



# 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

Effective Date ..... 3/15/2011  
Next Review Date..... 3/15/2012  
Coverage Policy Number ..... 0087

Subject External Insulin Pumps

## Table of Contents

Coverage Policy .....	1
General Background .....	3
Coding/Billing Information .....	10
References .....	11
Policy History .....	17

## Hyperlink to Related Coverage Policies

Diabetes Self-Management Education  
 Diabetic Supplies  
 Home Blood Glucose Monitors  
 Implantable Infusion Pumps

### 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 external insulin pumps 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, coverage of external insulin pumps 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 plans, coverage for DME is limited to the lowest cost alternative.

If coverage is available for an external insulin pumps, the following conditions of coverage apply.

CIGNA covers either a standard external insulin pump or a combined or integrated continuous subcutaneous insulin infusion pump and standard finger-stick blood glucose monitoring (CSII-BGM) system (e.g., Omnipod) as medically necessary for the management of type 1 diabetes mellitus when ALL of the following criteria have been met:

- completion of a diabetes self-management education program
- treatment program including at least three insulin injections per day with frequent self-adjustments of insulin dose for at least six months prior to initiation of the insulin pump
- documented blood glucose self-testing an average of at least four times per day during the two months prior to initiation of the insulin pump
- ANY of the following while on the multiple daily injection regimen:
  - glycated hemoglobin level (HbA1c) > 7.0%

- history of recurring hypoglycemia
- wide fluctuations in blood glucose before mealtime
- dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
- history of severe glycemic excursions

**CIGNA covers either a standard external insulin pump or a combined or integrated continuous subcutaneous insulin infusion pump and standard finger-stick blood glucose monitoring (CSII-BGM) system (e.g., Omnipod) as medically necessary for the management of type 2 diabetes mellitus when ALL of the following criteria have been met:**

- 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
- completion of a diabetes self-management education program
- treatment program including at least three insulin injections per day with frequent self-adjustments of insulin dose for at least six months prior to initiation of the insulin pump
- documented blood glucose self-testing an average of at least four times per day during the two months prior to initiation of the insulin pump
- ANY of the following while on the multiple daily injection regimen:
  - glycosylated hemoglobin level (HbA1c)  $>$  7.0%
  - history of recurring hypoglycemia
  - wide fluctuations in blood glucose before mealtime
  - dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
  - history of severe glycemic excursions

**CIGNA covers an external insulin pump with enhanced features as medically necessary when the criteria for a standard external insulin pump are met and ANY of the following apply:**

- documented special need, such as a hearing impairment, that requires an additional or enhanced feature for successful use of an insulin pump
- documented failure to achieve glycemic control adequate to prevent acute metabolic complications such as hyperglycemia, hypoglycemia or ketoacidosis with a standard external insulin pump
- less than age 18 years, and the request is for an integrated bolus wizard function

**CIGNA covers a combined or integrated continuous subcutaneous insulin infusion and blood glucose monitoring systems that includes a continuous blood glucose monitor (CBGM) (e.g., MiniMed Paradigm<sup>®</sup> REAL-Time Revel<sup>™</sup> System) as medically necessary for long-term use in the treatment of ANY of the following:**

- type 1 diabetic age 25 years or older
- type 1 diabetic age 24 years or younger 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)
- 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 covers the replacement of an external insulin pump as medically necessary for an individual with successfully managed type 1 or type 2 diabetes mellitus on an external insulin pump when the pump malfunctions, is no longer under warranty, and cannot be repaired.**

**CIGNA covers as medically necessary DME, the supplies required for the proper use of a medically necessary external insulin pump including custom-designed batteries and power supplies. However, off-the-shelf batteries that can also be used to power non-medical equipment are not considered DME and are therefore not covered.**

**CIGNA does not cover additional software or hardware required for downloading data to a personal computer to aid in self-management of diabetes mellitus because it is considered a convenience item and not medically necessary.**

---

## General Background

External insulin pumps are designed to provide continuous subcutaneous insulin infusion (CSII) in patients with diabetes mellitus. The external insulin pump is a programmable battery-powered mechanical syringe/reservoir regulated by a miniature computer that delivers a steady "basal" amount of insulin and releases a bolus dose at meals or smaller amounts at programmed times. Frequent monitoring of the blood glucose (e.g., four times per day) is essential to ensure appropriate delivery of insulin dosage.

CSII candidates include type 1 diabetics whose hyper- and/or hypoglycemia cannot be controlled with daily injections of insulin. Individuals with wide fluctuations in blood glucose before mealtime, a marked increase in fasting blood glucose levels at dawn (i.e., exceeding 200 milligrams/deciliter [mg/dL]), unpredictable hypoglycemia, persistent glycosylated hemoglobin levels greater than 7.0%, and patients unable to administer multiple daily injections (MDI) may also be candidates for CSII (Primary Care Education Consortium, 2006; White, 2007).

CSII in the treatment of type 2 diabetes may be indicated in a subgroup of patients 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, making them appropriate candidates for CSII. Insulinopenia is diagnosed in less than 5% of type 2 diabetics (Centers for Medicare and Medicaid [CMS], 2005; CMS, 2001).

### External Insulin Pumps

**U.S. Food and Drug Administration (FDA):** External insulin pumps are approved by the FDA as 510(k) Class II devices for the continuous infusion of insulin. Examples of approved devices include: Medtronic Minimed Paradigm<sup>®</sup> REAL-Time Revel 523/723 Insulin Pump (Medtronic Minimed, Northridge, CA); Animas OneTouch<sup>®</sup> Ping<sup>™</sup> (Animas Corp., Frazer, PA); and Dana Diabecare<sup>®</sup> II Insulin Pump (Sooil Development Co., Ltd., North Attleboro, MA).

### Literature Review

**Type 1 Diabetic Adults:** As evidenced by systematic reviews, meta-analysis (n=12–52 studies), randomized controlled trials, comparative studies and prospective longitudinal observational studies (n=100–1441), the use of external insulin pumps for the management of type 1 diabetes mellitus is a well-established, safe and effective treatment modality (Cummins, et al., 2010; Misso, et al., 2010; Monami, et al., 2010; Fatourechi, et al., 2009; Jeitler, et al., 2008; Giménez, et al., 2007; Hirsch, et al., 2005; Weissberg-Benchell, et al., 2003; Pickup, et al., 2002).

