Medical Policy

BlueCross BlueShield Kansas
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Title: Continuous Glucose Monitoring

Related Policies:	▪ *Automated Insulin Delivery Systems*

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Populations	Interventions	Comparators	Outcomes
Individuals: • With type 1 diabetes who are willing and able to use the device, and have adequate medical supervision	Interventions of interest are: • Long-term (real-time and intermittently scanned) glucose monitoring	Comparators of interest are: • Self-monitoring of blood glucose	Relevant outcomes include: • Symptoms • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With type 1 diabetes who have poor control of diabetes despite use of best practices or	Interventions of interest are: • Short-term glucose monitoring	Comparators of interest are: • Self-monitoring of blood glucose	Relevant outcomes include: • Symptoms • Morbid events • Quality of life

Populations	Interventions	Comparators	Outcomes
when basal insulin levels need to be determined prior to insulin pump initiation			• Treatment-related morbidity
Individuals: • With type 2 diabetes who are treated with insulin therapy	Interventions of interest are: • Long-term (real-time and intermittently scanned) glucose monitoring	Comparators of interest are: • Self-monitoring of blood glucose	Relevant outcomes include: • Symptoms • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With type 2 diabetes who are not treated with insulin therapy	Interventions of interest are: • Long-term (real-time and intermittently scanned) glucose monitoring	Comparators of interest are: • Self-monitoring of blood glucose	Relevant outcomes include: • Symptoms • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With type 2 diabetes who require multiple daily doses of insulin and have poor control of diabetes despite use of best practices or to help determine basal insulin levels prior to insulin pump initiation	Interventions of interest are: • Short-term glucose monitoring	Comparators of interest are: • Self-monitoring of blood glucose	Relevant outcomes include: • Symptoms • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • Who are pregnant with gestational diabetes	Interventions of interest are: • Long-term (real-time and intermittently scanned) or short-term glucose monitoring	Comparators of interest are: • Self-monitoring of blood glucose	Relevant outcomes include: • Symptoms • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With type 1 or type 2 diabetes	Interventions of interest are: • Continuous glucose monitoring with an implantable device (Eversense)	Comparators of interest are: • Self-monitoring of blood glucose	Relevant outcomes include: • Symptoms • Morbid events • Quality of life • Treatment-related morbidity

DESCRIPTION

Tight glucose control in patients with diabetes has been associated with improved health outcomes. Several devices are available to measure glucose levels automatically and frequently (e.g., every 5 to 10 minutes). The devices measure glucose in the interstitial fluid and are approved as adjuncts to or replacements for traditional self-monitoring of blood glucose levels. Devices can be used on a long-term (continuous) or short-term (often referred to as intermittent) basis.

OBJECTIVE

The objective of this evidence review is to determine whether continuous glucose monitoring improves the net health outcome in individuals with type 1, type 2, or gestational diabetes.

BACKGROUND

Blood Glucose Control

The advent of blood glucose monitors for use by patients in the home revolutionized the management of diabetes. Using fingersticks, patients can monitor their blood glucose levels both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes.

Tight glucose control, defined as a strategy involving frequent glucose checks and a target hemoglobin A_{1c} (HbA1c) level in the range of 7%, is now considered the goal for most adults with diabetes. Randomized controlled trials assessing tight control have demonstrated benefits for patients with type 1 diabetes in decreasing microvascular complications. The impact of tight control on type 1 diabetes and macrovascular complications such as stroke or myocardial infarction is less certain. The Diabetes Control and Complications Trial (2002) demonstrated that a relative HbA1c level reduction of 10% is clinically meaningful and corresponds to approximately a 40% decrease in risk for progression of diabetic retinopathy and a 25% decrease in risk for progression of renal disease.[1,]

Due to an increase in turnover of red blood cells during pregnancy, HbA1c levels are slightly lower in women with a normal pregnancy compared with nonpregnant women. The target HbA1cin women with diabetes is also lower in pregnancy. The American Diabetes Association (ADA) recommends that the A1C goal in pregnancy is <6% (<42 mmol/mol) if this can be achieved without significant hypoglycemia, but the goal may be relaxed to <7% (<53 mmol/mol) if necessary to prevent hypoglycemia.[2,]

Tight glucose control requires multiple daily measurements of blood glucose (i.e., before meals and at bedtime), a commitment that some patients may find difficult to meet. The goal of tight glucose control has to be balanced with an associated risk of hypoglycemia. Hypoglycemia is known to be a risk in patients with type 1 diabetes. While patients with insulin-treated type 2 diabetes may also experience severe hypoglycemic episodes, there is a lower relative likelihood of severe hypoglycemia compared with patients who had type 1 diabetes.[3,] An additional limitation of periodic self-measurements of blood glucose is that glucose levels are seen in isolation, and trends in glucose levels are undetected. For example, while a diabetic patient's fasting blood glucose level might be within normal values, hyperglycemia might be undetected postprandially, leading to elevated HbA1c levels.

Management

Measurements of glucose in the interstitial fluid have been developed as a technique to measure glucose values automatically throughout the day, producing data that show the trends in glucose levels. Although devices measure glucose in the interstitial fluid on a periodic rather than a continuous basis, this type of monitoring is referred to as continuous glucose monitoring (CGM).

Currently, CGM devices are of 2 designs; real-time CGM (rtCGM) provides real-time data on glucose level, glucose trends, direction, and rate of change, and intermittently scanned (isCGM)

devices that show continuous glucose measurements retrospectively. These devices are also known as flash-glucose monitors.

Approved devices now include devices indicated for pediatric use and those with more advanced software, more frequent measurements of glucose levels, or more sophisticated alarm systems. Devices initially measured interstitial glucose every 5 to10 minutes and stored data for download and retrospective evaluation by a clinician. With currently available devices, the intervals at which interstitial glucose is measured range from every 1 to 2 minutes to 5 minutes, and most provide measurements in real-time directly to patients. While CGM potentially eliminates or decreases the number of required daily fingersticks, according to the U.S. Food and Drug Administration (FDA) labeling, some marketed monitors are not intended as an alternative to traditional self-monitoring of blood glucose levels but rather as adjuncts to monitoring, supplying additional information on glucose trends not available from self-monitoring while other devices are factory calibrated and do not require fingerstick blood glucose calibration.

Devices may be used intermittently (i.e., for periods of 72 hours) or continuously (i.e., on a long-term basis).

REGULATORY STATUS

Multiple CGM systems have been approved or cleared by the FDA (see Table 1). FDA product codes: [PMA] QCD, MDS, PQF; [510(k)] QBJ, QLG, SAF.

CGM devices labeled as "Pro" for specific professional use with customized software and transmission to health care professionals are not enumerated in this list.

The Flash glucose monitors (e.g. FreeStyle Libre, Abbott) use intermittent scanning. The current version of the FreeStyle Libre device includes real-time alerts, in contrast to earlier versions without this feature.

Some CGM devices might no longer be on the market, or the manufacturers associated with these systems may have changed.

Table 1. CGM Systems Approved or Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Approval or Clearance	Indications
Continuous Glucose Monitoring System (CGMS®)	MiniMed (now Medtronic)	1999	3-d use in physician's office. Not available; Minimed CGMs have largely being phased out.
GlucoWatch G2® Biographer	Cygnus	2001	Not available since 2008
Guardian®-RT (Real-Time) CGMS	MiniMed (now Medtronic)	2005	Not available; it was a predecessor to Guardian Connect system (see below) which offered more advanced features.
Dexcom® STS CGMS system	Dexcom	2006	Not available; discontinued by Dexcom in 2020.

Device	Manufacturer	Approval or Clearance	Indications
Paradigm® REAL-Time System (second-generation called Paradigm Revel System)	MiniMed (now Medtronic)	2006	Integrates CGM with a Paradigm insulin pump. Not available; replaced by newer Medtronic models.
FreeStyle Navigator® CGM System	Abbott	2008	Not available since 2011
Dexcom® G4 Platinum	Dexcom	2012	Adults ≥18 y; can be worn for up to 7 d; Not available; Dexcom stopped selling the G4 Platinum and G5 Mobile systems and their components in 2020, and all support and software for these older systems ceased by the end of that year. Individuals needed to transition to newer systems, such as the Dexcom G6 or Dexcom G7, to continue using a CGM from Dexcom.
		2014	Expanded to include patients with diabetes 2-17 y; Not available (see above)
Dexcom®G5 Mobile CGM	Dexcom	2016[a]	Replacement for fingerstick blood glucose testing in patients ≥2 y. System requires at least 2 daily fingerstick tests for calibration purposes, but additional fingersticks are not necessary because treatment decisions can be made based on device readings; Not available since 2020 (see above)
Dexcom® G6 Continuous Glucose Monitoring System	Dexcom	2018	Children, adolescents, and adults > 2 years; indicated for the management of diabetes in persons age ≥2 years. Intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems with 10-day wear. Dexcom G6 system is still available, but Dexcom is in the process of transitioning users to the Dexcom G7 system (see below); availability may be limited or change over time.
Freestyle Libre® Flash Glucose Monitoring System	Abbott	2017	Adults ≥18 y. Indicated for the management of diabetes and can be

Device	Manufacturer	Approval or Clearance	Indications
			worn up to 10 days It is designed to replace blood glucose testing for diabetes treatment decisions; The FreeStyle Libre 2 and FreeStyle Libre 3 systems are being discontinued and replaced with the FreeStyle Libre 3 Plus and Freestyle Libre 2 Plus sensors. The current FreeStyle Libre 2 and 3 sensors will be available until September 30, 2025. After this date, users will need a new prescription for the updated Plus versions.
		2018	Adults ≥18 y. Extended duration of use to 14 days. Not available (see above)
Freestyle Libre® 2 Flash Glucose Monitoring System	Abbott	2020	Children, adolescents, and adults >2 years, including pregnant women; FreeStyle Libre 2 system is being discontinued and replaced with the Plus sensor (see above).
Guardian Connect	Medtronic MiniMed	2018	Adolescents and adults (14-75 years) Continuous or periodic monitoring of interstitial glucose levels. Provides real-time glucose values, trends, and alerts through a Guardian Connect app installed on a compatible consumer electronic mobile device; Not available; being discontinued by Medtronic, with the last transmitter sale on April 25, 2025, and the app removed from app stores on October 24, 2025.
Eversense Continuous Glucose Monitoring System	Senseonics	2018/2019	Adults ≥18 y. Continually measuring glucose levels up to 90 days. Use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. Adults ≥18 y. Continually measuring glucose levels up to 90 days. Indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions. Historical data from the system can be interpreted to aid in providing therapy adjustments.

Device	Manufacturer	Approval or Clearance	Indications
Eversense E3 Continuous Glucose Monitoring System	Senseonics	2022	Adults ≥18 y. Continually measuring glucose levels up to 180 days. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions. The system is intended to provide real-time glucose readings, provide glucose trend information, and provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns and trends seen over time. Now called Eversense 365 (see below).
FreeStyle Libre® 3 Continuous Glucose Monitoring System	Abbott	2022	Children, adolescents, and adults >2 years, including pregnant women; FreeStyle Libre 2 and FreeStyle Libre 3 sensors will be available until September 30, 2025; being transitioned to FreeStyle Libre 3 Plus or FreeStyle Libre 2 Plus sensor
Dexcom® G7 Continuous Glucose Monitoring System	Dexcom	2022	Children, adolescents, and adults >2 years, including pregnant women
Dexcom® Stelo Glucose Biosensor System (OTC)	Dexcom	2024	Over-the-counter (OTC) Adults 18 years and older not on insulin Helps to detect normal (euglycemic) and low or high (dysglycemic) glucose levels. May also help the user better understand how lifestyle and behavior modification, including diet and exercise, impact glucose excursion. The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional.

Device	Manufacturer	Approval or Clearance	Indications
Eversense 365 Continuous Glucose Monitoring (CGM) System	Senseonics	2024	Indicated for continually measuring glucose levels for up to 1 year in people (18 years or older) with diabetes. The system is indicated for use to replace fingerstick blood glucose measurements for diabetes treatment decisions.
Abbott Lingo and Libre Rio Continuous Glucose Monitoring (CGM) Systems (OTC)	Abbott	2024	Abbott Lingo is designed for individuals 18 years and older for overall health and wellness. Libre Rio is for adults with Type 2 diabetes who do not use insulin and typically manage their diabetes through lifestyle modifications.
Dexcom G7 15-Day Continuous Glucose Monitoring (CGM) System	Dexcom	2025	Adults over the age of 18 with type 1, type 2, and gestational diabetes, offering 15.5 days of wear time (including a 12-hour grace period).

CGM: continuous glucose monitoring; OTC: over the counter.
[a] As a supplement to the G4 premarketing approval.

POLICY

A. **Individuals with Type 1 Diabetes**
Long-term and short-term continuous glucose monitoring (CGM) device monitoring of glucose levels in interstitial fluid is considered **medically necessary** in individuals with type 1 diabetes.

B. **Individuals with Type 2 Diabetes**
1. Long-term continuous glucose monitoring of glucose levels in interstitial fluid may be considered **medically necessary** in individuals with type 2 diabetes when:
    a. Individuals who are willing and able to use the device; **AND**
    b. Individuals who have adequate medical supervision; **AND**
    c. Individuals who experience significant hypoglycemia or are treated with insulin therapy.

2. Short-term continuous glucose monitoring of glucose levels in interstitial fluid may be considered **medically necessary** in individuals with type 2 diabetes who require multiple daily doses of insulin whose diabetes is poorly controlled, despite current use of best practices (see Policy Guidelines Section). Poorly controlled type 2 diabetes includes the following clinical situations:
    a. Unexplained hypoglycemic episodes **OR**
    b. Hypoglycemic unawareness **OR**
    c. Persistent hyperglycemia **OR**
    d. Hemoglobin A1c levels above target

3. Short-term continuous glucose monitoring of glucose levels in interstitial fluid may be considered **medically necessary** in individuals with type 2 diabetes who require multiple daily doses of insulin to determine basal insulin levels prior to insulin pump initiation.

4. Short-term and long-term continuous glucose monitoring of glucose levels in interstitial fluid in individuals with type 2 diabetes is considered **experimental / investigational** for individuals who do not meet the above criteria.

C. **Gestational Diabetes**
Long-term CGM or short-term intermittent glucose monitoring may be considered **medically necessary** in pregnant individuals (≥18 years of age) diagnosed with gestational diabetes to achieve recommended glycemic goals.

D. The use of implantable CGM devices for management of Type 1 and Type 2 diabetes mellitus is considered **not medical necessary** (see policy guidelines).

POLICY GUIDELINES

A. For a service to be considered medically necessary, it should not be more costly than an alternative service or supply or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results for the illness, injury, or disease.
B. This policy only evaluates continuous (real time or intermittent) interstitial glucose monitors and does not evaluate insulin pumps. Insulin pumps systems with a built-in CGM and low glucose suspend (LGS) feature are addressed elsewhere.

C. Short-term continuous glucose monitoring is generally conducted over 72-hour periods. It may be repeated subsequently depending on the individual's level of diabetes control.
D. Best practices in diabetes control include compliance with a self-monitoring blood glucose regimen of 4 or more finger sticks each day and use of an insulin pump or multiple daily injections of insulin. During pregnancy, 3 or more insulin injections daily could be considered best practice for individuals not on an insulin pump prior to pregnancy. Prior short-term (72-hour) use of an intermittent glucose monitor would be considered a part of best practices for those considering long-term use of a continuous glucose monitor.
E. Significant hypoglycemia may include recurrent, unexplained, severe hypoglycemia or impaired awareness of hypoglycemia that puts the individual or others at risk.
F. Individuals with type 1 diabetes taking insulin who are pregnant or about to become pregnant with poorly controlled diabetes are another subset of individuals to whom the policy statement on short-term continuous glucose monitoring may apply.
G. The strongest evidence exists for use of CGM devices in individuals age 25 and older. However, age may be a proxy for motivation and good control of disease, so it is also reasonable to select patients based on their ability to self-manage their disease, rather than age. Multiple continuous glucose monitoring (CGM) devices have U.S. Food and Drug Administration labeling related to age.
H. Providers board certified in endocrinology, perinatologists, and/or providers with a focus on the practice of diabetes care may be considered qualified to evaluate and oversee individuals for continuous (i.e., long-term) monitoring.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

This evidence review was created using searches of the PubMed database. The most recent literature update was performed through September 15, 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other

types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

The evidence review focuses on the clinical utility of continuous glucose monitoring (CGM) systems. That is, their ability to provide additional information on glucose levels leads to improved glucose control, or to reduce the morbidity and mortality associated with clinically significant severe and acute hypoglycemic or hyperglycemic events. Because diabetic control encompasses numerous variables, including the diabetic regimen and patient self-management, RCTs are important to isolate the contribution of interstitial glucose measurements to overall diabetes management.

For the evaluation of the clinical utility of CGM, studies would need to use the test as either an adjunct or a replacement to current disease status measures to manage treatment decisions in patients with diabetes. Outcomes would include measures of glucose control, QOL and measures of disease progression. Hemoglobin A1c (HbA1c) has commonly been accepted as a marker of glucose control; more recent studies have also reported time in hyperglycemia, time in hypoglycemia, and time in range as intermediate outcome measures.

Continuous Glucose Monitoring Devices for Long-Term Use in Type 1 Diabetes
In some parts of the analysis of type 1 diabetes, BCBSA combines discussion of real-time and intermittently scanned glucose monitoring because several systematic reviews provided information relevant to both types of devices.

Clinical Context and Therapy Purpose
The purpose of long-term CGM devices is to provide a testing option that is an alternative to or an improvement on existing testing used in the management of individuals with type 1 diabetes.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with type 1 diabetes. All individuals with type 1 diabetes require engagement in a comprehensive self-management and clinical assessment program that includes assessment of blood glucose control.

Interventions
The test being considered is the use of a CGM device to assess blood glucose levels as part of optimal diabetes management. Long-term use is generally use for more than 72 hours.

Currently, CGM devices are of 2 designs; real-time CGM (rtCGM) provides real-time data on glucose level, glucose trends, direction, and rate of change, and intermittently scanned (isCGM) devices that show continuous glucose measurements retrospectively. These latter devices are also known as flash-glucose monitors.

Comparators
The following practice is currently being used to measure glucose levels: capillary blood sampling (finger stick) for self-monitoring of blood glucose (SMBG). Standard treatment for patients with type 1 diabetes includes injection of long-acting basal insulin plus multiple daily injections (MDI) of rapid-acting insulin boluses as required for meal intake. Activity level may require patients

need to modify the timing and dose of insulin administration. Individuals with type 1 diabetes may also use an insulin pump either for initial treatment or convert to pump use after a period of MDI. Individuals are required to check their blood glucose before making preprandial insulin calculations, in response to symptoms of hypoglycemia or related to activity-related insulin adjustments.

