



Cigna Medical Coverage Policy

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Subject **Diabetic Supplies**

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, 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 supersedes** 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. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 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. In addition, consumable medical supplies, insulin pens and needle-free injection systems are specifically excluded under many medical benefit plans therefore some of the items referenced below may not be covered under the medical benefit. 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 the specific diabetic supply 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 (copayment may apply):

- 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 a home glycosylated serum protein (GSP) monitor because it 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
- hypoglycemic wristband alarm (e.g., Sleep Sentry)
- 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 and are typically controlled with diet and exercise. In some cases, oral hypoglycemic agents are indicated in the treatment of type 2 diabetics. GDM develops during pregnancy and involves a degree of glucose intolerance. It generally subsides following 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.

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 (Heinemann, 2013; Baxter and Mitragotri, 2006).

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 stated 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 stated 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, 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 hyperglycemia. For these reasons, SMBG is the preferred method of monitoring glycemic status on a daily basis (National Institute for Health and Clinical Excellence [NICE], 2010; ADA, 2008d). The 2013 ADA recommendations for diabetes care state that patients on multiple-dose insulin or insulin pump therapy should perform SMBG at least prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving. Any condition leading to deterioration in glycemic control necessitates more frequent monitoring of blood glucose. SMBG results may help to guide self-management for patients using less frequent insulin injections or noninsulin therapies. The need for SMBG may vary with type 2 diabetics, but before a meal and two hours after a meal are common times.

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. Different pens are compatible with different types of insulin so the patient needs to ensure that they have the correct pen. Pens also differ in their dosing increments and the maximum amount of insulin that can be dispensed at a single time. Some pens have dials that assist the patient in selecting accurate dosage. Disposable pens come prefilled with a cartridge of insulin, are stored in the refrigerator, kept at room temperature after opening and then discarded when all of the insulin is used (ADA 2012; Stockl, et al., 2007; Salsali and Nathan, 2006).

Insulin pen are approved by the FDA 510(k) process. Examples of current disposable pens include the Original Prefilled Pen (Eli Lilly, Indianapolis, IN) that uses Humulin[®] N and Humulin 70/30, the Flexpen[®] (Novo Nordisk, Inc., Princeton, NJ) that uses Levemir[®], Novolog[®] and Novolog Mix 70/30 insulin and the Lantus[®] Solostar[®] (Sanofi-Vantis, Bridgewater, NJ) which uses Apidra[®] or Lantus[®] insulin. Examples of reusable pens include the Humapen Luxura[™] HD by Eli Lilly for the administration of Humalog[®] insulin and the Novopen Echo by Novo Nordis for Novolog insulin.

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, ADA stated 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 indicates that either blood or urine ketone testing are appropriate when ketone testing is indicated. Urine ketone testing may be indicated when the blood sugar is over 300mg/dl; when experiencing symptoms of hypoglycemia, hyperglycemia, or vomiting; when the breath smells fruity and/or during illness (e.g., cold, flu, infection). Women with type 1 diabetes who are pregnant should be offered ketone testing strips and advised to test for ketones in urine (ketonuria) or ketones in blood (ketonaemia) if they become hyperglycemic or unwell (ADA, 2013; NICE, 2009; Weber, et al., 2009; Laffel and Wood, 2008; Laffel, et al., 2006; ADA, 2004b).

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 to reduce microvascular and neuropathic complication, in general, should be an A1C < 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, 2011; NICE, 2010).

Home glycated hemoglobin tests include FDA 510(k) approved products, such as the A1c Now[®] (Bayer HealthCare LLC, Tarrytown, NY) and the AccuBase A1c Glycohemoglobin Test Kit[™] (Diabetes Technologies, Inc., Thomasville, GA).

In a technology assessment on home tests for the management of chronic disease, the Agency for Healthcare Research and Quality (AHRQ, 2008) reported that there was insufficient evidence to determine the feasibility, diagnostic accuracy and impact of home A1C testing on decision making and clinical outcomes.

Hypoglycemic Wrist Band Alarm

A hypoglycemic alarm that looks like a wristband or watch has been proposed to alert diabetics to hypoglycemic episodes. Through sensors on the back surface of the device, electronic information is sent to a built-in microprocessor. When there is deviation from preset levels for skin temperature and/or perspiration, an alarm will sound. The device may be worn on the forearm, wrist or ankle. One of the disadvantages of the device is that activities that cause changes in skin temperature and/or perspiration can set off false alarms. An example of this device is the Sleep Sentry[®] (Diabetes Sentry Products, Inc., Bellingham, WA). The product is FDA approved by the premarket approval process (PMA) as a temperature and skin resistance measuring device. The clinical

utility of these devices has not been proven. Therefore, these devices are considered convenience items and are not considered medically necessary.

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. To apply an infuser 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.

One example of an infuser is the i-port[®] (Patton Medical Devices, Austin, TX) which 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 (FDA, 2005). A similar device is the insuflon[™] (IntraPump Infusion Systems, Grapevine, TX). The insuflon can be left in place for up to three days.

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, suppurative, skin irritation, itching, bruising at the i-port insertion site and five events of severe hyperglycemia.

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) have been suggested as alternative methods for routine monitoring of glycemic control in patients with diabetes. 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 proposed for use in pregnant diabetics 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 not been established (ADA, 2011; 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 (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.

Use Outside of the US

The National Institute for Health and Clinical Excellence (2004; 2011), United Kingdom, stated that self-care of diabetes includes self-monitoring for glycemic control and ketoacidosis. Various options for insulin injections should be offered including a pen injector or disposable pen. Special devices should be offered to individuals with manual or visual disabilities.

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.

Evidence in the published peer reviewed scientific literature does not support home monitoring of glycated serum protein (GSP). Overall, randomized controlled trials have reported that GSP testing did not improve glycemic control. The clinical utility and benefit to net health outcomes for home GSP testing have not been established. Home testing for glycated hemoglobin (A1C), hypoglycemic wristband alarm (e.g., Sleep Sentry), insulin infusers (e.g., I-Port) and laser lancets are considered convenience items and are not medically necessary.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

- 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Covered when medically necessary:

HCPCS Codes	Description
A4206	Syringe with needle; sterile 1 cc or less, 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
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
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)

Experimental/Investigational/Unproven when used to report a home glycated serum protein (GSP) monitor.

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous

Not Medically Necessary/Convenience Item/Not Covered when used to report home glycated hemoglobin (A1C) monitors, hypoglycemic wristband alarm (e.g., Sleep Sentry) and/or insulin infusers (e.g., i-port®).

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

*Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.

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