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## Subject: External Insulin Infusion Pumps and Continuous Glucose Monitors

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### DESCRIPTION:

The American Diabetes Association (ADA) classifies four general categories of diabetes:

1. Type 1 diabetes (due to autoimmune  $\beta$ -cell destruction, usually leading to absolute insulin deficiency)
2. Specific types of diabetes due to other causes, e.g., monogenic diabetes syndromes (such as neonatal diabetes and maturity-onset diabetes of the young); diseases of the exocrine pancreas (such as cystic fibrosis and pancreatitis); and drug or chemical-induced diabetes (such as with glucocorticoid use) in the treatment of HIV/AIDS, or after organ transplantation
3. Gestational diabetes mellitus (diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation)
4. Type 2 diabetes (due to a progressive loss of adequate  $\beta$ -cell insulin secretion frequently on the background of insulin resistance)

Other causes of diabetes include genetic mutations, other diseases, damage to the pancreas and certain medications.

### External Insulin Pumps

For people living with diabetes, multiple daily insulin injections may be insufficient to adequately control glucose levels. In such cases, an external insulin pump may be recommended. The pumps can release small doses of insulin continuously (basal), or a bolus dose close to mealtime to control the rise in blood glucose after a meal. Pumps are worn externally, and doses of insulin are delivered through a subcutaneous catheter placed into the skin. This delivery mimics the body's normal release of insulin.

The insulin pump may integrate with a continuous glucose monitor (CGM) to help understand how blood glucose is trending.

### **Continuous Glucose Monitoring (CGM)**

Continuous glucose monitors track blood glucose levels through a sensor inserted in the skin. Glucose levels are available any time, at a glance, including changes in glucose levels over a few hours or days to see trends. Several devices are available to measure glucose levels automatically and frequently. The devices measure glucose in the interstitial fluid and are approved as adjuncts to or replacements for traditional self-monitoring of blood glucose levels. Devices can be used on a long-term (continuous) or short-term (intermittent) basis.

## **POSITION STATEMENT:**

### **Insulin Infusion Pumps**

External insulin infusion pumps and related supplies **meet the definition of medical necessity** for youth or adults with insulin dependent diabetes related to any of the four general categories of diabetes as noted by the ADA, when the following criteria are met:

- The member has a new or existing diagnosis of Type 1 diabetes, **OR**
- The member has a Type 2 diagnosis and follows a program of multiple daily injections of insulin, **AND**
- The member meets the FDA age limit for device, **AND**
- The member is capable of using the device safely (either by themselves or with a caregiver)

The use of an insulin pump pre-conception or during pregnancy to reduce the incidence of fetal mortality or anomaly **meets the definition of medical necessity.**

The individual with diabetes mellitus successfully using a continuous insulin infusion pump during the month prior to enrollment **meets the definition of medical necessity.**

**NOTE:** If the Medical Necessity criteria for the external insulin infusion pump are met, the pump and related supplies will require an order or prescription signed by a physician or healthcare professional qualified to treat diabetes. A physician order or prescription is required at the onset of external insulin pump therapy and must be updated no less than once per year thereafter.

The physician order or prescription must include:

- The number of infusion sets required, including the type, needle versus cannula, the number of cartridges, and syringes required; **AND**
- The brand of pump device and supporting documentation for any special features required (such as large reservoir or special alarm due to hearing impairment)
- Any additional medically necessary supplies specifically required to treat diabetes must be specified by the physician. (See Reimbursement Section for Medical Supplies)

The replacement of external insulin pumps **meets the definition of medical necessity** when it is out of warranty and is malfunctioning and cannot be refurbished. For requests for replacement pumps, an expired warranty must be verified.

Replacement of an external insulin infusion pump that is functional **meets the definition of medical necessity** when the current device no longer meets the member's medical needs (e.g., when hemoglobin A1C is not maintained in range, despite documentation of adherence to the physician or health care professional's plan of care). Documentation of the specific medical need must be submitted for review.

Personal computer, tablet or smartphone software or apps that are not part of the insulin pump system but are available as separate accessories for use in remote or self-monitoring are considered a convenience and thus, **do not meet the definition of medical necessity**.

The replacement of an external insulin pump for the purpose of upgrading technology **does not meet the definition of medical necessity**.

Implantable insulin infusion pumps are considered **experimental or investigational** for treating diabetes mellitus. The available scientific evidence is insufficient to permit conclusions concerning the effect of this technology on net health outcomes.

### **Continuous Glucose Monitors**

Short-term monitoring of glucose levels in interstitial fluid **meets the definition of medical necessity** in members who are insulin dependent.

Short-term monitoring of glucose levels in interstitial fluid also **meets the definition of medical necessity** in members with who are insulin dependent prior to insulin pump initiation to determine basal insulin levels.

Continuous long-term monitoring of glucose levels in interstitial fluid, including real-time monitoring, as a technique of diabetic monitoring, **meets the definition of medical necessity** for the following:

- Adults with diabetes who are:
  - On multiple daily insulin injections, **OR**
  - On continuous subcutaneous insulin infusion, **OR**
  - On basal insulin, **AND**
  - Capable of using the devices safely (either independently or with the assistance of a caregiver), **AND**
  - Meets the FDA age limit for the device
- Youth with type 1 diabetes or type 2 diabetes who are:
  - On multiple daily insulin injections, **OR**
  - On continuous subcutaneous insulin infusion, **AND**

- Capable of using the devices safely (either independently or with the assistance of a caregiver), **AND**
- Meets the FDA age limit for the device

The use of an external insulin pump with wireless communication to a compatible continuous glucose monitoring sensor/transmitter, or an integrated continuous glucose monitor and insulin pump [an “artificial pancreas device system”], such as low glucose suspend devices or hybrid closed loop systems] **meets the definition of medical necessity** when **ALL** the following have been met:

- The criteria for a long-term continuous glucose monitoring device have been met (see above), **AND**
- The criteria for an external insulin infusion pump device have been met (see above), **AND**
- Meets FDA age limit for device

The use of implantable interstitial glucose sensors **meets the definition of medical necessity** when **ALL** of the following are met:

- 18 years of age or older, **AND**
- Has diabetes mellitus, **AND**
- Is on multiple daily insulin injections, **OR**
- Is on continuous subcutaneous insulin infusion, **OR**
- Is on basal insulin

If the **Medical Necessity** criteria for long term continuous glucose monitoring are met, the monitoring device and related supplies will require an order or prescription signed by a physician or healthcare professional qualified to treat diabetes. A physician order or prescription is required at the onset of continuous long-term glucose monitoring therapy and must be updated no less than once per year thereafter. The physician order or prescription must include the number of sensors required per month, and the type of glucose monitoring device ordered to verify the number of sensors required.

**(See Reimbursement Section for Medical Supplies)**

The replacement of an existing CGM device **meets the definition of medical necessity** when it is out of warranty and is malfunctioning and cannot be refurbished. For requests for replacement devices, an expired warranty must be verified.

Replacement of existing functional equipment for the purpose of upgrading technology **does not meet the definition of medical necessity**.

The following devices are considered **experimental or investigational**, as there is insufficient clinical evidence that demonstrates the use of these devices results in improved health outcomes:

- The use of software to transmit or share data with a healthcare provider from a remote glucose monitoring device
- The use of a remote, mobile communication device or software that uses a wireless connection to transmit or share glucose levels with a healthcare provider

- Infrared light spectroscopy to measure glucose levels transcutaneously

Personal computer, tablet or smartphone software or apps that are not part of the continuous glucose monitoring system, but are available as separate accessories for use in remote or self-monitoring, are considered a convenience and thus, **do not meet the definition of medical necessity**.