Outcomes

The general outcomes of interest are change in HbA1c levels, time spent in hypoglycemia and hyperglycemia, time in range (generally glucose of 70 to 180 mg/dl), the incidence of hypoglycemic events, complications of hypoglycemia, and QOL. To assess short-term outcomes such as HbA1c levels, a minimum follow-up of 8 to 12 weeks is appropriate.

Study Selection

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews

A number of systematic reviews and meta-analyses have assessed RCTs evaluating CGM for long-term, daily use in treating type 1 diabetes.[4,5,6,7,8,9,] These systematic reviews have focused on slightly different populations, and some did not separate real-time CGM from intermittent glucose monitoring.[7,]

The only analysis to use individual patient data was published by Benkhadra et al (2017).[10,] The meta-analysis evaluated data from 11 RCTs that enrolled patients with type 1 diabetes and compared real-time CGM with a control intervention. Studies in which patients used insulin pumps or received multiple daily insulin injections were included. Reviewers contacted corresponding study authors requesting individual patient data; data were not obtained for 1 trial. Mean baseline HbA1c levels were 8.2% in adults and 8.3% in children and adolescents. The overall risk of bias in the studies was judged to be moderate. In pooled analyses, there was a statistically significantly greater decrease in HbA1c levels with real-time CGM versus control conditions. Overall, the degree of difference between groups was 0.26%. In subgroup analyses by age, there was a significantly greater change in HbA1c levels among individuals 15 years and older, but not among the younger age groups. There were no significant differences between groups in the time spent in hypoglycemia or the incidence of hypoglycemic events. Key findings are shown in Table 2.

Table 2. Individual Patient Data Meta-Analytic Outcomes for Real-Time CGM in Type 1 Diabetes

No. of Trials	N	Group	Point Estimate	95% Confidence Intervals	p
Change in HbA1c levels, %					
8	1371	Overall	-0.258	0.464 to -0.052	.014
7	902	Age >15 y	-0.356	0.551 to -0.160	<.001
7	178	Age 13-15 y	-0.039	-0.320 to 0.242	.787
7	291	Age ≤12 y	-0.047	0.217 to 0.124	.592
Time spent in hypoglycemia <60 mg/dL, min					
4	706	Overall	-8.549	-31.083 to 13 985	.457
4	467	Age >15 y	-8.095	-32.615 to 16.425	.518
3	109	Age 13-15 y	-13.966	31.782 to 3.852	.124
3	130	Age ≤12 y	-9.366	19.898 to 1.167	.081
Incidence of hypoglycemic events <70 mg/dL, mean no. events					
3	351	Overall	0.051	-0.314 to 0.416	.785
3	277	Age >15 y	-0.074	-0.517 to 0.368	.742
2	47	Age 13-15 y	0.536	0.243 to 1.316	.177
2	27	Age ≤12 y	0.392	0.070 to 0.854	.097

Adapted from Benkhadra et al (2017).[10,]
CGM: continuous glucose monitoring: HbA1c: hemoglobin A_{1c}.

Randomized Controlled Trials

Recent RCTs are described next and in Tables 3 and 4. HbA1c, blood glucose, event rates, and patient reported outcomes were assessed at 6 months. None of the studies were blinded. The studies had a large number of pre-specified secondary endpoints, and analyses took into consideration the statistical impact of multiple comparisons.

Two 2017 RCTs evaluated long-term, real-time CGM in patients with type 1 diabetes treated with multiple daily insulin injections. Both trials used the Dexcom G4 CGM device. [Note: This study used the Dexcom G4 Platinum system, which, along with the G5 Mobile system, was discontinued in 2020. Users of these CGM devices were required to upgrade to newer models to continue receiving services from Dexcom. Studies assessing devices that are no longer in use remain relevant and have been retained in this policy, as they form the basis for the advancement and design of newer CGM technologies.]

Lind et al (2017) reported on a crossover study with 142 adults ages 18 and older who had baseline HbA1c levels of 7.5% or higher (mean baseline HbA1c level, >8.5%).[11,] Enrolled patients underwent 26-week treatment periods with a CGM device and conventional therapy using SMBG, in random order. There was a 17-week washout period between intervention phases. The primary endpoint was the difference in HbA1c levels at the end of each treatment period. Mean HbA1c levels were 7.9% during CGM use and 8.4% during conventional therapy (MD, -0.4%; p<.01). Treatment satisfaction (measured by the Diabetes Treatment Satisfaction Questionnaire)

was significantly higher in the CGM phase than in the conventional treatment phase (p<.001). There was 1 (0.7%) severe hypoglycemic event during the CGM phase and 5 (3.5%) events during conventional therapy. The percentage of time with hypoglycemia (<70 mmol/L) was 2.8% during CGM treatment and 4.8% during conventional therapy.

In the second study, Beck et al (2017) randomized 158 patients on a 2:1 basis to 24 weeks of CGM (n=105) or usual care (n=53).[12,] The primary outcome (change in HbA1c levels at 24 weeks) was 1.0% in the CGM group and 0.4% in the usual care group (p<.001), with a between-group difference of 0.6%. Prespecified secondary outcomes on the proportion of patients below a glycemic threshold at 24 weeks also favored the CGM group. The proportion of patients with HbA1c levels less than 7.0% was 18 (18%) in the CGM group and 2 (4%) in the control group (p=.01). Prespecified secondary outcomes related to hypoglycemia also differed significantly between groups, favoring the CGM group. Comparable numbers for time spent at less than 50 mg/dL were 6 minutes per day in the CGM group and 20 minutes per day in the usual care group (p=.001). The median change in the rate per 24 hours of hypoglycemia events lasting at least 20 minutes at less than 3.0 mmol/L (54 mg/dL) fell by 30% from 0.23 at baseline to 0.16 during follow-up in the CGM group but was practically unchanged (0.31 at baseline and 0.30 at follow-up) in the usual care group (p=.03).[13,] Quality of life measures assessing overall well-being (World Health Organization Well-Being Index), health status (EQ-5D-5L), diabetes distress (Diabetes Distress Scale), hypoglycemic fear (worry subscale of the Hypoglycemia Fear Survey), and hypoglycemic confidence (Hypoglycemic Confidence Scale) have also been reported.[14,] There were no significant differences between CGM and usual care in changes in well-being, health status, or hypoglycemic fear. The CGM group demonstrated a greater increase in hypoglycemic confidence (p=.01) and a greater decrease in diabetes distress (p=.01) than the usual care group.

Two RCTs were published in 2020 that assessed real-time CGM with a Dexcom G5 in adolescents and young adults (Laffel et al 2020) [15,], and in older adults (Pratley et al 2020)[16,] Both studies found modest but statistically significant differences in HbA1c between patients who used the CGM devices compared to the control arm at follow-up. Secondary measures of HbA1c and blood glucose were mostly better in the CGM arm. Patient-reported outcome measures were not significantly different between the groups, except that glucose monitoring satisfaction was higher in the adolescents and young adults who used CGM. With the newer technology, patients were able to use a smartphone app to monitor glucose levels.

Two RCTs have evaluated long-term use of intermittently-scanned CGM. Leelarathna et al (2022) reported results of the FLASH-UK (NCT03815006) multicenter RCT including individuals age 16 years and older in the United Kingdom with type 1 diabetes and HbA1c levels between 7.5% and 11.0% who were receiving either continuous subcutaneous insulin infusion or multiple daily injections of insulin.[17,] The trial was conducted from 2019 to 2021 and compared intermittently-scanned CGM (FreeStyle Libre 2; n=78) worn on the arm for 14 days versus usual care with fingerstick testing (n=78). The primary outcome was the HbA1c at 24 weeks. The difference in decrease in HbA1c level at 24 weeks was −0.5% (95% CI, −0.7 to −0.3; p<.001) favoring CGM. The difference in time per day that the glucose level was in target range was 9.0% (95% CI, 4.7 to 13.3) higher or 130 minutes (95% CI, 68 to 192) longer in the CGM group compared to usual care. No participants in the CGM group versus 2 participants in the usual care group had an episode of severe hypoglycemia.

Yan et al (2023) reported results of a multicenter RCT (NCT03522870) conducted in China from 2019 to 2022 comparing intermittently-scanned CGM (FreeStyle Libre; n=54) to capillary blood glucose monitoring (n=50) in adults with sub-optimally controlled type 1 diabetes.[18,] Participants had HbA1c between 7% and 10%. The primary outcome was change in HbA1c at 24 weeks. The mean reduction in the primary outcome in the CGM group was 0.7% versus 0.3% in the control group (difference, 0.3%; 95% CI, 0.0 to 0.6; p=.04). The mean time-in-range increased to 63% at 24 weeks in CGM versus 58% in control (difference, 6% [1.4 hours / day]; 95% CI, -11 to -1; p=.02). No participants in the CGM group versus 4 participants in the control group experienced an event of diabetic ketoacidosis. No participants in either group experienced severe hypoglycemia.

Table 3. Summary of Key RCT Characteristics in Patients with Type 1 Diabetes

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					CGM	SMBG
Beck et al (2017)[12,] DIAMOND				Adults aged 25 or older with baseline HbA1c levels between 7.5% and 10%	Dexcom G4 real-time CGM (n=105)	Usual care (n=53)
Laffel et al (2020)[15,]	US	14	2018-2019	Adolescents and young adults age 14 to 24 years with HbA1c 7.5% to 10.9% with multiple daily insulin injections or an insulin pump	Dexcom G5 real-time CGM, with training on use and a smartphone app and 2 calibration BG per day (n=74)	Fingerstick blood glucose meter checks at least 4 times daily (n=79)
Pratley et al (2020)[16,](WISDM)	US	22	1993-2012	Older adults >60 years of age with HbA1c <10.0% with multiple daily insulin injections or an insulin pump	Dexcom G5 real-time CGM with training on use and 2 calibration BG checks per day (n=103)	Fingerstick blood glucose meter checks at least 4 times daily (n=100)
Leelarathna et al (2022)[17,]	UK	8	2019-2021	Ages 16 and older with type 1 diabetes and HbA1c levels between 7.5% and 11.0% who were receiving either continuous subcutaneous	FreeStyle Libre 2 intermittently-scanned CGM worn on the arm for 14 days (n=78)	Usual care with fingerstick testing (n=78)

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					CGM	SMBG
				insulin infusion or multiple daily injections of insulin; mean age, 44 yr; mean HbA1c, 8.6%		
Yan et al (2023)[18,]	China	3	2018-2022	Ages 18 and older with type 1 diabetes and HbA1c between 7% and 10% with stable insulin regimen; 64% female; mean age, 34 yr; mean HbA1c, 8.1%	FreeStyle Libre intermittently scanned CGM (n=54)	Fingerstick blood glucose meter checks (n=50)
Gupta et al (2024)[19,]	India	1	2021-2023	Adolescents or adults ≥15 y with T1D on basal-bolus insulin, HbA1c between 8% and 12% and normal awareness of hypoglycemia; mean age, 20y	A) rt-CGMS for 2 weeks initially, followed by is-CGMS for 2 weeks at 3 months (n=20) B) is-CGMS for 2 weeks initially followed by rt-CGMS for 2 weeks at 3 months (n=20)	C) Fingerstick blood glucose meter checks (n=40)

BG: blood glucose; CGM: continuous glucose monitoring; HbA1c: hemoglobin A1C; is: intermittently scanned; RCT: randomized controlled trial; rt: real-time; SMBG: self-monitored blood glucose; WISDM: Wireless Innovation for Seniors With Diabetes Mellitus.

Table 4. Summary of Key RCT Results in Patients with Type 1 Diabetes

Study	HbA1c	HbA1c	Blood Glucose (SD) mg/dL	Hypoglycemic Episodes	Patient Reported Outcomes	Patient Reported Outcomes
Beck et al (2017)[12,] DIAMOND	*Change from Baseline*	*Proportion <7.0%*		*Minutes per day <70 mg/dL*		
CGM	1.0%	18 (18%)		43		
SMBG	0.4%	2 (4%)		80		

Study	**HbA1c**	**HbA1c**	**Blood Glucose (SD) mg/dL**	**Hypoglycemic Episodes**	**Patient Reported Outcomes**	**Patient Reported Outcomes**
Diff (95% CI)	0.6%					
p	<.001	.01		.002		
Laffel et al (2020)[15,]	*Change from Baseline*	*Percent with Reduction of 0.5%*	*Mean (SD)*	*Per Week*	*PAD-PS Survey*	*Glucose Monitoring Satisfaction*
CGM	-0.4 (1.0)	44%	199 (36)	1.4 (0.4 to 2.6)		
SMBG	0.1 (0.8)	21%	217 (35)	1.7 (1.0 to 3.1)		
Diff (95% CI)	-0.37 (-0.66 to -0.08)	23% (7% to 37%)	-14.3 (-23.6 to -5.1)	-0.3 (-0.7 to 0.1)	-0.1 (-3.0, 4.0)	0.27 (0.06, 0.54)
p	.01	.005	.003	.11	.73	.003
Pratley et al (2020)[16,](WISDM)	*At follow-up*	*Percentage of time glucose values <70 mg/dL*		*Per week*	*Quality of life*	*Hypoglycemia Awareness*
CGM	7.2 (0.9)	2.7%	162 (23)	0.8 (0.3-2.2)		
SMBG	7.4 (0.9)	4.9%	171 (30)	1.8 (0.7-4.0)		
Diff (95% CI)	-0.3 (-0.4 to -0.1)	-1.9% (-2,8 to -1.1)	−7.7 (−13.1 to −2.4)	−0.9 (−1.3 to −0.5)		
p		<.001	.005	<.001	NS	NS
Leelarathna et al (2022)[17,]	Change from baseline, mean (SD)	Proportion ≤ 7.0%, n (%)	At 24 weeks follow-up	Severe hypoglycemia, n (%)	NR	NR
CGM	-0.8 (0.8)	11 (15)	178 (32)	0 (0)		
SMBG	-0.2 (0.6)	5 (7)	185 (40)	2 (3)		
Diff (95% CI)	-0.5 (-0.7 to -0.3)	OR=2.4 (0.8 to 7.8)	-11 (-20 to 0)	NR		
p	<.001	NR	NR	NR		
Yan et al (2023)[18,]	Change from baseline, mean (SD)				NR	NR

Study	HbA1c	HbA1c	Blood Glucose (SD) mg/dL	Hypoglycemic Episodes	Patient Reported Outcomes	Patient Reported Outcomes
CGM	0.7%		153 (26)	0		
SMBG	0.3%		166 (29)	0		
Diff (95% CI)	0.3% (0.0 to 0.6)		11 (1 to 21)			
p	.04		0.03			
Gupta et al (2024)[19,]	At 3 mo				NR	NR
CGM	A) 7.9 B) 8.5		Unclear; compared different treatment periods instead of between treatment groups	Unclear; compared different treatment periods instead of between treatment groups		
SMBG	C) 8.9					
Diff (95% CI)	NR					
p	Unclear					

CGM: continuous glucose monitor; CI: confidence interval; HbA1c: hemoglobin A1c; NR: not reported; NS: not significant; PAD-PS; Problem Areas in Diabetes-Pediatric Survey; RCT: randomized controlled trial; SD: standard deviation; SMBG: self monitored blood glucose; WISDM: Wireless Innovation for Seniors With Diabetes Mellitus

Observational Studies

Because several RCTs exist, observational studies will be summarized briefly below only if they capture longer periods of follow-up- (>6 months), larger populations, or particular subgroups of interest.

Long-term follow-up

Observational studies with follow-up of more than 6 months including adults with type 1 diabetes have shown that reductions in acute diabetes events, including severe hypoglycemia and diabetic ketoacidosis are maintained for 1 to 2 years.[20,21,]

Pregnant People

One trial of real-time CGM in pregnant women with type 1 diabetes has been reported. Study characteristics, results, and gaps are summarized here and in Tables 5 to 8. Feig et al (2017) reported results of 2 multicenter RCTs in women ages 18 to 40 with type 1 diabetes who were receiving intensive insulin therapy and who were either pregnant (≤13 weeks and 6 days of gestation) or planning a pregnancy.[22,]The trial enrolling pregnant women is reviewed here. Women were eligible if they had a singleton pregnancy and HbA1c levels between 6.5% and 10.0%. The trial was conducted at 31 hospitals in North America and Europe. Women were

randomized to CGM (Guardian REAL-Time (RT) or MiniMed Minilink system) plus capillary glucose monitoring or capillary glucose monitoring alone.

Women in the CGM group were instructed to use the devices daily. Women in the control group continued their usual method of capillary glucose monitoring. The target glucose range was 3.5 to 7.8 mmol/L and target HbA1c levels were 6.5% or less in both groups. The primary outcome was the difference in change in HbA1c levels from randomization to 34 weeks of gestation. The proportion of completed scheduled study visits was high in both groups; however, participants using CGM had more unscheduled contacts, which were attributed both to sensor issues and to sensor-related diabetes management issues. The median frequency of CGM use was 6.1 days per week (interquartile range, 4.0 to 6.8 d/wk) and 70% of pregnant participants used CGM for more than 75% of the time. The between-group difference in the change in HbA1c levels from baseline to 34 weeks of gestation was statistically significant favoring CGM (MD, -0.19%; 95% CI, -0.34 to -0.03; p=.02). Women in the CGM group spent an increased percentage of time in the recommended glucose control target range at 34 weeks of gestation (68% vs. 61%; p=.003). There were no between-group differences in maternal hypoglycemia, gestational weight gain, or total daily insulin dose. A smaller proportion of infants of mothers in the CGM group were large-for-gestational-age (odds ratio [OR], 0.51; 95% CI, 0.28 to 0.90; p=.02). In addition, for infants of mothers in the CGM group, there were fewer neonatal intensive care admissions lasting more than 24 hours (OR, 0.48; 95% CI, 0.26 to 0.86; p=.02), fewer incidences of neonatal hypoglycemia requiring treatment with intravenous dextrose (OR, 0.45; 0.22 to 0.89; p=.025), and reduced total hospital length stay (3.1 days vs. 4.0 days; p=.0091). Skin reactions occurred in 49 (48%) of 103 CGM participants and 8 (8%) of 104 control participants.

