



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject Home Blood Glucose Monitors

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Hyperlink to Related Coverage Policies

- Diabetes Self-Management Education
- Diabetic Supplies
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- Implantable Infusion Pumps
- Nutritional Counseling

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer'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 Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. 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 benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

Coverage for home blood glucose monitors may be subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. In addition, coverage for home blood glucose monitors may be governed by state mandates. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

If coverage is available for a home blood glucose monitor, CIGNA covers as medically necessary EITHER of the following devices when used for the management of diabetes mellitus:

- standard home blood glucose monitor
- enhanced feature glucose monitor (e.g., large readout, audio monitor, integrated lancing/blood sample) for an individual who is able to both self-monitor and self-administer insulin, but has a visual or physical impairment that precludes the successful use of a standard home blood glucose monitor

CIGNA covers a minimally invasive, continuous glucose monitoring system (CGMS) as medically necessary for ANY of the following:

- up to three days (72 hours) under the core medical benefits of the plan for the management of difficult to control insulin-treated diabetes mellitus (e.g., hypo- or hyperglycemic episodes unresponsive to

adjustments in therapy, asymptomatic nocturnal hypoglycemia) for up to six separate sessions in any given 12-month period

- long-term use in a type 1 diabetic age 25 years or older
- long-term use in a type 1 diabetic age 24 years or younger with recurrent, severe hypoglycemic events (i.e., blood glucose < 50 mg/dL) despite appropriate modifications in insulin therapy and compliance with frequent self monitoring of blood glucose (i.e., at least four times daily)
- long-term use in a type 2 diabetic with recurrent, severe hypoglycemic events (i.e., blood glucose < 50mg/dL) despite appropriate modifications in insulin therapy, and compliance with frequent self monitoring of blood glucose (i.e., at least four times daily) and EITHER of the following:
 - fasting C-peptide level \leq 110% of the lower limit of normal of the laboratory's measurement method AND a concurrently obtained fasting glucose \leq 225 mg/dL
 - renal insufficiency with a creatinine clearance (actual or calculated from age, gender, weight and serum creatinine) \leq 50 ml/minute AND a fasting C-peptide level \leq 200% of the lower limit of normal of the laboratory's measurement method

CIGNA does not cover EITHER of the following because each is considered experimental, investigational or unproven:

- alternative site blood glucose monitor
- GlucoWatch[®] G2[™] Biographer

CIGNA does not cover EITHER of the following because each is considered a convenience item and not medically necessary:

- additional software or hardware required for downloading data from blood glucose monitors to computers for the management of diabetes mellitus
- combination devices that include a home blood glucose monitor combined with a cellular telephone or other device not specifically indicated for the management of diabetes mellitus (e.g., blood pressure monitor, cholesterol screening analyzer)

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 diabetics to detect and treat fluctuations in blood glucose levels. The normal fasting blood glucose concentration ranges from 70–100 milligrams (mg) per deciliter (dL) in blood serum or plasma, although capillary blood glucose concentrations may be higher (e.g., 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. Frequent blood glucose monitoring to maintain normoglycemia facilitates treatment designed to reduce the incidence and severity of diabetes-related microvascular and neurological complications.

Standard Home Blood Glucose Monitoring

The American Diabetes Association (ADA) recommends finger-stick self-monitoring of blood glucose (SMBG) as an integral component of diabetes therapy for type 1 and type 2 diabetics, as well as diabetes during pregnancy (maternal diabetes) or diabetes that develops during pregnancy (i.e., gestational diabetes). They also stress that the patient/caregiver should receive instructions in, and routine follow-up of, SMBG technique and their capability to use the data to adjust therapy. The ADA reports that clinical trials assessing the impact of glycemic control on diabetes complications have included SMBG as part of multifactorial interventions, suggesting that SMBG is a component of effective therapy. SMBG allows patients to evaluate their individual response to therapy and assess whether glycemic targets are being achieved (ADA, 2011).

The ADA's 2011 recommendations for home blood glucose testing by patients include:

- "SMBG should be carried out three or more times daily for patients using multiple insulin injections or insulin pump therapy.