## BILLING/CODING INFORMATION:

### CPT Coding (Glucose Monitoring)

95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report
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
0740T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; initial set-up and patient education (e.g., d-Nav® Insulin Guidance System) <b>(non-covered)</b>
0741T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; provision of software, data collection, transmission, and storage, each 30 days (e.g., d-Nav® Insulin Guidance System) <b>(non-covered)</b>

### HCPCS Coding (Continuous Glucose Monitoring Device)

A4238	Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial continuous glucose monitoring system, one unit = 1 day supply
A9277	Transmitter; external, for use with non-durable medical equipment interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with non-durable medical equipment interstitial continuous glucose monitoring system
E2102	Adjunctive, non-implanted continuous glucose monitor or receiver
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver

## HCPCS Coding (Insulin Infusion Pumps)

A4224	Supplies for maintenance of insulin infusion catheter, per week
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week
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
E0784	External ambulatory infusion pump, insulin
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing

### LOINC Codes:

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, treatment plan, prescription for DME and/or supplies, medication history and laboratory reports.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Treatment plan	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Prescription for medical equipment or product	57829-4	18807-8	Include all data of the selected type that represents observations made one year or less before starting date of service for the claim.
History of medication use	10160-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Laboratory studies	26436-6	18805-2	Include all data of the selected type that represents observations made six months or

			fewer before starting date of service for the claim.
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## REIMBURSEMENT INFORMATION:

### Reimbursement for supplies used with external insulin infusion pumps is as follows:

Supplies used with an external infusion pump, **A4224**, **A4225**, **A4230**, **A4231**, **A4232**, and **A9274** are limited to a 90-day supply purchase every 90 days.

- Code **A4224** is reimbursable up to 13 infusion sets within a 90-day period. Infusions sets ordered in excess of 13 within a three-month period require submission of documentation of **medical necessity**. This code is billed per unit; one unit equals one week's supplies.
- Code **A4225** is reimbursable up to 45 infusion sets within a 90-day period. Infusions sets ordered in excess of 45 within a three-month period require submission of documentation of **medical necessity**. This code is billed per unit; one unit equals one infusion set.
- Code **A4226** is reimbursable up to 13 units within a 90-day period. Supplies ordered in excess of 13 within a three-month period require submission of documentation of medical necessity. This code is billed per unit; one unit equals one week's supplies.
- Code **A4230** is reimbursable up to 45 infusion sets within a 90-day period. Infusions sets ordered in excess of 45 within a three-month period require submission of documentation of medical necessity. This code is billed per unit; one unit equals one infusion set.
- Code **A4231** is reimbursable up to 45 infusion sets within a 90-day period. Infusions sets ordered in excess of 45 within a 90-day period require submission of documentation of **medical necessity**. This code is billed per unit; one unit equals one infusion set.
- Code **A4232** is reimbursable up to 45 syringes within a 90-day period. Syringes ordered in excess of 45 within a 90-day period require submission of documentation of **medical necessity**. This code is billed per unit; one unit equals one syringe.
- Code **A9274** is reimbursable up to 45 disposable insulin delivery devices in a 90-day period. Disposable insulin delivery devices in excess of 45 require submission of documentation of **medical necessity**.

Batteries that can be used to power non-medical equipment are not considered durable medical equipment and are not eligible for coverage (K0601, K0602, K0603, K0604, and K0605).

### Reimbursement for supplies used with continuous glucose monitors is as follows:

Sensors used with a continuous glucose monitoring device, or a combination infusion and monitoring device, are limited to a 90-day supply purchase every 90 days.

- Code **0446T** is limited to one implanted sensor every 90 days
- Code **A4238** [supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service] is limited to 3 units in a 3-month period
- Code **A4239** [supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service] is limited to 3 units in a 3-month period
- Code **A9276** is reimbursable per unit; one unit equals one day supply.

- Code **A9277** (transmitter device) is limited to the device manufacturer's recommended replacement guidelines, not to exceed 4 in 12 months
- Code **A9278** (receiver/monitor device) is limited to 1 device in a 12-month period
- Code **E2102** (adjunctive, non-implanted monitor or receiver) is limited to 1 device in a 12-month period
- Code **E2103** (non-adjunctive, non-implanted monitor or receiver) is limited to 1 device in a 12-month period

**\*NOTE:** Transmitter devices (A9277) with non-replaceable batteries (e.g., silver oxide) may require more frequent replacement (e.g., every 6 months).

Short-term monitoring (**codes 95249, 95250**) should be reported only once per monitoring period. Short-term monitoring is limited to two monitoring periods in twelve months.

Analysis and interpretation of continuous glucose monitoring data by a health care professional (**code 95251**) is limited to six times in twelve months.

## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

### Medicare Advantage Products:

The following Local Coverage Determinations (LCDs) were reviewed on the last guideline review date: External Infusion Pumps L33794; Glucose Monitors L33822; and Implantable Continuous Glucose Monitors (I-CGM) L38664.

The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: Home Blood Glucose Monitors 40.2; Outpatient Intravenous Insulin Treatment 40.7; Durable Medical Equipment Reference List 280.1; and Infusion Pumps 280.14.

## DEFINITIONS:

**Artificial pancreas:** a closed-loop glucose management system with a continuous glucose monitor and an insulin pump programmed with a computer algorithm that calculates insulin doses from the CGM readings and sends a signal to the pump to deliver the medication.

**Basal Insulin:** a steady trickle of low levels of longer-acting insulin, such as that used in insulin pumps.

**Bolus insulin:** an extra amount of insulin taken to cover an expected rise in blood glucose, often related to a meal or snack.

**Hemoglobin A1c:** the main fraction of glycosylated hemoglobin (glycohemoglobin) that is hemoglobin to which glucose is bound. Hemoglobin A1c is tested to monitor the long-term control of diabetes mellitus.



**Implantable insulin infusion pump:** similar to the previously described external insulin pump, but the pump is surgically implanted inside the abdomen with a channel connecting to the outside for monthly insulin refills.

**Interstitial fluid:** an extracellular fluid found between cells in tissue that provides much of the liquid environment of the body.

**Insulin dependent diabetes:** diabetes mellitus that requires daily insulin therapy.

**Low glucose suspend;** automatic suspension of insulin delivery when glucose levels fall below a pre-programmed threshold.

**Subcutaneous:** beneath the skin or dermal layer.

## **RELATED GUIDELINES:**

[Blood Glucose Monitors and Supplies, 09-E0000-14](#)

## **OTHER:**

### **Florida statute 627.6408: Diabetes treatment services**

A health insurance policy or group health insurance policy sold in this state must provide coverage for all medically appropriate and necessary equipment, supplies, and diabetes outpatient self-management training and educational services used to treat diabetes, if the patient's treating physician or a physician who specializes in the treatment of diabetes certifies that such services are necessary. The policy may require that diabetes outpatient self-management training and educational services be provided under the direct supervision of a certified diabetes educator or a board-certified endocrinologist. The policy may further require that nutrition counseling be provided by a licensed dietitian. The Agency for Health Care Administration shall adopt standard for diabetes outpatient self-management training and educational services, taking into consideration standards approved by the American Diabetes Association.

### **Florida statutes 641.31 and 627.65745: Health maintenance contracts**

Each health maintenance organization and prepaid health plan shall provide coverage for all medically appropriate and necessary equipment, supplies, and services used to treat diabetes, including outpatient self-management training and educational services, if the patient's primary care physician, or the physician to whom the patient has been referred who specializes in treating diabetes, certifies that the equipment, supplies, or services are necessary. The contract may require that diabetes outpatient self-management training and educational services are provided under the direct supervision of a certified diabetes educator or a board-certified endocrinologist under contract with or designated by the health maintenance organization or prepaid health plan. The Agency for Health Care Administration shall adopt standards for outpatient self-management training and educational services, taking into consideration standards approved by the American Diabetes Association.

