



CIGNA MEDICAL COVERAGE POLICY

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Subject Implantable Infusion Pumps

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- Minimally Invasive Treatment of Back Pain
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- Reflex Sympathetic Dystrophy/Complex Regional Pain Syndrome Treatment
- RimabotulinumtoxinB (Myobloc®)
- Transcatheter Arterial Chemoembolization (TACE) of Liver Tumors

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Coverage Policy

CIGNA covers the use of an implantable infusion pump and supplies, when used to administer drugs that are specifically approved by the U.S. Food and Drug Administration (FDA) for the intended use, as medically necessary for EITHER of the following conditions:

- intrahepatic arterial infusion of chemotherapeutic drugs when the cancer is unresectable or the individual is not a surgical candidate for-EITHER of the following indications:
 - primary hepatocellular cancer
 - metastatic cancer that is limited to the liver
- intrathecal administration of anti-spasmodic drugs for the treatment of chronic intractable spasticity or chronic intractable dystonia when BOTH of the following criteria are met:
 - there is failure, contraindication or intolerance to at least a six-week trial of oral antispasmodic drugs and physical therapy
 - history of a of a favorable response to a trial of an intrathecal dose of anti-spasmodic drug

CIGNA covers a short term (i.e., temporary) trial of an implantable infusion pump and supplies for the treatment of severe, chronic, intractable pain, when used to administer drugs that are specifically

approved by the U.S. Food and Drug Administration (FDA) for the intended use, as medically necessary for EITHER of the following conditions:

- cancer-related pain when there is failure of, or intolerance, or contraindications to, noninvasive methods of pain control, including systemic opioids.
- non cancer-related pain when BOTH of the following criteria are met:
 - failure of, or intolerance, or contraindications to, noninvasive methods of pain control, including systemic opioids.
 - attempts have been made to eliminate physical and behavioral contributors to an exaggerated sensation of pain.

CIGNA covers a permanent implantable infusion pump for intrathecal or epidural administration of analgesics for the treatment of severe, chronic, intractable pain conditions when a preliminary trial of intraspinal opioid drug administration, that meets the above medical necessity criteria, demonstrates successful pain relief, and individual tolerance and acceptance.

CIGNA does not cover the use of an implantable infusion pump ANY other indication, including the following, because it is considered experimental, investigational or unproven (this list may not be all-inclusive):

- administration of insulin for diabetes
- administration of antibiotics for osteomyelitis
- administration of heparin for thromboembolic disease

General Background

Infusion pumps are used to provide a method of drug delivery for a variety of medical conditions. Implantable infusion pumps are used to deliver therapeutic levels of drugs to a target organ or body compartment (site-specific) for a prolonged period of time (several weeks to years). The infusion pump may be either nonprogrammable fixed rate (i.e., deliver a predetermined constant rate of infusion) and generate flow by fluorocarbon propellant, or programmable (i.e., variable delivery rates) and generate flow by direct electromechanical action. Fixed rate infusion pumps allow the physician to change dose by changing the concentration of the drug in the reservoir; programmable infusion pumps allow the physician to alter the dose, give single doses, timed-specific doses, or change the continuous infusion rate by an external programmer. The pump is surgically implanted into a subcutaneous pocket and connects to a catheter that has been placed in the desired position. Implantable infusion pumps are able to provide a constant or a variable rate of infusion. Minimal intervention is required for refilling or reprogramming the pump. The drug reservoir can be refilled as needed through an external needle injection in the pump. Bacteriostatic water, saline and heparin are used during interruption of drug therapy to maintain catheter patency. Possible routes of administration include: intravenous, intra-arterial, subcutaneous, intraperitoneal, intrathecal, epidural, and intraventricular.

The objectives for using an implantable infusion pump are to allow long-term access to various compartments enabling site-specific drug delivery, to reduce infections associated with external devices, and to provide drug therapy that promotes patient mobility and independence (Agency for Healthcare Research and Quality [AHRQ], 1994). In addition to the infusion pump itself, components that may be a part of the device include: a reservoir, optional access port, connectors, catheters, filters, handheld programmer and other accessories.

