Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Systems Clinical Coverage Criteria

Overview

Continuous glucose monitoring (CGM) devices are FDA-approved according to their intended use as a professional CGM or personal CGM.

Professional use CGMs are owned by the healthcare professional's office and used in the management of diabetes, similar to the way a Holter monitor is used in the management of cardiac conditions. The CGM records and stores data for a minimum of 72 hours and up to 7 to 14 days while the patient goes about their normal activities of daily living. Professional use CGMs can collect data in a "blinded" mode, whereby the patient is unable to view data during device wear, or the data can be displayed in real time. Regardless of whether using realtime or blinded modes, the clinician can use the data collected to assess current glycemic status and variability, enable a conversation to ground and advance education on certain topics of diabetes management, and determine how to optimize treatment whether through behavioral modifications or through adjustments in the medications used or doses prescribed to achieve more targeted glycemia (Grunberger et al., 2021).

Currently, there are 2 types of CGM system technologies available for personal use: rtCGM and isCGM, which historically was referred to as "flash" CGM. rtCGM systems automatically transmit data to the receiver and/or smartphone of a person with diabetes, whereas isCGM systems require a person to "swipe" the receiver and/or smartphone close to the sensor to obtain current and historical sensor glucose data (thus, intermittent based on how often the levels are checked/recorded). Until recently, a key differentiator between these technologies was the added safeguard of active alarms/alerts that can warn a person with diabetes of immediate or impending glycemic events, such as hypoglycemia and hyperglycemia. New isCGM systems offer optional alerts that warn users when glucose levels fall below or rise above the programmed threshold; however, the current iteration of these technologies do not warn users of predicted low or high glucose levels. Both rtCGM and isCGM technologies are available as standalone devices. However, only the current rtCGM systems can be linked to sensor-augmented insulin pumps or automated insulin delivery systems (Grunberger et al., 2021).

Additionally, the FDA classifies continuous glucose monitors (CGMs) as therapeutic or non-therapeutic, and whether they are adjunctive or non-adjunctive. A therapeutic or non-adjunctive CGM can be used to make treatment decisions without the need for a stand-alone blood glucose meter (BGM) to confirm testing results. A non-therapeutic or adjunctive CGM requires the user verify their glucose levels or trends displayed on a CGM with a BGM prior to making treatment decisions.

Approved CGMs now include devices indicated for pediatric use and those with more advanced software, more frequent measurements of glucose levels, or more sophisticated alarm systems. Devices initially measured interstitial glucose every 5 to10 minutes and stored data for download and retrospective evaluation by a clinician. With currently available devices, the intervals at which interstitial glucose is measured range from every 1 to 2 minutes to 5 minutes, and most provide

measurements in real-time directly to patients. While the CGM potentially eliminates or decreases the number of required daily fingersticks, according to the U.S. Food and Drug Administration (FDA) labeling, some marketed monitors are not intended as an alternative to traditional self-monitoring of blood glucose levels but rather as adjuncts to monitoring, supplying additional information on glucose trends not available from self-monitoring while other devices are factory calibrated and do not require fingerstick blood glucose calibration (Grunberger et al., 2021).

Intensive insulin therapy involves the use of either multiple daily injections (MDIs), defined as 3 or more injections per day, or the use of a continuous subcutaneous insulin infusion (CSII) pump. The use of CSII pumps has led to improvement in the quality of care for people with T1D in terms of lowered hemoglobin A1c and reductions in the frequency and severity of hypoglycemia. Insulin pumps provide convenience for the use of multiple boluses per day without the need for separate injections. Ongoing innovations in CSII technology have since led to the development of a diverse array of insulin infusion products, ranging from disposable patch-like devices to sophisticated insulin pumps with advanced features to automate insulin dosing (Grunberger et al., 2021).

The integration of CGM with CSII technologies has led to the development of automated insulin delivery (AID) systems that combine automated basal insulin delivery, with some systems now incorporating automatic correction boluses, based on rtCGM glucose values. Importantly, these technologies have the potential to improve clinicians' effectiveness and efficiency by providing critical data in standardized formats, such as the ambulatory glucose profile, which facilitates more rapid, better informed decision-making. Automated insulin delivery systems may be referred to as hybrid closed-loop systems, integrated CGMs, or artificial pancreas device systems (Grunberger et al., 2021).