- For patients using less frequent insulin injections, noninsulin therapies, or medical nutrition therapy (MNT) alone, SMBG may be useful as a guide to the success of therapy.
- To achieve postprandial glucose targets, postprandial SMBG may be appropriate.
- When prescribing SMBG, ensure that patients receive initial instruction in, and routine follow-up evaluation of, SMBG technique and their ability to use data to adjust therapy.”

The following features may 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 (ADA, 2011; ADA, 2008; ECRI, 2008)

U.S. Food and Drug Administration (FDA): The standard glucose monitor and test strips are approved under the Class II, 510(k) process for the purpose of providing quantitative measurement of glucose in whole blood. Examples of home blood glucose meters approved by the FDA include: Accu-Chek[®] (Roche Diagnostics, Indianapolis, IN), Freestyle[®] (Therasense, Inc., Alameda, CA), Ascensia[®] (Bayer HealthCare, Mishawaka, IN), and One Touch[®] (LifeScan, Inc., Milpitas, CA).

Literature Review: As recommended by the ADA, the use of SMBG is an established, primary technique available for diabetic patients to assess blood glucose levels. The evidence in the published peer-reviewed scientific literature including meta-analysis, systematic reviews, randomized controlled trials and case series reported statistically significant decreases in hemoglobin A1c (HbA1c) in SMBG subjects, increased regularity of medication usage, improved glucose control and better metabolic control in type 1 and type 2, insulin and non-insulin treated diabetics (Schutt, et al., 2006; Sarol, et al., 2005; Welschen, et al., 2005; Soumerai, et al., 2004).

Professional Societies/Organizations: The National Institute for Clinical Excellence (NICE) (United Kingdom) (2008c) recommended SMBG by type 1 adult diabetics in conjunction with appropriate insulin regimens and diabetic education. Meters and strips should be chosen based on the needs of each individual patient. The frequency of SMBG depends on the characteristics of the individual’s glucose control, the insulin regimen, and personal preferences in using results to achieve desired lifestyle. Regarding the management of type 2 diabetes, NICE (2008a) recommended that SMBG be available to newly diagnosed diabetics, individuals who are insulin-treated or are on oral glucose lowering medications to assess changes in glucose control resulting from medications and lifestyle changes, to monitor changes during intercurrent illness, and to ensure safety during activities.

Enhanced Feature Glucose Monitors

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 speaking in

Spanish and data management systems (ADA, 2011; ADA, 2008). The Prodigy Voice™ Glucose Meter (Diagnostic Devices, Inc., Deerfield, IL) is an example of an FDA-approved audio blood glucose monitor.

Home Continuous Glucose Self-Monitoring (CGM)

A proposed alternative to intermittent SMBG is continuous glucose monitoring (CGM). CGM devices provide ongoing, real-time monitoring and recording of blood glucose levels by continuous measurement of interstitial fluid which generally lags from three to 20 minutes behind finger-stick values. Therefore, CGM is only to be used with finger-stick blood glucose monitoring. The continuous glucose monitoring system (CGMS) consists of a sensor, transmitter and receiver. Some monitors provide real-time information, while others require that data be downloaded and reviewed retrospectively. Depending on the device, a sensor may be worn for 3–7 days before it must be changed.

CGM may be used by treating physicians as a one-time evaluation tool (i.e., 72-hour, three-day period) for type 1 and type 2 insulin-treated individuals who are experiencing hypo- or hyperglycemic episodes unresponsive to adjustments in therapy (e.g., insulin administration and nutrition). It may also be used to detect asymptomatic nocturnal hypoglycemia and for lowering A1c levels without risking severe hypoglycemia (Behrman, 2004). The 72-hour recording may identify fluctuations in blood glucose levels that were not detected by intermittent fingersticks. This data allows adjustments to be made in the therapeutic regimen (e.g., oral medication, insulin therapy, diet, exercise) to minimize glucose excursion. Repeat 72-hour assessments may be needed periodically until the individual stabilizes and achieves ideal treatment targets (Inzucchi and Sherwin, 2007).