**Type 1 Diabetic Children:** CSII is an accepted treatment alternative for type 1 diabetic children. Overall, results from systematic reviews, randomized controlled trials, case series, comparative studies, and retrospective reviews reported a significant initial improvement in glycated hemoglobin (HbA1c or A1c) and a decrease in the severity of hypoglycemic events. Additional outcomes included lower fasting blood glucose levels, less severe lipohypertrophy, less blood glucose variability, an absence of diabetic ketoacidosis (DKA), and fewer sick-day calls. Outcomes varied based on age and the number of years the subject had been a diabetic (Cummins, et al., 2010; Churchill, et al., 2009; Naghan, et al., 2009; Skogsberg, et al., 2008; Opipari-Arrigan, et al. 2007; Alemzadeh, et al., 2007; Kapellen, et al., 2007; McVean, et al., 2007; Pańkowska, et al., 2007; Berhe, et al., 2006; Kordonouri, et al., 2006; Wood, et al., 2006; Fox, et al., 2005; DiMeglio, et al., 2004; Plotnick, et al., 2003).

**Type 2 Diabetics:** Insulin pumps are an established treatment option for a subgroup of type 2 diabetics who are producing minimal amounts of insulin (i.e., insulinopenia). There are relatively few published clinical trials regarding the safety and efficacy of CSII in type 2 diabetics. However, the available randomized controlled trials and case series reported improvement in HbA1c, reduction in fasting plasma glucose and postprandial plasma glucose levels, reduction in the glucose area under the curve values, and/or decreased insulin demand following use of CSII. Overall, complications were not greater with CSII (Johnson, et al., 2010; Noh, et al., 2008; Parkner, et al., 2008; Berthe, et al., 2007; Wainstein, et al., 2005).

Based on a review of nine scientific studies (n=20–5699) that investigated the use of C-peptide levels to differentiate between type 1 and type 2 diabetes, the CMS concluded that type 2 diabetics who would benefit from CSII could be diagnosed based on the C-peptide level. A fasting C-peptide level that was  $\leq 110\%$  of the lower limit of normal of the laboratory's measurement method and a concurrently obtained fasting glucose of  $\leq 225$  mg/dL was indicative of insulinopenic type 2 diabetes. In patients with compromised renal function, a creatinine clearance (actual or calculated from age, gender, weight and serum creatinine)  $\leq 50$  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 was also 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  $\leq 0.86$  ng/mL and with renal sufficiency would have a value of  $\leq 1.56$  ng/mL. This subset of individuals may be candidates for CSII (CMS, 2005; CMS, 2001).

**Pregnancy:** Because pregnancy causes an increase in insulin resistance, there may be a need for increased insulin dosage during pregnancy in type 1 diabetics. In type 2 diabetics, oral hypoglycemics are discontinued during pregnancy. If the type 2 diabetic and the gestational diabetic (i.e., diabetes that occurs only during pregnancy) are unable to maintain glycemic control with diet, exercise, and self-monitoring blood glucose (SMBG), insulin injections may be required. Poor blood sugar control during pregnancy can lead to congenital abnormalities, miscarriages, stillborns, and unusually large babies. In a carefully selected subset of pregnant diabetics, an insulin pump may be considered when intensive insulin therapy is required for glycemic control. One concern regarding the use of an insulin pump during pregnancy is the potential for ketoacidosis due to interruption in the flow of insulin secondary to pump malfunction. Ketoacidosis may occur more rapidly in the pregnant diabetic and can result in fetal loss (ADA, 2011; Trujillo, 2008; Farrar, et al., 2007; Mukhopadhyay, et al., 2007; American Association of Clinical Endocrinologists [AACE], 2007b; American College of Obstetricians and Gynecologists [ACOG], 2010; ADA, 2004).

González-Romero et al. (2010) conducted a comparative prospective study to evaluate the outcome of type 1 pregnant diabetic women treated with CSII (n=35 pregnancies/26 women) compared to MDI (n=64 pregnancies/53 women) (control group). CSII was implemented during prepregnancy for women who did not reach A1c  $<7.5\%$ , had dawn phenomenon not responsive to a change in bedtime insulin dosage, had uncontrolled hypoglycemic episodes or an unfavorable obstetrical history. CSII was started on two women during pregnancy. The control group was treated with 3–6 insulin injections per day. The A1c was significantly lower ( $p<0.05$ ) before pregnancy in the CSII group and also significantly improved ( $p<0.001$ ) in 3–6 months following CSII. CSII had lower insulin requirements ( $p<0.05$ ) during the first trimester. There were no significant differences between severity and frequency of hypoglycemic events in the two groups. One CSII and one control group patient experienced ketoacidosis. Women in the CSII group weighed more than MDI women, but the increase in weight between the first and third trimesters was lower in the CSII group. No significant differences were reported between the groups regarding hypertension or progression of retinopathy or nephropathy. There were no significant differences between the groups in miscarriages, perinatal mortality,

congenital anomalies, or birth weight. The study did not show an advantage of CSII over MDI in metabolic control or obstetrical or perinatal outcomes.

Farrar et al. (2007) conducted a systematic review of randomized controlled trials comparing CSII to MDI in pregnant women with diabetes, preexisting and gestational. Two studies (n=61 pregnancies) were found that met inclusion criteria. Compared to MDI, a significant increase in mean birthweight was reported with the use of CSII. No conclusion could be made on the limited amount of data. No significant differences were reported in perinatal mortality, fetal anomaly, maternal hypoglycemia or maternal hyperglycemia. However, due to the small patient population in two trials and “questionable generalisability of the trial population” the authors stated that conclusions could not be made from the data available.

Mukhopadhyay et al. (2007) also conducted a systematic review and meta-analysis of published and unpublished randomized controlled trials comparing MDI to CSII in pregnant diabetic women. Six studies (n=213) met inclusion criteria with only two studies being truly randomized. Pregnancy outcomes and glycemic control were not significantly different between the study groups. Although ketoacidotic episodes and diabetic retinopathy were reported more often in the CSII groups, the differences were not statistically significant. There were no reported advantages for the use of CSII over MDI. The authors noted that the small number of trials and subjects which could contribute to a lack of statistical power were limitations of the study. The outcomes of the study did not demonstrate a “clear-cut” benefit of using CSII over MDI. They suggested that the use of CSII in pregnant diabetics might be reserved for women requiring very high doses of insulin or cases in which normoglycemia is not achieved by conventional therapy.

In their 2008 technology assessment on CSII, NICE stated that the criteria for use of CSII with pregnant women should not be different than for other adults. They reviewed six observational studies of type 1 pregnant diabetics using CSII and reported no overall statistically significant differences in outcomes of MDI vs. CSII.

