



Clinical Medical Policy Continuous Glucose Monitoring Devices

Benefit Coverage:

Continuous glucose monitoring is allowed for up to 3 days when determined to be medically necessary per this policy. The benefit is limited to two monitoring episodes (each up to 3 days) per twelve (12) month period.

Continuous glucose monitoring for longer than two three-day monitoring sessions in a twelve month period is not a covered benefit. It is considered investigational and the technology has clinically significant limitations which require considerable patient management of data and equipment, as well as extensive training and ongoing support.

Home Blood Glucose disposable monitors, including test strips (A9275) are noncovered because these monitors do not meet the definition of DME. DME is equipment which:

- Can withstand repeated use; i.e., could normally be rented and used by successive patients;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of illness or injury; and,
- Is appropriate for use in a patient's home.

Description:

A continuous glucose monitoring system (CGMS) is an FDA-approved device that records glucose levels throughout the day and night, using a sensor which is inserted under the skin. The system automatically records an average glucose value every 5 minutes for up to 72 hours, while the person with diabetes continues daily activities at home. The sensor measures the level of glucose in the tissue every 10 seconds and sends the information via a wire to a pager-sized device called a "monitor."

It provides real time information about the current interstitial fluid glucose concentration as well as short-term feedback about the effectiveness of diabetes intervention and warning when blood glucose becomes dangerously low. According to the FDA labeling, these devices are not intended as an alternative to traditional self monitoring of blood glucose levels, but rather serve as a complement in supplying additional information about a patient's glucose trends that are not available solely from self monitoring.

The most important use of continuous blood glucose monitoring is to facilitate adjustments in therapy to improve control.

Coverage Determination:



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Continuous glucose monitoring is a clinical option when medical necessity criteria are met. Prior authorization is required.

Situations which support 3 day monitoring with a continuous glucose monitoring device include adjustments in therapy, quantifying the response in a trial of a diabetes therapy, assessing the impact of lifestyle modifications on glycemic control, and monitoring when attempting to tighten control without causing hypoglycemia.

Criteria:

Documentation of all of the following criteria is required for authorization of continuous glucose monitoring:

1. Member currently has diabetes mellitus that is being treated with insulin.
2. There have been repeated documented hypoglycemic (<50 mg/dl) and/or hyperglycemic (>300 mg/dl) episodes in spite of traditional efforts at measurement and at adjustment of insulin dosages; or, there is hypoglycemia unawareness. Traditional efforts at measurement would include 3 or more fingersticks per day.
3. Blood sugar fluctuations have occurred in spite of consultation or care by an endocrinologist or other physician specializing in diabetes.
4. Continuous glucose monitoring is limited to two monitoring episodes per twelve (12) month period.

NOTE: In the event the ordering practitioner prescribes a third monitoring episode in the twelve month period, submission of current documentation of all of the above criteria will be required in order to consider the request for authorization.

Covered Procedures:

STS-7 Continuous Glucose Monitoring System approved 6/4/2007

Paradigm and Guardian REAL-Time approved 3/8/2007

Codes: A9276, A9277, A9278, , , S1031, 95250, 95251, 99091

Exclusions:

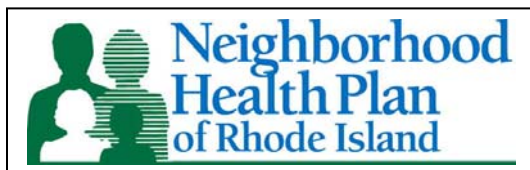
GlucoWatch G2

Home Blood Glucose disposable monitors, including test strips (A9275)

CMP Number: CMP-032.02

CMP Cross Reference:

References:



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Garg, Satish, et al, "The Role of Continuous Glucose Sensors in Diabetes Care", *Endocrinology and Metabolism Clinics*, vol 33, no. 1 (March 2004).
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Charlton M. Commentary: The technology of continuous glucose monitoring. *British Medical Journal* 2008; 337:a1733

National Government Services, DME, Region: Jurisdiction B: Article for Glucose Monitors – Policy Article, Revision Effective Date
<http://www.ngsmedicare.com/content.aspx?CatID=3&DOCID=65>



**Clinical Medical Policy
Continuous Glucose Monitoring
Devices**

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