Clinical Policy Bulletin: Infusion Pumps

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Policy

I. Implantable Infusion Pumps

Aetna considers implanted infusion pumps medically necessary durable medical equipment (DME) when all of the following criteria are met:

- It is medically necessary that the drug be administered by an implanted infusion pump; and
- The drug is medically necessary for the treatment of members (see medical necessity criteria for various types of infusion pumps below); and
- The infusion pump has been approved by the FDA for infusion of the particular drug that is to be administered.

A. Anti-spasmodic drugs

Aetna considers an implantable infusion pump medically necessary when used to intrathecally administer anti-spasmodic drugs (e.g., baclofen) to treat chronic intractable spasticity in persons who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

1. Member has failed a six-week trial of non-invasive methods of spasticity control, such as oral anti-spasmodic drugs, either because these methods fail to adequately control the spasticity or produce intolerable side effects; and
2. Member has a favorable response to a trial intrathecal dosage of the anti-spasmodic drug prior to pump implantation.
Intrathecal baclofen (Lioresal) is considered medically necessary for the treatment of intractable spasticity caused by spinal cord disease, spinal cord injury, or multiple sclerosis and for stiff person syndrome. Baclofen is considered medically necessary for persons who require spasticity to sustain upright posture, balance in locomotion, or increased function.

Documentation in the member's medical record should indicate that the member's spasticity was unresponsive to other treatment methods and that the oral form of baclofen was ineffective in controlling spasticity or that the member could not tolerate the oral form of the drug. A trial of oral baclofen is not a required prerequisite to intrathecal baclofen therapy in children ages 12 years old or less due to the increased risk of adverse effects from oral baclofen in this group.

The medical record should document that the member showed a favorable response to the trial dosage of the baclofen before subsequent dosages are considered medically necessary. An implanted pump for continuous fusion is considered not medically necessary for members who do not respond to a 100 mcg intrathecal bolus.

Intrathecal baclofen is considered experimental and investigational as a treatment for neuromyotonia (Isaac's syndrome), hydrocephalus, and rheumatoid arthritis.

B. Drugs for treatment of chronic intractable pain

An implantable infusion pump is considered medically necessary when used to administer opioid drugs (e.g., morphine), ziconotide, and/or clonidine intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or non-malignant origin in persons who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

1. The member's history must indicate that he or she has not responded adequately to non-invasive methods of pain control, such as systemic opioids (including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain); and
2. A preliminary trial of intraspinal opioid drug administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief, the degree of side effects (including effects on the activities of daily living), and acceptance.

Implantable infusion pumps for intrathecal or epidural infusion of opioids, ziconotide, and clonidine are considered experimental and investigational as a treatment for gastroparesis and for all other indications because their effectiveness for indications other than the one listed above.
has not been established. \(\text{Note:}\) Currently, morphine and ziconotide are the only FDA-approved analgesics for long-term intrathecal infusion [Turk et al, 2011]).

C. \textit{Intrahepatic chemotherapy infusion for liver metastases from colorectal cancer}

Implantable infusion pumps are considered medically necessary for administration of intrahepatic chemotherapy (e.g., floxuridine) to members with colorectal cancer and liver metastases.

Aetna considers "one-shot" arterial chemotherapy for persons with liver metastases from colorectal cancer experimental and investigational.

\text{Note:} An average 3 to 5 days inpatient hospitalization is medically necessary for intrahepatic chemotherapy. Hospital discharge is dependent on resolution of pain, nausea and vomiting which complicate the procedure.

D. \textit{Contraindications to implantable infusion pumps}

Implantable infusion pumps are considered not medically necessary for persons with the following contraindications to implantable infusion pumps:

1. Members who have an active infection that may increase the risk of the implantable infusion pump; or
2. Members whose body size is insufficient to support the weight and bulk of the device; or
3. Members with known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.); or
4. Members with other implanted programmable devices where the crosstalk between devices may inadvertently change the prescription.

E. \textit{Experimental and investigational uses of implanted infusion pumps}

Implanted infusion pumps are considered experimental and investigational for all other indications, including any of the following:

1. Implantable infusion pumps for intrahepatic administration of chemotherapy for indications other than noted above, including treatment of primary hepatocellular carcinoma or hepatic metastases from cancers other than colorectal cancer; or
2. Implantable pumps for the infusion of heparin for recurrent thromboembolic disease; or
3. Implantable pumps for the infusion of insulin to treat diabetes; or
4. Implantable pumps for the infusion of baclofen for chronic neuropathic pain (e.g., complex regional pain syndrome/reflex sympathetic dystrophy).
See also CPB 0607 - Anesthetic and Antiemetic Infusion Pumps.

II. External Infusion Pumps

Aetna considers external infusion pumps medically necessary DME for administration of any of the following medications:

A. Certain parenteral anticancer chemotherapy drugs (e.g., cladribine, fluorouracil, cytarabine, bleomycin, flouxuridine, doxorubicin, vincristine, vinblastine, cisplatin, paclitaxel) if the drug is part of an evidence-based chemotherapy regimen and parenteral infusion of the drug at a strictly controlled rate is necessary to avoid systemic toxicity or adverse effects, and the drug is administered either: (i) by continuous infusion over 8 hours; or (ii) by intermittent infusions lasting less than 8 hours that do not require the person to return to the physician's office prior to the beginning of each infusion; or

B. Certain parenteral antifungal or antiviral drugs (e.g., acyclovir, foscarnet, amphotericin B, or ganciclovir); or

C. Chemotherapy for primary hepatocellular carcinoma or colorectal cancer where the tumor is unresectable or the member refuses surgical excision of the tumor; or

D. Deferoxamine for the treatment of acute iron poisoning and iron overload (only external infusion pumps are considered medically necessary); or

E. Heparin for the treatment of thromboembolic disease and/or pulmonary embolism (only external infusion pumps used in an institutional setting are considered medically necessary); or

F. Heparin to adequately anticoagulate women throughout pregnancy (warfarin compounds are not routinely used for this indication); or

G. Insulin for persons with diabetes mellitus who meet the selection criteria for external insulin infusion pumps for diabetes set forth below; or

H. Morphine or other narcotic analgesics (except meperidine) for intractable pain caused by cancer; or

I. Other parenterally administered drugs where an infusion pump is necessary to safely administer the drug at home; or

J. Parenteral epoprostenol or treprostinil for persons with pulmonary hypertension; or

K. Parenteral inotropic therapy with dobutamine, milrinone, and/or dopamine.

Aetna considers external infusion pumps experimental and investigational for all other indications. See also CPB 0468 - Terbutaline Pump for Preterm Labor.

