Medical Policy

Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information.

Category: Durable Medical Equipment
***Current Policy Effective Date: 7/1/09**

Title: Continuous Noninvasive Glucose Monitoring Device (e.g., GlucoWatch®)

****Procedure Code(s): S1030, S1031**

Description / Background

The continuous noninvasive glucose monitoring device that is worn like a watch (e.g., GlucoWatch® G2 Biographer, Cygnus) received FDA approval in 2002. It is utilized along with the standard finger-stick blood sugar test to track trends in blood glucose levels. The device extracts sodium across the skin by the process of iontophoresis. Glucose is measured in the extracted fluid using glucose oxidase to oxidize glucose to peroxide; a platinum-containing electrode then oxidizes the peroxide and generates an electrical current. The device requires a prescription and automatically measures and displays glucose levels in the interstitial fluid collected through the skin six times per hour, for up to 13 hours. A three-hour calibration period is necessary, during which the glucose flux across the skin is established. Information provided by the device regarding glucose level patterns is intended to be used by physicians to guide adjustments to therapy with the goal of improving diabetic disease management.

Animas Corporation, which is now a Johnson & Johnson company, purchased the intellectual property and all of the assets of the original manufacturer of the GlucoWatch G2 Biographer, Cygnus Inc. in Redwood City, California. Animas Corporation is no longer selling the current model GlucoWatch G2 Biographer system. Animas continues to sell AutoSensors and provided customer support for the GlucoWatch system through July 31, 2008.

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CPT / HCPCS Level II Codes and Description *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

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)

Diagnoses / Medical Conditions

- Type 1 Diabetes
- Type 2 Diabetes
- Hypoglycemia secondary to insulin
- Hypoglycemia, unspecified
- Gestational diabetes

Medical Policy Statement

The continuous noninvasive glucose monitoring device (e.g., GlucoWatch®) is considered experimental/investigational. While safe, these devices have not been scientifically demonstrated to be as effective as conventional equipment in the treatment of diabetes.

Rationale

The Diabetes Research in Children Network (DirecNet) study group assessed youth and parent satisfaction with the use of the GlucoWatch G2 Biographer, as well as psychological aspects of CGM in pediatric patients with type 1 diabetes. Both studies were based on a randomized trial of 200 pediatric patients aged 7 to 17 years with type 1 diabetes. In the first study, management of type 1 diabetes was based on conventional self-monitoring blood glucose (SMBG) alone versus conventional SMBG supplemented with the GlucoWatch. Investigators developed a survey capturing CGM satisfaction and therapeutic impact. The questionnaire was completed in an independent fashion using a personal computer by both parents and youth older than 11 years of age. For 81% of parents and 73% of youths, the mean satisfaction rating was < 3.0, which indicated less than favorable reactions to the use

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of the GlucoWatch. In total, all patients were mildly dissatisfied with the GlucoWatch. Additionally, the absence of glycemic benefit from using the GlucoWatch, skin irritation, frequent skips, excessive alarms, and inaccurate readings all contributed to the declining use of the CGM device over the course of the study.

Medical Policy Position Summary (Non-clinical summary statement for customer use)

The GlucoWatch® G2 Biographer (GW2B) is worn like a watch and has a special sensor, which measures blood sugar levels without breaking the skin. A three-hour calibration period is necessary during which the glucose flow across the skin is established. Information collected by the device regarding blood sugar patterns is used by the patient's doctor to make changes in treatment with the goal of improving diabetic disease management. While safe, the clinical effectiveness of the continuous noninvasive glucose monitoring device has not been established and is considered experimental/investigational in the care and management of diabetes.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

Related Policies

- Diabetes Self-Management, Education and Supplies
- Continuous Invasive Glucose Monitoring
- Insulin Pumps
- Blood Glucose Monitors (retired)

Medicare Information

There are no national or local Medicare policies regarding this specific device. Medicare does not reimburse for this device.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

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References

- Blue Cross Blue Shield Association, "Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid," *Medical Policy Reference Manual, Policy* #1.01.20, Issue 10: 2008, original policy date 8/18/00, last review date October 2008.
- Diabetes Research in Children Network (DirectNet), "Accuracy of the GlucoWatch G2 Biographer and the Continuous Glucose Monitoring System During Hypoglycemia," *Diabetes Care*, Vol.27, No. 3, March 2004, pp. 722-726.
- Diabetes Research in Children Network (DirectNet), "A Randomized Multicenter Trial Comparing the GlucoWatch Biographer with Standard Glucose Monitoring in Children with Type 1 Diabetes," *Diabetes Care,* Vol. 28, No. 5, May 2005, pp. 1101-1106.
- Diabetes Research in Children Network (DirectNet), "Youth and Parent Satisfaction with Clinical Use of the GlucoWatch G2 Biographer in the Management of Pediatric Type 1 Diabetes," *Diabetes Care*, Vol. 28, No. 8, 2005, pp. 1929-1935.
- Garg, Satish K., MD, et al., "The role of continuous glucose sensors in diabetes care," *Endocrinol Metab Clin N Am,* 2004, Vol. 33, 163-173.
- Garg, Satish, MD et al., "Improvement in Glycemic Excursions with a Transcutaneous, Real-Time Continuous Glucose Sensor," *Diabetes Care,* Vol. 29, No. 1, January 2006, pp. 44-50.
- Hathout, Eba, et al., "Home Use of the GlucoWatch G2 Biographer in Children with Diabetes," *Pediatrics*, 2005, Vol. 115, pp. 662-666.
- *HAYES Medical Technology Directory*, "Continuous Glucose Monitoring Systems," Lansdale, PA: HAYES, Inc., December 17, 2008.
- *Michigan Department of Community Health, Medicaid Provider Manual*, Section 2.3, "Blood Glucose Monitoring Equipment and Supplies," January 1, 2009, pp. 20-21.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 10, 2009, the date the research was completed.

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Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
2/16/04	2/16/04	3/01/04	Joint policy established
5/19/05	5/19/05	5/19/05	Routine maintenance, references updated.
11/1/06	8/25/06	9/16/06	Routine maintenance
3/1/08	12/11/07	11/18/07	Routine maintenance
7/1/09	4/21/09	5/11/09	Routine maintenance; policy retired as obsolete, GlucoWatch is no longer being sold.

Next Review: This device has been determined to be obsolete and is no longer subject to routine review.

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A
BCBSM: N/A	Revised: N/A

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BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CONTINUOUS NONINVASIVE GLUCOSE MONITORING DEVICE (E.G., GLUCOWATCH®)

I. Short Description:

The GlucoWatch® G2 Biographer (GW2B) is worn like a watch and has a special sensor, which measures blood sugar levels without breaking the skin. A three-hour calibration period is necessary during which the glucose flow across the skin is established. Information collected by the device regarding blood sugar patterns is used by the patient's doctor to make changes in treatment with the goal of improving diabetic disease management. While safe, the clinical effectiveness of the continuous noninvasive glucose monitoring device has not been established and is considered investigational/experimental in the care and management of diabetes.

II. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	Not covered.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
BlueCaid	Not covered.

III. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate benefits and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.

IV. Effective Dates:

Policy updated: 5/19/05, 11/1/06, 3/1/08, 7/1/09
JUMP policy effective date: 2/16/04

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