156 doi: 10.2337/dc19-1459	Study Design
Majewska, A, Stanirowski, PJ, Wielgos, M, et al. Efficacy of continuous glucose monitoring on glycaemic control in pregnant women with gestational diabetes mellitus-a systematic review. *J Clin Med*. 2022. 11:doi: 10.3390/jcm11102932	Study Design
Mattishent, K, Loke, YK. Detection of asymptomatic drug-induced hypoglycemia using continuous glucose monitoring in older people - Systematic review. *J Diabetes Complications*. 2018. 32:805-812 doi: 10.1016/j.jdiacomp.2018.05.005	Study Design
McMillan, KA, Kirk, A, Hewitt, A, et al. A systematic and integrated review of mobile-based technology to promote active lifestyles in people with type 2 diabetes. *J Diabetes Sci Technol*. 2017. 11:299-307 doi: 10.1177/1932296816656018	Study Design
Meade, LT. The use of continuous glucose monitoring in patients with type 2 diabetes. *Diabetes Technol Ther*. 2012. 14:190-5 doi: 10.1089/dia.2011.0086	Study Design
Middleton, TL, Constantino, MI, McGill, M, et al. Improving beta-cell secretory function and glycaemia in young-onset type 2 diabetes: a pilot, 12-month, randomized trial of a novel, continuous glucose monitor-guided, rapid treatment intensification strategy incorporating empagliflozin and liraglutide. *Diabetes Obes Metab*. 2022. 24:747-751 doi: 10.1111/dom.14621	Intervention
Moy, FM, Ray, A, Buckley, BS, et al. Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes. *Cochrane Database Syst Rev*. 2017. 6:CD009613 doi: 10.1002/14651858.CD009613.pub3	Study Design
Moy, FM, Ray, A, Buckley, BS. Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes. *Cochrane Database Syst Rev*. 2014. CD009613 doi: 10.1002/14651858.CD009613.pub2	Study Design
Murphy, HR, Rayman, G, Duffield, K, et al. Changes in the glycemic profiles of women with type 1 and type 2 diabetes during pregnancy. *Diabetes Care*. 2007. 30:2785-91 doi: 10.2337/dc07-0500	Study Design
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	Population
National Institute for Health and Care Excellence. Type 2 diabetes in adults: diagnosis and management. Evidence reviews for continuous glucose monitoring in adults with type 2 diabetes.. 2022.	Study Design
Negreiros, Fdds, Araujo, AL, Mattos, SM, et al. Digital technologies in the care of people with diabetes during the COVID-19 pandemic: a scoping review. *Rev Esc Enferm USP*. 2021. 55:e20210295 doi: 10.1590/1980-220X-REEUSP-2021-0295	Study Design

New, JP, Ajjan, R, Pfeiffer, AF, et al. Continuous glucose monitoring in people with diabetes: the randomized controlled Glucose Level Awareness in Diabetes Study (GLADIS). *Diabet Med*. 2015. 32:609-17 doi: 10.1111/dme.12713	Population
Newman, SP, Cooke, D, Casbard, A, et al. A randomised controlled trial to compare minimally invasive glucose monitoring devices with conventional monitoring in the management of insulin-treated diabetes mellitus (MITRE). *Health Technol Assess*. 2009. 13:iii-iv, ix-xi, 1-194 doi: 10.3310/hta13280	Intervention
Newman, SP, Cooke, D, Casbard, A, et al. A randomised controlled trial to compare minimally invasive glucose monitoring devices with conventional monitoring in the management of insulin-treated diabetes mellitus (MITRE). *Health Technol Assess*. 2009. 13:iii-iv, ix-xi, 1-194 doi: 10.3310/hta13280	Population
Obermayer, A, Tripolt, NJ, Pferschy, PN, et al. Efficacy and safety of intermittent fasting in people with insulin-treated type 2 diabetes (INTERFAST-2)-a randomized controlled trial. *Diabetes Care*. 2023. 46:463-468 doi: 10.2337/dc22-1622	Intervention
Olafsdottir, AF, Lind, M. Evaluating a systematic intensive therapy using continuous glucose monitoring and intermittent scanning glucose monitoring in clinical diabetes care: a protocol for a multi-center randomized clinical trial. *Front Clin Diabetes Healthc*. 2023. 4:1247616 doi: 10.3389/fcdhc.2023.1247616	Population
