Medical Coverage Policy

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Diabetes Equipment and Supplies

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Related Coverage Resources

Afrezza
Foot Care Services
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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 equipment and supplies. This includes continuous glucose monitoring systems, external insulin pumps, and insulin pens.

Coverage Policy

Coverage for Durable Medical Equipment including continuous glucose monitors, external insulin pumps, and consumable medical supplies (e.g., insulin pens) 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, external insulin pumps, and specific diabetic supplies the following conditions of coverage apply.

Continuous Glucose Monitoring System (CGMS)

A minimally invasive, continuous glucose monitoring system (CGMS) is considered medically necessary for the management of difficult to control insulin-treated diabetes mellitus (e.g., hypo- or hyperglycemic episodes unresponsive to adjustments in therapy, asymptomatic nocturnal hypoglycemia) for up to 14 days under the core medical benefits of the plan, for up to six separate sessions in any given 12-month period (CPT® code 95249, 95250, 95251).

Therapeutic/non-adjunctive Continuous Glucose-Monitoring Systems

A minimally invasive, therapeutic/non-adjunctive continuous glucose monitoring system (CGMS) (HCPCS A4238, A4239, E2102, E2103), which may include sensors (HCPCS A4238, A4239, A9276), transmitters (HCPCS A4238, A4239, A9277) and reader/receiver (HCPCS A9278, E2102, E2103), is considered medically necessary for the management of type 1 or type 2 diabetes mellitus:

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

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

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

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

- sensors (HCPCS A4238, A4239, A9276)**:**
  - Freestyle Libre 10-day system: three sensors every 30 days
  - Freestyle Libre 14-day system, Freestyle Libre 2 and Freestyle Libre 3: two sensors every 28 days
  - Dexcom G6 and Dexcom G7: three sensors every 30 days

- transmitters (HCPCS A4238, A4239, A9277):
  - Dexcom G6: one transmitter every 90 days

- reader/receiver (HCPCS A9278, E2102, E2103):
  - Freestyle Libre 10 day and Freestyle Libre 14 day: one reader every 720 days
  - Freestyle Libre 2 and Freestyle Libre 3: one reader every 720 days
  - Dexcom G6 and Dexcom G7: one receiver every 365 days

<u>Non- therapeutic/adjunctive Continuous Glucose-Monitoring Systems</u>

A minimally invasive non-therapeutic/adjunctive continuous glucose monitoring system (CGMS) including sensors (HCPCS A4238, A4239, A9276), transmitters (HCPCS A4238, A4239, A9277) and reader/receiver (HCPCS A9278, E2102, E2103) (e.g., Guardian Sensor 3 [HCPCS A4238, A4239, A9276], Guardian Sensor 4 [HCPCS A4238, A9276, A9277], Guardian® REAL-Time [HCPCS code A4238, A4239, A9277, A9278, E2102, E2103]) used with a fingerstick blood glucose monitor is considered medically necessary for the management of type 1 or type 2 diabetes mellitus when used according to the U.S. Food and Drug Administration (FDA) approved indications and ALL of the following criteria have been met:

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

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

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

- transmitters (HCPCS A4238, A4239, A9277):
  - Medtronic transmitter: one transmitter every 365 days

<u>Continuous Glucose Monitoring System with an Implantable Interstitial Glucose Sensor</u>

A continuous glucose monitoring system with an implantable interstitial glucose sensor (i.e., Eversense®) (CPT® codes 0446T, 0447T, 0448T) is considered medically necessary for the management of type 1 or type 2 diabetes mellitus for an individual age 18 years or older who is on ANY of the following insulin regimens:

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

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 Monitoring Not Covered

Each of the following has not demonstrated an improvement to health outcomes and is therefore, considered not medically necessary and/or a convenience item.

- additional software or hardware required for downloading data to a device such as personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus
- combination devices that include a home blood glucose monitor combined with a cellular telephone or other device not specifically indicated for the management of diabetes mellitus (e.g., blood pressure monitor, cholesterol screening analyzer)
- remote glucose monitoring device (e.g., mySentry)
- hypoglycemic wristband alarm (e.g., Diabetes Sentry™)

External Insulin Pumps

An approved U. S. Food and Drug Administration (FDA) external insulin pump* used in accordance with the FDA indications for use is considered medically necessary for the management of type 1 and type 2 diabetes.

***Notes:**
- **Omnipod 5 and Omnipod Dash are only covered under the pharmacy benefit.**
- **A transdermal insulin delivery system (e.g., V-Go, CeQur) does not require Physician supervision, is considered self-use and therefore, may be excluded from coverage under standard medical benefit plans. Some transdermal insulin delivery systems may be covered under a Cigna pharmacy benefit plan.**

Replacement of External Insulin Pump or System Component

The replacement of an existing external insulin pump or an insulin pump system component required for the delivery of insulin is considered medically necessary for an individual with successfully managed type 1 or type 2 diabetes mellitus when BOTH of the following criteria are met:

- documentation that the pump/component is malfunctioning, 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 replacement device

Supplies

The supplies required for the proper use of a medically necessary external insulin pump including custom-designed batteries and power supplies are considered medically necessary DME. However, off-the-shelf batteries that can also be used to power non-medical equipment are considered not medically necessary.

Not Covered

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

- replacement of a currently functioning insulin pump for the sole purpose of receiving the most recent insulin pump technology (i.e., "upgrading" for improved technology)
- additional software or hardware required for downloading data to a device such as personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus

Diabetic Supplies

Each of the following diabetic supplies is considered medically necessary under the pharmacy benefit (copayment may apply):

- alcohol wipes
- blood test strips (glucose/ketone)
- insulin pens (medical necessity criteria may apply)
- needles and syringes for insulin administration
- standard lancets
- urine test tablets/strips (glucose/ketone)

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

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

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

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

- sensors (HCPCS A4238, A4239, A9276)**:**
  - Freestyle Libre 10-day system: three sensors every 30 days
  - Freestyle Libre 14-day system, Freestyle Libre 2 and Freestyle Libre 3: two sensors every 28 days
  - Dexcom G6 and Dexcom G7: three sensors every 30 days

- transmitters (HCPCS A4238, A4239, A9277):

  - Dexcom G6: one transmitter every 90 days

- reader/receiver (HCPCS A9278, E2102, E2103):
  - Freestyle Libre 10 day and Freestyle Libre 14 day: one reader every 720 days
  - Freestyle Libre 2 and Freestyle Libre 3: one reader every 720 days
  - Dexcom G6 and Dexcom G7: one receiver every 365 days

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

- home glycated hemoglobin (A1C) monitor
- hypoglycemic wristband alarm (e.g., Sleep Sentry)
- insulin infuser (e.g., i-port®)
- laser lancet

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], 2023a).

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, 2023c). "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. U-500 insulin is available for patients who are extremely insulin resistant (ADA 2023c; ADA, 2023d). 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 (See Cigna Drug and Biologic Coverage Policy on Afrezza).

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.

According to the American Diabetes Association (ADA) 2023 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.

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, 2023b; Inzucchi and Sherwin, 2007).

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 (additionally) 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, and G7 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, 2022; Edge, et al., 2017; Haak, et al., 2017; Bolinder, et al., 2016; Bailey, et al., 2015; Kalra and Gupta, 2015).

The Freestyle Libre 2 and Freestyle Libre 3 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, 2022; 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, 2022).

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, 2022; FDA, 2018). Per the manufacturer, the G5 is no longer being produced. The Dexcom 7 obtained FDA approval in December 2022 and will be 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 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., 2022).

U.S. Food and Drug Administration (FDA): Some continuous glucose monitors provide a sensor that records data for a limited period of time and are intended for occasional use by the health care profession rather than everyday use by the patient. The Medtronic's iPro2™ Professional CGM (Medtronic MiniMed, Inc., Northridge, CA) and the Freestyle Libre Pro Flash Glucose Monitoring System (Abbott Diabetes Care, Inc., Alameda, CA) are examples of CGM systems for professional use only. The Medtronic iPro2 system received FDA approval for use with the Elite sensor which records data for up to six days (FDA, 2016). The Freestyle LibrePro is indicated for use in persons age 18 years and older and records data for up to 14 days. The data in the FreeStyle LibrePro cannot be viewed by the patient.

Non-therapeutic/adjunctive CGMS are used only as an adjunct to self-monitoring blood glucose (SMBG) and should never replace or be used instead of SMBG. Examples of FDA approved adjunctive CGMs include the DexCom™ G4 Platinum Continuous Glucose Monitoring System (DexCom, Inc., San Diego, CA), DexCom G4 Platinum (Pediatric) Continuous Glucose Monitoring System (ages 2–7 years), and the Medtronic Guardian® REAL-Time Continuous Glucose Monitoring System. These systems provide data for up to five to seven days. Per the manufacturer, the G4 is no longer being produced.

The Freestyle Libre and Freestyle Libre 14 day continuous glucose monitoring systems (Abbott Diabetes Care Inc., Alameda, CA) and the Dexcom G6 (Dexcom Inc., San Diego, CA) are examples of therapeutic/non-adjunctive monitoring systems that do not require adjunctive fingersticks. The Freestyle Libre continuous glucose monitoring system is FDA PMA approved "for the management of diabetes in persons age 18 years and older. It is designed to replace blood glucose testing for diabetes treatment decisions" (FDA, 2017). It is a sensor-based continuous glucose monitoring system that uses an ambulatory glucose profile (AGP) that assesses glycemic levels on a 24-hour basis through a minimally invasive method called flash glucose monitoring. This device is factory-calibrated and is never calibrated by the patient. The first FDA approved device includes a sensor that can be worn for up to 10 days. The Libre 14 day and Libre 2 have sensors that are intended to be worn up to 14 days. The FreeStyle Libre 2 Flash Glucose Monitoring System received 510(k) approval as a Class 2 device on June 12, 2020 and is indicated for the management of diabetes in persons age four and older. The device has real time alarms capability and the system transmits glucose measurement data to digitally connected devices where the end user manually controls actions for therapy decisions. The system is not intended to be used with automated insulin dosing (AID) systems (FDA, 2020).

The Dexcom G6 was FDA approved for marketing on March 27, 2018 for determining blood glucose levels in people with diabetes age two years and older. The G6 is the first type of continuous glucose monitoring (CGM) system permitted by the FDA to be used as part of an integrated system with other compatible medical devices and electronic interfaces including automated insulin dosing systems, insulin pumps, blood glucose meters or other electronic devices used for diabetes management. With approval of the G6, the FDA reduced the regulatory burden of integrated CGMs and classified them as moderate risk Class II devices with special controls. The G6 has three key parts: the applicator with built-in sensor, the transmitter that sends the glucose information from the sensor to the display device and the display device (receiver and/or smart device).