Implantable infusion pumps may be considered medically necessary when the drug is medically necessary for the treatment of the patient's condition; when it is medically necessary that the drug be administered by an implanted infusion pump; the drug is approved by the U.S. Food and Drug Administration (FDA) for the intended use; and when the infusion pump has been approved by the FDA to administer the drug prescribed. In addition, the prescribed drug must be stable and compatible with the implantable infusion device. Drugs that have been approved by the FDA for use with implantable infusion pumps include the following (this list may not be all-inclusive):

- chemotherapeutic agents (e.g., floxouridine [FUDR], methotrexate) for intrahepatic arterial infusion
- antispasmodic drugs (e.g., baclofen) for intrathecal infusion

- analgesics (e.g., morphine, ziconitide, clonidine) for epidural or intrathecal infusion

U.S. Food and Drug Administration (FDA)

Devices such as programmable, implantable infusion pumps are regulated by the FDA as Class III devices. Class III is the most stringent regulatory category for devices. Implantable infusion pumps that have been granted FDA approval include, but are not limited to, SynchroMed Infusion System (Medtronic, Neurological, Minneapolis, MN), InfusAid[®] pump, (Arrow International, Walpole, MA) and Codman[®] 3000 Drug pump (Codman and Shurtleff, Inc. [a Johnson and Johnson company], Raynman, MA).

Although various implantable infusion pumps have been approved by the FDA for intraspinal delivery of medications, the indications for the use of the pumps are typically similar. According to the manufacturer (Medtronic), indications (within the U.S.) for the use of the SynchroMed EL drug infusion systems include the following:

- chronic intraspinal infusion of preservative-free morphine sulfate for the treatment of chronic intractable pain
- chronic intrathecal infusion of preservative-free ziconotide for the management of severe chronic pain
- chronic intrathecal infusion of baclofen for treatment of severe spasticity
- chronic intravascular infusion of floxuridine (FUDR) or methotrexate for the treatment of primary or metastatic cancer

According to the manufacturer (Codman and Shurtleff, Inc.) the indications for the Codman[®] 3000 implantable infusion pump include the following:

- continuous intrathecal therapy for the treatment of chronic pain and spasticity
- continuous hepatic arterial infusion of chemotherapy directly to the site of the tumor

Hepatic Artery Chemotherapy

The hepatic artery is the main pathway in which a liver tumor receives its blood supply. Normal hepatocytes derive most of their blood supply from the portal vein and little from the hepatic artery. Hepatic arterial infusion by way of an implanted infusion pump provides delivery of chemotherapeutic agents directly to the liver through a catheter placed into the hepatic artery. This method of administration improves efficacy by increasing drug delivery directly to the site of the tumor. In addition, the primary function of the liver is metabolism and excretion. The ability of the liver to metabolize the infused agents increases the opportunity to increase dosages while limiting systemic effects (Fraker, Soulen, 2002). It has been suggested that intra-arterial infusion may increase survival time, delay tumor progression, and reduce side effects, thereby improving quality of life.

There is no single chemotherapy drug or combination that clearly demonstrates improved survival or improved quality of life. Combination chemotherapy generally produces better response rates than single drug therapies. The standard systemic therapy for metastatic colorectal cancer consists of various combinations of 5-fluorouracil (5-Fu) based regimens (e.g., Saltz regimen, De Gramont regimen). Floxuridine (FUDR) is a 5-Fu analog and is commonly used for intrahepatic arterial infusion. It is often used in combination with other chemotherapeutic agents (e.g., cisplatin, doxorubicin). Pharmacologic studies demonstrate that 97–99% of FUDR is cleared or metabolized during the first pass of infusion to the liver, while the clearance of 5-FU is lower.

Literature Review: Intrahepatic chemotherapy has been found to improve time to hepatic progression for unresectable disease in select individuals with primary hepatocellular cancer or metastatic cancer that is limited to the liver and unresectable. Some trials have demonstrated improved survival with this treatment. Evidence in the form of randomized trials and meta-analyses have demonstrated higher response rates (e.g., tumor response, tolerability of treatment, adverse effects) for hepatic artery infusion when compared to intravenous infusion (Harmantas, et al., 1996; Meta-Analysis Group in Cancer, 1996; Allen-Mersh, et al., 1994; Kemeny, et al., 1987). Treatment of unresectable colorectal liver metastasis with systemic chemotherapy results in response rates of 25–30%, and with the use of more recent regimens is reported at 36–40%. Hepatic arterial infusion of chemotherapy in patients who were previously untreated yields response rates of approximately 50–70% (Kemeny, et al., 2002). Survival advantage has not been consistently reported in the medical literature and remains unclear.