Table 5. RCT Characteristics for Real-Time CGM in Pregnant People With Type 1 Diabetes

Study; Registration	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Feig et al (2017)[22]; NCT01788527	Canada, England, Scotland, Spain, Italy, Ireland, U.S.	31	2013-2016	Pregnant women (<14 wk gestation) with type 1 diabetes receiving intensive insulin therapy with HbA1c levels between 6.5% and 10.0% (mean, 6.9%); mean age, 31 y	CGM (real-time) (n=108)	SMBG (n=107)

CGM: continuous glucose monitoring: HbA1c: hemoglobin A_{1c}; NCT: national clinical trial; RCT: randomized controlled trial; SMBG: self-monitored blood glucose.

Table 6. RCT Outcomes for Real-Time CGM in Pregnant People With Type 1 Diabetes

	Infant				Maternal	
Study	**Large-for-Gestational Age**	**Gestational Age at Delivery, wk**	**Severe Hypoglycemia**	**Caesarean Section**	**HbA1c Levels: Change From Baseline to 34 Wk of Gestation**	**Severe Hypoglycemia**
Feig et al (2017)[22,]						
N	211	201	200	202	173	214
CGM	53 (53%)	Median, 37.4	15 (15%)	63 (63%)	-0.54	11 (11%)
Control	69 (69%)	Median, 37.3	28 (28%)	74 (73%)	-0.35	12 (12%)
TE (95% CI)	OR, 0.51 (0.28 to 0.90)	NR	OR, 0.45 (0.22 to 0.89)	NR	-0.19% (-0.34% to -0.03%)	NR
p	.02	.50	.025	.18	.02	1.0

Values are n or n (%) or as otherwise indicated.
CGM: continuous glucose monitoring; CI: confidence interval; HbA1c: hemoglobin A_{1c}; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; TE: treatment effect.

The purpose of the limitations tables (see Tables 7 and 8) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 7. Study Relevance Limitations of RCTs for Real-Time CGM in Pregnant People With Type 1 Diabetes

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Feig et al (2017)[22,]	4. Run-in period requirement may have biased selection to highly compliant participants	3. More unscheduled contacts in CGM group	3. More unscheduled contacts in CGM group		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
CGM: continuous glucose monitoring; RCT: randomized controlled trial.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use; 5. Enrolled study populations do not reflect relevant diversity.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 8. Study Design and Conduct Limitations of RCTs for Real-Time CGM in Pregnant People With Type 1 Diabetes

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Feig et al (2017)[22,]		1. Not blinded; chance of bias in clinical management				3, 4. Treatment effects and confidence intervals not calculated for some outcomes

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
CGM: continuous glucose monitoring; RCT: randomized controlled trial.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Section Summary: Continuous Glucose Monitoring Devices for Long-Term Use in Type 1 Diabetes

Numerous RCTs and several systematic reviews of RCTs have evaluated CGM in patients with type 1 diabetes. RCTs have evaluated both real-time and intermittently scanned CGM devices. Two recent RCTs in patients who used multiple daily insulin injections and were highly compliant with CGM devices during run-in phases found that CGM was associated with a larger reduction in HbA1c levels than previous studies. Reductions were 0.4% and 0.6%, respectively, compared with approximately 0.2% to 0.3% in previous analyses. One RCT prespecified hypoglycemia-related outcomes and time spent in hypoglycemia were significantly lower in the CGM group.

One RCT in pregnant women with type 1 diabetes (N=215) has compared CGM with SMBG. Adherence was high in the CGM group. The difference in the change in HbA1c levels from baseline to 34 weeks of gestation was statistically significant favoring CGM, and women in the CGM group spent an increased percentage of time in the recommended glucose control target range at 34 weeks of gestation. There were no between-group differences in maternal hypoglycemia, gestational weight gain, or total daily insulin dose. A smaller proportion of infants of mothers in the CGM group were large for gestational age, had neonatal intensive care admissions lasting more than 24 hours, and had neonatal hypoglycemia requiring treatment. The total hospital length of stay was shorter by almost 1 day in the CGM group.

CONTINUOUS GLUCOSE MONITORING DEVICES FOR SHORT-TERM USE IN TYPE 1 DIABETES

Clinical Context and Therapy Purpose

The purpose of the short-term use of CGM devices is to provide a testing option that is an alternative to or an improvement on existing testing used in the management of individuals with type 1 diabetes.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with type 1 diabetes. All individuals with type 1 diabetes require engagement in a comprehensive self-management and clinical assessment program that includes assessment of blood glucose control. Individuals with type 1 diabetes may have poorly controlled diabetes, despite current use of best practices, including situations such as unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis. In addition, individuals with type 1 diabetes may need to determine basal insulin levels prior to insulin pump initiation.

Interventions

The testing being considered is the short-term use of a CGM device to assess blood glucose levels as part of optimal diabetes management. Short-term use is generally for 72 hours. However, reports of use range from 3 to 30 days.

Comparators

The following practice is currently being used to measure glucose levels: capillary blood sampling (finger stick) for SMBG. Standard treatment for patients with type 1 diabetes includes injection of long-acting basal insulin plus MDI of rapid-acting insulin boluses as required for meal intake. Activity level may require patients need to modify the timing and dose of insulin administration. Individuals with type 1 diabetes may also use an insulin pump either for initial treatment or convert to pump use after a period of MDI. Individuals are required to check their blood glucose before making preprandial insulin calculations, in response to symptoms of hypoglycemia or related to activity-related insulin adjustments

Outcomes

For short-term use of CGM, the general outcomes of interest include time in range (generally glucose of 70 to 180 mg/dl), frequency and time spent in hypoglycemia, and frequency and time spent in hyperglycemia for the duration of the monitoring. Repeat CGM may be necessary to assess the impact of changes in management.

Study Selection

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews
Meta-analyses of glucose monitoring devices for type 1 diabetes tend to combine studies of short-term glucose monitoring with studies of long-term CGM. For this body of evidence, there is variability in the definitions of short-term monitoring and the specific monitoring protocols used. Also, many of the trials of short-term monitoring have included additional interventions to optimize glucose control (e.g., education, lifestyle modifications).

Two meta-analyses were identified that reported separate subgroup analyses for short-term, intermittent monitoring. In a Cochrane review by Langendam et al (2012), 4 studies (N=216) compared real-time short-term glucose monitoring systems with SMBG, and the pooled effect estimate for change in HbA1c levels at 3 months was not statistically significant (MD change, -0.18; 95% CI, -0.42 to 0.05).[6,] The meta-analysis by Wojciechowski et al (2011), which assessed RCTs on CGM (described previously), also included a separate analysis of 8 RCTs of short-term intermittent monitoring.[8,] On pooled analysis, there was a statistically significant reduction in HbA1c levels with short-term intermittent glucose monitoring compared with SMBG (WMD, -0.26; 95% CI, -0.45 to -0.06).

Randomized Controlled Trials
The largest RCT was the Management of Insulin-Treated Diabetes Mellitus (MITRE) trial, published by Newman et al (2009); it evaluated whether the use of the additional information provided by minimally invasive glucose monitors improved glucose control in patients with poorly controlled insulin-requiring diabetes.[23,] This 4-arm RCT was conducted at secondary care diabetes clinics in 4 hospitals in England. This trial enrolled 404 people over the age of 18 years, with insulin-treated diabetes (types 1 or 2) for at least 6 months, who were receiving 2 or more injections of insulin daily. Most (57%) participants had type 1 diabetes (41% had type 2 diabetes, 2% were classified as "other"). Participants had to have 2 HbA1c values of at least 7.5% in the 15 months before trial entry and were randomized to 1 of 4 groups. Two groups received minimally invasive glucose monitoring devices (GlucoWatch Biographer or MiniMed Continuous Glucose Monitoring System [CGMS]). Short-term glucose monitoring was used (i.e., monitoring was performed over several days at various points in the trial). These groups were compared with an attention control group (standard treatment with nurse feedback sessions at the same frequency as those in the device groups) and a standard control group (reflecting common practice in the clinical management of diabetes). Changes in HbA1c levels from baseline to 3, 6, 12, and 18 months were the primary indicator of short- to long-term efficacy. At 18 months, all groups demonstrated a decline in HbA1c levels from baseline. Mean percentage changes in HbA1c levels were -1.4% for the GlucoWatch group, -4.2% for the CGMS group, -5.1% for the attention control group, and -4.9% for the standard care control group. In the intention-to-treat analysis, no significant differences were found between any groups at any assessment times. There was no evidence that the additional information provided by the devices changed the number or nature of treatment recommendations offered by the nurses. Use and acceptability indicated a decline for both devices, which was most marked in the GlucoWatch group by 18 months (20% still using GlucoWatch vs 57% still using the CGMS). In this trial of unselected patients, glucose monitoring (CGMS on an intermittent basis) did not lead to improved clinical outcomes.

PREGNANT PEOPLE

Systematic Reviews

Voormolen et al (2013) published a systematic review of the literature on CGM during pregnancy.[24,] They identified 11 relevant studies (N=534). Two were RCTs, one of which was the largest of the studies (n=154). Seven studies used CGM devices that did not have data available in real-time; the remaining 4 studies used real-time CGM. Reviewers did not pool study findings; they concluded that the evidence was limited to the efficacy of CGM during pregnancy. The published RCTs are described next.

Randomized Controlled Trials

Three RCTs of short-term glucose monitoring in pregnant women with type 1 or type 2 diabetes are summarized in Tables 9 to 12 and the following paragraphs. While both trials included a mix of women with type 1 and type 2 diabetes, most women had type 1 diabetes in both trials, so the trials are reviewed in this section.

Voormolen et al (2018) reported results of the GlucoMOMS trial, a multicenter, open-label RCT conducted between 2011 and 2015 in the Netherlands including pregnant women age 18 years and over with either diabetes mellitus type 1 (n=109), type 2 (n=82), or gestational (n=109) diabetes requiring insulin therapy before 30 weeks of gestation. The trial compared blinded CGM (n=147) to standard treatment (n=153).[25,]. Glycemic control was measured by CGM for 5 to 7 days every 6 weeks in the CGM group and SMBC was used in both groups. The primary outcome was macrosomia (birth weight above the 90th percentile). The incidence of large-for-gestational-age was 31% in the CGM group and 28% in the standard treatment group (RR=1.1; 95% CI, 0.8 to 1.4). HbA1c levels were similar between treatment groups.

Secher et al (2013) randomized 154 women with type 1 (n=123) and type 2 (n=31) diabetes to real-time CGM in addition to routine pregnancy care (n=79) or routine pregnancy care alone (n=75).[26,]. Patients in the CGM group were instructed to use the CGM device for 6 days before each of 5 study visits and were encouraged to use the devices continuously; 64% of participants used the devices per-protocol. Participants in both groups were instructed to perform 8 daily self-monitored plasma glucose measurements for 6 days before each visit. Baseline mean HbA1c levels were 6.6% in the CGM group and 6.8% in the routine care group. The 154 pregnancies resulted in 149 live births and 5 miscarriages. The prevalence of large-for-gestational-age infants (at least 90th percentile), the primary study outcome, was 45% in the CGM group and 34% in the routine care group. The difference between groups was not statistically significant (p=.19). Also, no statistically significant differences were found between groups for secondary outcomes, including the prevalence of preterm delivery and the prevalence of severe neonatal hypoglycemia. Women in this trial had low baseline HbA1c levels, which might explain the lack of impact of CGM on outcomes. Other factors potentially contributing to the negative findings included the intensive SMBG routine in both groups and the relatively low compliance rate in the CGM group.

Murphy et al (2008) in the U.K. randomized 71 pregnant women with type 1 (n=46) and type 2 (n=25) diabetes to CGM or usual care.[27,] The intervention consisted of up to 7 days of CGM at intervals of 4 to 6 weeks between 8 weeks and 32 weeks of gestation. Neither participants nor physicians had access to the measurements during sensor use; data were reviewed at study visits. In addition to CGM, the women were advised to measure blood glucose levels at least 7 times per day. Baseline HbA1c levels were 7.2% in the CGM group and 7.4% in the usual care group. The primary study outcome was maternal glycemic control during the second and third

trimesters. Eighty percent of women in the CGM group wore the monitor at least once per trimester. Mean HbA1c levels were consistently lower in the intervention arm, but differences between groups were statistically significant only at week 36. For example, between 28 weeks and 32 weeks of gestation, mean HbA1c levels were 6.1% in the CGM group and 6.4% in the usual care group (p=.10). The prevalence of large-for-gestational-age infants (at least 90th percentile) was a secondary outcome. Thirteen (35%) of 37 infants in the CGM group were large-for-gestational age compared with 18 (60%) of 30 in the usual care group. The odds for reduced risk of a large-for-gestational-age infant with CGM was 0.36 (95% CI, 0.13 to 0.98; p=.05).

Table 9. RCT Characteristics for Short-Term CGM in Pregnant People With Type 1 Diabetes

Study; Registration	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Voormolen et al (2018)[25,]	Netherlands and Belgium	23	2011-2015	Pregnant women with type 1 (n=109) or type 2 (n=82) diabetes who were undergoing insulin therapy at gestational age <16 weeks, or women who were undergoing insulin treatment for gestational diabetes (n=109) at gestational age <30 weeks; mean age, 32 y; mean HbA1c, 52 mmol/mol.	CGM (for 5-7 days every 6 weeks) plus SOC (n=147)	SOC (n=153)
Secher et al (2013)[26,]; NCT00994357	Denmark	1	2009-2011	Pregnant women with type 1 (80%) or type 2 (20%) diabetes; mean gestational age, <14 wk); median HbA1c level, 6.7%; median age, 32 y	CGM (for 6 d before each study visit; encouraged to used continuously) plus SOC (n=79)	SOC (n=75)
Murphy et al (2008)[27,]; ISRCTN84461581	U.K.	2	2003-2006	Pregnant women with type 1 (65%) or type 2 (35%) diabetes; mean gestational age, 9.2 wk; mean HbA1c level, 7.3%; mean age, 31 y	CGM (up to 7 d of CGM at intervals of 4-6 wk) plus SOC (n=38)	SOC (n=33)

CGM: continuous glucose monitoring; HbA1c: hemoglobin A_{1c}; NCT: national clinical trial; RCT: randomized controlled trial; SOC: standard of care.

Table 10. RCT Results for Short-Term CGM in Pregnant People With Type 1 Diabetes

Study	Infant				Maternal	
	Large-for-Gestational Age	Gestational Age at Delivery	Severe Hypoglycemia	Caesarean Section	HbA1c Levels at 36 Weeks of Gestation[a]	Severe Hypoglycemia
Voormolen et al (2018)[25,]						
N	290	290	290	290		NR
CGM	(31)	266	25 (18%)	23 (21%)		
Control	(28)	266	25 (17%)	26 (23%)		
TE (95% CI)	RR=1.1 (0.8 to 1.4)	1.1 (0.9 to 1.4)	1.0 (0.6 to 1.7)	NR	'No difference'	
p						
Secher et al (2013)[26,]						
N	154	154	145	154	NR	154
CGM	34 (45%)	Median, 263	9 (13%)	28 (37%)	Median, 6.0%	16%
Control	25 (34%)	Median, 264	10 (14%)	33 (45%)	Median, 6.1%	16%
TE (95% CI)	NR	NR	NR	NR	NR	NR
p	.19	.14	.88	.30	.63	.91
		Weeks				
Murphy et al (2008)[27,]						
N	71	71	68	69	71	NR
CGM	13 (35%)	Mean, 37.6	3 (8%)	27 (71%)	Mean, 5.8%	
Control	18 (60%)	Mean, 37.5	5 (17%)	21 (61%)	Mean, 6.4%	
TE (95% CI)	OR=0.36 (0.13 to 0.98)	NR	NR	NR	0.6% (CI NR)	
p	.05	.80	.50	.40	.007	

Values are n or n (%) or as otherwise indicated.
CGM: continuous glucose monitoring; CI: confidence interval; HbA1c: hemoglobin A_{1c}; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; TE: treatment effect.
[a] N inconsistently reported for HbA1c outcome.

Tables 11 and 12 display notable limitations identified in each study.

Table 11. Study Relevance Limitations of RCTs of Intermittent CGM in Pregnant People With Type 1 Diabetes

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Voormolen et al (2018)[25],		4. Only 66% of the participants used devices per protocol			
Secher et al (2013)[26],	4. Study population had relatively low HbA1c levels	4. Only 64% of the participants used devices per protocol			
Murphy et al (2008)[27],					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
CGM: continuous glucose monitoring; HbA1c: hemoglobin A_{1c}; RCT: randomized controlled trial.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use; 5. Enrolled study populations do not reflect relevant diversity.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 12. Study Design and Conduct Limitations of RCTs of Short-Term CGM Glucose Monitoring in Pregnant People With Type 1 Diabetes

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Voormolen et al (2018)[25],		1. Not blinded; chance of bias in clinical management				
Secher et al (2013)[26],		1. Not blinded; chance of bias in clinical management				3, 4. Treatment effects and confidence intervals not calculated
Murphy et al (2008)[27],		1. Not blinded; chance of bias in clinical management				3, 4. Treatment effects and confidence intervals not calculated for some outcomes

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
CGM: continuous glucose monitoring; RCT: randomized controlled trial.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Section Summary: Glucose Monitoring Devices for Short-Term Use in Type 1 Diabetes
For short-term monitoring of type 1 diabetes, there are few RCTs and systematic reviews. The evidence for short-term monitoring on glycemic control is mixed, and there was no consistency in HbA1c levels. Some trials have reported improvements in glucose control for the intermittent monitoring group but limitations in this body of evidence preclude conclusions. The definitions of control with short-term CGM use, duration of use and the specific monitoring protocols varied. In some studies, short-term monitoring was part of a larger strategy aimed at optimizing glucose control, and the impact of monitoring cannot be separated from the impact of other interventions. Studies have not shown an advantage for intermittent glucose monitoring in reducing severe hypoglycemia events but the number of events reported is generally small and effect estimates are imprecise. The limited duration of use may preclude an assessment of any therapeutic effect. RCTs of short-term CGM use for monitoring in pregnancy included women with both type 1 and 2 diabetes, with most having type 1 diabetes. One trial reported a difference in HbA1c levels at 36 weeks; the proportion of infants that were large for gestational age (>90th percentile) favored CGM while other trials did not. The differences in the proportions of infants born via cesarean section, gestational age at delivery, and infants with severe hypoglycemia were not statistically significant.

Continuous Glucose Monitoring Devices for Use in Individuals with Type 2 Diabetes Who Are Treated with Insulin Therapy
There is limited ability to distinguish between long-term and short-term glucose monitoring in the analysis of the data for type 2 diabetes, consistent with the literature.