**Professional Societies/Organizations:** The American Association of Clinical Endocrinologists (AACE) Consensus Panel (2010) on insulin pump management proposed the following three classifications of clinical characteristics of patients with diabetes mellitus (DM) who are considered suitable candidates for insulin pump therapy:

- Class 1 - “Patients with type 1 DM who do not reach glycemic goals despite adherence to a maximum MDI, non-CSII program, especially if they have: very labile DM (erratic and wide glycemic excursions, including recurrent DKA); frequent severe hypoglycemia and/or hypoglycemia unawareness; significant “dawn phenomenon,” extreme insulin sensitivity; and special populations (e.g., preconception, pregnancy, children, adolescents with eating problems, competitive athletes)”.
- Class 2 - “Patients with type 1 DM who are on a maximized basal-bolus MDI insulin regimen, regardless of their level of glycemic control and who, after investigation and careful consideration, feel that CSII would be helpful or more suitable for lifestyle reasons.”
- Class 3 - “Selected patients with insulin-requiring type 2 DM who satisfy any or all of the following: C-peptide positive but with suboptimal control on a maximal program of basal/bolus injections; substantial “dawn phenomenon”; erratic lifestyle (e.g., frequent long distance travel, shift-work, unpredictable schedules leading to difficulty maintaining timing of meals); severe insulin resistance, candidate for U500 insulin by CSII; and selected patients with other DM types (e.g., postpancreatectomy)”.

AACE stated that little guidance and evidence exists for the use of insulin pumps in children. Available data does not suggest that insulin pump therapy lowers HbA1c, but evidence does indicate that pump therapy reduces the risk of hospitalization due to recurrent episodes of diabetic ketoacidosis in children. Regarding insulin therapy during pregnancy, AACE stated that although there is not clear evidence that pump therapy in pregnant women with type 1 diabetes is necessary for optimal treatment, pump therapy can be used. Pump therapy seems to be safe and effective for maintaining glycemic control in pregnancies complicated by gestational diabetes and in type 2 diabetics requiring large doses of insulin.

According to AACE, characteristics of patients who are not good candidates for insulin pump therapy include:

- unable or unwilling to perform multiple daily insulin injections (≥3 to 4 daily), frequent blood glucose monitoring (≥4 to 6 daily), and carbohydrate counting

- lack motivation to achieve tighter glucose control and/or have a history of nonadherence to insulin injection protocols
- history of serious psychologic or psychiatric condition(s) (e.g., psychosis, severe anxiety, or depression)
- reservations about pump usage interfering with lifestyle (e.g., contact sports or sexual activity)
- unrealistic expectations of pump therapy (e.g., belief that it eliminates the need to be responsible for diabetes management)".

In their 2010 guidance document for the treatment of type 1 diabetes, the National Institute for Clinical Excellence (NICE) (United Kingdom) stated CSII is an option for these individuals if multiple-dose insulin therapy has failed and those using CSII have the commitment and competence to effectively use the therapy. In their 2008 clinical guidelines on the management of diabetes from pre-conception to postnatal care, NICE stated that clinical trials have shown no advantages or disadvantages of use of an insulin pump compared to MDI during pregnancy. CSII may be indicated in insulin-treated pregnant women if adequate glycemic control is not achieved by MDI.

A 2007 consensus statement endorsed by the ADA and the European Association for the Study of Diabetes, the European Society for Pediatric Endocrinology, Lawson Wilkins Pediatric Endocrine Society, International Society for Pediatric and Adolescent Diabetes listed the following considerations for CSII therapy in all pediatric patients with type 1 diabetes, regardless of age:

- "recurrent severe hypoglycemia
- wide fluctuations in blood glucose levels, regardless of A1c
- suboptimal diabetes control (i.e., A1c exceeds target range for age)
- microvascular complications and/or risk factors for macrovascular complications
- good metabolic control but insulin regimen that compromises lifestyle"

Other circumstances in which CSII may be beneficial include:

- "young children and especially infants and neonates
- adolescents with eating disorders
- children and adolescents with a pronounced dawn phenomenon
- children with needle phobia
- pregnant adolescents, ideally preconception
- ketosis-prone individuals
- competitive athletes"

The guidelines included a discussion regarding the importance of the involvement and support of a multidisciplinary team and family members in the initiation and ongoing pump management and glucose monitoring of CSII in children (Phillip, et al., 2007).

A 2005 ADA position statement regarding children and adolescents with type 1 diabetes stated that "pump use is increasing rapidly in the pediatric population. There is no best predetermined age to initiate insulin pump therapy. As with all diabetes management issues, individualized treatment plans that consider the needs of the patient as well as those of the family are best" (Silverstein, et al., 2005).

The 2005 pregestational diabetes ACOG guideline listed insulin injections or continuous subcutaneous infusion as a treatment option for pregnant women with diabetes. They noted that "if the delivery of insulin is interrupted or impaired by battery failure or infection at the infusion site, diabetic ketoacidosis may develop rapidly and is a potential harm" of use of an insulin pump.

#### **Standard Features for External Insulin Pumps**

**Adults:** A review of the literature shows that the minimum requirements for a standard ambulatory insulin pump include (ADA 2011; ADA, 2010; ADA, 2009; ECRI, 2008; ADA, 2004):

- The pump should be comfortable to wear.
- It should not disturb the patient during sleep.
- It should not be conspicuous during daily use.

- It should be able to provide insulin for 72 hours without requiring battery replacement or recharging.
- It should be able to deliver from a 3 ml capacity external reservoir connected by luer lock fittings or integral tubing.

The pump should include all of the following:

- distal air filters
- air-in-line detectors
- upstream occlusion alarm and indicator

The pump should suspend infusion when downstream pressure is  $\geq 10$  psi.

Basal flow capabilities should include:

- deliver 5–100 units per day with a resolution of two units per day
- increments
- $\geq 24$  programmable rate changes per day
- accuracy within 5% of basal flow rate

Bolus dose range of 0.5 to  $\geq 25$  units per bolus with resolution of 0.5 units

Bolus volume released after an occlusion is cleared should be:

- 0.5 milliliters (mL)
- minimum  $\leq 0.5$ ; maximum  $\geq 25$

The pump should have audible alarms for all conditions that could result in interrupted infusions, including:

- high pressure/occlusion
- low or depleted battery
- data entry error
- pump malfunction
- empty or near empty reservoir
- runaway infusion

Data logs should be able to store up to 200 events (or up to 24 hours of data), including:

- volume delivered
- program settings
- error codes
- alarms
- flow rate

It should have easy-to-read display screens that indicate:

- time
- basal rate
- bolus dose
- accumulated dose

Standard systems may combine an insulin pump (e.g., OmniPod<sup>®</sup>, Insulet Corporation, Boston, MA) with a standard non-continuous glucose meter and be used as a combination system.

**Children:** Standards for external insulin pumps in pediatric patients may differ from those in adults. Children may require additional features to accommodate their unique needs. Some features to be considered include:

- a pump that is easy and intuitive for the user to program, with a child-block feature
- a programmable reminder alarm for the user with occlusion detection at  $\leq 3$  units and a low reservoir alert, vibrator or audible alarm
- a reservoir that is easy to fill and to see and that is intuitive to the user, with a feature that can be set to calculate dosage for blood glucose levels outside of a target range

Other features that might be considered are:

- Bolus:
  - minimum of 0.1 units and maximum of 25.0 units
  - options of a dual- or square-wave delivery bolus
  - bolus wizard feature that can be set to calculate dosage for carbohydrates consumed
  - easy-to-cancel programming
- Basal rate:
  - increment of 0.05 or lower
  - options for a number of basal patterns
  - availability of a temporary basal rate
  - ability to see the specific length of time of temporary basals up to 24 hours, with specific rates based on any percentage of either the current rate or a specific rate
  - basal profiles that are programmable every 30 minutes
- Display that includes:
  - total boluses
  - total basal and total 24-hour insulin delivery
  - amount of insulin on board

Standard systems may combine an insulin pump (e.g., OmniPod) with a standard non-continuous glucose meter and be used as a combination system.