## REFERENCES:

1. Abrahamson MJ et. al. AACE Comprehensive Diabetes Management Algorithm 2013. *Endocr Pract.* 2013;19(No. 2).
2. Agrawal P, et al. Usage and Effectiveness of the Low Glucose Suspend Feature of the Medtronic Paradigm Veo Insulin Pump. *Journal of Diabetes Science and Technology* Volume 5 Issue 5, September 2011.
3. AHRQ National Guideline Clearinghouse. Guideline Summary NGC-7431. Evaluation and management of adult hypoglycemic disorders: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2009 Mar;94(3):709-28.
4. AHRQ Effective Health Care Program. Comparative Effectiveness Review No. 57: Methods for Insulin Delivery and Glucose Monitoring: Comparative Effectiveness July 2012.
5. AHRQ National Guideline Clearinghouse. NGC-8919. Continuous Glucose Monitoring: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab* 2011 Oct; 96(10): 2968-79.
6. AHRQ National Guideline Clearinghouse. Standards of medical care in diabetes. NGC-7723. *Diabetes Care* 2008 Jan;31(Suppl 1):S16-24.
7. AHRQ National Guideline Clearinghouse. Guideline Summary NGC-8220. Standards of medical care in diabetes. *Diabetes Care* 2011 Jan;34(Suppl 1):S16-27.
8. AHRQ National Guideline Clearinghouse. Guideline Summary NGC-8577. American Association of Clinical Endocrinologists medical guidelines for clinical practice for developing a diabetes mellitus comprehensive care plan. *Endocr Pract* 2011 Mar-Apr;17(Suppl 2):1-53.
9. Akturk HK, Brackett S. A Novel and Easy Method to Locate and Remove First Approved Long-Term Implantable Glucose Sensors. *Diabetes Technol Ther.* 2020 Jul;22(7):538-540. doi: 10.1089/dia.2020.0023. Epub 2020 Feb 27.
10. Alexeeva NV, Arnold MA. Near-Infrared Microspectroscopic Analysis of Rat Skin Tissue Heterogeneity in Relation to Noninvasive Glucose Sensing. *J Diabetes Sci Technol.* 2009 March; 3(2): 219–232.
11. American Diabetes Association. Position statement: Tests of glycemia in diabetes. *ADA Clinical Practice Recommendations Diabetes Care* 27: S91-S93, 2004.
12. American Diabetes Association. Poster Presentations: Clinical Diabetes/Therapeutics. 976-P: Post Market Clinical Follow-Up (PMCF) Registry to Demonstrate the Long-Term Safety of the Eversense CGM System. *Diabetes* Jun 2019, 68 (Supplement 1) 976-P; DOI: 10.2337/db19-976-P.
13. American Diabetes Association. Standards of Medical Care in Diabetes-2006; *Diabetes Care*, Vol 29, Supplement 1, Jan 2006.
14. American Diabetes Association. Standards of Medical Care in Diabetes-2008. *Diabetes Care*, Vol 31 Supplement 1, January 2008.
15. American Diabetes Association. Standards of Medical Care in Diabetes-2009. *Diabetes Care*, Vol 33 Supplement 1, January 2010.
16. American Diabetes Association. Standards of Medical Care in Diabetes-2009. *Diabetes Care*, Vol 32 Supplement 1, January 2009.
17. American Diabetes Association. Standards of Medical Care in Diabetes-2012. *Diabetes Care*, Volume 35, Supplement 1, January 2012.
18. American Diabetes Association. Standards of Medical Care in Diabetes-2013. *Diabetes Care*, Volume 36, Supplement 1, January 2013.
19. American Diabetes Association. Standards of Medical Care in Diabetes – 2015. January 2015 Volume 38, Supplement 1.

20. American Diabetes Association. Standards of Medical Care in Diabetes – 2017. *Diabetes Care* Volume 40, Supplement 1, January 2017.
21. American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes – 2020. *Diabetes Care* 2020;43(Suppl. 1): S14–S31.
22. American Diabetes Association. Diabetes Technology: Standards of Medical Care in Diabetes 2020. *Diabetes Care* 2020;43(Suppl. 1): S77–S88.
23. American Diabetes Association. Diabetes Technology: Standards of Medical Care in Diabetes 2021. *Diabetes Care* 2021;44(Suppl. 1): S85–S99.
24. American Diabetes Association. Diabetes Technology: Standards of Care in Diabetes—2023. *Diabetes Care* 2023;46(Suppl. 1): S111–S127 | <https://doi.org/10.2337/dc23-S007>.
25. Aronson R, et al. First assessment of the performance of an implantable continuous glucose monitoring system through 180 days in a primarily adolescent population with type 1 diabetes. *Diabetes Obes Metab*. 2019 Jul;21(7):1689-1694.
26. Bally L, Thabit H, et al. Assessing the effectiveness of a 3-month day-and-night home closed-loop control combined with pump suspend feature compared with sensor-augmented pump therapy in youths and adults with suboptimally controlled type 1 diabetes: a randomised parallel study protocol. *BMJ Open*. 2017 Jul 13;7(7): e016738.
27. Bally L, Thabit H, Hovorka R. Closed-loop for type 1 diabetes - an introduction and appraisal for the generalist. *BMC Med*. 2017 Jan 23;15(1):14.
28. Barnard KD, Kropff J, Choudhary P, et al. Acceptability of Implantable Continuous Glucose Monitoring Sensor. *J Diabetes Sci Technol* 2018; 12:634-8.
29. Battelino A et al. Effect of Continuous Glucose Monitoring on Hypoglycemia in Type 1 Diabetes. *Diabetes Care* 34:795–800, 2011.
30. Beck RW, Riddlesworth TD, Ruedy K, et al. Continuous Glucose Monitoring Versus Usual Care in Patients with Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial. *Ann Intern Med* 2017; 167:365-74. (Beck, 2017a). PMID: 28828487.
31. Beck RW, Riddlesworth T, Ruedy K, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. *JAMA* 2017; 317:371-8. (Beck, 2017b). PMID: 28118453.
32. Bergenstal Rm, et al. Threshold-Based Insulin-Pump Interruption for Reduction of Hypoglycemia. *N ENGL J MED* 369;3. July 18, 2013.
33. Bergenstal RM, Johnson M, Passi R, Bhargava A, Young N, Kruger DF, Bashan E, Bisgaier SG, Isaman DJM, Hodish I. Automated insulin dosing guidance to optimise insulin management in patients with type 2 diabetes: a multicentre, randomised controlled trial. *Lancet*. 2019 Mar 16;393(10176):1138-1148. doi: 10.1016/S0140-6736(19)30368-X. Epub 2019 Feb 23.
34. Blevins TC, et. al. Statement by the American Association of Clinical Endocrinologists Consensus Panel on Continuous Glucose Monitoring. *Endocr Pract*. 2010; 16(No. 5).
35. Blue Cross Blue Shield Association Evidence Positioning System®. 1.01.20 - Continuous Glucose Monitoring, 08/23.
36. Blue Cross Blue Shield Association Evidence Positioning System®. 1.01.30 - Artificial Pancreas Device Systems, 08/23.
37. Blue Cross Blue Shield Association. Technology Evaluation Center (TEC). Artificial Pancreas Device Systems. TEC Assessments. 2013; Volume 28.
38. Boscari F, Vettoretti M, Amato AML, et al. Comparing the accuracy of transcutaneous sensor and 90-day implantable glucose sensor. *Nutr Metab Cardiovasc Dis*. 2021 Feb 8;31(2):650-657. doi: 10.1016/j.numecd.2020.09.006. Epub 2020 Sep 12. PMID: 33594987.

39. Boscari F, Vettoretti M, Cavallin F, et al. Implantable and transcutaneous continuous glucose monitoring system: a randomized cross over trial comparing accuracy, efficacy and acceptance. *J Endocrinol Invest*. 2022 Jan;45(1):115-124. doi: 10.1007/s40618-021-01624-2. Epub 2021 Jul 1.
40. Boucher-Berry C, Parton EA, Alemzadeh R. Excess weight gain during insulin pump therapy is associated with higher basal insulin doses. *J Diabetes Metab Disord*. 2016 Oct 18; 15:47.
41. Buckingham BA, et al. Outpatient Safety Assessment of an In-Home Predictive Low-Glucose Suspend System with Type 1 Diabetes Subjects at Elevated Risk of Nocturnal Hypoglycemia. *DIABETES TECHNOLOGY & THERAPEUTICS* Volume 15, Number 8, 2013.
42. Canadian Agency for Drugs and Technologies in Health (CADTH). Issues in Emerging Technologies. Subcutaneous Open-loop Insulin Delivery for Type 1 Diabetes: Paradigm Real-Time System. Issue 105, October 2007. Accessed 02/11/08.
43. Canadian Coordinating Office for Health Technology Assessment (CCOHTA) – Issues in Emerging Health Technologies – “Continuous Glucose Monitoring in the Management of Diabetes Mellitus” – Issue 32, May 2002.
44. Carlson AL, Mullen DM, Bergenstal RM. Clinical Use of Continuous Glucose Monitoring in Adults with Type 2 Diabetes. *Diabetes Technol Ther*. 2017 May;19(S2): S4-S11. doi: 10.1089/dia.2017.0024.
45. Cengiz E. Putting Brakes on Insulin Pump Infusion to Prevent Hypoglycemia. *Journal of Diabetes Science and Technology* Volume 5 Issue 5, September 2011.
46. Centers for Medicare and Medicaid Services (CMS). CMS Ruling 1682-R (Classification of Continuous Glucose Monitoring Systems as Durable Medical Equipment under Part B of the Medicare Program) (January 12, 2017). Accessed at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf>.
47. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) (L6179): Continuous Glucose Monitoring. (Retired 02/02/09).
48. Centers for Medicare and Medicaid (CMS). Local Coverage Determination (LCD): External Infusion Pumps (L33794) (10/01/15) (Revised 01/01/24).
49. Centers for Medicare and Medicaid (CMS). Local Coverage Determination (LCD): Glucose Monitors (L33822) (10/01/15) (Revised 04/01/24).
50. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD): Implantable Continuous Glucose Monitors (I-CGM) (L38664) (10/11/20) (Revised 04/21/22).
51. Centers for Medicare and Medicaid (CMS). National Coverage Determination (NCD): Durable Medical Equipment Reference List (280.1) (05/16/23).
52. Centers for Medicare and Medicaid (CMS). National Coverage Determination (NCD): Home Blood Glucose Monitors (40.2) (06/19/06).
53. Centers for Medicare and Medicaid (CMS). National Coverage Determination (NCD): Infusion Pumps (280.14) (12/17/04).
54. Centers for Medicare and Medicaid (CMS). National Coverage Determination (NCD) Outpatient Intravenous Insulin Treatment (40.7) (12/23/09).
55. Centers for Medicare and Medicaid (CMS). National Coverage Determination (NCD) for Infusion Pumps (280.14). 12/17/04.
56. Chase H, Roberts P, Wightman MD, et al. Use of the GlucoWatch biographer in children with type 1 diabetes. *Pediatrics* 2003; 111(4): 1-10.
57. Chase HP, et al. Use of the GlucoWatch Biographer in Children with Type I Diabetes. *Pediatrics* 2003; 111(4): 790-794.