III. External Insulin Infusion Pumps for Diabetes

Aetna considers external insulin infusion pumps medically necessary DME for the persons with diabetes who meet the criteria in section A or in section B below:
A. Members must meet all of the following criteria:

1. The member has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump*; and
2. The member has completed a comprehensive diabetes education program; and
3. The member has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump**; and
4. The member meets at least one of the following criteria while on multiple daily injections (more than 3 injections per day) of insulin:
   a. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; or
   b. Elevated glycosylated hemoglobin level (HbA1c greater than 7.0%, where upper range of normal is less than 6.0%; for other HbA1c assays, 1% over upper range of normal); or
   c. History of recurring hypoglycemia (less than 60 mg/dL); or
   d. History of severe glycemic excursions; or
   e. Wide fluctuations in blood glucose before mealtime (e.g., pre-prandial blood glucose levels commonly exceed 140 mg/dL);

or

B. The member has been on a pump prior to enrollment in Aetna, and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Aetna enrollment.

Aetna considers external infusion pumps for diabetes experimental and investigational where the above-listed criteria are not met.

Footnote:

* It may be considered medically necessary to initiate the use of insulin infusion pumps during pregnancy earlier than the criteria stated above to avoid fetal and maternal complications of diabetes and pregnancy. It may be considered medically necessary for poorly controlled women with diabetes to sometimes get started on the pump pre-pregnancy or in the first trimester.

Notes on external insulin infusion pumps:

Aetna considers a programmable disposable external insulin infusion pump (e.g., OmniPod Insulin Management System) an acceptable alternative to a standard insulin infusion pump
for persons who meet medical necessity criteria for external insulin infusion pumps.

Aetna’s medical necessity criteria for external infusion pumps for diabetes have been adapted from Medicare national policy on external insulin infusion pumps, as outlined in CMS's Coverage Issues Manual Section 60-14.

Documentation of continued medical necessity of the external insulin infusion pump requires that the member be seen and evaluated by the treating physician at least once every 6 months.

External subcutaneous insulin infusion pumps are only considered medically necessary for persons who have demonstrated ability and commitment to comply with a regimen of pump care, frequent self-monitoring of blood glucose, and careful attention to diet and exercise.

Some external insulin infusion pumps (e.g., Paradigm Real-Time Insulin Pump and Continuous Glucose Monitoring System, Animas OneTouch PING) are able to take results of the blood glucose reading, calculate the appropriate insulin infusion rate, wirelessly transmit the results from the blood glucose monitor to the pump, and automatically adjust the insulin infusion rate, saving the member some extra steps. These insulin pump features, when present, are considered integral to the external insulin infusion pump and blood glucose monitor.

The pump must be ordered by and follow-up care of the member must be managed by a physician with experience managing persons with insulin infusion pumps and who works closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of insulin infusion pumps.

See also CPB 0070 - Diabetes Tests, Programs and Supplies.

IV. Supplies and Drugs used with Implantable or External Infusion Pumps

Aetna considers supplies that are needed for the effective use of the DME medically necessary.

Such supplies include those drugs and biologicals that must be put directly into the equipment in order to achieve the therapeutic benefit of the DME or to assure the proper functioning of the equipment.

V. Replacement Pumps

A. Replacement of a functioning insulin pump with an insulin pump with wireless communication to a glucose monitor is considered not medically necessary as such wireless communication has not been shown to improve clinical outcomes

B. Replacement of an external insulin pump is considered medically necessary for children who require a larger insulin reservoir.
C. The replacement of infusion pumps that are out of warranty, are malfunctioning, and cannot be refurbished is considered medically necessary.

VI. Nonprogrammable Disposable Insulin Delivery Systems

Aetna considers nonprogrammable disposable insulin delivery systems (e.g., V-Go™ disposable insulin delivery device) experimental and investigational because their effectiveness has not been established.

Background

Baclofen (Lioresal) is a derivative of gamma aminobutyric acid (GABA) that acts specifically at the spinal end of the upper motor neurons to cause muscle relaxation. Intrathecal baclofen may be indicated for patients with severe chronic spasticity of spinal cord origin. An implantable infusion pump is required for the administration of intrathecal baclofen. Intrathecal baclofen therapy is indicated for persons with severe chronic spasticity of spinal cord origin (including multiple sclerosis) that is refractory to oral baclofen or where there are unacceptable side effects from oral baclofen at the effective dose. The patient should be shown to respond to a single intrathecal bolus dose of up to 100 mcgs of baclofen. A positive response is defined as an average two-point drop on an objective muscle tone or spasm screening system (e.g., The Ashworth and Spasm scale). According to available guidelines, intrathecal baclofen therapy is not considered appropriate if the patient has a history of hypersensitivity to Lioresal, is pregnant or has inadequate birth control, has severely impaired renal function, has severe hepatic or gastrointestinal disease, or has cerebral lesions as the source of spasticity.

