Medical Policy

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***Current Policy Effective Date: 7/1/23**
(See policy history boxes for previous effective dates)

Title: Intermittent (72 Hours or Greater) or Continuous Invasive Glucose Monitoring

Description/Background

BLOOD GLUCOSE CONTROL

The advent of blood glucose monitors for use by patients in the home over 20 years ago revolutionized the management of diabetes. Using fingersticks, patients could monitor their blood glucose level both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. Tight diabetic control, defined as a strategy involving frequent glucose checks and a target HgA_{1c} in the range of 7%, is now considered standard of care for diabetic patients. Randomized controlled trials (RCTs) of tight control have demonstrated benefits for type I diabetics in decreasing microvascular complications. The impact of tight control on type II diabetic patients and on macrovascular complications such as stroke or myocardial infarction (MI) is less certain. The Diabetes Control and Complications Trial (2002) demonstrated that a relative HbA_{1c} level reduction of 10% is clinically meaningful and corresponds to approximately a 40% decrease in risk for progression of diabetic retinopathy and 25% decrease in risk for progression of renal disease.[1]

Due to an increase in turnover of red blood cells during pregnancy, HbA_{1c} levels are slightly lower in women with a normal pregnancy compared with nonpregnant women. The target A_{1c} in women with diabetes is also lower in pregnancy. The American Diabetes Association recommends that, if achievable without significant hypoglycemia, the A_{1c} levels should range between 6.0% to 6.5%; an A_{1c} levels less than 6% may be optimal as the pregnancy progresses.[2]

Tight glucose control requires multiple daily measurements of blood glucose (i.e., before meals and at bedtime), a commitment that some patients may be unwilling or unable to meet. In addition, 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 to patients with type 1 diabetes.[3,4] 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 post-prandially, leading to elevated hemoglobin A_{1c} values.

Management

Recently, measurements of glucose in interstitial fluid have been developed as a technique of automatically measuring glucose values throughout the day, producing data that show the trends in glucose measurements, in contrast to the isolated glucose measurements of the traditional blood glucose measurements. Although devices measure glucose in 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 viewed (iCGM) 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, it should be noted that, 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. The devices must be calibrated twice daily with blood glucose measurements from fingersticks, and are less reliable when used after exercise or post-prandial. Devices may be used intermittently (i.e., for periods of 72 hours) or continuously (i.e., on a long-term basis).

Eversense® CGM system provides continuous blood glucose monitoring for up to 90 days via an under-the-skin sensor, a removable and rechargeable smart transmitter, and a convenient app for real-time diabetes monitoring and management. This system provides real-time glucose readings, glucose trend information and alerts for the detection and prediction of episodes of low blood glucose and high blood glucose. The Eversense® system was originally approved for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. In June of 2019, the FDA expanded the indications for the Eversense® CGM to allow for replacement of fingerstick blood glucose testing for diabetes treatment decisions. However, its incremental advantages over other therapeutic CGM devices has not been established.

In addition to stand-alone continuous glucose monitors, several insulin pump systems have included a built-in CGM. This policy addresses continuous glucose monitoring devices, not the insulin pump portion of these systems.

Regulatory Status

Multiple CGM systems have been approved by the FDA through the premarket approval process (see Table 1). FDA product codes: QCD, MDS

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.

Several CGM systems have been approved by FDA through the premarket approval process (see Table 1).

Table 1a. CGM Systems Approved by the FDA

Device	Manufacturer	Approval	Indications
Continuous Glucose Monitoring System (CGMS®)	MiniMed	1999	3-d use in physician’s office
GlucoWatch G2® Biographer[a]		2001	
Guardian®-RT (Real-Time) CGMS	MiniMed (now Medtronic)	2005	
Dexcom® STS CGMS system	Dexcom	2006	
Paradigm® Real-Time System (second generation called Paradigm Revel System)	MiniMed (now Medtronic)	2006	System integrates a CGM with a paradigm insulin pump
FreeStyle Navigator® CGM System	Abbott	2008	
Dexcom® G4 Platinum	Dexcom	2012 2014	Adults ≥18 y; can be worn for up to 7 d; Expanded use to include patients with diabetes 2-17 y
Dexcom® G5 Mobile CGM	Dexcom	2016[b]	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.[3]
Freestyle Libre® Pro Flash Glucose Monitoring System	Abbott	2017	Adults ≥18 y. Indicated for the management of diabetes and can be worn up to 10 days. It is designed to replace blood glucose testing for diabetes treatment decisions.
Freestyle Libre® 14 Day Flash Glucose Monitoring System	Abbott	2018	Adults ≥18 y. Extended duration of use to 14 days. It is designed to replace blood glucose testing for diabetes treatment decisions.
Freestyle Libre® 2 Flash Glucose Monitoring System	Abbott	2020	Children, adolescents, and adults ≥ 4 years
Dexcom® G6 Mobile CGM	Dexcom	2018	For determining blood glucose (sugar) levels in children ages 2 and older and adults with diabetes.

			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.
Eversense® Continuous Glucose Monitoring System	Senseonics, Inc.	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.
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.

CGM: continuous glucose monitoring.
[a] Neither the GlucoWatch nor the autosensors have been available since July 2008.
[b] As a supplement to the G4 premarketing approval.

Table 1b. CGM Systems FDA Approved as Therapeutic* Device Systems

Device	Manufacturer	Approval
Dexcom® G5 Mobile CGM	Dexcom	2016, Therapeutic* Device
Freestyle Libre® Pro Flash Glucose Monitoring System	Abbott	2017, Therapeutic* Device
Freestyle Libre® 14 Day Flash Glucose Monitoring System	Abbott	2018, Therapeutic* Device
Dexcom® G6 Mobile CGM	Dexcom	2018, Therapeutic* Device
Eversense® Continuous Monitoring System	Senseonics, Inc.	2019, Therapeutic* Device

*Therapeutic devices do not require fingerstick blood glucose testing, these devices should be billed with the appropriate HCPCS (K) codes.

FDA product codes: MDS, PQF

Medical Policy Statement

The safety and effectiveness of FDA approved continuous glucose monitoring systems, on an intermittent (72 hours or greater) or continuous basis, have been established. Both may be considered useful therapeutic devices for patients meeting the relevant patient selection criteria.

