Medical Policy

Northwood

Continuous Glucose Monitoring Systems

Description

Continuous Glucose Monitoring Systems (CGMS) are minimally invasive or noninvasive devices that measure glucose levels in the interstitial fluid surrounding skin cells over a period of several days and provide continuous information about glucose fluctuations that is not otherwise captured by intermittent testing. CGMS require calibration with blood glucose levels as determined by finger-stick tests and the readings are intended to supplement not replace information obtained from standard home glucose monitoring devices.

Policy

Non-Medicare Members

CGMS is considered reasonable and necessary as an adjunct to finger stick testing in type 1 diabetics meeting the criteria listed below.

Medicare Members

Continuous Glucose Monitoring Systems and supplies are considered therapeutic CGMs (and therefore DME), if the equipment:

- Is approved by the Food and Drug Administration for use in place of a blood glucose monitor for making diabetes treatment decisions (for example, changes in diet and insulin dosage)
- Is generally not useful to the individual in the absence of an illness or injury
- Is appropriate for use in the home
- Includes a durable component (a component that CMS determines can withstand repeated use and has an expected lifetime of at least 3 years) that is capable of displaying the trending of the continuous glucose measurements
- **Policy Guidelines**

CGMS use is reasonable and necessary as an adjunct to finger stick testing of blood glucose in type 1 diabetics who have had:

Continuous Glucose Monitoring Systems

- Compliance with frequent self-monitoring (at least four finger sticks per day); AND
- Recurrent episodes of severe hypoglycemia (blood glucose <50mg/dl) despite appropriate modifications in insulin regimen; OR
- Hypoglycemic unawareness

All other uses of CGMS are considered experimental and investigational. CGMS are not considered reasonable and necessary when the applicable criteria outlined are not met.

Limitations

Non-invasive continuous glucose monitors (S1030, S1031)(e.g., GlucoWatch) and related supplies are considered experimental/investigational, and therefore not reasonable and necessary. Despite the fact that these devices have received FDA approval, there is a lack of long-term studies demonstrating that the use of these devices is associated with an improvement in final health outcomes, i.e., improved diabetic control based either on decreasing hemoglobin A1c values and/or decreasing incidence of hypoglycemia.

Artificial Pancreas (Closed loop glucose monitoring system)

Use of an artificial pancreas system, including but not limited to closed-loop monitoring devices with low-glucose suspend (LGS) features, are considered investigational. Current studies in the medical literature do not provide conclusive evidence that closed-loop systems lead to improved health outcomes in persons with diabetes. There is insufficient evidence that improved health outcomes, if any, are durable over time. Further controlled studies with larger numbers of patients and longer periods of closed-loop insulin management are needed to assess the safety and efficacy of these systems.

HCPCS Level II Codes and Description

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

Continuous Glucose Monitoring Systems

K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 unit of service = 1 month's supply.
K0554	Receiver (Monitor), dedicated, for the use with therapeutic continuous glucose monitor system
S1030	Continuous non-invasive glucose monitoring device, purchase
S1031	Continuous non-invasive glucose monitoring device, rental, including sensor, sensor placement, and download to monitor.
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system

Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

Continuous Glucose Monitoring Systems

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

References

1. Centers for Medicare and Medicaid Services, National Coverage Determination Manual. 280.1 Durable Medical Equipment Reference List.

2. Health Net National Medical Policy: Continuous Glucose Monitoring Devices. https://www.healthnet.com/static/general/unprotected/pdfs/national/policies/ContinuousGlucoseMonitoringDevices.pdf

3. Cigna: Home Blood Glucose Monitors http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0106_coveragepositioncriteria_blood_glucose_monitors.pdf

4. Aetna: Diabetes Tests, Programs and Supplies http://www.aetna.com/cpb/medical/data/1_99/0070.html#dummyLink1 Accessed December 6, 2019.

5. Chase HP, Roberts MD, Wightman C, Klingensmith G, Garg SK, Van Wyhe M, et al. Use of the GlucoWatch biographer in children with type 1 diabetes. Pediatrics. 2003 Apr;111(4 Pt 1):790-4.

6. Chase HP, Beck R, Tamborlane W, Buckingham B, Mauras N, Tsalikian E, et al. the diabetes research in children (DirectNet) study group. A randomized multicenter trial comparing the GlucoWatch Biographer with standard glucose monitoring in children with type 1 diabetes. Diabetes Care. 2005 May;28(5):1101-6.

7. Hayes, Inc. Continuous glucose monitoring systems. Hayes Medical Technology Directory. May 22, 2007.

8. Newman SP, Cooke D, Casbard A, Walker S, Meredith S, Nunn A, et al. A randomized controlled trial to compare minimally invasive glucose monitoring devices with conventional monitoring in the management of insulin-treated diabetes mellitus (MITRE). Health Technol Assess 2009;13(28).

Applicable URAC Standard

Core 8	Staff operational tools and support.

Change/Authorization History

Revision Number	Date	Description of Change	Prepared / Reviewed by	Approved by	Review Date:	Effective Date:
A	1-31-11	Initial Release	Susan Glomb	Kenneth G. Fasse		
01	07-20-	Added Important Note to all Medical Policies	Susan Glomb	Dr. B. Almasri		

	11					
02	11-08-11	Added Reference to Policy	Susan Glomb	Dr. B. Almasri	Nov. 2011	
03	1-10-12	Including experimental/investigational exclusions. Updated references.	Susan Glomb	Dr. B. Almasri	Jan. 2012	
04	04-03-12	Added reference to NH Medicaid	Susan Glomb	Dr. B. Almasri		
05	11-28-12	Annual Review – No changes	Susan Glomb	Dr. B. Almasri	Nov 12	
06	12-18-13	Annual Review. No changes	Susan Glomb	Dr. B. Almasri	Dec 13	
07	12-29-14	Annual Review. No changes	Susan Glomb	Dr. B. Almasri		
08	11-23-15	Annual Review. Updated policy regarding Medicare non-coverage and added Artificial Pancreas codes and policy.	Lisa Wojno	Dr. B. Almasri	November 2015	
09	12-14-	Annual review. No	Lisa Wojno	Dr. B. Almasri	December	

	16	Changes.			2016	
10	08-02-17	Updated Policy regarding Medicare coverage of new K Codes for Therapeutic Continuous Glucose Monitors under the DME MAC	Lisa Wojno	Dr. C. Lerchin	August 2017	
11	12-11-17	Annual review. No changes since 8-2-17.	Carol Dimech	Dr. C. Lerchin	December 2017	
12	12-6-18	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2018	
13	12-06-19	Annual review. Additional reference added to policy.	Carol Dimech	Dr. C. Lerchin	December 2019	December 6, 2019