Authors have evaluated the administration of adjuvant chemotherapy to patients after hepatic resection (Martin, et al., 2004; Onaitis, et al., 2003; Kemeny, et al., 2002). Reported outcomes are inconsistent, and the

administration of hepatic artery chemotherapy as an adjuvant therapy to resection or ablation for colorectal metastasis is considered controversial. Most authors fail to report improved survival outcomes and have demonstrated significant toxicity (biliary sclerosis). A Cochrane review (Nelson, Freels, 2004) assessing the effect of posthepatic resection hepatic artery chemotherapy concluded that, although recurrence happened less in the remaining liver, overall survival was not improved and favored the control group. Currently, adjuvant posthepatic intra-arterial chemotherapy for colorectal metastasis is not considered a standard and recommended treatment (Elias, et al., 2004; Lorenz, Muller, 2000).

Chronic Intractable Spasticity

Baclofen (Lioresal intrathecal) is a medication that diminishes nerve cell sensitivity. The drug binds to receptors in the spinal cord, causing the inhibition of spinal reflexes. When introduced directly into the spinal subarachnoid space, baclofen can achieve effective cerebrospinal fluid concentrations with plasma levels lower than those following oral administration. The advantage of intrathecal baclofen is the ability to achieve effectiveness at lower dosages.

Intrathecal baclofen is used for managing severe intractable spasticity for patients who do not respond to or who cannot tolerate oral medications, and who have a positive response to a screening trial of intrathecal baclofen. Intrathecal dosing decreases spasticity in the lower extremities and has been shown to improve gait in ambulatory patients (Brochard, et al., 2009; Green, et al., 2003). The body size of the patient must be an approximate weight of at least 30 pounds to be able to support an implanted infusion pump. This allows the spasticity to be measured and the effectiveness of the baclofen to be monitored. A positive response of decreased spasticity then allows for intrathecal pump placement. The goal of therapy is to maintain muscle tone as close to normal as possible, minimizing spasms without intolerable side effects.

An initial screening trial involving a bolus dose is required due to the variable sensitivity to intrathecal administration. The trial or screening phase involves a test dose of 25–50 mcg administered into the intrathecal space by bolus over one minute or more. A positive response is defined as clinically important decrease in muscle tone and/or frequency of spasms over a 4-8 hour observation period. If the response is inadequate, a second test dose increased by a 25 mcg increment is given 24 hours after the first. If the response is still inadequate, further doses may be administered in 24-hour intervals until a maximum dose of 100-150 mcg is given. Individuals unresponsive to the maximum dose are generally not considered candidates for the implantable pump.

Baclofen has been associated with potentially life-threatening adverse reactions (e.g., central nervous system depression, cardiovascular collapse, respiratory failure). Because of the risks associated with the screening procedure and dosage adjustment, these phases must be conducted in a medically supervised and adequately equipped environment. In addition, close monitoring is recommended when adjusting future doses and concentrations of the drug.

Literature Review: A number of studies have provided evidence supporting the safety and efficacy of intrathecal baclofen for the treatment of spasticity (Abel, Smith, 1994; Middel, et al., 1997; Plassat, et al., 2004; Guglielmino, et al., 2006; Koulousakis and Kuchta, 2007; Hoving, et al., 2009; Krach, et al., 2009; Al Khudhairi, 2010; Ucar, et al., 2011; Rekand, et al., 2011; Motta, et al., 2011).

The Ontario Health Technology Advisory Committee (OHTAC) conducted a health technology assessment on intrathecal baclofen for spasticity and concluded there is some evidence of functional improvement and effectiveness of intrathecal baclofen infusion for the short- and long-term reduction of severe spasticity in patients who are unresponsive or who cannot tolerate oral baclofen (OHTAC, 2005).

Professional Societies/Organizations: Intrathecal administration of baclofen is one of the several accepted therapies for cerebral palsy (United Cerebral Palsy [UCP], 2001) and for spasticity associated with multiple sclerosis (National Multiple Sclerosis Society, 2004).

