

PEIA PPB Benefit Guidelines

Subject: Benefit Guidelines for Continuous Glucose Monitoring System (CGMS)

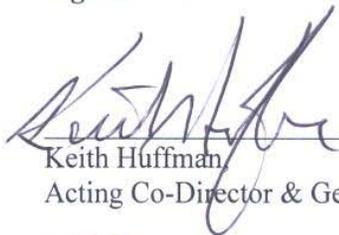
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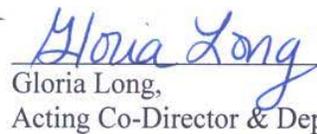
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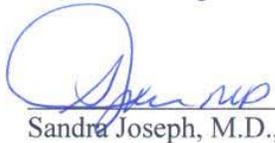
Effective

Date: 04/18/2005

Signatures:

 Date 7/18/05
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 Date 7-14-05
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Purpose of the Guideline: Limited benefits are available under the PEIA PPB benefit plan for the continuous glucose monitoring system (CGMS). Eligibility for benefits under the Plan is limited to *primarily* insulin-dependent diabetics and in very limited circumstances, non-insulin dependent diabetics. This guideline sets forth the details of this benefit below.

Description

Implantable (minimally invasive) or noninvasive continuous glucose monitoring systems measure glucose levels in the interstitial fluid at various periods throughout the day. These devices produce data that show the trends in glucose measurements, in contrast to the isolated glucose measurements of the traditional blood glucose measurements. Physicians can use these systems to retrospectively review blood glucose levels, and adjust therapy to assist in overall glycemic control.

To date, two devices have received FDA approval:

1. Minimed® Continuous Glucose Monitoring System (CGMS), reads the glucose level every five minutes through a subcutaneously implanted sensor attached to a small plastic disk taped to the skin, which holds the sensor in place. A thin wire connects the sensor to a pager-sized glucose monitor, which records and stores glucose values in memory.
2. The GlucoWatch® is an external device worn like a wristwatch that measures glucose every 20 minutes in interstitial fluid extracted through the skin with an electric current or reverse iontophoresis.

According to FDA labeling, neither device is intended to be an alternative to traditional self-monitoring of blood glucose. These devices are intended to serve as an adjunct, supplying additional information on glucose trends that are not available from traditional self-monitoring. 2

Benefit Maximums:

Coverage of the CGMS study is limited to one 72-hour testing per 12 months. If medically necessary, one repeat study at least 6 months after the preceding study, may be covered. Documentation explaining why the initial CGMS did not provide sufficient information for stabilization of the patient's blood glucose must be submitted.

As such, no more than 2 studies may be covered in a 12 month period. Services, included in this limit, include the monitoring and the interpretation of the tracings.

Coverage:

Services determined to be medically necessary and which meet Plan guidelines are covered at 80% for in-network providers after the deductible is met. Out-of-network services are covered at 60% after the deductible is met. Office visits for covered services require a \$15.00 copayment.

Requirements for Coverage:

1. To be eligible for coverage, prior approval from PEIA's TPA is required and CGMS **must** be requested prior to the testing episode. No post-testing requests will be approved.
2. Only the following providers will be paid for CGMS:

Pediatric and internal medicine physicians who are board certified, have completed an endocrinology fellowship, and are board certified in endocrinology.

Continuous monitoring of glucose, in the interstitial fluid via an implanted sensor (e.g., Minimed® Continuous Glucose Monitoring System) for the treatment or monitoring of unstable diabetes is considered medically necessary if

All of the following medical appropriateness criteria are met:

- Type I or Type II diabetes
- Completed a comprehensive diabetic education program
- Have documented frequency of glucose self testing 4 or more times per day
- compliant with the regime recommended by board certified endocrinologist
- have glycohemoglobin (HbA1C) values greater than 7%, or less than 7% with documented frequent or severe hypoglycemia (less than 50 mg/dl) in a compliant individual. (Note: An individual with type I diabetes can be in poor control despite a good Hgb A1c level, since they can be experiencing frequent lows followed by highs, which averages out.)

