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 pump, the following conditions of coverage apply.

Coverage Policy

External Insulin Pumps

Cigna covers ANY of the following external insulin pumps (HCPCS code E0784) as medically necessary for the management of type 1 or type 2 diabetes mellitus:

- standard external insulin pump
- external insulin pump with micro-delivery feature (e.g., t:slim®)
- combined or integrated continuous subcutaneous insulin infusion pump and standard finger-stick blood glucose monitoring (CSII-BGM) system (e.g., Omnipod® and Personal Diabetes Manager)

When ALL of the following criteria have been met:

- ONE of the following:
- history of diabetic ketoacidosis
- positive autoantibody test as evidenced by any one of the following:
  - islet cell cytoplasmic autoantibodies [ICA]
  - glutamic acid decarboxylase autoantibodies [GADA]
  - insulinoma-associated-antigen 2 autoantibodies [IA-2A]
- fasting C-peptide level ≤ 110% of the lower limit of normal of the laboratory’s measurement method AND a concurrently obtained fasting glucose ≤ 225 mg/dL
- renal insufficiency with a creatinine clearance (actual or calculated from age, gender, weight and serum creatinine) ≤ 50 ml/minute AND a fasting C-peptide level ≤ 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

- ONE 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 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

**Combined or Integrated Continuous Subcutaneous Insulin Infusion and Continuous Blood Glucose Monitor**

Cigna covers EITHER of the following combined or integrated continuous subcutaneous insulin infusion and blood glucose monitoring systems (HCPCS code E0784) as medically necessary:

- combined or integrated continuous subcutaneous insulin infusion and blood glucose monitoring system that includes a continuous blood glucose monitor
- combined or integrated continuous subcutaneous insulin infusion and blood glucose monitoring system that includes a continuous blood glucose monitor with automated insulin suspension (e.g., MiniMed 530G with Enlite™ Insulin Pump)

when ALL of the following criteria are met:

- ONE of the following is met:
  - history of diabetic ketoacidosis
  - positive autoantibody test as evidenced by any one of the following:
    - islet cell cytoplasmic autoantibodies [ICA]
    - glutamic acid decarboxylase autoantibodies [GADA]
    - insulinoma-associated-antigen 2 autoantibodies [IA-2A]
- fasting C-peptide level ≤ 110% of the lower limit of normal of the laboratory’s measurement method
  AND a concurrently obtained fasting glucose ≤ 225 mg/dL
- renal insufficiency with a creatinine clearance (actual or calculated from age, gender, weight and serum creatinine) ≤ 50 ml/minute AND a fasting C-peptide level ≤ 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
- ONE 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

AND

- ONE 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)

Replacement of External Insulin Pump or System Component

Cigna covers the replacement of an existing external insulin pump or an insulin pump system component required for the delivery of insulin as medically necessary for an individual with successfully managed type 1 or type 2 diabetes mellitus when BOTH of the following criteria are met:

- documentation that the pump/component is ALL of the following:
  - malfunctioning
  - no longer under warranty
  - cannot be repaired
- health care provider managing the diabetes has seen the individual in the last six month and supports the need for a replacement device

Supplies

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.

Not Covered

Cigna does not cover a transdermal insulin delivery system (e.g., V-Go™ Disposable Insulin Delivery Device) (HCPCS code A9274; E1399) because it is considered experimental, investigational or unproven.
Cigna does not cover EITHER of the following because each is considered a convenience item and not medically necessary:

- replacement of a currently functioning insulin pump for the sole purpose of receiving the most recent insulin pump technology (i.e., “upgrading” for improved technology)
- additional software or hardware required for downloading data to a device such as personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus

**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 a diabetic who’s 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 glycated 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, 2009; White, 2007).

**Diabetes Mellitus**

According to the American Diabetes Association (ADA), "diabetes is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both". 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 in which the pancreas produces very little or no insulin. Type 1 diabetes occurs in 5–10% of cases and typically occurs in patients less than age 20-30 years. Type 1 diabetics require insulin therapy for life. 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 (ADA, 2013; Merck Manual, 2013).