The ADA recommends that the following items be compared when selecting an insulin pump for a child: size, weight, battery life, infusion sets, number of basal rates available, basal range, smallest basal possible, obstruction alarm, over-delivery alarm, near-empty alarm, warranty and special features.

### **Enhanced Features**

A number of technological advances have been made in insulin infusion pumps over the past several years, including decrease in size and weight, improved safety features, voice synthesizers, larger digital displays, and more sophisticated programming options. New models are introduced periodically, and patients who are undergoing CSII may wish to upgrade to these newer devices as they become commercially available. There is limited information available in the peer-reviewed literature regarding replacing pumps with newer models, features that might provide additional health benefits and features that are primarily for convenience or ease of use. However, in certain situations such as hearing or visual impairment, or when glycemic control with a standard external pump has not been achieved enhanced features may be warranted (e.g., an integrated bolus wizard feature for an individual less than age 18 years).

### **Data Management Systems**

Although data management systems offer convenience in tracking test results and glucose levels, there is insufficient evidence in the peer-reviewed literature to demonstrate that data management systems improve diabetic management. Due to the limitations of the studies (e.g., lack of randomization, heterogeneous patient populations, various outcome measures, participant attrition) the benefit of data management systems in overall health outcomes in diabetics is unknown (Costa, et al., 2009).

### **Combined Continuous Subcutaneous Insulin Infusion Pump and Standard Finger-Stick Blood Glucose Monitoring Systems (CSII-BGM)**

Combination systems consisting of an insulin pump and a standard finger-stick blood glucose meter (e.g., OmniPod) are considered a type of standard external insulin pump. Combined systems may have various features but, at a minimum, include a glucose sensor, computer controller, and insulin delivery system. The patient performs a finger stick and applies a drop of blood to the glucose meter to calculate the blood glucose level. Under the user's direction, the glucose meter transmits information, using wireless radiofrequency or infrared communication technology, to the insulin pump for insulin administration. Some systems include software that will calculate and deliver boluses. Others devices have an optional software system for tracking, trending and downloading data.

**U.S. Food and Drug Administration (FDA):** External insulin pumps, including the three CSII-BGM systems noted below, are subject to 510(k) review and approval by the FDA. The Medtronic MiniMed requires the use of computer software and access to an interactive web-based diabetes management program to fully utilize their coordinated CSII and BGM features. The OmniPod is a wireless insulin pump that consists of a disposable insulin pod and Personal Diabetes Manager. The pod is filled with insulin by the patient and replaced every 72 hours. Other examples of combination systems approved by the FDA include:

- iXL-II Diabetes Management System with Blood Glucose Measurement (Insulet Corporation, Boston, MA) marketed as OmniPod™ Insulin Management System
- Medtronic MiniMed Paradigm® Models 523 and 723 Insulin Pumps used in conjunction with the OneTouch® Ultralink™ Meter (Medtronic MiniMed, CA)

In 2008, 510(k) approval was issued by the FDA for the Symphony™ Glucose Management System. The system consists of an Animas external insulin pump that wirelessly communicates with a LifeScan blood glucose meter-remote. The system is a predicate device to the Paradigm Model 512 Insulin Pump and the Paradigm Link Glucose Monitor. Bidirectional wireless communication occurs between the glucose meter and the insulin pump and allows the individual to remotely operate insulin dosing using the glucose meter-remote. The FDA also approved the ezManager® MAX Diabetes Management Software which allows uploading of data to a computer. The insulin pump, glucose meter and software are marketed as the OneTouch® Ping Glucose Management System (FDA, 2008a; FDA 2008b). The ACCU-CHEK Spirit Insulin Pump Systems (Roche Diagnostics, Indianapolis, IN) is a similar system.

**Literature Review:** Although minimal literature has been published specifically related to the clinical use of combined continuous subcutaneous insulin infusion and standard finger-stick blood glucose monitoring devices, these systems have become an established method of blood glucose monitoring and insulin administration. Clinical trials reporting outcomes comparing the use of a combined continuous insulin infusion and blood glucose monitoring system to the use of separate external insulin pumps and blood glucose monitoring devices are lacking. In the 510(k) approval document, the FDA determined that the combined CSII-BGM systems using wireless technology to communicate between the insulin pump and BGM are substantially equivalent to the predicate devices (i.e., separate pump and meter).

### **CSII Systems with Continuous Blood Glucose Monitor (CBGM) Systems**

A CSII used in conjunction with a CBGM (CSII-CBGM) is also referred to as sensor-augmented pump therapy. The MiniMed Paradigm® REAL-Time Revel™ System (Medtronic MiniMed, Northridge, CA) is an example of a device that includes a continuous glucose monitor as opposed to the standard glucose monitor. The glucose sensor inserts under the skin and connects to the MiniLink® transmitter that sends data to the insulin pump using wireless radiofrequency technology. The system also includes CareLink™ Therapy Management Software, a free online tool. A combined system with a CSII and a CBGM may be used on a long-term basis for the treatment of type 1 diabetes mellitus. The outcomes of clinical trials support CBGM in type 1 diabetics who are age 25 years or older. A significant improvement of up to 1% in A1c levels has been reported. It has been proposed that one of the reasons for better outcomes in older individuals is because they are typically more compliant in the use of CBGM than younger users. In individuals less than age 25 years, CBGM has been shown to be effective in patients who experience severe episodes of hypoglycemia with a blood glucose level < 50mg/dL not corrected by adjustments in conventional therapies (i.e., SMBG four or more times per day, insulin therapy).

**U.S. Food and Drug Administration (FDA):** The Paradigm REAL-Time Revel System including an insulin pump (model 523/723), continuous glucose monitor and management software was approved by the FDA PMA process. The sensor was approved by the FDA for use by individuals age 18 years and older and can be worn for up to 72 hours.

**Literature Review:** CSII with CBGM has become an accepted method for monitoring diabetes in a subgroup of type 1 and type 2 diabetics. Although a limited number of randomized controlled trials and case series 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 in the number of hypoglycemic episodes (Bergenstal, et al., 2010; Raccach, et al., 2009; Halvorson, et al., 2007; Mastrototaro, et al., 2006).