An integrated continuous glucose monitor is the Bigfoot Unity™ Diabetes Management System which received FDA 510(k) approval on May 7, 2021. "The Bigfoot Unity Diabetes Management

System is indicated for the management of diabetes in persons age 12 years and older. Bigfoot Unity provides glucose monitoring data via the Abbott FreeStyle Libre 2 Flash Glucose Monitoring sensor. The system incorporates real time alarm capabilities and is designed to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated. The device is intended to provide insulin dose information using the available glucose data to assist persons with diabetes mellitus who use disposable pen-injectors for the self-injection of insulin in implementing health care provider recommended insulin dose regimens. The device is intended for single patient use only and requires a prescription. Bigfoot Unity is also intended to communicate autonomously with digitally connected medical devices where the user manually controls therapy decisions (FDA, 2021)."

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., 2006a; Garg, et al., 2006; Lagarde, et al., 2006; Chico, et al., 2003; Ludvigsson, et al., 2003; Chase, et al., 2001).

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 2023 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 for CGM include:

- "Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring should be offered for diabetes management in adults with diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.
- Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring should be offered for diabetes management in adults with diabetes on basal insulin who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.
- Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring 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 devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.
- Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring should be offered for diabetes management in youth with type 2 diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.
- In people with diabetes on multiple daily injections or continuous subcutaneous insulin infusion, real-time continuous glucose monitoring (CGM) devices should be used as close to daily as possible for maximal benefit. Intermittently scanned CGM devices should be scanned frequently, at a minimum once every 8 h. People with diabetes should have uninterrupted access to their supplies to minimize gaps in continuous glucose monitoring.
- When used as an adjunct to pre- and postprandial blood glucose monitoring, continuous glucose monitoring can help to achieve A1C targets in diabetes and pregnancy.
- Periodic use of real-time or intermittently scanned continuous glucose monitoring or use of professional continuous glucose monitoring can be helpful for diabetes management in circumstances where continuous use of continuous glucose monitoring is not appropriate, desired, or available."

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 regards 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 (Grunbergerger, 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 for CGM include the following:

- Recommend real-time continuous glucose monitoring (RT-CGM) devices for adults with type 1 diabetes who have A1C levels above target and are willing and able to use the devices on a nearly daily basis (strong recommendation; high level of evidence).
- Recommend RT-CGM for well-controlled adults with type 1 diabetes who are willing and able to use these devices on a nearly daily basis (strong recommendation; high level of evidence).
- Suggest short-term real-time continuous glucose monitoring (RT-CGM) use in adults with type 2 diabetes not on prandial insulin who have A1C levels ≥ 7% and are willing and able to use the device (weak recommendation; weak level of evidence). Although the number of studies is limited, results showed a significant improvement in A1C compared to baseline with CGM.

In Choosing Wisely statements, the American Academy of Family Physicians (2018) and the Society of General Internal Medicine (2017) did not recommend daily home finger glucose testing in people with type 2 diabetes who are not on hypoglycemic medications or insulin. According to the Society, there is no benefit to self-monitoring blood glucose (SMBG) in this subpopulation and potential negative clinical impact is possible. SMBG should be reserved for use during titration of medication doses or periods of change in diet and exercise routines. The Endocrine Society 2013 Choosing Wisely statement recommended avoiding routine multiple daily SMBG in adults with stable type 2 diabetes on agents that do not cause hypoglycemia when target control is achieved. Exceptions include acute illness, change in medication, significant change in weight, A1c drifts off course and any other time when SMBG is needed to maintain targets and/or needed for learning.

In the 2016 consensus statement on outpatient glucose monitoring, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) 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 consensus statement on glycemic control for people with type 2 diabetes, the AACE and ACE (Rodbard, et al., 2009) stated that CGM may be considered for the management of people with type 2 diabetes who are receiving insulin and the disease is otherwise difficult to control. 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."

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, and 3) a mobile medical application (MMA) which displays the glucose readings. A 24-hour warm-up phase is required prior to initial calibration and calibration is required twice per day.

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, 2022; 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, 2022).

U.S. Food and Drug Administration (FDA): Eversense E3 Continuous Glucose Monitoring System (Senseonics™ Inc., Germantown, MD). received premarket approval application (PMA) approval on February 10, 2022 (P160048/S016) to expand the indications for use to continually measure glucose levels in adults (18 years and older) with diabetes for up to 180 days. Previous FDA PMA notice of approval was issued June 21, 2018 for the Eversense® continuous glucose monitoring system. Eversense is approved for "measuring glucose levels in adults (age 18 and older) with diabetes for up to 90 days". The system is intended to: provide real-time glucose readings, glucose trend information, and alerts for the detection and prediction of episodes of low and high blood glucose levels. Historical data from the system can be interpreted to aid in providing therapy adjustments on patterns seen over time. The system was initially indicated for use as an adjunctive device, but has been reclassified by the FDA as a non-adjunctive device. The device is indicated to replace information obtained from standard blood glucose monitoring devices to make diabetes-related treatment decisions. During sensor removal procedures in the earlier clinical study (PRECISE) there were several instances where the end cap of the sensor was broken off or missing after sensor removal. In some cases, the broken end caps were located, and in other cases the end caps were not located. A root-cause analysis into this failure concluded that the cause was most likely physicians grasping the end cap with the forceps during removal, instead of grabbing the sensor body. To reduce the potential for this failure, Senseonics redesigned the sensor end cap to be flush with the end of the sensor and changes were also made to the algorithm used in the FDA preapproval study (FDA, 2018).

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.

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). Gestational diabetes typically subsides following delivery. Uncontrolled diabetes during pregnancy can be associated with miscarriage, pre-eclampsia, preterm labor, stillbirth, congenital malformations and other complications. Both 72-hour and long-term CGM have been proposed for use during pregnancy (NICE, 2015, updated 2020; 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 2023 ADA Standards of Care Guidelines state that real-time continuous glucose monitoring when used as an adjunct to pre- and postprandial self-monitoring of blood glucose can help to achieve A1C targets in diabetes and pregnancy (ADA, 2023g). One well-designed RCT (Feig, et al., 2017) showed a reduction in A1C levels in adult women with type 1 diabetes on multiple daily injections (MDI) or continuous subcutaneous insulin infusion (CSII) who were pregnant and neonatal outcomes were better when the mother used CGM. However, two studies in which subjects used intermittent CGM showed no difference in neonatal outcomes in women with type 1 diabetes or gestational diabetes.

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.

Data Management Systems

Although data management systems offer convenience in tracking test results and glucose levels, disadvantages of some of the management systems include the complexity, time and labor intensiveness of downloading the data. There is insufficient evidence in the peer-reviewed literature to support that data management systems improve diabetic management. Due to the limitations of the available studies (e.g., lack of randomization, heterogeneous patient populations, various outcome measures, participant attrition) the benefits of data management systems in overall health outcomes in the treatment of diabetes mellitus is unknown (Costa, et al., 2009; Russell-Minda, 2009). Additional software or hardware for downloading data to computers, iPhones®, iPad® or iPods® for data management are not medically indicated.

U.S. Food and Drug Administration (FDA): Data management systems are approved as an FDA 510(k) Class II device. An example is the Telserve Data Management System (Telcare, Inc., Bethesda, MD). The System serves as an accessory to blood glucose meters to assist in the review and evaluation of blood glucose test results and related information to aid in diabetes management. The software system consists of two different levels of functionality, one for home use and one for professional use.

Literature Review: Laffel et al. (2007) conducted a randomized controlled trial (n=205) to evaluate glycemic control in insulin-treated patients who utilized an integrated glucose meter and electronic logbook compared to patients who used a conventional glucose meter and paper logbook. Type 1 and type 2 adult and pediatric patients (n=70) were recruited from seven centers to participate in the study. Participants were either using continuous insulin infusion or multiple daily injections of insulin, performing SMBG two or more times a day, and had an A1c ≥ 8% with stable glycemic control. During the first four weeks, all patients used their glucose monitor and written logbooks. At week four, patients were randomized to either a glucose monitor and written logs (i.e., paper group) (n=92) or to an integrated glucose meter/logbook (i.e., electronic group) (n=113). Follow-up visits occurred at four, eight, 12, 16 and 20 weeks. Upon completion of the study, mean A1c decreased -0.27% in the paper group compared to -0.35% in the electronic group (p=0.022). Pediatric patients also demonstrated similar results (p=0.024). The electronic group reported performing more average daily SMBG checks than the paper group (p=0.03). There was no significant difference in the mean amplitude of glycemic excursion between the two groups, but the rate of reported hypoglycemic events was lower in the paper group (p<0.0001). A total of 104 patients were available for a follow-up visit at 66 weeks, and patients were identified by four subgroups (i.e., group 1a had continued with meter/paper log since the 20-week visit; group 1b switched to integrated meter/electronic log; group 2a continued with integrated meter/electronic log; and group 2b switched to meter/paper log). Between the four-week follow-up visit and the 66-week follow-up visit, mean A1c decreased significantly in those who continued using the electronic logbook (p=0.008) compared to the other three subgroups who experienced an increase. A1c levels returned to the pre-trial level in these three groups. There was a statistically significant difference in mean A1c in those who used paper logbooks the entire time compared to those who used the electronic logbooks (p=0.006). The same trend was seen among the pediatric patients (p=0.053). From the last study visit to the 66-week visit, A1c increased in all groups. Limitations noted by the authors included short-term follow-up, neither patients or providers could be fully blinded, the "greater reduction in A1c in the electronic group may have yielded a greater number of measured hypoglycemic episodes," the increased recognition of hypoglycemic episodes in the electronic users may have resulted from more frequent monitoring and detection of events, and the choice of switching was made by the patient and provider. The authors noted that, although statistically significant, the differences between the two study groups from the end of the RCT and the absolute reductions in A1c were modest and stated that additional studies were needed to confirm the outcomes of this study.

Remote Glucose Monitoring Device

mySentry (Medtronic MiniMed, Inc., Northridge, CA) is a remote glucose monitor that can be placed at the bedside of a parent or guardian to allow monitoring of glucose information throughout the night. The system consists of a monitor, power source and radio-frequency operated Outpost that transmits information from a Medtronic MiniMed Paradigm REAL-Time Revel insulin pump. The Outpost allows monitoring from 50 feet away or greater. The monitor displays the same information and sounds the same alarms as the pump itself if the alarm silence option is off. The device is not used for making therapy adjustments nor does it control the insulin pump in any way (Medtronic, 2022). Remote glucose monitoring devices purely for the intent of surveillance of the original device, like the mySentry, are considered a convenience item and not medically necessary in the treatment of diabetes mellitus.

mySentry was FDA approved as a supplement to the original premarket agreement (PMA) for the Medtronic continuous glucose monitoring system. The approval order included a monitor and a remote outpost for use with the paradigm real-time system (FDA, 2011).