Inclusionary and Exclusionary Guidelines

Inclusions:

72-hour monitoring of glucose levels in interstitial fluid, to optimize patient management, may be considered established in the following situations when any of the following criteria are met:

- Patients with insulin requiring diabetes who despite current use of best practices* have poorly controlled diabetes, including hemoglobin A_{1C} not in acceptable target range for the patient's clinical situation, unexplained hypoglycemic episodes, evidence suggesting postprandial hyperglycemia, or recurrent diabetic ketoacidosis.
- Patients with insulin requiring diabetes prior to insulin pump initiation to determine basal insulin levels.
- Women with insulin requiring diabetes who are pregnant or about to become pregnant and have poorly controlled diabetes.

Continuous (i.e., long-term) monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique in diabetic monitoring may be considered established for patients with diabetes who require multiple (three or more) daily administrations of insulin or a continuous subcutaneous infusion of insulin* and:

- Have recurrent, unexplained, severe hypoglycemia (generally blood glucose levels <50 mg/dL) or impaired awareness of hypoglycemia that puts the patient or others at risk; **OR**
- Have poorly controlled insulin requiring diabetes who are pregnant. Poorly controlled insulin requiring diabetes includes unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected postprandial hyperglycemia, and recurrent diabetic ketoacidosis.
- Are pregnant and have unexplained hypoglycemic episodes, hypoglyemic unawareness, postprandial hyperglycemia or recurrent diabetic ketoacidosis.

* An intensive diabetic regimen requiring multiple insulin injections or an insulin pump and not meeting glycemic targets.

Exclusions:

- Patients who have not demonstrated an understanding of the technology
- Patients not capable of using the device to recognize alerts and alarms
- Patients not expected to adhere to a comprehensive diabetes treatment plan
- Use of a continuous glucose monitoring device for convenience purposes such as (but not limited to) lifestyle or employment circumstances

Replacement:
Replacement of a CGMS may be considered when:

- The transmitter is out of warranty or replacement parts are unavailable;
- The transmitter is malfunctioning; and
- There is documented evidence of patient compliance provided, if no evidence of compliance is provided or if the member is not compliant, benefit of CGMS may be withdrawn

Continuation of sensor use after one year may be considered when:

- The CGMS has been previously approved by the Health Plan or the CGMS is in use prior to the user enrolling in the Health Plan; and
- There is documented evidence of patient compliance provided, if no evidence of compliance is provided or if the member is not compliant, benefit of CGMS may be withdrawn

All covered supplies must be compatible with the CGMS.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

95249	95250	95251	A4238	A4239	A9276
A9277	A9278	A9279	0446T	0447T	0448T
E2102	E2103				

Other codes (investigational, not medically necessary, etc.):

99091 S1030 S1031

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a technology, 2 domains are examined: the relevance and the 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.

Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

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.

CGM DEVICES FOR LONG-TERM USE IN TYPE I DIABETES

Clinical Context and Therapy Purpose

The purpose of long-term CGM devices is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does use of CGM devices improve the net health outcome for individuals with type 1 diabetes?

The following **PICOs** were 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 or 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 a CGM device to assess blood glucose levels as part of optimal diabetes management.

Comparators

The following practice is currently being used to measure glucose levels: capillary blood sampling (finger stick) for blood glucose meters. Standard treatment for patients with type 1 or 2 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 or Type 2 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 hemoglobin A_{1c} (HbA_{1c}) levels, time spent in hypoglycemia, incidence of hypoglycemic events, complications of hypoglycemia and quality of life.

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.

Systematic Reviews

A number of systematic reviews and meta-analyses of RCTs evaluating CGM for long-term, daily use in treating type 1 diabetes have been published.[7-12] These systematic reviews have focused on slightly different populations, and some did not separate long-term CGM from intermittent glucose monitoring.[10] The most recent meta-analysis, which was also the only analysis that used individual patient data, was published by Benkhadra et al in 2017.[13] The meta-analysis evaluated data from 11 RCTs that enrolled patients with type 1 diabetes and compared real-time CGM to 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 hemoglobin A1c (HbA_{1c}) 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 HbA_{1c} levels with real-time CGM vs. control conditions. Overall, the degree of difference between groups was 0.26%. In subgroup analyses by age, there was significantly greater change in HbA_{1c} 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 in 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 I 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					

No. of Trials	N	Group	Point Estimate	95% Confidence Intervals	p
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).[12]
CGM: continuous glucose monitoring: HbA1c: hemoglobin A_{1c}.

Earlier meta-analyses of glucose monitoring devices for type 1 diabetes tended to combine studies of intermittent glucose monitoring with studies of long-term CGM. Several reported separate subgroup analyses for long-term CGM. A Cochrane review (2012) of CGM in type 1 diabetes in adults and children included RCTs comparing CGM with conventional self-monitored blood glucose (SMBG).[9] In pooled analysis (6 studies; n=963 patients) of studies of long-term CGM, the average decline in HbA_{1c} levels 6 months after baseline was statistically significantly larger for CGM users than for SMBG users (mean difference [MD] change, -0.2%; 95% confidence interval [CI], -0.4% to -0.1%), but there was no difference in decline in HbA_{1c} levels at 12 months (1 study, n=154 patients; MD change, 0.1%; 95% CI, -0.5% to 0.7%). In a meta-analysis of 4 RCTs (n=689 patients), there was no significant difference in the risk of severe hypoglycemia between CGM and SMBG users and the confidence interval for the relative risk was wide (relative risk, 1.05; 95% CI, 0.63 to 1.77), indicating lack of precision in estimating the effect of CGM on hypoglycemia risk. Reviewers were unable to compare longer term change in HbA_{1c} levels or hypoglycemia outcomes for real-time CGM. Trials reporting results by compliance subgroups found larger treatment effects in highly compliant patients.