Olsen, MT, Klarskov, CK, Pedersen-Bjergaard, U, et al. Summary of clinical investigation plan for The DIATEC trial: in-hospital diabetes management by a diabetes team and continuous glucose monitoring or point of care glucose testing - a randomised controlled trial. *BMC Endocr Disord*. 2024. 24:60 doi: 10.1186/s12902-024-01595-4	Intervention
Ontario, Health. Flash Glucose monitoring system for people with type 1 or type 2 diabetes: a health technology assessment. *Ont Health Technol Assess Ser*. 2019. 19:1-108	Study Design
Oser, TK, Litchman, ML, Allen, NA, et al. Personal continuous glucose monitoring use among adults with type 2 diabetes: clinical efficacy and economic impacts. *Curr Diab Rep*. 2021. 21:49 doi: 10.1007/s11892-021-01408-1	Study Design
Paramasivam, SS, Chinna, K, Singh, AKK, et al. Continuous glucose monitoring results in lower HbA(1c) in Malaysian women with insulin-treated gestational diabetes: a randomized controlled trial. *Diabet Med*. 2018. 35:1118-1129 doi: 10.1111/dme.13649	Intervention
Park, C, Le, QA. The effectiveness of continuous glucose monitoring in patients with type 2 diabetes: a systematic review of literature and meta-analysis. *Diabetes Technol Ther*. 2018. 20:613-621 doi: 10.1089/dia.2018.0177	Study Design
Park, SW, Kim, G, Hwang, YC, et al. Validation of the effectiveness of a digital integrated healthcare platform utilizing an AI-based dietary management solution and a real-time continuous glucose monitoring system for diabetes management: a randomized controlled trial. *BMC Med Inform Decis Mak*. 2020. 20:156 doi: 10.1186/s12911-020-01179-x	Intervention
Patton, SR, Clements, MA. Psychological reactions associated with continuous glucose monitoring in youth. *J Diabetes Sci Technol*. 2016. 10:656-61 doi: 10.1177/1932296816638109	Publication Type
Pepe, VM, Wisniewski, S, Fall-Mostaine, F, et al. Cost analysis of continuous glucose monitoring in patients hospitalized in a diabetes department. *Diabetes Metab*. 2023. 49:101473 doi: 10.1016/j.diabet.2023.101473	Publication Type

Peters, AL, Ahmann, AJ, Hirsch, IB, et al. Advances in glucose monitoring and automated insulin delivery: supplement to Endocrine Society clinical practice guidelines. *J Endocr Soc*. 2018. 2:1214-1225 doi: 10.1210/js.2018-00262	Publication Type
Phillip, M, Danne, T, Shalitin, S, et al. Use of continuous glucose monitoring in children and adolescents (*). *Pediatr Diabetes*. 2012. 13:215-28 doi: 10.1111/j.1399-5448.2011.00849.x	Publication Type
Poolsup, N, Suksomboon, N, Kyaw, AM. Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. *Diabetol Metab Syndr*. 2013. 5:39 doi: 10.1186/1758-5996-5-39	Study Design
Pustozerov, E, Popova, P, Tkachuk, A, et al. Development and evaluation of a mobile personalized blood glucose prediction system for patients with gestational diabetes Mellitus. *JMIR Mhealth Uhealth*. 2018. 6:e6 doi: 10.2196/mhealth.9236	Study Design
Quah, PL, Tan, LK, Lek, N, et al. Continuous glucose monitoring feedback in the subsequent development of gestational diabetes: a pilot, randomized, controlled trial in pregnant women. *Am J Perinatol*. 2024. 41:e3374-e3382 doi: 10.1055/s-0043-1778664	Population
Rademaker, D, van der Wel, AWT, van Eekelen, R, et al. Continuous glucose monitoring metrics and pregnancy outcomes in insulin-treated diabetes: A post-hoc analysis of the GlucoMOMS trial. *Diabetes Obes Metab*. 2023. 25:3798-3806 doi: 10.1111/dom.15276	Intervention
Raghinaru, D, Calhoun, P, Bergenstal, RM, et al. The optimal duration of a run-in period to initiate continuous glucose monitoring for a randomized trial. *Diabetes Technol Ther*. 2022. 24:868-872 doi: 10.1089/dia.2022.0274	Population
Raj, R, Mishra, R, Jha, N, et al. Time in range, as measured by continuous glucose monitor, as a predictor of microvascular complications in type 2 diabetes: a systematic review. *BMJ Open Diabetes Res Care*. 2022. 10:doi: 10.1136/bmjdrc-2021-002573	Study Design
Raman, P, Shepherd, E, Dowswell, T, et al. Different methods and settings for glucose monitoring for gestational diabetes during pregnancy. *Cochrane Database Syst Rev*. 2017. 10:CD011069 doi: 10.1002/14651858.CD011069.pub2	Study Design