The Quality Standards Subcommittee of the American Academy of Neurology (ANA) and the Practice Committee of the Child Neurology Society (ANA, 2010) published a practice parameter for pharmacologic treatment of spasticity in children and adolescents with cerebral palsy, as an evidence based review. Regarding intrathecal baclofen the data was limited; the AAN reviewed six studies in total with all studies reporting reduced spasticity in children with cerebral palsy. Adverse events included headache, vomiting, lethargy, disorientation,

agitation, irritability, and meningitis. Cerebral spinal fluid leaks, catheter malfunction, and wound infection were reported more frequently. Due to insufficient data the AAN did not support or contest intrathecal baclofen for treatment of spasticity.

Dystonia

Dystonia is a neurological movement disorder characterized by involuntary muscle contractions, which force certain parts of the body into abnormal, sometimes painful, movements or postures and may coexist with muscle spasticity. Typical treatment consists of oral medications, botulinum toxin injections, and surgery, although no single treatment has been universally effective. Implantation of the intrathecal baclofen pump has been proposed by some authors as a treatment for dystonia. Although originally developed as a treatment for spasticity, some results suggest that there may be benefit for treatment of dystonia also. Intrathecal baclofen used for the treatment of dystonia is based on the same principle as utilization for treatment of spasticity.

Literature Review: In a published systematic review approved by the American Academy for Cerebral Palsy and Developmental Medicine (AAPDM), authors evaluated the evidence of the effects of intrathecal baclofen for spastic and dystonic cerebral palsy (Butler and Campbell, 2000). With regard to the effects of intrathecal baclofen on dystonic cerebral palsy, the authors concluded, "the evidence is preliminary, but generally, positive findings warrant more definitive investigation. Issues of description and assessment of dystonic cerebral palsy must be addressed first, however. A standardized classification of cerebral palsy is needed to allow for consistent diagnosis of dystonic cerebral palsy, and a valid and reliable measurement scale is needed to document the degree of dystonia."

The European Federation of Neurological Societies /Movement Disorder Society, European Section (EFNS/MDS-ES) Task Force provided evidence-based recommendations for the diagnosis and treatment of primary dystonia and dystonia plus (Albanese, et al., 2006). Within the recommendations for treatment, the Task Force indicates intrathecal baclofen has been used in patients with severe generalized dystonia. The authors noted that there is insufficient evidence to use this treatment in primary dystonia, however the treatment procedure may be indicated where secondary dystonia is combined with spasticity.

Although limited in quantity and quality, there is evidence in the form of randomized controlled trials, prospective and retrospective case series, and systematic reviews published in the peer-reviewed literature that demonstrate intrathecal baclofen can improve symptoms and quality of life for select patients with dystonia (Motta, et al., 2011; Motta, et al., 2009; Motta, et al., 2008; Woon, et al., 2007; Dykstra, et al., 2005; Albright, et al., 2001; Jaffe and Nienstedt, 2001; van Hilten, et al., 2000; Walker, et al., 2000; Albright, et al., 1998). In general, the studies involved small patient populations and lacked controls or comparison groups. The lengths of follow-up evaluations vary among studies, and the etiology of dystonia varied, making comparisons across studies difficult. Improvement of symptoms was reported in some study groups; however, in others, worsening of symptoms was reported (Walker, et al. 2000). Specific patient selection criteria have not been firmly established and intrathecal baclofen for the treatment of dystonia appears to have limited efficacy. Furthermore, predictors of a positive treatment response have not been identified in the published, peer reviewed scientific literature. Despite these findings however, intrathecal baclofen is considered an alternative treatment for patients who have not responded to other medical treatment and who have responded to a screening trial of intrathecal baclofen.

Severe Chronic Intractable Pain Conditions

Chronic nonmalignant pain is usually described as ongoing pain that lasts over six months, is due to non-life threatening causes, and does not respond to available treatment methods. Chronic pain has also been associated with various forms of cancer (i.e., cancer pain, malignant pain).

The treatment of severe chronic pain conditions involves a multidisciplinary approach with accurate diagnosis based on both medical and psychological evaluations. A medical evaluation typically includes a history and physical examination and diagnostic work-up if necessary, in addition to screening trials. A psychological evaluation typically includes mental status examination, psychological testing as needed, and determination of the suitability of the patient to undergo the intervention (Prager and Jacobs, 2001).

