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Subject: External Insulin Infusion Pumps and Continuous Glucose Monitors

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Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

The advent of blood glucose monitors for use in the home revolutionized the management of diabetes. Using finger sticks, individuals can monitor their blood glucose levels both to determine the adequacy of hyperglycemia control and to evaluate hypoglycemic episodes. Tight diabetic control, defined as a strategy involving frequent glucose checks and a target hemoglobin A1c level in the range of 7%, is now considered standard of care for diabetes. The American Diabetes Association has recommended a glycosylated hemoglobin level below 7% for most patients. Randomized controlled trials assessing tight control have demonstrated benefits in decreasing microvascular complications.

Hypoglycemia may place a limit on the ability to achieve tighter glycaemic control. Hypoglycemic events in adults range from mild to severe, based on a number of factors including the glucose nadir, presence of symptoms, and whether the episode can be self-treated or requires help for recovery.

Insulin Infusion Pumps

An external insulin infusion pump is a small, battery-powered, programmable device controlled by a micro-computer to provide continuous subcutaneous insulin infusion (CSII) in individuals with diabetes mellitus. Typically, the syringe has a two-three day insulin capacity and is connected to an infusion set attached to a small needle or cannula, which the individual inserts into the subcutaneous tissue. The syringe is activated by a battery operated pump programmed to deliver a continuous dose of insulin (basal insulin dose), and release a surge of insulin at meals and at programmed intervals (bolus insulin dose). The purpose of the insulin pump is to provide accurate, continuous and controlled delivery of insulin, which can be regulated by the user to achieve intensive glucose control and to prevent the metabolic complications of hypoglycemia, hyperglycemia and diabetic ketoacidosis.

Continuous Glucose Monitoring Systems (CGMS)

Continuous glucose monitoring systems (CGMS) are devices that measure glucose levels in interstitial fluid at programmable intervals. These readings, used along with fingerstick results, help detect any patterns or trends with an individual's glucose levels and are intended to assist in calculating the insulin dosage needed to manage glycemic control. CGMS use sensors that are inserted under the skin in the abdomen and work by extracting glucose from the interstitial fluid, measuring and recording the glucose level, and converting these measurements into equivalent blood glucose readings. Sensors are designed to be worn three to seven days, depending on the product. Calibration is required whenever a new glucose sensor is inserted, which requires obtaining blood glucose from a traditional fingerstick sample. Measurements of glucose in interstitial fluid provide glucose values automatically throughout the day, producing data that show the trends in glucose levels.

Continuous Glucose Monitoring Systems (CGMS) with Low Glucose Suspend Feature (LGS)

The first device (MiniMed 530G) categorized by FDA as an artificial pancreas device system (subcategory: threshold suspend device system) was approved in 2013. The system integrates a continuous glucose monitor (CGM) and insulin pump and includes a low-glucose suspend (LGS) feature that can automatically and temporarily suspend insulin delivery when glucose levels fall below a prespecified level. Threshold suspend is the first step towards an artificial pancreas device system (APDS). This technology allows the user to set a low blood sugar threshold value. When the CGM sensor detects the preset low glucose threshold, insulin delivery is suspended. The MiniMed 530G System 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 requiring insulin, as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 630G with SmartGuard™ was approved in 2016. The system is similar to the 530G but offers updates to the system components including waterproofing.

Artificial pancreas

FDA has described 3 main categories of artificial pancreas device systems: threshold suspend device, control-to-range, and control-to-target systems. With threshold suspend device systems, also called LGS systems, the delivery of insulin is suspended for a set time when 2 glucose levels are below a specified low level indicating hypoglycemia. With control-to-range systems, the patient sets his or her own insulin dosing within a specified range, but the artificial pancreas device system takes over if glucose levels are detected outside that range (higher or lower). Patients using this type of system still need to check blood glucose levels and administer insulin as needed. With control-to-target systems, the device aims to maintain glucose levels near a target level (eg, 100 mg/dL). Control-to-target systems are automated and do not require user participation except to calibrate the continuous glucose monitoring system. The MiniMed® 670G, a hybrid closed loop insulin delivery system, was approved by FDA in 2016. It consists of an insulin pump, a glucose meter, and a transmitter, linked by a proprietary algorithm, the SmartGuard HCL. The system includes an LGS feature that suspends insulin delivery when glucose levels get low and has an optional alarm. Additionally, the system involves semiautomatic insulin-level adjustment to preset targets. It is called a hybrid system; basal insulin levels are automatically adjusted but the patient needs to administer premeal insulin boluses.