It has also been proposed that CGM be used on a long-term basis for the treatment of type 1 diabetics. The ADA and a recent clinical trial by the Juvenile Diabetes Research Foundation (JDRF) support the use of long-term CGM in type 1 diabetics age 25 years or older. A reduction of up to 1.0% in the A1c level has been reported. One of the reasons for better outcomes in older individuals is because they are typically more compliant in the use of CGM than adolescents and children. In individuals less than age 25 years, CGM has been shown to be effective in those who experience severe episodes of hypoglycemia with a blood glucose level < 50mg/dL not corrected by adjustments in conventional therapies (e.g., SMBG four or times per day, insulin therapy). Although the limited number of clinical trials with short-term follow-ups are lacking in strong, definitive conclusions, the evidence is suggestive of improved clinical outcomes including normalization of A1c levels and a reduction of hypoglycemic episodes. Professional societies and organizations (e.g., American Association of Clinical Endocrinologists, ADA and NICE) state that CGM may have a role in the ongoing assessment and management of this subgroup of type 1 diabetics.

Long-term use of CGM may also be indicated in a subgroup of type 2 diabetics who are producing minimal amounts of insulin (i.e., insulinopenia). One way to determine the insulin level in the body is by using a blood test called a connecting peptide (C-peptide) test. C-peptide is a polypeptide of 31 amino acids and a byproduct of insulin production. The level of C-peptide in the body reflects the amount of insulin being produced. Type 2 diabetics with an extremely low C-peptide level may be considered to have a “burned-out pancreas,” act like a type 1 diabetic, and benefit from an intense insulin regimen. Insulinopenia is diagnosed in less than 5% of type 2 diabetics. A fasting C-peptide level that is $\leq 110\%$ of the lower limit of normal of the laboratory’s measurement method and a concurrently obtained fasting glucose of ≤ 225 milligrams/deciliter (mg/dL) is indicative of insulinopenic type 2 diabetes mellitus. In patients with compromised renal function, a creatinine clearance (actual or calculated from age, gender, weight and serum creatinine) ≤ 50 milliliters (mL)/minute, and a fasting C-peptide level that was $\leq 200\%$ of the lower limit of normal of the laboratory’s measurement methods is indicative of insulinopenia. For example, if the laboratory normal C-peptide range was 0.78–1.89 nanograms/milliliter (ng/mL) then the insulinopenic type 2 diabetic without renal insufficiency would have a value of ≤ 0.86 ng/mL and with renal sufficiency would have a value of ≤ 1.56 ng/mL. This subset of individuals may be candidates for CGM (Centers for Medicare and Medicaid [CMS], 2005; CMS, 2001).

U.S. Food and Drug Administration (FDA): Continuous glucose monitors require FDA premarket approval (PMA). CGMS are used only as an adjunct to SMBG and should never replace or be used instead of SMBG. Some monitors provide a sensor that records data for 72 hours and are intended for occasional rather than everyday use. Examples of this device are Medtronic’s IPro™ Professional CGM and the CGMS® System Gold™ Continuous Glucose Monitoring System (Medtronic MiniMed, Inc., Northridge, CA). Other monitors provide data for up to five to seven days, such as the DexCom™ SEVEN PLUS Continuous Glucose Monitoring System (DexCom, Inc., San Diego, CA), the Medtronic Guardian® REAL-Time Continuous Glucose Monitoring System, and the FreeStyle Navigator® Continuous Glucose Monitoring System (Abbott Diabetes Care, Alameda, CA).

Literature Review: The evidence in the peer-reviewed literature supports the 72-hour CGM when used in conjunction with SMBG to aid in the management of insulin dependent diabetics who are difficult to control and not achieving treatment targets. Studies including type 1 and type 2 adult and child diabetics have been in the form of systematic reviews and meta-analysis, randomized controlled trials and case series (Chetty, et al., 2008; Golicki, et al., 2008; Yoo, et al., 2008; Weber, et al., 2007; Zisser, et al., 2007; Deiss, et al., 2006a; Garg, et al., 2006; Lagarde, et al., 2006; Chico, et al., 2003; Ludvigsson, et al., 2003; Chase, et al., 2001).