Rao, H, Fakourfar, N, Sun, C, et al. The use of continuous glucose monitoring in older people with type 2 diabetes. *Sr Care Pharm*. 2021. 36:556-567 doi: 10.4140/TCP.n.2021.556	Study Design
Reed, J, Dong, T, Eaton, E, et al. Continuous glucose monitoring for glycaemic control and cardiovascular risk reduction in patients with type 2 diabetes not on insulin therapy: A clinical trial. *Diabetes Obes Metab*. 2024. 26:2881-2889 doi: 10.1111/dom.15608	Study Design
Reznik, Y, Carvalho, M, Fendri, S, et al. Should people with type 2 diabetes treated by multiple daily insulin injections with home health care support be switched to hybrid closed-loop? The CLOSE AP+ randomized controlled trial. *Diabetes Obes Metab*. 2024. 26:622-630 doi: 10.1111/dom.15351	Intervention
Reznik, Y, Habteab, A, Castaneda, J, et al. Contribution of basal and postprandial hyperglycaemia in type 2 diabetes patients treated by an intensified insulin regimen: Impact of pump therapy in the OPT2mise trial. *Diabetes Obes Metab*. 2018. 20:2435-2441 doi: 10.1111/dom.13398	Population
Rubin, RR, Peyrot, M. Patient-reported outcomes and diabetes technology: a systematic review of the literature. *Pediatr Endocrinol Rev*. 2010. 7 Suppl 3:405-12	Study Design
Ruissen, MM, Torres-Pena, JD, Uitbeijerse, BS, et al. Clinical impact of an integrated e-health system for diabetes self-management support and shared decision making	Intervention

(POWER2DM): a randomised controlled trial. *Diabetologia*. 2023. 66:2213-2225 doi: 10.1007/s00125-023-06006-2	
Sato, J, Kanazawa, A, Ikeda, F, et al. Effect of treatment guidance using a retrospective continuous glucose monitoring system on glycaemic control in outpatients with type 2 diabetes mellitus: A randomized controlled trial. *J Int Med Res*. 2016. 44:109-21 doi: 10.1177/0300060515600190	Intervention
Sato, S, Tajiri, Y, Shimono, D, et al. Changes in psychological behavior accompanied by the short-term usage of flash glucose monitoring for newly diagnosed type 2 diabetes mellitus. *Therapeutic research*. 2020. 41:577-586	Unable to locate
Schipfer, M, Albrecht, C, Ehrmann, D, et al. Makes FLASH the difference between the intervention group and the treatment-as-usual group in an evaluation study of a structured education and treatment programme for flash glucose monitoring devices in people with diabetes on intensive insulin therapy: study protocol for a randomised controlled trial. *Trials*. 2018. 19:91 doi: 10.1186/s13063-018-2479-9	Intervention
Scott, EM, Feig, DS, Murphy, HR, et al. Continuous glucose monitoring in pregnancy: importance of analyzing temporal profiles to understand clinical outcomes. *Diabetes Care*. 2020. 43:1178-1184 doi: 10.2337/dc19-2527	Population
Secher, AL, Ringholm, L, Andersen, HU, et al. The effect of real-time continuous glucose monitoring in pregnant women with diabetes: a randomized controlled trial. *Diabetes Care*. 2013. 36:1877-83 doi: 10.2337/dc12-2360	Population
Seidu, S, Kunutsor, SK, Ajjan, RA, et al. Efficacy and safety of continuous glucose monitoring and intermittently scanned continuous glucose monitoring in patients with type 2 diabetes: a systematic review and meta-analysis of interventional evidence. *Diabetes Care*. 2024. 47:169-179 doi: 10.2337/dc23-1520	Study Design
Seisa, MO, Saadi, S, Nayfeh, T, et al. A systematic review supporting the endocrine society clinical practice guideline for the management of hyperglycemia in adults hospitalized for noncritical illness or undergoing elective surgical procedures. *J Clin Endocrinol Metab*. 2022. 107:2139-2147 doi: 10.1210/clinem/dgac277	Study Design
Selvin, E, Wang, D, Rooney, MR, et al. The associations of mean glucose and time in range from continuous glucose monitoring with HbA1c in adults with type 2 diabetes. *Diabetes Technol Ther*. 2023. 25:86-90 doi: 10.1089/dia.2022.0178	Intervention
Singh, LG, Satyarengga, M, Marcano, I, et al. Reducing inpatient hypoglycemia in the general wards using real-time continuous glucose monitoring: the glucose telemetry system, a randomized clinical trial. *Diabetes Care*. 2020. 43:2736-2743 doi: 10.2337/dc20-0840	Follow-up