58. Choudhary P, et al. Editorial: Insulin Pump Therapy with Automated Insulin Suspension: Toward Freedom from Nocturnal Hypoglycemia. *JAMA* September 25, 2013, Volume 310, Number 12.
59. Choudhary P, et al. Insulin Pump Therapy with Automated Insulin Suspension in Response to Hypoglycemia. *Diabetes Care* 34:2023–2025, 2011.
60. Christiansen M, et al. A New Generation Continuous Glucose Monitoring System: Improved Accuracy and Reliability Compared with a Previous Generation System. *DIABETES TECHNOLOGY & THERAPEUTICS* Volume 15, Number 10, 2013.
61. Christiansen MP, et al. A Prospective Multicenter Evaluation of the Accuracy of a Novel Implanted Continuous Glucose Sensor: PRECISE II. *Diabetes Technol Ther.* 2018 Mar;20(3):197-206. doi: 10.1089/dia.2017.0142. Epub 2018 Jan 30.
62. Christiansen MP, et al. A Prospective Multicenter Evaluation of the Accuracy and Safety of an Implanted Continuous Glucose Sensor: The PRECISION Study. *DIABETES TECHNOLOGY & THERAPEUTICS* Volume 21, Number 5, 2019.
63. Chun J, Strong J, Urquhart S. Insulin Initiation and Titration in Patients With Type 2 Diabetes. *Diabetes Spectr.* 2019 May;32(2):104-111. doi: 10.2337/ds18-0005.
64. ClinicalTrials.gov. NCT02912728. Strategies to Enhance New CGM Use in Early Childhood (SENCE) (SENCE). Jaeb Center for Health Research. September 2018.
65. ClinicalTrials.gov. NCT00569907. Observational Study of Interstitial Glucose Monitoring with Continuous Glucose Monitoring to Track Patients Treated with Exenatide. Park Nicollet Institute. August 2010.
66. ClinicalTrials.gov. NCT01072565. Modal Day Analysis of Self-Monitoring Blood Glucose Versus Continuous Glucose Monitoring. Park Nicollet Institute. February 2012.
67. ClinicalTrials.gov. NCT00949221: Study of Insulin Therapy Augmented by Real Time Sensor IN Type 1 Children and Adolescents (START-IN!). Assistance Publique - Hôpitaux de Paris. July 2012.
68. ClinicalTrials.gov. NCT00824148: Use of Real-time Continuous Glucose Monitoring System in Patients with Type 1 Diabetes Mellitus. Norwegian University of Science and Technology. July 2012.
69. ClinicalTrials.gov. NCT02463097: Hybrid Closed Loop Pivotal Trial in Type 1 Diabetes. Medtronic Diabetes (May 2017).
70. ClinicalTrials.gov. NCT02488616: Closed-loop Control of Glucose Levels (Artificial Pancreas) for 5 Days in Adults with Type 1 Diabetes. Institut de Recherches Cliniques de Montreal (August 2017).
71. ClinicalTrials.gov. NCT02523131: Home Testing of Day and Night Closed Loop With Pump Suspend Feature (APCam11). Juvenile Diabetes Research Foundation, et al. (March 2017).
72. ClinicalTrials.gov. NCT02660827: Safety Evaluation of the Hybrid Closed Loop (HCL) System in Pediatric Subjects With Type 1 Diabetes. Medtronic Diabetes (July 2017).
73. ClinicalTrials.gov. NCT04836546: Eversense® Non-adjunctive Use Post Approval Study (NA-PAS). Senseonics (April 2021).
74. ClinicalTrials.gov. NCT03908125: Post Approval Study of the Eversense® Continuous Glucose Monitoring (PAS). Senseonics (July 2020).
75. Colvin AE, Jiang H. Increased in vivo stability and functional lifetime of an implantable glucose sensor through platinum catalysis. *Biomed Mater Res Part A* 2012;00A:000–000.
76. Conrad SC, et al. The use of a continuous glucose monitoring system in hypoglycemic disorders. *J Pediatr Endocrinol Metab.* 2004 Mar; 17i(3): 281-8 Conrad SC, et al. The use of a continuous glucose monitoring system in hypoglycemic disorders. *J Pediatr Endocrinol Metab.* 2004 Mar; 17i(3): 281-8.

77. Cowart K. A Review of the First Long-term Implantable Continuous Glucose Monitoring System Available in the United States. *J Diabetes Sci Technol*. 2021 Jan;15(1):160-166. doi: 10.1177/1932296819890865. Epub 2019 Dec 13.
78. Cryer P, Axelrod L, Grossman A, Heller S, Montori V, Seaquist E, Service FJ. Evaluation and Management of Adult Hypoglycemic Disorders: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology and Metabolism*, March 2009, 94(3): 709 – 728. ©The Endocrine Society, 2009.
79. Danne T, Nimri R, Battelino T, et al. International Consensus on Use of Continuous Glucose Monitoring. *Diabetes Care* 2017;40:1631-40.
80. Dehennis A, Mortellaro MA, Ioacara S. Multisite Study of an Implanted Continuous Glucose Sensor Over 90 Days in Patients With Diabetes Mellitus. *J Diabetes Sci Technol* 2015;9:951-6.
81. Deiss D, Irace C, et al.. Real-World Safety of an Implantable Continuous Glucose Sensor Over Multiple Cycles of Use: A Post-Market Registry Study. *Diabetes Technol Ther*. 2020 Jan;22(1):48-52. doi: 10.1089/dia.2019.0159.
82. Deiss D, Szadkowska A, Gordon D, et al. Clinical Practice Recommendations on the Routine Use of Eversense, the First Long-Term Implantable Continuous Glucose Monitoring System. *Diabetes Technol Ther* 2019;21:254-64.
83. DeVries JH, Bergenstal RM, Welsh JB, Shin JJ. Editorial: Threshold Insulin-Pump Interruption to Reduce Hypoglycemia. *N ENGL J MED* 369;15. October 10, 2013.
84. DexCom STS CGMS: FDA Summary of Safety and Effectiveness. Accessed at <http://www.fda.gov/>.
85. Diabetes Research in Children Network (DirectNet) Study Group. Youth and parent satisfaction with clinical use of the GlucoWatch G2 Biographer in the management of pediatric type 1 diabetes. *Diabetes Care* 2005 Aug; 28(8): 1929-35.
86. Diabetes Technology & Therapeutics; The Accuracy of the CGMS™ in Children with Type 1 Diabetes: Results of the Diabetes Research in Children Network (DirecNet) Accuracy Study; Oct 2003, Vol. 5. No. 5:781-789.
87. Didyuk O, Econom N, et al. Continuous Glucose Monitoring Devices: Past, Present, and Future Focus on the History and Evolution of Technological Innovation. *J Diabetes Sci Technol*. 2021 May;15(3):676-683. doi: 10.1177/1932296819899394. Epub 2020 Jan 13.
88. Donnelly R, Carr S, Harper R. Diabetes Insulin Guidance System: a real-world evaluation of new technology (d-Nav) to achieve glycaemic control in insulin-treated type 2 diabetes. *Practical Diabetes*. 2015 Sep;32(7):247-52a.
89. Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determinations (LCD) L11520. Glucose Monitors. Retired 09/30/15.
90. Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determinations (LCD) L11555. External Infusion Pumps. Retired 09/30/15.
91. ECRI Health Technology Assessment Information Services – Target Fact Sheet – “Iontophoretic Glucose Monitoring System for Diabetes Patients” (07/01).
92. ECRI Health Technology Assessment Information Services, Target Report: “Continuous subcutaneous glucose monitoring system for diabetes patients” (05/02; updated 08/02).
93. ECRI Health Technology Forecast database; “Implantable sensors for continuous glucose monitoring” (12/05).
94. ECRI Health Technology Forecast, “FDA approves first continuous glucose monitor” (08/19/05).
95. ECRI Target database Report. Real-time continuous glucose monitoring (07/07) (Updated 11/07).
96. ECRI. Custom Hotline Response. Real-time Continuous Glucose Monitoring. Plymouth Meeting, PA: ECRI update 08/29/08.