The Canadian Agency of Drugs and Technologies in Health (CADTH) (2007) published a report on the Paradigm Real-Time System. Based on the limited amount of published research to date, they concluded that the “impact of the Paradigm Real-Time System on long-term glycemic control, prevention of diabetic complications, or quality of life is unclear.” The report included four studies, three of which were abstracts presented at the 2007 ADA Scientific Sessions. Limitations of the studies noted by CADTH included: small patient populations, inexperienced pump users, selection of patients with poor baseline glycemic control, and a possible overlap of patient populations. They also stated that the studies did not evaluate improvement or increased likelihood of reaching glycemic targets. Three uncontrolled studies demonstrated improvement in glycemic control or a reduction in symptomatic hypoglycemic episodes, or favorable acceptance and ease of use of the system (Pohar, 2007).

**Professional Societies/Organizations:** The 2011 ADA clinical recommendations for the treatment of diabetes state that CGM in conjunction with intensive insulin therapy may be a useful tool in selected type 1 diabetics (age  $\geq 25$  years) and may be helpful in children, teens and younger adults although the evidence is less strong. “CGM may be a supplemental tool to SMBG in those with hypoglycemia and/or frequent hypoglycemic episodes. “ The ADA states that when treatment goals are not met increasing SMBG, initiation of CGM, frequent contact with the patient and an endocrinology referral may be appropriate.

NICE (2010) stated that CGMS have 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.

In their guidelines for the management of diabetes, the American Association of Clinical Endocrinologists (2007a) lists CGM as a clinical consideration for type 1 diabetics with unstable glucose control and patients who cannot achieve an acceptable HbA1c. They stated that CGM is “particularly valuable in detecting both unrecognized nocturnal hypoglycemia and postprandial hyperglycemia.”

### **Summary**

The use of a standard external insulin pump, or an insulin pump combined with a standard finger-stick blood glucose monitor, or an insulin pump combined with a continuous blood glucose monitor is indicated for a specific subset of insulin-treated type 1 and type 2 diabetics who have completed a self-management educational program and adhere to a regimen of self-management blood glucose monitoring.

The replacement of an existing fully functional external insulin pump with newer models and additional features or for use with a continuous glucose monitor is primarily for convenience or ease of use. The use of additional software or hardware for downloading data to a personal computer is considered a convenience item and not medically necessary for the treatment of diabetes.

---

## **Coding/Billing Information**

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

**Covered when medically necessary**

<b>HCPCS Codes</b>	<b>Description</b>
A4230	Infusion set for external insulin pump, non-needle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3cc
A9274	External ambulatory delivery system, disposable, each, includes all supplies and accessories
E0784	External ambulatory infusion pump, insulin
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
250.00-250.93	Diabetes mellitus

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

## References

1. Alemzadeh R, Palma-Sisto P, Holzum M, Parton E, Kicher J. Continuous subcutaneous insulin infusion attenuated glycemic instability in preschool children with type 1 diabetes mellitus. *Diabetes Technol Ther.* 2007 Aug;9(4):339-47.
2. 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/>
3. American Association of Clinical Endocrinologists (AACE). Statement by the American Association of Clinical Endocrinologists Consensus Panel on insulin pump management. Sep/Oct 2010. Accessed Jan 20, 2011. Available at URL address: <http://www.aace.com/pub/positionstatements/>
4. American Association of Clinical Endocrinologists (AACE). Medical guidelines for clinical practice for the management of diabetes mellitus. May/June 2007a. Accessed Jan 24, 2011. Available at URL address: <http://www.aace.com/pub/guidelines/>
5. American Association of Clinical Endocrinologists (AACE). Diabetes Mellitus Clinical Practice Guidelines Task Force. Diabetes mellitus guidelines. Diabetes and pregnancy. *Endocr Pract* 2007b May-Jun;13(Suppl 1):55-9. Accessed Jan 24, 2011. Available at URL address: [http://www.guideline.gov/summary/summary.aspx?doc\\_id=11099](http://www.guideline.gov/summary/summary.aspx?doc_id=11099)
6. American College of Obstetricians and Gynecologists (ACOG). Pregestational diabetes mellitus. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Mar. Reaffirmed 2010. 11 p. (ACOG practice bulletin; no. 60). Accessed Feb 1, 2010. Available at URL address: [http://www.guidelines.gov/summary/summary.aspx?ss=15&doc\\_id=10933&string=pregestational+AND+diabetes](http://www.guidelines.gov/summary/summary.aspx?ss=15&doc_id=10933&string=pregestational+AND+diabetes)
7. American Diabetes Association (ADA). Clinical practice recommendations. 2011. Accessed Jan 24, 2011. Available at URL address: [http://care.diabetesjournals.org/content/34/Supplement\\_1](http://care.diabetesjournals.org/content/34/Supplement_1)
8. American Diabetes Association (ADA). Clinical practice recommendations. 2010. Accessed Jan 24, 2011. Available at URL address: [http://care.diabetesjournals.org/content/33/Supplement\\_1](http://care.diabetesjournals.org/content/33/Supplement_1)

