

# MedStar Health, Inc.

## POLICY AND PROCEDURE MANUAL

Policy Number: PA.034.MH  
Last Review Date: 05/11/2017  
Effective Date: 07/01/2017

### PA.034.MH – Continuous Glucose Monitors

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar MA – DSNP – CSNP → *NOTE: See Medicare Variation Section below*
- ✓ MedStar CareFirst PPO

MedStar Health considers continuous glucose monitors medically necessary for the following indications:

**INITIAL AND CONTINUATION OF REQUEST FOR CONTINUOUS GLUCOSE MONITORING SYSTEMS (CGMS): The initial request covers six month trial of the device and reevaluation of the device effectiveness before further authorization is provided to the member**

Long-term use of continuous interstitial glucose monitoring devices as an adjunct to standard care is considered medically necessary for the following:

*Members with type 1 diabetes (including members who are pregnant or desire to become pregnant).*

And

When **ALL** of the following criteria are met:

1. The device must be prescribed by a physician who should have appropriate interfacing equipment with the member's monitoring system to receive reports.
2. The member's A1C is <7% and they wish to continue good control or the member's A1C is ≥7% and they are candidates for improving their control to < 7%.
3. Compliance is demonstrated by monitoring logs maintained for at least three months prior to request.
4. Insulin injections are required three or more times per day or an insulin pump is used for maintenance of blood sugar control.
5. Four or more finger sticks are required per day, including the two times needed to calibrate the CGMS.
6. The member has been instructed by a health care professional in the management of diabetes.

And

7. The member (parent or caregiver if member is a child) must have the ability to understand the technology and be willing to use the monitor (i.e., hear alarms, read and interpret glucose data, and can take action based on the data interpretation).

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**Note:** Blood glucose (audible devices) monitors with special features to allow easy use for members with visual impairment are considered medically necessary if the device and the special features are approved by the FDA.

### **REQUEST FOR CGM SENSORS AFTER INITIAL SIX MONTHS APPROVAL:**

Continuation of sensors for the CGM devices as an adjunct to standard care is considered medically necessary for the following:

1. Members meet all of the above criteria; and
2. Downloaded CGMS logs for three months demonstrating the member is utilizing the CGM on a daily basis.

### **Limitations**

1. Long term CGMS is not covered for Type 2 diabetes (patients on multiple doses of insulin per day or continuous sub-continuous insulin infusion are considered as having Type 1 diabetes when they are demonstrated by C-peptide levels to be insulinopenic: C-peptide level that is less than or equal to 110% of the lower limit of normal).
2. CGMS that are not approved by the FDA are not covered.
3. CGMS with an integrated insulin pump require prior authorization.
4. CGMS is not currently approved by the FDA for use in children under seven years old and is therefore not recommended in children under seven years old.
5. Not all test strip brands are covered. Medicare coverage: Lifescan, Bayer. Select coverage: OneTouch coverage with the pharmacy benefit.
6. MiniMed Paradigm REAL-Time Closed-Loop Continuous Insulin Infusion and Blood Glucose Monitoring System is considered experimental and investigational, and therefore not covered.

### **Variations - Medicare:**

According to CMS, therapeutic CGM may be covered by Medicare when all of the following criteria are met:

- The beneficiary has diabetes mellitus; and,
- The beneficiary has been using a home blood glucose monitor (BGM) and performing frequent (four or more times a day) BGM testing; and,
- The beneficiary is insulin-treated with multiple daily injections (MDI) of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,
- The patient's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of therapeutic CGM testing results.

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*\*Please note that coverage for Dexcom needs to go through the medical benefit, and not pharmacy.*

Dexcom G5 Mobile is the only system approved by the FDA to meet that criteria.

- NOTE: Dexcom system does not require finger sticks 4x per day. This system can be calibrated with the finger sticks 2x per day

### Background

Diabetes is increasing worldwide at an unprecedented pace and has become a serious health concern during the last two decades, causing the World Health Organization (WHO) to declare it a global epidemic. Diabetes is also one of the most common diseases in the United States, affecting more than 29 million Americans. Type I diabetes mellitus refers to the juvenile onset stage when the pancreas cannot produce sufficient insulin, while type II diabetes mellitus reflects the inability of the body to use the secreted insulin.

Diabetes management involves monitoring to ensure an individual's glucose levels remain within the normal range. Continuous Glucose Monitoring Systems (CGMS) measure glucose levels frequently and allow for patient-specific adjustments to therapy. Current CGMS indicate the glucose level, the direction and magnitude of change of glucose levels, and can be used to assess glycaemic variability. In addition, real-time CGMS sensors can serve as a tool to predict impending glucose excursions, thereby providing alarm signals of hypo- and hyperglycaemic values warning the patient to take preventative actions.

### Codes:

HCPCS Codes	
Code	Description
A9276	Sensor; invasive (e.g. subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one 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

### HCPCS Codes – DEXCOM

Code	Description
E1399	Durable Medical Equipment, Miscellaneous

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A9999	Durable Medical Equipment, Miscellaneous Supply (1 unit of service per month)
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2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Article: External Infusion Pumps – Policy Article – A52507 (Contractor: NHIC, Corp.). Revision Effective Date: 10/01/2015. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52507&ver=5&ContrId=137&ContrVer=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Maryland&Keyword=External+Infusion+Pumps&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAABAAAAAAA%3d%3d&>
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### Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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