Evidence also supports the safety and efficacy of long-term CGM in the management of type 1 diabetics age 25 years or older, a subgroup of type 1 diabetics who are less than age 25 years, and type 2 diabetics with uncontrolled blood glucose levels despite appropriate management and adherence to a prescribed diabetic regimen. Randomized controlled trials, comparative studies and case series typically reported reductions in A1c levels that were maintained through out the studies, as well as fewer hypo- and hyperglycemic events (Juvenile Diabetes Research Foundation [JDRF], 2009a; JDRF, 2009b; Newman, et al., 2009; Rodbard, et al., 2009; JDRF, 2008; Mazze, et al., 2008; Weinzimer, et al., 2008b; Deiss, et al., 2006b; Wilson, et al., 2007; Bailey, et al., 2007; Diabetes Research in Children Network [DirecNet] Study Group, 2007; Garg, et al., 2007; Ludvigsson, et al., 2003).

Chase et al. (2010) reported on the 12-month follow-up of patients age 8–17 years (n=80) who participated in the Juvenile Diabetes Research Foundation CGM randomized controlled trial. Patients with type 1 diabetics on an insulin pump or three daily insulin injections with an A1c of 7.0% to < 10% were randomized to either a CGM or SMBG. At the end of six months, 76 patients were using CGM a median of 5.5 days per week. Only 44% of patients were using CGM ≥ 6 days per week at six months. At 12 months, 67 patients were using CGM a median of 4.0 days/week, and 17 patients (18%) were using CGM ≥ 6 days per week. Use of CGM ≥ 6 days per week was more likely in younger children (ages 8–12 years) (n=42) than in adolescents (ages 13–17 years) (n=38). Compared to baseline A1cs, the patients who used CGM ≥ 6 days per week had a significantly greater improvement in A1c (p<0.001) than patients who used CGM less than six days per week. Patients who used CGM ≥ 6 days per week the first six months and not the last six months lost most of the A1c benefit gained in the first six months. There was a low incidence of severe hypoglycemia in all patients. Patient satisfaction with CGM was significantly higher (p<0.001) in those who used CGM ≥ 6 days per week. Based on the results of this study, the authors noted that for CGM to “achieve more widespread and consistent use in pediatrics, future generations of devices will need to be simpler to use, less painful to insert, and more accurate and reliable with fewer false alarms, especially at night.” The data indicated that “protocol aimed at optimizing the implementation of CGM in pediatric populations through provision of realistic expectations and ongoing education and emotional support” is needed.

In a 2010 technology assessment, ECRI concluded that CGM when used by type 1 and type 2 diabetics as an adjunct to SMGB “may provide a significant benefit if tighter control is achieved.” A significant improvement in mean difference in A1c values plus patient-oriented outcomes of severe hypoglycemic events and life style improvement were reported. They also noted that the evidence (five trials) only allowed for a qualitative conclusions regarding improved glycemic control. A quantitative conclusion regarding how much glycemic control improved was not evident.

Professional Societies/Organizations: The ADA’s 2011 standards of care for the treatment and management of diabetes mellitus include the following recommendations for CGM:

- “Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1c in selected adults (age ≥ 25 years) with type 1 diabetes.
- Although the evidence for A1c lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device.
- CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes.”

They also list the initiation of CGM as a treatment option for individuals when treatment goals are not met.

Based on the available evidence and expert opinion, the 2010 consensus statement on CGM by the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) included the recommendations listed below and are intended as a “a guide to decision making.” They also noted that there

was not enough evidence to identify the patients that would most likely experience the best outcomes and longer-term studies (3- to 5-year) are needed to assess CGM durability beyond 6 to 12 months. AACE stated that “although the evidence supporting the use of personal CGM is derived from studies in patients with type 1 DM [diabetes mellitus], it is reasonable to expect that similar results would be seen in patients using basal-bolus insulin regimens or CSII.”