A systematic review by Wojciechowski et al (2011) evaluating CGM included RCTs conducted in adults and children with type 1 diabetes.[11] Reviewers selected studies having a minimum of 12 weeks of follow-up and requiring patients be on intensive insulin regimens. Studies compared CGM to SMBG; there was no restriction on type of CGM device, but CGM readings had to be used to adjust insulin dose or modify diet. Fourteen RCTs met eligibility criteria. Study durations ranged from 3 to 6 months. Baseline mean HbA_{1c} levels ranged from 6.4% to 10%. Five included studies found a statistically significant decrease in HbA_{1c} levels favoring CGM while 9 did not. In a pooled analysis, there was a statistically significant reduction in HbA_{1c} levels with CGM compared with SMBG (weighted mean difference [WMD] = -0.26%; 95% CI, -0.34% to -0.19%). For the subgroup of 7 studies that reported on long-term CGM, this difference was statistically significant (WMD = -0.26; 95% CI, -0.34 to -0.18). In a subgroup analysis by age, there were significant reductions in HbA_{1c} levels with CGM in studies of adults (n=5; WMD = -0.33; 95% CI, -0.46 to -0.20) and in studies with children and/or adolescents (n=8; WMD = -0.25; 95% CI, -0.43 to -0.08). Four of the studies provided data on the frequency of hypoglycemic episodes. Pooled results showed a significant reduction in hypoglycemic events for CGM versus SMBG (standardized mean difference,-0.32; 95% CI, -0.52 to -0.13). Five of the studies reported the percentage of patients with severe hypoglycemic episodes and there were no differences in the percentage of patients with severe hypoglycemic episodes using CGM and SMBG in any of them.

Randomized Controlled Trials

Recent RCTs not included in the meta-analyses above are described next and in Tables 3 and 4. HbA_{1c}, 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.

In the second study, Beck et al (2017) randomized 158 patients on a 2:1 basis to 24 weeks of CGM (n=105) or to usual care (n=53).[15] The trial included patients with type 1 diabetes who were ages 25 or older and had baseline HbA_{1c} levels between 7.5% and 10%. Before randomization, patients underwent a 2-week period using a CGM system (without seeing data from the CGM) to ensure compliance. To be eligible, patients had to wear the CGM on at least 85% of days, calibrate the device at least twice daily and perform SMBG at least 3 times daily. The primary outcome (change in HbA_{1c} levels at 24 weeks) was 1.0% in the CGM group and 0.4% in the usual care group (p<0.001), 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 HbA_{1c} levels less than 7.0% was 18 (18%) in the CGM group and 2 (4%) in the control group (p=0.01). The proportion of patients with HbA_{1c} levels less than 7.5% was 39 (38%) in the CGM group and 6 (11%) in the control group (p<0.001). Moreover, prespecified secondary outcomes related to hypoglycemia also differed significantly between groups, favoring the CGM group. The time spent in hypoglycemia less than 70 mg/dL was 43 minutes per day in the CGM group and 80 minutes per day in the usual care group (p=0.002). 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=0.001). 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=0.03).[16] Quality of life measures assessing overall well-being (WHO-5), health status (EQ-5D-5L), diabetes distress (DDS), hypoglycemic fear (worry subscale of the HFS-II), and hypoglycemic confidence (HCS) have also been reported.[19] 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=0.01) and a greater decrease in diabetes distress (p=0.01) than the usual care group.

Two RCTs were published in 2020 that assessed CGM with a Dexcom G5 in adolescents and young adults (Laffel et al, 2020)18, and in older adults (Pratley et al, 2020).19 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.

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)[14.] DIAMOND				Adults aged 25 or older with baseline HbA1c levels between 7.5% and 10%	Dexcom G4 (n=105)	Usual care (n=53)
Laffel et al (2020)[17.]	US	14	2018-2019	Adolescents and young adults age 14 to 24 years with HbA1c 7.5% to 10.9% with multiple daily	Dexcom G5, 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)

				insulin injections or an insulin pump		
Pratley et al (2020)[18.](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 with training on use and 2 calibration BG per day(n=103)	Fingerstick blood glucose meter checks at least 4 times daily (n=100)

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

Table 4. Summary of Key RCT Results

Study	**HbA1c**	**HbA1c**	**Blood Glucose (SD) mg/dL**	**Hypoglycemic Episodes**	**Patient Reported Outcomes**	
Beck et al (2017)[14.] 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		
Diff (95% CI)	0.6%					
P	<.001	.01		0.002		
Laffel et al (2020)[17.]	*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)[18.](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
Summary[2]	Range					

CI: confidence interval; CGM: continuous glucose monitor; HbA1c: hemoglobin A1c; 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

Pregnant Women

One trial of real-time CGM in pregnant women with type 1 diabetes has been reported. Study design 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. [20] The trial enrolling pregnant women is reviewed here. Women were eligible if they had a singleton pregnancy and HbA_{1c} 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 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 HbA_{1c} levels were 6.5% or less in both groups. The primary outcome was the difference in change in HbA_{1c} 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, 4.0-6.8) and 70% of pregnant participants used CGM for more than 75% of the time. The between-group difference in the change in HbA_{1c} levels from baseline to 34 weeks of gestation was statistically significant favoring CGM (MD = -0.19%; 95% CI, -0.34 to -0.03; p=0.02). 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=0.003). 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=0.02). 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=0.02), fewer incidences of neonatal hypoglycemia requiring treatment with intravenous dextrose (OR=0.45, 0.22 to 0.89; p=0.025), and reduced total length of hospital stay (3.1 days vs. 4.0 days; p=0.0091). 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 Women With Type 1 Diabetes

Study; Registration	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Feig et al (2017)[19]; 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 Women 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)[19]						
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.
CI: confidence interval; CGM: continuous glucose monitoring; HbA1c: hemoglobin A_{1c}; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; TE: treatment effect.

The purpose of the gaps tables (see Tables 5 and 6) is to display notable gaps 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. Relevance Limitations of RCTs for Real-Time CGM in Pregnant Women With Type 1 Diabetes

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Feig et al (2017)[19]	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.
[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 Women With Type 1 Diabetes

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Feig et al (2017)[19]		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.

CGM Devices for Short-Term Use in Type 1 Diabetes

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 intermittent 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 intermittent monitoring. In the 2012 Cochrane review, 4 studies (total N=216 patients) compared real-time intermittent glucose monitoring systems to SMBG, and the pooled effect estimate for change in HbA_{1c} levels at 3 months was not statistically significant (MD change, -0.18; 95% CI, -0.42 to 0.05).[9] The 2011 meta-analysis of RCTs on CGM described previously also included a separate analysis of 8 RCTs of intermittent monitoring.[11] On pooled analysis, there was a statistically significant reduction in HbA_{1c} levels with intermittent glucose monitoring compared with SMBG (WMD = -0.26; 95% CI, -0.45 to -0.06).

