Continuous Interstitial Glucose Monitoring Clinical Coverage Criteria

Overview

The term continuous glucose monitoring refers to both: (1) the short-term professional use of a continuous glucose monitoring device as a diagnostic tool, and (2) the long-term personal use of a patient-owned continuous monitoring device. Unlike self-monitoring devices that measure glucose levels in capillary blood, continuous glucose monitoring devices measure glucose levels in interstitial fluid.

Continuous glucose monitoring devices are FDA-approved for professional use store and provide data retrospectively or provider real-time results depending on the type of meter. The patient wears the device during daily activities like work, sleep, eating, and exercise. This enables the physician to view a comprehensive pattern of glucose values around the clock for determining therapy adjustments with the goal of improving glycemic control and reducing complications of chronic diabetes. Some Continuous glucose monitors have the ability to predict hyperglycemic and hypoglycemic events before they occur, and monitor for glucose variations that may not be detectable with self-monitoring.

The components of a continuous glucose monitoring device include a receiver and a transmitter. A disposable interstitial glucose sensor is inserted into the subcutaneous tissue of the abdomen and attached to the transmitter. The sensor measures interstitial glucose continuously and converts individual glucose measurements to an average value which is sent to the transmitter approximately every 5 minutes or less. The transmitter sends data wirelessly to the receiver.

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:

☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☒ PACE

Continuous glucose monitoring devices for personal use require prior authorization by Fallon Health. Short-term monitoring does not require prior authorization but is subject to the below criteria. These requests must be supported by the treating provider(s) medical records.

Medicare Advantage plan members

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for ambulatory continuous glucose monitoring. National Government Services does not have an LCD or LCA for ambulatory continuous glucose monitoring (MCD search 01/24/2022).

Medicare does not have an NCD for continuous glucose monitors. Noridian Healthcare Solutions, LLC is the DME MAC with jurisdiction in our service area. Noridian Healthcare Solutions, LLC has an LCD for Glucose Monitors (L33822) and an LCA: Glucose Monitor - Policy Article (A52464) (MCD search 01/24/2022). Please use the following links to access the Noridian LCD/LCA:
Glucose Monitors (L33822)
Glucose Monitor - Policy Article (A52464)

NaviCare and PACE plan members

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In situations where there is no Medicare guidance or if the plan member does not meet coverage criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members.

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.

MassHealth ACO

Fallon Health follows MassHealth Guidelines for Medical Necessity Determination for MassHealth members. Please use the following link to access the MassHealth Medical Necessity Guideline:

Diabetes Management Devices: Continuous Glucose Monitoring Systems and Insulin Pumps

Fallon Health Clinical Coverage Criteria

Short-term professional use as a diagnostic tool:
Fallon Health will cover short-term (a minimum of 72 consecutive hours) continuous glucose monitoring 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.

Long-term personal use of a patient-owned device:
Fallon Health will cover continuous glucose monitoring devices for personal use as an adjunct to standard medical care with the goal of achieving or maintaining optimal glycemic control, i.e., HbA1c level, for plan members with Type 1 and Type 2 when all of the following medical necessity criteria are met:

Initial Approval Criteria:
1. The plan member is motivated to achieve and/or maintain optimal HbA1c.
2. The plan member is capable of using of the technology.
3. The plan member receives intensive insulin therapy with either an insulin pump or multiple (3 or more) daily injections.
4. The plan treatment plan is for frequent home blood glucose monitoring (4 or more times per day).
5. The plan member's current (baseline) HbA1c level is >/= 7.0% OR the prescriber believes the member is at high risk of hypoglycemia, recurring episodes of hypoglycemia, or hypoglycemia unawareness.
6. Training and education and ongoing support services are available to ensure optimal chances of success for patients transitioning onto continuous glucose monitoring.
7. Downloaded data is reviewed, interpreted and reported by a healthcare professional at least twice per year for plan members meeting treatment goals and quarterly for those who either have not met their glycemic control goals or have recently changed therapy. The written report includes an assessment of the therapeutic regimen and identification of any modifications in patient management that are needed.
8. HbA1c is performed at least twice per year for plan members meeting treatment goals and quarterly for those who either have not met their glycemic control goals or have recently changed therapy.
9. For devices with alarms documentation the physician believes the member is at high risk of hypoglycemia, recurring episodes of hypoglycemia, or hypoglycemia unawareness.