Intraspinal (i.e., intrathecal, epidural) administration of pain medication offers an effective alternative for pain control in patients who have not experienced adequate pain control, or who otherwise are unable to tolerate medications due to side effects or toxicities. Intraspinal drug administration delivers medication into the vicinity

of the spinal cord (i.e., intrathecal) or into the epidural space (i.e., epidural) and requires diffusion of the drug through the dura to produce an effect and exposes the spinal nerve roots to the drug. Evidence in the literature suggests the principal benefit of intraspinal delivery appears to be the reduction in opioid side effects, rather than improved analgesia, although patients have reported improved pain scores in clinical trials. Additionally, intraspinal administration allows a reduction of the amount of the drug administered in comparison to oral or parenteral routes of administration. Although close monitoring is required, titration of the drugs can be performed more rapidly, allowing for more aggressive pain control with reduction of side effects and toxicities.

Although there is a paucity of evidence evaluating safety and efficacy (Ilias, et al., 2008), external accessory devices (e.g., Personal Therapy Manager [Medtronic, Inc., Minneapolis, MN]) have been developed for use with some implanted infusion pumps allowing patients to self administer bolus doses of medication for the control of intermittent episodes of increased pain. Proponents of these devices suggest that by allowing the administration of a predetermined bolus of medication there is improvement in pain relief, less need for supplemental oral analgesics, and improved quality of life. The devices are proposed for individuals with intermittent episodes of increased pain unrelieved by the continuous dosing of the prescribed analgesic and when supplemental oral analgesic therapy is inadequate or results in intolerable side effects.

Intraspinal therapy has been associated with various risks, including adverse events from the medications, development of comorbid conditions, and problems with the implantable device. Risks associated with long-term use include tolerance and dependency. Comprehensive medical management of various pain conditions includes the use of analgesics as well as adjuvant medications. Nonetheless, many patients develop adverse effects from medications that affect performance status, and in some cases diminish function and quality of life. In a published systematic review evaluating the safety and efficacy of long-term opioid therapy (oral, transdermal, intrathecal) for chronic noncancer pain, Noble et al. (2008) acknowledged that many patients withdrew from studies, mainly due to adverse events and insufficient pain relief. An estimated 48.9% of patients treated with intrathecal opioids had at least 30% reduction in pain and an estimated 40% had at least a 50% reduction in pain by the longest follow-up (range from 6 months to a mean of 29 months).

Literature Review: While morphine and ziconitide (Prialt) are the only agents currently approved by the FDA for use in intrathecal pumps for the long-term management of chronic intractable pain (as monotherapy), other narcotic and nonnarcotic agents are reportedly being used (Belverud, et al., 2008; Deer, et al., 2007; Waara-Wolleat, et al., 2006). Stability of combination therapy remains a concern. There is a growing body of evidence suggesting that combination therapy involving ziconitide and opioids is safe and well-tolerated (Deer, et al., 2009; Smith, Deer, 2009). Clonidine hydrochloride is FDA approved for continuous epidural administration as adjunctive therapy with intraspinal opiates for the treatment of pain in cancer patients. In addition, the safety and efficacy of morphine and other nonopioid analgesics, such as clonidine and ziconitide, for the treatment of both malignant and nonmalignant pain is well-established in the published scientific literature and textbooks. Webster and colleagues (2009) evaluated long-term safety and efficacy of ziconitide as part of an open-label, multicenter extension trial. The study population involved subjects from two previous open-label trials investigating safety and efficacy of ziconitide in patients with severe chronic pain. The authors noted ziconitide was well-tolerated and effective, and there was no evidence of accumulated toxicity during approximately three years use.

Fentanyl and sufentanil are FDA approved for short-term epidural administration in treating moderate to severe pain during or after labor or surgery. Nonetheless, fentanyl and sufentanil are often administered intrathecally for treatment of chronic pain management for individuals who are not able to tolerate side effects from morphine or who do not obtain adequate pain relief. Both fentanyl and sufentanil are synthetic opioids, have a more rapid onset of action, are more potent and more lipid soluble than morphine. Sufentanil is approximately 8–10 times more potent than fentanyl.