Hypoglycemic Alarm Wristband
Alarm devices that can be worn on the wrist or ankle have been proposed for use by a person with diabetes to detect changes in skin conditions as an alert for hypoglycemia. The FDA approved Diabetes Sentry (Diabetes Sentry Products, LLC. Fort Worth, TX) is an example of a hypoglycemic alarm that can be worn on the wrist, ankle or bicep. The device is proposed to detect an increase in perspiration and/or drop in skin temperature and alert the wearer. The Sentry does not measure glucose levels. This type of device is not used for making decision regarding treatment and is considered a convenience item and not medically necessary.

GlucoWatch® G2™ Biographer
The GlucoWatch® G2™ Biographer (Cygnus, Inc., Redwood, CA) was an FDA, PMA CGMS that was worn on the wrist like a watch and took noninvasive glucose measurements through the skin every 10 minutes for up to 13 hours at a time. It was approved for use in patients seven years and older. After a two-hour warm-up period and calibration, the GlucoWatch began monitoring by producing an electrical current that pulled fluid from the skin and measured the glucose in the fluid. It has a high/low glucose alarm feature. This device is no longer available.

Literature Review: The overall evidence in the published peer-reviewed literature in the form of randomized controlled trials (Newman, et al., 2009; Chase, et al., 2005; Chase, et al., 2003) indicated that the use of the GlucoWatch resulted in minimal or no significant improvements in glycemic control or in a reduction in the occurrence of hypoglycemic attacks. Use of the device was associated with skin irritation, edema, erythema, skipped readings, false alarms, and inaccurate results (Weinzimer, et al. 2008).

Other Home Blood Glucose Monitors
Some monitors combine a standard finger-stick blood glucose meter with non-medical devices and/or non-diabetic testing capabilities. Examples of these monitors include a finger-stick meter combined with a cellular telephone (glucophone), (e.g., GlucoPack™, HealthPia America Corp., Newark, NJ), a blood pressure monitor (e.g., Advocate DUO, Diabetic Supply of Suncoast, Taipei County, Taiwan), and a cholesterol screening analyzer (e.g., CardioChek PA Analyzer, Polymer Technology Systems, Inc. Indianapolis, IN). These devices are considered convenience items for the individual and not medically necessary in the treatment of diabetes mellitus.

Use Outside of the US
Different systems for standard and continuous glucose monitoring (CGM) are available outside of the United States. The Navigator Continuous Glucose Monitor (Abbott Diabetes Care, Alameda, CA) is available in Europe and other countries such as Israel and Australia. The Optical Glucose Monitor CGM system (C8 MediSensors, Inc., San Jose, CA) is Conformité Européenne (CE) Mark approved for marketing in Europe.

GlucoTrack® (Integrity Applications, Ashdod, Israel) is a CE Mark approved, non-invasive device for measuring glucose levels of persons with Type 2 diabetes or at risk of developing diabetes. The device is clipped on the earlobe when the user wants to measure the glucose level. The principle of operation is based on tracking the physiological effects of glucose variations in the earlobe tissue. GlucoTrack measures ultrasonic, electromagnetic and thermal parameters of the tissue which occur due to glucose-related shifts in ion concentration, density, compressibility, and hydration of both cellular and extracellular compartments of the tissue (Bahartan et al., 2017; Harman-Boehm, et al., 2009). The intended use of GlucoTrack Model DF-F is for non-invasive intermittent glucose monitoring for home-use for adults 18 years and older with type 2 diabetes or pre-diabetes.

Two Eversense CGM systems (Senseonics Holdings, Inc., Germantown, MD) have been approved in Europe, the 90-day Eversense and the 180-day Eversense XL. The FreeStyle Libre™ Flash CGM (Abbott Diabetes Care, Alameda, CA) for individual use is currently available in Austria, Belgium, France, Germany, Italy, Netherlands, Norway, Spain, Sweden and the United Kingdom. Outside the US, the FreeStyle is approved for use by children and teens with diabetes aged 4-17 years old as well as adults.

Literature Review – Eversense XL: Kropff et al. (2017) conducted a prospective, multicenter, observational study (n=71) to evaluate the safety and accuracy of the 180-Eversense CGM system. Subjects were age ≥ 18 years with type 1 and type 2 diabetes and used insulin therapy. Exclusion criteria included: history of severe hypoglycemia, diabetic ketoacidosis; known severe microvascular complications, diabetic retinopathy, macular edema, and other comorbidities. The primary outcome was mean absolute relative difference (MARD) for venous reference glucose values > 4.2 mmol/L (75 mg/dL), defined as the average of the absolute difference of paired CGM system and Yellow Springs Instrument (YSI) readings (reference) divided by the YSI reading multiplied by 100. Secondary outcomes included Clarke Error Grid Analysis and alarm performance which was defined as confirmed and missed event detection rates and true and false alarm rates given for low and high glucose alarm (<3.9 mmol/L and >10 mmol/L or < 70 mg/dL and >180 mg/dL, respectively).The MARD value against reference glucose values > 4.2 mmol/L was 11.1%. Performance of the system in the hypoglycemic range was less than the overall performance 21.7% vs.11.6% MARD (p<0.0.001). Analysis for sensors survival estimated that 100%, 82% and 40% of sensors were functional through day 45, day 90, and day 180 respectively (median sensor life 149 days). Twelve sensors were lost to the study due to subjects withdrawing or electronic or mechanical failure. Five sensors were replaced due to electronic or mechanical failure within three months of initiation of the study. There was a significant improvement (p<0.001) in the HbA1c from baseline (7.54%) to study end (7.19%). Subjects with a baseline HbA1c < 7.5% did not significantly change during the study (p=0.669). Clarke Error Grid Analysis showed 99.2% of samples in the clinically acceptable error zones, A and B. Eighty-one percent of hypoglycemic events were detected by the CGM system within 30 minutes. The in-clinic alarm performance for hypoglycemia and hyperglycemia showed detection rates of 81% and 88%, and an event true rate of 67% and 90%, respectively. Short-Form (SF-36) quality of life scores were unchanged from baseline to end of study. A statistically significant reduction of CGM measurement accuracy was seen in the last month of use. Fourteen device or procedure-related nonsevere adverse events occurred in 11 patients. A total of 147 sensors were implanted, used and removed. Adverse events included skin rashes (n=5) and incision site infection (n=2). Limitations of the study include the uncontrolled observational study design, lack of a comparator, small patient population and short-term follow-up.

Professional Societies/Organizations: Based on a review of the evidence-based literature, the Working Group Diabetes Technology of the German Diabetes Association published a consensus statement (Liebl, et al., 2013) that included the following indications for CGM use for people with type 1 diabetes:

- hypoglycemia, i.e., frequent, severe hypoglycemic episodes (requiring assistance from third parties), severe nocturnal hypoglycemia, and/or proven hypoglycemia unawareness;
- unsatisfactory metabolic control if, despite the use of all available forms of treatment (including also CSII), good compliance and the exclusion of severe psychological/psychiatric problems, the target HbA1c level cannot be achieved;
- before/during pregnancy with inadequate metabolic control using conventional forms of treatment; and

- the need to perform more than 10 blood glucose measurements per day to achieve the target HbA1c level.

The Scottish Intercollegiate Guidelines Network (SIGN) recommendations on the management of diabetes (2010; updated 2017) stated that CGM may be a useful adjuvant to conventional self-monitoring in selected adults with type 1 diabetes who have persistent problems with glycemic control. However, further research is required to identify individuals who will gain the most benefit. CGM should not be used routinely in people with diabetes. Although there is limited evidence that continuous glucose monitoring may be of benefit to women during pregnancy, CGM may be considered for those with type 1 and type 2 diabetes in pregnancy.

The National Institute for Clinical Excellence (NICE) (United Kingdom) (2015; updated 2022) recommended self-monitoring of blood glucose levels for all adults with type 1 diabetes at least four times a day, including before each meal and before bed. Testing may be performed up to ten times per day in various situations including the following: A1C isn't achieved; the frequency of hypoglycemic episodes increases; before, during and after sports; when planning pregnancy, during pregnancy and while breastfeeding; or during illness. NICE stated that CGM could be considered for adults with type 1 diabetes who commit to using CGM at least 70% of the time and who have any of the following despite optimized insulin therapy and conventional blood glucose monitoring:

- More than one episode a year of severe hypoglycemia with no obviously preventable precipitating cause.
- Complete loss of awareness of hypoglycemia.
- Frequent asymptomatic hypoglycemia (more than two episodes a week) that is causing problems with daily activities.
- Extreme fear of hypoglycemia.
- Hyperglycemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.

Regarding pregnancy, NICE (2015, updated 2020) recommended the following:

- "Offer continuous glucose monitoring (CGM) to all pregnant women with type 1 diabetes to help them meet their pregnancy blood glucose targets and improve neonatal outcomes.
- Offer intermittently scanned CGM (isCGM, commonly referred to as flash) to pregnant women with type 1 diabetes who are unable to use continuous glucose monitoring or express a clear preference for it.
- Consider continuous glucose monitoring for pregnant women who are on insulin therapy but do not have type 1 diabetes, if:
    - they have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) or
    - they have unstable blood glucose levels that are causing concern despite efforts to optimize glycaemic control.
- For pregnant women who are using isCGM or continuous glucose monitoring, a member of the joint diabetes and antenatal care team with expertise in these systems should provide education and support (including advising women about sources of out-of-hours support)."

External Insulin Pumps

External insulin pumps are designed to provide continuous subcutaneous insulin infusion (CSII) in patients with diabetes mellitus. The external insulin pump is a programmable battery-powered mechanical syringe/reservoir regulated by a miniature computer that delivers a steady, continuous ("basal") amount of insulin and releases a bolus dose at meals or smaller amounts at programmed times. Frequent monitoring of the blood glucose (e.g., four times per day) is essential to ensure appropriate delivery of insulin dosage.

CSII candidates include a person with diabetes whose hyper- and/or hypoglycemia cannot be controlled with daily injections of insulin. Individuals with wide fluctuations in blood glucose before mealtime, a marked increase in fasting blood glucose levels at dawn (i.e., exceeding 200 milligrams/deciliter [mg/dL]), unpredictable hypoglycemia, persistent glycated hemoglobin levels greater than 7.0%, and patients unable to administer multiple daily injections (MDI) may also be candidates for CSII (White, 2007).