97. ECRI. Health Technology Forecast. Study shows continuous glucose monitoring improves glycemic control in type 1 diabetes. Plymouth Meeting, PA: ECRI 09/12/08.
98. ECRI Institute Evidence Report: Real-Time Continuous Glucose Monitoring for Type 1 and Type 2 Diabetes. January 2010. Issue No. 172.
99. ECRI Institute Health Technology Forecast: Portable closed-loop glucose management system (artificial pancreas) for treating diabetes. 05/04/11.
100. ECRI Institute Health Technology Forecast: U.S. trial allows patients to test artificial pancreas at home for the first time. 06/01/12.
101. ECRI Institute Health Technology Forecast: Type 2 Diabetes Mellitus. August 15, 2012.
102. ECRI Institute Health Technology Forecast: Data suggests three-year benefit of sensor-augmented pump therapy for type 1 diabetes. January 18, 2013.
103. ECRI Institute Health Technology Forecast: MiniMed 530G Artificial Pancreas (Medtronic, Inc.) for Treating Diabetes Requiring Exogenous Insulin. December 2013.
104. ECRI Institute Health Technology Forecast: Insulin pump with "threshold suspend" feature receives U.S. marketing approval. October 17, 2013.
105. Edelman SV, Argento NB, Pettus J, Hirsch IB. Clinical Implications of Real-time and Intermittently Scanned Continuous Glucose Monitoring. *Diabetes Care* 2018;41:2265-74. PMID: 30348844.
106. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, Collins BS, Hilliard ME, Isaacs D, Johnson EL, Kahan S, Khunti K, Leon J, Lyons SK, Perry ML, Prahalad P, Pratley RE, Seley JJ, Stanton RC, Gabbay RA, on behalf of the American Diabetes Association. 6. Glycemic Targets: Standards of Care in Diabetes-2023. *Diabetes Care*. 2023 Jan 1;46(Suppl 1):S97-S110. doi: 10.2337/dc23-S006.
107. Executive Summary: Standards of Medical Care in Diabetes-2010. *Diabetes Care*, Volume 33, Supplement 1, January 2010. ©2010 by the American Diabetes Association.
108. Facchinetti A. Continuous Glucose Monitoring Sensors: Past, Present and Future Algorithmic Challenges. *Sensors (Basel)*. 2016 Dec 9;16(12). pii: E2093.
109. Fiallo-Scharer R; Diabetes Research in Children Network Study Group. Eight-point glucose testing versus the continuous glucose monitoring system in evaluation of glycemic control in type 1 diabetes. *J clin endocrinol Metab* 2005June; 90(6): 3387-91. Epub 2005 Mar 22.
110. First Coast Service Options, Inc. (FCSO). Local Coverage Determination (LCD): Noncovered Services (L33777) (retired 07/01/20).
111. Fleming GA, Petrie JR, Bergenstal RM, Holl RW, Peters AL, Heinemann L. Diabetes Digital App Technology: Benefits, Challenges, and Recommendations. A Consensus Report by the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group. *Diabetes Care*. 2020 Jan;43(1):250-260. doi: 10.2337/dci19-0062. Epub 2019 Dec 5.
112. Fokkert M, van Dijk PR, et al. Performance of the Eversense versus the Free Style Libre Flash glucose monitor during exercise and normal daily activities in subjects with type 1 diabetes mellitus. *BMJ Open Diabetes Res Care*. 2020 Aug;8(1):e001193. doi: 10.1136/bmjdr-2020-001193.
113. Fonseca VA, et al. Fonseca VA, Grunberger G, et al. Continuous Glucose Monitoring: A Consensus Conference of the American Association of Clinical Endocrinologists and American College of Endocrinology. *Endocr Pract* 2016;22:1008-21.
114. Foster HC, et al. Continuous Glucose Monitoring in Patients With Type 1 Diabetes Using Insulin Injections. *Diabetes Care*. 2016 Jun;39(6):e81-2.
115. Funtanilla VD, Candidate P, Caliendo T, Hilas O. Continuous Glucose Monitoring: A Review of Available Systems. *P T*. 2019;44(9):550-553.

116. Gabriely, I., Wozniak, R., Mevorach, M. et al. (1999). Transcutaneous glucose measurement using near-infrared spectroscopy during hypoglycemia. *Diabetes Care*, 22(12), 2026-2032.
117. Garg S, et al. Reduction in Duration of Hypoglycemia by Automatic Suspension of Insulin Delivery: The In-Clinic ASPIRE Study. *DIABETES TECHNOLOGY & THERAPEUTICS* Volume 14, Number 3, 2012.
118. Garg S, Jovanovic L. Relationship of fasting and hourly blood glucose levels to HbA1c values: safety, accuracy, and improvements in glucose profiles obtained using a 7-day continuous glucose sensor. *Diabetes Care*. 2006 Dec; 29(12): 2644-9.
119. Garg SK, Liljenquist D, Bode B, et al. Evaluation of Accuracy and Safety of the Next-Generation Up to 180-Day Long-Term Implantable Eversense Continuous Glucose Monitoring System: The PROMISE Study. *Diabetes Technol Ther*. 2022 Feb;24(2):84-92. doi: 10.1089/dia.2021.0182. Epub 2021 Sep 9.
120. Garg S, Zisser H, Schwartz S, Bailey T, Kaplan R, Ellis S, Jovanovic L. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care*. 2006 Jan; 29(1): 44-50.
121. Ghazanfar H, et al. Impact of insulin pump on quality of life of diabetic patients. *Indian J Endocrinol Metab*. 2016 Jul-Aug;20(4):506-11.
122. Green W, Taylor M. Cost-Effectiveness Analysis of d-Nav for People with Diabetes at High Risk of Neuropathic Foot Ulcers. *Diabetes Ther*. 2016 Sep;7(3):511-25. doi: 10.1007/s13300-016-0183-x. Epub 2016 Jul 11.
123. Guardian-RT CGMS: FDA Summary of Safety and Effectiveness. Accessed at <http://www.fda.gov/>.
124. Hannah G. Piper, MD, Jamin L. Alexander, BA, Avinash Shukla, MD, Frank Pigula, MD, John M. Costello, MD, Peter C. Laussen, MD, Tom Jaksic, MD, PhD and Michael S.D. Agus, MD. Real-Time Continuous Glucose Monitoring in Pediatric Patients During and After Cardiac Surgery. *Pediatrics* Vol. 118 No. 3 September 2006, pp. 1176 – 1184.
125. Harper R, Bashan E, Bisgaier SG, Willis M, Isaman DJM, Hodish I. Temporary Reductions in Insulin Requirements Are Associated with Hypoglycemia in Type 2 Diabetes. *Diabetes Technol Ther*. 2018 Dec;20(12):817-824. doi: 10.1089/dia.2018.0266.
126. Harper R, Bashan E, Williams KJ, Sritharan S, Willis M, Marriott DJ, Hodish I. Challenging the 50-50 rule for the basal-bolus insulin ratio in patients with type 2 diabetes who maintain stable glycaemic control. *Diabetes Obes Metab*. 2023 Feb;25(2):581-585. doi: 10.1111/dom.14904. Epub 2022 Dec 2.
127. Hayes Medical Technology Directory, Continuous Glucose Monitoring System, (05/22/07).
128. Hayes Search and Summary Report. Closed-Loop Combined Continuous Subcutaneous Insulin Infusion (CSII) and Blood Glucose Monitoring (BGM) Systems (12/22/06).
129. Hayes Technology Brief. MiniMed Paradigm Real-Time Closed-Loop Continuous Insulin Infusion and Blood Glucose Monitoring System (Medtronic MiniMed Inc.) (07/09/07).
130. Hermanides J, Phillip M, Devries JH. Current Application of Continuous Glucose Monitoring in the Treatment of Diabetes. *DIABETES CARE*, VOLUME 34, SUPPLEMENT 2, MAY 2011.
131. Hirsch, IB, Abelson, J, et al. Sensor Augmented Insulin Pump Therapy: Results of the First Randomized Treat-to-Target Study. *Diabetes Technol Ther*. 2008 Oct; 10(5): 377-83.
132. Hirsch IB, et al. Editorial: Reducing Hypoglycemia in Type 1 Diabetes: An Incremental Step Forward. *DIABETES TECHNOLOGY & THERAPEUTICS* Volume 15, Number 7, 2013.
133. Hirsch IB, Balo AK, Sayer K, Garcia A, Buckingham BA, Peyser TA. A Simple Composite Metric for the Assessment of Glycemic Status from Continuous Glucose Monitoring Data: Implications for Clinical Practice and the Artificial Pancreas. *Diabetes Technol Ther*. 2017 Jun;19(S3):S38-S48.



