Implantable Infusion Pump for Pain and Spasticity

Policy Number: 7.01.41
Origination: 1/1988

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for implantable infusion pumps when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Implantable infusion pumps are considered medically necessary when used to deliver drugs for this route of access which are regulated by U.S. Food and Drug Administration and which are used for the related indication for the treatment of:

- Severe, chronic, intractable pain (intravenous, intrathecal, and epidural injection of opioids), following a successful temporary trial of opioid or non-opioid analgesics by the same route of administration as the planned treatment. A successful trial is defined as greater than 50% reduction in pain following implementation of treatment; and
- Severe spasticity of cerebral or spinal cord origin in patients who are unresponsive to or who cannot tolerate oral baclofen therapy (intrathecal injection of baclofen).

When Policy Topic is not covered
Implantable infusion pumps are considered investigational for all other uses related to pain and spasticity.

Considerations
Implantable infusion pumps should not be confused with the type of portable pumps used to infuse short-term analgesia directly into a post operative wound site. These types of pumps are external, with the tip of the catheter sutured into place near the surgical site.

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
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<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• With cancer pain</td>
<td>• intravenous, intrathecal,</td>
<td>• Oral medication</td>
<td>• Symptoms</td>
</tr>
</tbody>
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Implantable infusion pumps can provide long-term drug infusion at constant or variable rates; several devices are commercially available.

### Pain
For individuals who have cancer pain who receive intravenous, intrathecal, or epidural injection of opioids with an implantable infusion pump, the evidence includes randomized controlled trials (RCTs) and a systematic review. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. A systematic review identified 2 RCTs on implantable infusion pumps for cancer pain; one did not find a difference between groups in pain scores but was likely underpowered. The other RCT found a higher rate of pain reduction with an implantable pump compared with medical management alone; the difference between groups was marginally significant. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have severe, chronic, intractable noncancer pain who receive intravenous, intrathecal, or epidural injection of opioids with an implantable infusion pump, the evidence includes observational studies and systematic reviews. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. A 2013 systematic review of retrospective and prospective cohort studies indicated reduced pain with intrathecal opioids. A 2009 systematic review included 4 observational studies; 2 showed positive results for pain relief, 1 study had negative results, and results for the fourth were unavailable. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Severe Spasticity
For individuals who have severe spasticity of cerebral or spinal cord origin, unresponsive to or intolerant of oral therapy, who receive intrathecal baclofen with an implantable infusion pump, the evidence includes observational studies, a nonrandomized comparative study, and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Uncontrolled studies and systematic reviews of these studies have

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reported improvements in spasticity for patients treated using implantable infusion pumps. A nonrandomized comparative study comparing patients with implantable infusion pumps for baclofen delivery to patients on a wait list found significantly greater reductions in spasticity in the group with pump implantation on some outcomes, but not others. RCTs are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Because of the strong rationale for use, suggestive evidence, and support from clinical guidelines, infusion pumps may be considered medically necessary for cancer pain, chronic, intractable noncancer pain, and severe spasticity.

**Background**

An implantable infusion pump is intended to provide long-term continuous or intermittent drug infusion. Possible routes of administration include intravenous, intra-arterial, subcutaneous, intraperitoneal, intrathecal, and epidural. The implantable infusion pump is surgically placed in a subcutaneous pocket under the infraclavicular fossa or in the abdominal wall, and a catheter is threaded into the desired position. Intrathecal and epidural catheter positions are both intraspinal; however, the intrathecal position is located in the subarachnoid space, which is passed through the epidural space and dura mater and through the theca of the spinal cord.

A drug is infused over an extended period and may be delivered at a constant or variable rate by calibrating the implantable infusion pump per physician specifications. The drug reservoir may be refilled as needed by an external needle injection through a self-sealing septum in the implantable infusion pump. Bacteriostatic water or physiological saline is often used to dilute drugs. A heparinized saline solution may also be used during an interruption of drug therapy to maintain catheter patency.

The driving mechanisms may include peristalsis, fluorocarbon propellant, osmotic pressure, piezoelectric disk benders, or the combination of osmotic pressure with an oscillating piston.

**Regulatory Status**

Several implantable infusion pumps have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process, including, but not limited to, the SynchroMed® (Medtronic, Fridley, MN) family of pumps; the IsoMed® infusion system (Medtronic, Minneapolis, MN); the Prometra® programmable pump (Flowonix, Mount Olive, NJ); and Shiley Infusaid® pumps (Norwood, MA).

Baclofen for intrathecal injection was approved for an additional indication in 1996, for use with Medtronic’s implantable infusion pump in the treatment of spasticity of cerebral origin; the drug and pump were originally approved in 1992 for use in patients with severe spasticity of spinal origin. In August 2012, the MedStream™ Programmable Infusion System (Codman and Shurtleff, a division of DePuy),
which includes an implantable pump, was approved by FDA through the premarket approval process for intrathecal delivery of baclofen in patients with spasticity.

On November 14, 2018, the FDA issued a safety communication: “Use Caution with Implanted Pumps for Intrathecal Administration of Medicines for Pain Management.” When considering a medicine for use in an implanted pump the communication recommends, in part, awareness of medicines not FDA approved for intrathecal administration or intrathecal implanted pump use (for example, hydromorphone, bupivacaine, fentanyl, clonidine). Further, the communication indicates that any mixture of two or more different kinds of medications as well as any compounded medications is not approved.1

**Rationale**

This evidence review was created in November 1996 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through January 26, 2019.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Pain**

**Cancer Pain**

A systematic review of the literature on intraspinal techniques for managing pain in cancer patients was published by Myers et al (2010).2 Reviewers identified 12 RCTs; studies were required to report pain as an outcome measure using a validated scale. Investigators did not identify the type or types of cancer
addressed in individual studies and did not pool study findings. Two RCTs specifically addressed implantable infusion pumps. One compared intrathecal morphine delivered via an implantable infusion pump plus medical management (n=101) with medical management alone (n=99) in patients who had refractory cancer pain. The difference between groups in clinical success (defined as a minimum 20% reduction in pain score and a minimum 20% reduction in drug toxicity at 4 weeks) reached borderline statistical significance, favoring the implantable pump group over the control group (85% vs 71%, respectively, p=0.05). The proportion of patients who experienced a minimum 20% pain score reduction was 52% in the implantable pain pump group and 39% in the control group; this result was not a statistically significant difference (p=0.55). The other RCT on implantable pumps compared epidural morphine delivered as a continuous infusion by the Infusaid pump with intermittent delivery by a Port-a-Cath (Deltec, St. Paul, MN). The 2 groups did not differ significantly in their pain scores; scores were low in both groups, and the trial, which had only 29 participants, was likely underpowered.

**Section Summary: Cancer Pain**
A systematic review identified two RCTs on implantable infusion pumps for cancer pain: one did not find a difference between groups in pain scores but was likely underpowered and the other found a higher rate of pain reduction with an implantable pump compared with medical management alone (p=0.05).

**Noncancer Pain**
Falco et al (2013) published a systematic review of intrathecal infusion for the treatment of chronic noncancer pain. The outcome of interest was pain relief, defined as a minimum 50% reduction of pain in at least 40% of patients, or a minimum 3-point reduction in pain scores. Both short-term (<12 months) and long-term (≥12 months) outcomes were considered. Twenty-eight studies were identified, but 21 were excluded for not meeting 1 or more inclusion criteria (eg, outcomes not related to pain relief; sample size <50; minimum quality assessment). All seven selected studies were retrospective or prospective cohort studies. Six studies that each reported short-term (668 patients) or long-term (637 patients) pain outcomes indicated reduced pain with intrathecal opioids. Reviewers concluded that the evidence for intrathecal opioid infusion in chronic noncancer pain was limited. Suggested contraindications to intrathecal opioid therapy (eg, active infection) and indications to proceed with therapy (eg, oral opioid therapy contraindicated) were provided.