Brennan and Whittle (2008) stated that continuous infusion of intrathecal baclofen (ITB) via a subcutaneously implanted pump has developed over the past 2 decades as a powerful tool in the management of spasticity in various adult and pediatric neurological conditions. Acting more focally on spinal GABA receptors, ITB causes fewer systemic side effects than orally administered baclofen. The result is facilitation of daily caring, and symptomatic relief from painful spasm. With increasing experience of ITB use, novel applications and indications are emerging. These include the management of dystonia and chronic neuropathic pain. However, despite some recent authoritative reviews, there is still uncertainty about optimal use and evaluation of this therapy.

Shilt et al (2008) stated that ITB is an effective treatment of spasticity in patients with cerebral palsy (CP). However, several recent reports have raised concerns that the treatment may be associated with a rapid progression of scoliosis. The objective of this study was to further examine the effect of ITB treatment on the progression of scoliosis in patients with CP. Spastic CP patients who were ITB
candidates were followed radiographically. Baseline Cobb angles of the primary curve were measured during the period of ITB pump insertion and at the most recent follow-up visit. Each patient was matched with a control patient by the diagnosis of CP, age, sex, topographical involvement, and initial Cobb angle. The mean rate of change in Cobb angle was compared between ITB and control patients using paired-t test. A multiple linear regression model was used to examine the difference, controlling for age, sex, topographical involvement, and initial Cobb angle. A total of 50 ITB patients and 50 controls were included in the analysis. There was no statistically significant difference between the mean change in Cobb angle in ITB patients (6.6 degrees per year) compared with the matched control patients (5.0 degrees per year, p = 0.39). The results from the multiple regression analysis also failed to show a statistically significant difference (0.92 degrees per year difference between ITB patients and controls, p = 0.56). The authors concluded that the progression of scoliosis in CP patients with ITB treatment is not significantly different from those without ITB treatment. The findings suggest that patients receiving ITB experience a natural progression of scoliosis similar to the natural history reported in the literature.

The discovery of spinal opiate receptors, and that the binding of morphine at relatively low concentrations to these receptors produced effective analgesia have led to the development of intraspinal analgesia for the management of pain. This mode of opioid administration has become an attractive alternative for cancer patients whose pain is not relieved by conventional drugs and/or routes; and for others who cannot tolerate the side effects of systemic administration of opioids in the dose needed for adequate analgesia as the disease progresses. A popular procedure for intraspinal administration of opioids analgesics is the implantation of an infusion pump which allows the direct delivery of opioids to the receptors in the spinal cord continuously and/or in an intermittent manner.

Available evidence indicates that chronic intrathecal opioids administration via implantable pumps can provide satisfactory pain relief for patients who suffer from intractable cancer pain. In addition, it allows the patients to be less dependent on hospital services, thus improving the quality of their lives. Studies have also shown that the same method of treatment was successful in providing quality analgesia to carefully selected patients who experienced chronic pain from nononcologic origins, although reductions in pain and improvements in function is observed less consistently in noncancer pain. Some investigators have reported untoward side effects of intrathecal opioid administration, including development of a fibrous mass around the tip of the catheter, resulting in compression of the intrathecal space with displacement of the spinal cord.

To be considered for spinal analgesia, a patient must have a normal platelet count and no coagulation disorder, infection, or other problems that might preclude the use of spinal drugs. Before the implantation of a permanent infusion system, an efficacy test is usually performed to assess the patient's response and dose. One or several trial doses of 5 to 10 mg of epidural morphine, or 0.5 to 1.0 mg intrathecal morphine is/are administered while all other analgesic medications are stopped. Subjective pain ratings and undesirable side effects are evaluated for several days. A decision to implant the pump is made only if pain is markedly reduced and other opioid analgesics are not needed by the patient.
Aetna's medical necessity criteria for external infusion pumps for diabetes have been adapted from Medicare national policy on external insulin infusion pumps, as outlined in CMS's Coverage Issues Manual Section 60-14.

There is some limited evidence that external insulin infusion pumps improve glycemic control over multiple daily injections in persons with type 2 diabetes (Hammond, 2004; Pickup & Renard, 2008; Fatourechi, et al., 2009), although not all studies have been consistent (see, e.g., Raskin, et al., 2003; Herman, et al., 2005; Berthe, et al., 2007; Parkner, et al., 2008).

Fatourechi et al (2009) reported on a metaanalysis of randomized controlled clinical trials of continuous subcutaneous insulin infusion (CSII) over multiple daily injections (MDI) in persons with diabetes. The investigators identified 15 eligible randomized trials of moderate quality, with elevated baseline and end-of-study hemoglobin A1c (HbA1c) levels. The investigators reported that patients with type 1 diabetes using CSII had slightly lower HbA1c [random-effects weighted mean difference, -0.2 %; 95 % confidence interval (CI): -0.3 to -0.1, compared with MDI], with no significant difference in severe (pooled odds ratio, 0.48; 95 % CI: 0.23 to 1.00) or nocturnal hypoglycemia (pooled odds ratio 0.82, 95 % CI: 0.33 to 2.03). Adolescents and adults with type 1 diabetes enrolled in cross-over trials had nonsignificantly fewer minor hypoglycemia episodes per patient per week (-0.08; 95 % CI: -0.21 to 0.06) with CSII than MDI; children enrolled in parallel trials had significantly more episodes (0.68; 95 % CI: 0.16 to 1.20; p (interaction) = 0.03).

The investigators reported that outcomes were not different in patients with type 2 diabetes. The investigators concluded that "[c]ontemporary evidence indicates that compared to MDI, CSII slightly reduced HbA1c in adults with type 1 diabetes, with unclear impact on hypoglycemia. In type 2 diabetes, CSII and MDI had similar outcomes. The effect in patients with hypoglycemia unawareness or recurrent severe hypoglycemia remains unclear because of lack of data."