Personal CGM is recommended for the following patients:

- “Those with type 1 DM and the following characteristics:
 - “Hypoglycemic unawareness or frequent hypoglycemia
 - Hemoglobin A1c (HbA1c) over target, or with excess glycemic variability (e.g., hypoglycemia judged to be excessive, potentially disabling, or life-threatening)
 - Requiring HbA1c lowering without increased hypoglycemia
 - During preconception and pregnancy
- Children and adolescents with type 1 DM who have achieved HbA1c levels less than 7.0% (these patients and their families are typically highly motivated)
- Youth with type 1 DM who have HbA1c levels of 7.0% or higher and are able to use the device on a near-daily basis.

The following patients might be good candidates for personal CGM, and a trial period of 2 to 4 weeks is recommended:

- youth who frequently monitor their blood glucose levels
- committed families of young children (younger than 8 years), especially if the patient is having problems with hypoglycemia

Intermittent use of professional CGM may be useful for youth with type 1 DM who are experiencing changes to their diabetes regimen or have problems with:

- nocturnal hypoglycemia/dawn phenomenon
- hypoglycemia unawareness
- postprandial hyperglycemia”

In their consensus statement on glycemic control for type 2 diabetics, the AACE and ACE (2009) stated that CGM may be considered for the management of type 2 diabetics who are receiving insulin and the disease is otherwise difficult to control. CGM may help to “educate the patient regarding the glycemic effects of various foods, help the patient titrate insulin, and provide warnings when the patient is experiencing hyperglycemia or hypoglycemia.

NICE (2010) stated that CGM has a role in the treatment of adults with consistent glucose control problems such as repeated hyper- or hypoglycemia at the same time of day, or hypoglycemia unawareness that is unresponsive to conventional insulin dose adjustment. For type 1 diabetic children and young adults, NICE concluded that CGMS “should be offered” to children and young adults with persistent hypoglycemia unawareness or repeated hypo- or hyperglycemic episodes.

Continuous Glucose Monitoring in Pregnancy

Management of diabetes during pregnancy (maternal diabetes) is essential for healthy outcomes for the mother and the infant. An individual with preexisting type 1 or type 2 diabetes mellitus may become pregnant or a woman can develop diabetes during the pregnancy (i.e., gestational diabetes). Gestational diabetes typically subsides following delivery. Uncontrolled diabetes during pregnancy can be associated with miscarriage, pre-eclampsia, preterm labor, stillbirth, congenital malformations and other complications. Both 72-hour and long-term CGM have been proposed for use during pregnancy (Kitzmilller, et al., 2008; NICE, 2008b).

Literature Review: Murphy et al. (2008) conducted a randomized controlled trial to compare the outcomes of type 1 (n=46) and type 2 (n=25) diabetic women, age range 16–45 years, who used CGMS (n=38) compared to SMBG (n=33) during pregnancy. CGM was performed for up to seven days at 4–6 week intervals, between 8–32 weeks’ gestation. Data were downloaded and reviewed during follow-up visits and, in correlation with SMBG values, adjustments were made to diet, exercise and insulin therapy as indicated. The CGMS was used 0–8 times, mean 4.2 times, with 80% of the women wearing the monitor at least once per trimester. No significant differences were found in the mean A1c level between the two groups prior to week 32, but the CGM group had

a consistently lower A1c level. A significant difference in A1c was seen between 32–36 weeks' gestation with the CGMS group having a lower mean A1c ($p=0.007$). Although not statistically significant, the CGMS group had a trend toward reduced emergency caesareans ($p=0.08$). There was no significant difference in infant morbidity between the two groups. Compared with healthy singletons of women in the SMBG group ($n=30$), women in the CGMS group ($n=32$) had significantly decreased mean birth weight standard deviation scores ($p=0.05$) and median birth weight centiles ($p=0.02$). Thirteen infants in the CGMS group compared to 18 infants in the SMBG group were macrosomic ($p=0.05$). The study suggested that the use of CGMS during pregnancy was associated with third-trimester improved glycemic control, lower birth weights and reduced risk of macrosomia. Author-noted limitations of the study included: the health professionals were not blinded, the small patient population, women were predominantly of white European ethnicity, and “differences in the maternal characteristics with longer duration of diabetes in the intervention group.”

Kestilä et al. (2007) conducted a randomized controlled trial to compare CGM ($n=36$) to SMBG ($n=37$) in detecting patients with gestational diabetes mellitus (GDM) who needed antidiabetic drug treatment. High-risk pregnant women at 22–34 gestational weeks who had at least two abnormally high glucose values on oral glucose tolerance testing were included in the study. The mean CGM period was 47.4 ± 2.5 hours. SMBG was performed at least five times per day. Treatment modalities were offered within five days of monitoring. As a result of CGMS, 11 women were treated with either oral agents or insulin compared to three patients in the SMBG group ($p=0.0149$). Within the CGM group, SMBG values were compared to the CGM values, and five SMBG patients were identified with indications for antihyperglycemic treatment compared to 16 CGM patients.

McLachlan et al. (2007) conducted a 72-hour CGM study as a tool for medical decision-making ($n=68$) in pregnant women with diabetes. The CGM detected postprandial hyperglycemia that was not detected or was underestimated by SMBG. Compared to SMBG, 42 of 63 CGM studies provided additional information (e.g., postprandial elevation, hyperglycemia and hypoglycemia), more so in GDM and type 1 diabetics compared to type 2 diabetics. The authors noted that a limitation of the study was that all targeted women did not agree to participate.

Professional Societies/Organizations: Regarding pregnancy, NICE (2008b) stated that CGM has been proposed to help identify women in whom short-term postprandial peaks of glycemia are not detected by SMBG which may help reduce the incidence of adverse outcomes of pregnancy (e.g., fetal macrosomia, caesarean section and neonatal hypoglycemia) through adjustments in therapy. However, they stated that there is a lack of evidence to assess the effectiveness of CGM in preconception or during pregnancy.

Data Management Systems

Although data management systems offer convenience in tracking test results and glucose levels, the ADA (2008) stated that the systems are not a necessity and a “well-kept, handwritten logbook may provide all the information necessary.” Disadvantages of these systems include the complexity, time and labor intensiveness of downloading the data (Laffel, et al., 2006). There is insufficient evidence in the peer-reviewed literature to support that data management systems improve diabetic management. Due to the limitations of the available studies (e.g., lack of randomization, heterogeneous patient populations, various outcome measures, participant attrition) the benefits of data management systems in overall health outcomes in the treatment of diabetes mellitus is unknown (Costa, et al., 2009).

U.S. Food and Drug Administration (FDA): Data management systems are approved as an FDA 510(k) Class II device. An example is the Animas ezManager[®] Plus Diabetes Management Software (Animal Corporation, West Chester, PA) which is intended for use with Animas glucose meters to support diabetes management by the patient and/or health professional to allow for review, analysis and evaluation of blood glucose history information.

Literature Review: Laffel et al. (2007) conducted a randomized controlled trial ($n=205$) to evaluate glycemic control in insulin-treated patients who utilized an integrated glucose meter and electronic logbook compared to patients who used a conventional glucose meter and paper logbook. Type 1 and type 2 adult and pediatric patients ($n=70$) were recruited from seven centers to participate in the study. Participants were either using continuous insulin infusion or multiple daily injections of insulin, performing SMBG two or more times a day, and had an A1c $\geq 8\%$ with stable glycemic control. During the first four weeks, all patients used their glucose monitor and written logbooks. At week four, patients were randomized to either a glucose monitor and written logs (i.e., paper group) ($n=92$) or to an integrated glucose meter/logbook (i.e., electronic group) ($n=113$). Follow-up visits

occurred at four, eight, 12, 16 and 20 weeks. Upon completion of the study, mean A1c decreased -0.27% in the paper group compared to -0.35% in the electronic group ($p=0.022$). Pediatric patients also demonstrated similar results ($p=0.024$). The electronic group reported performing more average daily SMBG checks than the paper group ($p=0.03$). There was no significant difference in the mean amplitude of glycemic excursion between the two groups, but the rate of reported hypoglycemic events was lower in the paper group ($p<0.0001$). A total of 104 patients were available for a follow-up visit at 66 weeks, and patients were identified by four subgroups (i.e., group 1a had continued with meter/paper log since the 20-week visit; group 1b switched to integrated meter/electronic log; group 2a continued with integrated meter/electronic log; and group 2b switched to meter/paper log). Between the four-week follow-up visit and the 66-week follow-up visit, mean A1c decreased significantly in those who continued using the electronic logbook ($p=0.008$) compared to the other three subgroups who experienced an increase. A1c levels returned to the pre-trial level in these three groups. There was a statistically significant difference in mean A1c in those who used paper logbooks the entire time compared to those who used the electronic logbooks ($p=0.006$). The same trend was seen among the pediatric patients ($p=0.053$). From the last study visit to the 66-week visit, A1c increased in all groups. Limitations noted by the authors included short-term follow-up, neither patients or providers could be fully blinded, the “greater reduction in A1c in the electronic group may have yielded a greater number of measured hypoglycemic episodes,” the increased recognition of hypoglycemic episodes in the electronic users may have resulted from more frequent monitoring and detection of events, and the choice of switching was made by the patient and provider. The authors noted that, although significant, the differences between the two study groups from the end of the RCT and the absolute reductions in A1c were modest and stated that additional studies were needed to confirm the outcomes of this study.

Alternative Site Testing

Monitors are available that allow only alternative site testing (AST) which involves drawing the blood sample from sites that are less sensitive than fingertips (e.g., fleshy parts of the hand or thenar, upper arm, thigh, or calf). AST is proposed to be less painful and may decrease anxiety of SMBG for new diabetics and children. The blood glucose values obtained from these sites may differ from those obtained from the finger especially at certain times of the day (e.g., after a meal). Not all alternative site testing meters are FDA approval for each site. Other devices obtain glucose measurements from interstitial fluid (ISF) using various techniques. One technique involves reverse iontophoresis in which an electrical current is used to draw ISF, along with glucose, to the surface of the skin to be collected and tested. Another method involves use of a laser to create micropores in the dead layer of the skin from which ISF can be drawn allowing the glucose level to be read using an adhesive patch. Most of these devices are not intended to replace finger-stick SMBG and abnormal readings should also be verified using a blood glucose monitor (ECRI, 2008).

There are a number of concerns about AST 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 may put diabetic patients at risk for infection due to decreased blood flow. The FDA (2009) stated that further research is needed to better understand the differences in test values between readings of AST monitors and fingerstick type monitors, as well as discrepancies' possible impact on the health of diabetic patients. The ADA states that alternate site testing may be used when an individual's blood glucose is not changing (e.g., before a meal). However, because “measurements taken from the fingertips reflect your “real time” glucose levels, whereas the glucose levels in alternate sites take 20 to 30 minutes to catch up” finger stick testing should be used after a meal, or during a hypoglycemic episode (ADA, 2008a). Insufficient evidence exists in the peer-reviewed literature to support the safety and efficacy of AST monitors.

U.S. Food and Drug Administration (FDA): Many 510(k) FDA-approved finger-stick glucose monitors also include AST capability, but there are some monitors that are AST only and do not have finger-stick capabilities. An example of an AST-only monitor approved by the FDA is the AtLast Meter (Amira Medical, Scotts Valley CA).

Literature Review: Lucidarme et al. (2005) conducted a study with 29 children, age range 5–17 years, with type 1 diabetes for at least one year, who performed SMBG ≥ 3 times per day. Patients were randomized to two consecutive eight-day periods during which two sampling sites were used, the thenar and the forearm. At the end of the 16-day period, patients were allowed to choose between fingertip and AST for a month and were then asked if AST was better. Fingertip testing was more accurate than forearm during hypoglycemia. Sixty-six percent of patients preferred AST at the end of the first 16 days, and, at the end of the study, 73% reported that AST was better. The authors reported that this is the first study of AST in children under real-life conditions.

They concluded that thenar and forearm sampling were reliable, but the forearm should not be used during hypoglycemia or high-risk hypoglycemia conditions.

In their guidelines for the management of diabetes in type 1 adults, NICE (2008c) does not recommend the use of alternate site testing (i.e., sites other than the finger tips) as a “routine alternative to conventional self-blood glucose monitoring.”

GlucoWatch® G2™ Biographer

The GlucoWatch® G2™ Biographer (Cygnus, Inc., Redwood, CA) is an FDA, PMA CGMS that is worn on the wrist like a watch and takes noninvasive glucose measurements through the skin every 10 minutes for up to 13 hours at a time. It is approved for use in patients seven years and older. After a two-hour warm-up period and calibration, the GlucoWatch begins monitoring by producing an electrical current that pulls fluid from the skin and measures the glucose in the fluid. It has a high/low glucose alarm feature (FDA, 2002).

Literature Review: The overall evidence in the published peer-reviewed literature in the form of randomized controlled trials (Newman, et al., 2010; Chase, et al., 2005; Chase, et al., 2003) indicates that the use of the GlucoWatch resulted in minimal or no significant improvements in glycemic control or in a reduction in the occurrence of hypoglycemic attacks. Use of the device was associated with skin irritation, edema, erythema, skipped readings, false alarms, and inaccurate results (Weinzimer, et al. 2008a; Ellis, et al., 2007; Klonoff, 2007).

Other Home Blood Glucose Monitors

Some monitors combine a standard finger-stick blood glucose meter with non-medical devices and/or non-diabetic testing capabilities. Examples of these monitors include a finger-stick meter combined with a cellular telephone (e.g., GlucoPack™, HealthPia America Corp., Newark, NJ), a blood pressure monitor (e.g., Advocate DUO, Diabetic Supply of Suncoast, Taipei County, Taiwan), and a cholesterol screening analyzer (e.g., CardioChek PA Analyzer, Polymer Technology Systems, Inc. Indianapolis, IN). These devices are considered convenience items for the individual and not medically necessary in the treatment of diabetes mellitus.

Summary

Self-monitoring of blood glucose (SMBG) is an integral component of diabetes management, provided that the patient or caregiver is given instruction in technique and is capable of using the data to adjust therapy. While conventional monitors are adequate for most individuals, continuous self-monitoring of glucose is appropriate for a carefully selected subset of individuals.

There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of alternative site testing (AST) blood glucose monitors or the GlucoWatch. The use of these devices has not been proven to have an impact on meaningful net health outcomes. The use of data management systems has also not been shown to improve health outcomes. Finger-stick blood glucose monitors combined with non-medical devices (e.g., cellular phones) or non-diabetes related testing capabilities (e.g., blood pressure monitor) are considered a convenience and not medically necessary in the treatment of diabetes mellitus.

Coding/Billing Information

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

Covered when medically necessary:

CPT®* Codes	Description
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum 72 hours; physician interpretation and

	report
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HCPCS Codes	Description
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
E0607	Home blood glucose monitor
E2100	Blood glucose monitor with integrated voice synthesizer
E2101	Blood glucose monitor with integrated lancing/blood sample
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)

ICD-9-CM Diagnosis Codes	Description
250.00-250.93	Diabetes mellitus
648.00-648.04	Maternal diabetes mellitus, complicating pregnancy, childbirth, or the puerperium
648.80-648.84	Gestational diabetes

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

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3. American Association of Clinical Endocrinologists (AACE). Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology Consensus Panel on type 2 diabetes mellitus: An algorithm for glycemic control. Sep/Oct 2009. Accessed Jan 20, 2011. Available at URL address: <http://www.aace.com/pub/positionstatements/>
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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	9/15/2008	0106	Home Blood Glucose Monitors
Great-West Healthcare	6/21/2007	02.206.03	Continuous Glucose Monitoring (CGM) Systems

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