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

1. Type 1 diabetes (due to autoimmune β -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 β -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.

POSITION STATEMENT:

Insulin Infusion Pumps

External insulin infusion pumps and related supplies **meet the definition of medical necessity** for individuals 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:

- Completed a comprehensive diabetes education program within the past two years (not required for replacement pumps if education was completed prior to beginning pump therapy), **AND**
- Follows a program of multiple daily injections of insulin (i.e., at least 3 injections per day), **AND**
- Has frequent self-adjustments of insulin doses for the past 6 months, **AND**
- Has documented frequency of glucose self-testing an average of at least 4 times per day the 2 months prior to initiation of the insulin pump, **OR** documented use of a therapeutic factory calibrated CGM during the two months prior to initiation of an insulin pump, **AND**
- Meets FDA age limit for device, **AND**

Has documentation of **ANY** of the following while on a multiple daily injection regimen:

- Glycosylated hemoglobin level (HbA1c) > 7.0 percent, **OR**
- Diabetes mellitus with recurrent episodes of diabetic ketoacidosis, hypoglycemia or both, resulting in recurrent and/or prolonged hospitalization, **OR**
- History of recurring hypoglycemia or severe glycemic excursions, **OR**
- Wide fluctuations in blood glucose before mealtime (e.g., pre-prandial blood glucose levels commonly exceed 140 mg/dL), **OR**
- "Dawn phenomenon" with fasting blood sugars frequently exceeding 200 mg/dl

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 prior to enrollment with documented frequency of glucose self-testing on average of at least 4 times per day 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 and whose diabetes is poorly controlled*, despite current use of best practices. Best practices include compliance with a treatment regimen of 4 or more finger sticks per day, for the purpose of identifying glucose excursions and facilitating therapy adjustments.

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** when the following situations occur despite use of best practices which include compliance with:

- A regimen of 4 or more finger sticks per day, **OR**
- 3 or more insulin injections per day, or member is using an insulin infusion pump

In addition, one of the following must be met:

- Members with poorly controlled* type 1 diabetes, who are receiving insulin therapy, **OR**
- Members with poorly controlled diabetes due to other causes referenced in the ADA list above, who are receiving insulin therapy, **OR**
- Pregnant members (gestational) with poorly controlled* diabetes, who are receiving insulin therapy, **OR**
- Members with poorly controlled* type 2 diabetes, who are receiving insulin therapy, **AND** meet **ALL** of the following:
 - Documented glycemic control attempts in the past without success, This includes, for example: minimal improvement in hemoglobin A1C despite evidence of dietary compliance and adherence to medical therapy, **AND**
 - Participated in a diabetic training and education program regarding use of continuous glucose monitor, **AND**
 - Are either not meeting glycemic targets or experiencing hypoglycemia (including hypoglycemic unawareness)
 - Reported baseline HbA1c is greater than or equal to 7%

***Poorly controlled insulin dependent diabetes includes the following clinical situations:**

- Unexplained hypoglycemic episodes, (generally, blood glucose levels less than 50 mg/dl, despite appropriate modifications in insulin therapy, and compliance with frequent self-monitoring of blood glucose), **OR**
- Hypoglycemic unawareness, **OR**
- Suspected postprandial hyperglycemia, **OR**
- Recurrent diabetic ketoacidosis

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
- Has diabetes mellitus
- Three or more daily administrations of insulin
- Insulin treatment regimen requires frequent adjustment based on blood glucose monitor or CGM testing results
- The treating practitioner conducted an in-person visit with the individual to evaluate their diabetes control and determined that criteria above are met, in the 6 months immediately preceding the prescription of implantable sensors

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. The number of sensors will differ by device for 3-day or 7-day monitors.

(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 a remote glucose monitoring device
- The use of a remote, mobile communication device that uses a wireless connection to transmit glucose levels
- 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 (non-covered)
0741T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; provision of software, data collection, transmission, and storage, each 30 days (non-covered)

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.

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 Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determinations (LCDs) were reviewed on the last guideline reviewed date: External Infusion Pumps (L33794), and Glucose Monitors (L33822), located at cgsmedicare.com.

The following Local Coverage Determination (LCD) was reviewed on the last guideline review date: Implantable Continuous Glucose Monitors (I-CGM) (L38664), located at cms.gov.

The following National Coverage Determinations (NCD) was reviewed on the last guideline reviewed date: National Coverage Determination (NCD) for Infusion Pumps (280.14), located at cms.gov.

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.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/28/22.

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 Advantageprogram 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.