Clinical Context and Therapy Purpose
The purpose of long-term and short-term CGM devices is to provide a treatment option that is an alternative to or an improvement on existing therapies such as SBGM.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with type 2 diabetes who are treated with insulin therapy and who experience poor diabetes control despite current use of best practices. Poor control includes situations such as unexplained hypoglycemic episodes, hypoglycemic unawareness, and persistent hyperglycemia and A1C levels above target.

In addition, some individuals with type 2 diabetes may need to determine basal insulin levels prior to insulin pump initiation.

All individuals with type 2 diabetes require engagement in a comprehensive self-management and clinical assessment program that includes assessment of blood glucose control.

Interventions
The testing being considered is the use of long-term or short-term CGM devices to assess blood glucose levels as part of optimal diabetes management.

Comparators
Blood glucose monitoring is an essential component of type 2 diabetes management in order to monitor for and prevent hypoglycemia and hyperglycemia. For these individuals, guidelines recommend blood glucose monitoring prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise, when low blood glucose is suspected, after treating low blood glucose, and prior to and while performing critical tasks such as driving. The following practice is currently being used to measure glucose levels: SMBG (capillary blood sampling (finger stick) using blood glucose meters) and periodic measurement of HbA1c.

Outcomes
The general outcomes of interest are change in HbA1c levels, frequency of and time spent in hypoglycemia, frequency and time spent in hyperglycemia, complications of hypoglycemia and hyperglycemia, and QOL. To assess short-term outcomes such as HbA1c levels, a minimum follow-up of 8 to 12 weeks is appropriate. To assess long-term outcomes such as time spent in hypoglycemia, the incidence of hypoglycemic events, complications of hypoglycemia, and QOL, follow-up of 6 months to 1 year would be appropriate.

Study Selection
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews
Kong et al (2024) published a systematic review and meta-analysis of CGM in type 2 diabetes.[28,] The review included 17 RCTs (N=1619) of participants on insulin therapy (11 RCTs; n=1188) and not on insulin therapy (6 RCTs; n=431) published prior to May 2023 in Korean or English. All types of CGM were included. Ten of the 17 RCTs were published after 2015. Six of the RCTs were conducted in the United States, and 12 of the RCTs were multicenter. The meta-analytic effect size of CGM on HbA1c was -0.42 (95% CI, -0.79 to -0.05) for trials including

participants on insulin therapy. The effect size was -0.25 (95% CI, -0.44 to -0.05) for trials including participants not receiving insulin therapy.

Randomized Controlled Trials

Several RCTs evaluated CGM in individuals on insulin therapy. Select trials are described below and in Tables 13 and 14.

Beck et al (2017) reported on the DIAMOND RCT.[29,] DIAMOND compared CGM with the Dexcom device to SMBG in 158 participants at 25 endocrinology practices in North America (22 in the U.S., 3 in Canada). Participants who were adherent during a run-in period were eligible for randomization. Change in HbA1c level from baseline to 24 weeks was the primary outcome. Analyses were adjusted for baseline HbA1c levels and were performed using intention-to-treat analysis with missing data handling by multiple imputations. Week 24 follow-up was completed by 97% of the CGM group and 95% of the control group. Mean CGM use was greater than 6 days/week at 1 month, 3 months, and 6 months. The adjusted difference in mean change in HbA1c level from baseline to 24 weeks was -0.3% (95% CI, -0.5% to 0.0%; p=.022) favoring CGM. The adjusted difference in the proportion of patients with a relative reduction in HbA1c level of 10% or more was 22% (95% CI, 0% to 42%; p=.028) favoring CGM. There were no events of severe hypoglycemia or diabetic ketoacidosis in either group. The treatment groups did not differ in any of the QOL measures.

Haak et al (2017) compared intermittently scanned CGM with the Freestyle Libre device in 224 individuals at 26 European centers.[30,] At 6 months, there was no difference between groups in the primary outcome of change in HbA1c (p=.8222). However, results for secondary outcomes including time in hypoglycemia and treatment satisfaction favored the CGM group. No serious adverse events or severe hypoglycemic events were reported related to device use.

Yaron et al (2019) reported higher treatment satisfaction (the primary outcome) in 101 individuals using a flash glucose monitor compared to SMBG.[31,] On secondary glycemic control measures, HbA1c was reduced by 0.82% compared to 0.33% in the control group (p=.005) without an increase in the frequency of hypoglycemic events.

Martens et al (2021) reported results of an RCT comparing real-time CGM with SMBG in 176 patients with poorly controlled type 2 diabetes (HbA1c levels 7.8% to 11.5%) treated with basal insulin without prandial insulin.[32,]At 8 months, there was a statistically significantly greater decrease in mean HbA1c in the CGM group (adjusted difference, -0.4%; 95% CI -0.8% to -0.1%; p=.02), with 1 hypoglycemic event in each group. Aleppo et al (2021) reported a 6-month follow-up study of 163 patients who had been randomized in this same trial (93.1%).[33,] Patients originally randomized to SMBG continued to use SMBG for another 6 months, and the CGM group was randomly reassigned either to continue CGM or discontinue CGM and resume SMBG. In the group that discontinued CGM, mean HbA1c increased from 7.9% at 8 months to 8.2% at 14 months, whereas in the group that continued CGM, mean HbA1c decreased from 8.2% to 8.1%.

Table 13. Key RCT Characteristics for CGM in Individuals with Type 2 Diabetes on Insulin

Study; Registration	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Beck et al (2017) (DIAMOND)[29]; NCT02282397	U.S., Canada	25	2014-2016	Adults with T2D using multiple daily injections of insulin with HbA1c levels 7.5%-10.0% (baseline mean, 8.5%); mean age, 60 y	Real-time CGM (n=79)	SMBG (n=79)
Haak et al (2017)[30]; NCT02082184	Multiple European	26	2014-2015	Adults with T2D treated with insulin for at least 6 months and on their current regimen for 3 months or more; HbA1c 7.5 to 12.0%	Flash glucose monitoring with FreeStyle Libre device n=149	SMBG n=75
Yaron et al (2019)[31]; NCT02809365	Israel	2	2016-2017	Adults with T2D on multiple daily insulin injections for at least 1 year	Flash glucose monitoring with FreeStyle Libre device n=53	SMBG n=48
Martens et al (2021);[32] Aleppo et al (2021)[33]; NCT03566693	U.S.	15	2018-2019	Adults with T2D treated with 1 to 2 daily injections of basal insulin without prandial insulin; HbA1c levels 7.8% to 11.5% (baseline mean, 9.1%); mean age, 57 y	Real-time CGM (n=116)	SMBG (n=59)
Lind et al (2024)[34];	Denmark	1	2020-2022	Adults with T2D treated with insulin, HbA1c ≥7.5% (baseline mean, 8.3%); mean age, 61 y	CGM (Dexcom G6) for 12 months (n=40)	SMBG for 12 months (n=36)

CGM: continuous glucose monitoring; HbA1c: hemoglobin A_{1c}; NCT: national clinical trial;NR: not reported; RCT: randomized controlled trial; SMBG: self-monitored blood glucose; T2D: type 2 diabetes.

Table 14. Key RCT Outcomes for CGM in Individuals with Type 2 Diabetes on Insulin

Study	Reduction in HbA1c Levels (Mean Range), %	HbA1c Level <7.0%, n (%)	Relative Reduction in HbA1c Level ≥10%, n (%)	Hypoglycemic or Ketoacidosis Events	Diabetes Complications (retinopathy, nephropathy, neuropathy, diabetic foot)	Health-Related Quality of Life
	Baseline to 24 Wk	At 24 Wk	At 24 Wk			DTSQ Overall Mean Score at 24 Wk
Beck et al (2017)[29], NCT02282397						
N	158	158	158	158	NR	150
CGM	8.6 to 7.7	11 (14%)	40 (52%)	0		Baseline: 1.78 24 weeks: 1.61
Control	8.6 to 8.2	9 (12%)	24 (32%)	0		Baseline: 1.69 24 weeks: 1.78
TE (95% CI)	-0.3 (-0.5 to 0.0)	3% (-9% to 14%)	22% (0% to 42%)			0.22 (0.08 to 0.36)
p	.022	.88	.028			.009
Haak et al (2017)[30], NCT02082184	HbA1c change from baseline to 6 months: -3.1 (SE 0.75) mmol/L (-0.29% ± 0.07%) vs. -3.4 (SE 1.04 [-0.31 ± 0.09%]) p=.8222			Time in hypoglycemia: <3.9 mmol/L: reduced by mean 0.47 (SE 0.13) hours/day; p=.0006 <3.1 mmol/L reduced by 0.22 ± 0.07 hours/day; p=.0014		
Yaron et al (2019)[31], NCT02809365	Change in HbA1c –0.82% (9				NR	Treatment satisfaction (Primary

Study	Reduction in HbA1c Levels (Mean Range), %	HbA1c Level <7.0%, n (%)	Relative Reduction in HbA1c Level ≥10%, n (%)	Hypoglycemic or Ketoacidosis Events	Diabetes Complications (retinopathy, nephropathy, neuropathy, diabetic foot)	Health-Related Quality of Life
	mmol/mol) vs. –0.33% (3.6 mmol/mol) p=.005					outcome, DTSQc) at 10 weeks: 2.47 (0.77) vs. 2.18 (0.83); p=.053
Martens et al (2021);[32] Aleppo et al (2021)[33] NCT03566693						
N	156	156	156	175	NR	NR
CGM	9.1 to 8.0	20 (19%)	66 (63%)	1 hypoglycemic event, 1 ketoacidosis event		
Control	9.0 to 8.4	5 (10%)	21 (41%)	1 hypoglycemic event		
TE (95% CI)	-0.4 (-0.8 to -0.1)	11.8 (0.6 to 24.5)	22.4 (12.0 to 32.0)			
p	.02	.04	<.001			
Lind et al (2024)[34]	12 months				'General health' at 12 months	
N	76				76	
CGM	7.6			0	3.3	
Control	8.4			0	2.6	
TE (95% CI)	-0.9 (-1.4 to -0.3)				0.5 (0.1 to 0.9)	
p	<.01				.02	

CGM: continuous glucose monitoring; CI: confidence interval; DTSQ: Diabetes Treatment Satisfaction; HbA1c: hemoglobin A_{1c}; NCT: national clinical trial; NR: not reported; RCT: randomized controlled trial; SE: standard error; TE: treatment effect.

[a] serious hypoglycemic event defined as requiring third-party assistance.

Observational Studies
Because several RCTs exist, observational studies will be summarized briefly below only if they capture longer periods of follow-up (>6 months), larger populations, or particular subgroups of interest.

Long-term follow-up
Observational studies with follow-up of more than 6 months including adults with type 2 diabetes, the majority of whom were on insulin, have shown that reduction in mean HbA1c is maintained for 12 months,[35,] and reductions in acute diabetes events, including severe hypoglycemia and diabetic ketoacidosis are maintained for 1 to 2 years.[20,36,21,]

Individuals with Significant Hypoglycemia
Twelve-month open-access, follow-up results for long-term CGM with the Freestyle Libre device in 108 individuals from the Haak et al (2017) 6-month trial were reported in a second publication by Haak et al (2017).[37,] Hypoglycemia was analyzed using 3 different glucose level thresholds (<70 mg/dl, <55 mg/dl, and <45 mg/dl). At 12-month follow-up, hypoglycemic events were reduced by 40.8% to 61.7% with a greater relative reduction in the most severe thresholds of hypoglycemia. At all 3 glucose level thresholds, there were statistically significant reductions in time in hypoglycemia, frequency of hypoglycemic events, time in nocturnal hypoglycemia, and frequency of nocturnal hypoglycemia. Change for hypoglycemic events per day at 12 months compared to baseline was also significant: -40.8% (glucose <70 mg/dl; p<.0001); -56.5% (glucose <55 mg/dl; p<.0001); -61.7% (glucose <45 mg/dl; p=.0001).

Pregnant People
Wilkie et al (2023) reported results of a systematic review of CGM in type 2 diabetes in pregnancy.[38,] The review includes the same 3 RCTs described below. The meta-analytic treatment effect estimate of large-for-gestational-age infants (CGM, n=56 vs. control, n=53) was OR, 0.8 (95% CI, 0.3 to 1.8). There was no difference in development of preeclampsia (OR, 1.6, 95% CI, 0.3 to 7.2).

As discussed in the section on CGM in pregnant women with type 1 diabetes, 3 RCTs have evaluated short-term glucose monitoring in pregnant women with type 1 and type 2 diabetes. Most women had type 1 diabetes in both trials. There were 25 (35%) women with type 2 diabetes in Murphy et al (2008)[27,], 31 (20%) with type 2 diabetes in Secher et al (2013),[26,] and 82 (27%) women with type 2 diabetes in Voormolen (2018).[25,] Results for women with type 2 diabetes were not reported in Murphy et al (2008). Secher et al (2013) reported that 5 (17%) women with type 2 diabetes experienced 15 severe hypoglycemic events, with no difference between groups; other analyses were not stratified by diabetes type.

Section Summary: Continuous Glucose Monitoring Devices for Use in Individuals with Type 2 Diabetes Who Are Treated with Insulin
RCTs have evaluated CGM compared to SMBG in individuals with type 2 diabetes on intensive insulin therapy including both real-time CGM and intermittently scanned devices. One RCT evaluated CGM in patients treated with basal insulin using real-time CGM. All RCTs found either improved glycemic outcomes or no difference between groups with no increase in hypoglycemic events. In the DIAMOND trial, the adjusted difference in mean change in HbA1c level from baseline to 24 weeks was -0.3% (95% CI, -0.5% to 0.0%; p=.022) favoring CGM. The adjusted difference in the proportion of patients with a relative reduction in HbA1c level of 10% or more

was 22% (95% CI, 0% to 42%; p=.028) favoring CGM. There were no events of severe hypoglycemia or diabetic ketoacidosis in either group. Yaron et al (2019) reported higher treatment satisfaction with CGM compared to control (the primary outcome). At 12-month follow-up in one of the trials of the Freestyle Libre device, hypoglycemic events were reduced by 40.8% to 61.7% with a greater relative reduction in the most severe thresholds of hypoglycemia. In the Martens trial of individuals treated with basal insulin without prandial insulin, there was a statistically significantly greater decrease in mean HbA1c in the CGM group (adjusted difference, -0.4%; 95% CI -0.8% to -0.1%; p=.02), with 1 hypoglycemic event in each group.

CONTINUOUS GLUCOSE MONITORING DEVICES FOR USE IN INDIVIDUALS WITH TYPE 2 DIABETES WHO ARE NOT TREATED WITH INSULIN THERAPY

Clinical Context and Therapy Purpose

The purpose of long-term and short-term CGM devices is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with type 2 diabetes.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with type 2 diabetes who are not treated with insulin therapy.

All individuals with type 2 diabetes require engagement in a comprehensive self-management and clinical assessment program that includes assessment of blood glucose control.

Interventions

The testing being considered is the long-term or short-term use of CGM devices to assess blood glucose levels as part of optimal diabetes management.

Currently, CGM devices are of 2 designs; rtCGM provides real-time data on glucose level, glucose trends, direction, and rate of change, and iCGM devices that show continuous glucose measurements retrospectively. These devices are also known as flash-glucose monitors.

Comparators

SMBG (capillary blood sampling [finger stick]) using blood glucose meters and periodic measurement of HbA1c is used to measure glucose levels.

In contrast to recommendations in individuals on intensive insulin regimens, guidelines are less clear on when to prescribe blood glucose monitoring and how often monitoring is needed in individuals with type 2 diabetes who are not on insulin therapy. In individuals on oral antidiabetic agents only, routine glucose monitoring may be of limited additional clinical benefit.[39,]

Outcomes

The general outcomes of interest are change in HbA1c levels, frequency of and time spent in hypoglycemia, frequency and time spent in hyperglycemia, complications of hypoglycemia and hyperglycemia, and QOL. To assess short-term outcomes such as HbA1c levels, a minimum follow-up of 8 to 12 weeks is appropriate. To assess long-term outcomes such as time spent in

hypoglycemia, the incidence of hypoglycemic events, complications of hypoglycemia, and QOL, follow-up of 6 months to 1 year would be appropriate.

Study Selection
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

There is limited ability to distinguish between long-term and short-term glucose monitoring in the analysis of the data for type 2 diabetes, consistent with reporting in the literature. Therefore, this section includes both long-term and short-term uses.

REVIEW OF EVIDENCE

Systematic Reviews
As described in the previous section, Kong et al (2024) published a systematic review and meta-analysis of CGM in type 2 diabetes.[28,] The review included 17 RCTs, 6 (n=431) of which included participants not on insulin therapy. All types of CGM were included. The effect size was -0.25 (95% CI, -0.44 to -0.05) for trials including participants not receiving insulin therapy.

Randomized Controlled Trials
Select RCTs that evaluated CGM in individuals with Type 2 diabetes who are not treated with insulin therapy are described below and in Tables 15 and 16.

Ehrhardt et al (2011) reported the results of a RCT evaluating the intermittent use of a CGM device over 12 weeks in adults with type 2 diabetes treated with diet/exercise and/or glycemia-lowering medications but not prandial insulin who had an initial HbA1c level of at least 7% but not more than 12%.[40,]Twenty-nine of 100 participants (29.0%) were using basal insulin alone or in combination with oral agents. The trial compared real-time CGM with the Dexcom device used for 4 cycles (2 weeks on and 1 week off) with SMBG. Vigersky et al (2012) reported follow up data through 52 weeks.[41,] The primary efficacy outcome was a mean change in HbA1c levels. Mean HbA1c levels in the CGM group were 8.4% at baseline, 7.4% at 12 weeks, 7.3% at 24 weeks, and 7.7% at 52 weeks. In the SMBG group, these values were 8.2% at baseline, 7.7% at 12 weeks, 7.6% at 24 weeks, and 7.9% at 52 weeks. During the trial, the reduction in HbA1c levels was significantly greater in the CGM group than in the SMBG group (p=.04). After adjusting for potential confounders (e.g., age, sex, baseline therapy, whether the individual started taking insulin during the study), the difference between groups over time remained statistically significant (p<.001). The investigators also evaluated SMBG results for both groups. The mean proportions of SMBG tests less than 70 mg/dL were 3.6% in the CGM group and 2.5% in the SMBG group (p=.06).