An American Association of Clinical Endocrinologists (2010) consensus statement on insulin pumps in diabetes included a recommendation for use of insulin pumps in persons with type 2 diabetes. The consensus stated that the ideal continuous subcutaneous insulin infusion (CSII) candidate would be a patient with type 1 diabetes mellitus or absolutely insulin-deficient type 2 diabetes mellitus who currently performs 4 or more insulin injections and 4 or more self-monitored blood glucose measurements daily, is motivated to achieve tighter blood glucose control, and is willing and intellectually and physically able to undergo the rigors of insulin pump therapy initiation and maintenance. The consensus statement also included a recommendation for use of insulin infusion pumps in selected patients with insulin-requiring type 2 diabetes mellitus who satisfy any or all of the following:
1) C-peptide positive but with suboptimal control on a maximal program of basal/bolus injections; 2) substantial "dawn phenomenon"; 3) erratic lifestyle (eg, frequent long distance travel, shift-work, unpredictable schedules leading to difficulty maintaining timing of meals); 4) severe insulin resistance, candidate for
U500 insulin by continuous subcutaneous insulin infusion (CSII). The consensus statement said that current literature on insulin pump use has focused primarily on the benefits of CSII in patients with type 1 diabetes mellitus, with some attention to the role of CSII in patients with severely insulin-deficient type 2 diabetes mellitus. The consensus statement indicated that "few clinical investigations have examined CSII use in patients with type 2 DM." The consensus statement noted that one analysis of 4 randomized controlled trials in patients with type 2 diabetes mellitus (citing Monami, et al.) found no significant HbA1c improvements and no significant differences in hypoglycemic risk with CSII versus multiple daily injection therapy over 12 weeks. The consensus statement noted, however, that there was a nonsignificant trend toward decreased insulin requirements was observed among CSII patients. The statement also cited other recent meta-analysis of insulin pump therapy in type 2 diabetes, one by Jeitler, et al. (2008) which they interpreted as finding "no conclusive CSII benefits for patients with type 2 DM", and a meta-analysis by Fatourechi, et al. (2009), which they interpreted as finding "CSII and MDI outcomes were similar among patients with type 2 DM."

The consensus statement also referenced a nested case-control study of the use of insulin infusion pumps versus non-pump therapy in pregnant women with type 2 diabetes or gestational diabetes (Simmons, et al., 2001).

A systematic evidence review by Mukhopadhyay et al (2007) found no advantage of using continuous subcutaneous insulin infusion (CSII) over multiple daily injections in pregnant women with diabetes. The investigators identified randomized controlled clinical trials of the effects of CSII versus multiple daily insulin injections on glycemic control and pregnancy outcome in women with diabetes. Studies were rated for quality independently by 2 reviewers. Summary weighted mean differences and odds ratios were estimated for insulin dose, birthweight, gestational age, mode of delivery, hypoglycemic/ketotic episodes, worsening retinopathy, neonatal hypoglycemia, and rates of intrauterine fetal death. Six randomized clinical trials met the inclusion criteria. The investigators found that pregnancy outcomes and glycemic control were not significantly different among treatment groups. The investigators found higher numbers of ketoacidotic episodes and diabetic retinopathy in the CSII group, but these differences did not reach statistical significance. The investigators found that this systematic review did not find any advantage or disadvantage of using CSII over multiple daily injections in pregnant diabetic women.

Cummins et al (2010) examined the clinical effectiveness and cost-effectiveness of using CSII to treat diabetes. These investigators updated the previous assessment report by reviewing evidence that has emerged since the last appraisal, and took account of developments in alternative therapies, in particular the long-acting analog insulins, which cause fewer problems with hypoglycaemia. The primary focus for type 1 diabetes mellitus (T1DM) was the comparison of CSII with MDI, based on the newer insulin analogs, but trials of neutral protamine Hagedorn (NPH)-based MDI that had been published since the last assessment were identified and described in brief. For type 2 diabetes mellitus (T2DM), all trials of MDI versus CSII were included, whether the long-acting insulin was analog or not, because there was no evidence that analog-based MDI was better than NPH-based MDI. Trials that were shorter than 12 weeks were excluded. Information on the patients' perspectives was obtained from 4 sources: (i) the submission from the pump users group -- Insulin Pump Therapy (INPUT); (ii) interviews with
parents of young children who were members of INPUT; (iii) some recent studies; and (iv) from a summary of findings from the previous assessment report. Economic modeling used the Center for Outcomes Research (CORE) model, through an arrangement with the NICE and the pump manufacturers, whose submission also used the CORE model. The 74 studies used for analysis included 8 randomized controlled trials (RCTs) of CSII versus analog-based MDI in either T1DM or T2DM, 8 new (since the last NICE appraisal) RCTs of CSII versus NPH-based MDI in T1DM, 48 observational studies of CSII, 6 studies of CSII in pregnancy, and 4 systematic reviews. The following benefits of CSII were highlighted: better control of blood glucose levels, as reflected by HbA1c levels, with the size of improvement depending on the level before starting CSII; reduction in swings in blood glucose levels, and in problems due to the dawn phenomenon; fewer problems with hypoglycemic episodes; reduction in insulin dose per day, thereby partly off-setting the cost of CSII; improved quality of life, including a reduction in the chronic fear of severe hypoglycemia; more flexibility of lifestyle -- no need to eat at fixed intervals, more freedom of lifestyle and easier participation in social and physical activity; and benefits for the patients' family. The submission from INPUT emphasised the quality of life gains from CSII, as well as improved control and fewer hypoglycemic episodes. Also, there was a marked discrepancy between the improvement in social quality of life reported by successful pump users, and the lack of convincing health-related quality of life gains reported in the trials. With regard to economic evaluation, the main cost of CSII is for consumables, such as tubing and cannulae, and is about 1800 to 2000 pounds per year. The cost of the pump, assuming 4-year life, adds another 430 to 720 pounds per year. The extra cost compared with analog-based MDI averages 1700 pounds. Most studies, assuming a reduction in HbA1c level of 1.2 %, found CSII to be cost-effective. The authors concluded that based on the totality of evidence, using observational studies to supplement the limited data from RCTs against best MDI, CSII provides some advantages over MDI in T1DM for both children and adults. However, there was no evidence that CSII is better than analog-based MDI in T2DM or in pregnancy. They stated that further trials with larger numbers and longer durations comparing CSII and optimized MDI in adults, adolescents and children are needed. In addition, there should be a trial of CSII versus MDI with similar provision of structured education in both arms. A trial is also needed for pregnant women with pre-existing diabetes, to investigate using CSII to the best effect.