Randomized Controlled Trial

The largest RCT was the 2009 Management of Insulin-Treated Diabetes Mellitus (MITRE) trial, published by Newman et al, which evaluated whether the additional information provided by minimally invasive glucose monitors resulted in improved glucose control in patients with poorly controlled insulin-requiring diabetes.[27] This was a 4-arm RCT conducted at secondary care diabetes clinics in 4 hospitals in England. In this study, 404 people aged older than 18 years, with insulin-treated diabetes mellitus (types 1 or 2) for at least 6 months, who were receiving 2 or more injections of insulin daily, were eligible. The majority of participants, 57%, had type 1 diabetes, 41% had type 2 diabetes and 2% were classified as “other.” Participants had 2 HbA_{1c} values of at least 7.5% in the 15 months prior to 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). Intermittent CGM was used i.e. monitoring was performed over several days at various points in the study. 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). Change in HbA_{1c} from baseline to 3, 6, 12, and 18 months was the primary indicator of short- to long-term efficacy in this study. At 18 months, all groups demonstrated a decline in HbA_{1c} levels from baseline. Mean percentage changes in HbA_{1c} 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 intent-to-treat (ITT) analysis, no significant differences were found between any of the groups at any of the assessment times. There was no evidence that the additional information provided by the devices resulted in any change in the number or nature of treatment recommendations offered by the nurses. Use and acceptability indicated a decline in use of 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 study of unselected patients, use of continuous glucose monitors (CGMS on an intermittent basis) did not lead to improved clinical outcomes.

Pregnant Women

Systematic Reviews

Voormolen et al (2013) published a systematic review of the literature on CGM during pregnancy.[28] They identified 11 relevant studies (total N=534 women). Two were RCTs, one of which was the largest of the studies (N=154). Seven studies used CGMs that do 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 on the efficacy of CGM during pregnancy. The published RCTs are described next.

Randomized Controlled Trials

Two RCTs of intermittent 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.

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). [29] 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 HbA_{1c} 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=0.19). 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 HbA_{1c} 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.[30] 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 a day. Baseline HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} levels were 6.1% in the CGM group and 6.4% in the usual care group (p=0.10). 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=0.05).

Table 9. Key RCT Characteristics for Intermittent CGM in Pregnant Women With Type 1 Diabetes

Study; Registration	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Secher et al (2013)[22]; 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 visits; encouraged to used continuously) plus SOC (n=79)	SOC (n=75)
Murphy et al (2008)[23]; 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 Outcomes of Intermittent CGM in Pregnant Women 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
		Days				
Secher et al (2013)[22]						
n	154	154	145	154		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)[23]						
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.

In summary, 2 studies of intermittent glucose monitoring conducted in Europe included pregnant women with type 1 or 2 diabetes, with most having type 1 diabetes. Murphy et al (2008) included intermittent, retrospective monitoring with CGM; Secher et al (2013) included intermittent, real-time monitoring. The intervention started in early pregnancy in these studies; mean age was in the early thirties and mean baseline HbA_{1c} level was greater than 6.5% There was no statistically significant difference between CGM and routine care for maternal HbA_{1c} levels at 36 weeks in Secher; the difference in HbA_{1c} levels at 36 weeks was about 0.6% (p=0.007) in Murphy. Secher also reported no difference in severe maternal hypoglycemia. The proportion of infants that were large for gestational age (>90th percentile) was higher in the CGM group in Secher, although not statistically significantly higher; the difference in large for gestational age was statistically significantly lower for CGM in Murphy. The differences in the proportions of infants born via caesarean section, gestational age at delivery, and infants with severe hypoglycemia were not statistically significant in either trial. Tables 11 and 12 display notable gaps identified in each study.

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

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Secher et al (2013)[22]	4. Study population had relatively low HbA1c levels	4. Only 64% of the participants used devices per protocol			
Murphy et al (2008)[23]					

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. CGM: continuous glucose monitoring; HbA_{1c}: 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.
[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 Intermittent Glucose Monitoring in Pregnant Women with Type 1 Diabetes

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Secher et al (2013)[22]		1. Not blinded; chance of bias in clinical management				3, 4. Treatment effects and confidence intervals not calculated
Murphy et al (2008)[23]		1. Not blinded; chance of bias in clinical management				3, 4. Treatment effects and confidence intervals not calculated for some outcomes

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive limitations 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 (intermittent) monitoring of type 1 diabetes, there are few RCTs and systematic reviews. 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 intermittent control and the specific monitoring protocols varied. In some studies, intermittent 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.

Two RCTs of intermittent glucose monitoring have been conducted in pregnant women with both type 1 and 2 diabetes, with most having type 1 diabetes. One study reported a difference in HbA_{1c} levels at 36 weeks and the proportion of infants that were large for gestational age (>90^{th} percentile) favoring CGM while the second study did not. The differences in the proportions of infants born via caesarean section, gestational age at delivery, and infants with severe hypoglycemia were not statistically significant in either study.

Continuous Glucose Monitoring Devices for Use in Individuals with Type 2 Diabetes Who Require Multiple Daily Doses of Insulin or an Insulin Pump

Randomized Controlled Trials
Three RCTs evaluated CGM in individuals with type 2 diabetes using multiple daily insulin injections or an insulin pump (Tables 13 and 14).[24,25,26.] One evaluated real-time CGM using the Dexcom device and 2 evaluated intermittently scanned CGM using the Freestyle Libre system.

Beck et al (2017) reported on the DIAMOND RCT.[24.] 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. [25.] 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.[26] 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.