Price et al (2021) reported results from the COntinuous Glucose Monitoring & Management In TypE 2 Diabetes (COMMITED; NCT03620357) RCT comparing rt-CGM (10 days a month for 3

months) to SMBG in adult patients with type 2 diabetes (HbA1c between 7.8% and 10.5%) who were receiving 2 or more oral antidiabetic drugs, but not insulin, in the U.S. and Canada between 2018 and 2020.[42,] Participants were 47% female, 74% White, 14% Asian, 7% Black and 29% Hispanic. The mean age was 60 years. The change in HbA1c at week 12 was not statistically different (-0.5 (1.3)% vs -0.2 (1.1)% for the CGM and SMBG groups, respectively; p=.74). The reduction in HbA1c was not sustained at month 9 for either group (-0.2 (0.9)% vs 0.1 (1.3)%, respectively, for CGM versus SMBG groups (p=.79).

Wada et al (2020) reported results of an open-label, multicenter RCT in Japan including participants with non-insulin-treated type 2 diabetes with HbA1c ≥7.5% and <8.5%.[43,] The trial compared flash glucose monitoring worn for 12 weeks (n=49) and conventional SMBG (n=51). The primary outcome was change in HbA1c level at 12 weeks. There was no significant between-group difference in the change from baseline in the 2 groups at 12 weeks (CMG, -0.43% vs. SMBG, -0.30%; difference=-0.13%; 95% CI, −0.35 to 0.09; p=.24) but there was a difference favoring CGM at 24 weeks (difference, −0.29%; 95% CI, −0.54 to −0.05; p=.02).

Aronson et al (2022) reported results of the IMMEDIATE multicenter RCT (NCT04562714) conducted in Canada including adults with type 2 diabetes and HbA1c of 7.5% or higher who were using at least 1 non-insulin antihyperglycemic therapy.[44,] The 2 treatment groups were the flash glucose monitor CGM group (FreeStyle Libre Pro; n=58) worn 14 days at baseline and again at week 14 plus diabetes self-management education versus diabetes self-management education alone (DSME; n=58). DSME included instruction to self-monitor blood glucose at least 4 times daily. The primary outcome was the difference in percentage mean Time In Range (TIR; glucose 70-180 mg/dl) at 16 weeks. At 16 weeks, the CGM group had significantly greater mean TIR (difference=9.9%; 2.4 hours; 95% CI, 17.3% to 2.5%; p<.01).The mean HbA1c at 16 weeks was 7.6% in the CGM group compared to 8.1% in the DSME group (adjusted mean difference, 0.3%; 95% CI, 0% to 0.7%; p=.05). The Glucose monitoring satisfaction score was higher in the CGM group compared with the DSME group but there were no differences in the other patient-reported outcomes (Diabetes Distress Score, Adherence to Refills and Medications Scale for Diabetes and Skills, Confidence & Preparedness Index).

Tables 17 and 18 display notable limitations identified in the studies. These include a lack of blinding and heterogeneity in the participant populations, lack of data on diabetic events and percent of patients meeting target goals, and insufficient duration to determine effects on diabetic complications.

Table 15. Key RCT Characteristics for CGM in Individuals with Type 2 Diabetes not on Insulin Therapy

Study; Registration	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Ehrhardt et al (2011)[40,]Vigersky et al (2012) [41,]	U.S.	1	NR	Adults with T2D using oral antidiabetic agents without prandial insulin; HbA1c levels 7.0% to 12.0% (baseline mean, 8.3%); mean age, 58 y	Real-time CGM for 4 cycles of 3 wk (n=50)	SMBG (n=50)

Study; Registration	Countries	Sites	Dates	Participants	Interventions	
				29 of 100 (29%) were using basal insulin		
Price et al (2021)[42,]	U.S. and Canada	8	2018-2020	Adults with T2D receiving 2+ oral antidiabetic drugs, HbA1c between 7.8% and 10.5%, not receiving insulin; mean age, 60 y, mean HbA1c, 8.4%	Real-time CGM (Dexcom G6) for 10 days a month for 3 months (n=46)	SMBG (n=24)
Wada et al (2020)[43,]	Japan	5	2017-2018	Ages 20 to 70 with non-insulin-treated type 2 diabetes with HbA1c ≥7.5%and <8.5%; mean age, 58 y; mean HbA1c, 7.8%	Flash glucose monitor (Freestyle Libre) for 12 weeks (n=49)	SMBG schedule not described (n=51)
Aronson et al (2022)[44,]	Canada	6	2020-2021	Adults with type 2 diabetes and HbA1c ≥7.5% who were using at least one non-insulin antihyperglycemic therapy; mean age, 58y; mean HbA1c, 8.6%	Flash glucose monitor (FreeStyle Libre Pro) for 14 days plus diabetes self-management education (n=58)	Diabetes self-management education alone (included SMBG) (n=58)
Rama et al (2024) (NCT04564911)[45,]	Singapore	5	2020-2022	Adults with type 2 diabetes and HbA1c between 7.5% and 10% using oral antihyperglycemic therapy or basal insulin (~30% were on basal insulin); mean age, 55 y; mean HbA1c, 8.4%	Flash glucose monitor (FreeStyle Libre Pro); continuous use for 6 weeks followed by intermittent use every 2 weeks up to 24 weeks with diabetes education (n=90)	SMBG (preferably 4x per day) with diabetes education (n=86)

CGM: continuous glucose monitoring; HbA1c: hemoglobin A_{1c}; ; NR: not reported; RCT: randomized controlled trial; SMBG: self-monitored blood glucose; T2D: type 2 diabetes.

Table 16. Key RCT Outcomes for CGM in Individuals with Type 2 Diabetes not on Insulin Therapy

Study	HbA1c Levels (Mean Range), %	HbA1c Level <7.0%, n (%)	Relative Reduction in HbA1c Level ≥10%, n (%)	Hypoglycemic or Ketoacidosis Events	Diabetes Complications (retinopathy, nephropathy, neuropathy, diabetic foot)	Patient Reported Outcomes
Ehrhardt et al (2011)[40,] Vigersky et al (2012) [41,]						
N	100	NR	NR	NR	NR	NR
CGM	8.4 to 7.4					
Control	8.2 to 7.7					
TE (95% CI)	NR					
p	.006					
Price et al (2021)[42,]	At week 12	At week 12	NR			
N	67	67				
CGM	8.0 (1.1)	(18%)		0		
Control	8.1 (1.0)	(9%)		1		
TE (95% CI)	NR			NR		
p	.74	.26		NR		
Wada et al (2020)[43,]	Change from baseline to 12 weeks	NR	NR	Hypoglycemia, n		Diabetes Treatment Satisfaction Questionnaire (DTSQ) score, mean (SD)
N	93			93		90
CGM	-0.43			2		35 (5)
Control	-0.30			1		31 (7)
TE (95% CI)	-0.13 (-0.35 to 0.09)			NR		NR
p	.24			NR		<.001

Study	HbA1c Levels (Mean Range), %	HbA1c Level <7.0%, n (%)	Relative Reduction in HbA1c Level ≥10%, n (%)	Hypoglycemic or Ketoacidosis Events	Diabetes Complications (retinopathy, nephropathy, neuropathy, diabetic foot)	Patient Reported Outcomes
Aronson et al (2022)[44,]	At 16 weeks	NR	NR	At least one hypoglycemic event, n(%)	NR	Glucose monitoring satisfaction score (GMSS), mean (SD) at week 16
N	108					NR
CGM	7.6			30 (59%)		3.9 (0.5)
Control	8.1			24 (50%)		3.4 (0.5)
TE (95% CI)	0.3% (0.0 to 0.7) favoring CGM			NR		0.5 (0.7 to 0.3) favoring CGM
p	.05			NR		<.01
Rama et al (2024) (NCT04564911)[45,]	At week 24			Severe hypoglycaemia or diabetes ketoacidosis		EQ-5D at week 24
N	173					173
CGM	-0.57			0		-0.02
Control	-0.63			0		-0.05
TE (95% CI)	0.05 (-0.16, 0.27)					0.03
p	0.62					0.21

CGM: continuous glucose monitoring; CI: confidence interval; DDS: Diabetes Distress Scale; DTSQ: Diabetes Treatment Satisfaction; HbA1c: hemoglobin A_{1c}; NCT: national clinical trial;NR: not reported; RCT: randomized controlled trial; TE: treatment effect.
[a]Serious hypoglycemic event defined as requiring third-party assistance.

Table 17. Study Relevance Limitations of RCTs of CGM in Individuals with Type 2 Diabetes Not on Insulin Therapy for Glucose Monitoring in Type 2 Diabetes

Study; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Ehrhardt et al (2011)[40,] Vigersky et al (2012) [41,]	1. Study population a mix of participants using basal insulin or			1. Focused on HbA1c; did not include outcomes on adverse events, QOL, or diabetic complications	1. Follow-up not sufficient to determine effects on diabetic complications

Study; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
	oral agents alone			6. No justification for clinically significant difference	
Price et al (2021)[42,]					1. Treatment and follow-up of 3 months
Wada et al (2020)[43,]	5. Study conducted in Japan			1. Did not report key outcomes on participants meeting target A1c levels	1. Treatment for 12 weeks with 12 additional weeks of follow-up
Aronson et al (2022)[44,]	5. Study conducted in Canada			1. Did not report key outcomes on participants meeting target A1c levels	1. Follow-up of 16 weeks
Rama et al (2024) (NCT04564911)[45,]	5. Study conducted in Singapore			1. Did not report key outcomes on participants meeting target A1c levels	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
CGM: continuous glucose monitoring; HbA1c: hemoglobin A_{1c}; QOL: quality of life; RCT: randomized controlled trial.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use; 5. Enrolled study populations do not reflect relevant diversity.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 18. Study Design and Conduct Limitations of RCTs of CGM in Individuals with Type 2 Diabetes Not on Insulin Therapy

Study; Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Ehrhardt et al (2011)[40,] Vigersky et al (2012) [41,]		1. Not blinded; chance of bias in clinical management				
Price et al (2021)[42,]		1. Not blinded			1, 2, 3: No information on power or sample size calculations	

Study; Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Wada et al (2020)[43,]		1. Not blinded				
Aronson et al (2022)[44,]		1. Not blinded				
Rama et al (2024) (NCT04564911)[45,]		1. Not blinded				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
CGM: continuous glucose monitoring; RCT: randomized controlled trial.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Section Summary: Continuous Glucose Monitoring Devices for Use in Individuals with Type 2 Diabetes Who Are Not Treated with Insulin Therapy

The trials reported mixed results with respect to benefits of CGM regarding glycemic control. However, participant populations were heterogenous with regard to their diabetic treatment regimens, and participants might not have been receiving optimal therapy. In individuals on oral antidiabetic agents only, routine glucose monitoring may be of limited additional clinical benefit. Additional evidence would be needed to show what levels of improvements in HbA1c over the short-term in this population would be linked to meaningful improvements over the long-term in health outcomes such as diabetes-related morbidity and complications.

CONTINUOUS GLUCOSE MONITORING USE IN PREGNANT PEOPLE WITH GESTATIONAL DIABETES

Clinical Context and Therapy Purpose

The purpose of long-term CGM and short-term (intermittent) glucose monitoring devices is to provide a treatment option that is an alternative to or an improvement on existing therapies in persons with gestational diabetes mellitus (GDM).

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are pregnant persons with gestational diabetes mellitus (GDM). GDM is a form of glucose intolerance that is first recognized during pregnancy. The

standard of care is to screen asymptomatic individuals at 24-28 weeks gestation using a non-fasting 50g oral glucose load with 1 hour blood glucose measurement. Abnormal results are followed up with additional testing as clinically appropriate. Early pregnancy screening may be appropriate to identify undiagnosed T2 diabetes mellitus in individuals with diabetic risk factors including a history of prior gestational diabetes. Postpartum evaluation for resolution of glucose intolerance is recommended. GDM often represents previously undiagnosed prediabetes, type 2 diabetes, maturity-onset diabetes of the young, or developing type 1 diabetes.

Interventions
The testing being considered are devices that provide continuous, long-term glucose levels to the patient to direct insulin regimens and intermittent (i.e., 72 hours), short-term monitoring of glucose levels used by the provider to optimize management.

Comparators
The following practice is currently being used to measure glucose levels: capillary blood sampling (finger stick) for blood glucose meters for self-monitoring.

Outcomes
In general, HbA1C levels remain an outcome of interest. Due to increased red blood cell turnover, A1C is slightly lower during pregnancy in people with and without diabetes. Ideally, the A1C goal in pregnancy is <6% (<42 mmol/mol), if this can be achieved without significant hypoglycemia, but the goal may be relaxed to <7% (<53 mmol/mol) if necessary to prevent hypoglycemia.

Acceptable glucose control is also evaluated using the glucose management metrics of time in range (TIR), time above range (TAR) and time below range (TBR). Gestational diabetes mellitus (GDM) blood glucose goals have been recommended by the Fifth International Workshop-Conference on Gestational Diabetes Mellitus[46,] as summarized in Table 19.

Table 19. Blood Glucose Goals In Pregnancies Associated With Diabetes*

	Blood glucose goal		
Glucose measurement	**Type 1 diabetes or type 2 diabetes[a]**	**GDM treated with insulin**	**GDM not treated with insulin**
Fasting glucose	70–95 mg/dL (3.9-5.3 mmol/L)	70–95 mg/dL (3.9-5.3 mmol/L)	<95 mg/dL (<5.3 mmol/L)
1-h postprandial glucose	110–140 mg/dL[b] (6.1-7.8 mmol/L)	110–140 mg/dL[b] (6.1-7.8 mmol/L)	<140 mg/dL[b] (<7.8 mmol/L)
2-h postprandial glucose	100–120 mg/dL (5.6-6.7 mmol/L)	100–120 mg/dL (5.6-6.7 mmol/L)	<120 mg/dL (<6.7 mmol/L)

*Gestational diabetes mellitus (GDM) blood glucose goals shown are recommended by the Fifth International Workshop-Conference on Gestational Diabetes Mellitus (Metzger et al (2007)[46,]
[a]Lower glucose limits do not apply to individuals with type 2 diabetes treated with nutrition alone. Aim for less stringent goals if these cannot be achieved without significant hypoglycemia, based on clinical experience and individualization of care.
[b]Optimal goal includes either a 1-h postprandial glucose level or 2-h postprandial glucose level within column of type of diabetes.

Study Selection
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews
Balaji et al. (2025) conducted a qualitative systematic review of 35 studies (including 11 randomized trials, N=5,627) comparing CGM with SMBG among women with GDM.[47,]A meta-analysis was not undertaken due to heterogeneity in study designs, differences in CGM devices used, and differential outcome reporting across studies. Evidence from randomized trials found CGM to be preferred by individuals and at least comparable to SMBG for TIR and glycemic control. Overall, the review findings for CGM were associated with better maternal and neonatal outcomes, including reduced rates of large-for-gestational-age infants, preterm births, and NICU admissions.

Randomized Controlled Trials
Voormolen et al (2018) (GlucoMOMS trial), reviewed previously, included 109 women with GDM requiring insulin therapy before 30 weeks of gestation.[25,]No significant difference was observed between groups in the primary outcome of macrosomia (birth weight above the 90th percentile) between groups (11 (20%) in CGM vs. 9 (17%) in standard treatment; relative risk, 1.22, 95% CI, 0.55 to 2.71). HbA1c levels were also similar between treatment groups and no differences were observed in the secondary outcome of hypertensive disorders (p=.79).

Two trials of glucose monitoring in women with GD have been published since the Balaji systematic review. Amylidi-Mohr et al (2025) conducted an open-label, single-center RCT to compare the effects of rtCGM with SMBG on perinatal outcomes in pregnant individuals with GDM.[48,]The study enrolled 302 participants aged 18-45 years, based pre-pregnancy BMI, prior GDM, family history of type 2 diabetes, and ethnicity. The participants were allocated at random in a 1:1 ratio to rtCGM (n=156, using the Dexcom G6) or SMBG (n=143). The primary composite endpoint included large for gestational age, macrosomia, polyhydramnios, neonatal hypoglycemia, and stillbirth. Of the participants, 297 (of 299) completed the study, and analysis showed no significant difference in the primary composite outcome between the groups (odds ratio 1·02, 95% CI, 0·63 to 1·66). Skin changes were the only reported adverse events (n=6 (4%) in rtCGM group compared to n=1 (<1%) in SMBG group). Study participants did express a higher preference for the rtCGM device which suggests that rtCGM could be offered to simplify the management of GDM.

Valent et al (2025), in another open-label, RCT, assessed whether rtCGM improves %TIR over SMBG alone in pregnant individuals with GDM.[49,] The single-center trial enrolled 111 women with GDM and at least 20 weeks gestation, randomizing participants in a 2:1 ratio to CGM plus SMBG

(n=74) or SMBG alone (n=37). The intervention group used the Dexcom G6 CGM continuously until delivery, while controls performed SMBG four times daily and underwent blinded CGM every 20 days. The primary outcome, CGM %TIR (60–140 mg/dL), was significantly higher in the CGM group (93 ± 6 min) versus controls (88 ± 14 min; p=.027). Secondary outcomes also favored CGM, with greater daytime TIR, lower mean glucose, and less time above 140 mg/dL.

Study relevance and design limitations across both RCTs are shown in Tables 20 and 21.

Table 20. Study Relevance Limitations of RCTs for CGM in Pregnant People With Gestational Diabetes

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Amylidi-Mohr et al (2025)[48,]	4. Study cohort exhibited a lower average BMI compared with populations in other studies of women with gestational diabetes5. Single-center (university hospital)			6. Patient preferences for CGM based on low patient numbers returning the questionnaire after giving birth and wearing the blinded CGM device	
Valent et al (2025)[49,]	5. Single-center trial (academic center)	3. Study conducted prior to FDA approval of CGM device; participants had to follow safety protocols with CGM which may may not reflect pragmatic uses of current CGM in practice			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
CGM: continuous glucose monitoring; HbA1c: hemoglobin A_{1c}; RCT: randomized controlled trial.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use; 5. Enrolled study populations do not reflect relevant diversity.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 21. Study Design and Conduct Limitations of RCTs for CGM in Pregnant People With Gestational Diabetes

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Amylidi-Mohr et al (2025)[48,]		1. 43% (61 of 143) of the participants in the SMBG control group declined the use of the blinded rtCGM device.				
Valent et al (2025)[49,]					2. Not powered to determine differences in perinatal or neonatal outcomes	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
CGM: continuous glucose monitoring; CI: confidence interval; RCT: randomized controlled trial.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Section Summary: Continuous Glucose Monitoring Use in Pregnant People With Gestational Diabetes

Systematic reviews and RCTs compared CGM to SMBG in individuals with GDM. Evidence suggests CGM offers better detection of glycemic fluctuations, improved TIR, and enhanced maternal and neonatal outcomes. RCTs found CGM to be preferred by individuals and at least comparable to SMBG for TIR and glycemic control. Overall, CGM demonstrates potential benefits in GDM management to optimize glucose control.