Standard External Insulin Pumps
An external insulin pump is a battery-powered device worn and programmed by the user to deliver a continuous subcutaneous insulin infusion (CSII). Most conventional insulin pumps deliver insulin by applying pressure from behind the contents of the reservoir. Some newer pumps, like the t-slim®, draw insulin from the reservoir into a micro-delivery chamber allowing the insulin to be delivered in smaller increments from 0.001 units per hour (u/hr) to above 0.1 u/hr. Other pumps may be combined or integrated with standard finger-stick glucose monitoring system (CSII-BGM).

U.S. Food and Drug Administration (FDA): Most external insulin pumps are approved by the FDA as 510(k) Class II devices for the continuous infusion of insulin. Examples of FDA approved devices include:

- Animas® OneTouch® Ping™ (Animas Corp., Frazer, PA) insulin pump with a OneTouch® Ping™ Meter Remote for people with diabetes requiring continuous subcutaneous insulin delivery and measurement of glucose and Animas® Vibe® Insulin Pump intended for the continuous subcutaneous infusion of insulin for the management of insulin-requiring diabetes. Animas Corporation has exited the insulin pump business and discontinued the manufacturing and sale of Animas Vibe and OneTouch Ping insulin pumps.
- Dana Diabecare® II Insulin Pump (Sooil Development Co., Ltd., North Attleboro, MA) for subcutaneous delivery of insulin
- Minimed™ Paradigm™ Real-Time Revel™ Insulin Pump (Medtronic, Northridge, CA) for the management of diabetes mellitus in persons requiring continuous delivery of insulin (MMT-523/723 for adults and MMT-523K/723K for ages 7–17 years).
- MiniMed Paradigm Revel™ Insulin Pump (Medtronic MiniMed, Inc. Northridge, CA) used in conjunction with the Contour® Next Link glucose meter (Bayer HealthCare, Tarrytown, NY) for the continuous delivery of insulin in persons requiring insulin and the quantitative measurement of glucose in fresh capillary whole blood. This pump was discontinued by Medtronic in October 2018.
- OmniPod® Insulin Management System (Insulet Corporation, Billerica, MA) is a wireless insulin pump that consists of a disposable insulin pod and Personal Diabetes Manager that includes a built-in FreeStyle® glucose meter. The pod is filled with insulin by the patient and replaced every 72 hours. Per the manufacturer the OmniPod is for children of all ages and adults.
- Omnipod® DASH® Insulin Management System (Insulet Corporation, Billerica, MA) is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus and is interoperable with Contour® NEXT ONE Blood Glucose Meter (Ascensia Diabetes Care, Mishawake, IN) for wireless transfer of blood glucose readings to the DASH® Personal Diabetes Manager (PDM). The pod is replaced every 72 hours.
- Accu-Chek® Solo™ MicroPump Delivery System (Roche Diabetes Care, Middle East) for the management of diabetes mellitus in persons requiring insulin. Not currently available in the United States.

- t:slim® micro-delivery insulin pump (Tandem Diabetes Care, Inc., San Diego CA) for the subcutaneous delivery of insulin for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater
- t:flex™ Insulin Delivery System (Tandem Diabetes Care, Inc., San Diego CA) is a t:slim predicate device intended for the subcutaneous delivery of insulin for individuals 12 years of age and greater. The t:flex includes a 4.8 mL cartridge vs. 3.0 mL cartridge in the t:slim.
- t:slim X2™ (Tandem Diabetes Care, Inc., San Diego CA) is a t:slim predicate device approved for the subcutaneous delivery of insulin for individuals six years of age and greater. The device is indicated for use with NovoLog or Humalog U-100 insulin.
- Tandem Mobi (Tandem Diabetes Care, Inc., San Diego CA) approved for the subcutaneous delivery of insulin for individuals six years of age and greater. The device is indicated for use with NovoLog or Humalog U-100 insulin.

Literature Review

Adults with Type 1 Diabetes: As evidenced by systematic reviews, meta-analysis (n=12–52 studies), randomized controlled trials, comparative studies and prospective longitudinal observational studies (n=100–1441), the use of external insulin pumps for the management of type 1 diabetes mellitus is a well-established, safe and effective treatment modality (Cummins, et al., 2010; Misso, et al., 2010; Monami, et al., 2010; Fatourechi, et al., 2009; Raccah, et al., 2009; Jeitler, et al., 2008; Giménez, et al., 2007; Hirsch, et al., 2005; Weissberg-Benchell, et al., 2003; Pickup, et al., 2002).

Children with Type 1 Diabetes: CSII is an accepted treatment alternative for children with type 1 diabetes. Overall, results from systematic reviews, randomized controlled trials, case series and comparative studies reported a significant initial improvement in glycated hemoglobin (HbA1c or A1c) and a decrease in the severity of hypoglycemic events. Additional outcomes included lower fasting blood glucose levels, less severe lipohypertrophy, less blood glucose variability, absence of diabetic ketoacidosis (DKA), and fewer sick-day calls. Outcomes varied based on age and the number of years the subject had diabetes (Overgaard, et al., 2015; Cummins, et al., 2010; Churchill, et al., 2009; Nabhan, et al., 2009; Skogsberg, et al., 2008; Opipari-Arrigan, et al. 2007; Alemzadeh, et al., 2007; Kapellen, et al., 2007; McVean, et al., 2007; Pańkowska, et al., 2007; Berhe, et al., 2006; Kordonouri, et al., 2006; Wood, et al., 2006; Fox, et al., 2005; DiMeglio, et al., 2004; Plotnick, et al., 2003).

Type 2 Diabetes: In general, insulin pump usage in people with type 2 diabetes is not an established treatment modality. However, insulin pumps are a treatment option for a subgroup of patients with type 2 diabetes who are not being controlled (e.g., A1C >7.0%, recurring hypo- and/or hyperglycemic episodes) despite frequent adjustments in therapy and adherence to treatment regimens including daily self-management of blood glucose levels and three or more daily injections of insulin for three or more months. There are relatively few published clinical trials regarding the safety and efficacy of CSII in patients with type 2 diabetes. Available randomized controlled trials and case series have reported an improvement in HbA1c, reduction in fasting plasma glucose and postprandial plasma glucose levels, reduction in the glucose area under the curve values, and/or decreased insulin demand following use of CSII while other studies reported no significant difference in MDI and insulin pump outcomes. Overall, complications were not greater with CSII (Reznik, et al., 2014; Bode, 2010; Johnson, et al., 2010; Noh, et al., 2008; Parkner, et al., 2008; Pickup and Renard, 2008; Berthe, et al., 2007; Wainstein, et al., 2005; Raskin, et al., 2003).

Pregnancy: Because pregnancy causes an increase in insulin resistance, there may be a need for increased insulin dosage during pregnancy in people with type 1 diabetes. In people with type 2 diabetes, oral hypoglycemic agents are discontinued during pregnancy. If the patient with type 2 diabetes and the patient with gestational diabetes (i.e., diabetes that occurs only during pregnancy) are unable to maintain glycemic control with diet, exercise, and self-monitoring blood glucose (SMBG), insulin injections may be required. Poor blood sugar control during pregnancy can lead to congenital abnormalities, miscarriages, stillborns, and unusually large babies. In a carefully selected subset of pregnant patients with diabetes, an insulin pump may be considered when intensive insulin therapy is required for glycemic control. One concern regarding the use of an insulin pump during pregnancy is the potential for ketoacidosis due to interruption in the flow of insulin secondary to pump malfunction. Ketoacidosis may occur more rapidly in the pregnant patient with diabetes and can result in fetal loss (ADA, 2023g; American College of Obstetricians and Gynecologists [ACOG], 2018; Mukhopadhyay, et al., 2007; Rodbard, et al., 2007).

Farrar et al. (2016) conducted a Cochrane systematic review of randomized controlled trials comparing CSII to MDI in pregnant women with diabetes, preexisting and gestational. Five studies (n=154 pregnancies) were found that met inclusion criteria. No significant differences were reported in caesarean section rates, large-for-gestational age, maternal weight gain during pregnancy, maternal hypoglycemia or hyperglycemia, mean HbA1c, perinatal mortality, fetal anomaly and fetal birthweight. The authors concluded that there was no evidence to support the use of one form of insulin administration over another for pregnant women with diabetes. Due to the small number of trials and subjects generalizability of the results to all pregnant women was questionable.

González-Romero et al. (2010) conducted a comparative prospective study to evaluate the outcome of pregnant women with type 1 diabetes treated with CSII (n=35 pregnancies/26 women) compared to MDI (n=64 pregnancies/53 women) (control group). CSII was implemented during prepregnancy for women who did not reach A1c <7.5%, had dawn phenomenon not responsive to a change in bedtime insulin dosage, had uncontrolled hypoglycemic episodes or an unfavorable obstetrical history. CSII was started on two women during pregnancy. The control group was treated with 3–6 insulin injections per day. The A1c was significantly lower ($p<0.05$) before pregnancy in the CSII group and also significantly improved ($p<0.001$) in 3–6 months following CSII. CSII had lower insulin requirements ($p<0.05$) during the first trimester. There were no significant differences between severity and frequency of hypoglycemic events in the two groups. One CSII and one control group patient experienced ketoacidosis. Women in the CSII group weighed more than MDI women, but the increase in weight between the first and third trimesters was lower in the CSII group. No significant differences were reported between the groups regarding hypertension or progression of retinopathy or nephropathy. There were no significant differences between the groups in miscarriages, perinatal mortality, congenital anomalies, or birth weight. The study did not show an advantage of CSII over MDI in metabolic control or obstetrical or perinatal outcomes.

Mukhopadhyay et al. (2007) conducted a systematic review and meta-analysis of published and unpublished randomized controlled trials comparing MDI to CSII in pregnant women with diabetes. Six studies (n=213) met inclusion criteria with only two studies being truly randomized. Pregnancy outcomes and glycemic control were not significantly different between the study groups. Although ketoacidotic episodes and diabetic retinopathy were reported more often in the CSII groups, the differences were not statistically significant. There were no reported advantages for the use of CSII over MDI. The authors noted that the small number of trials and subjects which could contribute to a lack of statistical power were limitations of the study. The outcomes of the study did not demonstrate a "clear-cut" benefit of using CSII over MDI. They suggested that the use of CSII in pregnant women with diabetes might be reserved for women requiring very high doses of insulin or cases in which normoglycemia is not achieved by conventional therapy.