AND

- one or more of the following criteria are met:
 - a) insulin dependent having frequent, unexplained hypoglycemic episodes (less than 50 mg/dl), or
 - b) insulin dependent having unexplained, large fluctuations in their daily preprandial blood sugars (greater than 150 mg/dl) and not well controlled as evidenced by a high HbA1C, or
 - c) insulin dependent having episodes of ketoacidosis or hospitalizations for glucose out of control, or
 - d) Administering insulin injections multiple (three or more) times per day, about to start insulin for the first time, or start an insulin pump regime, or
 - e) Compliant Type II diabetic whose therapy results in unexplained hypoglycemia or poor response of HbA1C values, or
 - f) Diabetic and newly pregnant, or about to conceive, or
 - g) A pregnant diabetic who is having trouble controlling her diabetes.

Limitations

Routine use of continuous glucose monitoring in insulin dependent diabetics is not indicated.

Use of a non-implanted (non-invasive), external device (e.g., GlucoWatch®) in the monitoring of glucose levels, in the interstitial fluid as a technique for diabetic monitoring, is considered investigational.

Any implantable sensor utilized for this procedure must have FDA approval specific to the indication, otherwise its use will be considered investigational.

Billing For Services

Providers must follow PEIA billing procedures and guidelines for PEIA PPB Plan members.

Coding Guidelines:

1. For CGMS, CPT code 95250 is accepted. Modifiers -26 and -TC are not accepted for this code.
2. Only one (1) unit of service may be billed per testing episode.
3. Use the appropriate E&M codes to bill for evaluation of the downloaded data, planning of new insulin regimens and modified diabetic instructions for the patient--document the time spent, in the medical record.

Prohibition of Balance Billing

The PEIA PPB Plan is governed in part by the Omnibus Health Care Act which was enacted by the West Virginia Legislature in April 1989. This Law requires that any West Virginia health care provider who treats a PEIA PPB Plan participant must accept assignment of benefits and cannot balance bill the participant for any portion of charges over and above the PEIA fee allowance or for any discount amount applied to a provider's charge or payment. This is known as the "prohibition of balance billing."

The prohibition of balance billing applies when services are provided in West Virginia and when the PEIA PPB Plan is the primary payor. When the PPB Plan is the secondary payor, the provider may bill the patient for disallowed amounts and for the provider discounts. The patient is always responsible for deductible, copayment, coinsurance amounts and for non-covered services.

PEIA reimburses professional services according to a Resource Based Relative Value Scale (RBRVS) fee schedule. The payment system set fees for professional medical services based on the relative amounts of work, practice expense, and malpractice insurance expense involved.

References:

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2. "Continuous Monitoring of Glucose in the Interstitial Fluid," Blue Cross Blue Shield of Tennessee Medical Policy Manual, 06/17/2004. Accessed 09/03/04, [www.bcbst.com/mpmanual/continuous monitoring of glucose in the interstitial fluid.htm](http://www.bcbst.com/mpmanual/continuous_monitoring_of_glucose_in_the_interstitial_fluid.htm)
3. "Blood Glucose Meters-GlucoWatch Biographer." Accessed 10/18/04, www.diabetesmall.org/diabetes_technology/glucowatch.php
4. "FDA approves New Glucose Test for Adult Diabetics," FDA News, March 22, 2001. Accessed 10/18/04, www.fda.gov/bbs/topics/NEWS/2001/NEW00758.html
5. "Diabetes Programs and Supplies," Aetna Clinical Policy Bulletins, No. 0070, March 19, 2004. Accessed 10/18/04 www.aetna.com/cpb/data/CPBA0070.html
6. "Continuous Glucose Monitoring," Draft LMRP Policy Number 345, Cahaba GBA, 02/15/03. accessed 09/03/04, www.gamedicare.com/policies/drafts/345.htm