134. Hommel E, et al. Impact of continuous glucose monitoring on quality of life, treatment satisfaction, and use of medical care resources: analyses from the SWITCH study. *Acta Diabetol* (2014) 51:845–851.
135. Howard-Thompson A, Khan M, Jones M, George CM. Type 2 Diabetes Mellitus: Outpatient Insulin Management. *Am Fam Physician*. 2018 Jan 1;97(1):29-37.
136. HYGIEIA d-Nav® Value Dossier.
137. Irace C, Cutruzzolà A, Nuzzi A, et al. Clinical use of a 180-day implantable glucose sensor improves glycated haemoglobin and time in range in patients with type 1 diabetes. *Diabetes Obes Metab*. 2020 Jul;22(7):1056-1061. doi: 10.1111/dom.13993. Epub 2020 Feb 27.
138. Jafri RZ, Balliro CA, et al. A Three-Way Accuracy Comparison of the Dexcom G5, Abbott Freestyle Libre Pro, and Senseonics Eversense Continuous Glucose Monitoring Devices in a Home-Use Study of Subjects with Type 1 Diabetes. *Diabetes Technol Ther*. 2020 Nov;22(11):846-852. doi: 10.1089/dia.2019.0449. PMID: 32453604.
139. Janapala RN, Jayaraj JS, Fathima N, et al. Continuous Glucose Monitoring Versus Self-monitoring of Blood Glucose in Type 2 Diabetes Mellitus: A Systematic Review with Meta-analysis. *Cureus*. 2019;11(9):e5634. Published 2019 Sep 12. doi:10.7759/cureus.5634.
140. JDRF Press Release: FDA's Approval of the Medtronic Hybrid Closed Loop System Will Significantly Improve Glucose Control and Reduce the Burden of Type 1 Diabetes (09/28/17). Accessed at <http://www.jdrf.org/press-releases/jdrf-celebrates-fda-approval-of-artificial-pancreas-system/>.
141. Jaha GS, et al. Continuous glucose monitoring and the reality of metabolic control in preschool children with type 1 diabetes. *Diabetes Care* 2004 Dec; 27(12): 2881-6.
142. Joseph JI. Review of the Long-Term Implantable Senseonics Continuous Glucose Monitoring System and Other Continuous Glucose Monitoring Systems. *J Diabetes Sci Technol*. 2021 Jan;15(1):167-173. doi: 10.1177/1932296820911919. Epub 2020 Apr 29.
143. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. *N Engl J Med* 2008; 359(14): 1469-76.
144. Kropff J, DeJong J, et al., Psychological outcomes of evening and night closed-loop insulin delivery under free living conditions in people with Type 1 diabetes: a 2-month randomized crossover trial. *Diabet Med*. 2017 Feb;34(2):262-271.
145. Kropff J, et al. Accuracy and Longevity of an Implantable Continuous Glucose Sensor in the PRECISE Study: A 180-Day, Prospective, Multicenter, Pivotal Trial. *Diabetes Care* 2016 Nov; dc161525.
146. Larson N, Pinsker JE. The role of continuous glucose monitoring in the care of children with type 1 diabetes. *International Journal of Pediatric Endocrinology* 2013, 2013:8.
147. Leinung M, Thompson S, Nardacci E. Benefits of Continuous Glucose Monitor Use in Clinical Practice. *Endocr Pract*. 2009 Nov 26:1-14.
148. Lind M, Polonsky W, Hirsch IB, et al. Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults with Type 1 Diabetes Treated with Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. *JAMA* 2017; 317:379-87. PMID: 28118454.
149. Lorenz C, et al. Interference Assessment of Various Endogenous and Exogenous Substances on the Performance of the Eversense Long-Term Implantable Continuous Glucose Monitoring System. *Diabetes Technol Ther*. 2018 May;20(5):344-352. doi: 10.1089/dia.2018.0028. Epub 2018 Mar 30.
150. Ly TT, et al. Analysis of Glucose Responses to Automated Insulin Suspension with Sensor-Augmented Pump Therapy. *Diabetes Care* 35:1462–1465, 2012.

151. Ly TT, et al. Effect of Sensor-Augmented Insulin Pump Therapy and Automated Insulin Suspension vs Standard Insulin Pump Therapy on Hypoglycemia in Patients with Type 1 Diabetes: A Randomized Clinical Trial. *JAMA* 2013;310(12):1240-1247.
152. Marchetti L, et al. A Novel Insulin/Glucose Model after a Mixed-Meal Test in Patients with Type 1 Diabetes on Insulin Pump Therapy. *Sci Rep*. 2016 Nov 8; 6:36029.
153. Maura N, et al. A Randomized Clinical Trial to Assess the Efficacy and Safety of Real-Time Continuous Glucose Monitoring in the Management of Type 1 Diabetes in Young Children Aged 4 to <10 Years. *Diabetes Care* 35:204–210, 2012.
154. Medtronic MiniMed® 670G System: Product Highlights. Accessed at <https://www.medtronicdiabetes.com/products/minimed-670g-insulin-pump-system>.
155. Melki V, Ayon F, Fernandez M, Hanaire-Broutin H. Value and limitations of the Continuous Glucose Monitoring System in the management of type 1 diabetes. *Diabetes Metab*. 2006 Apr; 32(2):123-9.
156. Mortellaro M, DeHennis A. Performance characterization of an abiotic and fluorescent-based continuous glucose monitoring system in patients with type 1 diabetes. *Biosens Bioelectron* 2014; 61:227-31.
157. Murphy HR, Rayman G, Lewis K, et al. Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomised clinical trial. *BMJ*. 2008 Sep 25; 337: a1680. DOI: 10.1136/bmj.a1680.
158. National Institute of Health and Care Excellence (NICE). Medtech innovation briefing [MIB285]: d-Nav insulin management app for type 2 diabetes (February 2022). Accessed at <https://www.nice.org.uk/advice/mib285/>.
159. Nevoret C, Gervaise N, Delemer B, Bekka S, Detournay B, Benkheilil A, Bahloul A, d'Orsay G, Penfornis A. The Effectiveness of an App (Insulia) in Recommending Basal Insulin Doses for French Patients with Type 2 Diabetes Mellitus: Longitudinal Observational Study. *JMIR Diabetes*. 2023 Mar 1;8: e44277. doi: 10.2196/44277.
160. Olafsdottir AF, Polonsky W, Bolinder J, et al. A Randomized Clinical Trial of the Effect of Continuous Glucose Monitoring on Nocturnal Hypoglycemia, Daytime Hypoglycemia, Glycemic Variability, and Hypoglycemia Confidence in Persons with Type 1 Diabetes Treated with Multiple Daily Insulin Injections (GOLD-3). *Diabetes Technol Ther* 2018; 20:274-84.
161. Oppel E, Kamann S, Heinemann L, Reichl FX, Högg C. The implanted glucose monitoring system Eversense: An alternative for diabetes patients with isobornyl acrylate allergy. *Contact Dermatitis*. 2020 Feb;82(2):101-104. doi: 10.1111/cod.13392. Epub 2019 Sep 17. PMID: 31463958.
162. Pandit K. Continuous glucose monitoring. *Indian J Endocrinol Metab*. 2012 December; 16(Suppl 2): S263–S266.
163. Paradigm REAL-Time and Guardian-REAL-Time Systems: FDA Summary of Safety and Effectiveness. Accessed at <http://www.fda.gov/>.
164. Petrie JR, et al. Improving the Clinical Value and Utility of CGM Systems: Issues and Recommendations: A Joint Statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group. *Diabetes Care*. 2017 Dec;40(12):1614-1621.
165. Pickup JC, Freeman SC, Sutton AJ. Glycemic control in type 1 diabetes during real time continuous glucose monitoring compared with self-monitoring of blood glucose: meta-analysis of randomized controlled trials using individual patient data. *BMJ* 2011;343: d3805.
166. Polonsky WH, et al. A structured self-monitoring of blood glucose approach in type 2 diabetes encourages more frequent, intensive, and effective physician interventions: results from the STeP study. *Diabetes Technol Ther*. 2011 Aug;13(8):797-802.