9. American Diabetes Association (ADA) Continuous subcutaneous insulin infusion. Jan, 2004. Accessed Jan 24, 2011. Available at URL address: [http://care.diabetesjournals.org/cgi/reprint/27/suppl\\_1/s110](http://care.diabetesjournals.org/cgi/reprint/27/suppl_1/s110)
10. American Diabetes Association (ADA). Diabetes Forecast. 2011 Consumer guide charts. Accessed Jan 24, 2011. Available at URL address: <http://forecast.diabetes.org/consumerguide/charts>
11. American Diabetes Association (ADA). Diabetes Forecast. 2011 Insulin pumps. Accessed Jan 24, 2011. Available at URL address: <http://forecast.diabetes.org/magazine/features/2011-insulin-pumps>
12. American Diabetes Association (ADA). Diabetes Forecast. Insulin pumps and infusion sets. 2010. Accessed Jan 24, 2011. Available at URL address: <http://forecast.diabetes.org/insulin-pumps>
13. American Diabetes Association (ADA). Diabetes Forecast. Insulin pumps. 2009. Accessed Jan 24, 2011. Available at URL address: <http://forecast.diabetes.org/magazine/resource-guide/insulin-pumps>
14. Bergenstal RM, Tamborlane WV, Ahmann A, Buse JB, Dailey G, Davis SN, Joyce C, Peoples T, Perkins BA, Welsh JB, Willi SM, Wood MA; STAR 3 Study Group. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes. *N Engl J Med*. 2010 Jul 22;363(4):311-20. Epub 2010 Jun 29.
15. Berhe T, Postellon D, Wilson B, Stone R. Feasibility and safety of insulin pump therapy in children aged 2 to 7 years with type 1 diabetes: a retrospective study. *Pediatrics*. 2006 Jun;117(6):2132-7.
16. Berthe E, Lireux B, Coffin C, Goulet-Salmon B, Houlbert D, Boutreux S, Fradin S, Reznik Y. Effectiveness of intensive insulin therapy by multiple daily injections and continuous subcutaneous infusion: a comparison study in type 2 diabetes with conventional insulin regimen failure. *Horm Metab Res*. 2007 Mar;39(3):224-9.
17. Bloomgarden Z. Treatment issues in type 1 diabetes. *Diabetes Care*. 2002;25(1):230-8.
18. Bode BW. Insulin pump use in type 2 diabetes. *Diabetes Technol Ther*. 2010 Jun;12 Suppl 1:S17-21.
19. Centers for Medicare and Medicaid (CMS). Decision memo for insulin pump: C-peptide levels as a criterion for use (CAG-00092N). May 11, 2001. Accessed Jan 24, 2011. Available at URL address: <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=41>
20. Centers for Medicare and Medicaid (CMS). CMS Manual System. Pub. 100-03 Medicare national coverage determination. Transmittal 27. Feb 4, 2005. Insulin pumps: C-peptide levels as a criterion for use. Accessed Jan 24, 2011. Available at URL address: <http://www.cms.hhs.gov/transmittals/downloads/R27NCD.pdf>
21. Chico A, Saigi I, Garcia-Patterson A, Santos MD, Adelantado JM, Ginovart G, de Leiva A, Corcoy R. Glycemic control and perinatal outcomes of pregnancies complicated by type 1 diabetes: influence of continuous subcutaneous insulin infusion and lispro insulin. *Diabetes Technol Ther*. 2010 Dec;12(12):937-45.
22. Churchill JN, Ruppe RL, Smaldone A. Use of continuous insulin infusion pumps in young children with type 1 diabetes: a systematic review. *J Pediatr Health Care*. 2009 May-Jun;23(3):173-9.
23. Conget I, Battelino T, Giménez M, Gough H, Castañeda J, Bolinder J; SWITCH Study Group. The SWITCH study (sensing with insulin pump therapy to control HbA(1c): design and methods of a randomized controlled crossover trial on sensor-augmented insulin pump efficacy in type 1 diabetes suboptimally controlled with pump therapy. *Diabetes Technol Ther*. 2011 Jan;13(1):49-54.
24. Cope JU, Morrison AE, Samuels-Reid J. Adolescent use of insulin and patient-controlled analgesia pump technology: a 10-year Food and Drug Administration retrospective study of adverse events. *Pediatrics*. 2008 May;121(5):e1133-8.

25. Costa BM, Fitzgerald KJ, Jones KM, Dunning Am T. Effectiveness of IT-based diabetes management interventions: a review of the literature. *BMC Fam Pract*. 2009 Nov 17;10:72.
26. Cummins E, Royle P, Snaith A, Greene A, Robertson L, McIntyre L, et al. Clinical effectiveness and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes: systematic review and economic evaluation. *Health Technol Assess* 2010;14(11). Accessed Jan 26, 2011. Available at URL address: <http://www.hta.ac.uk/execsumm/summ1411.htm>
27. Danne T, von Schutz W, Lange K, Nestoris C, Datz N, Kordonouri O. Current practice of insulin pump therapy in children and adolescents - the Hannover recipe. *Pediatr Diabetes*. 2006 Aug;7 Suppl 4:25-31.
28. Davis SN, Horton ES, Battelino T, Rubin RR, Schulman KA, Tamborlane WV. STAR 3 randomized controlled trial to compare sensor-augmented insulin pump therapy with multiple daily injections in the treatment of type 1 diabetes: research design, methods, and baseline characteristics of enrolled subjects. *Diabetes Technol Ther*. 2010 Apr;12(4):249-55.
29. Diabetes Health. Product reference guide 2011. Accessed Feb 7, 2011. Available at URL address: <http://www.diabeteshealth.com/charts/>
30. DiMeglio LA, Pottorff TM, Boyd SR, France L, Fineberg N, Eugster EA. A randomized, controlled study of insulin pump therapy in diabetic preschoolers. *J Pediatr*. 2004 Sep;145(3):380-4.
31. ECRI Institute. Infusion pumps, ambulatory; infusion pumps, ambulatory insulin. Healthcare Product Comparison System. Plymouth Meeting (PA): ECRI Institute; 2008.
32. Eugster EA, Francis G; Lawson-Wilkins Drug and Therapeutics Committee. Position statement: Continuous subcutaneous insulin infusion in very young children with type 1 diabetes. *Pediatrics*. 2006 Oct;118(4):e1244-9.
33. Farrar D, Tuffnell DJ, West J. Continuous subcutaneous insulin infusion versus multiple daily injections of insulin for pregnant women with diabetes. *Cochrane Database Syst Rev*. 2007 Jul 18;(3):CD005542.
34. Fatourechí MM, Kudva YC, Murad MH, Elamin MB, Tabini CC, Montori VM. Clinical review: Hypoglycemia with intensive insulin therapy. A systematic review and meta-analyses of randomized trials of continuous subcutaneous insulin infusion versus multiple daily injections. *J Clin Endocrinol Metab*. 2009 Mar;94(3):729-40. Epub 2008 Dec 16.
35. Fox LA, Buckloh LM, Smith SD, Wysocki T, Mauras N. A randomized controlled trial of insulin pump therapy in young children with type 1 diabetes. *Diabetes Care*. 2005 Jun;28(6):1277-81.
36. Giménez M, Conget I, Jansà M, Vidal M, Chiganer G, Levy I. Efficacy of continuous subcutaneous insulin infusion in Type 1 diabetes: a 2-year perspective using the established criteria for funding from a National Health Service. *Diabet Med*. 2007 Nov 26;24(12):1419-1423.
37. González-Romero S, González-Molero I, Fernández-Abellán M, Domínguez-López ME, Ruiz-de-Adana S, Oliveira G, Soriguer F. Continuous subcutaneous insulin infusion versus multiple daily injections in pregnant women with type 1 diabetes. *Diabetes Technol Ther*. 2010 Apr;12(4):263-9.
38. Halvorson M, Carpenter S, Kaiserman K, Kaufman FR. A Pilot Trial in Pediatrics with the Sensor-Augmented Pump: Combining Real-Time Continuous Glucose Monitoring with the Insulin Pump. *J Pediatr*. 2007 Jan;150(1):103-105.
39. Herman WH, Ilag LL, Johnson SL, Martin CL, Sinding J, Al Harthi A, Plunkett CD, LaPorte FB, Burke R, Brown MB, Halter JB, Raskin P. A clinical trial of continuous subcutaneous insulin infusion versus multiple daily injections in older adults with type 2 diabetes. *Diabetes Care*. 2005 Jul;28(7):1568-73.
40. Hirsch IB, Bode BW, Garg S, Lane WS, Sussman A, Hu P, Santiago OM, Kolaczynski JW; Insulin Aspart CSII/MDI Comparison Study Group. Continuous subcutaneous insulin infusion (CSII) of insulin

aspart versus multiple daily injection of insulin aspart/insulin glargine in type 1 diabetic patients previously treated with CSII. *Diabetes Care*. 2005 Mar;28(3):533-8.