Spanakis, EK, Urrutia, A, Galindo, RJ, et al. Continuous glucose monitoring-guided insulin administration in hospitalized patients with diabetes: a randomized clinical trial. *Diabetes Care*. 2022. 45:2369-2375 doi: 10.2337/dc22-0716	Follow-up
Srinivasan, V, Agus, MS. Tight glucose control in critically ill children--a systematic review and meta-analysis. *Pediatr Diabetes*. 2014. 15:75-83 doi: 10.1111/pedi.12134	Study Design
Tanenberg, R, Bode, B, Lane, W, et al. Use of the continuous glucose monitoring system to guide therapy in patients with insulin-treated diabetes: a randomized controlled trial. *Mayo Clin Proc*. 2004. 79:1521-6 doi: 10.4065/79.12.1521	Population

Taylor, PJ, Thompson, CH, Brinkworth, GDM. Effectiveness and acceptability of continuous glucose monitoring for type 2 diabetes management: A narrative review. *J Diabetes Investig*. 2018. 9:713-725 doi: 10.1111/jdi.12807	Study Design
Thabit, H, Rubio, J, Karuppan, M, et al. Use of real-time continuous glucose monitoring in non-critical care insulin-treated inpatients under non-diabetes speciality teams in hospital: A pilot randomized controlled study. *Diabetes Obes Metab*. 2024. 26:5483-5487 doi: 10.1111/dom.15885	Intervention
Thielen, V, Scheen, A, Bringer, J, et al. Attempt to improve glucose control in type 2 diabetic patients by education about real-time glucose monitoring. *Diabetes Metab*. 2010. 36:240-3 doi: 10.1016/j.diabet.2010.03.002	Outcomes
Thullen, A, Gerber, R, Keen, A. glycemic outcomes and nurse perceptions of continuous glucose monitoring for hospitalized patients. *j nurs care qual*. 2024. 39:310-316 doi: 10.1097/ncq.0000000000000791	Intervention
Triki, N, Yekutiel, N, Levi, L, et al. The effects of continuous glucose monitoring system on patient outcomes and associated costs in a real-world setting. *Diabet Med*. 2021. 38:e14518 doi: 10.1111/dme.14518	Population
Tsuji, S, Ishikawa, T, Morii, Y, et al. Cost-effectiveness of a continuous glucose monitoring mobile app for patients with type 2 diabetes mellitus: analysis simulation. *J Med Internet Res*. 2020. 22:e16053 doi: 10.2196/16053	Setting
Tumminia, A, Milluzzo, A, Festa, C, et al. Efficacy of flash glucose monitoring in pregnant women with poorly controlled pregestational diabetes (FlashMom): a randomized pilot study. *Nutr Metab Cardiovasc Dis*. 2021. 31:1851-1859 doi: 10.1016/j.numecd.2021.03.013	Population
Uhl, S, Choure, A, Rouse, B, et al. Effectiveness of continuous glucose monitoring on metrics of glycemic control in type 2 diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials. *J Clin Endocrinol Metab*. 2024. 109:1119-1131 doi: 10.1210/clinem/dgad652	Study Design
Vallarino, CR, Wong-Jacobson, SH, Benneyworth, BD, et al. Costs and outcomes comparison of diabetes technology usage among people with type 1 or 2 diabetes using rapid-acting insulin. *J Diabetes Sci Technol*. 2023. 17:439-448 doi: 10.1177/19322968211052081	Population
van Steen, SC, Rijkenberg, S, Limpens, J, et al. The clinical benefits and accuracy of continuous glucose monitoring systems in critically ill patients-a systematic scoping review. *Sensors (Basel)*. 2017. 17:doi: 10.3390/s17010146	Study Design
Voormolen, DN, DeVries, JH, Evers, IM, et al. The efficacy and effectiveness of continuous glucose monitoring during pregnancy: a systematic review. *Obstet Gynecol Surv*. 2013. 68:753-63 doi: 10.1097/OGX.0000000000000002	Study Design
Voormolen, DN, DeVries, JH, Franx, A, et al. Effectiveness of continuous glucose monitoring during diabetic pregnancy (GlucoMOMS trial); a randomised controlled trial. *BMC Pregnancy Childbirth*. 2012. 12:164 doi: 10.1186/1471-2393-12-164	Population
Voormolen, DN, DeVries, JH, Sanson, RME, et al. Continuous glucose monitoring during diabetic pregnancy (GlucoMOMS): a multicentre randomized controlled trial. *Diabetes Obes Metab*. 2018. 20:1894-1902 doi: 10.1111/dom.13310	Intervention