Table 13. Key RCT Characteristics for Continuous Glucose Monitoring in Type 2 Diabetes

Study; Registration	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Beck et al (2017) (DIAMOND)[24]; 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)[25] NCT02082184	Multiple European	26	2014-2015	Adults with type 2 diabetes 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 montitoring with FreeStyle Libre device n = 149	SMBG n = 75
Yaron et al (2019)[26] NCT02809365	Israel	2	2016-2017	Adults with type 2 diabetes on multiple daily insulin injections for at least 1 year.	Flash glucose montitoring with FreeStyle Libre device n = 53	SMBG n = 48

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 Glucose Monitoring in Type 2 Diabetes on Mulitple Daily Insulin Injections or an Insulin Pump

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)[24]						
N	158	158	158	158	NR	150

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
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
	Baseline to 12 Wk					
Haak et al (2017)[25]	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)[26]	Change in HbA1c –0.82% (9 mmol/mol) –0.33% (3.6 mmol/mol) P =.005				NR	Treatment satisfaction (Primary outcome, DTSQc) at 10 weeks: 2.47 (0.77) vs. 2.18 (0.83); P =.053

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.

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).[27] 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 Women

As discussed in the section on CGM in pregnant women, 2 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)[29,] and 31 (20%) with type 2 diabetes in Secher et al (2013).[28,] 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.

Only 2 RCTs used blinded CGM; in 1, there was no difference in reduction in HbA1c levels between CGM and control.

Section Summary: Continuous Glucose Monitoring Devices for Use in Individuals with Type 2 Diabetes Who Require Multiple Daily Doses of Insulin or an Insulin Pump

Three RCTs have evaluated CGM compared to SMBG in individuals with type 2 diabetes on intensive insulin therapy, 1 using real-time CGM and 2 using an intermittently scanned device. All 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 (the primary outcome). 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. 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. 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.

Continuous Glucose Monitoring Devices for Use in Individuals with Type 2 Diabetes Who Do Not Require Multiple Daily Doses of Insulin or an Insulin Pump

Randomized Controlled Trials

Two RCTs evaluated CGM in individuals with Type 2 diabetes not on multiple daily insulin injections or an insulin pump (Tables 15 and 16).[28,29,30,]

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%.[28,]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.[31,] 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 (eg, 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).

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.[30,] 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%).[32,] 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%.

Tables 17 and 18 display notable limitations identified in the studies. These include a lack of blinding and heterogeneity in the participant populations, and insufficient duration to determine effects on diabetic complications. Additionally, in Martens et al, one-third of participants in the CGM group still had a HbA1c level above 8% after 8 months, indicating that their treatment regimen was less than optimal.

Table 15. Key RCT Characteristics for Continuous Glucose Monitoring in Individuals with Type 2 Diabetes not on Multiple Daily Insulin Injections or an Insulin Pump

Study; Registration	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Ehrhardt et al (2011)[28,]Vigersky et al (2012) [31,]	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 29 of 100 (29%) were using basal insulin	Real-time CGM for 4 cycles of 3 wk (n=50)	SMBG (n=50)
Martens et al (2021)[30,]Aleppo et al (2021)[32,]	U.S.	15	2018-2019	Adults with T2D treated with 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)

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 Multiple Daily Insulin Injections or an Insulin Pump

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
Ehrhardt et al (2011)[28], Vigersky et al (2012) [31],						
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					
Martens et al (2021)[30], Aleppo et al (2021)[32], NCT03566693						
N	156	156	156	175	NR	NR
CGM	9.1 to 8.0	20 (19%)	66 (63%)	1 hyopglycemic 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			

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 Multiple Daily Insulin Injections or an Insulin Pump for Glucose Monitoring in Type 2 Diabetes

Study; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Ehrhardt et al (2011)[28], Vigersky et al (2012) [31],	1. study population a mix of participants using basal insulin or oral agents alone			1. Focused on HbA1c; did not include outcomes on adverse events, QOL, or diabetic complications 6. No justification for clinically significant difference	1. Follow-up not sufficient to determine effects on diabetic complications
Martens et al (2021)[30], Aleppo et al (2021)[32], NCT03566693			2.Diabetes management therapy might have been less than optimal	1. Did not include outcomes on QOL or diabetic complications 24 participants could not complete clinic visits due to COVID-19 restrictions; fingerstick used instead of	1. Follow-up not sufficient to determine effects on diabetic complications

				capillary blood draw in these cases.	

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.
[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 Multiple Daily Insulin Injections or an Insulin Pump

Study; Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Ehrhardt et al (2011)[28,] Vigersky et al (2012) [31,]		1. Not blinded; chance of bias in clinical management				
Martens et al (2021)[30,]		1. Not blinded; chance of bias in clinical management				

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 Do Not Require Multiple Daily Doses of Insulin or an Insulin Pump

The trials found statistically significant 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 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 using basal insulin only. In individuals on oral antidiabetic agents only, routine glucose monitoring may be of limited additonal 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 Women With Gestational Diabetes

Randomized Controlled Trials

One trial of glucose monitoring in women with gestational diabetes has been published. Trial characteristics, results, and limitations are shown in Tables 19 to 22. In the RCT, Wei et al (2016)

evaluated the use of CGM in 120 women with gestational diabetes at 24 to 28 weeks.[33] Patients were randomized to prenatal care plus CGM (n=58) or SMBG (n=62). The CGM sensors were reportedly inserted for 48 to 72 hours on weekdays; it is not clear whether the readings were available in real-time. The investigators assessed a number of endpoints and did not specify primary outcomes; a significance level of p less than.05 was used for all outcomes. The groups did not differ significantly in a change in most outcomes, including a change in maternal HbA1c levels, rates of preterm delivery before the 35th gestational week, cesarean delivery rates, proportions of large-for-gestational-age infants, or rates of neonatal hypoglycemia. Women in the CGM group gained significantly less weight than those in the SMBG group.

Table 19. Key RCT Characteristics for CGM in Pregnant Women With Gestational Diabetes

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	***Comparator***
Wei et al (2016)[33]	China	1	2011-2012	Pregnant women with gestational diabetes diagnosed between 24 and 28 wk of gestation; mean HbA1c level, 5.8%; mean age, 30 y	CGM (48- 721 on weekdays) (n=51)	SMBG (n=55)

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

Table 20. RCT Outcomes for CGM in Pregnant Women With Gestational Diabetes

Study	Infant				Maternal	
	Large-for-Gestational Age, n (%)	***Gestational Age at Delivery, wk***	***Severe Hypoglycemia, n (%)***	***Caesarean Section, n (%)***	***HbA1c Levels at 36 Wk of Gestation[a]***	***Severe Hypoglycemia***
Wei et al (2016)[33]						
N	106	106	106	**106**		**NR**
CGM	18 (35)	Mean, 37.4	4 (8)	**31 (60)**	**Mean, 5.5%**	
Control	29 (53)	Mean, 37.5	7 (13)	**38 (69)**	**Mean, 5.6%**	
TE (95% CI)	NR	NR	NR	**NR**	**NR**	
p	.07	.92	.41	**.37**	**.09**	

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

Table 21. Study Relevance Limitations of RCTs for CGM in Pregnant Women With Gestational Diabetes

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Wei et al (2016)[33]	4. Study population had relatively low HbA1c level	4. Compliance with CGM not reported			

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.
[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 22. Study Design and Conduct Limitations of RCTs for CGM in Pregnant Women With Gestational Diabetes

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Wei et al (2016)[33]	3. Not reported	1. Not blinded; chance of bias in clinical management	1. Registration not reported	5. Exclusions not well justified	1. No power calculations reported; primary outcome not specified	3, 4. Treatment effects and CIs not calculated

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 Women With Gestational Diabetes

The RCT in women with gestational diabetes was conducted in China with the intervention starting in the second or third trimester and mean baseline HbA1c level less than 6.0%. The type of CGM monitoring was unclear. Trial reporting was incomplete; however, there were no differences between groups for most reported outcomes.

Continuous Glucose Monitoring Implanted Device

Nonrandomized Studies

Data from 3 nonrandomized prospective studies (PRECISE, PRECISE II, AND PRECISION) were provided to the U.S. Food and Drug Administration (FDA) for the initial approval of Eversense as an adjunctive device.[34,35,] 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.[36,] 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.[37.] 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.

Multiple post-marketing registry studies of the Eversense device have been published (Tables 23 and 24). 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.[38.] 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.[39.] 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.[40.] 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 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.

Limitations of the evidence base include lack of direct comparisons to SMBG, lack of differentiation in outcomes for type 1 diabetes versus type 2 diabetes, and variability in reporting of trends in secondary glycemic measures. 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 with either Type 1 or Type 2 diabetes (NCT04836546).[36.] The study is expected to be completed in March 2026.

Table 23. Postmarketing Studies of the Eversense Device- Characteristics

Study	Study Type	Country	Dates	Participants	Test/Treatment	Follow-Up
Deiss et al (2019)[39.]	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 days)	Up to 1 year
Sanchez et al (2019)[38.]	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)[40.]	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)[41.] NCT04160156	Prospective Single arm	Italy	2018-2019	Adults age 18 year and older with T1D; 56% used insulin pumps and 44% used multiple daily injections of insulin; 45% wer previous CGM users. Mean HbA1c 7.4% (SD 0.92%)	Implanted CGM 180-day system or 180 day system	180 days

CGM: continuous glucose monitoring; SD: standard deviation; T1D: type 1 diabetes; T2D: type 2 diabetes.

Table 24. Postmarketing Studies of the Eversense Device- Results

Study Efficacy Outcomes	Efficacy Results	Adverse Events
Deiss et al (2019)[39.]		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)[38.]	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%)

Mean SG (mg/dL)	161.8 Median 157.2 (IQR 138.4 to 178.9)	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
% 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)[40.]		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	
% 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)[41.]		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; CI: confidence interval; 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
There are no RCTs and no comparative observational studies of implantable CGM compared to SBMG. Nonrandomized prospective studies and postmarketing registry studies assessed the accuracy and safety of an implanted glucose monitoring system that provides continuous glucose monitoring 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, 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. Limitations of the evidence base include lack of direct comparisons to SMBG, lack of differentiation in outcomes for type 1 diabetes versus type 2 diabetes, and variability in reporting of trends in secondary glycemic measures.

SUMMARY OF EVIDENCE

Type 1 Diabetes

For individuals who have type 1 diabetes who are willing and able to use the device, and have adequate medical supervision, who receive long-term continuous glucose monitoring (CGM), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. Systematic reviews have generally found that, at least in the short-term, long-term CGM resulted in significantly improved glycemic control for adults and children with type 1 diabetes, particularly highly compliant patients. A 2017 individual patient data analysis, using data from 11 RCTs, found that reduction in hemoglobin A_{1c} (HbA_{1c}) levels was significantly greater with real-time CGM compared with a control intervention. Two newly added 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 HbA_{1c} levels than previous studies. One of the 2 RCTs prespecified hypoglycemia-related outcomes and reported that time spent in hypoglycemia was significantly less in the CGM group. One RCT in pregnant women with type 1 diabetes, which compared real-time CGM with self-monitoring of blood glucose, has also reported a difference in change in HbA1c levels, an increased percentage of time in the recommended glucose control target range, a smaller proportion of infants who were large for gestational age, a smaller proportion of infants who had neonatal intensive care admissions lasting more than 24 hours, a smaller proportion of infants who had neonatal hypoglycemia requiring treatment, and reduced total hospital length of stay all favoring CGM. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have type 1 diabetes who receive short-term (intermittent) glucose monitoring, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity as well as intermediate outcomes related to measures of glucose control such as frequency and time in hypoglycemia and hyperglycemia. The evidence for short-term monitoring of glycemic control is mixed, and there was no consistency in HbA_{1c} 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 imprecise. The limited duration of use may preclude an assessment of any therapeutic effect. Two 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 HbA_{1c} levels at 36 weeks; the proportion of infants that were large for gestational age (>90^{th} percentile) favored CGM while the second trial 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 in either study. Limitations of the published evidence preclude determining the effects of the technology on the net health outcome.

