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 that are FDA-approved for professional use store and provide data retrospectively (the glucose readings are not displayed). 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. Continuous glucose monitoring devices that are FDA-approved for personal use display interstitial glucose readings approximately every 5 minutes. In addition to displaying individual glucose values, these personal use devices display directional trends and alert patients to high or low glucose values. Continuous glucose monitors thus have the potential 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. The transmitter sends data wirelessly to the receiver. Continuous interstitial glucose monitoring does not eliminate or decrease the number of required daily fingersticks. The continuous glucose monitor must be calibrated with a capillary blood glucose value at least four times a day, and according to the FDA labeling, glucose values provided by the system are not intended to be used for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. All therapy adjustments should be based on blood glucose measurements obtained using a blood glucose monitor and not on interstitial glucose readings provided by the continuous glucose monitoring system.

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

Continuous glucose monitoring devices (i.e., receiver and/or transmitter) for personal use require prior authorization by Fallon Health. Glucose sensors also require prior authorization. Short-term monitoring does not requires prior authorization but is subject to the below criteria. These requests must be supported by the treating provider(s) medical records.

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%.
6. Training and education and ongoing support services are available to ensure optimal chances of success for patients transitioning onto continuous glucose monitoring.
7. Data is downloaded 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.

Abbott FreeStyle Libre:

The Abbott Libre CGM will 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.

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, Fallon Health 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.

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.

Glucose sensors:

Glucose sensors will be authorized initially for a maximum of 12 months with the initial authorization of a continuous glucose monitoring device. Quantity limits apply depending on the particular brand of sensor.

Replacement of continuous glucose monitoring devices

The components of most continuous glucose monitoring devices (i.e., receiver and/or transmitter) have a limited useful life. Replacement of the receiver and/or transmitter requires prior authorization. Authorization for replacement of a receiver and/or transmitter 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:
For continued approval of CGM related supplies the below criteria must be met and documented in the member's medical records.

1. The member must be compliant with use of the CGM.
2. The member's HbA1c remains stable or improves as result of usage of the CGM.

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)

Codes

Code type	Code	Description
CPT	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.
	A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit= 1 day supply
	A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system.
	A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system.
	K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
	K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system

References

1. Garg SK, Kelly WC, Voelmle MK et al. Continuous Home Monitoring of Glucose: Improved Glycemic Control with Real-Life use of Continuous Glucose Sensors in Adult Subjects with Type 1 Diabetes Diabetes Care; Mar 2011; 34(3) 574-579.
2. Tanenberg R, Bode B, Lane W et al. Use of the Continuous Glucose Monitoring System to Guide Therapy in Patients with Insulin-Treated Diabetes: A Randomized Controlled Trial. Mayo Clin Proc. 2004;79(12):1521-6.
3. Mazze RS, Strock E, Borgman S et al. Evaluating the Accuracy, Reliability, and Clinical Applicability of Continuous Glucose Monitoring (CGM): Is CGM Ready for Real Time. Diabetes Technol Ther. 2009;11(1):11-8.
4. Hay LC, Wilmshurst EG, Fulcher G et al. Unrecognized Hypo-and Hyperglycemia in Well-Controlled Patients with Type 2 Diabetes Mellitus: The Results of Continuous Glucose Monitoring. Diabetes Technol Ther. 2003;5(1):19-26.
5. Hirsh IB. Clinical Review: Realistic Expectations and Practical use of Continuous Glucose Monitoring for the Endocrinologist. J Clin Endocrinol Metab. 2009;94(7):2232-8.
6. Boland E, Monsod T, Delucia M et al Limitations of Conventional Methods of Self-Monitoring of Blood Glucose, Diabetes Care. 2001;24(11):1858-62.
7. Hayes Inc . Hayes Directory. Continuous Glucose Monitoring Systems. December 1, 2010. Annual Review completed July 26, 2017.
8. Noridian Healthcare Solutions Inc. Local Coverage Determination (LCD) for Glucose Monitors (L33822) Effective October 1, 2015. Last updated January 12, 2017
9. Gandhi GY, Kovalaske M, Kudva Y et al. Efficacy of continuous glucose monitoring in improved glycemic control and reducing hypoglycemia: a systematic review and meta-analysis of randomized trials. J Diabetes Sci Technol 2011; 5(4):952-65.
10. Floyd B, Chandra P, Hall S et al. Comparative analysis of the efficacy of continuous glucose monitoring and self-monitoring of blood glucose in type 1 diabetes mellitus. J Diabetes Sci Technol 2012; 6(5):1094-102.
11. Poolsup N, Suksomboon N, Kyaw AM. Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. Diabetol Metab Syndr 2013; 5(1):39.
12. Voormolen DN, Devries JH, Evers IM et al. The efficacy and effectiveness of continuous glucose monitoring during pregnancy: a systematic review. Obstet Gynecol Surv 2013; 68(11):753-63.
13. Zanon M, Sparacino G, Facchinetti et al. Non-invasive continuous glucose monitoring: improved accuracy of point and trend estimates of the Multisensor system. Med Biol Eng Comput. 2012 Oct;50(10):1047-57. doi: 10.1007/s11517-012-0932-6. Epub 2012 Jun 22.
14. Gehlaut RR, Dogbey GY, Schwartz FL, Marling CR, Shubrook JH.Hypoglycemia in Type 2 Diabetes - More Common Than You Think: A Continuous Glucose Monitoring Study J Diabetes Sci Technol. 2015 Apr 27. pii: 1932296815581052.
15. Pettus J, Price D, Edelman S How Patients with Type 1 Diabetes Translate Continuous Glucose Monitoring Data into Diabetes Management Decisions. Endocr Pract. 2015 Feb 25:1-25.
16. Bailey KJ, Little JP, Jung ME. Self-monitoring using continuous glucose monitors with real-time feedback improves exercise adherence in individuals with impaired

blood glucose: a pilot study. Diabetes Technol Ther. Mar 2016;18(3):185-193. PMID 26885934
17. American Diabetes Association. Standards of Medical Care in Diabetes – 2017. Diabetes Care Volume 41, Supplement 1, January 2018
18. Wallia A, Umpierrez GE, Rushakoff RJ, et al. Consensus Statement on Inpatient Use of Continuous Glucose Monitoring. J Diabetes Sci Technol. 2017 Apr 1:1932296817706151. doi: 10.1177/1932296817706151. [Epub ahead of print]

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)

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. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.