Professional Societies/Organizations: In the 2018 American College of Obstetricians and Gynecologists (ACOG) practice bulletin on pregestational diabetes mellitus, ACOG stated that in those women without good control, conversion to a subcutaneous insulin pump before pregnancy may improve glycemic control, particularly in those with type 1 diabetes. ACOG went on to explain that patients who use continuous subcutaneous insulin infusion must be highly motivated and compliant. Advantages of the insulin pump may include a decrease in episodes of severe hypoglycemia, better control of hyperglycemia, and a more flexible lifestyle. In addition to the disadvantage of the increased cost of the pump and pump supplies, adverse events with the pump have been reported to occur approximately three times per year of use and of these events approximately 38% are pump malfunctions. If the delivery of insulin is interrupted or impaired by battery failure or infection at the infusion site, diabetic ketoacidosis (DKA) may develop rapidly with 9.8% of pump adverse events leading to high ketones or DKA. Despite potential advantages and modest evidence that glycemic control may be improved, a meta-analysis of five small randomized trials evaluating insulin pump versus injectable insulin, reported that there were no statistically significant differences in outcomes. Thus, women who have euglycemia with multiple dose injectable insulin can be maintained on that insulin dosage approach.

The 2014 consensus statement on insulin pump management by the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) (Grunberger, et al., 2014) included recommendation for the use of continuous subcutaneous insulin infusion (CSII). Ideal CSII candidates include people with type 1 diabetes or intensively managed insulin-dependent people with type 2 diabetes who meet the following:

- currently performing ≥ 4 insulin injections and ≥ 4 self-monitored blood glucose (SMBG) measurements daily
- motivated to achieve optimal blood glucose control
- willing and able to carry out the tasks that are required to use this complex and time consuming therapy safely and effectively
- willing to maintain frequent contact with their health care team

Recommendations for pediatric patients included an individual with elevated HbA1c levels on injection therapy with frequent, severe hypoglycemic events and widely fluctuation glucose levels. Families should be motivated to monitor blood glucose ≥ 4 times/day and have a working understanding of basic diabetes management. The patient's age and duration of diabetes should not be factors in determining the transition from injections to CSII (Grunberger, et al., 2014).

Regarding pregnant women with type I diabetes, AACE/AAC stated that the literature does not provide clear evidence that CSII is necessary for optimal treatment. For patients with gestational or type 2 diabetes, insulin pump therapy seems to be safe and effective for maintaining glycemic control in women requiring large insulin doses (Grunberger, et al., 2014).

A 2007 consensus statement endorsed by the ADA and the European Association for the Study of Diabetes, the European Society for Pediatric Endocrinology, Lawson Wilkins Pediatric Endocrine Society, International Society for Pediatric and Adolescent Diabetes (Phillip, et al., 2007) listed the following considerations for CSII therapy in all pediatric patients with type 1 diabetes, regardless of age:

- "recurrent severe hypoglycemia
- wide fluctuations in blood glucose levels, regardless of A1c
- suboptimal diabetes control (i.e., A1c exceeds target range for age)
- microvascular complications and/or risk factors for macrovascular complications
- good metabolic control but insulin regimen that compromises lifestyle"

Other circumstances in which CSII may be beneficial include:

- "young children and especially infants and neonates

- adolescents with eating disorders
- children and adolescents with a pronounced dawn phenomenon
- children with needle phobia
- pregnant adolescents, ideally preconception
- ketosis-prone individuals
- competitive athletes”

The guidelines included a discussion regarding the importance of the involvement and support of a multidisciplinary team and family members in the initiation and ongoing pump management and glucose monitoring of CSII in children.

Standard Features for External Insulin Pumps
A number of factors should be taken into consideration when deciding what insulin pump is best suited for each individual patient. Attention should be given to the ease of use and reading of the screens; reservoir size; type of insulin used by the pump; basal capabilities; bolus capabilities; dosing increments (especially for children); alarms and settings; compatibility with standard glucose monitor and/or continuous glucose monitor; type of battery needed; data management capabilities; device size and weight; and patient and/or caregivers ability to operate the pump. Standards for external insulin pumps in pediatric patients may differ from those in adults. Children may require additional features to accommodate their unique needs. The following features may be compared when selecting an insulin pump for a child: size, weight, battery life, infusion sets, number of basal rates available, basal range, smallest basal possible, obstruction alarm, over-delivery alarm, near-empty alarm, and warranty and special features.

Data Management Systems
Although data management systems offer convenience in tracking test results and glucose levels, there is insufficient evidence in the peer-reviewed literature to demonstrate that data management systems improve diabetic management. Due to the limitations of the studies (e.g., lack of randomization, heterogeneous patient populations, various outcome measures, participant attrition) the benefit of data management systems in overall health outcomes in peole with diabetes is unknown (Costa, et al., 2009; Russell-Minda, et al., 2009). Additional software or hardware for downloading data to computers, iPhones®, iPad® or iPods® for data management are not medically indicated.

Replacement of External Insulin Pump
The average warranty on an insulin pump is four years. Warranties for other components of a pump or combined or integrated systems (e.g., remote control, reservoirs, transmitters) range from six months to two years. Some components may have no warranty (e.g., sensors) (Medtronic, 2023; Omnipod, 2023). There is a lack of evidence to support improved outcomes (e.g., A1C) because of insulin pump enhanced technology. People with diabetes should be routinely followed by a physician and seen by their physician within six months of a request for a replacement pump to ensure compliance to the management of their diabetes.

Combined or Integrated Continuous Subcutaneous Insulin Infusion (CSII) and Blood Glucose Monitoring System That Includes a Continuous Blood Glucose Monitor (CBGM) System
A CSII used in conjunction with a CBGM (CSII-CBGM) is also referred to as sensor-augmented pump therapy. These systems include an insulin pump and continuous glucose monitor and may or may not include software for tracking and trending glucose readings. Some systems connect the insulin pump to the CGM using wired technology while others are wireless. Newer models are offering wireless technology to allow transmission of data to mobile phones. All wireless capabilities are considered an integral part of the system. The MiniMed Paradigm® REAL-Time Revel™ System (Medtronic, Northridge, CA) is an example of a device that includes a continuous

glucose monitor as opposed to the standard finger-stick glucose monitor. The glucose sensor inserts under the skin and connects to the MiniLink® transmitter that sends data to the insulin pump using wireless radiofrequency technology. The system also includes CareLink™ Therapy Management Software, a free online tool. A combined system with a CSII and a CBGM may be used on a long-term basis for the treatment of type 1 diabetes mellitus.

U.S. Food and Drug Administration (FDA): Combination systems are FDA approved under the premarket approval (PMA) process. Examples of approved devices include:

- Minimed™ Paradigm™ REAL-Time Revel™ System includes an insulin pump, continuous glucose monitor and management software. The continuous glucose monitor is intended to continuously record interstitial glucose levels. The sensor was approved by the FDA for use by individuals age 18 years and older and can be worn for up to 72 hours. The insulin pump is indicated for the continuous delivery of insulin at set and variable rates for the management of diabetes.
- Animas® Vibe™ System consists of the Animas Vibe Insulin Pump paired with the Dexcom G4 PLATINUM Sensor and Transmitter. The Animas Vibe insulin pump is indicated for continuous subcutaneous insulin infusion for the management of insulin-requiring diabetes. In December 2015, the FDA approval of the Animas Vibe System included the Dexcom® G4 Platinum Sensor and Transmitter continuous glucose monitor (CGM) for ages two years and older. The system if indicated for detecting trends and tracking patterns in persons with diabetes. CGM is intended to complement, not replace, information obtained from standard home glucose monitoring devices. The insulin pump can be used with or without the CGM. Animas Corporation has exited the insulin pump business and discontinued the manufacturing and sale of Animas Vibe and OneTouch Ping insulin pumps.
- t:slim G4 Insulin Pump with Dexcom G4 Platinum CGM includes the t:slim G4 Insulin Pump intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons age 12 or older who require insulin. The CGM is indicated for detecting trends and tracking patterns in persons with diabetes for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices. The insulin pump can be used alone without the CGM.
- T:slim X2™ can be paired with the Dexcom G6 CGM. The t:slim X2 Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin and can be used solely for continuous insulin delivery or as part of the t:slim X2 System to receive and display continuous glucose measurements from the Dexcom G6 Mobile Sensor and Transmitter. The t:slim X2 System is indicated for use in individuals 6 years of age and older.

Literature Review: CSII with CBGM has become an accepted method for monitoring diabetes in a subgroup of pateints with type 1 and type 2 diabetes. Although a limited number of randomized controlled trials and case series with short-term follow-ups are lacking in strong, definitive conclusions, the evidence is suggestive of improved clinical outcomes including normalization of A1c levels and a reduction in the number of hypoglycemic episodes (Bergenstal, et al., 2010; Kordonouri, et al., 2010; Raccah, et al., 2009; Halvorson, et al., 2007; Mastrototaro, et al., 2006).

Schaeffer et al. (2015) conducted a randomized controlled trial (n=72) to compare usability and training needs for the t:slim insulin pump and the Medtronic MiniMed Paradigm Revel insulin pump. Subjects were 18 years of age or older, used multiple daily insulin injections to manage their diabetes, had a basic understanding of insulin pumps, and had correct or corrected vision and hearing. Subjects attended a 90-minute training session on pump use. At the second visit, subjects completed a usability evaluation for their pump and were unknowingly observed as they performed pump tasks. The t:slim group took statistically significant less amount of time (27%) for training than the Revel group (p=0.025) and were more satisfied with the length of training (p=0.46). The t-slim subjects also took statistically significant less time to complete the task of delivering an extended bolus with correction (p-0.034) and time to complete the task of resuming therapy ($p<0.001$) and had fewer failure rates ($p<0.001$). The results of questionnaires on ease of use and global usability were higher in the t:slim group.

Professional Societies/Organizations: The 2023 ADA Standards of Care include the following recommendation for insulin pumps:

- "Automated insulin delivery systems should be offered for diabetes management to youth and adults with type 1 diabetes and other types of insulin-deficient diabetes who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.
- Insulin pump therapy can be offered for diabetes management to youth and adults on multiple daily injections with type 2 diabetes who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs."

ADA notes that there is no consensus to guide choosing which form of insulin administration is best for a given patient. The choice of multiple daily injections (MDIs) or an insulin pump should be based on the individual characteristics of the patient and which is most likely to benefit them. The use of pump therapy varies geograpghically across the United States which may be due to provider preference or center characteristics and socioeconomic status. Pump therapy is utilized most commonly in patients of higher socioeconomic status as reflected by race/ethnicity, private health insurance, family income, and education (Willi, et al., 2015; Lin et al, 2013). The ADA states: "Given the additional barriers to optimal diabetes care observed in disadvantaged groups (Redondo, et al, 2018), addressing the differences in access to insulin pumps and other diabetes technology may contribute to fewer health disparities."

