CIGNA HEALTHCARE COVERAGE POSITION

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Coverage Position Number 0106

Subject **Home Blood Glucose Monitors**

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INSTRUCTIONS FOR USE

*Coverage Positions are intended to supplement certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Positions are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Position. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Positions. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Positions and; 4) the specific facts of the particular situation.*

Coverage Position

CIGNA HealthCare covers home blood glucose monitors as medically necessary Durable Medical Equipment (DME) for all patients with diabetes.

- Special feature glucose monitors (e.g., large readout, audio monitor) are generally considered medically necessary for diabetic patients who have visual impairment and are able to self-monitor and self-administer insulin.

CIGNA HealthCare does NOT cover continuous glucose monitoring systems (CGMS) or alternate site blood glucose monitors, because these are considered experimental, investigational or unproven benefit for the treatment of diabetes.

General Background

Blood glucose monitors (BGMs) measure blood glucose concentration using a reagent strip, cartridge or cuvette and a drop of capillary blood from a finger puncture. Used at home, portable BGMs allow people with diabetes to detect and treat fluctuations in blood glucose levels. The normal fasting blood glucose concentration ranges from 70-110 mg/dL in blood serum or plasma, although capillary blood glucose concentrations may be higher (by 10-15%). A person with diabetes can adjust insulin dosage, food intake, and exercise in response to the monitor's readings to achieve normoglycemia. According to research of the Diabetes Control and Complications Trial (DCCT), frequent blood glucose monitoring to maintain normoglycemia facilitates treatment designed to reduce the incidence and severity of diabetes-related microvascular and neurological complications.

Most BGMs are automatic and require no user intervention to operate. With these monitors, the test strip is inserted either before or after the addition of blood to the pad. Timing begins automatically when the

monitor senses blood on the strip; no wiping is required. A few BGMs are manual and require reaction timing and wiping of the reagent strip. For some manual and automatic monitors, the user can also compare the color of the reacted reagent area with a chart to estimate blood glucose concentration. However, concentration estimates from color charts are only semiquantitative, since they are influenced by ambient lighting and vision, and yield less accurate results than the BGMs. Some monitoring systems use check strips to periodically evaluate optical components of the monitor. Most monitors use glucose-control solutions that have a specific range of glucose values and that must be run periodically to check the operation of the test strips and the monitor together, as well as operator technique.

Some portable BGMs use reflectance photometry (e.g., Glucometer Encore by Bayer, Inc.) to measure the amount of light produced by a light-emitting diode (LED) and reflected from a reagent-impregnated test pad that has reacted with a drop of blood. Some units use absorbance photometry, an optical reading method that measures glucose concentration using two wave lengths, rather than the single wave length used by reflectance photometry. Other BGMs employ electrochemical methodology (e.g., One Touch® Ultra by Lifescan). Electrochemical BGMs use electrodes to measure the current that is produced by the conversion of glucose to gluconic acid via glucose oxidase, glucose dehydrogenase, or hexokinase when blood is applied to the test strip.

Manual BGMs that require timing and wiping are reliable only if the operator adheres strictly to the testing procedure. ECRI (2003) does not recommend the purchase of BGMs that require wiping but recommends automatic BGMs instead. Some monitors require cleaning, while others do not. Inadequate cleaning can cause false readings.

Audio monitors are available for the patient who has severe visual impairment. The monitor gives instructions and results verbally, allowing the patient to use the equipment without assistance. Monitors are also available with large readouts for those with impaired vision. BGMs may have various other features, such as data management systems. Although the management systems offer convenience in tracking test results and glucose levels, the ADA (2004) considers the systems a luxury, not a requirement.

Reflectance colorimeter devices used for measuring blood glucose levels in clinical settings are not covered as durable medical equipment for use in the home. Their need for frequent professional recalibration makes them unsuitable for home use.