Transdermal A nonprogrammable insulin delivery system using a transdermal microneedle has been advocated as a needle-free alternative to subcutaneous injection conventionally used to treat type 2 diabetes (Johns, et al., 2014; Rosenfeld, et al., 2012; Kapitza, et al., 2008). However, the effectiveness of a nonprogrammable transdermal microneedle insulin delivery in the management of diabetic patients has not been established.

Zu et al (2011) described the preparation and characterization of chitosan (CS)-polyvinyl alcohol (PVA) blend hydrogels for the controlled release of nano-insulin; CS-PVA blend hydrogels were prepared using glutaraldehyde as the cross-linking agent. The obtained hydrogels, which have the advantages of both PVA and CS, can be used as a material for the transdermal drug delivery (TDD) of insulin. The nano-insulin-loaded hydrogels were prepared under the following conditions: 1.2g of polyethylene glycol, 1.5 g of CS, 1.2 g of PVA, 1.2 ml of 1 % glutaraldehyde
solution, 16 ml of water, and 40 mg of nano-insulin with 12 mins of mixing time and 3 mins of cross-linking time. The nano-insulin-loaded hydrogels were characterized using scanning electron microscopy, energy dispersive spectrometry, Fourier-transform infrared spectroscopy, differential scanning calorimetry, thermogravimetric analysis, X-ray diffraction, and its mechanical properties were analyzed. The results showed that all molecules in the hydrogel have good compatibility and they formed a honeycomb-like structure. The hydrogel also showed good mechanical and thermal properties. The in-vitro drug release of the hydrogel showed that the nano-insulin accorded with Fick's first law of diffusion and it has a high permeation rate (4.421 μg/(cm(2)hr)). The authors concluded that these results suggested that the nano-insulin-loaded hydrogels are a promising non-invasive TDD system for diabetes chemotherapy.

Ito et al (2012) developed a dissolving microneedle (DM) application system, where 225 to 300 insulin-loaded DMs were formed on a chip. After the heat-sealed sheet is removed, the system covered with the press-through package layer is put on the skin. By pressing with the hand, insulin DMs were inserted into the skin. Factors affecting the penetration depth of DM were studied using applicator in-vitro and in-vivo experiments. The penetration depth was determined for rat and human skin. Two-layered DM array chips were prepared to obtain complete absorption of insulin and administered to the rat abdominal skin. Plasma glucose levels were measured for 6 hrs. By comparing the hypoglycemic effect with that obtained after subcutaneous injection, relative pharmacological availability was determined. The penetration depth increased from 21 +/- 3 μm to 63 +/- 2 μm in proportion to application speed to isolated rat skin, at 0.8 to 2.2 m/s. Human skin showed similar results in the penetration depth. The in-vivo penetration depth was dependent on the force (0.5 to 2.5 N) and duration (1 to 10 mins), as the secondary application force. The penetration depth was 211 +/- 3 μm with 3-min duration in the in-vivo rat experiment. Dissolving microneedle array chips having an insulin-loaded space of 181.2 +/- 4.2 and 209 +/- 3.9 μm were evaluated in the rat. Relative pharmacological availability values of insulin from DMs were 98.1 +/- 0.8 % and 98.1 +/- 3.1 %, respectively. The authors concluded that these findings suggested the usefulness of the 2-layered DM application system for the transdermal delivery of insulin.

Rosenfeld et al (2012) described patient perceptions regarding their experience and reported findings in a retrospective analysis of glycemic control in a cohort of patients who used the V-Go, a mechanical, 24-hr disposable, subcutaneous continuous insulin delivery device that delivers a preset basal infusion rate and on-demand insulin. Patients used the V-Go and answered telephone surveys about their perception of device use. Corresponding clinical data were retrospectively collected before V-Go initiation, after 12 weeks of use, at the end of treatment, and 12 weeks after discontinuation. Analyses were performed with non-parametric statistical tests. A total of 23 patients participated in this study. Mean values of the following characteristics were documented: patient age, 61 years; body mass index, 30 kg/m2; diabetes duration, 16 years; duration of insulin therapy, 7 years; average duration of V-Go use, 194 days; and mean total daily insulin dose, 50 U at baseline, 46 U while on V-Go, and 51 U after stopping V-Go treatment. Mean patient rating of the overall experience was 9.1 at 12 weeks on a scale from 1 to 10 (10 being most positive). Mean hemoglobin A1c value decreased from baseline (8.8 % to 7.6 %; [p = 0.005]) while using the V-Go, and it increased to 8.2
% after treatment. Fasting plasma glucose trended from 205 mg/dL at baseline to 135 mg/dL while using V-Go and increased to 164 mg/dL after V-Go was stopped. Weight was essentially unchanged. No differences in hypoglycemic events were found; site reactions were minor. The authors concluded that glycemic control improved when patients were switched to the V-Go for insulin delivery, and it deteriorated when the V-Go was discontinued. The main drawbacks of this study were its retrospective nature, small sample size, and short-term follow-up. These preliminary findings need to be validated by well-designed studies.