167. Poolsup N, Suksomboon N, Kyaw AM. Systematic review, and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. *Diabetol Metab Syndr*. Jul 23, 2013;5(1):39.
168. Renard E, Riveline JP, Hanaire H, Guerci B; on behalf of the investigators of France Adoption Clinical Trial. Reduction of clinically important low glucose excursions with a long-term implantable continuous glucose monitoring system in adults with type 1 diabetes prone to hypoglycaemia: the France Adoption Randomized Clinical Trial. *Diabetes Obes Metab*. 2022 May;24(5):859-867. doi: 10.1111/dom.14644. Epub 2022 Feb 7. PMID: 34984786.
169. Robard H, Gellinger P, Davidson J, Einhorn D, Garber A, Grunberger G, Handelsman Y, Horton E, Lebovitz H, Levy P, Moghissi E, Schwartz S. Statement by an American Association of Clinical Endocrinologists / American College of Endocrinology Consensus Panel on Type 2 Diabetes Mellitus: An Algorithm for Glycemic Control. *Endocrine Practice* Volume 15 No. 6 September/October 2009.
170. Rodbard D. Continuous Glucose Monitoring: A Review of Recent Studies Demonstrating Improved Glycemic Outcomes. *Diabetes Technol Ther*. 2017 Jun;19(S3): S25-S37.
171. Rodbard H, Blonde L, Braithwaite S, Brett E, Cobin R, Handelsman Y, Jellinger P, Jovanovic L, Levy P, Mechanick J, Zangen F. American Association of Clinical Endocrinologists. Medical Guidelines for Clinical Practice for the Management of Diabetes Mellitus. *Endocrine Practice* Volume 13 (Supplement 1). May/June 2007.
172. Samson SL, Vellanki P, Blonde L, Christofides EA, Galindo RJ, Hirsch IB, Isaacs SD, Izuora KE, Low Wang CC, Twining CL, Umpierrez GE, Valencia WM. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm - 2023 Update. *Endocr Pract*. 2023 May;29(5):305-340. doi: 10.1016/j.eprac.2023.02.001.
173. Sanchez P, Ghosh-Dastidar S, Tweden KS, Kaufman FR. Real-World Data from the First U.S. Commercial Users of an Implantable Continuous Glucose Sensor. *Diabetes Technol Ther*. 2019 Dec;21(12):677-681. doi: 10.1089/dia.2019.0234. Epub 2019 Aug 28.
174. Schneider JE, Parikh A, Stojanovic I. Impact of a Novel Insulin Management Service on Non-insulin Pharmaceutical Expenses. *J Health Econ Outcomes Res*. 2018 Feb 20;6(1):53-62. doi: 10.36469/9783.
175. Seaquist ER, et al. Hypoglycemia and Diabetes: A Report of a Workgroup of the American Diabetes Association and The Endocrine Society. *Diabetes Care* 36:1384–1395, 2013.
176. Secher AL, Ringholm L, Andersen HU, et al. The Effect of Real-Time Continuous Glucose Monitoring in Pregnant Women with Diabetes: A randomized controlled trial. *Diabetes Care*. Jan 24, 2013.
177. Senseonics Dossier: Eversense® Continuous Glucose Monitoring (CGM) System.
178. Slattery D, Choudhary P. Clinical Use of Continuous Glucose Monitoring in Adults with Type 1 Diabetes. *Diabetes Technol Ther*. 2017 May;19(S2): S55-S61. doi: 10.1089/dia.2017.0051.
179. Streja D. Can continuous glucose monitoring provide objective documentation of hypoglycemia unawareness? *Endocr Pract*. 2005 mar-Apr; 11(2): 83-90.
180. Tamborlane WV, et al. Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes. *The New England journal of medicine* 359.14 (2008): 1464-1476.
181. Tanenberg R, Bode B, Lane W, Levetan C, Mestman J, Harmel AP, Tobian J, Gross T, Mastrototaro J. Use of the Continuous Glucose Monitoring System to guide therapy in patients with insulin-treated diabetes: a randomized controlled trial. *Mayo Clin Proc*. 2004 Dec; 79(12): 1521-6.
182. Tansey, MJ, et al. Accuracy of the modified Continuous Glucose Monitoring system (CGMS) sensor in an outpatient setting: results from diabetes research in children network (DirectNet) study. *Diabetes Technol Ther* 2005 Feb; 7(1): 109-14.

183. Tauschmann M, et al. Day-and-Night Hybrid Closed-Loop Insulin Delivery in Adolescents with Type 1 Diabetes: A Free-Living, Randomized Clinical Trial. *Diabetes Care* 2016; 39:1168–1174.
184. Thabit H, Hartnell S, et al. Closed-loop insulin delivery in inpatients with type 2 diabetes: a randomised, parallel-group trial. *Lancet Diabetes Endocrinol.* 2017 Feb;5(2):117-124.
185. Torimoto K, et al. Relationship between fluctuations in glucose levels measured by continuous glucose monitoring and vascular endothelial dysfunction in type 2 diabetes mellitus. *Cardiovascular Diabetology* 2013, 12:1.
186. Trevitt S, Simpson S, Wood A. Artificial Pancreas Device Systems for the Closed-Loop Control of Type 1 Diabetes: What Systems Are in Development? *Journal of Diabetes Science and Technology.* 2016 May;10(3):714.
187. Tweden KS, Deiss D, Rastogi R, Addaguduru S, Kaufman FR. Longitudinal Analysis of Real-World Performance of an Implantable Continuous Glucose Sensor over Multiple Sensor Insertion and Removal Cycles. *Diabetes Technol Ther.* 2020 May;22(5):422-427. doi: 10.1089/dia.2019.0342.
188. UpToDate. Glucose monitoring in the management of nonpregnant adults with diabetes mellitus. 2024. Accessed at [uptodate.com](http://uptodate.com).
189. UpToDate. Insulin therapy for children and adolescents with type 1 diabetes mellitus. 2024. Accessed at [uptodate.com](http://uptodate.com).
190. UpToDate. Insulin therapy in type 2 diabetes mellitus. 2024. Accessed at [uptodate.com](http://uptodate.com).
191. U.S. Food and Drug Administration, GlucoWatch Automatic Glucose Biographer-P990026, 03/22/01 & Minimed, 02/26/96.
192. U.S. Food and Drug Administration. FDA approves GlucoWatch device for children with diabetes, (08/27/03).
193. U.S. Food and Drug Administration (FDA). Approval Order P120010: MiniMed 530G System. September 26, 2013. Accessed at <http://www.fda.gov/>.
194. U.S. Food and Drug Administration (FDA). Approval Order P160017: MiniMed 670G System. September 28, 2016. Accessed at <http://www.fda.gov/>.
195. U.S. Food and Drug Administration (FDA). News Release: FDA approves first continuous glucose monitoring system with a fully implantable glucose sensor and compatible mobile app for adults with diabetes (June 21, 2018). Accessed at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611454.htm>.
196. U.S. Food and Drug Administration (FDA). FDA Executive Summary: Eversense Continuous Glucose Monitoring System Senseonics, Inc. (March 29, 2018). Accessed at <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ClinicalChemistryandClinicalToxicologyDevicesPanel/UCM602657.pdf>.
197. U.S. Food & Drug Administration (FDA). Types of Artificial Pancreas Device Systems. Accessed at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ArtificialPancreas/ucm259555.htm#TSDS>.
198. U.S. Food & Drug Administration (FDA). Premarket approval application (PMA) supplement P160048/S006: Eversense Continuous Glucose Monitoring System (April 29, 2019).
199. van Beers CA, DeVries JH. Continuous Glucose Monitoring: Impact on Hypoglycemia. *J Diabetes Sci Technol.* 2016 Nov 1;10(6):1251-1258.
200. Vereshchetin P, et al. Comparison of rechargeable versus battery-operated insulin pumps: temperature fluctuations. *Med Devices (Auckl).* 2016 Oct 14; 9:371-376.
201. Vigersky RA et al. Short- and Long-Term Effects of Real-Time Continuous Glucose Monitoring in Patients with Type 2 Diabetes. *Diabetes Care* 11/18/11.