Pump therapy can be successfully started at the time of diagnosis. Practical aspects of pump therapy initiation include: assessment of patient and family readiness, selection of pump type, initial pump settings, patient/family education of potential pump complications (e.g., diabetic ketoacidosis (DKA) with infusion set failure), transition from MDI, and introduction of advanced pump settings (e.g., temporary basal rates, extended/square/dual wave bolus). There is evidence that pump therapy in youth may reduce DKA risk and diabetes complication (i.e. retinopathy and peripheral neuropathy) while improving treatment satisfaction and quality-of-life measures. ADA (2023) states when "based on shared decision-making by people with diabetes and health care professionals, insulin pumps may be considered in all children and adolescents with type 1 diabetes. In particular, pump therapy may be the preferred mode of insulin delivery for children under 7 years of age."

The use of insulin pumps can be considered for the treatment of patients with type 2 diabetes who are on MDI as well as those who have other types of diabetes resulting in insulin deficiency (i.e. those who have had a pancreatectomy and/or individuals with cystic fibrosis). The data regarding use of pump therapy on the reduction in A1C levels in patients with type 2 diabetes is similar to that on patients with type 1 diabetes (Layne et al., 2017; Reznik, et. al., 2014). The ADA concludes that in insulin-requiring patients with any type of diabetes, the use of insulin pumps may improve patient satisfaction and simplify therapy.

Regarding automated insulin delivery systems, ADA states that with these systems, insulin delivery cannot only be suspended but also increased or decreased based on sensor glucose values. Emerging evidence suggests such systems may reduce A1C levels, improve time in range, lower the risk of exercise related hypoglycemia and may have psychosocial benefits.

The 2021 American Association of Clinical Endocrinology clinical practice guideline (Grunbergerger, et al., 2021) on the use of advanced technology in the management of persons with diabetes recommend the use of an insulin pump with continuous glucose monitoring (separate devices or sensor-augmented pump) to manage all persons with diabetes treated with intensive insulin management who prefer not to use automated insulin suspension/dosing systems or have no access to them.

The 2016 Endocrine Society guidelines on continuous subcutaneous insulin infusion (CSII) therapy in adults included the following:

- Recommend CSII over analog-based basal-bolus multiple daily injections (MDI) in patients with type 1 diabetes who have not achieved their A1C goal, as long as the patient and caregivers are willing and able to use the device (strong recommendation; moderate quality of evidence)
- Recommend CSII over analog-based basal-bolus MDI in patients with type 1 diabetes who have achieved their A1C goal but continue to experience severe hypoglycemia or high glucose variability, as long as the patient and caregivers are willing and able to use the device (strong recommendation; low level of evidence)
- Suggest CSII in patients with type 1 diabetes who require increased insulin delivery flexibility or improved satisfaction and are capable of using the device (weak recommendation; low level of evidence)
- Suggest CSII for patients with type 2 diabetes with good adherence to monitoring and dosing who have poor glycemic control despite intensive insulin therapy, oral agents, other injectable therapy, and lifestyle modifications (weak recommendation; low level of evidence). The Society noted that randomized controlled trials (RCTs) have shown mixed results, and subsequent meta-analyses have failed to show significant reductions of A1C or reductions in hypoglycemia for patients with type 2 diabetes on CSI. However, one RCT with a defined subset of patients reported a statistically superior reduction in A1C of 1.1% from the baseline mean of 9.0% in the CSII group and a 0.4% reduction in the MDI. The study (Reznik, et al., 2014) included insulin resistant patients with type 2 diabetes with an A1C between 8.0%–10%.

Combined or Integrated Continuous Subcutaneous Insulin Infusion and Blood Glucose Monitoring System with Automatic Insulin Suspension

Medtronic MiniMed pump models include the 630G, 670G, 770G, and 780G systems. The 630G is combined with the Enlite® sensor (ages 16 years or older) or the Guardian Sensor 3 (ages 14 years or older), and SmartGuard™ technology. This system also includes the one-press serter (helps to insert the sensor), Guardian® Link Transmitter, CareLink® USB, Contour® Next Link 2.4 wireless meter, and Contour® Next test strips. Similar to the 530G, the system automatically pauses insulin delivery for up to two hours if the glucose values go below a preset level and the user does not respond (Medtronic, 2023, FDA, 2016).

The 670G system includes the Guardian® Sensor 3 (7-day wear), Guardian Link 3 Transmitter, one press serter (helps to insert the sensor) and the Contour® Next Link 2.4 glucose meter. The Guardian Link 3 Transmitter powers the glucose sensor, collects and calculates sensor data, and wirelessly sends the data to the 670G insulin pump. The Guardian Sensor 3 is used as an adjunctive device to a standard blood glucose meter. The SmartGuard technology is available in a manual mode and an auto mode. In the manual mode the suspend before low feature stops insulin delivery 30 minutes before the pre-selected low limit is reached and resumes after sensor glucose levels recover. The auto mode automatically adjusts basal insulin delivery using continuous glucose monitor data and can automatically increase or decrease the amount of insulin delivered based on sensor values. The auto mode uses a target of 120mg/dL (Medtronic, 2023; FDA, 2016).

The MiniMed 770G system is identical to the MiniMed 670G system except that the the 770G is only for patients with type 1 diabetes and has an indication for use with the ages 2–6 year olds. It has Bluetooth communication capability to connect with the MiniMed mobile app or Carelink connect app. The 770G system includes the: MiniMed 770G Insulin Pump, the Guardian Link 3 Transmitter, the Guardian Sensor 3, one-press serter, the Accu-Chek Guide™ Link blood glucose meter, and the Accu-Chek Guide™ Test Strips. The CGM requires a prescription (Medtronic, 2023; FDA, 2020).

The MiniMed 780G system differs from its predecessors in that the insulin pump makes automatic adjustments and corrections if carb counts are miscalculated or if a insulin bolus is missed. Additionally, after consulting with their health care provider, patients can personalize glucose targets to 100, 110, and 120 mg/dL. The MiniMed 780G system uses either the Guardian Sensor (3)/Guardian Link (3) Transmitter, or the Guardian 4 sensor/Guardian 4 transmitter. The Medtronic MiniMed™ 780G system includes the following devices: MiniMed™ 780G insulin pump, the Guardian™ 3 or 4 transmitter, the Guardian™ 3 or 4 sensor, One-press serter, the Accu-Chek™ Guide Link blood glucose meter, and the Accu-Chek™ Guide test strips. The system requires a prescription from a healthcare professional. The 780G system is intended for management of type 1 diabetes mellitus in persons seven years of age and older requiring continuous delivery of basal insulin, administration of insulin boluses and continuous monitoring and trending of glucose levels (Medtronic, 2023; FDA, 2023).

The Beta Bionics iLet ACE Pump works with the iLet Dosing Decision Software along with a compatible FDA-cleared integrated continuous glucose monitor (iCGM) for patients six years of age and older with type 1 diabetes. The patient inputs body weight at initialization and then estimates the amount of carbs in their meal as small, medium or large. The adaptive closed-loop algorithm independently determines and commands meal doses of insulin based on the meal announcements thereby learning over time to respond to users' individual insulin needs. The iLet Dosing Decision Software independently determines and commands an increase, decrease, maintenance or suspension of all basal insulin doses and determines and commands correction doses of insulin based on input from an iCGM (Beta Bionics, 2023, FDA, 2023).

U.S. Food and Drug Administration (FDA): The MiniMed 530G received FDA premarket approval (PMA) in 2013 as an artificial pancreas device system with threshold suspend. The 530G is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of diabetes mellitus in persons, sixteen years of age and older, requiring insulin as well as, for the continuous monitoring and trending of glucose levels in the fluid under the skin.

In August 2016, the MiniMed 630G System with SmartGuard™ technology was FDA PMA approved "for continuous delivery of basal insulin (at user selected rates) and administration of insulin boluses (in user selectable amounts) for the management of diabetes mellitus in persons, sixteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin" (FDA, 2016).

The 670G was FDA PMA approved in 2016 "intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of Type 1 diabetes mellitus in persons, fourteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin". The Guardian Sensor is indicated for seven days of continuous use (FDA, 2016). June 21, 2018 the FDA expanded the indications of the 670G to include patients age 7 to 13 years (FDA, 2018).

The MiniMed 770G system received PMA approval on August 31, 2020 for "continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of type 1 diabetes mellitus in persons two years of age and older requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 770G System includes SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values." (FDA, 2020).

The MiniMed 780G system received PMA approval on April 21, 2023 (P160017/S091). It is indicated for use with either the Guardian Sensor (3)/Guardian Link (3) Transmitter, or with the Guardian 4 sensor/Guardian 4 transmitter. The Guardian 4 sensor is only intended for use with the MiniMed 780G system for up to seven days of continuous use. The Guardian Sensor 4 received PMA approval on July 6, 2023 (P160017/S111). The MiniMed 780G system is "intended for continuous delivery of basal insulin at selectable rates, and the administration of insulin boluses at selectable amounts for the management of type 1 diabetes mellitus in persons seven years of age and older requiring insulin. The system is also intended to continuously monitor glucose values in the fluid under the skin. The MiniMed 780G system includes SmartGuard (SG) technology, which can be programmed to automatically adjust insulin delivery based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values (FDA, 2023)."

Beta Bionics, Inc. iLet ACE Pump (K223846) and iLet Dosing Decision Software (K220916) received 510(k) approval on May 19, 2023. FDA indications for use for the iLet ACE Pump state: "The iLet ACE Pump is an alternate controller enabled (ACE) pump intended to deliver insulin under the skin based on input from an integrated continuous glucose monitor (iCGM) and an interoperable automated glycemic controller (iAGC), in people 6 years of age or older with diabetes mellitus. The iLet ACE Pump is intended for single-person use; it is not to be shared." FDA indications for use for the iLet Dosing Decision Software state: "The iLet Dosing Decision Software is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps. A self-monitoring of blood glucose (SMBG) meter may also be used for manual input of blood glucose values to continue insulin dosing for a limited period of time when input from the iCGM is temporarily not available. The iLet Dosing Decision Software autonomously determines and commands an increase, decrease, maintenance, or suspension of all basal doses of insulin and autonomously determines and commands correction doses of insulin based on input from an iCGM, and it autonomously determines and commands meal doses of insulin based on meal announcements. iLet Dosing Decision Software is intended for the management of type 1 diabetes mellitus in people 6 years of age or older. iLet Dosing Decision Software is intended for single patient use and requires a prescription (FDA, 2023)."

Literature Review: Randomized controlled trials have shown that threshold suspend pump therapy significantly reduced nocturnal hypoglycemic events without increasing glycated hemoglobin levels, reduced the occurrence of severe and moderate hypoglycemic events and reduced the duration and severity of induced hypoglycemia without rebound hyperglycemia (Garg, et al., 2017; Bergenstal et al., 2013; Ly et al., 2013; Garg, et al., 2012).

