7.01.41	Implantable Infusion Pump for Pain and Spasticity		
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Policy Statement

Implantable infusion pumps may be considered **medically necessary** when used to deliver drugs for this route of access which are regulated by U.S. Food and Drug Administration (FDA) and which are used for the related indication for the treatment of patients with any of the following conditions:

- Severe, chronic, intractable pain (intravenous, intrathecal, and epidural injection of opioids), after a successful temporary trial of opioid or nonopioid analgesics by the same route of administration as the planned treatment. A successful trial is defined as greater than 50% reduction in pain after implementation of treatment (see Policy Guidelines)
- 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*) (see Policy Guidelines)

Implantable infusion pumps are considered **investigational** for all other uses related to pain and spasticity.

Policy Guidelines

Preliminary Trial of Intrathecal Drug Delivery

A preliminary trial of percutaneous intrathecal (intraspinal) drug delivery may be considered for the treatment of patients with the following conditions:

- Baclofen (Lioresal®) intrathecal therapy for severe, refractory spasticity or chronic intractable dystonia of cerebral* or spinal cord origin when there is failure of, contradiction, or intolerance to at least a 6-week trial of oral antispasticity agents (i.e., baclofen [Lioresal®]) and other less-invasive methods (e.g., physical therapy)
  Note: Per the FDA, patients with spasticity due to traumatic brain injury should wait at least one year after the injury before consideration of long-term intrathecal baclofen therapy.
- Intrathecal (intraspinal) opiate or non-opiate medications, specifically approved by the U.S. Food and Drug Administration (FDA), for the treatment of severe, intractable chronic pain when the following exist:
  - There is documented pathology (i.e., an objective basis for the pain complaint)
  - Further surgical intervention or other treatment is not indicated or likely to be effective
  - Patient has a life expectancy of greater than 3 months (less invasive techniques such as external infusion pumps provide comparable pain relief in the short term and are consistent with standard of care)
  - Sufficient trial of opioids or other analgesics in adequate doses, with a fixed schedule (not on a PRN basis) dosing which have failed to relieve pain, or the patient has developed intolerable side effects to systemic opioids or other analgesics
  - Behavioral, psychological and social support stability* have been evaluated and indicate appropriateness of implantable therapy
    *Note: Attempts should be made to eliminate physical, psychological, and behavioral contributors to an exaggerated sensation of pain, and no active or untreated drug dependence should exist
  - Non-malignant pain including **all** of the following:
    - Intractable chronic pain, including but not limited to **any** of the following:
      - Failed back surgery syndrome with low back pain and/or radicular pain
      - Chronic arachnoiditis
      - Visceral pain syndromes

  - Complex regional pain syndrome (also known as reflex sympathetic dystrophy)
  - Post-herpetic neuralgia and other neuropathic pain syndromes
  - Phantom limb pain
  - Peripheral neuropathies
  - Spinal cord injuries
- Documentation of failure of a 6-month trial of other conservative treatment modalities for pain management (e.g., pharmacotherapy [antidepressant, anti-epileptic, anti-inflammatory and analgesia medications]), and minimally invasive interventions such as spinal injections)
- Documentation of active participation in a reasonable trial of an aggressive active rehabilitative exercise program (e.g., physical therapy), if appropriate and not contraindicated
- Documentation from a primary care physician, neurologist, physiatrist, psychiatrist or psychologist, supports the absence of untreated, underlying psychological conditions or psychosocial issues (e.g., depression, drug and alcohol dependence) as a contributor to chronic pain and that benefit will occur with implantation

The use of a percutaneous intrathecal drug delivery system for other indications, including other chronic pain conditions, will be reviewed on a case-by-case basis for medical necessity.

*Recommended medications are those approved by the FDA for infusion at the site requested (e.g., intrathecal, intravenous, intra-arterial, subcutaneous).

See applicable Blue Shield Pharmacy Policies.

Description

Implantable infusion pumps can provide long-term drug infusion at constant or variable rates; several devices are commercially available.

Related Policies

- Intravenous Anesthetics for the Treatment of Chronic Pain

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Several implantable infusion pumps have been approved by the U.S. Food and Drug Administration 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 1996¾for 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 2012, the MedStream™ Programmable Infusion System (Codman and Shurtleff, a division of DePuy), which includes an implantable pump, was approved by the Food and Drug Administration through the premarket approval process for intrathecal delivery of baclofen in patients with spasticity.

Food and Drug Administration product code: LKK.

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

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.

Literature Review
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.[3,] 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 meeting1 or more inclusion criteria (e.g., 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 (e.g., active infection) and indications to proceed with therapy (e.g., 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.[4,] 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 lumbospinal 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),[5] 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.[6] Sixty-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).[7] 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 (i.e., at the level of body structures or functions), such as range of motion and muscle strength; several studies used objective outcomes (e.g., 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.[12,] 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.[13,] 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.[14,] All patients experienced a reduction in lower-limb spasticity as measured by the ModifiedAshworth 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, e.g., 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.[15,] 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.[16,] 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.[17,] 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).[18,]

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 (e.g., 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.

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. The relevant outcomes are symptoms, QOL, 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. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Uncontrolled studies and systematic reviews of these studies have 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 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.

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 individuation 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 indications[23,]:

"…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.

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23. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Infusion Pumps (280.14). 2004; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&DocID=280.14&SearchType=Advanced&bc=IAAAABAAAAAA&. Accessed January 26, 2019.
24. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 7.01.41 (February 2019).

Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - Patient's life expectancy (for chronic pain only)
  - Previous and current pain or spasticity medication trials (doses, schedules) including duration, and response(s) (as applicable)
  - Previous conservative treatment(s), duration, and response(s) including physical therapy and alternative therapies
  - Behavioral, psychological and social support assessment
  - Psychological evaluation and clearance (if applicable)
  - Reason for the procedure outlining why there are no further treatment options for the patient's condition (e.g., spasticity, chronic pain)
  - Medication requested for the intrathecal infusion pump
- Pertinent physician progress notes
- Other pertinent multidisciplinary notes/reports: (e.g., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management)
- Make/Model of intrathecal implantable infusion device and FDA approved indications

Post Service

- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

Type	Code	Description
CPT®	36260	Insertion of implantable intra-arterial infusion pump (e.g., for chemotherapy of liver)
	36261	Revision of implanted intra-arterial infusion pump
	36262	Removal of implanted intra-arterial infusion pump
	36563	Insertion of tunneled centrally inserted central venous access device with subcutaneous pump
	36576	Repair of central venous access device, with subcutaneous port or pump, central or peripheral insertion site
	36583	Replacement, complete, of a tunneled centrally inserted central venous access device, with subcutaneous pump, through same venous access
	36590	Removal of tunneled central venous access device, with subcutaneous port or pump, central or peripheral insertion
	61215	Insertion of subcutaneous reservoir, pump or continuous infusion system for connection to ventricular catheter
	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; nonprogrammable pump
	62362	Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming
	62365	Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion
	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 or refill
	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
HCPCS	A4220	Refill kit for implantable infusion pump

Type	Code	Description
	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.)
	E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)
ICD-10 Procedure	0JH60VZ	Insertion of Infusion Pump into Chest Subcutaneous Tissue and Fascia, Open Approach
	0JH63VZ	Insertion of Infusion Pump into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH70VZ	Insertion of Infusion Pump into Back Subcutaneous Tissue and Fascia, Open Approach
	0JH73VZ	Insertion of Infusion Pump into Back Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JH80VZ	Insertion of Infusion Pump into Abdomen Subcutaneous Tissue and Fascia, Open Approach
	0JH83VZ	Insertion of Infusion Pump into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JHD0VZ	Insertion of Infusion Pump into Right Upper Arm Subcutaneous Tissue and Fascia, Open Approach
	0JHD3VZ	Insertion of Infusion Pump into Right Upper Arm Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JHF0VZ	Insertion of Infusion Pump into Left Upper Arm Subcutaneous Tissue and Fascia, Open Approach
	0JHF3VZ	Insertion of Infusion Pump into Left Upper Arm Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JHG0VZ	Insertion of Infusion Pump into Right Lower Arm Subcutaneous Tissue and Fascia, Open Approach
	0JHG3VZ	Insertion of Infusion Pump into Right Lower Arm Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JHH0VZ	Insertion of Infusion Pump into Left Lower Arm Subcutaneous Tissue and Fascia, Open Approach
	0JHH3VZ	Insertion of Infusion Pump into Left Lower Arm Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JHL0VZ	Insertion of Infusion Pump into Right Upper Leg Subcutaneous Tissue and Fascia, Open Approach
	0JHL3VZ	Insertion of Infusion Pump into Right Upper Leg Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JHM0VZ	Insertion of Infusion Pump into Left Upper Leg Subcutaneous Tissue and Fascia, Open Approach
	0JHM3VZ	Insertion of Infusion Pump into Left Upper Leg Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JHN0VZ	Insertion of Infusion Pump into Right Lower Leg Subcutaneous Tissue and Fascia, Open Approach
	0JHN3VZ	Insertion of Infusion Pump into Right Lower Leg Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JHP0VZ	Insertion of Infusion Pump into Left Lower Leg Subcutaneous Tissue and Fascia, Open Approach
	0JHP3VZ	Insertion of Infusion Pump into Left Lower Leg Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JHS03Z	Insertion of Infusion Device into Head and Neck Subcutaneous Tissue and Fascia, Open Approach
	0JHS33Z	Insertion of Infusion Device into Head and Neck Subcutaneous Tissue and Fascia, Percutaneous Approach

Type	Code	Description
	0JHT33Z	Insertion of Infusion Device into Trunk Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JHT3VZ	Insertion of Infusion Pump into Trunk Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JHV03Z	Insertion of Infusion Device into Upper Extremity Subcutaneous Tissue and Fascia, Open Approach
	0JHV33Z	Insertion of Infusion Device into Upper Extremity Subcutaneous Tissue and Fascia, Percutaneous Approach
	0JHW03Z	Insertion of Infusion Device into Lower Extremity Subcutaneous Tissue and Fascia, Open Approach
	0JHW33Z	Insertion of Infusion Device into Lower Extremity Subcutaneous Tissue and Fascia, Percutaneous Approach
	0RH003Z	Insertion of Infusion Device into Occipital-cervical Joint, Open Approach
	0RH033Z	Insertion of Infusion Device into Occipital-cervical Joint, Percutaneous Approach
	0RH043Z	Insertion of Infusion Device into Occipital-cervical Joint, Percutaneous Endoscopic Approach
	0RH103Z	Insertion of Infusion Device into Cervical Vertebral Joint, Open Approach
	0RH133Z	Insertion of Infusion Device into Cervical Vertebral Joint, Percutaneous Approach
	0RH143Z	Insertion of Infusion Device into Cervical Vertebral Joint, Percutaneous Endoscopic Approach
	0RH303Z	Insertion of Infusion Device into Cervical Vertebral Disc, Open Approach
	0RH333Z	Insertion of Infusion Device into Cervical Vertebral Disc, Percutaneous Approach
	0RH343Z	Insertion of Infusion Device into Cervical Vertebral Disc, Percutaneous Endoscopic Approach
	0RH403Z	Insertion of Infusion Device into Cervicothoracic Vertebral Joint, Open Approach
	0RH433Z	Insertion of Infusion Device into Cervicothoracic Vertebral Joint, Percutaneous Approach
	0RH443Z	Insertion of Infusion Device into Cervicothoracic Vertebral Joint, Percutaneous Endoscopic Approach
	0RH503Z	Insertion of Infusion Device into Cervicothoracic Vertebral Disc, Open Approach
	0RH533Z	Insertion of Infusion Device into Cervicothoracic Vertebral Disc, Percutaneous Approach
	0RH543Z	Insertion of Infusion Device into Cervicothoracic Vertebral Disc, Percutaneous Endoscopic Approach
	0RH603Z	Insertion of Infusion Device into Thoracic Vertebral Joint, Open Approach
	0RH633Z	Insertion of Infusion Device into Thoracic Vertebral Joint, Percutaneous Approach
	0RH643Z	Insertion of Infusion Device into Thoracic Vertebral Joint, Percutaneous Endoscopic Approach
	0RH903Z	Insertion of Infusion Device into Thoracic Vertebral Disc, Open Approach
	0RH933Z	Insertion of Infusion Device into Thoracic Vertebral Disc, Percutaneous Approach
	0RH943Z	Insertion of Infusion Device into Thoracic Vertebral Disc, Percutaneous Endoscopic Approach