Furthermore, UpToDate reviews on “General principles of insulin therapy in diabetes mellitus” (McCulloch, 2012a), “Insulin therapy in adults with type 1 diabetes mellitus” (McCulloch, 2012b), and “Insulin therapy in type 2 diabetes mellitus” (McCulloch, 2012c) do not mention the use of transdermal insulin delivery.

Jahn et al (2013) noted that as all major insulin pump manufacturers comply with the international infusion pump standard EN 60601-2-24:1998, there may be a general assumption that all pumps are equal in insulin-delivery accuracy. These researchers investigated single-dose and averaged-dose accuracy of incremental basal deliveries for 1 patch model and 3 durable models of insulin pumps. For each pump model, discrete single doses delivered during 0.5 U/hr basal rate infusion over a 20-hr period were measured using a time-stamped micro-gravimetric system. Dose accuracy was analyzed by comparing single doses and time-averaged doses to specific accuracy thresholds (± 5 % to ± 30 %). The percentage of single doses delivered outside accuracy thresholds of ± 5 %, ± 10 %, and ± 20 % were as follows: Animas OneTouch® Ping® (43.2 %, 14.3 %, and 1.8 %, respectively), Roche Accu-Chek® Combo (50.6 %, 24.4 %, and 5.5 %), Medtronic Paradigm® Revel™/Veo™ (54.2 %, 26.7 %, and 6.6 %), and Insulet OmniPod® (79.1 %, 60.5 %, and 34.9 %). For 30 mins, 1 hr, and 2 hrs averaging windows, the percentage of doses delivered outside a ± 15 % accuracy were as follows: OneTouch Ping (1.0 %, 0.4 %, and 0 %, respectively), Accu-Chek Combo (4.2 %, 3.5 %, and 3.1 %), Paradigm Revel/Veo (3.9 %, 3.1 %, and 2.2 %), and OmniPod (33.9 %, 19.9 %, and 10.3 %). The authors concluded that this technical evaluation demonstrated significant differences in single-dose and averaged-dose accuracy among the insulin pumps tested. Differences in dose accuracy were most evident between the patch pump model and the group of durable pump models. Of the pumps studied, the Animas OneTouch Ping demonstrated the best single-dose and averaged-dose accuracy.

CPT Codes / HCPCS Codes / ICD-9 Codes

**Implantable Infusion Pumps:**

CPT codes covered if selection criteria are met:

- 36563
- 36576
- 36578

http://qawww.aetna.com/cpb/medical/data/100_199/0161_draft2.html

12/08/2014
36583
36590
62350 - 62351
62355
62360 - 62362
62365
62367 - 62370
95990 - 95991
96365 - 96368
96374 - 96376
96409 - 96411
96413 - 96417
96422 - 96425
96522
96523
99601 - 99602

**HCPCS codes covered if selection criteria are met:**

A4220  Refill kit for implantable infusion pump

A4221  Supplies for maintenance of drug infusion catheter, per week (list drug separately)

A4223  Infusion supplies not used with external infusion pump, per cassette or bag (list drugs separately)

A4300  Implantable access catheter, (e.g., venous, arterial, epidural subarachnoid, or peritoneal, etc) external access
A4301  Implantable access total catheter, port/reservoir (e.g., venous, arterial, epidural, subarachnoid, peritoneal, etc.)

A4305  Disposable drug delivery system, flow rate of 50 ml or greater per hour [not covered for intralesional administration of narcotic analgesics and anesthetics]

A4306  Disposable drug delivery system, flow rate of less than 50 ml per hour [not covered for intralesional administration of narcotic analgesics and anesthetics]

C1772  Infusion pump, programmable (implantable)

C1891  Infusion pump, nonprogrammable, permanent (implantable)

C2626  Infusion pump, nonprogrammable, temporary (implantable)

C8957  Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than 8 hours), requiring use of portable or implantable pump

E0782  Infusion pump, implantable, nonprogrammable (includes all components, e.g., pump, catheter, connectors, etc.)

E0783  Infusion pump system, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)

E0785  Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement

E0786  Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)

J0475  Injection baclofen, 10 mg

J0476  Injection, baclofen, 50 mcg for intrathecal trial

J0735  Injection, clonidine HCl, 1 mg

J2270  Injection, morphine sulfate, up to 10 mg

J2271  Injection, morphine sulfate, 100 mg

J2275  Injection, morphine sulfate (preservative-free sterile solution), per 10 mg

J2278  Injection, ziconotide, 1 microgram

J9000 - J9999  Chemotherapy drugs

Q0081  Infusion therapy, using other than chemotherapeutic drugs, per visit

Q0084  Chemotherapy administration by infusion technique only, per visit
S0093  Injection, morphine sulphate, 500 mg (loading dose for infusion pump)

S5035  Home infusion therapy, routine service of infusion device (e.g., pump maintenance)

S5036  Home infusion therapy, repair of infusion device (e.g., pump repair)

S5497  Home infusion therapy, catheter care/maintenance, not otherwise classified; includes administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S5502  Home infusion therapy, catheter care/maintenance, implanted access device, includes administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment, (drugs and nursing visits coded separately), per diem (use this code for interim maintenance of vascular access not currently in use)

S5517  Home infusion therapy, all supplies necessary for restoration of catheter patency or declotting

S5518  Home infusion therapy, all supplies necessary for catheter repair

S9325  Home infusion therapy, pain management infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem (do not use this code with S9326, S9327 or S9328)

S9326  Home infusion therapy, continuous (24 hours or more) pain management infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9327  Home infusion therapy, intermittent (less than 24 hours) pain management infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9328  Home infusion therapy, implanted pump pain management infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9329  Home infusion therapy, chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem (do not use this code with S9330 or S9331)

S9330  Home infusion therapy, continuous (24 hours or more) chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9331  Home infusion therapy, intermittent (less than 24 hours) chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9363  Home infusion therapy, antispasmodic therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