Professional Societies/Organizations: The 2023 ADA Standards of Care include the following recommendations for combined insulin pump and sensor systems:

- "Insulin pump therapy alone with or without sensor-augmented pump therapy low glucose suspend feature should be offered for diabetes management to youth and adults on multiple daily injections with type 1 diabetes or other types of insulin-deficient diabetes who are capable of using the device safely (either by themselves or with a caregiver) and are not able

to use or do not choose an automated insulin delivery system. The choice of device should be made based on the individual's circumstances, preferences, and needs.
- Automated insulin delivery systems should be offered for diabetes management to youth and adults with type 1 diabetes and other types of insulin deficient diabetes who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.
- Individuals with diabetes may be using systems not approved by the U.S. Food and Drug Administration, such as do-it-yourself closed loop systems and others; health care professionals cannot prescribe these systems but should assist in diabetes management to ensure the safety of people with diabetes."

Use Outside of the US
The European equivalent of the MiniMed 530G is the Paradigm® Real Time Veo™ System (Medtronic MiniMed, United Kingdom). The software for the Threshold Suspend tool is the same for the 530G System and the Veo. Although the sensors for the two pumps are not identical, they operate using similar principles and fundamental scientific technology. The Veo received Conformite Europeenne (CE) mark approval in 2009 for marketing in Europe. Medtronic's MiniMed 640G with insulin suspension was launched in Australia and is also available in the United Kingdom and Denmark. Studies including randomized controlled trials and prospective case series have reported that the 640G resulted in a significant reduction in hypoglycemic events without adverse effects from rebound hyperglycemia (Battelino, et al., 2017; Biester, et al., 2017; Buckingham, et al., 2017).

The OmniPod System was launched in the United States in 2005 and subsequently became available in Latin America and Israel. In 2010, Ypsomed AG, an independent diabetes specialist and technology provider, began distributing OmniPod in a number of countries with a primary focus on Europe.

The Scottish Intercollegiate Guidelines Network (SIGN) recommendations on the management of diabetes (2017) stated that insulin pump therapy is associated with modest improvements in glycemic control and should be considered for patients unable to achieve their glycemic targets. CSII therapy should be considered in patients who experience recurring episodes of severe hypoglycemia.

The National Institute for Clinical Excellence (NICE) (United Kingdom) 2015 (updated 2022) guideline on the diagnosis and management of diabetes in children recommends that children be offered an insulin pump if a multiple daily injection regimen is not appropriate for the child with type 1 diabetes. In a 2015 (updated 2020) guideline on the management of diabetes and its complications in pregnancy, NICE stated that women with insulin-treated diabetes could be offered continuous subcutaneous insulin infusion during pregnancy if adequate blood glucose control is not obtained by multiple daily injections of insulin without significant disabling hypoglycemia.

In a Rapid Response Report (2015) on insulin pumps for adults, the Canadian Agency for Drugs and Technologies in Health (CADTH) concluded that the clinical effectiveness of CSII versus multiple daily injections in adult patients or pregnant women remains uncertain. However, an insulin pump integrated with a continuous glucose monitor, including a sensor-augmented pump, appeared to result in better glycemic control without an increase in hypoglycemia. Two systematic reviews, three randomized controlled trials, one economic evaluation study and two guidelines met inclusion criteria.

Interoperable Automated Glycemic Controller
"An interoperable automated glycemic controller is a device intended to automatically calculate drug doses based on inputs such as glucose and other relevant physiological parameters, and to

command the delivery of such drug doses from a connected infusion pump. Interoperable automated glycemic controllers are designed to reliably and securely communicate with digitally connected devices to allow drug delivery commands to be sent, received, executed, and confirmed. Interoperable automated glycemic controllers are intended to be used in conjunction with digitally connected devices for the purpose of maintaining glycemic control" (FDA, 2019).

U.S. Food and Drug Administration (FDA): Interoperable automated glycemic controllers are approved as an FDA 510 (k) Class II device. An example is the Control-IQ Technology (Tandem Diabetes Care, San Diego, CA). It was approved by the FDA De Novo premarket review pathway on Dec 13, 2019. This is the first controller that can be used with other diabetes devices that are also designed to be integrated into a customizable diabetes management system for automated insulin delivery. This is a software device used to control a compatible insulin pump and increase or reduce the insulin infusion based on inputs from a compatible glucose monitor (FDA, 2019).

Literature Review:
Brown et al. (2019) conducted a randomized (2:1 ratio), unblinded, multicenter trial (n=168) to assess whether closed-loop systems that automate insulin delivery improve glycemic outcomes in patients with type 1 diabetes. Inclusion criteria were age >14 years old, clinical diagnosis of type 1 diabetes, and treated with insulin via pump or multiple daily injections. The intervention was treatment with a closed-loop system (closed-loop group) (n=112) which consisted of a pump (t:slim X2 insulin pump with Control-IQ Technology, Tandem Diabetes Care) and a continuous glucose monitor (Dexcom G6, Dexcom). The control group (n=56) used a continuous glucose monitor and a sensor-augmented pump. The primary outcome was percentage of time that blood glucose level was within the target range of 70 to 180 mg/dL as measured by continuous glucose monitoring. Secondary outcomes measured were percentage of time that the glucose level was >180 mg/dL, mean glucose level, glycated hemoglobin level, and percentage of time that the glucose level was <70 mg/dL or <54 mg/dL. Patients had follow up visits at two, six, 13, and 26 weeks augmented by telephone contact at one, four, nine, 17, and 21 weeks. All 168 patients completed the six month trial. The mean (+/- Standard Deviation) percentage of time with glucose levels within the target range increased in the closed loop group from 61 +/- 17% at baseline to 71 +/-12% during the six months and remained unchanged in the control group at 59 +/-14% (p<0.001). This amounted to 2.6 more hours per day spent in the target range for the closed loop group. The secondary outcomes were decreased percentage of time with glucose >180 mg/dL (p<0.001), mean glucose level (p<0.001), improved glycated hemoglobin level (p=0.001), and decreased percentage of time with glucose level <70 mg/dL (p<0.001) or <54 mg/dL (p=0.02) demonstrated improved values while using the closed loop system. There were no serious hypoglycemic episodes in either group. There was one episode of diabetic ketoacidosis in the closed-loop group. Author noted limitations included more unscheduled contact in the closed-loop group attributed to the use of an investigational device and the control groups insulin pumps did not have a suspend insulin for predicted hypoglycemia feature. After six months, the closed-loop system increased time with glucose in target range, decreased hyperglycemic and hypoglycemic episodes and improved glycated hemoglobin levels.

Diabetic Supplies

Blood and Urine Glucose Testing
Self-monitoring of blood glucose (SMBG) has replaced urine glucose testing for most patients because urine glucose testing provides only a rough estimate of prevailing blood glucose levels. Urine glucose testing in the home setting consists of semi-quantitative measurements based on single voiding or, less often, by more quantitative blocks collected over 4–24 hours. The rationale for its use is that urinary glucose values reflect mean blood glucose during the period of urine collection. Urine testing is less accurate than blood glucose monitoring and does not provide a complete picture of diabetes. A urine test does not depict the presence of glucose until the blood

glucose level is above 180 milligrams per deciliter (mg/dl), making the test useless in monitoring for hyperglycemia. For these reasons, SMBG is the preferred method of monitoring glycemic status on a daily basis The 2023 ADA standards of medical care for diabetes state that patients on multiple daily injections or insulin pump therapy should perform SMBG (and/or CGM) prior to meals and snacks, occasionally postprandially, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to and while performing critical tasks such as driving. Any condition leading to deterioration in glycemic control necessitates more frequent monitoring of blood glucose. SMBG results may help to guide self-management for patients using less frequent insulin injections or noninsulin therapies. The need for SMBG may vary with patients with type 2 diabetes on insulin, but before a meal and two hours after a meal are common times. In patients with type 2 diabetes not on insulin, routine SMBG monitoring may be of limited additional clinical benefit. According to the Society of General Internal Medicine's (2017) Choosing Wisely recommendation, SMBG is an integral part of patient self-management in maintaining safe and target-driven glucose control in patients with type 1 diabetes. However, daily finger glucose testing is not indicated for patients with type 2 diabetes who are not on insulin or medications associated with hypoglycemia.

Blood glucose test strips are typically unique to the glucose meter being used by the patient with diabetes. For example the FreeStyle glucose test strips are used with a FreeStyle blood glucose monitor (Therasense, Inc., Alameda, CA) and a OneTouch® (LifeScan, Inc., Milpitas, CA) glucose monitor uses the corresponding OneTouch glucose strip.

Insulin Pens
Insulin pens are another alternative to the standard needle and syringe. Several pen-like needle devices and insulin cartridges are available for the administration of subcutaneous insulin. They may be used by patients on a multidose regime, and can also be helpful for the visually impaired, active individuals, and patients with a lack of coordination and/or dexterity issues. In many patients, the pens have been demonstrated to improve accuracy in insulin administration and/or adherence. The devices, resembling a large pen, have a fine needle under the cap and a plunger at the other end. They are prefilled with insulin or have disposable or reusable insulin cartridges. Different pens are compatible with different types of insulin so the patient needs to ensure that they have the correct pen. Pens also differ in their dosing increments and the maximum amount of insulin that can be dispensed at a single time. Some pens have dials that assist the patient in selecting accurate dosage. Disposable pens come prefilled with a cartridge of insulin, are stored in the refrigerator, kept at room temperature after opening and then discarded when all of the insulin is used (ADA, 2023; ADA, 2022; Stockl, et al., 2007; Salsali and Nathan, 2006).