The U.S. Food and Drug Administration (FDA) has given 510(k) approval to several portable blood glucose monitors, including Accu-Chek® (Roche Diagnostics, Basel, Switzerland), Freestyle® (Therasense, Alameda, California, USA), Ascensia® (Bayer, Tarrytown, New York, USA), and One Touch® (Lifescan, New Brunswick, New Jersey, USA).

Regulations from the Clinical Laboratory Improvement Amendment of 1988 apply to such BGM areas as patient test management, quality control, proficiency testing, personnel qualifications, and quality assurance programs. The regulations outline three levels of complexity: waived, moderate and high. BGMs fall into the waived category, because they require little training or experience to use and do not require elaborate quality control.

The following features should be considered when purchasing a home glucose monitor:

- Analytical ranges should be checked under the conditions in which it is to be used.
- Since accuracy may be measured by differing reference methods by manufacturer, the user should be aware of the reference used.
- The monitor should offer precision in measuring the reproducibility of test results, as expressed in a low variation coefficient
- Performance reliability should be checked using check strips or solutions to validate that the results are within the limits set by the ADA.
- The monitor should be simple to use and require minimal training to obtain reliable results. Displays should be large enough to read easily. Operation control buttons should not have multiple functions. Required codes should be easy to enter.

- Safety features should include strips designed for that unit only and should provide error messages for extremely high or low blood glucose levels.
- Memory and data management capabilities should store at least 10 glucose readings. The monitor should be capable of reading from memory if the battery is removed for changing.
- Battery-powered operation should include low-battery indicators to warn of low battery power. Monitors should use commonly available batteries.
- Monitors should be able to withstand rough handling and disassembly for cleaning or battery replacement.
- The monitor should be easy to clean, and cleaning instructions should be supplied by the manufacturer.

The American Diabetes Association recommends self-monitoring of blood glucose (SMBG) as an integral component of diabetes therapy, provided that the patient is given instruction in technique and is capable of using the data to adjust therapy. In a study published in March, 2004, Soumerai, et al., described the "Effects of Health Maintenance Organization Coverage of Self-Monitoring Devices on Diabetes Self-care and Glycemic Control." Using an interrupted time series analysis and controlling for pre-intervention trends, the study monitored changes in SMBG rates before and after introduction of a policy that provided free BGMs to 3,219 continuously enrolled patients receiving drug therapy. Changes in medication use and glucose levels were compared over time. Results indicated that increased SMBG was associated with increased regularity of medication use and improved glucose control. Introduction of the policy resulted in a small but significant increase in SMBG among insulin-treated patients (n=1,428). Among sulfonylurea-treated patients (n=1,791), the monthly initiation rate of SMBG increased by 14 new patients per 1000 (95% confidence interval). Compared with non-initiators of SMBG, initiators (n=593) showed sudden significant improvements in regularity of medication use and in glucose control (-0.63% mean HbA1c). The authors concluded that providing free glucose monitors improved rates of self-monitoring in the health maintenance organization (Harvard Pilgrim Health Care). Initiating SMBG was associated with increased regularity of medication use and a reduction in high blood glucose levels.

The American Diabetes Association (ADA) published a position statement in 2004 regarding tests of glycemia in diabetes. Given the results of the Diabetes Control and Complications Trail (DCCT) and other studies, there is broad consensus on the health benefits of normal or near-normal blood glucose levels. Self-monitoring of blood glucose (SMBG) in treatment efforts designed to achieve such glycemic goals has revolutionized diabetes management, enabling patients to maintain normal or near-normal blood glucose levels with a consistency that could not be achieved without SMBG. Because the accuracy of SMBG is instrument and user dependent, it is important for health care providers to evaluate each patient's monitoring technique. The ADA's recommendations for blood glucose testing by patients are:

- All programs should encourage routine daily monitoring, the frequency determined by individual needs and goals.
- SMBG is recommended for all insulin-treated patients with diabetes.
- Health care providers should evaluate each patient's monitoring technique.
- Patients should be taught optimal use of data to adjust medical nutritional therapy, exercise or pharmacotherapy. It is not known whether use of computer data management systems yields better glycemic control than patient review of results recorded in a log book.

