

# UPMC Health Plan POLICY AND PROCEDURE MANUAL

**POLICY NUMBER: MP.034**  
**REVISION DATE: 09/09**  
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**PAGE NUMBER: 1 of 8**

**SUBJECT:** Continuous Glucose Monitoring – Long Term, Interstitial  
**INDEX TITLE:** Medical Management  
**ORIGINAL DATE:** July 2008

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

<b>Commercial:</b>				
HMO ( )	POS ( )	PPO ( )	OOA/DOC ( )	
Fully Insured ( )	Self-funded/ASO ( )	HSA ( )	All (X)	
Medicare Select ( )	Medicare Supplement ( )			
<b>DPW-MA:</b>				
Health Choices ( )		Voluntary ( )		All ( )
<b>CMS-MA:</b>				
OH ( )	WV ( )	PA ( )	All (X)	Other ( )
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ( )	PFFS (X)
<b>PID-CHIP:</b>				
Free ( )	Sub ( )	Full ( )	All (X)	
<b>APPLICABLE TO:</b>				
Community Care ( )		Work Partners ( )		

## 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 (Medical Director).

## II. DEFINITIONS

**External Insulin Pump** – is an ambulatory infusion pump (electrical or battery operated) which is used to deliver insulin under pressure at a regulated flow rate. It is small, portable, and designed to be carried by the patient.

**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).

**Hypoglycemic Unawareness** – is a state in which a person does not feel or recognize the symptoms of hypoglycemia. People who have frequent episodes of hypoglycemia may no longer experience the warning signs of it and some people have no symptoms of hypoglycemia.

Hypoglycemia unawareness occurs more frequently in patients with an A1c  $\leq$  7%, in those who experience frequent hypoglycemia, patients with neuropathy (nerve damage), and those who take certain heart or high blood pressure medicines. However, hypoglycemia unawareness also occurs in other situations.

**Implantable Insulin Pump** – (also known as a true “closed loop” system) - An implantable insulin pump is linked to a continuous glucose monitoring system that provides continuous intraperitoneal insulin delivery. It measures glucose levels, feed information back to the insulin delivery pump, and adjusts insulin delivery as needed with minimal patient or clinician involvement. This system has not yet been approved by the Food and Drug Administration (FDA) for use in the United States.

**Real-Time Continuous Glucose Monitors** – (refer to Continuous Glucose Monitoring Systems listed below)

### **III. PURPOSE**

The purpose of this policy is to define the criteria for medical necessity for Continuous Glucose Monitoring - Long Term Interstitial.

### **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:**

**Continuous Glucose Monitoring Systems (CGMS)** - (also known as REAL-Time or interstitial) Continuous glucose monitors measure and record glucose levels in interstitial fluid and produce data that show trends in glucose measurements.

CGMS consist of a sensor, transmitter and receiver. 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. CGMS sensors can be used 3- 7 days before replacement, depending on purpose and manufacturer.

CGMS are designed to be used as an adjunct to standard care for short term use: 1) physician owned; and long term use for: 2) monitoring only or 3) by integrating with an insulin pump.

1. CGMS –Short Term, Physician Owned 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.

2. CGMS- Long Term Interstitial for Monitoring only - The CGMS measure glucose in the interstitial fluid using a wire-like sensor that is implanted subcutaneously into the abdomen. The sensor tip reacts with the glucose in the interstitial fluid to generate an electrical current that is converted to a glucose reading. The monitor displays the reading, the direction of the glucose trend, and sounds an alarm when high-or low-glucose values are detected. Monitoring is used by the patient to closely monitor their glucose levels and better manage their diabetes.
3. CGMS –Long Term Interstitial Integrated with Insulin Pump (also known as “open loop” system). Some CGMS can integrate with an External Insulin Pump. The sensor can transmit glucose data to an External Insulin Pump. The insulin is delivered using an infusion set (a flexible delivery cannula with a small needle on the end) through a pump about the size of a pager which can be worn on a belt. The pump can also calculate recommended insulin doses, which the patient can accept or modify. The pump displays the reading, the direction of the glucose trend, and sounds an alarm when high-or low-glucose values are detected. A conventional glucometer reading is needed before making adjustments, because there is a 10 minute time lag in the interstitial fluid relative to concentration in the blood.

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.