In 2007, Deer et al. published updated recommendations from the Polyanalgesic Consensus Conference for the management of pain by intrathecal drug delivery. The panel published previous recommendations from 2000 and 2003 conferences. The 2007 guidelines are based on preclinical and clinical evidence published between 2000 and 2006 relevant to opioid and nonopioid intrathecal analgesics, in addition to expert opinion. The number of published studies remains limited and the guidelines reflect the current best available evidence. The panel developed drug selection algorithms for intrathecal administration (six in total) of analgesics and reviews the side effects of various pharmaceutical agents used for intrathecal pain management. The panelists endorsed the use of polyanalgesia when monotherapy was not successful in relieving pain. First-line therapy (i.e., morphine, hydromorphone, ziconitide) are supported by extensive clinical experience and published

preclinical and clinical data. Recommendations for second-line therapy are based on less evidence and experience. Second-line therapy includes fentanyl alone, and morphine or hydromorphone combined with ziconitide, bupivacaine, or clonidine, however the authors suggest the data is too limited to accurately determine risks versus benefits of these medications and combinations. Algorithms for third-, fourth-, fifth- and sixth-line therapy are provided and are based on even less published information. Sixth-line therapies are considered experimental by the authors and have no or minimal preclinical or clinical data. According to the panelists, special rules apply for end-of-life pain management and line six therapies are reserved for this level.

Professional Societies/Organizations: The American Society of Anesthesiologists (ASA) published practice guidelines for chronic pain management (ASA, 2010). Within the guidelines chronic pain is defined as pain of any etiology not directly related to neoplastic involvement, associated with a chronic medical condition or extending in duration beyond the expected temporal boundary of tissue injury and normal healing, and adversely affecting the function or well-being of the individual. Regarding implanted intrathecal drug therapies, studies with observational findings indicate that intrathecal opioid injections can provide pain relief for assessment periods ranging from one to 12 months for patients with neuropathic pain. According to the guidelines, intrathecal opioid injection or infusion may be used for patients with neuropathic pain; shared decision making regarding intrathecal opioid injection or infusion should include a specific discussion of potential complications; and neuraxial opioid trials should be performed before considering permanent implantation of intrathecal drug delivery systems. The ASA practice guideline for cancer pain management (ASA, 1996) indicates there is sufficient literature to support the efficacy neuraxial analgesic delivery (i.e., epidural, subarachnoid, intraventricular) for the management of cancer pain.

Diabetes

Implantable insulin pumps is an emerging technology proposed as a method of delivering insulin either intraperitoneally or intravenously in a programmed and controlled manner to type I diabetic patients. These devices deliver insulin directly into the peritoneal cavity or superior vena cava and can be programmed for a continuous rate as well as a bolus of insulin. Proposed patient selection criteria generally include those with brittle type I diabetes. The goals of implantable insulin pump therapy are to achieve near normal blood glucose levels, control metabolic complications and to delay the onset of late-stage complications such as vascular disorders. Currently, there are no implantable insulin infusion pumps that are approved by the FDA; however, some devices have been granted Investigational Device status (e.g., Minimed 2007 [Minimed[®] Inc., Sylmar, CA]).

Literature Review: The quantity of published medical literature evaluating implantable insulin pumps is limited. In some of the preliminary studies authors have reported improved glycemic control, fewer hypoglycemic events, and less glycemic variability. ECRI reported (2001) that based on limited evidence, consisting of few randomized controlled trials and multicenter pretreatment/posttreatment trials, implantable insulin pumps appear to be as effective as other methods of intensive control for achieving near-normal glycemic control in carefully selected adult patients with diabetes, who are candidates for intensive therapy. Larger and longer term randomized controlled trials are necessary to demonstrate whether sustained statistically significant improvement of glycosolated hemoglobin levels occurs with the use of these devices when compared to other intense therapy methods. Gin and associates (2003) reported on the safety and efficacy of implantable insulin pumps in type 1 diabetic patients. The author's review of the available literature indicates the pump has been associated with a high incidence of malfunctioning (i.e., catheter obstruction); however, newer pump designs are expected to reduce the problem of obstruction. In a retrospective case series involving 63 patients Haveman et al. (2008) evaluated the surgical implications and complications of the implantable insulin pump device. Local infection and pain were the most common complications reported (19%), and in some cases required pump removal and reimplantation. The authors noted that with increased experience and technical improvements in the pump, operation-free periods for the subject group increased from 1.8 years to 6.5 years. In a randomized trial Logtenberg et al (2009) compared continuous intraperitoneal insulin infusion in type I diabetic subjects (n=12) with intensified insulin therapy in patients with inadequately controlled type I diabetes (n=12). There were no differences in the occurrence rate for severe hypoglycemic events or daily insulin use and no pump or catheter malfunction was observed during the study. The authors did note improved glycemic control with continuous infusion demonstrated by a 0.8% decrease in A1C and an 11% increase in the time spent in euglycemia compared with subcutaneous insulin administration.