Definitions

Glycated hemoglobin - Also known as HbA1c is a form of hemoglobin. (Hemoglobin is the iron-rich protein in red blood cells that gives blood its red color.) In the normal 120-day life span of a red blood cell, glucose molecules react with hemoglobin forming glycated hemoglobin. Individuals with diabetes have higher quantities of glucose in their capillary blood and as a result they also have increased numbers of glycated hemoglobin molecules. Once a hemoglobin molecule is glycated, it remains that way. A build-up of glycated hemoglobin within the red blood cells therefore reflects the average level of glucose to which the cell has been exposed during its life cycle. Measuring glycated hemoglobin assesses the effectiveness of therapy for the treatment of diabetes.

Hypoglycemia (Low Blood Sugar) - Occurs when there is too much insulin and not enough glucose in the blood. This is typically indicated when blood glucose levels reach the 65–70 mg/dL range; symptoms of hypoglycemia present at the 50–55 mg/dL range, and cognitive dysfunction occurs when blood glucose levels are in the 45–50 mg/dL range.

Interstitial fluid - A fluid that is found in the interstitial spaces of the body. Interstitial fluid provides the cells of the body with nutrients and a means of waste removal. Hydrostatic pressure generated by the pumping force of the heart pushes fluid out of the capillaries and into the interstitial spaces. Not all of the contents of the blood pass into the tissue, which means that tissue fluid and blood are not the same. (Red blood cells, platelets, and plasma proteins cannot pass through the walls of the capillaries.) The composition of interstitial fluid depends upon the exchanges between the cells in the tissue and the blood. Interstitial fluid has a different composition in different tissues and in different areas of the body. Tissue fluid passes into the surrounding lymph vessels, and eventually ends up rejoining the blood.

Policy

This Policy applies to the following Fallon Health products:

☒ Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)

☒ MassHealth ACO

☒ NaviCare HMO SNP

☒ NaviCare SCO
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care

Continuous glucose monitors, insulin pumps, and automated insulin delivery systems require prior authorization. Requests must be supported by the treating provider(s) medical records.

Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for continuous glucose monitoring or insulin delivery devices. Medicare has an NCD for Closed-Loop Blood Glucose Control Device (CBGCD) (40.3). NCD 40.3 is applicable for closed-loop blood glucose control devices used in an inpatient setting. National Government Services, Inc., the Part A and B Medicare Administrative Carrier (MAC) with jurisdiction in the Plan's service area has an LCD for Implantable Continuous Glucose Monitors (I-CGM) (L38623). Noridian Healthcare Solutions, LLC, the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) with jurisdiction in the Plan's service area has an LCD for Glucose Monitors (L33822) and an LCD for External Infusion Pumps (L33794) (Medicare Coverage Database Search 09/22/2024).

Coverage criteria for continuous glucose monitoring systems and insulin delivery devices are fully established by Medicare, therefore, the Plan's coverage criteria are not applicable.

Link: **NCD Closed-Loop Blood Glucose Control Device (CBGCD) (40.3)**
Link: **LCD Implantable Continuous Glucose Monitors (I-CGM) (L38623)**
Link: **LCD Glucose Monitors (L33822)**
Link: **LCD External Infusion Pumps (L33794)**

Note: Per LCD L33822, every six (6) months following the initial prescription of the CGM, the treating practitioner must conducts an in-person or Medicare-approved telehealth visit with the plan member to document adherence to their CGM regimen and diabetes treatment plan.

MassHealth ACO
Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth has Guidelines for Medical Necessity Determination for Diabetes Management Devices: Continuous Glucose Monitoring Systems and Insulin Pumps (MassHealth website search 09/22/2024), therefore the Plan's Clinical Coverage Criteria are not applicable.

Link: MassHealth Guidelines for Medical Necessity Determination for Diabetes Management Devices: Continuous Glucose Monitoring Systems and Insulin Pumps

Consult MassHealth regulations at 130 CMR 409.000: Durable Medical Equipment Services, 130 CMR 450.000: Administrative and Billing Regulations, Subchapter 6 of the Durable Medical

Equipment (DME) Manual, the online MassHealth Durable Medical Equipment and Oxygen Payment and Coverage Guidelines Tool for information about limitations and other requirements.