Abbott FreeStyle Libre
The Abbott Libre CGM will typically be covered under the plan's Pharmacy benefit and as such is subject to the member having Pharmacy benefits through Fallon. The above criteria for initial approval and renewal of supplies will be utilized for the Libre system. Fallon will cover the least costly CGM needed, documentation of failure of the Libre

system or other reason why it cannot be medically used is necessary. The Libre system is only currently approved for those 18 years of age and older.

Continuous glucose monitoring devices (i.e., receiver and/or transmitter) and/or glucose sensors will be authorized initially for 12 months for plan members who meet all of the medical necessity criteria listed above.

After the initial 12-month period, the Plan will authorize continued coverage of a continuous glucose monitoring device and/or glucose sensors when there is evidence that the plan member is benefiting from the use of this technology. Benefit will be demonstrated by HbA1c level at or below baseline. Optimal HbA1c level may vary for some plan members depending on individual considerations.

Dexcom G6
In addition to being available as a DME benefit Fallon will also cover the Dexcom via the Pharmacy benefit. Coverage through the Pharmacy requires the member to have Pharmacy benefits with Fallon. The above criteria for initial approvable is applicable. Documentation of whether or not the patient requires a Dexcom G6 Receiver (Note: Patients may use their smartphone in place of the receiver. Refer to the following website for compatible devices. Dexcom compatible devices

Continuous glucose monitoring devices (i.e., receiver and/or transmitter) and/or glucose sensors will be authorized initially for 12 months for plan members who meet all of the medical necessity criteria listed above.

After the initial 12-month period, the Plan will authorize continued coverage of a continuous glucose monitoring device and/or glucose sensors when there is evidence that the plan member is benefiting from the use of this technology. Benefit will be demonstrated by HbA1c level at or below baseline. Optimal HbA1c level may vary for some plan members depending on individual considerations.

Replacement of continuous glucose monitoring devices
The continuous glucose monitoring devices have a limited useful life. Replacement of the receiver requires prior authorization. Authorization for replacement of a receiver requires evidence that the plan member is benefiting from the use of the continuous glucose monitoring device. Benefit is demonstrated by HBA1c level at or below baseline. Optimal HbA1c level may vary for some plan members depending on individual considerations.

Renewal of Supplies
Effective August 1, 2018 Fallon Health no longer requires authorization for renewal of supplies only for the CGM receiver itself.

For a combined Insulin Pump and Continuous Glucose Monitor a member must meet criteria under this policy and Fallon Health's Insulin Pump policy. These devices are fairly new technology and as such specific documentation is needed from the prescribing Physician as to their necessity.

Exclusions

- Closed-loop subcutaneous insulin infusion and continuous interstitial glucose monitoring systems are not covered because they are considered experimental/ investigational or unproven.
- 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)

- Continuous Non-Invasive Glucose Monitors (codes S1030 and S1031)

Coding

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

Code	Description
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
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system

References

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Policy history

Origination date:	10/26/2004
Approval(s):	Technology Assessment Subcommittee: 05/25/2010 Technology Assessment Committee: 12/07/2004, 06/02/2010, 03/26/2013, 05/28/2014: (updated template, updated references, and removed age requirement for long term use) 06/03/2015 (added language regarding Mini-Med 530G, updated references) 05/25/2016 (added exclusionary language for non-invasive monitors, updated references) 05/24/2017 (updated language regarding combined insulin pumps/continuous glucose monitors, updated references) 12/06/2017 (added language for renewal of supplies, added codes K0553 and K0554), 02/28/2018 (added coverage for type 2 diabetics, clarified Abbott Libre coverage, updated references), 08/22/2018 (removed authorization from supplies, removed related criteria), 10/11/2018 (clarified overview section and age requirements on Libre system), 10/23/2019 (updated references), 01/22/2020 (updated general coverage and Dexcom G6 pharmacy coverage) *02/01/2022 (Added clarifying language related to Medicare Advantage, NaviCare, PACE and MassHealth ACO under policy section; added references)*

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