Type 2 Diabetes

For individuals with type 2 diabetes who require multiple daily doses of insulin or an insulin pump who receive long-term CGM, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. Three RCTs have evaluated CGM compared to SMBG in individuals with type 2 diabetes on intensive insulin therapy; 1 using real-time CGM and 2 using an intermittently scanned device. All 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 (the primary outcome). 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. 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. 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. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with type 2 diabetes who do not require multiple daily doses of insulin or an insulin pump who receive long-term CGM, the evidence includes 2 RCTs. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. The trials found statistically significant 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 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 using basal insulin only. 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 improvement in blood glucose excursions and HbA1c levels over the short-term in this population would be linked to meaningful improvement in long-term health outcomes such as diabetes-related morbidity and complications. The evidence

is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with type 2 diabetes who receive short-term CGM monitoring, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity. Systematic reviews of three to four RCTs have found statistically significant benefits from CGM regarding glycemic control. However, the degree of HbA1c reduction and the difference in HbA1c reductions between groups may not be clinically significant. Also, the limited number of RCTs and variability among interventions make it difficult to identify an optimal approach to CGM or a subgroup of type 2 diabetes patients who might benefit. Moreover, studies of CGM in patients with type 2 diabetes have generally not addressed the clinically important issues of severe hypoglycemia and diabetic complications. Very few pregnant women with type 2 diabetes have been included in RCTs. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with type 2 diabetes who receive short-term continuous glucose monitoring, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, QOL, and treatment-related morbidity as well as intermediate outcomes related to measures of glucose control such as frequency and time in hypoglycemia and hyperglycemia. The evidence for short-term monitoring of glycemic control is mixed, and there was no consistency in HbA1c levels. Some trials have reported improvements in glucose control for the short-term 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 imprecise. The limited duration of use may preclude an assessment of any therapeutic effect. Two 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 the second trial 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 in either study. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Gestational Diabetes

For individuals who are pregnant with gestational diabetes who receive long-term (continuous) or short-term (intermittent) glucose monitoring, the evidence includes RCT. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related morbidity. In the RCT, the type of CGM was unclear. Trial reporting was incomplete; however, there was no difference between the groups for the majority of the reported outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Continuous Glucose Monitoring with an Implantable Device (Eversense)

For individuals with type 1 or type 2 diabetes who receive continuous glucose monitoring with an implantable device, the evidence includes nonrandomized studies. There are no RCTs and no comparative observational studies of implantable CGM compared to SBMG. Nonrandomized prospective studies and post-marketing registry studies assessed the accuracy and safety of an implanted glucose monitoring system that provides continuous glucose monitoring 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, 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. Limitations of the evidence base include lack of direct comparisons to SMBG, lack of differentiation in outcomes for type 1 diabetes versus type 2 diabetes, and variability in reporting of trends in secondary glycemic measures. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov identified the following ongoing trials in Table 25.

Table 25. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03981328	The Effectiveness of Real Time Continuous Glucose Monitoring to Improve Glycemic Control and Pregnancy Outcome in Patients With Gestational Diabetes Mellitus	372	Oct 2021 (last update June 2019, not yet recruiting)
NCT03908125[a]	A Post- Approval Study to Evaluate the Long-term Safety and Effectiveness of the Eversense® Continuous Glucose Monitoring (CGM) System	400	Mar 2023
NCT04269655[a]	Scripps Digital Diabetes: Cloud-Based Continuous Glucose Monitoring (CB CGM)	300	Feb 2024
NCT04535830	The Effectiveness of Flash Glucose Monitoring System on Glycemic Control in Patients With New-onset Type 2 Diabetes#A Randomized Controlled Trial	200	Sep 2021
NCT03522870	Effects of Novel Flash Glucose Monitoring System on Glycemic Control in Adult Patients With Type 1 Diabetes Mellitus	104	Dec 2021
NCT04836546	A Post Approval Study to Evaluate the Safety and Effectiveness of the Eversense® Continuous Glucose Monitoring (CGM) System Used Non-adjunctively	925	Mar 2026
NCT05131139	Enhance Study: A Prospective, Multicenter Evaluation of Accuracy and Safety of the Eversense CGM System With Enhanced Features	120	Jan 2023
NCT03908125	A Post- Approval Study to Evaluate the Long-term Safety and Effectiveness of the Eversense® Continuous Glucose Monitoring (CGM) System	273	Mar 2023
Unpublished			

NCT03445065[a]	Benefits of a Long Term Implantable Continuous Glucose Monitoring System for Adults With Diabetes - France Randomized Clinical Trial	239	Aug 2020

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

SUPPLEMENTAL INFORMATION

Clinical Input Received through 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 one 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) 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 who have 2 diabetes who are (1) willing and able to use the CGM device and have adequate medical supervision and (2) experiencing significant hypoglycemia on multiple daily doses of insulin or an insulin pump in the setting of insulin deficiency who receive CGM 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.

2008
In response to requests, input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review in 2008. Input concurred that continuous glucose monitoring, particularly intermittent glucose monitoring, was helpful in a subset of patients with diabetes. Reviewers commented that this monitoring can improve diabetes care by reducing glucose levels (and improving hemoglobin A_{1c} levels) and/or by reducing episodes of hypoglycemia. Reviewers argued that there is persuasive data from case reports to demonstrate the positive impact of intermittent glucose monitoring.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Association of Clinical Endocrinologists
In 2021, the American Association of Clinical Endocrinology (AACE) published recommendations on the use of advanced technology in the management of diabetes and made the following recommendations (level of evidence) on CGM:[42,]

- 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**)

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[44,] and type 2[45,] 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"[44,]

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 hypoglycaemia or severe hypoglycaemia
- they have impaired hypoglycaemia 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."[45,]

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

American Diabetes Association
The American Diabetes Association (2022) "Standards of Medical Care in Diabetes[43,]" made the following recommendations (**level of evidence**) on CGM devices:

- "Real-time CGM (**A)** or intermittently scanned continuous glucose monitoring (**B**) should be offered for diabetes management in adults with diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs."
- Real-time CGM (**A**) or intermittently scanned continuous glucose monitoring (**C**) can be used for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs."
- Real-time CGM (**B**) or intermittently scanned continuous glucose monitoring (**E**) should be offered for diabetes management in youth with type 1 diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on patient circumstances, desires, and needs."
- When used as an adjunct to pre- and postprandial blood glucose monitoring, CGM can help to achieve A1c targets in diabetes and pregnancy (**B)**
- Periodic use of real-time or intermittently scanned cCGM or use of professional CGM can be helpful for diabetes management in circumstances where continuous use of CGM is not appropriate, desired, or available (**C)**.

Endocrine Society
In 2016, the Endocrine Society published clinical practice guidelines that included the following recommendations on CGM:[46]

6. "Real-time continuous glucose monitors in adult outpatients
6.1 We recommend real-time continuous glucose monitoring (RT-CGM) devices for adult patients with T1DM [type 1 diabetes mellitus] who have Ab_{1c} levels above target and who are willing and able to use these devices on a nearly daily basis.
6.2 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.