Consult Therapeutic Class Table 78: Diabetes Medical Supplies, of the MassHealth Drug List, for information Pharmacy coverage for continuous glucose monitoring systems.

NaviCare HMO SNP, NaviCare SCO
For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Ambulatory Continuous Glucose Monitoring (Professional Use)
Fallon Health Clinical Coverage Criteria for ambulatory continuous glucose monitoring applies to all plan members. Fallon Health covers ambulatory continuous glucose monitoring (CPT 95250, 95252) for diagnostic purposes when medically necessary to determine optimum therapeutic regimens for plan members with insulin-dependent diabetes.

Short-term continuous glucose monitoring is considered medically necessary when all of the following medical criteria are met:
1. The plan member has insulin-dependent type 1 or type 2 diabetes.
2. There is inadequate glycemic control despite compliance with frequent self-monitoring of blood glucose (at least 4 times per day).
3. The results of continuous glucose monitoring are reviewed, interpreted, and reported by a healthcare professional.

Note: Short-term continuous glucose monitoring is used episodically to direct changes in management. Given the several month timeframe necessary to determine the efficacy of treatment modifications, short-term continuous interstitial glucose monitoring is not medically necessary more than twice in a 12-month period.

Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Systems (Personal Use)
Fallon Health Clinical Coverage Criteria for continuous glucose monitors, insulin pumps, and automated insulin delivery systems apply to Community Care members.

Effective for dates of service on or after October 15, 2024, Fallon Health will use InterQual® Criteria when making medical necessity determinations for continuous glucose monitors, insulin pumps, and automated insulin delivery systems.

For coverage criteria for continuous glucose monitoring systems and insulin delivery devices, refer to the InterQual criteria in effect on the date of service:

- InterQual® CP:Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery, Adjunctive real time continuous glucose monitor
- InterQual® CP:Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery, Automated insulin delivery system including CGM, blood glucose device, insulin pump, and computer algorithm

  Note: Fallon Health does not use S1034, S1035, S1036 or S1037 for automated insulin-delivery systems, instead, report the appropriate HCPCS code for CGM and the insulin pump, for example, E2102 and E0784.
- InterQual® CP:Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery, External Ambulatory Insulin Delivery System, Disposable, Each, Includes All Supplies and Accessories
- InterQual® CP:Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery, External Ambulatory Infusion Pump, Insulin
- InterQual® CP:Durable Medical Equipment, Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery, Flash monitor (sensor, glucose, invasive, non-adjunctive, factory calibrated, user-initiated) with supply allowance

Fallon Health makes InterQual criteria available to the public through the transparency tool on our website, effective January 1, 2024.

Exclusions

- Supplies or accessories not required for the functioning of the continuous glucose monitor such as alcohol, alcohol wipes, adhesives, adhesive remover, carrying cases, clips, pouches, shower packs, etc. (Please note it is possible these are covered for certain Fallon products, consult the specific plan benefits).
- Non-Invasive continuous glucose monitors (codes S1030 and S1031).
- Implantable continuous glucose monitors (I-CGM) (0446T, 0447T, 0448T) are considered experimental/investigational and not medically necessary. Note: implantable continuous glucose monitors are covered for Medicare members in accordance with LCD L38623.
- Transdermal insulin delivery systems/disposable on-demand insulin delivery devices, such as the VGo®, do not require physician supervision and are considered self-use. These devices are not considered to be durable medical equipment and, therefore, are not addressed in these criteria.
- Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration (0740T, 0741T) is considered experimental/investigational and not medically necessary.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

Ambulatory Continuous Glucose Monitoring

CPT code 95249 and 95250 are used to report the service for subcutaneous interstitial sensor placement, hook-up of the sensor to the transmitter, calibration of continuous glucose monitoring (CGM) device, patient training on CGM device functions and management, removal of the interstitial sensor, and print-out of captured data recordings.