Previously, Patel et al (2009) published a systematic review of intrathecal infusion pumps used to treat chronic noncancer pain. Included studies evaluated an intrathecal device (programmable or fixed infusion rate), stated a specific indication and the drug injected, followed patients for at least 12 months, and included at least 25 patients. In addition, reviewers rated study quality; included studies scored at least 50 of 100 on a methodologic quality scale. The primary outcome of interest for the systematic review was pain relief. Fifteen studies on intrathecal infusion for noncancer pain were identified; however, 6 did not have sufficient follow-up, 4 included fewer than 25 patients, and 1 had unacceptably low
quality. All 4 eligible studies were observational and involved intrathecal opioid administration; sample sizes ranged from 69 to 120. Most patients experienced lumbospatial pain. Two of the four studies showed positive results for pain relief, one study had negative results, and results for the fourth were unavailable. Reviewers acknowledged the paucity of literature and lack of RCTs. Using the grading system developed by Guyatt et al (2006), reviewers concluded that a 1C recommendation for the use of intrathecal infusion systems in chronic noncancer pain was appropriate (i.e., a strong recommendation based on low-quality or very low-quality evidence in which the benefits outweigh the risks).

Hamza et al (2012) published a 36-month prospective cohort study of low-dose intrathecal opioids for chronic nonmalignant pain using the SynchroMed II programmable pump. Six-one patients with severe intractable pain who had failed multiple lines of pain therapy and were referred for intrathecal treatment underwent a blinded trial of intrathecal opioids. Three patients who experienced pain relief in response to saline were excluded. The mean age of the 58 included patients was 59 years, and the mean duration of symptoms was 6 years. Pain syndromes were failed back surgery syndrome in 60% of patients, chronic low back pain in 28%, and chronic complex regional pain syndrome, abdominal pain, or pelvic pain in 12%. All patients were weaned off opioids for 7 to 10 days before pump implantation and participated in a 12-week physical therapy program commencing at 8 weeks postimplant. At 36 months, there was a 55% reduction from baseline worst pain score (from 8.91 to 4.02 on the Brief Pain Inventory; scale range, 0-10; p=0.012) and a 54% reduction from baseline average pain score (7.47 to 3.41; p<0.001). Improvements in physical function and behavior (mood, relations, sleep) as measured by the Brief Pain Inventory also were statistically significant. Mean intrathecal opioid dose increased 11% from 1.4 to 1.6 morphine equivalents daily. Mean oral opioid dose decreased by 97% from 129 to 4 morphine equivalents daily. Adverse events were reported to be mild and limited (wound infection and pruritus in 3 [5%] patients each; peripheral edema and seroma in 2 [3%] patients each).

**Section Summary: Noncancer Pain**
The evidence on the use of infusion pumps for chronic, noncancer pain includes numerous uncontrolled observational studies; RCTs are lacking. A 2013 systematic review of retrospective and prospective cohort studies indicated reduced pain with intrathecal opioids. A 2009 systematic review included 4 observational studies; 2 showed positive results for pain relief, 1 study had negative results, and results for the fourth were unavailable.

**Severe Spasticity**
A 2014 systematic review of intrathecal baclofen for spasticity in patients with traumatic or nondramatic spinal cord injury identified 8 studies (total n=162 patients). At follow-up (range, 2-41 months), reductions in mean Modified Ashworth Scale score (scoring range, 0-5) were statistically significant, from 3.1 to 4.5 (limb rigidity or considerable increase in tone) at baseline to 1.0 to 2.0 (slight increase in tone; p<0.005). Adverse events associated with baclofen, pump/catheter malfunction (e.g., dislodging, kinking, breaking), and...
infections/seromas at the incision site were reported. Baclofen overdose in 3 (2%) patients and withdrawal seizure in 1 (<1%) patient were attributed to a pump malfunction.

A systematic review by Pin et al (2011) focused on intrathecal baclofen therapy for spasticity and/or dystonia of cerebral origin in children and adolescents.8 Reviewers identified 16 uncontrolled studies (total n=227 participants). All studies were judged to be of low quality. Most outcomes were intermediate measures (ie, at the level of body structures or functions), such as range of motion and muscle strength; several studies used objective outcomes (eg, motor function at the level of activities or participation as assessed by the Gross Motor Function Measure [GMFM], laboratory-based gait analysis, or gait assessment tools). Effects of intrathecal baclofen therapy were greater in patients who were ambulatory at baseline compared with those who were not. Adverse events were not consistently defined or reported but appeared to be common. One study that used objective outcomes was published by Motta et al (2011) in Italy.9 This study found a statistically significant increase in GMFM score after one year (higher scores on the GMFM indicate better motor function). Median GMFM score (as a percentage of maximum score) in 30 cerebral palsy patients with spasticity who received intrathecal baclofen increased from 65.0 to 69.4 (p=0.004).

Morton et al (2011) in the U.K. published findings from a nonrandomized controlled study of intrathecal baclofen therapy in nonambulatory children with severe spastic cerebral palsy.10 Patients who responded to a 1-time test intrathecal baclofen dose of 50 μg were fitted for a pump and placed on a waiting list for surgery. Investigators compared patients who had been on the waiting list between 6 to 12 months (group 1, n=18) with patients who had undergone surgery (group 2, n=20). Mean time between baseline and outcome assessment was 8.5 months in group 1 and 9.5 months in group 2. There was no statistically significant difference between groups in the primary outcome measure, the Pediatric Evaluation of Disability Inventory score. The authors noted, however, that given the small number of patients recruited, the study was underpowered to detect statistically significant differences between groups for this outcome. Several secondary outcomes favored group 2, including scores on the Modified Ashworth Scale (difference between groups, 1.7; p=0.008), scores on the Penn Spasm Frequency Scale (difference between groups, -1.3; p=0.001), and the range of motion score (difference between groups, 8.3; p=0.005).

A small 2012 study compared the mode of administration of intrathecal baclofen in 38 adults with muscle hypertonia due to brain injury or spinal cord disorder who were receiving intrathecal baclofen.11 Pumps were programmed to deliver a single daily bolus of baclofen with low background continuous dose (intervention group) or a continuous equivalent daily dose (controls). For patients receiving baclofen 75 to 85 mg daily, a neurophysiologic measure of spasticity (H-reflex in the soleus [calf] muscle) improved statistically significantly more in the intervention group than in controls. For patients receiving baclofen 100 to 150 mg daily, the difference between groups was not statistically significant.
Several authors have reported on long-term (1-14 years) outcomes in patients receiving intrathecal baclofen for treatment of intractable spasticity or dystonia. Malheiro et al (2015) reported on 145 patients followed for a mean of 7 years; 123 (85%) were treated for spastic conditions and 22 (15%) for pain. Nineteen (9%) infections occurred in 19 patients. Fourteen infections affected the pump site and developed a median of 3.2 months after pump implantation. Meningitis was reported in 5 (2.3%) patients; the median time to meningitis was 2.2 months. Of 158 adults at a single-center in France, 28 (18%) experienced an adverse event within 12 months of surgical insertion of the pump. Most adverse events (58%) occurred during the first month after surgery and were commonly related to the insertion site (scar dehiscence, hematoma; 53%), device dysfunction or migration (29%), and adverse events of baclofen (18%). Margetis et al (2014) reported on 2-year outcomes for 14 ambulatory adults with hereditary spastic paraplegia. All patients experienced a reduction in lower-limb spasticity as measured by the Modified Ashworth Scale; mean scores reduced from 2.6 (slight-to-moderate increase in tone) to 0.7 (no-to-slight increase in tone; p=0.000). Walking ability as assessed by a modified pediatric scale (functional walking scale of the Gillette Functional Assessment Questionnaire, scored 1-10) improved from a mean of 5.9 (walks >15-50 feet outside but uses a wheelchair for community distances) to 7.4 (walks community distances but requires moderate assistance on uneven terrain, eg, curbs; p=0.001). A responder analysis was not reported. Adverse events included catheter fracture in two patients. Ghosh et al (2013) reported on the 3-year experience of 119 children (mean age, 13 years) at a single U.S. center. Five (4%) patients underwent pump removal due to lack of efficacy. Mechanical complications requiring a pump and/or catheter revision occurred in 19%, infections in 22%, and meningitis in 6%. Vles et al (2013) reported on long-term (6-9 years) follow-up for 17 nonambulant children (mean age at enrollment, 13 years) with cerebral palsy who had participated in a Dutch trial of continuous intrathecal baclofen. Previously observed positive effects on pain, ease of care, and mental health of the child were maintained at follow-up. Of 430 children (mean age, 13 years) followed for a mean of 8 years at a single-center in Italy, 25% had 1 or more complications: 15% experienced a problem with the catheter (most commonly within 12 months after implant), 9% experienced an infection, 5% had a cerebrospinal fluid leak, and 1% had a pump-related problem. At 10 years or more of follow-up, 24 adults at a single U.S. outpatient spasticity clinic reported on average: low levels of pain, moderate life satisfaction, infrequent spasms (mild-to-moderate severity), and few adverse events (normal sleepiness, low-to-moderate fatigue).

Section Summary: Severe Spasticity
Evidence from uncontrolled studies and systematic reviews of these studies has reported improvements in spasticity for patients treated using implantable infusion pumps. A nonrandomized comparative study comparing patients using implantable infusion pumps for baclofen delivery with patients on a wait list did not find significant between-group differences in the primary outcome, disability score, but secondary outcomes (eg, spasm frequency, Modified Ashworth Scale score for spasticity) significantly favored the implantable pump group. However, high-quality RCTs are lacking.
Summary of Evidence

Pain
For individuals who have cancer pain who receive intravenous, intrathecal, or epidural injection of opioids with an implantable infusion pump, the evidence includes RCTs and a systematic review. The relevant outcomes are symptoms, QOL, and treatment-related morbidity. A systematic review identified two RCTs on implantable infusion pumps for cancer pain; one did not find a difference between groups in pain scores but was likely underpowered. The other found a higher rate of pain reduction with an implantable pump compared with medical management alone; the difference between groups was marginally significant. The evidence is insufficient to determine the effects of the technology on health outcomes.

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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Cancer Pain
Current National Comprehensive Cancer Network guidelines (v.1.2019) for the treatment of adult cancer pain recommend placement of epidural or intrathecal infusion pumps to deliver analgesic or anesthetic drugs.19,
Noncancer Pain
The American Society of Interventional Pain Physicians’ (2009) evidence-based guidelines on interventions for managing chronic spinal pain indicated that there is strong evidence to support the use of implantable intrathecal drug administration systems with proper patient selection criteria.20.

Spasticity

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence (2016) updated its guidance on the management of spasticity in children and young people with nonprogressive brain disorders.21, Intrathecal baclofen was recommended for “children and young people with spasticity if ... spasticity or dystonia are causing difficulties with ... pain or muscle spasms; posture or function; or self-care (or ease of care by parents or carers).” Additional recommendations included:

- Consider the potential adverse effects of reducing spasticity “because spasticity sometimes supports function (for example, by compensating for muscle weakness).”
- A trial of intrathecal baclofen to assess the efficacy and adverse events before deciding to implant the intrathecal pump.

European Working Group for Spasticity in Children
The European Working Group for Spasticity in Children (2010) published a consensus statement on the use of intrathecal baclofen therapy in children with spasticity.22. For children with spasticity that interferes with function or quality of life, the group recommended conservative treatment and a trial of oral medication before use of a pump to deliver intrathecal baclofen. It also recommended the individualization of treatment and involvement of parents and caregivers. The group received an unrestricted educational grant from Medtronic.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
Medicare provides coverage for implantable infusion pumps for the following indications23:

“...intra-arterial infusion of 5-FUdR [5-fluorouracil deoxyribose] for the treatment of liver cancer for patients with primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in whom metastases are limited to the liver and where the disease is unresectable or the patient refuses surgical excision of the tumor.”

Administration of “anti-spasmodic drugs intrathecally (e.g., baclofen) to treat chronic intractable spasticity in patients who have proven unresponsive to less invasive medical therapy as determined by the following criteria:
As indicated by at least a 6-week trial, the patient cannot be maintained on non-invasive methods of spasm control, such as oral anti-spasmodic drugs, either because these methods fail to control adequately the spasticity or produce intolerable side effects. And prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug.”

Administration of “opioid drugs (e.g., morphine) intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or nonmalignant origin in patients who have a life expectancy of at least 3 months, and who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

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

Other uses of implanted infusion pumps included:

- The drug is reasonable and necessary for the treatment of the individual patient;
- It is medically necessary that the drug be administered by an implanted infusion pump; and
- The Food and Drug Administration-approved labeling for the pump must specify that the drug being administered and the purpose for which it is administered is an indicated use for the pump.”