Insulin pen are approved by the FDA 510(k) process. Examples of disposable pens include the Original Prefilled KwikPen (Eli Lilly, Indianapolis, IN) that uses Humulin® N and Humulin 70/30, the FlexPen® (Novo Nordisk, Inc., Princeton, NJ) that uses Levemir®, Novolog® FlexPen and Novolog Mix 70/30 insulin and the Lantus® Solostar® (Sanofi-Vantis, Bridgewater, NJ) which uses Apidra® or Lantus® insulin. Eli Lilly also makes the Basaglar KwikPen, Humalog KwikPen and Humulin KwikPen disposable pens. Examples of reusable pens include the HumaPen Savvio and HumaPen Luxura™ HD by Eli Lilly for the administration of Humalog® insulin and the NovoPen Echo by Novo Nordis for Novolog insulin. Eli Lilly's HumanPen Ergo® II allows for injection of 1–60 units of Humulin or any Humalog 3 mL cartridge (100 IU/ml). The NovoPen Echo (Novodish Inc. Plainsboro, NJ) is a reusable pen that uses the PenFill® 3 mL cartridge of NovoLog® 100 units/mL (U-100) and a single use detachable and disposable pen needle. The pen allows the user to dial the desired dose from 0.5 to 30 units in 0.5 unit increments and has a memory feature that remembers the last dose injected. The InPen (Medtronic) is a reusable, rapid-acting smart pen approved for use in all ages (if below age seven, must use adult supervision). It pairs with a smartphone app via Bluetooth and can sync in real-time with Guardian Connect Continuous Glucose (CGM) system, with Dexcom CGM system with 3-hour delay and with Bluetooth-enabled blood glucose meters through Apple Health. The pen injector is compatible with Lilly Humalog® U-100, NovoLog U-100, and Fiasp U-100 pre-filled cartridges in half-unit increments. The pen injector allows the user to dial the desired dose from 0.5 to 30 units (ADA, 2022; FDA, 2016).

Blood and Urine Ketone Testing

Ketone bodies, by-products of the burning of fat in the absence of insulin, can build up and cause serious complications, including diabetic ketoacidosis (DKA), a condition that requires immediate medical attention. Three types of ketone bodies develop during DKA: ß-hydroxybutyrate (ß-HB), acetoacetate and acetone. The two methods of assessing and monitoring for ketone bodies are the semi-quantitative estimation of acetoacetate and acetone levels in the urine which are based on a nitroprusside reaction on urine dip sticks and the measurement of ß-HB in capillary blood based on an enzymatic reaction on a ketone finger-stick blood strip. Ketones will be present in the urine when the blood level of ketones surpasses a certain threshold and can be detected by ketone urine test strips. Acetoacetic and ß-HB are reabsorbed by the renal tubules and their final concentration in the urine exceeds that in the blood. The presence of urine ketones may be present long after blood levels have normalized. Ketone testing is indicated in the following situations: patients with type 1 diabetes with a blood glucose greater than 240 mg/dl; all patients with diabetes who are ill, under stress or have a blood glucose over 300 mg/dl; any patient with diabetes exhibiting signs of ketoacidosis, such as nausea, vomiting, or abdominal pain; when blood glucose levels are consistently elevated; and in pre-existing pregnancy diabetes and gestational diabetes mellitus. In a 2004 position statement on the tests of glycemia, ADA stated that blood ketone testing methods that quantify ß-hydroxybutyric acid, the predominant ketone body, are available and are preferred over urine ketone testing for diagnosing and monitoring ketoacidosis. Home tests for ß-hydroxybutyric acid are available. In their discussions of ketone testing, the ADA indicates that either blood or urine ketone testing are appropriate when ketone testing is indicated. Urine ketone testing may be indicated when the blood sugar is over 300 mg/dl; when experiencing symptoms of hypoglycemia, hyperglycemia, or vomiting; when the breath smells fruity and/or during illness (e.g., cold, flu, infection). Women with type 1 diabetes who are pregnant should be offered ketone testing strips and advised to test for ketones in urine (ketonuria) or ketones in blood (ketonaemia) if they become hyperglycemic or unwell (ADA; 2022e; Weber, et al., 2009; Kitabchi, et al., 2009; Laffel and Wood, 2008; Laffel, et al., 2006; ADA, 2004).

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 (2023f) 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 patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions, or long-standing diabetes in whom the goal is difficult to achieve despite diabetes self-management education, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin (ADA, 2023a; NICE, 2022). 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).

Hypoglycemic Wrist Band Alarm
A hypoglycemic alarm that looks like a wristband or watch has been proposed to alert people with diabetes to hypoglycemic episodes. Through sensors on the back surface of the device, electronic information is sent to a built-in microprocessor. When there is deviation from preset levels for skin temperature and/or perspiration, an alarm will sound. The device may be worn on the forearm, wrist or ankle. One of the disadvantages of the device is that activities that cause changes in skin temperature and/or perspiration can set off false alarms. An example of this device is the Sleep Sentry® (Diabetes Sentry Products, Inc., Bellingham, WA). The product is FDA approved by the premarket approval process (PMA) as a temperature and skin resistance measuring device. The clinical utility of these devices has not been proven. Therefore, these devices are considered convenience items and are not considered medically necessary.

Insulin Infusers
An insulin infuser is a device in which a cannula is inserted under the skin creating a portal that remains in place for 3–4 days. The presence of the cannula allows the patient to insert insulin into the subcutaneous tissue without subsequent injections. To apply an infuser an insertion needle guides a cannula under the skin, the insertion needle is removed and the cannula remains in the subcutaneous tissue. The insulin is then injected through the cannula. One of the concerns with this device is the development of an infection at the site of entry.

One example of an infuser is the i-port® (Patton Medical Devices, Austin, TX) which is FDA 510(k) approved as "a sterile, single use, low profile injection port through which physician prescribed medications can be injected subcutaneously from a standard syringe and needle, pen or alternative manual injection device. The device is designed to reduce the hardships of multiple daily subcutaneous injections by allowing users to receive physician prescribed medication, including insulin, without repeated needle punctures of the skin." It is intended for home and health care facility use (FDA, 2005). Other infusion devices include the insuflon™ (IntraPump Infusion Systems, Grapevine, TX), Inset 3® Infusion Set (Animas Corp., West Chester, PA) and the Medtronic Minimed® mio™ infusion set.

Blevins et al. (2008) conducted a randomized controlled cross-over trial to compare the outcomes of people with insulin-dependent diabetes (n=74) who used the i-port compared to standard multiple dose insulin injections. The patients with type 1 and type 2 diabetes were randomly assigned to one of four cohorts. Cohort 1 (n=18) compared standard injections (SI) to single i-port, cohort 2 (n=20) compared single i-port to SI, cohort 3 (n=18) compared dual I-Ports (i.e., one for regular human and rapid-acting insulin and one for glargine), to single i-Port, and cohort 4 (n=18) compared single i-port to dual i-ports. At the end of the first three weeks, each group switched to the alternative method for an additional three weeks. Sixty-four participants completed all five follow-up visits. The ten who did not complete the trial terminated for device related issues (i.e., adhesive failure, discomfort, hyperglycemia, cannula bends and adverse events). For the SI and single i-port patients, the glycosylated albumin were within normal limits (98.9% and 107.3%, respectively) (p=0.99). The results for the single i-port vs. the dual i-port were also within normal limits (99.5% vs. 110.99%, respectively) (p=0.97). The A1C levels were similar among all subjects initially and at the completion of the study. Via questionnaire, patients reported that it was significantly more difficult to control their diabetes during the SI phase (p=0.16) and that their overall health was very good or excellent using the i-port compared to SI (p<0.001). I-port adverse events included: erythema, suppuration, skin irritation, itching, bruising at the i-port insertion site and five events of severe hyperglycemia.

There is a lack of evidence demonstrating the clinical utility of insulin infusers. They are not considered medically necessary and are used primarily for the convenience of the patient.

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.

Professional Societies/Organizations: The National Institute for Health and Clinical Excellence (NICE) (2022), United Kingdom, guidance for diabetes management in children and young people who have type 1 diabetes included a recommendation to routinely perform at least five capillary blood glucose tests per day. A second recommendation stated that children and young people with type 1 diabetes should have blood ketone testing strips and a meter to test for ketonemia if they are ill or have hyperglycemia. Regarding diabetes and pregnancy (2020), NICE stated that if a woman with diabetes is planning to become pregnant she may need to increase the frequency of self-monitoring of blood glucose to include fasting levels and a mixture of pre-meal and post-meal levels if intensification of blood glucose-lowering therapy is needed. SMBG should be done in women with type 1 diabetes planning to become pregnant or who are pregnant, and in women with type 2 diabetes or gestational diabetes who are on insulin. Ketone testing is recommended if they are ill or have hyperglycemia. For adults (2022) on insulin, various options for insulin injections should be offered including a pen injector or disposable pen. Special devices should be offered to individuals with manual or visual disabilities. Ketone monitoring (blood or urine) should be available to facilitate self-management of an episode of hyperglycemia or illness. Routine SMBG for pateints with type 2 diabetes is not recommended unless the person is on insulin, experiencing hypoglycemic episodes, is on oral medication that may increase their risk of hypoglycemia while driving or operating machinery, or is pregnant, or planning to become pregnant. Consider short-term SMBG in adults with type 2 diabetes when starting treatment with oral or intravenous corticosteroids or to confirm suspected hypoglycemia.

Coding Information

Notes:

1. This list of codes may not be all-inclusive.
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:

CPT®* Codes	Description
95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum 72 hours; analysis, interpretation and report
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation

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

Considered Convenience Item/Not Medically Necessary when used to report the use of additional software or hardware required for downloading data to a device, combination devices, remote glucose monitoring devices and/or hypoglycemic wristband alarm:

HCPCS Codes	Description
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified
A9280	Alert or alarm device, not otherwise classified

External Insulin Pumps

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

HCPCS Codes	Description
A4224	Supplies for maintenance of insulin infusion catheter, per week
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
A4230	Infusion set for external insulin pump, non needle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3cc
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)

<u>Diabetic Supplies</u>

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

HCPCS Codes	Description
A4206	Syringe with needle, sterile, 1 cc or less, each
A4211	Supplies for self-administered injections
A4215	Needle, sterile, any size, each
A4245	Alcohol wipes, per box
A4250	Urine test or reagent strips or tablets (100 tablets or strips)
A4252	Blood ketone test or reagent strip, each
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4258	Spring-powered device for lancet, each
A4259	Lancets, per box of 100
S5560	Insulin delivery device, reusable pen; 1.5 ml size
S5561	Insulin delivery device, reusable pen; 3 ml size
S5570	Insulin delivery device, disposable pen (including insulin); 1.5 ml size
S5571	Insulin delivery device, disposable pen (including insulin); 3 ml size
S8490	Insulin syringes (100 syringes, any size)

Considered Not Medically Necessary/Convenience Item when used to report home glycated hemoglobin (A1C) monitors, hypoglycemic wristband alarm (e.g., Sleep Sentry), laser lancet and/or insulin infusers (e.g., i-port®):

HCPCS Codes	Description
A4257	Replacement lens shield cartridge for use with laser skin piercing device, each
E0620	Skin piercing device for collection of capillary blood, laser, each

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Revision Details

Type of Revision	Summary of Changes	Date
Focused review	• Added policy statement for Guardian Sensor 4 and quantity limit for Medtronic transmitter • Revised policy statement for insulin pump coverage • Removed policy statement for home glycated serum protein (GSP) monitor	11/15/2023