Medical Coverage Policy

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Diabetes Equipment and Supplies

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Related Coverage Resources

Kidney Transplantation, Pancreas-Kidney Transplantation, and Pancreas Transplantation Alone

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses various types of diabetic monitoring equipment and supplies, specifically continuous glucose monitoring systems.

Coverage Policy

Coverage for Durable Medical Equipment including continuous glucose monitors and consumable medical supplies varies across plans. Coverage for therapeutic/non-adjunctive continuous glucose monitors and sensors, and diabetic supplies may be available under the medical benefit or the pharmacy benefit. Please refer to the customer's benefit plan document for coverage details.

If coverage is available for continuous glucose monitoring and specific diabetic supplies, the following conditions of coverage apply.

Continuous Glucose Monitoring System (CGMS)

Therapeutic/non-adjunctive Continuous Glucose-Monitoring Systems

A minimally invasive, therapeutic/non-adjunctive continuous glucose monitoring system (CGMS) (HCPCS A4239, E2103), which may include sensors (HCPCS A4239, A9276), transmitters (HCPCS A4239, A9277) and reader/receiver (HCPCS A9278, E2103), is considered medically necessary for the management of type 1 or type 2 diabetes mellitus:

- Freestyle Libre, Freestyle Libre 14 day, and Dexcom G7 15-day for an individual age 18 years and older
- Freestyle Libre 2 and Freestyle Libre 3 for an individual age 4 years and older
- Freestyle Libre 2 Plus, Freestyle Libre 3 Plus, Dexcom G6® and Dexcom G7 for an individual age 2 years and older
- Simplera CGM for an individual age 18 years and older

WHEN the individual is on ANY of the following insulin regimens:

- multiple daily injections
- long-acting basal insulin (e.g. glargine, detemir, degludec, NPH)
- continuous subcutaneous external insulin pump

Minimed Instinct sensor (HCPCS A4239, A9276) is considered medically necessary for the management of type 1 diabetes mellitus in an individual seven years and older:

WHEN the individual is on ANY of the following insulin regimens:

- multiple daily injections

- long-acting basal insulin (e.g. glargine, detemir, degludec, NPH)
- continuous subcutaneous external insulin pump

When the above criteria for a minimally invasive, therapeutic/non-adjunctive continuous glucose monitoring system are met, the following quantities for supplies apply:

- sensors (HCPCS A4239, A9276)**:**
  - Freestyle Libre 10-day system: three sensors every 30 days
  - Freestyle Libre 14-day system, Freestyle Libre 2, Freestyle Libre 3, Freestyle Libre 2 Plus, and Freestyle Libre 3 Plus: two sensors every 28 days
  - Dexcom G6 and Dexcom G7: three sensors every 30 days
  - Dexcom G7 15-day and Minimed Instinct sensor: two sensors every 30 days
  - Simplera: five sensors every 30 days

- transmitters (HCPCS A4239, A9277):
  - Dexcom G6: one transmitter every 90 days

- reader/receiver (HCPCS A9278, E2103):
  - Freestyle Libre 10 day and Freestyle Libre 14 day: one reader every 720 days
  - Freestyle Libre 2 and Freestyle Libre 3: one reader every 720 days
  - Dexcom G6 and Dexcom G7: one receiver every 365 days

Non- therapeutic/adjunctive Continuous Glucose-Monitoring Systems

A minimally invasive non-therapeutic/adjunctive continuous glucose monitoring system (CGMS) including sensors (HCPCS A4238, A9276), transmitters (HCPCS A4238, A9277) and reader/receiver (HCPCS A9278, E2102) (e.g., Guardian Sensor 3 [HCPCS A4238, A9276], Guardian Sensor 4 [HCPCS A4238, A9276, A9277], Guardian® REAL-Time [HCPCS code A4238, A9277, A9278, E2102]) used with a fingerstick blood glucose monitor is considered medically necessary for the management of type 1 or type 2 diabetes mellitus when used according to the U.S. Food and Drug Administration (FDA) approved indications and ALL of the following criteria have been met:

WHEN the individual is on ANY of the following insulin regimens:

- multiple daily injections
- long-acting basal insulin (e.g. glargine, detemir, degludec, NPH)
- continuous subcutaneous external insulin pump

When the above criteria for a minimally invasive, non-therapeutic/adjunctive continuous glucose monitoring system are met, the following quantities for supplies apply:

- transmitters (HCPCS A4238, A9277):
  - Medtronic transmitter: one transmitter every 365 days

Continuous Glucose Monitoring System with an Implantable Interstitial Glucose Sensor

A continuous glucose monitoring system with an implantable interstitial glucose sensor (i.e., Eversense®) (HCPCS code G0564) is considered medically necessary for the management of type 1 or type 2 diabetes mellitus for an individual age 18 years or older who is on ANY of the following insulin regimens:

- multiple daily injections
- long-acting basal insulin (e.g. glargine, detemir, degludec, NPH)
- continuous subcutaneous external insulin pump

Replacement of a Continuous Glucose Monitoring System and Components

Replacement of an existing continuous glucose monitoring system or component is considered medically necessary for an individual managing type 1 or type 2 diabetes mellitus on a continuous glucose monitor when BOTH of the following criteria are met:

- documentation confirming that the monitor/component is malfunctioning, is no longer under warranty and cannot be repaired
- evidence of an evaluation by the health care provider managing the diabetes within the last six months that includes a recommendation supporting continued use of a continuous glucose monitor

Glucose sensors for EITHER of the following minimally invasive, therapeutic/non-adjunctive continuous glucose monitoring systems (CGMS) for the management of type 1 or type 2 diabetes mellitus are considered medically necessary under the pharmacy benefit (copayment may apply):

- Freestyle Libre, Freestyle Libre 14 day, and Dexcom G7 15-day for an individual age 18 years and older
- Freestyle Libre 2 and Freestyle Libre 3 for an individual age 4 years and older
- Freestyle Libre 2 Plus, Freestyle Libre 3 Plus, Dexcom G6® and Dexcom G7 for an individual age 2 years and older
- Simplera CGM for an individual age 18 years and older

WHEN the individual is on ANY of the following insulin regimens:

- multiple daily injections
- long-acting basal insulin (e.g. glargine, detemir, degludec, NPH)
- continuous subcutaneous external insulin pump

Minimed Instinct sensor (HCPCS A4239, A9276) is considered medically necessary for the management of type 1 diabetes mellitus in an individual seven years and older:

WHEN the individual is on ANY of the following insulin regimens:

- multiple daily injections
- long-acting basal insulin (e.g. glargine, detemir, degludec, NPH)
- continuous subcutaneous external insulin pump

When the above criteria for a minimally invasive, therapeutic/non-adjunctive continuous glucose monitoring system are met, the following quantities for supplies apply:

- sensors (HCPCS A4239, A9276)**:**
  - Freestyle Libre 10-day system: three sensors every 30 days
  - Freestyle Libre 14-day system, Freestyle Libre 2, Freestyle Libre 3, Freestyle Libre 2 Plus, and Freestyle Libre 3 Plus: two sensors every 28 days
  - Dexcom G6 and Dexcom G7: three sensors every 30 days

  - Dexcom G7 15-day and Minimed Instinct sensor: two sensors every 30 days
  - Simplera: five sensors every 30 days

- transmitters (HCPCS A4239, A9277):
  - Dexcom G6: one transmitter every 90 days

- reader/receiver (HCPCS A9278, E2103):
  - Freestyle Libre 10 day and Freestyle Libre 14 day: one reader every 720 days
  - Freestyle Libre 2 and Freestyle Libre 3: one reader every 720 days
  - Dexcom G6 and Dexcom G7: one receiver every 365 days

A home glycated serum protein (GSP) monitor is considered experimental, investigational or unproven.