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in January 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

**REFERENCES**


**Billing Coding/Physician Documentation Information**

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<th>Description</th>
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<td>36261</td>
<td>Revision of implantable intra-arterial infusion pump</td>
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<td>36262</td>
<td>Removal of implanted intra-arterial infusion pump</td>
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<tr>
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<td>Repair of tunneled or non-tunneled central venous access catheter, without subcutaneous port or pump, central or peripheral insertion site</td>
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<td>36576</td>
<td>Repair of central venous access device, with subcutaneous port or pump, central or peripheral insertion site</td>
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<tr>
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<td>Replacement, complete, of a tunneled centrally inserted central venous catheter, without subcutaneous port or pump, through same venous access</td>
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<td>61215</td>
<td>Insertion of subcutaneous reservoir, pump, or continuous infusion system for connection to ventricular catheter</td>
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<td>62350</td>
<td>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</td>
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<td>62351</td>
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<td>Implantation or replacement of device for Intrathecal or epidural drug infusion; subcutaneous reservoir – non programmable pump</td>
</tr>
<tr>
<td>62362</td>
<td>Implantation or replacement of device for Intrathecal or epidural drug infusion; subcutaneous reservoir – programmable pump</td>
</tr>
<tr>
<td>62365</td>
<td>Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion</td>
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<tr>
<td>62367</td>
<td>Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill</td>
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<td>62368</td>
<td>Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming</td>
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<tr>
<td>62369</td>
<td>Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill</td>
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</tbody>
</table>
Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring a physician’s skill)

Refill kit for implantable infusion pump

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

Infusion pump, implantable, non-programmable (includes all components, E.G., pump, catheter, connectors, etc.)

Infusion pump, implantable, programmable (includes all components, E.G., pump, catheter, connectors, etc.)

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

Durable medical equipment, miscellaneous

ICD-10 Codes

Vascular myelopathies

Multiple sclerosis

Causalgia of upper limb

Causalgia of lower limb

Cerebral palsy, code range

Flaccid hemiplegia code range

Spastic hemiplegia, code range

Hemiplegia, unspecified code range

Paraplegia, code range

Other paralytic syndromes, code range

Chronic pain, not elsewhere classified, code range

Chronic pain syndrome

Complex regional pain syndrome I, code range

Postlaminectomy syndrome, not elsewhere classified

Additional Policy Key Words

N/A

Policy Implementation/Update Information

1/1/88 New policy
6/1/00 No policy statement changes
6/1/01 Prior Authorization requirement added to the policy.
6/1/02 No policy statement changes
6/1/03 No policy statement changes
6/1/04 No policy statement changes, policy placed in Archives.
6/1/05 Policy removed from Archives. Prior authorization requirement statement removed from the policy.
6/1/06 No policy statement changes
6/1/07 No policy statement changes. Updated coding.
6/1/08 No policy statement changes.
6/1/09 No policy statement changes.
6/1/10 No policy statement changes.
10/1/10 First policy statement revised to indicate that, in order for implantable infusion pumps to be considered medically necessary for severe, chronic intractable pain, patients need to have had a successful trial of spinal opioid or non-opioid analgesics.
6/1/11 No policy statement changes.
1/1/12 Coding updated.
6/1/12 In medically necessary policy statement, fourth bullet point changed to say that a temporary trial of pain medication should use the same route of administration as the planned treatment.
6/1/13 Policy statements updated: Primary epithelial ovarian cancer (intraperitoneal infusion as component of chemotherapy) added as medically necessary. Head/neck cancers (intra-arterial injection of chemotherapeutic agents) changed to investigational.
6/1/14 Updated Regulatory Status w/latest info. No policy statement changes.
6/1/15 Bone and soft tissue sarcomas and skin cancers added to investigational policy statement.
6/1/16 No policy statement changes.
6/1/17 Medically necessary policy statements related to intraperitoneal infusion for primary epithelial ovarian cancer, and for intrahepatic artery therapy for primary liver cancer or hepatic metastases removed. Investigational statement changed to “…investigational for all other uses related to pain and spasticity”. Title changed to “Implantable Infusion Pump for Pain and Spasticity”.
6/1/18 No policy statement changes.
6/1/19 No policy statement changes.