Type 1 diabetes mellitus is primarily caused by cellular-mediated autoimmune destruction of the beta cells (β-cells) located in the islets of Langerhans in the pancreas. The primary purpose of β-cells is to store and release insulin. In type 1 diabetes the body’s immune system attacks and destroys the β-cells. Destruction of these cells leads to progressive insulin deficiency and hyperglycemia. The major types of circulating autoantibodies in type 1 diabetes include: islet cell autoantibodies (ICA); glutamic acid decarboxylase autoantibodies (GADA); and insulinoma-associated-antigen 2 autoantibodies (IA-2A). The best current criterion for diagnosis of immune-mediated diabetes is the presence of anti-islet autoantibodies. One and usually more of these autoantibodies are present in 85–90% of individuals when fasting hyperglycemia is initially detected. ICAs and GADAs are detected in about 80% of newly diagnosed diabetics and IA-2A is detected in about 60% of type1 diabetes. The rate of β-cell destruction varies being rapid in infants and children and slow in adults. Some diabetics may retain residual β-cell function sufficient to prevent DKA. Autoantibody testing is done to help distinguish type 1 from type 2 diabetes. The presence of insulin antibodies is common in individuals who are taking insulin and is not an indicator of the type of diabetes (ADA, 2013; Bylund and Nakamura, 2011; Eisenbarth and Buse 2011; Towns and Pietropaolo, 2011).

In some patients diabetic ketoacidosis (DKA) may be the first manifestation of the disease. DKA is an acute metabolic complication of diabetes characterized by hyperglycemia, hyperketonemia, and metabolic acidosis. The development of DKA occurs when insulin levels are unable to meet the body’s metabolic needs. Insulin deficiency causes the body to metabolize triglycerides and muscle instead of glucose for energy. When this occurs, there is a rise in the serum levels of glycerol and free fatty acids. As a result, ketones, the by products of

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. One way to determine the insulin level in the body is by using a blood test called a connecting peptide (C-peptide) test. The C-peptide level can be done to determine if a patient has type 1 of type 2 diabetes. A type 1 diabetic whose pancreas does not make insulin has a low level of C-peptide. Typically, a person with type 2 diabetes has a normal C-peptide level. 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. Insulopenia is diagnosed in less than 5% of type 2 diabetics (NLM, 2014; Centers for Medicare and Medicaid [CMS], 2005; CMS, 2001).

A fasting C-peptide level that is ≤ 110% of the lower limit of normal of the laboratory’s measurement method and a concurrently obtained fasting glucose of ≤ 225 mg/dL is indicative of insulinopenic type 2 diabetes. For example, if the laboratory normal C-peptide range was 0.78–1.89 nanograms/milliliter (ng/mL) then the insulopenic type 2 diabetic without renal insufficiency would have a value of ≤ 0.86 ng/mL and with renal sufficiency would have a value of ≤ 1.56 ng/mL. This subset of individuals may be candidates for CSII (CMS, 2005; CMS, 2001).

Another indication for insulin pumps for type 2 diabetics is renal insufficiency as demonstrated by an abnormal creatinine clearance. In patients with compromised renal function, a creatinine clearance (actual or calculated from age, gender, weight and serum creatinine) ≤ 50 milliliters (mL)/minute, and a fasting C-peptide level ≤ 200% of the lower limit of normal of the laboratory’s measurement methods is also indicative of insulinopenia (CMS, 2005; CMS, 2001). If the creatinine clearance level is not obtained from a laboratory, there are equations that can be used to estimate the glomerular filtration rate (eGFR). The two most commonly used equations for calculating creatinine clearance for adults are the Cockcroft-Gault (CG) and Modification of Diet in Renal Disease (MDRD) study equations (Levey formula). These equations are used because of the difficulty of obtaining an adequate urine specimen for a creatinine clearance. Both equations have disadvantages (Pincus, et al., 2011; National Kidney Disease Education Program [NKDEP], 2014; National Kidney Foundation [NKF], 2013).