Each of the following is considered a convenience item and not medically necessary:

- home glycated hemoglobin (A1C) monitor
- laser lancet

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Continuous Glucose Monitoring System (CGMS)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
A4238	Supply allowance for adjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply=1 unit of service
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply
A9277	Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
A9278	Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
E2102	Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
G0564	Creation of subcutaneous pocket with insertion of 365 day implantable interstitial glucose sensor, including system activation and patient training (Code deleted 4/1/2025)

Diabetic Supplies

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply=1 unit of service
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply
A9277	Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
A9278	Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver

Considered Experimental/Investigational/Unproven when used to report a home glycated serum protein (GSP) monitor:

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous

Considered Not Medically Necessary/Convenience Item when used to report home glycated hemoglobin (A1C) monitors and/or laser lancet:

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous

General Background

Diabetes Mellitus

Diabetes mellitus (DM) is a disease characterized by hyperglycemia resulting from abnormal insulin secretion and/or abnormal insulin action within the body. Chronic hyperglycemia, resulting from poorly controlled diabetes, may result in serious and life-threatening damage, including dysfunction and failure of the eyes, kidneys, nervous system and cardiovascular system. The presence of insulin, a hormone, is essential for the body to convert sugar, starches and other foods into energy.

There are three major types of diabetes mellitus: type 1, type 2 and gestational diabetes mellitus (GDM). Type 1 diabetes, insulin-dependent diabetes, or juvenile-onset diabetes is an autoimmune disease in which the pancreas produces very little or no insulin due to autoimmune β-Cell destruction. Type 1 diabetes occurs in 5–10% of cases and typically occurs in patients less than age 20-30 years. People with type 1 diabetes require insulin therapy for life. Type 2 diabetes is typically an adult-onset diabetes and includes those individuals who are insulin resistant (i.e., the

body fails to use insulin properly) due to a progressive loss of β-cell insulin secretion. Initially, people with type 2 diabetes do not require insulin therapy and are controlled with diet and exercise. However, in most cases, oral hypoglycemic agents are indicated in the treatment of people with type 2 diabetes. Over time, some will require insulin therapy. GDM is typically diagnosed in the second or third trimester of pregnancy and is not clearly overt prior to gestation. GDM involves a degree of glucose intolerance and generally subsides following delivery (American Diabetes Association [ADA], 2026a).

Diabetes is diagnosed and monitored by routine testing of blood glucose levels, glycosylated hemoglobin (HbA1c or A1C), plasma insulin levels and glycosuria. As a guide to adjustments in therapy (i.e., diet, exercise and medication), monitoring of blood glucose levels is a cornerstone of diabetes care.

Insulin is a naturally occurring hormone secreted by the pancreas. Individuals with diabetes may require insulin therapy because the pancreas does not produce insulin (type 1 diabetes) or the body does not use insulin properly (type 2 diabetes). Insulin is the mainstay of therapy for individuals with type 1 diabetes. Basal insulin refers to insulin that is long acting and used to keep blood sugar stable in between meals and during the night or the continuous delivery of rapid-acting insulin via an insulin pump (ADA, 2026c). "Bolus" refers to insulin that is fast acting and is given following a meal or to treat abnormally high blood glucose levels. There are different types of insulin depending on how quickly they work, when they peak, and how long they last. The types of insulin include rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting and pre-mixed.

Type of Insulins	**Onset**	**Peak**	**Duration**	**Compounds/Brands**
Rapid-acting insulin (Bolus)	10–30 minutes	30 minutes to 3 hours	3–5 hours	Glulisine (Apidra®), Lispro (Humalog®) Aspart (NovoLog®, Fiasp®; Ademelog®) Inhaled (Afrezza®)
Short-acting	30 minutes to 1 hour	1–5 hours	Up to 12 hours	Humulin Regular® Novolin Regular®
Intermediate-acting	1–4 hours	4–12 hours	12–24 hours	Humulin NPH Novolin NPH
Long-acting insulin (basal analogs)	1–2 hours	Minimal peak	Up to 24 hours	Detemir (Levemir®) Degludec (Tresiba®) Glargine (Lantus®) Glargine biosimilar (Basaglar®)
Ultra long-acting	6 hours	No peak	Up to 36 hours	Glargine U-300 (Toujeo®)

Premixed insulin (intermediate-acting and short-acting insulin) is available for individuals who have trouble drawing up insulin from two separate bottles. Humulin 70/30®, Novolin 70/30®, Novolog 70/30®, Humulin 50/50®, and Humalog mix 75/25® are premixed insulins. Most insulin comes dissolved or suspended in liquids. The standard and most commonly used is U-100, which means it has 100 units of insulin per milliliter of fluid. Concentrated insulin formulations may enhance convenience by reducing the number of injections required to achieve the prescribed dosage and may increase comfort through the administration of smaller volumes and decreased injection effort. These attributes have the potential to facilitate greater adherence to treatment regimens among individuals with insulin resistance who necessitate higher doses of insulin. U-500 insulin is five times more concentrated than U-100 regular insulin and is available for patients who

are extremely insulin resistant (ADA 2026c; ADA, 2025d). Afrezza (insulin human) is a rapid acting inhaled insulin used at the beginning of a meal. Afrezza is available in 4 unit, 8 unit and 12 unit single use cartridges.

Self-management of diabetes is essential for the control of the disease and curtailing irreversible dysfunction and possible failure of multiple body systems. To assist people with diabetes in self-management of their care, the use of diabetic supplies such as needles, syringes, needle-free insulin injection devices, insulin pens, test strips (i.e., glucose and ketone), lancets and alcohol wipes may be indicated. A subpopulation of people with diabetes may use a glucose meter, continuous glucose monitor and/or a continuous insulin infusion pump.

Home Blood Glucose Monitors

Blood glucose monitors (BGMs) measure blood glucose concentration using a reagent strip, cartridge or cuvette and a drop of capillary blood from a finger puncture. Some devices measure glucose level in the interstitial space on a continuous basis. Used at home, portable glucose monitors allow people with diabetes to detect and treat fluctuations in blood glucose levels. The normal fasting blood glucose concentration ranges from 70–100 milligrams (mg) per deciliter (dL) in blood serum or plasma, although capillary blood glucose concentrations may be higher (e.g., by 10–15%). A person with diabetes can adjust insulin dosage, food intake, and exercise in response to the monitor's readings of the blood glucose level to achieve normoglycemia. Frequent blood glucose monitoring to maintain normoglycemia facilitates treatment designed to reduce the incidence and severity of diabetes-related microvascular and neurological complications.

Home Continuous Glucose Self-Monitoring (CGM)
A proposed alternative to intermittent self-monitoring blood glucose (SMBG) is continuous glucose monitoring (CGM). CGM devices provide ongoing, real-time monitoring and recording of blood glucose levels by continuous measurement of interstitial fluid which generally lags from three to 20 minutes behind finger-stick values. There are three primary types of CGM systems: short-term/professional, non-therapeutic/adjunctive and therapeutic/non-adjunctive. CGM's can also be described as real-time CGM (rtCGM) and intermittently scanned CGM (isCGM). Short-term CGM systems can be used by a healthcare provider for up to 14 days for diagnostic purposes. Non-therapeutic/adjunctive and therapeutic/non-adjunctive CGMs are used on an ongoing basis by a subgroup of patients with diabetes who are on an intensive insulin treatment plan. Non-therapeutic/adjunctive CGMs must be used with a fingerstick blood glucose monitoring device. Therapeutic/non-adjunctive CGMs are a standalone device that can be used to make treatment decisions without adjunctive fingerstick monitoring.