NOTE: A UPMC Health Plan Hypoglycemia Unawareness’ Questionnaire (attached Appendix A) **may** be used by the prescriber to determine if the patient is experiencing “hypoglycemic symptoms without awareness”.

#### **B. Specific Indications:**

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

1. Members with Type 1 diabetes who are pregnant (during the course of the pregnancy) or desiring to become pregnant,

OR

Members with Type 1 or 2 diabetes who have documented experiences of clinically significant hypoglycemia without warning (Hypoglycemic Unawareness) indicated by the following:

- Fluctuations of blood glucose levels of  $\leq 50$  without symptoms documented either by glucometer, or by diagnostic CGMS (72 hours),

AND

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

AND

3. **All** of the following are met:

- Inadequate glycemic control despite compliance with frequent self-monitoring (*at least four times per day*) and including fasting hyperglycemia ( $>150$  mg/dl) or recurring episodes of severe hypoglycemia ( $<50$  mg/dl). This poor control is in spite of compliance with multiple alterations in self-monitoring and insulin administration regimens to optimize care
- Insulin injections are required 3 or more times per day or an insulin pump is used for maintenance of blood sugar control,

AND

- Four or more finger sticks are required per day,

AND

- The member **must have the ability to understand the technology** and is willing to use the monitor (i.e., hear alarms, read and interpret glucose data, and can take action based on the data interpretation),

AND

- The member has been instructed by a health care professional in the management of diabetes.

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 FDA.

### C. Limitations:

1. Implantable Insulin Pumps are not approved by the FDA and therefore not covered.
2. CGMS is not recommended in children under 7 years old. For children 7-17 years of age, non FDA approved monitors are considered experimental-investigational and therefore not covered.

### D. Information Required for Review:

1. Member's age and diagnosis,
2. History and physical,
3. Labs: fasting blood glucose,
4. Frequency of daily glucose testing and daily blood sugar levels.
5. Frequency of insulin injections or pump usage,

6. Type and amount of insulin used,
7. Verification that the member (Parent or caregiver if member is a child) has the ability to understand the technology and is willing to use the monitor (i.e., hear alarms, read and interpret glucose data, and can take action based on the data interpretation),
8. Verification that the member has been instructed by a health care professional in the management of diabetes.
9. Pregnancy- gestational date or documentation that the member is seeking pregnancy and is therefore requesting a CGMS.
10. Documentation (glucometer or 72 hour CGM) to support hypoglycemia unawareness when indicated.

**E. Review Process:**

1. The Medical Management Ancillary Service staff reviews the request. If the case does not meet the established criteria, it is referred to the Medical Director.
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management Ancillary Service staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan.

**F. Variations:**

N/A

**Records Retention**

Records Retention for UPMC Health Plan documents, regardless of medium are provided within the UPMC Health System Policy and as indicated in the UPMC Insurance Services Division Policy and Procedure.

**G. References:**

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<http://www.diabetes.org/diabetesdictionary.jsp?pageID=2&exitDictionaryTo=>
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16. American Diabetes Association Conditions and Treatment: Hypoglycemia, accessed 9-28-09. <http://www.diabetes.org/type-1-diabetes/hypoglycemia.jsp>

**Disclaimer:**

UPMC Health Plan 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 UPMC Health Plan 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.

UPMC Health Plan 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.

These policies are the proprietary information of UPMC Health Plan. Any sale, copying, or dissemination of said policies is prohibited.

**(Appendix A)**

**Hypoglycemia Unawareness Questionnaire**

	<b>NO</b>	<b>YES</b>
Does the patient obtain blood glucose readings below 50 mg/dL <b>without</b> adrenergic symptoms of hypoglycemia (Refer to symptoms of hypoglycemia below)?		
Does the patient have difficulty managing a hypoglycemic episode OR require the assistance of others?		
Has the patient ever had a seizure or loss of consciousness without any warning signs?		
Have others observed the patient in situations where they appeared confused, tired, appeared pale or acting as if they were in “slow motion?”		
Within the past year, did the patient have any low blood sugar episodes which required a visit to the emergency room or an intervention from emergency medical services?		

**Symptoms of Hypoglycemia**

- Shakiness
- Dizziness
- Sweating
- Hunger
- Headache
- Pale skin color
- Sudden moodiness or behavior changes, such as crying for no apparent reason
- Clumsy or jerky movements
- Seizure
- Difficulty paying attention, or confusion
- Tingling sensations around the mouth