The Cockcroft-Gault (CG) equation allows the creatinine clearance to be estimated from the serum creatinine in a patient with a stable serum creatinine. The equation is not adjusted for body surface area and does not take into account differences in creatinine production due to variation in muscle mass caused by disease states. It systematically overestimates the glomerular filtration rate (GFR) in individuals who have relatively low muscle mass in relation to their body weight (e.g., obese, edematous, or chronically debilitated individuals). The CG also does not take into account variations caused by extrarenal elimination and tubular secretion (Pincus, et al., 2011; NKDEP, 2014; NKF, 2013).

The MDRD equation takes into consideration race which CG does not. Per the NKDEP, the MDRD equation is not for all patients. “Although an excellent tool for assessing kidney function, eGFR derived from the MDRD Study equation may not be suitable for all populations. MDRD-based estimates of GFR, like all creatinine-based estimates of kidney function (e.g., Cockcroft-Gault, reciprocal of serum creatinine), are only useful when renal function is stable; serum creatinine values obtained while kidney function is changing will not provide accurate estimates of kidney function”. The equation is also not recommended for nonadults (age < 18 years), individuals with unstable creatinine concentrations, and persons with extremes in muscle mass and diet (Pincus, et al., 2011; NKDEP, 2014).

The modified Schwartz GFR equation is used to estimate GFR in children. The formula is similar to the MDRD equation with modifications made for children. A newer equation is the CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) formula that is proposed to be more accurate than CG & MDRD but the NIH says CKD-EPT is still under investigation (NKF, 2013; NKDEP, 2014; Levey, et al., 2009; Pincus, et al., 2011).

Standard External Insulin Pumps

An external insulin pump is a battery-powered device worn and programmed by the user to deliver a continuous subcutaneous insulin infusion (CSII). Most conventional insulin pumps deliver insulin by applying pressure from behind the contents of the reservoir. Some newer pumps, like the t-slim®, draw insulin from the reservoir into a
micro-delivery chamber allowing the insulin to be delivered in smaller increments from 0.001 units per hour (u/hr) to above 0.1 u/hr. Other pumps may be combined or integrated with standard finger-stick glucose monitoring system (CSII-BGM).

**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 FDA approved devices include:

- Accu-Chek® Combo System or Spirit Insulin Pump Systems (Roche Diagnostics, Indianapolis, IN) combined insulin pump with finger stick blood glucose meter for the treatment of insulin requiring diabetes and for the quantitative measurement of glucose in fresh capillary whole blood from the finger
- ADI Insulin Pump (NiliMedix Ltd., Haifa, Israel) for persons with diabetes requiring insulin
- Amigo® Insulin Pump (Nipro Diabetes Systems, Inc., Miramar, FLA) for subcutaneous infusion of insulin.
- Animas® OneTouch™ Ping™ (Animas Corp., Frazer, PA) insulin pump with a OneTouch™ Ping™ Meter Remote for diabetics requiring continuous subcutaneous insulin delivery and measurement of glucose
- Asante Snap (Asante Solutions, Sunnyvale, CA) for adult patients requiring insulin
- Dana Diabecare® II Insulin Pump (Soool Development Co., Ltd., North Attleboro, MA) for subcutaneous delivery of insulin
- Minimed Paradigm® Revel™ Insulin Pump (Medtronic Minimed, Northridge, CA) for the management of diabetes mellitus in persons requiring continuous delivery of insulin (MMT-523/723 for adults and MMT-523K/723K for ages 7–17 years)
- MiniMed Paradigm Revel™ Insulin Pump (Medtronic MiniMed, Inc. Northridge, CA) used in conjunction with the Contour® Next Link glucose meter (Bayer HealthCare, Tarrytown, NY) for the continuous delivery of insulin in persons requiring insulin and the quantitative measurement of glucose in fresh capillary whole blood
- OmniPod™ Insulin Management System (Insulet Corporation, Boston, MA) is a wireless insulin pump that consists of a disposable insulin pod and Personal Diabetes Manager that includes a built-in FreeStyle® glucose meter. The pod is filled with insulin by the patient and replaced every 72 hours.
- Solo™ MicroPump Delivery System (Medingo, Ltd., Yqneam, Israel) for the management of diabetes mellitus in persons requiring insulin
- t:slim™ micro-delivery insulin pump (Tandem Diabetes Care, Inc., San Diego CA) for the subcutaneous delivery of insulin for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater

**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; Raccah, 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 and comparative studies 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, 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:** In general, insulin pump usage in type 2 diabetics is not an established treatment modality. However, insulin pumps are a 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. 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 while other studies reported no significant difference in MDI and insulin pump outcomes. Overall, complications were not greater with CSII (Bode, 2010; Johnson, et al., 2010; Noh, et al., 2008; Parkner, et al., 2008; Pickup and Renard, 2008; Berthe, et al., 2007; Wainstein, et al., 2005; Raskin, et al., 2003).

**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 College of Obstetricians and Gynecologists [ACOG], 2012; Rodbard, et al., 2007).

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. (2011) 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 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.

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.

**Technology Assessment:** The Agency for Healthcare Research and Quality (AHRQ) (2012) conducted a comparative effectiveness systematic review on insulin delivery and glucose monitoring. The objective was to determine if CSII compared to MDI (at least three injections per day) resulted in “better glycemic control, less hypoglycemia, improved quality of life (QOL), and improved clinical outcomes” in individuals with type 1, type 2 or pre-existing diabetes in pregnancy. AHRQ also wanted to assess if the outcomes differed if real-time CGM (rt-CGM) was used compared to SMBG (at least three fingersticks a day). Randomized controlled trials and
Observational studies were included in the assessment. Only studies using rapid-acting insulin analogs and not regular insulin in the CSII groups were included and only randomized controlled trials were used in combined estimates for HbA1c and severe hypoglycemia. Meta-analysis was conducted when two or more studies were sufficiently homogeneous in the key variables. No studies were found that compared CSII with MDI that reported frequency of adjusting insulin therapy, adherence to therapy, health visits, or microvascular and macrovascular disease. The authors noted that the studies were “small”, and of “fair to poor quality”. Studies were heterogeneous in terms of insulin regimens and definitions of nonsevere hypoglycemia, hyperglycemia, and weight gain. Few studies included children age ≤ 12 years, adults age ≥ 65 years, or pregnant women with pre-existing type 2 diabetes. Therefore, conclusion could not be made regarding these populations. None of the studies included data on the microvascular and macrovascular complications associated with long-term diabetes. Few studies reported data on treatment adherence. AHRQ noted that the results of this report were not generalizable to nonspecialty settings or all patients with diabetes mellitus, as the initiation, instruction, monitoring, and therapeutic changes for CSII and rt-CGM use are often limited to expert settings and highly motivated patients and families.

Regarding comparative effectiveness of CSII vs. MDI, AHRQ reported:

- “In adults with type 1 diabetes, CSII showed favorable effect on glycemic control, but the result was influenced by one study”. When that study was removed, CSII and MDI had a similar effect on HbA1c.
- Randomized controlled trials showed no difference in the effect on HbA1c between CSII and MDI for children, adolescents, adults, and pregnant women with type 1 diabetes or for adults with type 2 diabetes.
- Overall, CSII use resulted in improvement in both general and diabetes-specific QOL measures when compared with MDI for children, adolescents, and adults with type 1 diabetes. Definitive conclusion could not be drawn re QOL for pregnant women.
- Severe hypoglycemia rates were similar in type 1 diabetics using MDI vs. CSII.
- “In pregnant women with pre-existing type 1 diabetes, observational studies showed no difference in gestational age at delivery between the CSII and MDI groups” Due to insufficient evidence definitive conclusions about other maternal and fetal outcomes could not be made.
- There was insufficient evidence to draw definitive conclusions about severe hypoglycemia rates in pregnant women with type 1 diabetes.