Short-term/professional CGM may be used by the treating physicians as a one-time evaluation tool for up to fourteen days for type 1 and type 2 insulin-treated individuals who are experiencing hypo- or hyperglycemic episodes unresponsive to adjustments in therapy (e.g., insulin administration and nutrition). CGM may also be used to detect asymptomatic nocturnal hypoglycemia and for lowering A1c levels without risking severe hypoglycemia The recording can identify fluctuations in blood glucose levels that were not detected by intermittent fingersticks. This data allows adjustments to be made in the therapeutic regimen (e.g., oral medication, insulin therapy, diet, exercise) to minimize glucose excursion. Repeat short-term assessments may be needed periodically until the individual stabilizes and achieves ideal treatment targets (ADA, 2026b).

Non-therapeutic/adjunctive CGM systems are used with finger-stick blood glucose monitoring and should never be used alone. The continuous glucose monitoring system (CGMS) consists of a sensor, transmitter and receiver. Some monitors provide real-time information, while others require that data be downloaded and reviewed retrospectively. Depending on the device, a sensor

may be worn for 3–7 days before it must be changed. CGM may be used on a long-term basis for the treatment of people with a subtype of type 1 or type 2 diabetes. The Medtronic Guardian REAL-time CGMS is an example of the non-therapeutic/adjunctive CGM.

A new class of CGM systems, called therapeutic/non-adjunctive CGMs, has been developed as a proposed replacement for the current non-therapeutic/adjunctive CGMs that must be used as an adjunct (in addition) to finger-stick glucose monitoring. Therapeutic/non-adjunctive CGMS are defined as a CGM system approved by the US Food and Drug Administration (FDA) to replace other blood glucose monitoring testing and to be used to make diabetes treatment decisions without adjunctive (additional) finger-sticks. The Abbott FreeStyle Libre, Freestyle Libre 14 day, Freestyle Libre 2, Freestyle Libre 3 (Abbott Diabetes Care Inc., Alameda, CA) and the Dexcom G5, G6, G7, and G7 15 day (Dexcom, San Diego, CA) and Simplera (Medtronic, Northridge, CA) are examples of FDA approved therapeutic/non-adjunctive CGMs.

The FreeStyle Libre therapeutic/non-adjunctive CGM is a sensor-based continuous glucose monitoring system that uses an ambulatory glucose profile (AGP) to assess glycemic levels on a 24-hour basis through a minimally invasive method called flash glucose monitoring. Unlike the FreeStyle Libre Pro used for a short period of time by the healthcare professional, the FreeStyle Libre Flash is used by the patient for continuous glucose monitoring. The System includes a Sensor kit, Reader Kit and software. The Sensor kit includes the sensor and the sensor applicator. The glucose sensor is worn under the skin and connected to a plastic patch worn on the back of the upper arm for up to 10 days. The Frestyle Libre 14 day has a 14 day sensor. About one hour after insertion, the sensor begins reading glucose levels and stores data every fifteen minutes, trending the information. The Reader is used to obtain glucose readings from the Sensor. Data are transferred by radiofrequency identification to the Reader when it is brought into close proximity to the Sensor. The Reader displays the current sensor glucose level, a glucose trend arrow, and glucose readings over the preceding eight hours at fifteen minute intervals. Scanning can be done as often as is needed for current glucose concentration. The Reader can store up to 90 days of glucose history data and has a built-in meter that can be used to test blood glucose and blood ketone levels. Notes can be entered into the Reader by the user. The data in the reader memory can be uploaded using the device software to generate summary glucose reports (including an ambulatory glucose profile). The Libre is proposed for use instead of fingerstick glucose measurements except when the user is hypoglycemic, experiencing rapid changes in glucose readings and/or when symptoms do not match the Libre's readings. There are no alarms on the system and it is calibrated at the point of manufacture (i.e., factory-calibrated) and does not require or accept any user-entered calibration (Abbott Laboratories, 2025; Edge, et al., 2017; Haak, et al., 2017; Bolinder, et al., 2016; Kalra and Gupta, 2015; Bailey, et al., 2014).

The Freestyle Libre 2, Freestyle Libre 3, Freestyle Libre 2 Plus, and Freestyle Libre 3 Plus are similar to the Freestyle Libre Flash and Freestyle Libre 14 day but have enhanced features. The Libre 2 sensor and Freestyle Libre 3 are worn for up to 14 days and are indicated for use in children age four and up. They have real time alarms and communicates autonomously with digitally connected devices (Abbott, 2025; FDA, 2020). The Freestyle Libre 3 is smaller, easier to apply and provides real-time blood glucose readings every minute viewable on a smartphone with the Freestyle Libre 3 app (Abbott, 2025). The Freestyle Libre 2 Plus and Freestyle Libre 3 Plus are worn for up to 15 days and are indicated for use in children age two and up. FreeStyle Libre 2 Plus sensor connects via Bluetooth to the Tandem t:slim X2 insulin pump. Glucose data is visualized on the t:connect mobile app and t:slim X2 insulin pump every minute. The FreeStyle Libre 3 Plus sensor has the capability to work with Automated Insulin Delivery (AID) systems but Abbott does not currently have a partner (Abbott, 2025).

The Dexcom G5 is another example of a therapeutic/non-adjunctive CGM and was also designed to replace fingerstick blood glucose testing. The G5 could be used to make treatment decisions in

people with diabetes age ≥ 2 years. The G5 has subsequently been replaced with the Dexcom G6. The Dexcom G6 is different from the Dexcom G5 because it is an integrated device to be used alone or with any compatible devices, is factory calibrated and does not require users to calibrate the sensor with fingerstick blood glucose measurements. The G6 has an updated sensor probe that minimizes interference with acetaminophen. Users are informed by Dexcom that if the glucose alerts and readings from the G6 do not match symptoms or expectations, to perform a fingerstick and use a blood glucose meter to make diabetes treatment decisions (Dexcom, 2026; FDA, 2018). Per the manufacturer, the G5 is no longer being produced. The Dexcom 7 obtained FDA approval in December 2022 and became available in early 2023. The Dexcom 7 is similar to the Dexcom 6, however it is smaller in size, an all-in-one wearable with no fingersticks or scanning required.

The Dexcom G7 15 Day Continuous Glucose Monitoring (CGM) System (Dexcom G7 15 Day CGM System or G7 15 Day) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons 18 years and older. The system is intended to replace fingerstick blood glucose (BG) testing for diabetes treatment decisions and is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems (Dexcom, 2026).

The Bigfoot Unity System is regulated as an integrated continuous glucose monitoring system. The Bigfoot Unity System provides insulin dose recommendations for people with diabetes who use multiple daily injections (MDI) of insulin by using smart pen caps that incorporate integrated continuous glucose monitor (iCGM) data from FreeStyle Libre 2 sensors and health care provider instructions. The dosing recommendations display on connected smart caps for disposable insulin pens. The mobile app allows the input of data, displays current glucose range and provides real-time alerts. The starter kit contains Bigfoot's smart pen caps for long-acting (black cap) and rapid-acting insulins (white cap), two FreeStyle Libre 2 sensors, pen needles, a backup blood glucose meter and supplies (Bigfoot Biomedical, Inc., 2024).