CONTINUOUS GLUCOSE MONITORING IMPLANTED DEVICE

Clinical Context and Therapy Purpose

The purpose of an implantable CGM device is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with diabetes.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with type 1 or type 2 diabetes.

Interventions

One implantable CGM device (Eversense) is FDA cleared for use in the US. The Eversense Continuous Glucose Monitoring System is implanted in the subcutaneous skin layer and provides continuous glucose measurements over a 40 to 400 mg/dL range. The system provides real-time glucose values, glucose trends, and alerts for hypoglycemia and hyperglycemia and through a mobile application installed on a compatible mobile device platform. The Eversense CGM System is a prescription device indicated for use in adults (age 18 and older) with diabetes for up to 180 days. The device was initially approved as an adjunctive glucose monitoring device to complement information obtained from standard home blood glucose monitoring devices. Prescribing providers are required to participate in insertion and removal training certification.

Comparators

The following practice is currently being used to measure glucose levels: capillary blood sampling (finger stick) with blood glucose meters for self-monitoring.

Outcomes

The general outcomes of interest are a change in HbA1c levels, time spent in hypoglycemia, the incidence of hypoglycemic events, complications of hypoglycemia and QOL.

To assess short-term outcomes such as HbA1c levels, time spent in hypoglycemia, the incidence of hypoglycemic events, and complications of hypoglycemia, a minimum follow-up of 8 to 12 weeks is appropriate. To assess long-term outcomes such as QOL and maternal and infant outcomes, follow-up of 24 to 36 weeks would be appropriate.

Study Selection

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Randomized Studies

One trial of implantable CGM in people with diabetes has been published. Trial characteristics, results, and limitations for the RCTs are shown in Tables 22 to 25 and briefly described below.

Renard et al (2022) reported results of the multicenter France Adoption Randomized Clinical Trial (NCT03445065) comparing implantable Eversense real-time CGM (n=159) versus self-monitoring of blood glucose or intermittently scanned CGM (n=80) in individuals with type 1 or type 2 diabetes.[50,] Participants were adults, age 18 years and older, on multiple daily insulin injections or insulin pump. Participants were enrolled in 2 cohorts. Cohort 1 (n=149) included participants with type 1 or type 2 diabetes with HbA1c levels >8%. Cohort 2 (n=90) included participants with type 1 with time spent with glucose values below 70 mg/dL for more than 1.5 hours per day in the previous 28 days. The primary outcomes were changes in HbA1c at day 180 in cohort 1 and change in time spent with glucose below 54 mg/dL between days 90 and 120 in cohort 2. In cohort 1, there was no difference in HbA1c at day 180 (difference=-0.1; 95% CI, -0.4 to 0.1; p=.34) or in time in range (difference=-0.9; 95% CI, -6.7 to 4.8; p=.75). For cohort 2, the mean difference in time spent below 54 mg/dL between days 90 and 120 was statistically significant favoring implantable CGM (difference=-1.6% [23 minutes]; 95% CI, -3.1 to -0.1; p=.04). Six out of 239 (3%) participants experienced skin irritation and/or redness from sensor insertion; 5 (2%) reported itching or pruritus and 5 (2%) reported at least one hematoma formation. Results for the patient-reported outcomes were not provided, but the text indicated that there were 'no significant changes'.

Table 22. Key RCT Characteristics for implantable CGM in People With Diabetes

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	***Comparator***
Renard et al (2022) [50,]	France	20	2018-2020	Adults, age ≥18 years, with type 1 or type 2 diabetes on multiple daily insulin injections or insulin pump. Cohort 1 (n=149) included participants with type 1 or type 2 diabetes with HbA1c levels >8%; 55% female; 87% type 1 diabetes; mean age, 43 y Cohort 2 (n=90) included participants with type 1 with time spent with glucose values <70 mg/dL for >1.5 hours per day in the previous 28 days; 28% female; mean age, 46 y	'Enabled' Eversense sensor; Not allowed to use any other CGM Cohort 1 n=97 Cohort 2 n=62	Blinded Eversense sensor; Continued using SMBG or intermittently-scanned CGM Cohort 1 n=52 Cohort 2 n=28

Table 23. Summary of Key RCT Results for implantable CGM in People With Diabetes

Study	HbA1c	Blood Glucose (SD) mg/dL	Hypoglycemic Episodes	Patient Reported Outcomes
Renard et al (2022)[50,]				
Cohort 1 (type 1 or type 2, high baseline HbA1c)	At day 180, primary outcome	Time below range (<54) between day 90 and 120		
N	149	149	149	NR
Implantable CGM	8.7 (1.1)	1.2 (2.0)	0	
Control	8.8 (1.0)	1.4 (1.8)	1	
Diff (95% CI)	-0.1 (-0.4 to 0.1)	-0.1 (-0.7 to 0.4)		'No difference'
p	.34	.68		
Cohort 2 (type 1, significant time with low glucose)	At day 180	Time below range (<54) between day 90 and 120; primary outcome		
N	90	90	90	NR
Implantable CGM	7.4 (0.9)	3.9 (3.1)	0	
Control	6.9 (1.0)	6.0 (5.3)	0	
Diff (95% CI)	0.1 (-0.2 to 0.4)	-1.6 (-3.1 to -0.1)		'No difference'
p	.62	.04		

Table 24. Study Relevance Limitations of RCTs for implantable CGM in People With Diabetes

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Renard et al (2022) [50,]	5. Study conducted entirely in France; racial characteristics not reported			1. Percent of participants meeting target HbA1c goals not reported	1, 2. Follow-up limited to 180 days

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
CGM: continuous glucose monitoring; RCT: randomized controlled trial.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use; 5. Enrolled study populations do not reflect relevant diversity.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not

prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 25. Study Design and Conduct Limitations of RCTs for implantable CGM in People With Diabetes

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Renard et al (2022) [50,]		1. Control arm described as 'blinded' but only participants in the implantable CGM arms were trained to use the system and were not allowed to use other CGM while participants in the control arm were allowed to use other CGM devices	2. Several outcomes reported as no change without numeric results	1. ITT analyses were reported. However, 50% of participants had primary outcome measurements taken outside of window in cohort 1. In cohort 2, 27% of participants had less than 70% of CGM data available for the primary outcome.	1. Assumptions for power calculations not given	3, 4. Numeric results not given for several outcome measures

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
CGM: continuous glucose monitoring; RCT: randomized controlled trial.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Nonrandomized Studies

Data from 3 nonrandomized prospective studies (PRECISE, PRECISE II, AND PRECISION) were provided to the FDA for the initial approval of Eversense as an adjunctive device.[51,52,] Expanded approval was granted in June 2019 and Eversense is now approved as a device to replace fingerstick blood glucose measurements for diabetes treatment decisions.[53,] Historical data from the system can be interpreted to aid in providing therapy adjustments. No new clinical studies were conducted to support the change in the indications for the device. The sponsor had

previously performed clinical studies to establish the clinical measurement performance characteristics of the device, including accuracy across the claimed measuring range (40 to 400 mg/dL glucose), precision, claimed calibration frequency (every 12 hours), the wear period for the sensor (90 days), and performance of the alerts and notifications. This same clinical study information was used to support what the FDA considered a reasonable assurance of safety and effectiveness of the device for the replacement of fingerstick blood glucose monitoring for diabetes treatment decisions.

In 2022, Eversense was FDA approved for use up to 180 days. Approval was based on the PROMISE pivotal study, which was designed to assess the safety and accuracy of the 180-day device.[54,] PROMISE was a prospective, multicenter, unblinded, nonrandomized study of 181 adults with type 1 (69.6%) and type 2 (30.4%) diabetes conducted at 8 sites in the U.S. Participants had diabetes for at least 1 year. Participants were heterogenous with regard to diabetes treatment: 50.8% were using a continuous insulin infusion pump, 35.9% multiple daily injections of insulin, 8.8% oral diabetes medications only, and 4.4% basal insulin or only 1 injection per day (4.4%). Accuracy of the device was evaluated by comparing CGM to glucose analyzer values during 10 clinic visits. Sensors were removed after day 180. The safety endpoint was the rate of device-related or sensor insertion/removal procedure-related serious adverse events. For primary sensors, the percent CGM readings within 20% of glucose analyzer values was 92.9%; the overall mean absolute relative difference was 9.1%. There were no serious adverse events related to the device or insertion/removal procedures. There were no unanticipated adverse events and the most frequently reported adverse events were dermatological (e.g. skin irritation). All primary sensors were successfully removed on the first attempt.

In September 2024, Eversense was FDA approved for use up to 1 year. Approval was based on the ENHANCE pivotal study, which was a prospective, multicenter, nonrandomized study involving study participants with diabetes ≥18 years of age at four clinical sites in the United States.[55,]During 14 in-clinic visits, the accuracy and adverse events of the Eversense 365 CGM System were assessed by comparing it to reference glucose measurements, including during hyperglycemia and hypoglycemia challenges. A total of 110 participants had the Eversense 365 CGM System implanted. The system showed an overall mean absolute relative difference of 8.8%, with mostly one calibration per week. The confirmed alert detection rate was 96.6% for low blood sugar (70 mg/dL) and 97.9% for high blood sugar (180 mg/dL). Ninety percent (90%) of the sensors lasted the full 365 days. The Eversense 365 CGM met all special controls for interoperable CGMs and reported no serious adverse events.

Multiple post-marketing registry studies of the Eversense device have been published (Tables 26 and 27). Sanchez et al (2019) reported glucometric and safety data on the first 205 patients in the U.S. to use the Eversense device for at least 90 days.[56,] Of the 205 patients, 62.9% reported having type 1 diabetes, 8.8% type 2 diabetes, and 28.3% were unreported; results were not reported separately by diabetes type. Diess et al (2019) reported safety outcomes for 3023 patients from 534 sites in Europe and South Africa who had used the device for 6 months or longer.[57,] There were no serious adverse events, and the most commonly reported adverse events were sensor site infection and skin irritation. Tweden et al (2019) reported accuracy and safety data from 945 patients in Europe and South Africa who used either the 90-day or 180 day Eversense system for 4 insertion-removal cycles.[58,] The percentage of patients using the 180-day system increased from cycle 1 to 4 as the device became more widely available (9%, 39%, 68%

and 88% in cycles 1 to 4). There was no evidence of degradation of performance of the device over repeated insertion/removal cycles. Adverse events were not otherwise reported. Irace et al (2020) reported results of an uncontrolled study of 100 adults with type 1 diabetes at 7 centers in Italy who had the Eversense 180-day device inserted for the first time. Forty-five percent of participants were previous CGM users. Overall, HbA1c declined from a mean of 7.4% at baseline to 6.9% at 180 days (p<.0001). The greatest mean reduction was in the subgroup of participants who were CGM naive. No serious device-related adverse events occurred. There were 2 device-related adverse events: a mild incision site infection in one participant and inability to remove the device on the first attempt in a second participant. As a condition of approval, the Eversense sponsor is required to conduct a post-approval-study to evaluate the safety and effectiveness of the system compared to self-monitoring of blood glucose using a blood glucose meter in participants (N=925) with either type 1 or type 2 diabetes (NCT04836546).[53,] The study is expected to be completed in March 2026 (see Table 28).

Table 26. Postmarketing Studies of the Eversense Device- Characteristics

Study	Study Type	Country	Dates	Participants	Test/Treatment	Follow-Up
Deiss et al (2019)[57,]	Prospective, single-arm	Europe and South Africa	2016-2018	Adults (≥18 years) with T1D or T2D (% not reported) Consecutive patients who reached 4 sensor insertion/removal cycles Total N=3023; 6 months of use (N=969), 1 year of use (N=173)	Implanted CGM Single sensor (90-day or 180-day)	Up to 1 year
Sanchez et al (2019)[56,]	Prospective, single-arm	United States	2018-2019	Consecutive participants who reached a 90-day wear period of the device (62.9% T1D, 8.8% T2D, 28.3% unreported) (N=205)	Implanted CGM	90 days
Tweden et al (2019)[58,]	Prospective, single-arm	Europe and South Africa	2016-2019	Adults with T1D or T2D (% not known) for whom the Eversense CGM System was prescribed and inserted by their health care provider across approximately 1000 centers in Europe and South Africa (N=945)	Implanted CGM 90-day system or 180-day system	4 insertion-removal cycles
Irace et al (2020)[59,] NCT04160156	Prospective, single-arm	Italy	2018-2019	Adults (≥18 years) with T1D; 56% used insulin pumps and 44% used multiple daily injections of insulin; 45% were previous CGM users. Mean HbA1c 7.4% (SD 0.92%)	Implanted CGM 180-day system	180 days

CGM: continuous glucose monitoring; HbA1c: hemoglobin $A_{1c;}$ SD: standard deviation; T1D: type 1 diabetes; T2D: type 2 diabetes.

Table 27. Postmarketing Studies of the Eversense Device- Results

Study Efficacy Outcomes	Efficacy Results	Adverse Events
Deiss et al (2019)[57,]		N=3023
	NR (safety only)	133 adverse events (85 procedure-related, 22 device-related, 6 drug-related, 4 device/procedure related; 16 not related) No related serious adverse events through 4 insertion/removal cycles. infection (n=29 patients); adhesive patch irritation (n=20 patients); unsuccessful first removal attempt (n=23 patients)
Sanchez et al (2019)[56,]	N=205	N=205
MARD (glucose range 40-400 mg/dl)	11.2% (SD 11.3%, median 8.2%).	10 (5%) transient skin irritation, redness, and/or swelling. 4 (2%) mild infection, 3 (1.5%) hypoglycemia that was self-treated, 4 (2%) failure to remove the sensor on the first attempt, and 5 (2.5%) skin irritation due to the adhesive
Mean SG (mg/dL)	161.8 Median 157.2 (IQR 138.4 to 178.9)	
% SG values in hypoglycemia (<54 mg/dL), 24-hour period	1.2% (18.0 minutes)	
% SG values in hypoglycemia (<54 mg/dL), nighttime	1.7%	
TIR, 24-hour period	62.3% (~15 hours)	
TIR, nighttime	61.8%	
Time in mild hyperglycemia, 24-hour period	21.9%	
Time in mild hyperglycemia, nighttime	21.5%	
Time in significant hyperglycemia, 24-hour period	11.6%	
Time in significant hyperglycemia, nighttime	12.1%	
Tweden et al (2019)[58,]		No evidence of degradation of performance from the repeated insertion and removal procedures occurring in approximately the same subcutaneous tissue of the body. Adverse events otherwise not reported.
MARD (glucose range 40-400 mg/dl)	Mean 11.5% to 11.9% during each sensor cycle	
Mean SG (mg/dL)	156.5 to 158.2 mg/dL across 4 sensor cycles	

Study Efficacy Outcomes	Efficacy Results	Adverse Events
% SG values in significant hypoglycemia (<54 mg/dL), 24-hour period	1.1% to 1.3% (16 to 19 minutes)	
% SG values in significant hypoglycemia (<70 mg/dL), 24-hour period	4.6% to 5.0% (66 to 72 minutes)	
TIR, 24-hour period	63.2% to 64.5% (910 to 929 minutes)	
Time in hyperglycemia (>180-250 mg/dL), 24-hour period	22.8% to 23.2% (328 to 334 minutes)	
Time in significant hyperglycemia (>250 mg/dL), 24-hour period	8.1% to 8.8% (117 to 127 minutes)	
Irace et al (2020)[59,]		No serious device-related adverse events occurred. There were 2 device-related adverse events: A mild incision site infection in one participant and inability to remove the device on the first attempt in a second participant.
HbA1c change from baseline % (SD)	7.4 % (0.92) to 6.9 (0.76)	
Mean change from baseline to 180 days, % (SD)	0.43 (0.69); p<.001	
Time in range change from baseline	63% to 69%	
Mean change from baseline to 18 days	6%; p<.0001	

CGM: continuous glucose monitoring; HbA1c: hemoglobin $A_{1c;}$ IQR: interquartile range; MARD: mean absolute relative difference; NR: not reported; SD: standard deviation; SG: sensor glucose; TIR: time in range.

Section Summary: Continuous Glucose Monitoring Implanted Device for Long-Term Use

One RCT compared implantable CGM with control (self-monitoring of blood glucose or intermittently scanned CGM). The RCT was conducted in France and enrolled participants in 2 cohorts; cohort 1 (n=149) included participants with type 1 or type 2 diabetes with HbA1c >8.0% while cohort 2 (n=90) included participants with type 1 diabetes with time spent with glucose values below 70 mg/dL for more than 1.5 hours per day in the previous 28 days. In cohort 1, there was no difference in mean HbA1c, time in range, or patient-reported outcomes at day 180. In cohort 2, the mean difference in time spent below 54 mg/dL between days 90 and 120 was statistically significant favoring implantable CGM (difference=-1.6% [23 minutes]; 95% CI, -3.1 to -0.1; p=.04). There were no differences in patient reported outcomes.

Nonrandomized prospective studies and postmarketing registry studies assessed the accuracy and safety of an implanted glucose monitoring system that provides CGM for up to 4 insertion/removal cycles as an adjunct to home glucose monitoring devices. Accuracy measures included the mean absolute relative difference between paired samples from the implanted device and a reference standard blood glucose measurement. The accuracy tended to be lower in

hypoglycemic ranges. The initial approval of the device has been expanded to allow the device to be used for glucose management decision making. The same clinical study information was used to support what the FDA considered a reasonable assurance of safety and effectiveness of the device for the replacement of fingerstick blood glucose monitoring for diabetes treatment decisions. In February 2022, the FDA expanded approval of the device for use up to 180 days. Approval was based on the PROMISE pivotal clinical trial, which assessed accuracy and safety but not glycemic outcomes. In September 2024, Eversense was FDA approved for use up to 1 year based on the ENHANCE pivotal clinical trial, a prospective, multicenter, nonrandomized study involving study participants with diabetes ≥18 years of age at four clinical sites in the United States. These studies indicate that the device provides accuracy comparable to laboratory blood glucose testing, aligning with established standards. The latest ADA Standards of Care in Diabetes (2025) recognize implantable devices as equivalent to non-implantable devices.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2019 Input

Clinical input was sought to help determine whether the use of continuous or intermittent monitoring of glucose in the interstitial fluid would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 3 respondents, including 3 physician-level responses identified through 1 specialty society, including 2 physicians with academic medical center affiliations.