In conclusions AHRQ stated “that intensive insulin therapy delivered by either CSII or MDI using current rapid-acting insulin analogs with CSII is equally effective in lowering HbA1c in several patient populations with diabetes—adolescents and pregnant women with type 1 diabetes”.

Professional Societies/Organizations: In a clinical practice guideline for diabetes and pregnancy, the Endocrine Society (2013) recommended the use of continuous insulin infusion during pregnancy if the pump was started or used prior to the pregnancy. The Society does not recommend initiation of pump therapy during pregnancy unless other strategies such as multiple daily doses of insulin have proven unsuccessful.

The American Association of Clinical Endocrinologists (AACE) Consensus Panel (Rodbard, et al., 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 I - “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)

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 (Phillip, et al., 2007) 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.

The 2005 (reaffirmed 2012) 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):

- 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®, 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 ≤ 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 basal rates 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 and an integrated bolus wizard feature for an individual less than age 18 years is medically necessary.

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; Russell-Minda, et al., 2009). Additional software or hardware for downloading data to computers, iPhones®, iPad® or iPods® for data management are not medically indicated.

Replacement of External Insulin Pump
The average warranty on an insulin pump is four years. Warranties for other components of a pump or combined or integrated systems (e.g., remote control, reservoirs, transmitters) range from six months to two years. Some components may have no warranty (e.g., sensors) (Medtronic, 2013; Animas, 2014; Omnipod, 2014). There is a lack of evidence to support improved outcomes (e.g., A1C) because of insulin pump enhanced technology. Diabetics should be routinely followed by a physician and seen by their physician within six months of a request for a replacement pump to ensure compliance to the management of their diabetes.

**Combined or Integrated Continuous Subcutaneous Insulin Infusion and Blood Glucose Monitoring System That Includes a Continuous Blood Glucose Monitor (CBGM) System**

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 finger-stick 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, 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; Kordonouri, et al., 2010; Raccah, et al., 2009; Halvorson, et al., 2007; Mastrototaro, et al., 2006).

**Professional Societies/Organizations:** The 2014 ADA clinical recommendations for the treatment of diabetes state that CGM in conjunction with intensive insulin therapy is a useful tool in selected type 1 diabetics (age ≥ 25 years) and may be helpful in children, teens and younger adults although the evidence is less strong. Success correlates with adherence to ongoing use of the device. "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.

**Combined or Integrated Continuous Subcutaneous Insulin Infusion and Blood Glucose Monitoring System with Automatic Insulin Suspension**

The MiniMed 530G, called The MiniMed Paradigm® Veo™ in Europe, is a new insulin delivery system that consists of an insulin pump integrated with a continuous glucose monitor and advanced software algorithms. The System includes the following devices that can be used in combination or individually: MiniMed 530G Insulin Pump, Enlite™ Sensor, Enlite™ Serter, the MiniLink Real-Time System, the Bayer Contour NextLink glucose meter, CareLink® Professional Therapy Management Software for Diabetes, and CareLink Personal Therapy Management Software for Diabetes. There are two models, the MMT-551 and the MMT-751. The only difference is the size of the reservoir. The pump was designed for adults and children (Medtronic, 2013, FDA, 2013).

The Threshold Suspend automation component automatically stops the delivery of insulin if the glucose level reaches a preset threshold between 60–90mg/dL. An alarm alerts the user who can take appropriate action. If the user is unable to respond, insulin delivery will be suspended for up to two hours or sooner if reset by the user.
**U.S. Food and Drug Administration (FDA):** The MiniMed 530G received FDA premarket approval (PMA) in 2013 as an artificial pancreas device system with threshold suspend. The 530G is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of diabetes mellitus in persons, sixteen years of age and older, requiring insulin as well as, for the continuous monitoring and trending of glucose levels in the fluid under the skin.