The Simplera™ System is a prescription-only real-time continuous glucose monitoring (CGM) device designed for adults aged 18 and older with diabetes. It includes a wearable sensor and a mobile app that provide real-time glucose data. The sensor is approved for up to 6 days of use, with an additional 24-hour grace period, and is intended for use in home settings. The Simplera™ app in combination with the Simplera™ sensor is intended for use only by patients and caregivers using a compatible mobile device and operating system, and who have sufficient experience to adjust mobile device audio and notification settings (Medtronic, 2026). Calibration is not required; however, blood glucose (BG) readings are necessary under specific conditions:

- during the first 12 hours of sensor use
- when sensor data is unavailable
- if symptoms do not align with sensor glucose (SG) values
- when using certain medications

Failure to perform BG checks as indicated may result in inaccurate SG readings, potential insulin over-administration, and increased risk of hypoglycemia.

The Instinct sensor (made by Abbott) is indicated for the management of type 1 diabetes mellitus in persons aged seven and up with a wear time of 15 days. The Instinct sensor has been studied and is approved for use in the arm insertion site only. It is compatible with the MiniMed™ 780G system (Medtronic, 2026).

U.S. Food and Drug Administration (FDA): Continuous glucose monitoring systems (CGMS) for diabetes management are regulated by the U.S. Food and Drug Administration (FDA) primarily as Class II medical devices. These devices are cleared via the 510(k) pathway or approved through the Premarket Approval (PMA) process, depending on their intended use and

technological features. Most CGMS are indicated for monitoring glucose levels in individuals with diabetes, with specific age ranges and usage scenarios (e.g., professional use, non-therapeutic/adjunctive use, or therapeutic/non-adjunctive use). Common attributes of device indications include real-time or retrospective glucose data collection, sensor wear duration, and integration capabilities with other diabetes management devices. Some systems are intended to replace fingerstick blood glucose testing for treatment decisions, while others are adjuncts to self-monitoring blood glucose (SMBG). Contraindications typically relate to age restrictions, device compatibility, and use with automated insulin dosing systems.

CGM systems for professional use only

Device or Product	Identifier	Manufacturer
Medtronic iPro2™ Professional CGM	P150029	Medtronic MiniMed, Inc.
Freestyle Libre Pro Flash Glucose Monitoring System	P150021	Abbott Diabetes Care, Inc
Dexcom G4 Platinum Professional Continuous Glucose Monitoring System	P120005 S001	DexCom, Inc.

*FDA product codes: MDS, OZO

Non-therapeutic/adjunctive CGMs

Device or Product	Identifier	Manufacturer
Medtronic Guardian® REAL-Time CGM	P980022 S017	Medtronic MiniMed, Inc.
DexCom™ G4 Platinum CGM	P120005	DexCom, Inc.
DexCom G4 Platinum (Pediatric) CGM	P120005 S002	DexCom, Inc.

*FDA product codes: MDS, OYC

Therapeutic/non-adjunctive CGMs

Device or Product	Identifier	Manufacturer
Freestyle Libre	P160030	Abbott Diabetes Care, Inc.
Freestyle Libre 14 day CGM	P160030 S017	Abbott Diabetes Care, Inc.
FreeStyle Libre 2	K193371 K222447 K233537	Abbott Diabetes Care, Inc.
Freestyle Libre 3	K212132 K222447 K233537	Abbott Diabetes Care, Inc.
Dexcom G5	P120005 S033	DexCom, Inc.
Dexcom G6	DEN170088 K182041	DexCom, Inc.
Dexcom G7	P120005 S091	DexCom, Inc.
Dexcom G7 15 Day Continuous Glucose Monitoring System	K243214	DexCom, Inc.
Simplera	P160007 S047	Medtronic MiniMed, Inc.
Bigfoot Unity™ Diabetes Management	K202145	Bigfoot Biomedical, Inc.

*FDA product codes: KGX, MDS, NBW, PQF, PZE, QBJ, QDK, QLG, QOG

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review – Non-therapeutic/adjunctive CGM used in conjunction with a standard home blood glucose monitor: The evidence in the published peer-reviewed literature supports the use of a CGM when used in conjunction with self-monitoring blood glucose (SMBG) to aid in the management of people with insulin dependent diabetes who are difficult to control and not achieving treatment targets. Studies including adults and children with type 1 and type 2 diabetes have been in the form of systematic reviews and meta-analysis, randomized controlled trials and case series (Beck, et al., 2017a; Beck, et al., 2017b; Lind, et al., 2017, Poolsup, et al., 2013; Langendam, et al., 2012; Battelino, et al, 2011; Hoeks, et al., 2011; Gandhi, et al., 2011; Chase et al., 2010; Juvenile Diabetes Research Foundation [JDRF], 2009a; JDRF, 2009b; Newman, et al., 2009; Rodbard, et al., 2009; JDRF, 2008; Mazze, et al., 2008; Weinzimer, et al., 2008; Chetty, et al., 2008; Golicki, et al., 2008; Yoo, et al., 2008; Weber, et al., 2007; Zisser, et al., 2007; Wilson, et al., 2007; Bailey, et al., 2007; Diabetes Research in Children Network [DirecNet] Study Group, 2007; Garg, et al., 2007; Deiss, et al., 2006; Garg, et al., 2006; Lagarde, et al., 2006).

Literature Review – Therapeutic/non-adjunctive CGM: Randomized controlled trials and case series have reported a significant reduction in mean time spent in hypoglycemia, nocturnal hypoglycemia, daytime hypoglycemia, reduction in the number of hypoglycemic events, and/or improvement in perceived frequency of hyperglycemia and patient satisfaction when using a therapeutic/non-adjunctive CGM. Some studies also reported an improvement in A1C levels (Boscari, et al., 2018a; Boscari, et al., 2018b; Aleppo, et al., 2017; Bolinder, et al., 2016; Haak, et al., 2017a; Haak, et al., 2017b).

Professional Societies/Organizations: The American Diabetes Association (ADA)'s 2026 Standards of Care in Diabetes (2026b) clinical practice recommendations for the treatment and management of diabetes mellitus states that continuous glucose monitoring (CGM) has an important role in assessing the effectiveness and safety of treatment of patients with type 1 diabetes and type 2 diabetes. ADA recommendations are assigned ratings of **A**, **B**, or **C**, depending on the quality of the evidence in support of the recommendation. Expert opinion **E** is a separate category for recommendations in which there is no evidence from clinical trials, clinical trials may be impractical, or there is conflicting evidence (ADA, 2026i). ADA (2026b) recommendations for CGM include:

- "Use of CGM is recommended at diabetes onset and anytime thereafter for children, adolescents, and adults with diabetes who are on insulin therapy, **A** on noninsulin therapies that can cause hypoglycemia, **C** and on any diabetes treatment where CGM helps in management. **C** The specific CGM device and method for use should be made based on the individual's circumstances, preferences, and needs. **E**
- In people with diabetes on insulin therapy, rtCGM devices should be used as close to daily as possible for maximal benefit. **A** People with diabetes should have uninterrupted access to their supplies to minimize gaps in CGM. **A**
- During pregnancy for individuals with type 1 diabetes, CGM can help achieve glycemic goals (e.g., time in range and time above range) **A** and A1C goal **B** and may be beneficial for other types of diabetes in pregnancy. **E**
- In circumstances when consistent use of CGM is not feasible, consider periodic use of personal or professional CGM to adjust medication and/or lifestyle. **C**
- Skin reactions, either due to irritation or allergy, should be assessed and addressed to aid in successful use of devices. **E**