41. Institute for Clinical Systems Improvement (ICSI). ICSI healthcare guideline. Management of type 2 diabetes mellitus 12th ed. Bloomington, MN: ICSI; Jul 2010. Accessed Jan 25, 2011. Available at: [http://www.icsi.org/guidelines\\_and\\_more/gl\\_os\\_prot/other\\_health\\_care\\_conditions/diabetes\\_mellitus\\_\\_t\\_\\_type\\_2/diabetes\\_mellitus\\_\\_type\\_2\\_\\_management\\_of\\_\\_\\_6.html](http://www.icsi.org/guidelines_and_more/gl_os_prot/other_health_care_conditions/diabetes_mellitus__t__type_2/diabetes_mellitus__type_2__management_of___6.html)
42. Jeitler K, Horvath K, Berghold A, Gratzner TW, Neeser K, Pieber TR, Siebenhofer A. Continuous subcutaneous insulin infusion versus multiple daily insulin injections in patients with diabetes mellitus: systematic review and meta-analysis. *Diabetologia*. 2008 Jun;51(6):941-51.
43. Johnson SL, McEwen LN, Newton CA, Martin CL, Raskin P, Halter JB, Herman WH. The impact of continuous subcutaneous insulin infusion and multiple daily injections of insulin on glucose variability in older adults with type 2 diabetes. *Diabetes Complications*. 2010 Nov 8. [Epub ahead of print].
44. Juvenile Diabetes Research Foundation (JDRF) Continuous Glucose Monitoring Study Group, Bode B, Beck RW, Xing D, Gilliam L, Hirsch I, Kollman C, Laffel L, Ruedy KJ, Tamborlane WV, Weinzimer S, Wolpert H. Sustained benefit of continuous glucose monitoring on A1C, glucose profiles, and hypoglycemia in adults with type 1 diabetes. *Diabetes Care*. 2009 Nov;32(11):2047-9. Epub 2009a Aug 12.
45. Juvenile Diabetes Research Foundation (JDRF) Continuous Glucose Monitoring Study Group. The effect of continuous glucose monitoring in well-controlled type 1 diabetes. *Diabetes Care*. 2009 Aug;32(8):1378-83. Epub 2009b May 8.
46. Kapellen TM, Heidtmann B, Bachmann J, Ziegler R, Grabert M, Holl RW. Indications for insulin pump therapy in different age groups: an analysis of 1,567 children and adolescents. *Diabet Med*. 2007 Aug;24(8):836-42.
47. Kordonouri O, Hartmann R, Lauterborn R, Barnekow C, Hoeffe J, Deiss D. Age-specific advantages of continuous subcutaneous insulin infusion as compared with multiple daily injections in pediatric patients: one-year follow-up comparison by matched-pair analysis. *Diabetes Care*. 2006 Jan;29(1):133-4.
48. Mastrototaro JJ, Cooper KW, Soundararajan G, Sanders JB, Shah RV. Clinical experience with an integrated continuous glucose sensor/insulin pump platform: a feasibility study. *Adv Ther*. 2006 Sep-Oct;23(5):725-32.
49. McVean JJ, Eickhoff JC, MacDonald MJ. Factors correlating with improved A1C in children using continuous subcutaneous insulin infusion. *Diabetes Care*. 2007 Oct;30(10):2499-500.
50. Meneghini L. Why and how to use insulin therapy earlier in the management of type 2 diabetes. *South Med J*. 2007 Feb;100(2):164-74.
51. Meneghini L, Kennedy L, Koff R, Kuritzky L, Leal S, Peterson K, Zamudio V. Appropriate advancement of type 2 diabetes therapy. *J Fam Pract*. 2007 Oct;56(10 Suppl A):19A-29A.
52. Misso ML, Egberts KJ, Page M, O'Connor D, Shaw J. Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews* 2010, Issue 1. Art. No.: CD005103. DOI: 10.1002/14651858.CD005103.pub2.
53. Monami M, Lamanna C, Marchionni N, Mannucci E. Continuous subcutaneous insulin infusion versus multiple daily insulin injections in type 1 diabetes: a meta-analysis. *Acta Diabetol*. 2010 Dec;47(Suppl 1):77-81.
54. Mukhopadhyay A, Farrell T, Fraser RB, Ola B. Continuous subcutaneous insulin infusion vs intensive conventional insulin therapy in pregnant diabetic women: a systematic review and metaanalysis of randomized, controlled trials. *Am J Obstet Gynecol*. 2007 Nov;197(5):447-56.

55. Nabhan ZM, Kreher NC, Greene DM, Eugster EA, Kronenberger W, DiMeglio LA. A randomized prospective study of insulin pump vs. insulin injection therapy in very young children with type 1 diabetes: 12-month glycemic, BMI, and neurocognitive outcomes. *Pediatr Diabetes*. 2009 May;10(3):202-8.
56. Nahata L. Insulin therapy in pediatric patients with type I diabetes: continuous subcutaneous insulin infusion versus multiple daily injections. *Clin Pediatr (Phila)*. 2006 Jul;45(6):503-8.
57. Nathan DM, Buse JB, Davidson MB, Ferrannini E, Holman RR, Sherwin R, Zinman B; American Diabetes Association; European Association for Study of Diabetes. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care*. 2009 Jan;32(1):193-203.
58. National Institute for Health and Clinical Excellence (NICE). CG66 Diabetes - type 2: full guideline. May 28, 2008a. Accessed Jan 24, 2011. Available at URL address: <http://www.nice.org.uk/guidance/index.jsp?action=download&o=40803>
59. National Institute for Clinical Excellence (NICE). Diabetes in pregnancy. Management of diabetes and its complications from pre-conception to the postnatal period. Jul 2008b. Accessed Jan 24, 2011. Available at URL address: <http://guidance.nice.org.uk/CG63>
60. National Institute for Clinical Excellence (NICE). TA151 Diabetes - insulin pump therapy: guidance. Jul 23, 2008d. Accessed Jan 24, 2011. Available at URL address: <http://www.nice.org.uk/Guidance/TA151/Guidance/pdf/English>
61. National Institute for Clinical Excellence (NICE). CG15 Type 1 diabetes: diagnosis and management of type 1 diabetes in children, young people and adults: Full guideline. Apr 2010. Accessed Feb 3, 2011. Available at URL address: <http://guidance.nice.org.uk/CG15/NICEGuidance/pdf/English>
62. National Institute for Clinical Excellence (NICE). Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. Review of technology appraisal guidance 57. Jul 2008f. Accessed Jan 24, 2011. Available at URL address: <http://www.nice.org.uk/Guidance/TA151>
63. Nimri R, Weintrob N, Benzaquen H, Ofan R, Fayman G, Phillip M. Insulin pump therapy in youth with type 1 diabetes: a retrospective paired study. *Pediatrics*. 2006 Jun;117(6):2126-31.
64. Noh YH, Lee SM, Kim EJ, Kim DY, Lee H, Lee JH, Lee JH, Park SY, Koo JH, Wang JH, Lim IJ, Choi SB. Improvement of cardiovascular risk factors in patients with type 2 diabetes after long-term continuous subcutaneous insulin infusion. *Diabetes Metab Res Rev*. 2008 Jul-Aug;24(5):384-91.
65. Opari-Arrigan L, Fredericks EM, Burkhart N, Dale L, Hodge M, Foster C. Continuous subcutaneous insulin infusion benefits quality of life in preschool-age children with type 1 diabetes mellitus. *Pediatr Diabetes*. 2007 Dec;8(6):377-83.
66. Pańkowska E, Szybowska A, Lipka M, Skórka A. Sustained metabolic control and low rates of severe hypoglycaemic episodes in preschool diabetic children treated with continuous subcutaneous insulin infusion. *Acta Paediatr*. 2007 Jun;96(6):881-4.
67. Parkner T, Laursen T, Vestergaard ET, Hartvig H, Smedegaard JS, Lauritzen T, Christiansen JS. Insulin and glucose profiles during continuous subcutaneous insulin infusion compared with injection of a long-acting insulin in Type 2 diabetes. *Diabet Med*. 2008 May;25(5):585-91.
68. Phillip M, Battelino T, Rodriguez H, Danne T, Kaufman F; European Society for Paediatric Endocrinology; Lawson Wilkins Pediatric Endocrine Society; International Society for Pediatric and Adolescent Diabetes; American Diabetes Association; European Association for the Study of Diabetes. Use of insulin pump therapy in the pediatric age-group: consensus statement from the European