Alternate site blood glucose monitors (e.g., One Touch® Ultra by Lifescan, New Brunswick, New Jersey, USA) permit testing from sites other than the fingertips. There are a number of concerns about alternate site blood glucose monitors. It may be more difficult to start and stop the bleeding with this process than with the fingerstick. Alternate site blood glucose monitors may induce bruising, and there is concern that they may put diabetic patients at risk for infection due to decreased blood flow. Another concern is that alternate site testing may not reflect systemic glucose levels as accurately as fingerstick, particularly after meals or exercise. The FDA recommended labeling precautions and called a public meeting to discuss types of information and labeling concerns. The FDA (2004) believes that further research is needed to better understand the differences in test values between readings of alternate site blood glucose monitors and fingerstick-type monitors, as well as the discrepancies' possible impact on the health of diabetic patients. Insufficient evidence exists in the peer-reviewed scientific literature to support the safety and efficacy of alternate site blood glucose monitors.

Continuous glucose monitoring (CGM) systems are minimally invasive devices that are inserted subcutaneously into the abdomen or worn on the wrist to record interstitial fluid glucose levels. The goal of CGM is to record patterns in diurnal glucose levels and use these patterns to guide patient management and improve overall glycemic control. This information is intended to supplement, not replace, blood glucose information obtained using standard home glucose monitoring devices.

Two CGM systems, the MiniMed® Continuous Glucose Monitoring System (CGMS) (MiniMed, Inc., Northridge, California, USA) and the GlucoWatch® Automated Biographer (Cygnus, Inc., Redwood City, California, USA), have been FDA-approved to detect trends and track patterns in glucose levels over a period of several days. Information they add can be used to optimize insulin therapy, thereby potentially improving glycemic control. The MiniMed CGMS is a minimally invasive device that is inserted into the subcutaneous tissues of the abdomen. The GlucoWatch, on the other hand, is a noninvasive device that is worn on the wrist like a watch. Both devices extract glucose from the interstitial fluid, measure and record the glucose level, and convert the measurement into an equivalent blood glucose reading. The readings are intended to supplement, not replace, information obtained from standard home glucose monitoring devices and, as such, are not available to the patient in real time.

There is limited evidence that the MiniMed CGMS can detect asymptomatic hypoglycemic episodes, especially nocturnal episodes, that standard SMBG cannot detect. Findings for the noninvasive GlucoWatch Biographer® (Cygnus, Inc., Redwood City, California, USA) are similar; its interstitial fluid glucose measurements correlate well with fingerstick blood glucose measurements when glucose concentrations are between 40 mg/dL and 400 mg/dL, although one report documented significant error when glucose levels rose above 250 mg/dL. Skipped readings are most commonly caused by perspiration, which can be a symptom of hypoglycemia. Skipped readings occur when the data do not meet certain integrity criteria programmed into the device. Frequent skipped readings were reported with GlucoWatch.

The available evidence for the minimally invasive CGMS is limited, with varying short duration and two- to three-month follow-up. Chase, et al. (2001), reported a randomized, controlled trial with children (mean age 14.8 years; n=11). The trial evaluated MiniMed CGMS as an adjunct to SMBG for glycemic control in children. All patients were asked to perform SMBG ≥ 4 times a day. Patients in the CGM-plus-SMBG group (n=6) underwent 18 days of CGM during a 30-day period. CGM was calibrated with SMBG readings. Results suggest that, while CGM may improve detection of asymptomatic hypoglycemia, it does not improve glycemic control. Study limitations include small sample size and manufacturer support.