Type 1 Diabetes

For individuals who have type 1 diabetes who receive short-term glucose monitoring, clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice when used in specific situations such as poor control of type 1 diabetes despite the use of best practices and to help determine basal insulin levels prior to insulin pump initiation.

Type 2 Diabetes

For individuals who have type 2 diabetes who do not require insulin who receive long-term continuous glucose monitoring (CGM), clinical input does not support a clinically meaningful improvement in net health outcome and does not indicate this use is consistent with generally accepted medical practice.

For individuals with type 2 diabetes who are willing and able to use the device and have adequate medical supervision and who experience significant hypoglycemia on multiple daily doses of insulin or an insulin pump in the setting of insulin deficiency who receive long-term continuous glucose monitoring, clinical input supports that this use provides a clinically

meaningful improvement in net health outcome and is consistent with generally accepted medical practice.

For individuals with type 2 diabetes who require multiple daily doses of insulin who receive short-term CGM, clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice when used in specific situations such as poor control of diabetes despite use of best practices and to help determine basal insulin levels prior to insulin pump initiation.

Further details from clinical input are included in the Appendix.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

The 2025 American Diabetes Association (ADA) "Standards of Medical Care in Diabetes" support the use of CGM to help achieve glycemic targets, including TIR and time above range, as well as A1C goals during pregnancy for individuals with type 1 diabetes.[60,] CGM may also benefit those with other types of diabetes during pregnancy. This guidance is informed by a evidence review which includes 1 multicenter international RCT (Feig et al, 2017 discussed in the previous section); 3 observational studies (published between 2017 and 2024) for type 1 diabetes; and 2 qualitative systematic reviews (from 2021 and 2022) focused on type 2 diabetes. The American Association of Clinical Endocrinology (AACE, 2021)[61,] also supports CGM use for women with gestational diabetes who are either on insulin therapy or not on insulin therapy (see below).

American Association of Clinical Endocrinology
In 2023, the American Association of Clinical Endocrinology (AACE) published an updated consensus statement on an algorithm for type 2 diabetes management. A subset of the statements regarding CGM are below.[62,]

- "CGM is highly recommended to assist persons with diabetes in reaching goals safely. CGM has provided a major advance in the treatment of persons with all forms of DM."
- "The use of CGM is recommended for persons treated with insulin to optimize glycemic control while minimizing hypoglycemia."

In 2022, AACE published clinical practice guideline for developing diabetes care plans and made the following recommendations (level of evidence) on CGM:[63,]

- "All persons who use insulin should use continuous glucose monitoring (CGM) or perform blood glucose monitoring (BGM) a minimum of twice daily and ideally before any insulin injection." **(Grade A; Best Evidence Level 1)**
- "Real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM) is recommended for all persons with T1D [type 1 diabetes], regardless of insulin delivery system, to improve A1C levels and to reduce the risk for hypoglycemia and DKA." **(Grade A; Best Evidence Level 1)**

- "rtCGM or isCGM is recommended for persons with T2D [type 2 diabetes] who are treated with insulin therapy, or who have high risk for hypoglycemia and/or with hypoglycemia unawareness." **(Grade A; Best Evidence Level 1)**

In 2021, AACE published recommendations on the use of advanced technology in the management of diabetes and made the following recommendations (level of evidence) on CGM:[61,]

- CGM is strongly recommended for all persons with diabetes treated with intensive insulin therapy, defined as 3 or more injections of insulin per day or the use of an insulin pump. (**Grade A; High Strength of Evidence**)
- CGM is recommended for all individuals with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness).(**Grade A; Intermediate-High Strength of Evidence**)
- CGM is recommended for children/adolescents with T1D. (**Grade A; Intermediate-High Strength of Evidence**)
- CGM is recommended for pregnant women with T1D and T2D treated with intensive insulin therapy. (**Grade A; Intermediate-High Strength of Evidence**)
- CGM is recommended for women with gestational diabetes mellitus (GDM) on insulin therapy. (**Grade A; Intermediate Strength of Evidence**)
- CGM may be recommended for women with GDM who are not on insulin therapy. (**Grade B; Intermediate Strength of Evidence**)
- CGM may be recommended for individuals with T2D who are treated with less intensive insulin therapy. (**Grade B; Intermediate Strength of Evidence**)

American Diabetes Association
The American Diabetes Association (ADA) "Standards of Medical Care in Diabetes", particularly regarding CGM, have evolved significantly over the past years. Key changes in 2025 include broader recommendations for CGM use, increased emphasis on time in range (TIR), and expanded access to CGM technology for various populations.

The ADA recommendations (**level of evidence**) regarding the use of CGM state:[2,]

7. Diabetes Technology: Standards of Care in Diabetes - 2025[64,]

- "7.2 Initiation of continuous glucose monitoring (CGM) should be offered to people with type 1 diabetes early in the disease, even at time of diagnosis. **(A)**
- 7.3 The type(s) and selection of devices should be individualized based on a person's specific needs, preferences, and skill level. In the setting of an individual whose diabetes is partially or wholly managed by someone else (e.g., a young child or a person with cognitive impairment or dexterity, psychosocial, and/or physical limitations), the caregiver's skills and preferences are integral to the decision-making process. **(E)**
- 7.4 When prescribing a device, ensure that people with diabetes and caregivers receive initial and ongoing education and training, either in person or remotely, and ongoing evaluation of technique, results, and the ability to utilize data, including uploading/sharing data (if applicable), to monitor and adjust therapy. **(C)**
- 7.6 People with diabetes who have been using CGM, continuous subcutaneous insulin infusion (CSII), and/or automated insulin delivery (AID) for diabetes management should have continued access across third-party payors, regardless of age or A1C levels. **(E)**

- 7.8 Recommend early initiation, including at diagnosis, of CGM, CSII, and AID depending on a person's or caregiver's needs and preferences. **(C)**
- 7.15 Recommend real-time CGM (rtCGM) A or intermittently scanned CGM (isCGM) for diabetes management to youth **(C)** and adults **(B)** with diabetes on any type of insulin therapy. The choice of CGM device should be made based on the individual's circumstances, preferences, and needs.
- 7.16 Consider using rtCGM and isCGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals. The choice of device should be made based on the individual's circumstances, preferences, and needs. **(B)**
- 7.17 In people with diabetes on insulin therapy, rtCGM devices should be used as close to daily as possible for maximal benefit. **(A)** isCGM devices should be scanned frequently, at minimum once every 8 h, to avoid gaps in data. **A** People with diabetes should have uninterrupted access to their supplies to minimize gaps in CGM. **(A)**
- 7.18 CGM can help achieve glycemic goals (e.g., time in range and time above range) **(A)** and A1C goal **(B)** in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy. **(E)**
- 7.19 In circumstances when consistent use of CGM is not feasible, consider periodic use of personal or professional CGM to adjust medication and/or lifestyle. **C**"

14. Children and Adolescents: Standards of Care in Diabetes - 2025[65,]

- "14.8 Advise frequent glucose monitoring before, during, and after exercise, via blood glucose meter and/or continuous glucose monitoring (CGM), is important to prevent, detect, and treat hypoglycemia and hyperglycemia associated with exercise. **(C)**
- 14.18 All youth with type 1 diabetes should monitor glucose levels multiple times daily (up to 10 times/day by blood glucose meter or CGM), including prior to meals and snacks, at bedtime, and as needed for safety in specific situations such as physical activity, driving, or the presence of symptoms of hypoglycemia. **(B)**
- 14.19 Real-time CGM **(A)** or intermittently scanned CGM **(E)** should be offered for diabetes management at diagnosis or as soon as possible in youth with diabetes on multiple daily injections or insulin pump therapy who are capable of using the device safely (either by themselves or with caregivers). The choice of device should be made based on the individual's and family's circumstances, desires, and needs.
- 14.23 A1C goals must be individualized and reassessed over time. An A1C of <7% (<53 mmol/mol) is appropriate for many children and adolescents. **(B)**
- 14.24 Less stringent A1C goals (such as <7.5% [<58 mmol/mol]) may be appropriate for youth who cannot articulate symptoms of hypoglycemia; have hypoglycemia unawareness; lack advanced insulin delivery technology and/or CGM; cannot check blood glucose regularly; or have nonglycemic factors that increase A1C (e.g., high glycators). **(B)**
- 14.25 Even less stringent A1C goals (such as <8% [<64 mmol/mol]) may be appropriate for individuals with a history of severe hypoglycemia, limited life expectancy or where the harms of treatment are greater than the benefits. **(B)**
- 14.26 Health care professionals may reasonably suggest more stringent A1C goals (such as <6.5% [<48 mmol/mol]) for selected individuals if they can be achieved without significant hypoglycemia, excessive weight gain, negative impacts on well-being, or undue burden of care or in those who have nonglycemic factors that decrease A1C (e.g., lower

erythrocyte life span). Lower goals may also be appropriate during the honeymoon phase. **(B)**
- 14.27 CGM metrics derived from continuous glucose monitor use over the most recent 14 days (or longer for youth with more glycemic variability), including time in range (70-180 mg/dL [3.9-10.0 mmol/L]), time below range (<70 mg/dL [<3.9 mmol/L] and <54 mg/dL [<3.0 mmol/L]), and time above range (>180 mg/dL [>10.0 mmol/L] and >250 mg/dL [>13.9 mmol/L]), are recommended to be used in conjunction with A1C whenever possible. **(E)**
- 14.58 Real-time CGM or intermittently scanned CGM should be offered for diabetes management in youth with type 2 diabetes on multiple daily injections or insulin pumps who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on an individual's and family's circumstances, desires, and needs. **(E)**
- 14.60 Consider setting an A1C goal of <6.5% (<48 mmol/mol)] for most children and adolescents with type 2 diabetes who have a low risk of hypoglycemia. For those at higher risk of hypoglycemia, A1C goals should be individualized as clinically appropriate. **(C)**"

15. Management of Diabetes in Pregnancy: Standards of Care in Diabetes - 2025[60,]
- "15.9 Due to increased red blood cell turnover, A1C is slightly lower during pregnancy in people with and without diabetes. Ideally, the A1C goal in pregnancy is <6% (<42 mmol/mol) if this can be achieved without significant hypoglycemia, but the goal may be relaxed to <7% (<53 mmol/mol) if necessary to prevent hypoglycemia. **(B)**
- 15.10 Continuous glucose monitoring (CGM) can help to achieve glycemic goals (e.g., time in range, time above range) **(A)** and A1C goal **(B)** in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy. **(E)**
- 15.11 Recommend CGM to pregnant individuals with type 1 diabetes. **(A)** In conjunction with aims to achieve traditional pre- and postprandial glycemic goals, real-time CGM can reduce the risk for large-for-gestational-age infants and neonatal hypoglycemia in pregnancy complicated by type 1 diabetes. **(A)**
- 15.12 CGM metrics may be used in combination with blood glucose monitoring to achieve optimal pre- and postprandial glycemic goals. **(E)**"

Endocrine Society

The Endocrine Society (2023) published clinical practice guidelines of management of individuals at high risk of hypoglycemia and included the following recommendations on CGM:[66,]
- "Recommendation 1 - We recommend continuous glucose monitoring (CGM) rather than self-monitoring of blood glucose (SMBG) by fingerstick for patients with type 1 diabetes (T1D) receiving multiple daily injections (MDIs). (1⊕⊕OO) (Strong recommendation, Low certainty of evidence)
- Recommendation 2 - We suggest using real-time continuous glucose monitoring (CGM) and algorithm-driven insulin pumps (ADIPs) rather than multiple daily injections (MDIs) with self-monitoring of blood glucose (SMBG) three or more times daily for adults and children with type 1 diabetes (T1D). (2⊕⊕OO) (Conditional recommendation, Low certainty of evidence)
- Recommendation 3 - We suggest real-time continuous glucose monitoring (CGM) be used rather than no continuous glucose monitoring (CGM) for outpatients with type 2 diabetes

(T2D) who take insulin and/or sulfonylureas (SUs) and are at risk for hypoglycemia. (2⊕OOO) (Conditional recommendation, Very Low certainty of evidence)
- Recommendation 4 - We suggest initiation of continuous glucose monitoring (CGM) in the inpatient setting for select inpatients at high risk for hypoglycemia. (2⊕OOO) (Conditional recommendation, Very Low certainty of evidence)
- Recommendation 5 - We suggest continuation of personal continuous glucose monitoring (CGM) in the inpatient setting with or without algorithm-driven insulin pump (ADIP) therapy rather than discontinuation. (2⊕OOO) (Conditional recommendation, Very Low certainty of evidence)"

The Endocrine Society (2016) published clinical practice guidelines that included the following recommendations on CGM[67,]:

6. Real-time continuous glucose monitors in adult outpatients

- "We recommend real-time continuous glucose monitoring (RT-CGM) devices for adult patients with T1DM who have A1C levels above target and who are willing and able to use these devices on a nearly daily basis. (Strong recommendation, High certainty of evidence)
- We recommend RT-CGM devices for adult patients with well-controlled T1DM who are willing and able to use these devices on a nearly daily basis. (Strong recommendation, High certainty of evidence)"

Use of continuous glucose monitoring in adults with type 2 diabetes mellitus [T2DM]

- "We suggest short-term, intermittent RT-CGM use in adult patients with T2DM (not on prandial insulin) who have A1C levels ≥7% and are willing and able to use the device. (Weak recommendation, Low certainty of evidence)"

National Institute for Health and Care Excellence

In 2022, the National Institute for Health and Care Excellence (NICE) updated its guidance on management of type 1[68,] and type 2[69,] diabetes. The guidance included the following updated recommendations on CGM (refer to source documents for complete guidance):

Type 1 Diabetes

- "Offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash'), based on their individual preferences, needs, characteristics, and the functionality of the devices available. "

"When choosing a (CGM) device:

- use shared decision making to identify the person's needs and preferences, and offer them an appropriate device
- if multiple devices meet their needs and preferences, offer the device with the lowest cost"[68,]

Type 2 Diabetes

"Offer intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') to adults with type 2 diabetes on multiple daily insulin injections if any of the following apply:

- they have recurrent hypoglycemia or severe hypoglycemia

- they have impaired hypoglycemia awareness
- they have a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them)
- they would otherwise be advised to self-measure at least 8 times a day."

"Offer isCGM to adults with insulin-treated type 2 diabetes who would otherwise need help from a care worker or healthcare professional to monitor their blood glucose."

"Consider real-time continuous glucose monitoring (rtCGM) as an alternative to isCGM for adults with insulin-treated type 2 diabetes if it is available for the same or lower cost."[69,]

The guidance and accompanying evidence review do not specifically mention implantable CGM devices.

U.S. Preventive Services Task Force Recommendations
Not applicable.

CGM with an Implantable Device
In 2020, Medicare assigned relative value units to the insertion, removal and removal/reinsertion codes uses for provision of the implantable glucose sensor device.

In 2024, the CMS issued a local coverage decision on Implantable Continuous Glucose Monitors (I-CGM) (L38743).[72,]

- Therapeutic I-CGMs are considered reasonable and necessary by Medicare when all of four coverage criteria (1-4) are met.
    1. The beneficiary has diabetes mellitus (DM); **and**,
    2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the I-CGM prescribed as evidenced by providing a prescription; **and**,
    3. The I-CGM is prescribed in accordance with its FDA indications for use; **and**,
    4. The beneficiary for whom an I-CGM is being prescribed, to improve glycemic control, meets at least 1 of the criteria below:
        a. The beneficiary is insulin-treated; **or**,
        b. The beneficiary has a history of problematic hypoglycemia with documentation of at least 1 (of 2) specified hypoglycemic events.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 27.

Table 27. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04836546[a]	A Post Approval Study to Evaluate the Safety and Effectiveness of the Eversense® Continuous Glucose Monitoring (CGM) System Used Non-adjunctively	925	Mar 2026 (last update posted: Aug 2025)
Unpublished			
NCT03981328	The Effectiveness of Real Time Continuous Glucose Monitoring to Improve Glycemic Control and Pregnancy Outcome in Patients With Gestational Diabetes Mellitus	375	Feb 2025
NCT03908125[a]	A Post- Approval Study to Evaluate the Long-term Safety and Effectiveness of the Eversense® Continuous Glucose Monitoring (CGM) System	273	Feb 2024

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report
99091	Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation
A4238	Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial continuous glucose monitoring system, one unit = 1 day supply
A9277	Transmitter; external, for use with non-durable medical equipment interstitial continuous glucose monitoring system

CPT/HCPCS	
A9278	Receiver (monitor); external, for use with non-durable medical equipment interstitial continuous glucose monitoring system
E2102	Adjunctive, non-implanted continuous glucose monitor or receiver
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver
S1030	Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)

REVISIONS	
01-26-2004	Deleted "Certain diabetic and newly pregnant or who are about to conceive" and "Patients who are about to start insulin for the first time using an insulin pump regimen"
	Added "Suboptimal glycemic control as reflected by a glycohemoglobin (HbA1c) value of greater than 7.0 percent."
	Added "Repeat testing for Continuous Glucose Monitoring System® (CGMS®): a. Prior Approval is recommended; and b. Patient is compliant on a prescribed intensive insulin program/therapy; and c. May occur four to six weeks following the initial study."
	Added "Use of noninvasive continuous glucose monitoring devices (e.g. Gluco Watch Biographer®) and related supplies is considered experimental/investigational for all indications."
04-21-2005	Added the definition of "intensive insulin therapy".
	Added, "The use of combined insulin, such as 70/30 insulin did not meet the criteria for "program involvement" of multiple daily injections."
11-02-2006 effective 01-02-2007	In "Description" section, deleted the paragraph starting with "The GlucoWatch is similar in appearance to a wristwatch that is worn on the inner or" as recommended by the Medical Director.
	In "Description" section, deleted the paragraph starting with "Although the noninvasiveness is an attractive quality of the device, it should be…" as recommended by the Medical Director..
	In "Description" section, deleted "For calibration purposes, the manufacturer recommends that the patient enter the results of 4 fingerstick blood glucose measurements per day into the monitor. For the Guardian CGMS, it is recommended that the device be calibrated with fingerstick blood glucose levels every 12 hours at a minimum. The Guardian CGMS does feature an audible alarm that sounds when glucose levels become too high or too low per parameters set by the patient and physician." as recommended by the Medical Director.
	In "Description" section, deleted the paragraph starting with "The definition of 'Intensive Insulin Therapy' is the use of an insulin regimen that…" as recommended by the Medical Director..
	In "Policy" section, first paragraph, added "(multiple daily injections (MDI) of 4-5 injections of insulin per day or insulin pump)." as recommended by the Medical Director.
	In "Policy" section, deleted "and one of the following conditions have been met:" and the "or" at the end of #1, #2, and #3 sentences per November MAC.
	In "Policy" section, added to the end of the opening sentence "The following conditions will be considered to determine medical necessity:" per November MAC.
	In "Policy" section, added "Unexplained" to the beginning of #3 and #4 per November MAC.
	In "Documentation" section, deleted "Program Involvement (all required):" as