Professional Societies/Organizations: The American Diabetes Association (ADA) 2010 Clinical Practice Recommendations do not include the use of an implantable insulin infusion pump for the treatment of diabetes.

Osteomyelitis

Osteomyelitis is an infection involving part or all of the bone. Most often, the bones that are affected are the legs, arms, spine, and pelvis. Treatment consists of antibiotic therapy and, in some cases, surgical debridement to remove areas that are slow healing or to drain abscesses. Prolonged intravenous therapy may be required in chronic cases. Outpatient parenteral antibiotic therapy has been proven to be effective for select patients. Implantable infusion pumps have been used to administer antibiotics (e.g., clindamycin) for the treatment of osteomyelitis in some cases. However, evidence in the published scientific literature is insufficient and does not support safety and efficacy regarding the use of implantable infusion pumps for the long-term administration of antibiotics. The evidence that is available dates back to the late 1980's and early 1990's and consists primarily of uncontrolled case series involving small patient populations.

Thromboembolic Disease

Implantable infusion pumps have been proposed for the administration of heparin for the treatment of recurrent thromboembolic disease, although few clinical trials have been conducted evaluating the effects of long-term intravenous heparin infusion (Buchwald, et al., 1980; Blackshear, et al., 1981). A review of the published scientific literature does not provide sufficient evidence to support safety and efficacy when used for these conditions.

Summary

There is sufficient evidence of improved clinical outcomes to support the use of implantable infusion pumps for the administration of intra-arterial chemotherapy for the treatment of unresectable liver cancer, and intrathecal baclofen for the treatment of moderate to severe spasticity and for some select patient subgroups with dystonia. Efficacy of intraspinal administration of opioids and nonopioid medications is well-established in the literature for the treatment of severe, chronic, intractable malignant and nonmalignant pain conditions. The use of an implantable infusion device for the treatment of diabetes is currently available only through clinical trials. The published, scientific literature does not provide sufficient evidence to support the use of these devices for the treatment of thromboembolic disease or osteomyelitis.

Coding/Billing Information

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

Covered when medically necessary:

CPT [®] * Codes	Description
36260	Insertion of implantable intra-arterial infusion pump (e.g., for chemotherapy of liver)
62350	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy
62360	Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir
62361	Implantation or replacement of device for intrathecal or epidural drug infusion; non-programmable pump
62362	Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming
62367	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural

	drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming
95990	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular);
95991	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular); administered by physician
96522	Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (e.g., intravenous, intra-arterial)

HCPCS Codes	Description
A4220	Refill kit for implantable infusion pump
A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code
C1772	Infusion pump, programmable (implantable)
C1891	Infusion pump, non-programmable, permanent (implantable)
C2626	Infusion pump, non-programmable, temporary (implantable)
E0782	Infusion pump, implantable, non-programmable (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)

Intrahepatic Arterial Infusion:

ICD-9-CM Diagnosis Codes	Description
155.0 – 155.2	Malignant neoplasm of liver and intrahepatic bile ducts
197.7	Secondary malignant neoplasm of respiratory and digestive systems; liver, specified as secondary

Chronic Intractable Spasticity or Chronic Intractable Dystonia:

ICD-9-CM Diagnosis Codes	Description
333.6	Genetic torsion dystonia
333.71	Athetoid cerebral palsy
333.79	Other acquired torsion dystonia
333.81 – 333.89	Fragments of torsion dystonia
340	Multiple sclerosis
334.1	Hereditary spastic paraplegia
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

Chronic Intractable Pain Conditions :

ICD-9-CM Diagnosis Codes	Description
337.20- 337.29	Reflex sympathetic dystrophy
338.21 – 338.29	Chronic pain
338.3	Neoplasm related pain (acute) (chronic)

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
	All Other Codes

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	6/15/2008	0370	Implantable Infusion Pumps
Great-West Healthcare	10/30/2007	05.322.02	Pumps, Implantable, for Management of Chronic Pain
	8/23/2007	95.305.06	Baclofen Pump

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