CPT code 95249 may only be reported once during the time that a patient owns a given CGM receiver, including the initial episode of data collection. CPT 95249 cannot be reported for subsequent episodes of data collection unless the patient obtains a new and/or different model receiver. Obtaining a new sensor and/or transmitter without a change in receive may not be reported with 95249.

Code	Description
95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a

	subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; 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; physician interpretation and report

Continuous Glucose Monitoring Systems and Insulin Delivery Devices for Medicare and Community Care Members

When a CGM (code E2102 or E2103) is covered, the related supply allowance (code A4238 or A4239) is also covered. Supplies (code A4238) for an adjunctive CGM integrated into an external insulin infusion pump are covered when the member meets both the CGM coverage criteria and the coverage criteria for an external insulin infusion pump.

The supply allowance (code A4238 or A4239) is a monthly allowance that may be billed up to a maximum of three (3) units of service (UOS) per ninety (90) days at a time. Billing more than three (3) UOS per ninety (90) days of code A4238 or A4239 will be denied as not reasonable and necessary.

Non-adjunctive CGM devices replace standard home BGMs (HCPCS codes E0607, E2100, E2101) and related supplies (HCPCS codes A4233, A4234, A4235, A4236, A4244, A4245, A4246, A4247, A4250, A4253, A4255, A4256, A4257, A4258, A4259). Claims for a BGM and related supplies, billed in addition to a non-adjunctive CGM device (code E2103) and associated supply allowance (code A4239), will be denied.

Adjunctive CGM devices do not replace a standard home BGM. The supply allowance for an adjunctive CGM (A4238) encompasses all items necessary for the use of the device and includes but is not limited to, CGM sensors and transmitters. Code A4238 does not include a home BGM and related BGM testing supplies. These items may be billed separately, in addition to code A4238.

All CGM devices billed using HCPCS code E2103 or E2102 must be reviewed for correct coding by the PDAC contractor and be listed on the PCL. If a CGM system is billed using HCPCS code E2102 or E2103 but the CGM system is not on the PCL for that particular HCPCS code, then the claim will be denied as incorrect coding.

Subcutaneous insulin is administered using ambulatory infusion pump E0784.

The HCPCS code combination of E0784 plus E2103 is used to describe external ambulatory insulin infusion pumps that incorporate dose rate adjustment using non-adjunctive continuous glucose sensing. Coverage for this HCPCS code combination is only met if the member meets all of the coverage criteria for insulin pumps outlined in LCD L33794 and all criteria for CGMs as outlined in LCD (L33822).

For claims with dates of service on or after April 1, 2022, insulin infusion pumps with integrated adjunctive continuous glucose monitor receiver functionality must be coded using HCPCS codes E0784 (external ambulatory infusion pump, insulin) and E2102 (adjunctive, non-implanted continuous glucose monitor or receiver). The related accessories/supplies for these integrated units must be coded using HCPCS codes A4224 (supplies for maintenance of insulin infusion catheter, per week), A4225 (supplies for external insulin infusion pump, syringe type cartridge, sterile, each), and A4238 (supply allowance for adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service).

Note: Effective for dates of service prior to April 1, 2022 and on and after January 1, 2023 HCPCS code A9276 and A9277 describe supplies used with a CGM that does not meet the DME

benefit category requirements. Similarly, effective for dates of service prior to April 1, 2022 and on and after January 1, 2023 HCPCS code A9278 describes a CGM that does not meet the Medicare definition of DME. A9277, A9278, or A9279 and will be denied as non-covered (no Medicare Benefit).

Code	Description
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
E0784	External ambulatory infusion pump, insulin
E2102	Adjunctive, non-implanted continuous glucose monitor or receiver
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver

MassHealth Covered Diabetes Management Devices

Code	Description
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4255	Platforms for home blood glucose monitor, 50 per box
A4256	Normal, low and high calibrator solution/chips
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
A9276	Sensor, invasive (e.g., subcutaneous), disposable, for use with interstitial CGM system
A9277	Transmitter, external for use with interstitial CGM system
A9278	Receiver (monitor), external for use with interstitial CGM system
E0784	External ambulatory infusion pump, insulin

Implantable Continuous Glucose Monitors (I-CGM)

Code	Description
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0446T	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

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Policy history

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Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans