



CIGNA MEDICAL COVERAGE POLICY

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

Effective Date 8/15/2009
Next Review Date 8/15/2010
Coverage Policy Number 0126

Subject **Diabetic Supplies**

Table of Contents

Coverage Policy	1
General Background	2
Coding/Billing Information	6
References	7
Policy History	10

Hyperlink to Related Coverage Policies

Diabetes Self-Management Education
 External Insulin Pumps
 Foot Care Services
 Home Blood Glucose Monitors

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. 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 Policies are based. For example, a participant'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 participant'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 group 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 ©2009 CIGNA

Coverage Policy

Under some benefit plans, coverage for needle-free insulin injection systems is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. In addition, diabetic supplies may be governed by state mandates. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

If coverage for diabetic supplies is available, the following conditions of coverage apply.

CIGNA covers needle-free insulin injection systems or jet injectors as medically necessary when EITHER of the following criteria is met:

- The individual has needle phobia.
- The individual/caregiver is unable to use standard syringes.

CIGNA covers ALL of the following diabetic supplies as medically necessary under the pharmacy benefit (copay applies):

- alcohol wipes
- blood test strips (glucose/ketone)

- insulin pens (medical necessity criteria may apply)
- needles and syringes for insulin administration
- standard lancets
- urine test tablets/strips (glucose/ketone)

CIGNA does not cover the use of a home glycosylated serum protein (GSP) monitor because its use is considered experimental, investigational or unproven.

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

- home glycosylated hemoglobin (A1C) monitors
- insulin infusers (e.g., I-Port™)
- laser lancets

General Background

Diabetes mellitus (DM) is a disease characterized by hyperglycemia resulting from abnormal insulin secretion and/or abnormal insulin action within the body. Chronic hyperglycemia, resulting from poorly controlled diabetes, may result in serious and life-threatening damage, including dysfunction and failure of the eyes, kidneys, nervous system and cardiovascular system. The presence of insulin, a hormone, is essential for the body to convert sugar, starches and other foods into energy.

There are three major types of diabetes mellitus: type 1, type 2, and gestational diabetes mellitus (GDM). Type 1 diabetes, insulin-dependent diabetes, or juvenile-onset diabetes, is an autoimmune disease and involves pancreatic β -cell destruction, failure of the body to produce insulin and total insulin dependence. Ketoacidosis may be the first manifestation of type 1 DM. Type 1 diabetes is strongly inherited and occurs in 5–10% of cases. Type 2 diabetes, adult-onset diabetes or non-insulin dependent diabetes, includes those individuals who are insulin resistant (i.e., the body fails to use insulin properly). Type 2 diabetics normally do not require insulin therapy. Type 2 diabetics are typically controlled with diet, exercise and in some cases, oral hypoglycemic agents are indicated. GDM develops during pregnancy and involves a degree of glucose intolerance. It generally subsides after delivery.

Diabetes is diagnosed and monitored by routine testing of blood glucose levels, glycosylated hemoglobin (HbA1c or A1C), plasma insulin levels and glycosuria. As a guide to adjustments in therapy (i.e., diet, exercise and medication), monitoring of blood glucose levels is a cornerstone of diabetes care (Goldstein, et al., 2004).

Self-management of diabetes is essential for the control of the disease and curtailing irreversible dysfunction and possible failure of multiple body systems. To assist diabetics in self-management of their care, diabetic supplies such as needles, syringes, needle-free insulin injection devices, insulin pens, test strips (i.e., glucose and ketone), lancets and alcohol wipes may be indicated.

Needle-Free Insulin Injection Systems/Jet Injectors

Alternatives to needles and syringes for insulin administration are needle-free insulin injection systems, also called jet injectors. These devices eject a high speed, narrow stream of insulin through a fine-holed nozzle that forces the insulin to penetrate the skin subcutaneously. The devices deliver 0.5–100 units of insulin with force produced by a powerful spring mechanism or by compressed carbon dioxide. Some injectors are single-dose (i.e., disposable cartridge jet injectors [DCJIs]) and may be totally disposable, while others have a disposable reservoir and nondisposable actuation mechanism. Use of jet injectors has been associated with consistently lower blood glucose levels, shortened peak action of regular insulin, reduced insulin requirements, more rapid absorption of short-acting insulin, and reduced occurrence of hyperglycemia. These injectors offer an advantage for patients unable to use syringes or those with needle phobias. The limitations of the devices include bruising and/or bleeding at the injection site. Jet injectors are not suitable for every patient with diabetes. Many patients are deterred by the noise the injector makes on delivery, the bulky size, the need to carry a vial, and the frequent maintenance and cleaning that the jet injectors require (ADA, 2008c; Baxter and Mitragotri, 2006; Robertson, et al., 2000).

Jet injectors are Class II, 510(k) U.S. Food and Drug Administration (FDA)-approved devices, described as nonelectrically powered fluid injectors. Examples of jet injectors approved by the FDA include the J-Tip[®] Needleless Injector (National Medical Products, Inc., Irvine, CA) and the Biojector[®] 2000 (Bioject, Inc., Portland, OR).

The ADA states that jet injection of insulin may be an appropriate alternative to conventional needle injection for carefully selected patients in the following situations:

- patients with needle phobia, since jet injectors may reduce their anxiety by making them more willing to self-administer multiple daily injections of insulin in order to maintain glycemic control and reduce the risk of long-term complications
- patients or caretakers who are unable to perform insulin injection by standard syringe (e.g., those who may be neurologically impaired)

They state that the use of jet injectors may result in more rapid absorption of short-acting insulin, and may cause trauma/bruising to the skin (ADA, 2007; ADA, 2004a).

Blood and Urine Glucose Testing

Self-monitoring of blood glucose (SMBG) has replaced urine glucose testing for most patients because urine glucose testing provides only a rough estimate of prevailing blood glucose levels. Urine glucose testing in the home setting consists of semi-quantitative measurements based on single voiding or, less often, by more quantitative blocks collected over 4–24 hours. The rationale for its use is that urinary glucose values reflect mean blood glucose during the period of urine collection. Urine testing is less accurate than blood glucose monitoring and does not provide a complete picture of diabetes. A urine test does not depict the presence of glucose until the blood glucose level is above 180 milligrams per deciliter (mg/dl), making the test useless in monitoring for hypoglycemia. For these reasons, SMBG is the preferred method of monitoring glycemic status on a daily basis (ADA, 2008d; American Association of Clinical Endocrinologists (AACE), 2007; National Institute for Health and Clinical Excellence [NICE], 2004a).

Insulin Pens

Insulin pens are another alternative to the standard needle and syringe. Several pen-like needle devices and insulin cartridges are available for the administration of subcutaneous insulin. They may be used by patients on a multidose regime, and can also be helpful for the visually impaired, active individuals and patients with a lack of coordination. In many patients, the pens have been demonstrated to improve accuracy in insulin administration and/or adherence. The devices, resembling a large pen, have a fine needle under the cap and a plunger at the other end. They are prefilled with insulin or have disposable or reusable insulin cartridges. Some pens have dials on them to assist the patient in selecting accurate dosage (e.g., Novolin[®] InnoLet[®], Novo Nordisk, Inc., Princeton, NJ) (ADA 2008c; Stockl, et al., 2007; Salsali and Nathan, 2006; ADA, 2004a; Robertson, et al., 2002).

Several insulin pen models have been FDA 510(k) approved, including the Autopen[®] (Ulster Scientific, Inc., New Paltz, NY), B-D Pen[®] (Becton, Dickinson & Co., Franklin Lakes, NJ) and the NovoPen[®] (Novo Nordisk, Inc., Princeton, NJ).

Blood and Urine Ketone Testing

Ketone bodies, by-products of the burning of fat in the absence of insulin, can build up and cause serious complications, including diabetic ketoacidosis (DKA), a condition that requires immediate medical attention. Three types of ketone bodies develop during DKA: β -hydroxybutyrate (β -HB), acetoacetate and acetone. The two methods of assessing and monitoring for ketone bodies are the semi-quantitative estimation of acetoacetate and acetone levels in the urine which are based on a nitroprusside reaction on urine dip sticks and the measurement of β -HB in capillary blood based on an enzymatic reaction on a ketone finger-stick blood strip. Ketones will be present in the urine when the blood level of ketones surpass a certain threshold and can be detected by ketone urine test strips. Acetoacetic and β -HB are reabsorbed by the renal tubules and their final concentration in the urine exceeds that in the blood. The presence of urine ketones may be present long after blood levels have normalized. Ketone testing is indicated in the following situations: type 1 diabetics with a blood glucose greater than 240 mg/dl; all diabetics who are ill, under stress or have a blood glucose over 300 mg/dl; any diabetic exhibiting signs of ketoacidosis, such as nausea, vomiting, or abdominal pain; when blood glucose

levels are consistently elevated; and in pre-existing pregnancy diabetes and gestational diabetes mellitus. In a 2004 position statement on the tests of glycemia, the ADA states that “blood ketone testing methods that quantify β -hydroxybutyric acid, the predominant ketone body, are available and are preferred over urine ketone testing for diagnosing and monitoring ketoacidosis. Home tests for β -hydroxybutyric acid are available”. In their discussions of ketone testing, the ADA and the AACE indicate that either blood or urine ketone testing are appropriate when ketone testing is indicated (Weber, et al., 2009; ADA, 2009; ADA, 2008d; Laffel and Wood, 2008; AACE, 2007; NICE, 2004; ADA, 2004b).

Laffel et al. (2006) conducted a randomized controlled trial to assess sick day management in type 1 diabetic children (n=123) using blood ketone testing (3-hydroxybutyrate [3-OHB]) compared to urine ketone testing. The patients were randomized to either the blood ketone (n=62) or urine ketone group (n=61), and instructed on sick day guidelines. Follow-up visits occurred at three months and six months. The number of times each group checked their glucose levels and ketone levels and the monitoring frequencies during hyperglycemia were not significantly different. There were 274 self-reported sick days in the urine group and 304 in the blood group. The frequency of ketone monitoring during sick days was significantly higher ($p < 0.001$) in the blood group (90.8%) compared to the urine group (61.3%). There were no significant differences in the baseline, three-month, or six-month A1C values between the two groups. In the blood ketone group, 97.7% of 3-OHB levels were within the ≤ 0.5 millimoles/liter (mmol/L) reference range, 2.3% were > 0.5 mmol/L, and 1.6% were ≥ 1.0 mmol/L. Virtually all 42 elevated blood ketone results occurred either with hyperglycemia or during illness, confirming the specificity of blood 3-OHB determination for uncovering impending ketosis or DKA. Forty-four of 102 positive urine ketone tests occurred with hyperglycemia or during sick days, indicating the potential for false positives. Analysis of the frequency of positive ketonuria and hyperketonemia during persistent hyperglycemia and during sick days revealed that the urine ketones were positive 4.2% compared to 3.3% of blood ketones > 0.5 mmol/L. During sick days, 15.5% of urine ketones were significantly elevated compared to 7.2% of blood ketones ($p < 0.01$). There were 60% fewer hospitalizations and 40% fewer emergency assessments in the blood group compared to the urine group. In the urine group, the rate of acute complications was significantly higher ($p = 0.05$) (75 per 100 patient-years) compared to the blood group (38 per 100 patient-years). Seventy percent of the blood ketone group participants reported that they preferred the blood ketone testing.

Home Glycated Hemoglobin (A1C) Monitors

Glycated hemoglobin (GHb) (also referred to as glycohemoglobin, glycosylated hemoglobin, HbA1c, HbA1, or A1C) is a term used to describe a series of stable minor hemoglobin components formed from a combination of hemoglobin and glucose. It is used primarily to identify the plasma glucose concentration over time. The normal life span of the red blood cell (RBC) is 120 days. Once hemoglobin is glycated, it remains that way. During the life cycle of the RBC, there is a build-up of glycated hemoglobin, reflecting the glycemic history of the previous 120 days. The A1C test has been shown to predict the risk for development of many of the chronic complications in diabetes and is performed routinely in patients with diabetes (e.g., twice a year in patients who are meeting goals, and quarterly in patients whose therapy has changed or who are not meeting goals). Based on the evidence, the ADA recommends that the goal of therapy for nonpregnant adults, in general, should be an A1C result of $< 7\%$. Less stringent A1C goals may be appropriate for patients with limited life expectancies, very young children, older adults and patients with comorbid conditions. The goal of therapy is to achieve and maintain an A1C as close to normal as possible without the patient experiencing hypoglycemic episodes. Home glycated hemoglobin monitors are not medically necessary because A1C testing can be performed during regularly scheduled office visits, where health care providers can properly interpret the test and modify the treatment plan as necessary (ADA, 2009; NICE 2004).

Home glycated hemoglobin tests include FDA 510(k) approved products, such as the A1c At-Home™ (Flex Side Diagnostics, Inc., Palm City, FL) and the AccuBase A1c Glycohemoglobin Test Kit™ (Diabetes Technologies, Inc., Thomasville, GA).

Insulin Infusers

An insulin infuser is a device in which a cannula is inserted under the skin creating a portal that remains in place for 3–4 days. The presence of the cannula allows the patient to insert insulin into the subcutaneous tissue without subsequent injections. One example of an infuser is the I-Port™ (Patton Medical Devices, Austin, TX). When applying the I-Port, an insertion needle guides a cannula under the skin. The insertion needle is removed and the cannula remains in the subcutaneous tissue. The insulin is then injected through the cannula. One of the concerns with this device is the development of an infection at the site of entry. The I-Port is FDA 510(k) approved as “a sterile, single use, low profile injection port through which physician prescribed medications can

be injected subcutaneously from a standard syringe and needle, pen or alternative manual injection device. The device is designed to reduce the hardships of multiple daily subcutaneous injections by allowing users to receive physician prescribed medication, including insulin, without repeated needle punctures of the skin". It is intended for home and health care facility use (ADA, 2008c; FDA, 2005).

Blevins et al. (2008) conducted a randomized controlled cross-over trial to compare the outcomes of insulin-dependent diabetics (n=74) who used the I-Port compared to standard multiple dose insulin injections. The patients, type 1 and type 2 diabetics, were randomly assigned to one of four cohorts. Cohort 1 (n=18) compared standard injections (SI) to single I-Port, cohort 2 (n=20) compared single I-Port to SI, cohort 3 (n=18) compared dual I-Ports (i.e., one for regular human and rapid-acting insulin and one for glargine), to single I-Port, and cohort 4 (n=18) compared single I-Port to dual I-Ports. At the end of the first three weeks, each group switched to the alternative method for an additional three weeks. Sixty-four participants completed all five follow-up visits. The ten who did not complete the trial terminated for device related issues (i.e., adhesive failure, discomfort, hyperglycemia, cannula bends and adverse events). For the SI and single I-Port patients, the glycosylated albumin were within normal limits (98.9% and 107.3%, respectively) (p=0.99). The results for the single I-Port vs. the dual I-Port were also within normal limits (99.5% vs. 110.99%, respectively) (p=0.97). The A1C levels were similar among all subjects initially and at the completion of the study. Via questionnaire, patients reported that it was significantly more difficult to control their diabetes during the SI phase (p=0.16) and that their overall health was very good or excellent using the I-Port compared to SI (p<0.001). I-Port adverse events included: erythema, suppuration, skin irritation, itching, and bruising at the I-Port insertion site. Five events of severe hyperglycemia were also reported.

There is a lack of evidence demonstrating the clinical utility of insulin infusers. They are not considered medically necessary and are used primarily for the convenience of the patient.

Laser Lancets

An alternative to the standard lancet used for skin perforation to obtain a capillary blood sample for glucose measurement is the use of a laser lancet. The device emits a single shot laser beam that produces a small hole in the finger. The laser may be used by individuals who prefer not to use a needle/blade. It is proposed that the laser reduces tissue trauma and is less painful than a standard lancet. The laser lancet requires 510(k) FDA approval. An example of the laser lancet is the Lasette[®] Plus (Cell Robotics International, Inc., Albuquerque, NM).

Laser lancets are not considered medically necessary because they have no proven clinical utility and are used primarily for the individual's convenience.

Glycated Serum Protein (GSP)

Measurements of total glycated serum proteins (GSPs) correlate well with A1C and have been suggested as alternative methods for routine monitoring of glycemic control in patients with diabetes. The degree of glycation of serum protein provides an index of glycemia over a shorter time than does glycation of hemoglobin. GSP (e.g., fructosamine assay) provides an index of glycemia over the preceding 1–2 weeks as opposed to a 2–3 month period as seen with A1C levels. GSP is proposed to be useful in situations where A1C cannot be measured or may not be useful (e.g., hemolytic anemia). It is also used in diabetic pregnancy or after major changes in therapy. However, the evidence is lacking as to the usefulness of GSP in these situations. According to Goldstein et al. (2004), "GSP is not equivalent to A1C and has not been shown to be related to the risk of the development or progression of chronic complications of diabetes." There is no conclusive evidence that correlates GSP concentration to the chronic complications of diabetes. Further studies are needed to determine whether these assays provide clinical information equivalent to A1C for routine management of patients with diabetes and, if so, whether they offer any significant advantages over A1C. Unlike the A1C test, GSP has not been shown to be related to the risk of development or progression of chronic complications of diabetes. The GSP is not considered equivalent to the A1C test, and the clinical utility of monitoring glycated serum protein has yet to be established (ADA, 2004b).

The first available home GSP device was the Duet[™] Glucose Control System (LXN Corporation, San Diego, CA), which received FDA 510(k) approval in 1999. This device was discontinued due to concerns that the test strips were producing false-high results. The Duet System was replaced by the InCharge[™] Diabetes Control System (LXN Corp., San Diego, CA). The InCharge has also been discontinued. Both of these devices

measured blood glucose and glycated protein. There are currently no home GSP monitors available on the market (Lindsey, et al., 2004).

Lindsey et al. (2004) conducted a prospective, three-center, randomized controlled study to “(1) compare the annual A1C results of subjects monitoring weekly fructosamine with those receiving usual care, (2) identify the number of subjects achieving goal A1C, and (3) determine if the addition of a weekly fructosamine test changed a subject’s quality of life (i.e., concerns re diabetes control, anxiety and worry, social burden, sexual functioning, energy and mobility).” The study group performed weekly fructosamine and daily glucose tests (n=42), while the control group performed daily glucose testing (n=30). The majority of subjects were middle-aged, type 2 diabetics. Follow-up visits occurred at three-month intervals for a year, baseline and quarterly A1C tests were conducted, and quality of life assessments were measured at baseline and at the final study visit. Quality of life remained constant in both groups; seven subjects in each group attained an A1C < 7%. At the end of one year, blood glucose alone testing was shown to be superior to blood glucose plus fructosamine testing. However, weekly fructosamine testing resulted in a decrease in A1C values earlier and more consistently than blood glucose monitoring.

Petitti et al. (2001) conducted a randomized trial which compared weekly fructosamine monitoring and daily glucose monitoring (n=70) to a control group of daily glucose only (n=70). Patients were type 2 diabetics, age 18 years or older, had an A1C of ≥ 8%, not pregnant, disease-free, and able to self-administer the tests. Both groups exhibited significant improvements in glycemic control during the course of the study. The authors concluded that the addition of fructosamine testing to glucose testing did not improve glycemic control and, initially, control was poor with the study group. Author-noted limitations of the study included: lack of guidelines regarding changes in diet, drugs, or medical follow-up based upon fructosamine test results; and patients were not instructed to reduce the frequency of glucose monitoring based upon fructosamine results.

Edelman et al. (2001) prospectively evaluated the use of home fructosamine testing (n=25). Patients were randomized to the study group (i.e., glucose and fructosamine testing) or to the glucose-only testing group. The study group conducted weekly fructosamine testing in addition to daily glucose testing. After three months, the A1C was evaluated on participants of both groups. The mean A1C value of the glucose-only group decreased from 9.4 ± 0.9% to 9.1 ± 1.3%, not statistically significant. The fructosamine group demonstrated a significant decrease in the mean A1C level from 9.2 ± 0.7% to 8.0 ± 0.5% (p<0.0001).

Summary

Evidence in the published, peer-reviewed scientific literature and professional organizations support home management of diabetes including: diet, exercise, blood and urine glucose testing, blood and urine ketone testing, and, when indicated, administration of oral agents or insulin. Insulin pens and needle-free insulin injection systems (i.e., jet injector devices) are alternative devices that may be used for the administration of insulin.

The use of home testing for glycosylated hemoglobin, and the use of insulin infusers (e.g., I-Port), and laser lancets are considered convenience items and are not medically necessary.

Coding/Billing Information

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

Covered when medically necessary:

HCPSC Codes	Description
A4206	Syringe with needle, sterile 1 cc, each
A4210	Needle-free injection device, each
A4211	Supplies for self administered injections
A4215	Needle, sterile, any size, each
A4245	Alcohol wipes, per box
A4250	Urine test or reagent strips or tablets (100 tablets or strips)

A4252	Blood ketone test or reagent strip, each
A4258	Spring powered device for lancet, each
A4259	Lancets, per box of 100
S5560	Insulin delivery device, reusable pen: 1.5 ml size
S5561	Insulin delivery device, reusable pen; 3 ml size
S5570	Insulin delivery device, disposable pen (including insulin), 1.5 ml size
S5571	Insulin delivery device, disposable pen (including insulin); 3 ml size
S8490	Insulin syringes (100 syringes, any size)

ICD-9-CM Diagnosis Codes	Description
249.00 - 249.91	Secondary diabetes mellitus
250.00 – 250.93	Diabetes mellitus
648.80 – 648.84	Abnormal maternal glucose tolerance, complicating pregnancy, childbirth, or the puerperium
V58.67	Long-term (current) use of insulin

Experimental/Investigational/Unproven/Not Medically Necessary/Convenience Item/Not Covered:

HCPCS Codes	Description
A4257	Replacement lens shield cartridge for use with laser skin piercing device, each
E0620	Skin piercing device for collection of capillary blood, laser, each
E1399†	Durable medical equipment, miscellaneous

†**Note:** Experimental/Investigational/Unproven when used to report use of a home glycosylated serum protein (GSP) monitor. Not Medically Necessary/Convenience Item/Not Covered when used to report home glycosylated hemoglobin (A1C) monitors.

*Current Procedural Terminology (CPT®) © 2008 American Medical Association: Chicago, IL.

References

1. American Association of Clinical Endocrinologists (AACE). The American Association of Clinical Endocrinologists Medical Guidelines for the Management of Diabetes Mellitus: the AACE system of intensive diabetes self-management--2002 update. *Endocr Pract.* 2002 Jan-Feb;8(1):40-82.
2. American Association of Clinical Endocrinologists. AACE medical guidelines for clinical practice for the management of diabetes mellitus. 2007. Accessed Jun 28, 2009. Available at URL address: <http://www.aace.com/pub/guidelines/>
3. American College of Endocrinology. Consensus statement on guidelines for glycemic control. *Endocr Pract.* 2002 Jan-Feb;8(1):5-11.
4. American Diabetes Association (ADA). 2009 resource guide. Accessed Jun 30, 2009. Available at URL address: <http://forecast.diabetes.org/magazine/resource-guide/2009-resource-guide>
5. American Diabetes Association (ADA). Standards of medical care in diabetes-2009. *Diabetes Care.* 2009 Jan;32 Suppl 1:S13-61. Accessed Jun 29, 2009. Available at URL address: http://care.diabetesjournals.org/content/32/Supplement_1/S13.full.pdf+html

6. American Diabetes Association (ADA). 2008a Resource Guide. A supplement to diabetes forecast 2008. Accessed Jun 28, 2009. Available at URL address: <http://forecast.diabetes.org/magazine/resource-guide/2008-resource-guide>
7. American Diabetes Association (ADA). Clinical practice recommendations 2008. Diabetes Care. January 2008b, Volume 31, Supplement 1. Accessed Jun 29, 2009. Available at URL address: http://care.diabetesjournals.org/content/vol31/suppl_1/#SUMMARY_OF_REVISIONS
8. American Diabetes Association (ADA). Insulin delivery. 2008c. Accessed Jun 28, 2009. Available at URL address: <http://forecast.diabetes.org/magazine/resource-guide/2008-resource-guide>
9. American Diabetes Association (ADA). Urine testing. 2008d. Accessed Jun 28, 2009. Available at URL address: <http://forecast.diabetes.org/magazine/resource-guide/2008-resource-guide>
10. American Diabetes Association (ADA). Insulin administration. Position statement. Diabetes Care. 2004a;27:S106-7. Accessed Jun 28, 2009. Available at URL address: http://care.diabetesjournals.org/cgi/reprint/27/suppl_1/s106
11. American Diabetes Association (ADA). Position statement. Tests of glycemia in diabetes. Diabetes Care. 2004b;27:S91-3. Accessed Jun 29, 2009. Available at URL address: http://care.diabetesjournals.org/cgi/reprint/27/suppl_1/s91?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&andorexactfulltext=and&searchid=1105956189473_1074&stored_search=&FIRSTINDEX=0&sortspec=relevance&volume=27&firstpage=s91&resourcetype=1&journalcode=diaca
12. Baxter J, Mitragotri S. Needle-free liquid jet injections: mechanisms and applications. Expert Rev Med Devices. 2006 Sep;3(5):565-74.
13. Blevins T, Schwartz SL, Bode B, et al. A Study assessing an injection port for administration of insulin. Diabetes Spectr. 2008;21:197-202.
14. Chase HP. Detection of ketosis and monitoring of diabetic ketoacidosis. Manag Care. 2004 Apr;13(4 Suppl):5-6; discussion 19-21.
15. Edelman SV, Bell JM, Serrano RB, Kelemen D. Home testing of fructosamine improves glycemic control in patients with diabetes. Endocr Pract. 2001 Nov-Dec;7(6):454-8.
16. Institute for Clinical Improvement. Health care guideline. Diagnosis and management of type 2 diabetes mellitus in adults. Mar 2008. Accessed Jun 29, 2009. Available at URL address: http://www.icsi.org/guidelines_and_more/gl_os_prot/other_health_care_conditions/
17. Kitabchi AE, Umpierrez GE, Murphy MB, Barrett EJ, Kreisberg RA, Malone JI, Wall BM; American Diabetes Association (ADA). Hyperglycemic crises in diabetes. Diabetes Care. 2004 Jan;27 Suppl 1:S94-102.
18. Laffel LM, Wentzell K, Loughlin C, Tovar A, Moltz K, Brink S. Sick day management using blood 3-hydroxybutyrate (3-OHB) compared with urine ketone monitoring reduces hospital visits in young people with T1DM: a randomized clinical trial. Diabet Med. 2006 Mar;23(3):278-84.
19. Laffel LMB, Wood JRS. Ch 143 – diabetes mellitus in children and adolescents. In: Rakel & Bope: Conn't Current Therapy 2008, 60th ed. W.B. Saunders, St. Louis, 2008.
20. Lindsey CC, Carter AW, Mangum S, Greene D, Richardson A, Brown SJ, Essary JL, McCandless B. A prospective, randomized, multicentered controlled trial to compare the annual glycemic and quality outcomes of patients with diabetes mellitus monitored with weekly fructosamine testing versus usual care. Diabetes Technol Ther. 2004 Jun;6(3):370-7.

21. Malone J, Lowitt S, Grove N, Shah S. Comparison of insulin levels after injection by jet stream and disposable insulin syringe. *Diabetes Care*. 1986 Nov-Dec;9(6):637-40.
22. Meas T, Taboulet P, Sobngwi E, Gautier JF. Is capillary ketone determination useful in clinical practice? In which circumstances?. *Diabetes Metab*. 2005 Jun;31(3 Pt 1):299-303.
23. Mitragotri. Current status and future prospects of needle-free liquid jet injectors. *Nat Rev Drug Discov*. 2006 Jun 23.
24. National Institute for Health and Clinical Excellence (NICE). CG15 Type 1 diabetes in children, young people and adults: NICE Guideline. Jul 21, 2004. Accessed Jun 29, 2009. Available at URL address: <http://guidance.nice.org.uk/CG15/niceguidance/pdf/English>
25. National Institute for Health and Clinical Excellence (NICE). CG15 Type 1 diabetes in adults: full guidance. Aug 27, 2008. Accessed Jun 29, 2009. Available at URL address: <http://www.nice.org.uk/guidance/index.jsp?action=download&o=29396>
26. National Institute for Health and Clinical Excellence (NICE). CG66 Diabetes - type 2 (update): full guideline. May 28, 2008. Accessed Jun 29, 2009. Available at URL address: <http://www.nice.org.uk/guidance/index.jsp?action=download&o=40803>
27. National Medical Products, Inc. J-Tip needle-free injection system. Accessed Jun 29, 2009. Available at URL address:<http://www.jtip.com/>
28. Patton Medical Devices, LP. I-Port Injection Port. 2007. Accessed Jun 28, 2009. Available at: <http://www.i-port.com/>.
29. Petitti DB, Contreras R, Dudl J. Randomized trial of fructosamine home monitoring in patients with diabetes. *Eff Clin Pract*. 2001 Jan-Feb;4(1):18-23.
30. Robertson K, Glazer N, Campbell R. The latest developments in insulin injection devices. *Diabetes Educ*. 2000 Jan/Feb;26:135-52.
31. Salsali A, Nathan M. A review of types 1 and 2 diabetes mellitus and their treatment with insulin. *Am J Ther*. 2006 Jul-Aug;13(4):349-61.
32. Soliman AT, Omar M, Rizk MM, El Awwa A, AlGhobashy FM. Glycaemic control with modified intensive insulin injections (MII) using insulin pens and premixed insulin in children with type-1 diabetes: a randomized controlled trial. *J Trop Pediatr*. 2006 Aug;52(4):276-81.
33. Stockl K, Ory C, Vanderplas A, Nicklasson L, Lyness W, Cobden D, Chang E. An evaluation of patient preference for an alternative insulin delivery system compared to standard vial and syringe. *Curr Med Res Opin*. 2007 Jan;23(1):133-46.
34. U. S. Food and Drug Administration (FDA). Hypex(TM) Jet Injector. Jun 8, 2009. Accessed Jun 28, 2009. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K945873>
35. U.S. Food and Drug Administration (FDA). I-Port Injection Port. 510(k) premarket notification. K052389. Sep 9, 2005. Accessed Jun 28, 2009. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=19336>.
36. U. S. Food and Drug Administration (FDA). I-Port™ 510 (k) summary. Sep 9, 2005. Accessed Jun 28, 2009. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=19336>
37. Weber C, Kocher S, Neeser K, Joshi SR. Prevention of diabetic ketoacidosis and self-monitoring of ketone bodies: an overview. *Curr Med Res Opin*. 2009 May;25(5):1197-207.

38. Welschen LM, Bloemendal E, Nijpels G, Dekker JM, Heine RJ, Stalman WA, Bouter LM. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin: a systematic review. *Diabetes Care*. 2005 Jun;28(6):1510-7.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	08/15/2007	0126	Diabetic Supplies

“CIGNA” and the “Tree of Life” logo are registered service marks of CIGNA Intellectual Property, Inc., licensed for use by CIGNA Corporation and its operating subsidiaries. All products and services are provided exclusively by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Behavioral Health, Inc., Intracorp, and HMO or service company subsidiaries of CIGNA Health Corporation and CIGNA Dental Health, Inc. In Arizona, HMO plans are offered by CIGNA HealthCare of Arizona, Inc. In California, HMO plans are offered by CIGNA HealthCare of California, Inc. and Great-West Healthcare of California, Inc. In Connecticut, HMO plans are offered by CIGNA HealthCare of Connecticut, Inc. In North Carolina, HMO plans are offered by CIGNA HealthCare of North Carolina, Inc. In Virginia, HMO plans are offered by CIGNA HealthCare Mid-Atlantic, Inc. All other medical plans in these states are insured or administered by Connecticut General Life Insurance Company.

Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA’s subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.