**Literature Review:** The European equivalent of the MiniMed 530G is the MiniMed Paradigm® Veo. The Veo has a wider glucose range to trigger suspension (40–110 mg/dL), a higher maximum bolus capacity (75 units vs. 25 units) and automatically recalibrates following suspension whereas the 530G asks the user if they want to recalibrate. The differences are due to FDA requirements. Therefore, studies evaluating the Veo are applicable to the 530G.

Bergenstal et al. 2013 conducted a randomized controlled trial to evaluate nocturnal hypoglycemia in type 1 diabetics using Veo threshold-suspend pump therapy (n=121) compared to non-threshold-suspend therapy (n=267). The primary outcome measures were changes in the glycated hemoglobin level and area under the curve (AUC) for nocturnal hypoglycemic events defined as a sensor glucose value of ≤ 65 mg/dL between the hours of 10:00 p.m. and 8:00 a.m., lasting for 20 consecutive minutes without pump interaction. Two-hour threshold-suspend events were analyzed with respect to subsequent sensor glucose values. Follow-ups occurred for three months. The changes in the glycated hemoglobin values were not significantly different in the two groups. However the AUC for nocturnal hypoglycemic events was significantly lower in the threshold-suspend group (p<0.001). The percentages of nocturnal sensor glucose values less than 50 mg/dL, 50 mg/dL to less than 60 mg/dL and 60 mg/dL to less than 70 mg/dL were all significantly reduced in the threshold-suspend group (p<0.001, each). Four patients in the non-threshold suspend group experienced a severe hypoglycemic event. There were no episodes of ketoacidosis in either group. Results of the study showed that threshold suspend pump therapy reduced nocturnal hypoglycemia without increasing glycated hemoglobin levels.

Ly et al. (2013) conducted a randomized controlled trial (n=95) to analyze the incidence of severe and moderate hypoglycemia using a sensor-augmented pump with low-glucose suspension (i.e., VEO system). Subjects were randomized to insulin pump only (n=49) or to insulin pump with automated insulin suspension (n=46). The primary outcome was the combined incidence of severe (i.e., hypoglycemic seizure or coma) and moderate hypoglycemic (i.e., an event requiring assistance for treatment) events. Counter regulatory hormone (epinephrine) responses to hypoglycemia were also assessed using hypoglycemic clamp technique in a subgroup. Following six months of treatment, the event rates in the pump-only group decreased from 28 to 16 and the suspension group dropped from 175 to 35 events. The adjusted incidence rate per 100 patient months was significantly different in the suspension group (p<0.001). There was no significant change in glycated hemoglobin or in the epinephrine response rate in the pump only group (p=0.74) or in the suspension group (p=0.26). There were no reported episodes of diabetic ketoacidosis or hyperglycemia with ketosis. The outcomes of the study showed that sensor-augmented pump therapy with automated insulin suspension resulted in a reduction of severe and moderate hypoglycemic events. Limitations of the study include the small patient population and short-term follow-up.