- People who wear CGM devices should be educated on potential interfering substances and other factors that may affect accuracy. **C**"

The 2022 American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan (Blonde, et al., 2022) recommends the following in regard to glucose monitoring:

- "All persons who use insulin should use continuous glucose monitoring (CGM) or perform blood glucose monitoring (BGM) a minimum of twice daily and ideally before any insulin injection. More frequent BGM may be needed by persons who are taking multiple daily injections (MDI) injections, persons not at A1C targets, or those with history of hypoglycemia. Persons who do not require insulin or insulin secretagogue therapy may often benefit from BGM, especially to provide feedback about the effects of their lifestyle choices (diet and physical activity), and to assess response to pharmacologic therapy.
- Real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM) is recommended for all persons with type 1 diabetes (T1D), regardless of insulin delivery system, to improve hemoglobin A1c (A1C) levels and to reduce the risk for hypoglycemia and diabetic ketoacidosis (DKA)
- rtCGM or isCGM is recommended for persons with type 2 diabetes (T2D) who are treated with insulin therapy, or who have high risk for hypoglycemia and/or with hypoglycemia unawareness"

The 2021 American Association of Clinical Endocrinology clinical practice guideline (Grunberger, et al., 2021) on the use of advanced technology in the management of persons with diabetes recommend continuous glucose monitoring (CGM) for the following individuals:

- 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
- for all individuals with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness)
- for children/adolescents with T1D
- for pregnant women with T1D and T2D treated with intensive insulin therapy
- for women with gestational diabetes mellitus (GDM) on insulin therapy

Regarding continuous glucose monitoring (CGM) in adults, the 2016 Endocrine Society Guidelines (Peters, et al., 2016) for CGM were retired on December 22, 2022.

In the 2016 consensus statement on outpatient glucose monitoring, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) (Bailey, et al., 2016) made the following recommendations for CGM use in people with diabetes:

- Type I diabetes in adults: CGM is recommended, particularly for patients with history of severe hypoglycemia, hypoglycemia unawareness and to assist in the correction of hyperglycemia in patients not at goal. CGM users must know basics of sensor insertion, calibration, and real-time data interpretation.
- Type 1 diabetes in pediatric patients: Recommendation same as for type 1 adults. However, the authors noted that prevalence and persistent use of CGM is lower in children and more in-depth training and follow up is recommended to ensure successful use of this technology.
- Patients with type 2 diabetes using insulin/ sulfonylureas, glinides: Data on CGM for this population are limited and trials are ongoing.
- Patients with type 2 diabetes with low risk of hypoglycemia: No recommendation was made.
- Patients with gestational diabetes: Based on current data, the benefit of CGM in pregnant women with preexisting diabetes is unclear. CGM can be used during pregnancy as a

teaching tool, to evaluate glucose patterns, and to fine-tune insulin dosing. CGM can also supplement blood glucose monitoring, especially for monitoring nocturnal hypoglycemia or hyperglycemia and postprandial hyperglycemia.

In their 2020 updated consensus statement on glycemic control for people with type 2 diabetes, the AACE and ACE (Garber, et al., 2020) stated that CGM may be considered for the management of people with type 2 diabetes who are receiving intensive insulin therapy (3 to 4 injections/day or on insulin pump), for those with history of hypoglycemia unawareness, or those with recurrent hypoglycemia. CGM may help to "educate the patient regarding the glycemic effects of various foods, help the patient titrate insulin, and provide warnings when the patient is experiencing hyperglycemia or hypoglycemia" (Rodbard, et al., 2009).

Continuous Glucose Monitoring System with an Implantable Interstitial Glucose Sensor (e.g., Eversense®)

The Eversense® (Senseonics™ Inc., Germantown, MD) is a continuous glucose monitoring (CGM) system with an implantable sensor. The system includes:

1) the sensor, which is inserted subcutaneously by a health care provider
2) a removable smart transmitter worn over the sensor
3) a mobile medical application (MMA) which displays the glucose readings

The Eversense CGM Systems are indicated for continually measuring glucose levels in persons with diabetes age 18 and older. The Eversense E3 CGM System is indicated for up to 180 days with fingerstick blood glucose (BG) measurements required for calibration primarily one time a day after day 21, and when symptoms do not match CGM information or when taking medications of the tetracycline class. The Eversense 365 CGM System is indicated for up to one year with fingerstick blood glucose (BG) measurements required for calibration primarily one time a day after day 13, and when symptoms do not match CGM information or when taking medications of the tetracycline class (Senseonics, 2025).

The sensor is 18.3 millimeters (mm) long and 3.5 mm in diameter. It has a silicone collar impregnated with 1.75 mg of dexamethasone acetate (DXA) (an anti-inflammatory steroid drug) that elutes an average of 3 micrograms (µg) per day over the life of the sensor to attenuate the body's local inflammatory response and prolong the sensor life. The sensor is inserted, by the health care provider, under the skin in the upper arm using local anesthesia. An approximately 5 mm incision is made at the insertion location to create a subcutaneous pocket approximately 3-5 mm below the skin surface. A suture or adhesive skin closure (e.g., Steri-Strip™) is used to close the incision. The device can be worn for up to 180 days (previously 90 days) and is activated to measure the glucose level every five minutes when it receives radio frequency power from the transmitter. The removable smart transmitter is worn externally over the sensor and powers the sensor. The transmitter calculates the glucose levels and wirelessly sends the data via Bluetooth to the mobile device app. At the end of the 180-day wear period, the sensor is removed by the healthcare provider (Senseonics, 2025; Christiansen, et al., 2018).

The smart transmitter provides on-body vibration alerts (e.g., low blood glucose, high blood glucose) and the mobile device sends alerts based on the glucose settings that the user chooses. It has a rechargeable battery, requires recharging every other day for about 15 minutes and is reusable for up to one year. The manufacturer notes that if the vibration is not felt by the user and the mobile device is not available, then the alerts will not be effective. Fingerstick blood glucose levels are indicated to validate hyperglycemia, hypoglycemia and to make treatment decisions. The Eversense App is a software application that runs on a mobile device (e.g., smartphone or tablet) and displays glucose data in a variety of ways. It also provides the user with an option to upload the data to the Senseonics Data Management System (DMS) for historic viewing and storing of glucose data (Senseonics, 2025).

U.S. Food and Drug Administration (FDA): The Eversense E3 and Eversense AP Continuous Glucose Monitoring (CGM) Systems are FDA-cleared implantable CGM devices for adults (≥18 years) with diabetes. The Eversense E3 received approval through the Premarket Approval (PMA) pathway and is classified as a Class III device, while the Eversense AP was granted marketing authorization via the De Novo pathway and is classified as Class II. Both systems share common attributes: they provide continuous glucose measurement for extended wear periods (up to 180 days for E3 and up to six months for AP), deliver real-time glucose readings, trend information, and alerts for hypo- and hyperglycemia, and are intended for non-adjunctive use to replace fingerstick blood glucose monitoring for diabetes treatment decisions. Both require a prescription, are for single-patient use, and support interpretation of historical data to aid therapy adjustments; the AP system additionally integrates with digitally connected devices, including automated insulin dosing systems.