Chase, et al. (2003), conducted a single-blinded, randomized, controlled trial to evaluate the GlucoWatch CGM system as an adjunct to SMBG for improvement of glycemic control in children (mean age 11.9 years; n=40). All patients were asked to perform SMBG ≥ 4 times a day. The CGM-plus-SMBG group was asked to wear CGM sensors four times per week for twelve hours, for three months. An alarm sounded during CGM for blood glucose ≤ 70 mg/dL. Alarms were verified by SMBG. Results suggested that in diabetic children, CGM improved glycemic control and detection of hypoglycemia. The study was conducted by the device manufacturer and limited by small sample size; patient withdrawal; failure to use blinded CGM for the SMBG group to determine whether CGM reduces the incidence of symptomatic hypoglycemia; wide variation in number of CGM uses per week; and reasons for the variation. There was no controlled follow-up.

Chico, et al. (2003), conducted a randomized, controlled trial (n=75) to evaluate MiniMed CGMS as an adjunct for improvement of glycemic control in adults with inadequately controlled type 1 diabetes. Patients were randomized to CGM as an adjunct to SMBG or to SMBG alone. No statistical differences were found in age, sex distributions, or HbA_1 before the study when comparing both groups of type 1 diabetic patients studied. All patients were asked to perform SMBG $\geq$ 4 times a day. Patients assigned to CGM underwent three days of CGM with calibration using data from SMBG and were then monitored for three months to assess the results of therapy modifications. The outcome measure was HbA1c levels. Results suggest that CGM does not improve glycemic control in adult patients with type 1 diabetes.

In a controlled crossover trial, Ludvigsson and Hasnas (2003) reported improved glycemic control in pediatric patients (mean age 12.5 years, n=27). The trial evaluated MiniMed CGMS as an adjunct to

SMBG for improved glycemic control. All patients underwent CGM for three days every other week for 24 weeks as an adjunct to SMBG ≥ 2 times a day. Patients were randomized to CGM data available for 12 weeks with crossover to data unavailable for 12 weeks. Once per week, patients underwent seven SMBG readings, and CGM was calibrated with SMBG readings. This study was very small, and improvements in insulin treatment that occurred before patient crossover from "CGM data known" to "CGM data not known" may have influenced outcomes after crossover. There was no follow-up, and the study was funded by the manufacturer.

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The benefits of CGM remain to be proven in large-scale, long-term studies that include patients with both type 1 and insulin-requiring type 2 diabetes and that evaluate the effect of CGM on patient management and health outcomes. Continuing glucose monitoring systems remain investigational.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

HCPCS	Description
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4256	Normal , low and high calibrator solution/chips
E0607	Home blood glucose monitor
E2100	Blood glucose monitor with integrated voice synthesizer

ICD-9-CM Diagnosis Codes	Description
648.80-648.84	Gestational diabetes
250.00-250.03	Diabetes Mellitus without mention of complication
250.10-250.13	Diabetes Mellitus with ketoacidosis
250.20-250.23	Diabetes Mellitus with hyperosmolarity
250.30-250.33	Diabetes with other coma
250.40-250-43	Diabetes with renal manifestation
250.50-250.53	Diabetes with ophthalmic manifestation
250.60-250.63	Diabetes with neurological manifestation
250.70-250.73	Diabetes with peripheral circulatory disorders
250.80-250.83	Diabetes with other special manifestations
250.90-250.93	Diabetes with unspecified complication

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
95250	Glucose monitoring for up to 72 hours by continuous recording and storage of glucose values for interstitial tissue fluid, via a subcutaneous sensor includes(includes hook up calibration, patient initiation and training, recording, disconnection, downloading with printout data.

HCPCS Codes	Description
E0620	Skin piercing device for collection of capillary blood, laser, each
S1030	Continuous non-invasive glucose monitoring device, purchase
S1031	Continuous non-invasive glucose monitoring device, rental, including sensor, sensor placement, and download to monitor

***Current Procedural Terminology (CPT®) 2003 American Medical Association: Chicago, IL.**

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