BlueCross BlueShield of Alabama

Name of Policy:

Continuous or Intermittent Monitoring of Glucose in the Interstitial Fluid (Wrist Glucose Monitor/Glucowatch Continuous Glucose Monitor)

Policy #: 038
Category: DME

Latest Review Date: March 2005
Policy Grade: B

Background:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts to have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Coding:

CPT code:	**95250**	Glucose monitoring for up to 72 hours by continuous recording and storage of glucose values from interstitial tissue fluid via a subcutaneous sensor (includes hook-up, calibration, patient initiation and training, recording disconnection, downloading with printout of data)
	99091	Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, requiring a minimum of 30 minutes of time
HCPCS:	**S1030**	Continuous noninvasive glucose monitoring device purchase (for physician interpretation of data, use CPT code)

S1031 Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)

Description of Procedure or Service:

The GlucoWatch Automatic Glucose Biographer and now a second generation GlucoWatch® G2™ Biographer is for use by adult diabetics, aged 18 years and older which is a minimally invasive wrist glucose monitor. This device now has approval for the GlucoWatch G2 Biographer for use in children and adolescents (ages 7 to 17), as well as adults.

It is made up of two parts: 1) the Biographer, which is the device worn like a watch that calculates, displays and stores glucose readings, and 2) the AutoSensor which is a single use component that collects and measures the glucose sample.

After a ~~3~~ 2-hour warm-up period, the patient sets the GlucoWatch® G2™ Biographer using a fingerstick blood glucose measurement.

After calibration, the GlucoWatch® will start monitoring glucose values by extracting interstitial fluid via reverse iontophoresis generated by tiny electrical currents through the skin into gel discs and then measures the glucose in the fluid. Levels are measured every ~~20~~ 10 minutes for ~~12~~ 13 hours (even during sleep). The alarm device sounds if the patient's glucose approaches dangerous levels that have been already determined. This helps patients manage what could be a potential problem.

The GlucoWatch® is intended not to replace, but supplement blood glucose information obtained using the fingerstick glucose meters and test strips.

Another device used by physicians for continuous glucose monitoring is the Continuous Glucose Monitoring System Gold™ (CGMS®) by Minimed. This device is used to monitor glycemic patterns not ordinarily captured by the HbA1c or traditional finger stick measurement over a 72-hour period. The system has two key components: a subcutaneous glucose sensor and a small, pager-type monitor. The glucose sensor is inserted into the subcutaneous tissue, most typically the abdomen, and worn for a period of 24-72 hours. The sensors measures glucose levels every 10 seconds and averages measurements every five minutes. The monitor will also store glucose data and event measurements entered manually by the patient. The device does not display glucose values but rather stores the data. The data is then downloaded by the healthcare professional to a computer allowing them to view retrospective data via graphs and statistical reports and to make changes in the diabetes therapy.

Minimed also states that the information from the CGMS® is intended to supplement, not replace, blood glucose information obtained using standard home glucose monitoring devices. At this time the device has only been tested in adults with Type I diabetes and has not been tested in children. The device is intended for occasional rather then everyday use.

Policy:

Monitoring of glucose levels in the interstitial fluid as a method of diabetes monitoring using either the GlucoWatch or the Continuous Glucose Monitoring System **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.
ICD-9 codes: 250-250.9, 648.8, 775.1, 790.2, and 790.6.

The purpose of Blue Cross and Blue Shield of Alabama's medical policy is to provide a guide to coverage. Medical policy is not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Key Points:

The manufacturer conducted clinical studies that showed the GlucoWatch® measurements generally were consistent with the results found in traditional fingerstick blood test. The results were different by more than 30 percent up to 25 percent of the time. The GlucoWatch® would not measure levels at all if a patient's arm had too much perspiration and was less effective at detecting very low levels than very high levels; therefore, giving erroneous readings. There was also mild to moderate skin irritation caused by the GlucoWatch® in at least 50 percent of the patients. With the GlucoWatch® G2 Biographer, 95% of the readings are clinically accurate or acceptable.

Clinical studies have not demonstrated the improvement to net health outcomes, and benefits of the GlucoWatch have not been established, in relation to established alternatives. The FDA warns that physicians and patients should not use the GlucoWatch® reading as the only monitoring device to make changes in insulin doses because there is potential for error. Instead, the results should be interpreted with several readings over time and confirmed with an additional fingerstick blood test. In addition, the Biographer is not intended to replace the common "finger-stick" testing method, but is to be used as an adjunctive device to supplement blood glucose testing. Interpretation of results should be based on the trends and patterns seen with several sequential readings over time. This G2 Biographer may not be appropriate for use every day or with every patient.

There has not been any documentation to show that net health outcome improvements have been attained outside the investigational setting.

Based on a recent TEC Assessment from October 2003, the review of the literature determined that no conclusions could be drawn regarding the effects of interstitial fluid glucose monitoring on health outcomes. This assessment concluded that use of the interstitial glucose monitoring in patients with diabetes does not meet the Blue Cross and Blue Shield Technology Evaluation Center (TEC) criteria. Of the trials reported, there were low patient numbers with short follow-up and it was reported that there was no statistically significant difference in HbA1c levels.

Key Words:

GlucoWatch®, wrist glucose monitor, Glucose Biographer, AutoSensor, and GlucoWatch® G2™ Biographer, continuous monitoring of glucose in the interstitial fluid, intermittent monitoring of

glucose in the interstitial fluid, Continuous Glucose Monitoring System, CGMS, CGMS® System Gold™, Minimed

Approved by Governing Bodies:

FDA approved March 22, 2001 for adults with diabetes (age 18 and over).
FDA approved April 2002 for GlucoWatch® G2™ Biographer (a second generation device) use with adults.
FDA approval August 28, 2002 for GlucoWatch® G2™ Biographer in children and adolescents (ages 7-17).
Continuous Glucose Monitoring System (CGMS) manufactured by Minimed received FDA approval June 1999

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational. Will be reviewed for medical necessity
BellSouth contracts: Considers investigational
Wal-Mart: Special benefit consideration may apply. Refer to member's benefit plan.
Pre-certification/Pre-determination requirements: Not applicable

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Policy History:

Medical Policy Administration Committee, March 2002
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Medical Policy Group, March 2003 **(1)**
Medical Policy Administration Committee, March 2003
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Medical Policy Group, March 2005 **(1)**