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	recommended by the Medical Director.
	In "Documentation" section, deleted #2 "Basal insulin usually involves "Ultralente" and "Lantus" insulin." as recommended by the Medical Director.
	In "Documentation" section, deleted #3 "Bolus insulin (insulin analogue) usually involves "Humalog" or "Novolog" insulin." as recommended by the Medical Director.
	In "Coding" Covered Diagnosis, deleted ICD-9 codes (for type II) 250.00, 250.02, 250.10, 250.12, 250.20, 250.22, 250.30, 250.32, 250.40, 250.42, 250.50, 250.52, 250.60, 250.62, 250.70, 250.72, 250.80, 250.82, 250.90, and 250.92 as recommended by the Medical Director.
	In "Reference" Government Agency; Medical Society; and Other Authoritative Publications section, added new #3 through #7.
07-17-2007	In Policy section: ▪ Added clarification to policy that continuous glucose monitoring system is limited to 72 hours. Extended use beyond 72 hours is considered patient deluxe, patient responsibility/non-covered. In Coding section: ▪ Removed code 99091.
01-01-2008	In Coding section: ▪ Added codes and nomenclature for A9276, A9277, A9278.
09-03-2008	In Coding section: ▪ Added codes and nomenclature for S1030, S1031. ▪ Corrected nomenclature for 95250.
	In Policy section: Revised wording from "requires prior approval" to "prior approval is encouraged".
09-09-2009	In Header: ▪ Revised title from Continuous Glucose Monitoring System (CGMS) to Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid. In Description section: ▪ Updated wording. In Policy section: ▪ Updated wording on intermittent monitoring, no change in policy position. ▪ Added indication of: Continuous, i.e., long-term, monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique of diabetic monitoring, may be considered medically necessary when the following situations occur despite use of best practices: • Patients with type I diabetes who have recurrent, unexplained, severe, symptomatic (generally blood glucose levels less than 50 mg/dl) hypoglycemia for whom hypoglycemia puts the patient or others at risk; or • Patients with type I diabetes who have recurrent diabetic ketoacidosis (DKA) requiring emergency room visits and admissions. • Patients with type I diabetes who are pregnant whose diabetes is poorly controlled. Poorly controlled type I diabetes includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis. Other uses of continuous monitoring of glucose levels in interstitial fluid as a technique of diabetic monitoring are considered investigational.
	Added Rationale section.
	In Coding section: ▪ Added CPT/HCPCS codes: 99091, A9278 ▪ Added Diagnoses codes: 648.80, 648.83

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03-25-2011	In Policy Guidelines section: ▪ Added "or multiple daily injections" to read "Best practices in diabetes control for patients with type I diabetes include compliance with a regimen of 4 or more finger sticks each day and the use of an insulin pump, or multiple daily injections."
	Updated Reference section.
10-04-2013	Updated Description section.
	In Policy section: ▪ Formatted medical policy language. ▪ In Item C, #1, removed "symptomatic" to read "Patients with type I diabetes who have recurrent, unexplained, severe (generally blood glucose levels less than 50 mg/.dl) hypoglycemia…" ▪ In Item D, inserted "experimental/" to read "Other uses of continuous monitoring of glucose levels in interstitial fluid as a technique of diabetic monitoring are considered experimental / investigational." ▪ Added Item E, "Use of artificial pancreas system, including but not limited to closed-loop monitoring devices with low-glucose suspend (LGS) features, are considered experimental / investigational." ▪ In Policy Guidelines, add the following statements: o "Several insulin pump systems (e.g., Omnipod Insulin Management System, Paradigm REAL-Time System) have a built-in continuous glucose monitor (CGM). This policy is evaluating the CGM-device only; the policy does not evaluate insulin pumps. In the case of insulin pumps systems with built-in CGM and low glucose feature, the CGM device and the low glucose suspend feature are evaluated in the policy, not the insulin pump." o "The strongest evidence exists for use of the CGM devices in patients age 25 and older. However, age may be a proxy for motivation and good control of disease, so it is also reasonable to select patients based on their ability to self-manage their disease rather than age."
	In Coding section: ▪ Added ICD-10 Diagnosis *(Effective October 1, 2014)*
	Updated Reference section.
03-06-2015	Updated Description section.
	In Policy section: ▪ Removed Item E, "Use of an artificial pancreas system, including but not limited to closed loop monitoring devices with low glucose suspend (LGS) features, are considered experimental/investigational."
	In Policy Guidelines section: ▪ In Item #2, removed "type I" and added "mellitus" to read, "Best practices in diabetes control for patients with diabetes mellitus include compliance with a regimen …" ▪ In Item #3, added "mellitus" to read, "Women with type I diabetes mellitus who are present or about to become …" ▪ In Item #4, removed "four weeks depending on the patient's level of diabetes control and medical necessity", and added "a subsequent time depending on the patient's level of diabetes control", to read, "Intermittent monitoring is generally conducted in 72-hour periods. It may be repeated at a subsequent time depending on the patient's level of diabetes control."
	Updated Rationale section.
	Updated References section.
08-04-2016	Updated Description section.
	In Policy section: ▪ In Policy Guidelines Item 1, removed "Omnipod Insulin Management System," to read

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	"Several insulin pump systems (e.g., Paradigm® REAL-Time System) have a built-in continuous glucose monitor (CGM). This policy is evaluating the CGM-device only; the policy does not evaluate insulin pumps. In the case of insulin pumps systems with a built-in CGM and low glucose suspend (LGS) feature, the CGM device and the low glucose suspend feature are evaluated in the policy, not the insulin pump."
	Updated Rationale section.
	Updated References section.
10-01-2016	In Coding section: ▪ Added ICD-10 codes effective 10-01-2016: E10.3211, E10.3212, E10.3213, E10.3291, E10.3292, E10.3293, E10.3311, E10.3312, E10.3313, E10.3391, E10.3392, E10.3393, E10.3411, E10.3412, E10.3413, E10.3491, E10.3492, E10.3493, E10.3511, E10.3512, E10.3513, E10.3521, E10.3522, E10.3523, E10.3531, E10.3532, E10.3533, E10.3541, E10.3542, E10.3543, E10.3551, E10.3552, E10.3553, 310.3591, E10.3592, E10.3593, E10.37X1, E10.37X2, E10.37X3, O24.415 ▪ Termed ICD-10 codes effective 09-30-2016: E10.321, E10.329, E10.331, E10.339, E10.341, E10.349, E10.351, E10.359
11-22-2016	In Policy section: ▪ In Policy Guidelines Item 3, removed "Women" and added "Individuals" to read, "Individuals with type I diabetes mellitus who are pregnant or about to become pregnant with poorly controlled diabetes are another subset of patients to whom the policy statement on intermittent monitoring may apply."
	In Coding section: ▪ Added CPT codes: 0446T, 0447T, 0448T.
07-01-2017	In Coding section: ▪ Added HCPCS codes: K0553, K0554 (Effective July 1, 2017).
09-01-2017	Updated Description section.
	In Policy section: ▪ In Item A, removed "mellitus" to read, "Intermittent monitoring, i.e., up to 72 hours, of glucose levels in interstitial fluid may be considered medically necessary in patients with type 1 diabetes whose diabetes is poorly controlled, despite current use of best practices (see Policy Guidelines). Poorly controlled type 1 diabetes includes the following clinical situations:" ▪ In Item C 1, added "or impaired awareness of hypoglycemia that" and removed "for whom hypoglycemia" to read, "Patients with type 1 diabetes who have recurrent, unexplained, severe (generally blood glucose levels less than 50 mg/dL) hypoglycemia or impaired awareness of hypoglycemia that puts the patient or others at risk;" ▪ Added new Item C 3, "Patients with poorly controlled type 1 diabetes who are pregnant. Poorly controlled type 1 diabetes includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis;" ▪ Updated Policy Guidelines.
	Updated Rationale section.
	Updated References section.
12-01-2017	In Policy section: ▪ In Policy Guidelines, Item 2, added "an average of", "(at least 30 days [1 month] prior to initiation)", and "or multiple daily injections. Compliance will also be required for other aspects of diabetic management including insulin bolusing or diet." to read, "Best practices in diabetes control include compliance with a regimen of 4 or more finger sticks each day (at least 30 days [1 month] prior to initiation) and use of an insulin pump or multiple daily injections. Compliance will also be required for other aspects of diabetic management including insulin bolusing or diet."

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	In Coding section: ▪ Added ICD-10 codes: O24.011, O24.012, O24.013. ▪ Removed ICD-10 codes: O24.410, O24.414, O24.415, O24.419, O99.810.
01-01-2018	In Coding section: ▪ Added CPT code: 95249. ▪ Revised nomenclature to CPT codes: 95250, 95251. ▪ Removed ICD-9 codes.
05-11-2018	Updated Description section.
	In Policy section: ▪ In Item D, added "and intermittent" to read, "Other uses of continuous and intermittent monitoring of glucose levels in interstitial fluid as a technique of diabetic monitoring are considered experimental / investigational."
	Updated Rationale section.
	Updated References section.
11-07-2018	In Policy section: ▪ Updated Policy Guidelines.
	Updated References section.
01-16-2019	Updated Description section.
	Updated Rationale section.
	In Revisions section: ▪ In Revision of 09-09-2009, CPT code 99091 was not added to the policy at that time and will remain omitted from the policy.
	Updated References section.
10-15-2020	Policy published 09-02-2020. Policy effective 10-15-2020
	Title of policy revised from • Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid to Continuous Glucose Monitoring Systems
	Updated Description section.
	In Policy section: • In Item A, added "glucose" to read, "Long-term continuous glucose monitoring of glucose levels in interstitial fluid, as a technique of diabetic monitoring, may be considered medically necessary when the following situations occur, despite use of best practices:" • Added new Item B, "Long-term continuous glucose monitoring of glucose levels in interstitial fluid may be considered medically necessary in patients with type 2 diabetes in: 1. Patients who are willing and able to use the device; AND 2. Patients who have adequate medical supervision; AND 3. Patients who experience significant hypoglycemia on 4 or more daily doses of insulin or on an insulin pump in the setting of insulin deficiency." • In Item C (previous Item B), removed "intermittent" and added "short-term continuous glucose" to read, "Short-term continuous glucose monitoring, of glucose levels in interstitial fluid may be considered *medically necessary* in patients with type 1 diabetes whose diabetes is poorly controlled, despite current use of best practices (see Policy Guidelines). Poorly controlled type 1 diabetes includes the following clinical situations:" • In Item C, removed "intermittent" and added "short-term continuous glucose" to read, "Short-term continuous glucose monitoring, of glucose levels in interstitial fluid may be considered medically necessary in patients with type 1 diabetes whose diabetes is poorly controlled, despite current use of best practices (see Policy Guidelines). Poorly controlled type 1 diabetes includes the following clinical situations:

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	• In Item D, "Short-term continuous glucose monitoring of glucose levels in interstitial fluid may be considered medically necessary in patients with type 2 diabetes who require multiple daily doses of insulin whose diabetes is poorly controlled, despite current use of best practices (see Policy Guidelines #2). Poorly controlled type 2 diabetes includes the following clinical situations: 1. Unexplained hypoglycemic episodes; OR 2. Hypoglycemic unawareness; OR 3. Persistent hyperglycemia and A1C levels above target." • Added new Item E, "Short-term continuous glucose monitoring of glucose levels in interstitial fluid may be considered medically necessary in patients with type 2 diabetes who require multiple daily doses of insulin to determine basal insulin levels prior to insulin pump initiation." In Item F (previous Item D), removed "continuous and intermittent" and added "long-term or short-term continuous glucose" and "including use in gestational diabetes" to read, "Other uses of long-term or short-term continuous glucose monitoring of glucose levels in interstitial fluid as a technique of diabetic monitoring, including gestational diabetes, are considered experimental /investigational."
	Updated Policy Guidelines.
	Updated Rationale section.
	In Coding section: Added ICD-10 codes: E11.00, E11.01, E11.10, E11.11, E11.21, E11.22, E11.29, E11.311, E11.319, E11.3211, E11.3212, E11.3213, E11.3291, E11.3292, E11.3293, E11.3311, E11.3312, E11.3313, E11.3391, E11.3392, E11.3393, E11.3411, E11.3412, E11.3413, E11.3491, E11.3492, E11.3493, E11.3511, E11.3512, E11.3513, E11.3521, E11.3522, E11.3523, E11.3531, E11.3532, E11.3533, E11.3541, E11.3542, E11.3543, E11.3551, E11.3552, E11.3533, E11.3591, E11.3592, E11.3593, E11.36, E11.37X1, E11.37X2, E11.37X3, E11.39, E11.40, E11.41, E11.42, E11.43, E11.44, E11.49, E11.51, E11.52, E11.59, E11.610, E11.618, E11.620, E11.621, E11.622, E11.628, E11.630, E11.638, E11.641, E11.649, E11.65, E11.69, E11.8, E11.9.
	Updated References section.
02-25-2021	Updated Description section
	Updated Rationale
	In the coding section: ▪ Removed ICD-10 codes O24.011, O24.012, and O24.013
	Updated Reference section
	Added Appendix
1-26-2022	Changed Title to Continuous Glucose Monitoring
	Updated Description Section
	Updated Policy Section ▪ Section A added phrase "device monitoring"
	Updated Policy Guideline Section ▪ Section B and E changed intermittent to "continuous glucose" ▪ Section C removed "(at least 30 days [1 month] prior to initiation)" and "Compliance will also be required for other aspects of diabetic management including insulin bolusing or diet" ▪ Section F added "Multiple continuous glucose monitoring (CGM) devices have U.S. Food and Drug Administration labeling related to age"
	Updated Rationale Section
	Updated Code Section ▪ Changed ICD-10 Codes to code range
	Updated References Section
02-16-2022	In Policy Section:

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	▪ Deleted Item G: "The use of intermittently scanned (flash) CGM devices is considered experimental / investigational."
07-01-2022	Updated Coding Section ▪ Added: G0308, G0309
09-13-2022	Updated Description Section
	Updated Policy Section ▪ Policy section reformatted; content unchanged
	Updated Rationale Section
	Updated References Section
01-03-2023	Updated Coding Section ▪ Removed deleted codes K0553 and K0554 ▪ Added codes A4238, A4239, E2102, and E2103 ▪ Updated nomenclature for A9276, A9277 and A9278
08-22-2023	Updated Description Section
	Updated Policy Section ▪ Section A1 Removed: o "when the following situations occur, despite use of best practices:" and o A1b-d "b. Individuals with type 1 diabetes who have recurrent, unexplained, severe (generally blood glucose levels less than 50 mg/dL) hypoglycemia or impaired awareness of hypoglycemia that puts the patient or others at risk; OR c. Individuals with poorly controlled type 1 diabetes who are pregnant. Poorly controlled type 1 diabetes includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis; OR d. Individuals with type 1 diabetes who have recurrent diabetic ketoacidosis (DKA) requiring emergency room visits and admissions" ▪ Added Section A3: "Short-term continuous glucose monitoring of glucose levels in interstitial fluid may also be considered medically necessary in individuals with type 1 diabetes prior to insulin pump initiation to determine basal insulin levels." ▪ Section B1c Removed: "on 4 or more daily doses of insulin or on an insulin pump in the setting of insulin deficiency." and added "or are treated with insulin therapy" ▪ Section D Added: " for management of Type 1 and Type 2 diabetes mellitus"
	Updated Rationale Section
	Updated Coding Section ▪ Removed IDC-10 Codes ▪ Removed G0308 and G0309
	Updated References Section
	Removed Appendix
Posted 08-27-2024 Effective 09-26-2024	Updated Description Section
	Update Policy Section ▪ Section D: Change from "experimental / investigational" to "not medically necessary"
	Policy Guideline Section ▪ Added Policy guideline: "For a service to be considered medically necessary, it should not be more costly than an alternative service or supply or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results for the illness, injury, or disease."
	Updated Rationale Section
	Updated References Section
Posted	Updated Description Section

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01-27-2026 Effective 02-26-2026	Updated Policy Section ▪ Section A Individual with Type 1 Diabetes o Removed: 1. Long-term continuous glucose monitoring (CGM) device monitoring of glucose levels in interstitial fluid, as a technique of diabetic monitoring, may be considered medically necessary in individuals with type 1 diabetes who: a. have demonstrated an understanding of the technology, b. are motivated to use the device correctly and consistently, c. are expected to adhere to a comprehensive diabetes treatment plan supervised by a qualified provider, AND d. are capable of using the device to recognize alerts and alarms 2. Short-term continuous glucose monitoring, of glucose levels in interstitial fluid may be considered medically necessary in individuals with type 1 diabetes whose diabetes is poorly controlled, despite current use of best practices (see Policy Guidelines). Poorly controlled type 1 diabetes includes the following clinical situations: a. Unexplained hypoglycemic episodes b. Hypoglycemic unawareness c. Suspected postprandial hyperglycemia; and d. Recurrent diabetic ketoacidosis. 3. short-term continuous glucose monitoring of glucose levels in interstitial fluid may also be considered medically necessary in individuals with type 1 diabetes prior to insulin pump initiation to determine basal insulin levels. o Added: 1. Long-term and short-term continuous glucose monitoring (CGM) device monitoring of glucose levels in interstitial fluid is considered medically necessary in individuals with type 1 diabetes. ▪ Section B Individuals with Type 2 Diabetes o Added: 4. Short-term and long-term continuous glucose monitoring of glucose levels in interstitial fluid in individuals with type 2 diabetes is considered experimental / investigational for individuals who do not meet the above criteria. ▪ Removed Section C: Other uses of long-term or and short-term continuous glucose monitoring of glucose levels in interstitial fluid as a technique of diabetic monitoring, including use in gestational diabetes, are considered experimental / investigational. ▪ Added Section C Gestational Diabetes: Long-term CGM or short-term intermittent glucose monitoring may be considered medically necessary in pregnant individuals (≥18 years of age) diagnosed with gestational diabetes to achieve recommended glycemic goals.
	Updated Rationale Section
	Updated Reference Section

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