HCPCS codes not covered for indications listed in the CPB:

J1817  Insulin for administration through DME (i.e., insulin pump) per 50 units

S9336  Home infusion therapy, continuous anticoagulant infusion therapy (e.g., Heparin), administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9353  Home infusion therapy, continuous insulin infusion therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

ICD-9 codes covered if selection criteria are met (not all inclusive):

153.0 - 154.8  Malignant neoplasm of colon, rectum, rectosigmoid junction, and anus

197.7  Secondary malignant neoplasm of liver, specified as secondary

336.1  Vascular myelopathies

338.0  Central pain syndrome

338.21 - 338.29  Chronic pain
338.3  Neoplasm related pain (acute) (chronic)
338.4  Chronic pain syndrome
340  Multiple sclerosis
342.10 - 342.12  Spastic hemiplegia
343.0 - 343.9  Infantile cerebral palsy
344.00 - 344.09  Quadriplegia and quadripareisis
344.1  Paraplegia
728.85  Spasm of muscle
781.0  Abnormal involuntary movements
781.2  Abnormality of gait
806.00 - 806.09  Fracture of vertebral column with spinal cord injury
952.00 - 952.09  Spinal cord injury without evidence of spinal bone injury

**ICD-9 codes not covered for indications listed in the CPB:**
001.0 - 139.8  Infectious and parasitic diseases
249.00 - 249.91  Secondary diabetes mellitus
250.00 - 250.93  Diabetes mellitus
415.11 - 415.19  Pulmonary embolism and infarction
444.0 - 445.89  Arterial embolism and thrombosis and atheroembolism
451.0 - 453.9  Phlebitis and thrombophlebitis and other venous embolism and thrombosis
648.00 - 648.04  Diabetes mellitus complicating pregnancy, childbirth, or the puerperium
648.80 - 648.84  Abnormal glucose tolerance complicating pregnancy, childbirth, or the puerperium
729.2  Neuralgia, neuritis, and radiculitis, unspecified
783.22  Underweight

V12.51  Personal history of venous thrombosis and embolism
V12.52  Personal history of thrombophlebitis
V14.5   Personal history of allergy to narcotic agent
V14.6   Personal history of allergy to analgesic agent
V45.00 - Cardiac device in situ
V45.09
V45.85  Insulin pump status
V58.67  Long-term (current) use of insulin

Other ICD-9 codes related to the CPB:
V10.05  Personal history of malignant neoplasm of large intestine
V10.06  Personal history of malignant neoplasm of rectum, rectosigmoid junction, and anus
V53.09  Fitting and adjustment of other devices related to nervous system and special senses
V58.11 - Encounter for antineoplastic chemotherapy and immunotherapy
V58.12

External Infusion Pumps:

CPT codes covered if selection criteria are met:

96365 - 96368
96374 - 96376
96409 - 96411
96413 - 96417
96422 - 96425
96521
99601 - 99602

HCPCS codes covered if selection criteria are met:
A4221  Supplies for maintenance of drug infusion catheter, per week (list drugs separately)

A4222  Infusion supplies for external drug infusion pump, per cassette or bag (list drugs separately)

A4230  Infusion set for external insulin pump, nonneedle cannula type

A4231  Infusion set for external insulin pump, needle type

A4232  Syringe with needle for external insulin pump, sterile, 3cc

A4300  Implantable access catheter, (e.g., venous, arterial, epidural subarachnoid, or peritoneal, etc) external access

A4301  Implantable access total catheter, port/reservoir (e.g., venous, arterial, epidural, subarachnoid, peritoneal, etc.)

A4305  Disposable drug delivery system, flow rate of 50 ml or greater per hour [not covered for intralesional administration of narcotic analgesics and anesthetics]

A4306  Disposable drug delivery system, flow rate of less than 50 ml per hour [not covered for intralesional administration of narcotic analgesics and anesthetics]

A9274  External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories

C8957  Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than 8 hours), requiring use of portable or implantable pump

E0779  Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater

E0780  Ambulatory infusion pump, mechanical, reusable, for infusion less than 8 hours

E0781  Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient

E0784  External ambulatory infusion pump, insulin [V-Go disposable insulin delivery device not covered]

E1520  Heparin infusion pump for hemodialysis

J0475  Injection baclofen, 10 mg

J0476  Injection baclofen, 50 mcg for intrathecal trial

J0895  Injection, defoxamine mesylate [Desferal], 500 mg

J1250  Injection, Dobutamine HCL, per 250 mg
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1644</td>
<td>Injection, Heparin sodium, per 1,000 units</td>
</tr>
<tr>
<td>J1815</td>
<td>Injection insulin, per 5 units</td>
</tr>
<tr>
<td>J1817</td>
<td>Insulin for administration through DME (i.e., insulin pump) per 50 units</td>
</tr>
<tr>
<td>J2260</td>
<td>Injection, milrinone lactate, 5 mg</td>
</tr>
<tr>
<td>J9000</td>
<td>Chemotherapy drugs</td>
</tr>
<tr>
<td>K0601</td>
<td>Replacement battery for external infusion pump owned by patient</td>
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<tr>
<td>K0605</td>
<td></td>
</tr>
<tr>
<td>Q0081</td>
<td>Infusion therapy, using other than chemotherapeutic drugs, per visit</td>
</tr>
<tr>
<td>Q0084</td>
<td>Chemotherapy administration by infusion technique only, per visit</td>
</tr>
<tr>
<td>S9140</td>
<td>Diabetic management program, follow-up visit to non-MD provider</td>
</tr>
<tr>
<td>S9141</td>
<td>Diabetic management program, follow-up visit to MD provider</td>
</tr>
<tr>
<td>S9145</td>
<td>Insulin pump initiation, instruction in initial use of pump (pump not included)</td>
</tr>
<tr>
<td>S9336</td>
<td>Home infusion therapy, continuous anticoagulant infusion therapy (e.g., Heparin), administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
<tr>
<td>S9345</td>
<td>Home infusion therapy, anti-hemophilic agent infusion therapy (e.g., factor VIII); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits codes separately), per diem</td>
</tr>
<tr>
<td>S9346</td>
<td>Home infusion therapy, alpha-1-proteinase inhibitor (e.g., Prolastin); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
<tr>
<td>S9347</td>
<td>Home infusion therapy, uninterrupted, long-term, controlled rate intravenous or subcutaneous infusion therapy (e.g., epoprostenol); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
</tbody>
</table>
S9348  Home infusion therapy, sympathomimetic/inotropic agent infusion therapy (e.g., Dobutamine); administrative services, professional pharmacy services, care coordination, all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9353  Home infusion therapy, continuous insulin infusion therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9355  Home infusion therapy, chelation therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9357  Home infusion therapy, enzyme replacement intravenous therapy; (e.g., Imiglucerase); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9359  Home infusion therapy, antitumor necrosis factor intravenous therapy; (e.g., Infliximab); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9363  Home infusion therapy, anti-spasmodic therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9373  Home infusion therapy, hydration therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem (do not use with hydration therapy codes S9374-S9377 using daily volume scales)