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

6.3 We suggest short-term, intermittent RT-CGM use in adult patients with T2DM (not on prandial insulin) who have A_{1c} levels ≥7% and are willing and able to use the device."

Government Regulations
National:

In January 2017, the Centers for Medicare & Medicaid Services (CMS) issued a ruling that CGM devices (therapeutic CGMs) approved by the FDA that can be used to make treatment decisions are considered durable medical equipment.[47]

For CY 2020, Medicare has assigned relative value units to the insertion, removal and removal /reinsertion codes uses for provision of the implantable glucose sensor device.

Local:

Local Coverage Determination (LCD) L33822; effective for services performed on or after 02/28/2022.
CONTINUOUS GLUCOSE MONITORS (CGM)

CGM devices covered by Medicare under the DME benefit are defined in CMS Ruling 1682R as therapeutic CGMs. Refer to the Non-Medical Necessity Coverage and Payment Rules in the LCD-related Policy Article for additional information.

Therapeutic CGMs and related supplies are covered by Medicare when all of the following coverage criteria (1-6) are met:

1. The beneficiary has diabetes mellitus (Reference ICD-10 Codes that Support Medical Necessity section for applicable diagnoses); and,
2. The beneficiary has been using a BGM and performing frequent (four or more times a day) testing; and,
3. The beneficiary is insulin-treated with multiple (three or more) daily injections of insulin or a Medicare-covered continuous subcutaneous insulin infusion (CSII) pump; and,
4. The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results; and,
5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-4) above are met; and,
6. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan.

When a therapeutic CGM (code K0554) is covered, the related supply allowance (code K0553) is also covered.

If any of coverage criteria (1-6) are not met, the CGM and related supply allowance will be denied as not reasonable and necessary.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Continuous Subcutaneous Insulin Infusion (CSII) (Insulin Pumps) and Transdermal Insulin Delivery Systems
- Chronic Intermittent Intravenous Insulin Therapy (CIIIT)
- Artificial Pancreas Devices

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50. HAYES Search & Summary. Dexcom G5 Continuous Glucose Monitoring (CGM) System (Dexcom, Inc.). Published May 25, 2017. Updated December 2018. Archived January 2020.
51. HAYES Health Technology Brief. Eversense Continuous Glucose Monitor for Maintaining Glycemic Control in Adults with Diabetes Mellitus. Published September 2019.
52. HAYES Health Technology Brief. FreeStyle Libre Flash Glucose Monitoring System for Maintaining Glycemic Control in Adults with Diabetes Mellitus. Published October 2019.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
8/3/02	8/3/02	8/3/02	Joint policy established.
5/17/05	5/17/05	5/25/05	Routine maintenance.
6/1/07	3/26/07	1/17/07	Change in status.
7/1/08	4/15/08	9/23/08	Routine maintenance, code updates.
11/1/09	8/18/09	8/18/09	Policy updated to reflect intermittent glucose monitoring services as established.
11/1/10	8/28/10	8/17/10	Enhanced description and rationale, clarified integrated units, references updated; title changed from “72 Hour or Continuous Invasive Glucose Monitors” to “Intermittent (72 Hours or Greater) or Continuous Invasive Glucose Monitoring”
5/1/12	2/21/12	2/21/12	Clarified Medicare coverage position on intermittent or continuous invasive glucose monitors. There is no LCD or NCD on the topic.
11/1/13	8/22/13	8/27/13	Routine update, mirrored BCBSA policy. No change in policy status.
11/1/14	8/19/14	8/25/14	Routine update. Added new codes for artificial pancreas (S1034-S1037). Updated rationale and references.
7/1/16	4/19/16	4/19/16	Routine policy update. No change in policy status.
5/1/17	2/21/17	2/21/17	Routine policy maintenance, removed all references to artificial pancreas devices (See separate policy on Artificial Pancreas).
11/1/17	8/15/17	8/15/17	Routine policy maintenance. Effective date changed to 7/1/17, the date the code was effective to accommodate NASCO systems.

5/1/18	2/20/18	2/20/18	Added code 95249 as established. Rationale section updated, references added (3, 11-15, 26, 27), some older references removed. CMS section updated.
7/1/18	4/17/18	4/17/18	Added references 1-2, 19-20 and 31. Added FreeStyle Libre Pro Flash and FreeStyle Libre Flash to regulatory section. Studies placed in chart format. Added “long-term” to MPS. Removed Type I diabetes language replaced with insulin requiring diabetes.
3/1/19	12/11/18		Added Dexcom G6 to policy. Added language for replacement of CGMS. Rationale section reformatted, reference #35 added. No change in policy status.
5/1/19	2/19/19		Nomenclature change for code 99091.
7/1/19	4/16/19		Table added to regulatory section for devices approved as therapeutic. Language change third bullet under Replacement section. No change in policy status.
11/1/19	9/5/19		Added Eversense® CGM to FDA approved CGM device table. Implantable CGM device is E/I. Added codes 0446T, 0447T and 0448T as E/I. No change in policy status.
11/1/20	9/30/20		Rationale section updated with studies on Eversense, added references 21-27, 32, 37 and 38. No change in policy status.
7/1/21	10/19/21		Codes 0046T-0048T are now established. MPS clarification with addition of Best Practices. Eversense® removed from the MPS.

7/1/22	4/19/22		Reviewed literature presented, no change in policy status or criteria. The body of the policy was reorganized per the BCBSA review. Added codes A4238 and E2102 as established.
7/1/22	9/30/22		9/30/22: Removed 4 finger stick requirement from inclusion section. Updated rationale section, references added. No change in policy status. (ds)
7/1/23	4/18/23		Routine policy maintenance, no change in policy status. Vendor managed: Northwood—PPO, J & B—BCN/BCNA. (ds)

Next review date: 2nd Qtr., 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: INTERMITTENT (72-HOURS OR GREATER) OR CONTINUOUS INVASIVE GLUCOSE MONITORING

I. Coverage Determination :

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered per policy guidelines
BCNA (Medicare Advantage)	See government regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service. Note: at the present time, the Centers for Medicare and Medicaid Services will not reimburse personal CGM with a patient-owned device.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate benefits and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.