Garg et al. (2012) conducted a randomized controlled trial (n=50) to evaluate the efficacy of automatic suspension of insulin delivery during induced hypoglycemia among type 1 diabetics. Subjects used a sensor-augmented insulin pump system with a low glucose suspend (LGS) feature that automatically stops insulin delivery for two hours following a sensor glucose value ≤ 70 mg/dL (i.e., VEO). After fasting overnight, subjects exercised until their plasma glucose (measured with the YSI 2300 STAT Plus™ glucose and lactate analyzer [YSI Life Sciences, Yellow Springs, OH]) value reached ≤ 85 mg/dL on different occasions. Subjects then underwent a washout periods for 3-10 days. Exercise sessions were done with suspension on (LGS-On) or with continued insulin delivery regardless of sensor glucose value (LGS-OFF). The order of LGS-On and LGS-Off sessions was randomly assigned. Outcome measures included the duration and severity of hypoglycemia with LGS-On and LGS-Off sessions and to estimate the risk of rebound hyperglycemia after pump suspension. A total of 98 out of 134 sessions were successful. The mean hypoglycemia duration was significantly less during LGS-On compared to LGS-OFF (p=0.006) and mean nadir YSI glucose was significantly higher in the LGS-On group (p<0.015). The mean end-observation YSI glucose was also significantly better in the LGS-On group (p<0.001). The results of this study show that automatic suspension of insulin significantly reduced the duration and severity of induced hypoglycemia without rebound hyperglycemia.
An ECRI technology assessment product report included three randomized controlled trials and one multicenter, prospective study. Outcomes of a standard insulin pump were compared to the Veo with threshold suspend. ECRI concluded that the data supported the clinical effectiveness of the Veo and VEO “might work better” than a standard insulin pump without a feedback glucose monitoring loop (ECRI, 2013).

**Professional Societies/Organizations:** In their 2014 Standards of Care for diabetes, the American Diabetes Association (ADA) recommendations for therapy for type 1 diabetics state that the use of sensor-augmented low glucose suspend threshold pump may be considered for patients with frequent nocturnal hypoglycemia and/or hypoglycemia unawareness.

**Transdermal Insulin Delivery System**
A proposed new method of insulin delivery is a transdermal, mechanical insulin delivery system. A patch-like device is filled with insulin and placed on the skin. The devices deliver a continuous low dose of basal insulin through the skin and/or deliver bolus insulin upon demand. Other than the device worn on the skin, there are no additional components or separate control devices that manage or monitor the insulin dosage. Overall this technology is proposed for type 2 diabetics. An example of this type of device is the V-Go Disposable Insulin Delivery Device (Valeritas, Inc., Bridgewater, NJ). Proposed advantages of these systems include not having to perform intermittent subcutaneous injections, ease of use, improved safety due to reduction in needle handling, and improved acceptance and compliance by the patients. However, the systemic blood levels of delivering insulin in this manner have generally proven to be inadequate for management of the diabetic patient (Anhalt and Bohannon, 2010; ECRI, 2010; Skladany, et al., 2008; Varshosaz, 2007).

V-Go is a basal-bolus insulin delivery device proposed for use by type 2 adult diabetics. The device, which uses the h-Patch™ delivery technology, is used for subcutaneous delivery of 24 hours of U-100 fast-acting insulin (i.e., Humalog® [insulin lispro] and Novolog® [insulin aspart]). V-Go is filled with insulin using the EZ Fill device and then applied to the body (e.g., arm or abdomen). By pushing a button, a microneedle is subcutaneously inserted into the body and insulin delivery begins at a continuous preset basal rate. When needed, a bolus can be delivered by pushing the bolus button. A window with a grey indicator allows visualization of the reservoir to monitor the progress of the infusion. The reservoir is replaced every 24 hours and discarded after use. V-Go is a fully mechanical device using a compressed spring and does not require electronics, batteries or software. Different preset basal rates are available (i.e., V-Go 20, V-Go 30, V-Go 40). The device is only available with a prescription for a 30-day supply (one kit). Two vials of insulin are required for the V-Go 20 and three vials for the V-Go 30 and V-Go 40 (Rosenfeld, et al., 2012; Valeritas, Inc., 2012).

V-Go is approved by the FDA as a Class II, 510(k) external insulin infusion pump. The system is indicated for continuous subcutaneous infusion of insulin in one 24-hour time period and on-demand bolus dosing in two-unit increments in adult patients requiring insulin. V-Go 20 delivers 20 units of insulin in one 24-hour time period (0.83 U/hr), V-Go 30 delivers 30 units of insulin in one 24-hour time period (1.25U/hr) and V-Go 40 delivers 40 units of insulin in one 24-hour time period (1.67U/hr). Each device can also deliver on-demand bolus dosing in two-unit increments (up to 36 units per one 24-hour time period). Per the FDA, no clinical performance data were required to validate the intended uses or user needs of the system (FDA, 2011).