Society for Paediatric Endocrinology, the Lawson Wilkins Pediatric Endocrine Society, and the International Society for Pediatric and Adolescent Diabetes, endorsed by the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care*. 2007 Jun;30(6):1653-62. Epub 2007 Mar 19.

69. Pickup J, Keen H. Continuous subcutaneous insulin infusion at 25 years. *Diabetes Care*. 2002;25(3):593-8.
70. Pickup JC, Sutton AJ. Severe hypoglycaemia and glycaemic control in Type 1 diabetes: meta-analysis of multiple daily insulin injections compared with continuous subcutaneous insulin infusion. *Diabet Med*. 2008 Jul;25(7):765-74.
71. Plotnick L, Clark L, Brancati F, Erlinger T. Safety and effectiveness of insulin pumps therapy in children and adolescents with type 1 diabetes. *Diabetes Care*. 2003 Apr;26(4):1142-6.
72. Pohar SL. Subcutaneous open-loop insulin delivery for type 1 diabetes: Paradigm Real-Time System. *Issues Emerg Health Technol*. 2007 Oct;(105):1-6. Accessed Jan 25, 2011. Available at URL address: [http://www.cadth.ca/media/pdf/E0045\\_Type-1-Diabetes-Paradigm-Real-Time-System\\_cetap\\_e.pdf](http://www.cadth.ca/media/pdf/E0045_Type-1-Diabetes-Paradigm-Real-Time-System_cetap_e.pdf)
73. Primary Care Education Consortium (PCEC). Primary Care Metabolic Group (PCMG). Practical insulin strategies for family physicians. Dec 2006. Accessed Jan 24, 2011. Available at URL address: [http://www.jfponline.com/uploadedFiles/Journal\\_Site\\_Files/Journal\\_of\\_Family\\_Practice/supplement\\_archive/JFPSupp\\_InsulinFP\\_1206.pdf](http://www.jfponline.com/uploadedFiles/Journal_Site_Files/Journal_of_Family_Practice/supplement_archive/JFPSupp_InsulinFP_1206.pdf)
74. Raccah D, Sulmont V, Reznik Y, Guerci B, Renard E, Hanaire H, Jeandidier N, Nicolino M. Incremental value of continuous glucose monitoring when starting pump therapy in patients with poorly controlled type 1 diabetes: the RealTrend study. *Diabetes Care*. 2009 Dec;32(12):2245-50.
75. Silverstein J, Klingensmith G, Copeland K, Plotnick L, Kaufman F, Laffel L, et al. Care of Children and Adolescents With Type 1 Diabetes A statement of the American Diabetes Association. *Diabetes Care*. 2005;28:186-212.
76. Skogsberg L, Fors H, Hanas R, Chaplin JE, Lindman E, Skogsberg J. Improved treatment satisfaction but no difference in metabolic control when using continuous subcutaneous insulin infusion vs. multiple daily injections in children at onset of type 1 diabetes mellitus. *Pediatr Diabetes*. 2008 Oct;9(5):472-9.
77. Trujillo A. Research overview: insulin treatment in pregnancy. *Drug Dev Res* 69:119-123.
78. U.S. Food and Drug Administration (FDA). 510(k) Summary. Animas Corporation ezManager® MAX Diabetes Management Software. K080587. May 15, 2008a. Accessed Jan 20, 2010. Available at URL address: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf8/K080587.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf8/K080587.pdf)
79. U.S. Food and Drug Administration (FDA). 510(k) Summary. Animas Corporation. Symphony Glucose management System. K080639. Jun 24, 2008b. Accessed Jan 20, 2010. Available at URL address: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf8/K080639.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf8/K080639.pdf)
80. Wainstein J, Metzger M, Boaz M, Minuchin O, Cohen Y, Yaffe A, Yerushalmy Y, Raz I, Harman-Boehm I. Insulin pump therapy vs. multiple daily injections in obese Type 2 diabetic patients. *Diabet Med*. 2005 Aug;22(8):1037-46.
81. Weissberg-Benchell J, Antisdell-Lomaglio J, Seshandri R. Insulin pump therapy. *Diabetes Care*. 2003;26:1079-87.
82. White RD. Insulin pump therapy (continuous subcutaneous insulin infusion). *Prim Care*. 2007 Dec;34(4):845-71.
83. Wood JR, Moreland EC, Volkening LK, Svoren BM, Butler DA, Laffel LM. Durability of insulin pump use in pediatric patients with type 1 diabetes. *Diabetes Care*. 2006 Nov;29(11):2355-60.

---

## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	8/15/2008	0087	External Insulin Pumps
Great-West Healthcare	12/20/2007	95.231.09	Insulin Pumps

"CIGNA", "CIGNA HealthCare" 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 by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Health and Life Insurance Company, CIGNA Behavioral Health, Inc., CIGNA Health Management, Inc., 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. 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 or CIGNA Health and Life Insurance Company.