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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 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.

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) **(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 (e.g., d-Nav® Insulin Guidance System) **(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

G0564	Creation of subcutaneous pocket with insertion of 365-day implantable interstitial glucose sensor, including system activation and patient training
G0565	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 365-day implantable sensor, including system activation

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 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.

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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.
01/01/25	Annual CPT/HCPCS coding update. Added G0564, G0565.