Device or Product	Identifier	Manufacturer
Eversense E3 CGM System	P160048 P160048/S016	Senseonics™ Inc.
Eversense AP CGM System	DEN230052	Senseonics™ Inc.

*FDA product codes: QCD, QHJ, SBA

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Literature Review: The evidence in the published, peer-reviewed literature to support the safety and effectiveness of the Eversense CGM has primarily been in the form of registry data, retrospective reviews, and case series with small patient populations and short-term follow-ups (Christiansen et al., 2019; Deiss et al., 2019; Sanchez, et al., 2019; Tweden et al., 2019; Christiansen, et al., 2018; Kropff, et al., 2017; DeHennis, et al., 2015; Wang et al., 2015; Mortellaro and DeHennis, 2014). The current data shows significant improvement in time in the target range for sensor glucose values of 70-180 mg/dL following the use of Eversense (Kropff et al., 2017).

Continuous Glucose Monitoring in Pregnancy
Management of diabetes during pregnancy (maternal diabetes) is essential for healthy outcomes for the mother and the infant. An individual with preexisting type 1 or type 2 diabetes mellitus may become pregnant or a woman can develop diabetes during the pregnancy (i.e., gestational diabetes [GDM]). Gestational diabetes typically subsides following delivery. Specific risks of diabetes in pregnancy include spontaneous abortion, fetal anomalies, preeclampsia, fetal demise, macrosomia, neonatal hypoglycemia, neonatal hyperbilirubinemia, and neonatal respiratory distress syndrome (ADA, 2026g). Both 72-hour and long-term CGM have been proposed for use during pregnancy (Kitzmiller, et al., 2008).

Literature Review: Feig et al. (2017) conducted a multicenter, open-label randomized controlled trial (n=325) to evaluate the effectiveness of CGM on maternal glucose control and obstetrical and neonatal health outcomes when used before pregnancy and from early pregnancy. The study included two parallel trials, a pregnancy trial with 215 subjects (n=108 CGM; n=117 controls without CGM) and a planning pregnancy trial with 110 subjects (n=53 CGM; n=57 controls). Subjects were included if they were age 18-40 years, had type 1 diabetes ≥ 12 months, receiving intensive insulin therapy via multiple daily injections or insulin pump, ≤ 13 weeks and 6 days' gestation, with an HBA1C 6.5%-10.0% or planning pregnancy with an HBA1C 7.0%-10.0%. Regular CGM users or medical conditions requiring hospitalization that could prevent a subject from completing the trial were excluded. The primary outcome in the pregnancy group was the

change in HBA1C from randomization to 34 weeks gestation and the change in HBA1C from randomization to 24 weeks or conception in the planning pregnancy group. Secondary outcomes for all subjects were percentage of time spent in, above, and below the recommended glucose control target range (3·5–7·8 mmol/L); area under the curve for glucose levels; episodes of hypoglycemia; and glucose variability measures derived from CGM measures. Secondary outcomes for the pregnancy group included: gestational weight gain, gestational hypertension, preeclampsia, mode of delivery, length of hospital stay, insulin dose, and questionnaires relating to fear of hypoglycemia, coping with diabetes, quality of life, and satisfaction with monitoring device. Neonatal secondary outcomes included: preterm delivery, hypoglycemia requiring intravenous dextrose, intensive care unit admission requiring a duration of at least 24 hours, cord blood gas pH, total length of hospital stay, birthweight, and macrosomia (birthweight ≥4 kg). Pregnancy group follow-up visits occurred at 8, 12, 16, 20, 24, 28, 32, 34, and 36 weeks gestation. Planning pregnancy group follow-ups occurred at 4, 8, 12, 16, 20, and 24 weeks after randomization. Women who conceived during the trial continued in their same randomized group and followed the pregnancy study visit schedule. Outcomes included the following:

- Significantly more pregnant CGM user than controls (p=0.0171) completed scheduled follow-up visits due to sensor issues (p<0.001) and sensor-related diabetes management issues (p<0.001).
- There was no difference in number of visits completed between the planning pregnancy groups.
- Frequency of CGM use was comparable in the pregnancy and pregnancy planning groups with highest sensor use in later gestation and earlier time (median 6.7 days) in pregnancy planning women.
- There was a significant between-group difference in improvement in HBA1C from baseline to 34 weeks' gestation, favoring CGM use (p=0.0207). There was no significant difference in planning pregnancy groups.
- Pregnant CGM users spent significantly more time in target (p=0.0034) and less time hyperglycemic (p=0·0279) compared to pregnant controls.
- There was no significant difference in the pregnancy group vs. the control group in severe hypoglycemic episodes and time spent hypoglycemic (p=0.10).
- Neonatal health outcomes were significantly improved, with lower incidence of large for gestational age (p=0.0210), fewer neonatal intensive care admissions lasting more than 24 h (p=0.0157), fewer incidences of hypoglycemia (p=0.0250), and 1-day shorter length of hospital stay (p=0.0091).
- There was no apparent reported benefit of CGM in women planning pregnancy.

The most common adverse events were skin reactions occurring in 49/103 CGM subjects and 8/104 control subjects in the pregnancy groups and in 23/52 CGM subjects and 5/57 controls planning pregnancy. The most common serious adverse events were nausea and vomiting in four pregnancy subjects and three planning pregnancy subjects. Author-noted limitations included: the planning pregnancy trial did not have sufficient power to detect the magnitude of differences that were significant in the pregnancy trial; HBA1C data and CGM data sets were missing due to dropouts, missing or lost samples, unavailable participants, pregnancy losses or delivery before 34 weeks; potential differences between the CGM data collected using real-time sensors in the CGM group and masked sensors in the control group; and there were no data on the frequency of capillary glucose monitoring and its relationship to glucose control or on the use of insulin suspension. The authors noted that this was the first study to indicate potential for improvements in non-glycemic outcomes for CGM users.

Wei et al. (2016) conducted a prospective, observational, open-label, randomized controlled trial (n=106) to investigate the effects of glucose monitoring (CGM) on maternal and neonatal outcomes. Subjects were randomized to antenatal care plus CGM vs. antenatal care plus fingerstick self-monitoring blood glucose (SMBG) following a gestational diabetes mellitus (GDM) diagnosis. The CGM group was subdivided into early (24-28 weeks) and late (28-36 weeks).

Subjects were included who were 24-28 weeks' gestation with a singleton pregnancy. Exclusion criteria were: diagnoses of diabetes mellitus, previous treatment for GDM, presence of infection or other severe metabolic, endocrine, medical or psychological comorbidities. Obstetrical and neonatal outcomes included: caesarean section, birthweight, standard deviation of weight for gestational weeks and Apgar score at five minutes. HBA1C and glycemic control were also recorded. Follow-ups occurred every 2-4 weeks until 28 gestational weeks, every two weeks until 32 gestational weeks and weekly thereafter. Four subjects in the CGM group and seven in the SMBG group were lost to follow-up. Thus, outcomes were reported for 51 CGM users and 55 SMBG subjects. Outcomes included the following:

- Caesarean delivery rate was greater in the SMBG group than in the CGMS group but was not statistically significant (p=0.37).
- No births occurred before 35th gestational week.
- No perinatal deaths occurred.
- There was no significant difference in Apgar scores at five minutes, macrosomia, neonatal hypoglycemia, extreme large-for-gestational age (LGA) (≥ 97th percentile) and small-for-gestational age (SGA) (≤ 10th percentile).
- Fewer LGAs were born in CGM group but the difference was not statistically significant (p=0.071).
- HbA1C levels were lower in the CGMS group but were not significantly different throughout the last two trimesters.
- Similar reductions in HbA1C levels were observed in the CGMS and SMBG groups (p=0.089) in later pregnancy (32 to 36 weeks gestation).
- Mean amplitude of glucose excursions (MAGE) was significantly higher in CGM group in the third trimester than among those wearing the CGMS in the second trimester (p=0.046).
- Significantly more insulin (p=0.02) and more regular insulin (p=0.027) were used in CGM group.
- Significantly more NPH insulin was used in the SMBG group (p=0.066).
- By the last visit there was no significant difference in required insulin doses between the groups (p=0.45).
- CGM users gained significantly less weight (p=0.004), had a lower proportion of subjects who experienced excess gestational weight gain and more subjects with appropriate weight gain.
- Significantly fewer CGM users gained an inadequate amount of gestational weight (p=0.039).
- Subjects who used CGM in the early stage gained significantly less weight than SMBG users (p=0.003).

