

UPMC Health Plan POLICY AND PROCEDURE MANUAL

POLICY NUMBER PAY.050
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PAGE NUMBER: 1 of 5

SUBJECT: Continuous Glucose Monitoring- Short Term Interstitial Physician Owned
INDEX TITLE: Medical Management
ORIGINAL DATE: September 2007

This policy applies to the following lines of business: (Check those that apply.)

Commercial:					
HMO ()	POS ()	PPO ()	OOA/DOC ()		
Fully Insured ()	Self-funded/ASO ()	HSA ()	All (X)		
Medicare Select ()	Medicare Supplement ()				
DPW-MA:					
Health Choices ()	Voluntary ()				All (X)
CMS-MA:					
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ()	PFFS (X)	All ()
PID-CHIP:					
Free ()	Sub ()				All (X)

I. POLICY

It is the policy of UPMC Health Plan to cover the Continuous Glucose Monitor- Long Term Interstitial, for members ages seven (7) years and older when it is medically necessary as detailed in this policy and covered under the member's benefit plan.

All denials are based on medical necessity and appropriateness as determined by a UPMC Health Plan Medical Director.

II. DEFINITIONS

Continuous Glucose Monitoring (CGM) utilizes the ability of glucose sensors to measure and record glucose levels in interstitial fluid and produce data that shows trends in glucose measurements over a 1-3 day period (short term). The stored information is retrieved and evaluated by the physician for widely varying glucose readings that may be missed by intermittent measurements. The information may be used by the physician to alter the current testing regimen and, ultimately, obtain tighter control of glucose levels. Some CGMs have sensors that can be used up to 7 days (long term) before replacement and can be integrated into an insulin pump device which interprets the glucose levels and release the correct amount of insulin needed and sound an alarm the if the glucose levels are too high or low.

These devices are not meant to replace the traditional (finger stick) self-monitoring measurements, but rather serve as a short term adjunct to these measurements.

Hgb A1C is a blood test used to determine the average blood glucose levels over a 3 month period. This test measures glycosylated hemoglobin in red blood cells that attaches to glucose (blood sugar).

Interstitial Glucose Monitoring Devices, also known as REAL-Time CGM, are short term physician owned or long term integrated with an insulin pump. These devices consist of a sensor, transmitter and receiver. The sensor is placed under the skin in the abdomen or other area to measure continuous intracellular (ICF) fluid. The sensor sends the information to a small monitor that stores the data. These devices are used episodically or continuously to monitor direct changes in diabetic management.

- Short Term Interstitial-Physician Owned:
REAL-Time CGM describes a newer technology which adds the ability to instantly read a value of interstitial glucose from the recording unit up to 72 hours. This device can allow trending of glucose data to assist in prescribing an insulin schedule, and is especially helpful in demonstrating nocturnal glucose patterns. However these values have to be corroborated using the traditional finger stick method.
- Long Term- Interstitial:
REAL-Time Continuous Glucose Monitors can also be integrated with an insulin pump which will release the correct amount of insulin based on the values of the CGM. They have an alarm system to instantly warn the patient of excessively high or low blood sugar readings in a manner that permit REAL-time therapeutic interventions. However, these values have to be corroborated using the traditional finger stick method.

III. PURPOSE

The purpose of this policy is to define the indications for medical necessity for CGM-Short Term Interstitial Physician Owned.

IV. SCOPE

This policy applies to various UPMC Health Plan departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.

V. PROCEDURE

A. Medical Description / Background

CGM is used as an adjunct to standard care. The equipment is owned and managed by the physician and is used to gather continuous glucose values for a short period of time in an effort to best manage the insulin needs.

CGM must be performed for a minimum of 24 hours to effectively show glucose trends. The recommended monitoring period is 72 hours. However, these values have to be corroborated using the traditional finger stick method.

Given the several month timeframe to determine the efficacy of these treatment modifications, the devices would be used only two (2) times in a given year.

B. Indications

CGM- Short Term Interstitial-Physician Owned is considered medically necessary for the following specific clinical indications:

1. Type I or Type II diabetic:
 - Who has documented frequency of glucose self-testing an average of at least 4 times per day during the previous month, **AND**
 - Who has been instructed by a health care professional in the management of diabetes, **AND**
 - Who has been on a program of multiple daily injections of insulin (at least 2 injections per day) with self-adjustment of their insulin dose based on self-testing results, **AND**
 - Who meets one or more of the following indications while on the multiple daily injection regimen:
 - Hgb A1C values > 9,
 - Unexplained frequent hypoglycemic attacks,
 - Unexplained large fluctuations in daily glucose values before meals,
 - Episodes of ketoacidosis or hospitalizations for glucose out of control.

OR

2. Type I or Type II diabetic woman who is pregnant or a woman who has developed gestational diabetes that requires insulin therapy.

AND

3. The device must be prescribed by an Endocrinologist, who should have appropriate interfacing equipment with the member's monitoring system to receive reports.

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

C. Limitations

1. Testing must be performed on a FDA approved device. Tests performed on any other device are non-covered.

2. CGM is intended for one-time or occasional testing and is limited to two (2) times in a 12 month period.
3. CGM is not accurate enough or reliable enough to allow therapeutic changes and interventions based on one or more readings, therefore readings must be confirmed by capillary glucometer testing.
4. CGM for less than 24 hours is not considered medically reasonable or necessary.
5. CGM devices lack precision and accuracy compared to capillary and venous glucose determinations. They are inaccurate at both the high and low extremes of glucose readings, which are the exact values that would benefit most from real-time intervention.
6. Even under the best of circumstances, CGM devices require that capillary blood sugar readings be obtained at least twice a day for calibration purposes.
7. CGM devices are not meant to replace the traditional (finger stick) self-monitoring measurements, but rather serve as a short-term adjunct to these measurements.
8. CGM may be helpful in identifying trends of hyper- or hypoglycemia. Even this suggestion is based on limited evidence.
9. It remains unclear whether CGM, real-time or otherwise, offers any benefit in reducing symptoms, in reducing Hgb A1C levels, or in improving any of the measures of long term diabetic complication.

D. Variations

N/A

E. Audits

Quality Assurance monitors policy compliance at the request of the UPMC Health Plan Technology Assessment Committee or Benefit Reimbursement Committee.

F. References

1. Highmark Medicare Services. Local Coverage Determination: Continuous Glucose Monitoring, # M-58C, Retired 11-29-07.
<http://www.highmarkmedicareservices.com/policy/partb/m1/m58c.html>
2. ECRI Target database, Real-time Continuous Glucose Monitoring 10/16/08.
http://www.target.ecri.org/summary/detail.aspx?e=6&doc_id=8935&q=glucose+monitoring&anm
3. Other carrier policies.
4. American Diabetes Association, Emerging Treatments and Technologies: Continuous Subcutaneous Glucose Monitoring in Diabetic Patients, *Diabetes Care* 25:347-352, 2002. <http://care.diabetesjournals.org/cgi/content/abstract/25/2/347>
5. Anneloes Kerksen, Harold W. De Valk, Gerard H.A. Visser. Diabetes Technology & Therapeutics: The Continuous Glucose Monitoring System During Pregnancy of Women with Type 1 Diabetes Mellitus: Accuracy Assessment, 2004, 6(5): 645-651. doi:10.1089/dia.2004.6.645.
6. Ingenix 2008 Codes Desk Reference- Procedures, Copyright 2007 Ingenix

Disclaimer:

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