S9374  Home infusion therapy, hydration therapy; 1 liter per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9375  Home infusion therapy, hydration therapy; more than 1 liter but no more than 2 liters per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

S9376  Home infusion therapy, hydration therapy; more than 2 liters but no more than 3 liters per day, administrative services,
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S9377</td>
<td>Home infusion therapy, hydration therapy; more than 3 liters per day, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
<tr>
<td>S9455</td>
<td>Diabetic management program, group session</td>
</tr>
<tr>
<td>S9460</td>
<td>Diabetic management program, nurse visit</td>
</tr>
<tr>
<td>S9490</td>
<td>Home infusion therapy, corticosteroid infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
<tr>
<td>S9494</td>
<td>Home infusion therapy, antibiotic, antiviral, or antifungal therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately, per diem) (do not use with home infusion codes for hourly dosing schedules S9497 - S9504)</td>
</tr>
<tr>
<td>S9497</td>
<td>Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 3 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
<tr>
<td>S9500</td>
<td>Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 24 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
<tr>
<td>S9501</td>
<td>Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 12 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
<tr>
<td>S9502</td>
<td>Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 8 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
<tr>
<td>S9503</td>
<td>Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 6 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
</tbody>
</table>
necessary supplies and equipment (drugs and nursing visits coded separately), per diem

**S9504**  
Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 4 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

**Other HCPCS codes related to the CPB:**

**E0607**  
Home blood glucose monitor

**J1642**  
Injection, heparin sodium, (heparin lock flush), per 10 units

**ICD-9 codes covered if selection criteria are met (not all-inclusive):**

001.0 - 139.8  Infectious and parasitic diseases

153.0 - 154.8  Malignant neoplasm of colon, rectum, rectosigmoid junction, and anus

155.0 - 155.2  Malignant neoplasm of liver and intrahepatic bile ducts

249.00 - 249.91  Secondary diabetes mellitus

250.00 - 250.93  Diabetes mellitus

275.0  Disorders of iron metabolism

338.3  Neoplasm related pain (acute) (chronic)

415.11 - 415.19  Pulmonary embolism and infarction

415.19  Pulmonary embolism and infarction

416.0  Primary pulmonary hypertension

416.8  Other chronic pulmonary heart diseases

444.0 - 445.89  Arterial embolism and thrombosis and atheroembolism

451.0 - 453.9  Phlebitis and thrombophlebitis and other venous embolism and thrombosis

648.00 - 648.04  Diabetes mellitus complicating pregnancy, childbirth, or the puerperium

648.80 - 648.84  Abnormal glucose tolerance complicating pregnancy, childbirth, or the puerperium

671.00 - 671.94  Venous complications in pregnancy and the puerperium
673.00 - Obstetrical pulmonary embolism
673.84

964.0 Poisoning by iron and its compounds

V58.67 Long-term (current) use of insulin

Other ICD-9 codes related to the CPB:

V45.85 Insulin pump status
V58.11 - Encounter for antineoplastic chemotherapy and
V58.12 immunotherapy

The above policy is based on the following references:

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    pain by intraspinal narcotics infusion via an implanted reservoir. JAMA. 
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    systemic fluorouracil for hepatic metastases from colorectal cancer. Arch 
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    (7):1112-1118.
15. U.S. Department of Health and Human Services, Health Care Financing 
17. No authors listed. Reappraisal of hepatic arterial infusion in the treatment of 
    nonresectable liver metastases from colorectal cancer. Meta-analysis 
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    (5B):3825-3833.
    Local Coverage Determination No. L5044. Durable Medical Equipment 
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    cisplatin and subcutaneous interferon-alpha-2b for patients with locally 
22. Rougier P. Are there indications for intraarterial hepatic chemotherapy or 
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    arterial embolization and one-shot chemotherapy in hepatocellular 
27. U.S. Department of Health and Human Services, Health Care Financing 
    Administration (HCFA). Continuous subcutaneous insulin infusion pump. 
    Decision Memorandum. Issue # CAG-00041. Baltimore, MD: HCFA; August


92. McCulloch DK. General principles of insulin therapy in diabetes mellitus. Last reviewed December 2012a. UpToDate Inc. Waltham, MA.
93. McCulloch DK. Insulin therapy in adults with type 1 diabetes mellitus. Last reviewed December 2012b. UpToDate Inc. Waltham, MA.
94. McCulloch DK. Insulin therapy in type 2 diabetes mellitus. Last reviewed December 2012c. UpToDate Inc. Waltham, MA.