There were no significant differences in adverse events or glycemic control between the two groups. The CGM group experienced mild erythema, itching, and inflammation. Author-noted limitations of the study included: the small patient population and the few perinatal complications possibly limited the generation of statistically significant results; education management was not blinded possibly creating the Hawthorne effect (altering behavior); some clinical data (e.g., sensor data on instrument failure, instrument error, pain, and discomfort) were unavailable and follow-up data at six weeks postpartum were deficient. The study showed that CGM, especially when initiated early, plus professional antenatal care helped to reduce maternal weight gain and glycemic variability. Additional studies are needed to assess the effectiveness of CGM on maternal weight gain in reducing perinatal problems, especially fetal macrosomia.

Raman et al. (2017) conducted a Cochrane systematic review to compare various glucose monitoring methods for women with gestational diabetes and the monitoring effects on maternal and fetal, neonatal, child and adult outcomes. Two randomized controlled trials that investigated CGM vs. self-monitoring of blood glucose reported no significant difference in caesarean section rates (n=179), large-for gestational age infants (n=106) and neonatal hypoglycemia (n=179). There were no perinatal deaths (n=179). The evidence was considered of very low quality.

Secher et al. (2013) conducted a randomized controlled trial including 123 type 1 and 31 type 2 women with pregestational diabetes. Patients were randomized to CGM (n=79) for six days at 8, 12, 21, 27, and 33 weeks in addition to routine care or routine care only (n=75). Routine care included self-monitored blood glucose seven times per day. Twenty-seven people with type 1 diabetes were on insulin pump therapy, most initiated prior to pregnancy. Forty-nine women used real-time CGM per protocol. At 33 weeks, there was no significant difference in HbA1c (p=0.64), episodes of severe hypoglycemia (p=0.91) and prevalence of large-for-gestational-age infants (p=0.19) between the groups. Other perinatal outcomes were also comparable. Intermittent use of CGM did not improve outcomes in this patient population. A limitation of the study is the low number of CGM users who followed protocol.

Murphy et al. (2008) conducted a randomized controlled trial to compare the outcomes of type 1 (n=46) and type 2 (n=25) women with diabetes, age range 16–45 years, who used CGMS (n=38) compared to SMBG (n=33) during pregnancy. CGM was performed for up to seven days at 4–6 week intervals, between 8–32 weeks' gestation. Data were downloaded and reviewed during follow-up visits and, in correlation with SMBG values, adjustments were made to diet, exercise and insulin therapy as indicated. The CGMS was used 0–8 times, mean 4.2 times, with 80% of the women wearing the monitor at least once per trimester. No significant differences were found in the mean A1c level between the two groups prior to week 32, but the CGM group had a consistently lower A1c level. A significant difference in A1c was seen between 32–36 weeks' gestation with the CGMS group having a lower mean A1c (p=0.007). Although not statistically significant, the CGMS group had a trend toward reduced emergency caesareans (p=0.08). There was no significant difference in infant morbidity between the two groups. Compared with healthy singletons of women in the SMBG group (n=30), women in the CGMS group (n=32) had significantly decreased mean birth weight standard deviation scores (p=0.05) and median birth weight centiles (p=0.02). Thirteen infants in the CGMS group compared to 18 infants in the SMBG group were macrosomic (p=0.05). The study suggested that the use of CGMS during pregnancy was associated with third-trimester improved glycemic control, lower birth weights and reduced risk of macrosomia. Author-noted limitations of the study included: the health professionals were not blinded, the small patient population, women were predominantly of white European ethnicity, and differences in the maternal characteristics with longer duration of diabetes in the intervention group.

Kestilä et al. (2007) conducted a randomized controlled trial to compare CGM (n=36) to SMBG (n=37) in detecting patients with gestational diabetes mellitus (GDM) who needed antidiabetic drug treatment. High-risk pregnant women at 22–34 gestational weeks who had at least two abnormally high glucose values on oral glucose tolerance testing were included in the study. The mean CGM period was 47.4 ± 2.5 hours. SMBG was performed at least five times per day. Treatment modalities were offered within five days of monitoring. As a result of CGMS, 11 women were treated with either oral agents or insulin compared to three patients in the SMBG group (p=0.0149). Within the CGM group, SMBG values were compared to the CGM values, and five SMBG patients were identified with indications for antihyperglycemic treatment compared to 16 CGM patients.

Professional Societies/Organizations: The 2025 American Diabetes Association (ADA) Standards of Care Guidelines provided recommendations for management of diabetes in pregnancy (2026g). ADA recommendations are assigned ratings of **A**, **B**, or **C**, depending on the quality of the evidence in support of the recommendation. Expert opinion **E** is a separate category for recommendations in which there is no evidence from clinical trials, clinical trials may be impractical, or there is conflicting evidence (ADA, 2026i). ADA recommendations regarding the use of CGMs in the management of diabetes in pregnancy include:

- Continuous glucose monitoring (CGM) can help to achieve glycemic goals (e.g., time in range, time above range) **A** and A1C goal **B** in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy. **E**
- Recommend CGM to pregnant individuals with type 1 diabetes. **A** In conjunction with aims to achieve traditional pre- and postprandial glycemic goals, CGM can reduce the risk for large-for-gestational-age infants and neonatal hypoglycemia in pregnancy complicated by type 1 diabetes. **A**
- CGM metrics may be used in combination with blood glucose monitoring to achieve optimal pre- and postprandial glycemic goals. **E**

(ADA, 2026g).

Additionally, the ADA states that the data is insufficient to support the use of CGM in all pregnant people with type 2 diabetes or gestational diabetes mellitus (GDM). An individualized treatment plan based on circumstances, preferences, and needs. should be applied in the decision-making process of whether to use CGM in pregnant individuals with type 2 diabetes or GDM.

Replacement of a Continuous Glucose Monitoring System and Components

Replacement of a Continuous Glucose Monitoring System (CGM) and/or components is indicated when the device malfunctions, cannot be repaired and is no longer under warranty. Warranties for continuous glucose monitor and various components range from six months to three years. There is a lack of evidence to support improved outcomes due to advanced technology for CGM. People with diabetes should be routinely followed by a health care provider and seen by their provider within six months of a request for a replacement monitor to ensure compliance to the management of their diabetes and the continued need for CGM.