202. Wang X, Ioacaru S, DeHennis A. Long-Term Home Study on Nocturnal Hypoglycemic Alarms Using a New Fully Implantable Continuous Glucose Monitoring System in Type 1 Diabetes. *Diabetes Technol Ther* 2015; 17:780-6. PMID: 26177299.
203. Wong JC, et al. A Minority of Patients with Type 1 Diabetes Routinely Downloads and Retrospectively Reviews Device Data. *Diabetes Technol Ther*. 2015 Aug 1; 17(8): 555–562.
204. Wong JC, et al. Real-time continuous glucose monitoring among participants in the T1D Exchange clinic registry. *Diabetes Care*. 2014 Oct;37(10):2702-9.
205. Yates K, Hasnat Milton A, Dear K, Ambler G. Continuous glucose monitoring-guided insulin adjustment in children and adolescents on near-physiological insulin regimens: a randomized controlled trial. *Diabetes Care*. 2006 Jul; 29(7): 1512-7.
206. Yeh H-C, et al. Comparative Effectiveness and Safety of Methods of Insulin Delivery and Glucose Monitoring for Diabetes Mellitus. *Ann Intern Med*. 2012; 157:336-347.
207. Yue X, Zheng Y, Cai Y, Yin N, Zhou J. Real-Time Continuous Glucose Monitoring Shows High Accuracy within 6 Hours after Sensor Calibration: A Prospective Study. *PLoS ONE* 8(3): e60070.
208. Zick R, Petersen B, Richter M, Haug C; SAFIR Study Group. Comparison of continuous blood glucose measurement with conventional documentation of hypoglycemia in patients with Type 2 diabetes on multiple daily insulin injection therapy. *Diabetes Technol Ther*. 2007;9(6):483-492.

### COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/25/24.

### GUIDELINE UPDATE INFORMATION:

07/15/01	Medical Coverage Guideline Original effective date.
01/01/02	New codes added.
06/15/02	Annual review for investigational; references updated.
11/15/02	Medicare coverage information added; references updated.
12/15/02	Addition of near-infrared information; references updated.
12/15/03	Reviewed; no change (investigational).
11/15/04	Scheduled review; no change (investigational).
01/01/06	Scheduled review; no change in coverage statement; references updated; HCPCS coding update (95250 revised; 95251 added).
10/15/06	Scheduled review; revised title of MCG; added descriptive information and investigational statement for combination glucose monitor & insulin pump systems; added cross-reference to other related MCGs; no change in investigational status for continuous glucose monitoring in the interstitial fluid.
09/15/07	Reviewed; added, “real time monitoring” to the position statement; reformatted guidelines; updated references.
01/01/08	Annual HCPCS coding update: added A9276, A9277, and A9278.
04/15/08	Scheduled review; revised description section; add coverage statement for 72 hour testing by healthcare professional. Update references.
01/01/09	Annual HCPCS coding update: updated descriptors for 95250 and 95251.
04/20/09	Unscheduled review. Revise position statement. Add Medicare statement. Add supply limitations. Update references.

08/15/09	Revision with removal of Medicare Advantage Exception from policy: LCD retired 02/02/09.
10/15/09	Revision of reimbursement for coverage of A9276.
05/15/10	Annual review with revision of position statement to include short term 72 hour intermittent continuous glucose monitoring for insulin requiring diabetics, and revision to long term monitoring use in pregnancy for poorly controlled insulin requiring diabetes. References updated.
11/15/10	Revision: position statement revised to include coverage for long-term glucose monitoring for patients with type II diabetes who are insulin dependent; related ICD-10 codes added; references updated; guideline reformatted.
09/15/11	Revision; formatting changes.
07/15/12	Scheduled review. Added E/I statement for remote glucose monitors. Revised description, index terms and examples of CGM devices and components. Updated references and reformatted guideline.
01/01/13	Annual CPT coding update. Revised code descriptor for 99091.
07/15/13	Scheduled review. Revised description. Revised position statement to include a coverage statement for the artificial pancreas (E/I); updated product names and descriptions. Revised definitions and program exceptions sections. Updated references and reformatted guideline.
02/15/14	Scheduled review. Revised description, position statement, reimbursement section, program exceptions and definitions. Updated references.
07/01/14	Quarterly HCPCS update. Added codes S1034, S1035, S1036 and S1037.
02/15/15	Scheduled review. Revised description added coverage statement for remote, mobile communication devices (E/I), revised definitions section, updated references. Reformatted guideline.
07/15/15	Revision; changes to the position statement regarding required documentation and length of coverage for CGM devices. Revised Medicare Advantage Products program exception. Reformatted guideline.
08/15/15	Revision; verbiage changes for clarity and formatting changes. Deleted requirement of prior use of a 72 hour monitor.
09/15/15	Revision: continuation criteria deleted.
11/15/15	Revision; updated Program Exceptions section.
12/15/15	Revision; updated Reimbursement Information section.
01/01/16	Revision; updated Reimbursement Information section.
07/15/16	Revision; addition of coverage statement regarding CGM device replacement.
10/01/16	Revision: Billing/Coding Information section updated.
04/15/17	Revision: deleted continuous glucose monitoring device proprietary names. Reformatted guideline.
07/01/17	Quarterly CPT/HCPCS update. Added codes K0553, K0554. Revised Reimbursement Information section.
10/15/17	Unscheduled review. Revised description section, position statement section, HCPCS coding section, reimbursement information section, and program exceptions section. Updated references.

01/01/18	Annual CPT/HCPCS coding update: added 95249; revised 95250, 95251.
04/15/18	Scheduled review. Revised MCG title, description section, position statement (added criteria for external insulin infusion pumps), CPT and HCPCS coding, reimbursement information, program exceptions, definitions, and related guidelines. Updated references.
11/15/18	Revision: updated reimbursement section [revised frequency limitation for professional analysis and interpretation of glucose data (codes 95251, 99091)]. Added coverage statement (E/I) for implanted glucose sensors. Updated references.
01/01/19	Annual CPT/HCPCS coding update. Deleted 99091.
06/15/19	Scheduled review. Revised criteria for insulin pumps. Updated references.
08/15/19	Unscheduled review. Maintained position statement, revised Medicare Advantage program exception, and updated references.
01/01/20	Annual CPT/HCPCS coding update. Added A4226, E0787. Revised reimbursement information section.
09/15/20	Scheduled review. Revised description and position statement. Updated references.
12/15/20	Unscheduled review. Maintained position statement and updated references.
08/15/21	Revision. Updated references and maintained position statement.
04/01/22	Quarterly CPT/HCPCS update. Added codes A4238, E2102. Revised descriptor codes A9276, A9277, A9278. Revised Reimbursement Information section.
07/01/22	Quarterly CPT/HCPCS coding update. Added G0308, G0309.
08/15/22	Scheduled review. Added coverage criteria for implantable glucose sensors; revised CGM coverage criteria for poorly controlled type 2 diabetes. Updated references.
01/01/23	Annual CPT/HCPCS coding update. Added A4239, E2103, 0740T, 0741T. Revised A4238, A9276, A9277, A9278, E2102. Deleted G0308, G0309, K0553, K0554.
07/01/23	Revision. Revised description. Revised medical necessity criteria for continuous glucose monitors (CGM) and insulin pumps. Updated references.
10/15/23	Revision. Added reference to d-Nav® Insulin Guidance System. Updated references and maintained position statement.
08/15/24	Scheduled review. Maintained position statement and updated references.
11/15/24	Revision. Updated Position Statement regarding the use of software and remote, mobile and wireless communication, for clarity.