Wei, Q, Sun, Z, Yang, Y, et al. Effect of a CGMS and SMBG on maternal and neonatal outcomes in gestational diabetes mellitus: a randomized controlled trial. *Sci Rep*. 2016. 6:19920 doi: 10.1038/srep19920	Setting
Weinstein, JM, Berkowitz, SA, Pratley, RE, et al. Statistically adjusting for wear time in randomized trials of continuous glucose monitors as a complement to intent-to-treat and as-treated analyses: application and evaluation in two trials. *Diabetes Technol Ther*. 2023. 25:457-466 doi: 10.1089/dia.2023.0029	Publication Type
Wilkie, G, Melnik, V, Brainard, L, et al. Continuous glucose monitor use in type 2 diabetes mellitus in pregnancy and perinatal outcomes: a systematic review and meta-analysis. *Am J Obstet Gynecol MFM*. 2023. 5:100969 doi: 10.1016/j.ajogmf.2023.100969	Study Design
Wilson, DM, Xing, D, Cheng, J, et al. Persistence of individual variations in glycated hemoglobin: analysis of data from the Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Randomized Trial. *Diabetes Care*. 2011. 34:1315-7 doi: 10.2337/dc10-1661	Population
Yan, RN, Cai, TT, Jiang, LL, et al. Real-time flash glucose monitoring had better effects on daily glycemic control compared with retrospective flash glucose monitoring in patients with type 2 diabetes on premix insulin therapy. *Front Endocrinol (Lausanne)*. 2022. 13:832102 doi: 10.3389/fendo.2022.832102	Comparator
Yang, H, Cheng, Y, Zhao, Y, et al. Exercise combing with short-term continuous glucose monitoring promotes diabetes health self-care scale and glycemic control in individuals with type 2 diabetes. *Sci Sports*. 2024. 39:483-488 doi: 10.1016/j.scispo.2023.11.006	Setting
Yao, Y, Zhao, YH, Zheng, WH, et al. Subcutaneous continuous glucose monitoring in critically ill patients during insulin therapy: a meta-analysis. *Am J Transl Res*. 2022. 14:4757-4767	Study Design
Yapanis, M, James, S, Craig, ME, et al. Complications of diabetes and metrics of glycemic management derived from continuous glucose monitoring. *J Clin Endocrinol Metab*. 2022. 107:e2221-e2236 doi: 10.1210/clinem/dgac034	Aim
Yaron, M, Roitman, E, Aharon-Hananel, G, et al. Effect of flash glucose monitoring technology on glycemic control and treatment satisfaction in patients with type 2 diabetes. *Diabetes Care*. 2019. 42:1178-1184 doi: 10.2337/dc18-0166	Follow-up
Yeh, HC, Brown, TT, Maruthur, N, et al. Comparative effectiveness and safety of methods of insulin delivery and glucose monitoring for diabetes mellitus: a systematic review and meta-analysis. *Ann Intern Med*. 2012. 157:336-47 doi: 10.7326/0003-4819-157-5-201209040-00508	Study Design
Yeoh, E, Lim, BK, Fun, S, et al. Efficacy of self-monitoring of blood glucose versus retrospective continuous glucose monitoring in improving glycaemic control in diabetic kidney disease patients. *Nephrology (Carlton)*. 2018. 23:264-268 doi: 10.1111/nep.12978	Intervention
Yu, Q, Aris, IM, Tan, KH, et al. Application and utility of continuous glucose monitoring in pregnancy: a systematic review. *Front Endocrinol (Lausanne)*. 2019. 10:697 doi: 10.3389/fendo.2019.00697	Study Design
Zafra-Tanaka, JH, Beran, D, Vetter, B, et al. Technologies for diabetes self-monitoring: a scoping review and assessment using the REASSURED criteria. *J Diabetes Sci Technol*. 2022. 16:962-970 doi: 10.1177/1932296821997909	Study Design

Zhang, X, Jiang, D, Wang, X. The effects of the instantaneous scanning glucose monitoring system on hypoglycemia, weight gain, and health behaviors in patients with gestational diabetes: a randomised trial. *Ann Palliat Med*. 2021. 10:5714-5720 doi: 10.21037/apm-21-439	Setting
Zheng, Y, Campbell Rice, B, Melkus, GDM, et al. Dietary self-management using mobile health technology for adults with type 2 diabetes: a scoping review. *J Diabetes Sci Technol*. 2023. 17:1212-1225 doi: 10.1177/19322968231174038	Study Design

Appendix M. MAUDE Reports

See attachment for results from the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database (pages M1 to M97).