Glycated Serum Protein (GSP)

Measurements of total glycated serum proteins (GSPs) have been suggested as alternative methods for routine monitoring of glycemic control in patients with diabetes. GSP (e.g., fructosamine assay and glycated albumin) provides an index of glycemia over the preceding 2–4 weeks as opposed to a 2–3-month period as seen with A1C levels (ADA, 2026f). GSP is proposed to be useful in situations where A1C cannot be measured or may not be useful (e.g., homozygous hemoglobin variants). It is also proposed for use in pregnant diabetics or after major changes in therapy. However, the evidence is lacking as to the usefulness of GSP in these situations. According to Goldstein et al. (2004), "GSP is not equivalent to A1C and has not been shown to be related to the risk of the development or progression of chronic complications of diabetes." There is no conclusive evidence that correlates GSP concentration to the chronic complications of diabetes. Further studies are needed to determine whether these assays provide clinical information equivalent to A1C for routine management of patients with diabetes and, if so, whether they offer any significant advantages over A1C. Unlike the A1C test, GSP has not been shown to be related to the risk of development or progression of chronic complications of diabetes. The GSP is not considered equivalent to the A1C test, and the clinical utility of monitoring glycated serum protein has not been established (ADA, 2004).

The first available home GSP device was the Duet™ Glucose Control System (LXN Corporation, San Diego, CA), which received FDA 510(k) approval in 1999. This device was discontinued due to concerns that the test strips were producing false-high results. The Duet System was replaced by the InCharge™ Diabetes Control System (LXN Corp., San Diego, CA). The InCharge has also been discontinued. Both of these devices measured blood glucose and glycated protein (Lindsey, et al., 2004).

Lindsey et al. (2004) conducted a prospective, three-center, randomized controlled study to "(1) compare the annual A1C results of subjects monitoring weekly fructosamine with those receiving usual care, (2) identify the number of subjects achieving goal A1C, and (3) determine if the addition of a weekly fructosamine test changed a subject's quality of life (i.e., concerns re

diabetes control, anxiety and worry, social burden, sexual functioning, energy and mobility)." The study group performed weekly fructosamine and daily glucose tests (n=42), while the control group performed daily glucose testing (n=30). The majority of subjects were middle-aged, type 2 diabetics. Follow-up visits occurred at three-month intervals for a year, baseline and quarterly A1C tests were conducted, and quality of life assessments were measured at baseline and at the final study visit. Quality of life remained constant in both groups; seven subjects in each group attained an A1C < 7%. At the end of one year, blood glucose alone testing was shown to be superior to blood glucose plus fructosamine testing. However, weekly fructosamine testing resulted in a decrease in A1C values earlier and more consistently than blood glucose monitoring.

Petitti et al. (2001) conducted a randomized trial which compared weekly fructosamine monitoring and daily glucose monitoring (n=70) to a control group of daily glucose only (n=70). Patients were type 2 diabetics, age 18 years or older, had an A1C of ≥ 8%, not pregnant, disease-free, and able to self-administer the tests. Both groups exhibited significant improvements in glycemic control during the course of the study. The authors concluded that the addition of fructosamine testing to glucose testing did not improve glycemic control and, initially, control was poor with the study group. Author-noted limitations of the study included: lack of guidelines regarding changes in diet, drugs, or medical follow-up based upon fructosamine test results; and patients were not instructed to reduce the frequency of glucose monitoring based upon fructosamine results.

Home Glycated Hemoglobin (A1C) Monitors
Glycated hemoglobin (GHb) (also referred to as glycohemoglobin, glycosylated hemoglobin, HbA1c, HbA1, or A1C) is a term used to describe a series of stable minor hemoglobin components formed from a combination of hemoglobin and glucose. It is used primarily to identify the plasma glucose concentration over time. The normal life span of the red blood cell (RBC) is 120 days. Once hemoglobin is glycated, it remains that way. During the life cycle of the RBC, there is a build-up of glycated hemoglobin, reflecting the glycemic history of the previous 120 days. The A1C test has been shown to predict the risk for development of many of the chronic complications in diabetes and is performed routinely in patients with diabetes (e.g., twice a year in patients who are meeting goals, and quarterly in patients whose therapy has changed or who are not meeting goals). Based on the evidence, the ADA (2026f) recommends that the goal of therapy for nonpregnant adults to reduce microvascular and neuropathic complication, in general, should be an A1C < 7%. Less stringent A1C goals may be appropriate for individuals with significant cognitive and/or functional limitations, frailty, or severe comorbidities or where the harms of treatment, including hypoglycemia, are greater than the benefits (ADA, 2026f). Home glycated hemoglobin monitors are not medically necessary because A1C testing can be performed during regularly scheduled office visits, where health care providers can properly interpret the test and modify the treatment plan as necessary.

Home glycated hemoglobin tests include FDA 510(k) approved products, such as the A1c Now® Self Check (Bayer HealthCare LLC, Tarrytown, NY), AccuBase A1c Glycohemoglobin Test Kit™ (Diabetes Technologies, Inc., Thomasville, GA) and the Home Access® A1C (Home Access Health Corp., Marlborough, MA) which the patient mails to the lab for analysis (FDA, 2017).

Laser Lancets
An alternative to the standard lancet used for skin perforation to obtain a capillary blood sample for glucose measurement is the use of a laser lancet. The device emits a single shot laser beam that produces a small hole in the finger. The laser may be used by individuals who prefer not to use a needle/blade. It is proposed that the laser reduces tissue trauma and is less painful than a standard lancet. The laser lancet requires 510(k) FDA approval. An example of the laser lancet is the Lasette® Plus (Cell Robotics International, Inc., Albuquerque, NM). Laser lancets are not considered medically necessary because they have no proven clinical utility and are used primarily for the individual's convenience.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

According to the American Diabetes Association (ADA) 2026 Standards of Care in Diabetes Improving Care and Promoting Health in Populations, "health inequities related to diabetes and its complications are well documented, are heavily influenced by social determinants of health (SDOH), and have been associated with greater risk for diabetes, higher population prevalence, and poorer diabetes outcomes". SDOH are defined as the economic, environmental, political, and social conditions in which people live and are responsible for a major part of health inequality worldwide. Ogunwole and Golden (2021) report that SDOH must be addressed at the structural and systems level where they originate in order to achieve health equity. The U.S. Department of Health and Human Services Healthy People 2030 sets data-driven national objectives to improve the health and well-being of the nation over the next decade. The objectives related to diabetes focus on reducing diabetes cases, complications and deaths.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Glycated Hemoglobin/Glycated Protein/190.21	1/01/2003
LCD	CGS Administrators Noridian Healthcare Solutions	Glucose Monitors includes glucose monitors, CGMs and supplies/L33822	10/01/2024
LCD	CGS	Implantable Continuous Glucose Monitors (I-CGM)/ L38662	10/16/2025
LCD	Palmetto GBA	Home Health Plans of Care: Monitoring Glucose Control in the Medicare Home Health Population with Type II Diabetes Mellitus/ L35132	9/30/2021
LCD	Multiple	Implantable Continuous Glucose Monitors (I-CGM)	Varies by contractor

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• Added coverage statements for Minimed Instinct sensor and Dexcom G7 15-day continuous glucose monitoring system • Removed policy statements for insulin pumps and insulin pens	2/15/2026
Focused review	• Added policy statement for Simplera continuous glucose monitor (CGM)	12/15/2025
Annual review	• No policy statement changes	2/15/2025
Focused review	• Added policy statement for home glycated serum protein (GSP) monitor	1/15/2025
Focused review	• Added Freestyle Libre 2 Plus and Freestyle Libre 3 Plus sensors	10/18/2024