There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of V-Go. Published studies include a case series of six type 2 diabetics who used V-G for seven days (Kapitza, et al., 2008) and a retrospective review with data collected by 22 type 2 diabetics and one type 1 diabetic using a patient questionnaire (Rosenfeld, et al., 2012).

**Use Outside of the US**
The European equivalent of the MiniMed 530G is the Paradigm® Real Time Veo™ System (Medtronic MiniMed, United Kingdom). The software for the Threshold Suspend tool is the same for the 530G System and the Veo. Although the sensors for the two pumps are not identical, they operate using similar principles and fundamental scientific technology. The Veo received Conformite Europeenne (CE) mark approval in 2009 for marketing in Europe.

The OmniPod System was launched in the United States in 2005 and subsequently became available in Latin America and Israel. In 2010, Ypsomed AG, an independent diabetes specialist and technology provider, began distributing OmniPod in a number of countries with a primary focus on Europe.
The Scottish Intercollegiate Guidelines Network (SIGN) recommendations on the management of diabetes (2010) stated that insulin pump therapy is associated with modest improvements in glycemic control and should be considered for patients unable to achieve their glycemic targets. CSII therapy should be considered in patients who experience recurring episodes of severe hypoglycemia.

In their 2008a 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 2008b 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.

In a technology assessment on CSII, NICE (2008f) 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.

NICE (2005) stated that CGMS has a role in the treatment of adults with consistent glucose control problems such as repeated hyper- or hypoglycemia at the same time of day, or hypoglycemia unawareness that is unresponsive to conventional insulin dose adjustment. For type 1 diabetic children and young adults, NICE concluded that CGMS “should be offered” to children and young adults with persistent hypoglycemia unawareness or repeated hypo- or hyperglycemic episodes.

The Canadian Agency of Drugs and Technologies in Health (CADTH) (Pohar, 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.

Summary
The use of a standard external insulin pump, microdelivery insulin pump, insulin pump combined with a standard finger-stick blood glucose monitor or a continuous blood glucose monitor, or an insulin pump with an automated insulin suspension component is indicated for a specific subset of insulin-treated type 1 and type 2 diabetics who meet a defined set of criteria including completion of a self-management educational program and adherence to a regimen of self-management blood glucose monitoring.

The replacement of an existing fully functional external insulin pump with newer models (i.e., “upgrade”) and additional features or for use with a continuous glucose monitor is primarily for convenience or ease of use. 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.

Evidence in the published peer-reviewed scientific literature does not support the safety and efficacy of a transdermal insulin delivery system (e.g., V-Go™ Disposable Insulin Delivery). A limited number of studies have primarily been in the form of case series and retrospective reviews with small patient populations, short-term follow-ups, and self-reported outcomes.

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

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>A4230</td>
<td>Infusion set for external insulin pump, non-needle cannula type</td>
</tr>
<tr>
<td>A4231</td>
<td>Infusion set for external insulin pump, needle type</td>
</tr>
<tr>
<td>A4232</td>
<td>Syringe with needle for external insulin pump, sterile, 3cc</td>
</tr>
<tr>
<td>A9274</td>
<td>External ambulatory delivery system, disposable, each, includes all supplies and accessories</td>
</tr>
<tr>
<td>E0784</td>
<td>External ambulatory infusion pump, insulin</td>
</tr>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
<tr>
<td>K0552</td>
<td>Supplies for external drug infusion pump, syringe type cartridge, sterile, each</td>
</tr>
<tr>
<td>S9145</td>
<td>Insulin pump initiation, instruction in initial use of pump (pump not included)</td>
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†Note: Covered when used per the criteria set forth in this policy.

Experimental/Investigational/Unproven/Not Covered when used to report a transdermal insulin delivery system (e.g., V-Go™ Disposable Insulin Delivery Device):

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