Type	Code	Description
	0RHA03Z	Insertion of Infusion Device into Thoracolumbar Vertebral Joint, Open Approach
	0RHA33Z	Insertion of Infusion Device into Thoracolumbar Vertebral Joint, Percutaneous Approach
	0RHA43Z	Insertion of Infusion Device into Thoracolumbar Vertebral Joint, Percutaneous Endoscopic Approach
	0RHB03Z	Insertion of Infusion Device into Thoracolumbar Vertebral Disc, Open Approach
	0RHB33Z	Insertion of Infusion Device into Thoracolumbar Vertebral Disc, Percutaneous Approach
	0RHB43Z	Insertion of Infusion Device into Thoracolumbar Vertebral Disc, Percutaneous Endoscopic Approach
	0RHE03Z	Insertion of Infusion Device into Right Sternoclavicular Joint, Open Approach
	0RHE33Z	Insertion of Infusion Device into Right Sternoclavicular Joint, Percutaneous Approach
	0RHE43Z	Insertion of Infusion Device into Right Sternoclavicular Joint, Percutaneous Endoscopic Approach
	0RHF03Z	Insertion of Infusion Device into Left Sternoclavicular Joint, Open Approach
	0RHF33Z	Insertion of Infusion Device into Left Sternoclavicular Joint, Percutaneous Approach
	0RHF43Z	Insertion of Infusion Device into Left Sternoclavicular Joint, Percutaneous Endoscopic Approach
	0RHG03Z	Insertion of Infusion Device into Right Acromioclavicular Joint, Open Approach
	0RHG33Z	Insertion of Infusion Device into Right Acromioclavicular Joint, Percutaneous Approach
	0RHG43Z	Insertion of Infusion Device into Right Acromioclavicular Joint, Percutaneous Endoscopic Approach
	0RHH03Z	Insertion of Infusion Device into Left Acromioclavicular Joint, Open Approach
	0RHH33Z	Insertion of Infusion Device into Left Acromioclavicular Joint, Percutaneous Approach
	0RHH43Z	Insertion of Infusion Device into Left Acromioclavicular Joint, Percutaneous Endoscopic Approach
	0RHJ03Z	Insertion of Infusion Device into Right Shoulder Joint, Open Approach
	0RHJ33Z	Insertion of Infusion Device into Right Shoulder Joint, Percutaneous Approach
	0RHJ43Z	Insertion of Infusion Device into Right Shoulder Joint, Percutaneous Endoscopic Approach
	0RHK03Z	Insertion of Infusion Device into Left Shoulder Joint, Open Approach
	0RHK33Z	Insertion of Infusion Device into Left Shoulder Joint, Percutaneous Approach
	0RHK43Z	Insertion of Infusion Device into Left Shoulder Joint, Percutaneous Endoscopic Approach
	0RHL03Z	Insertion of Infusion Device into Right Elbow Joint, Open Approach
	0RHL33Z	Insertion of Infusion Device into Right Elbow Joint, Percutaneous Approach
	0RHL43Z	Insertion of Infusion Device into Right Elbow Joint, Percutaneous Endoscopic Approach
	0RHM03Z	Insertion of Infusion Device into Left Elbow Joint, Open Approach

Type	Code	Description
	0RHM33Z	Insertion of Infusion Device into Left Elbow Joint, Percutaneous Approach
	0RHM43Z	Insertion of Infusion Device into Left Elbow Joint, Percutaneous Endoscopic Approach
	0RHN03Z	Insertion of Infusion Device into Right Wrist Joint, Open Approach
	0RHN33Z	Insertion of Infusion Device into Right Wrist Joint, Percutaneous Approach
	0RHN43Z	Insertion of Infusion Device into Right Wrist Joint, Percutaneous Endoscopic Approach
	0RHP03Z	Insertion of Infusion Device into Left Wrist Joint, Open Approach
	0RHP33Z	Insertion of Infusion Device into Left Wrist Joint, Percutaneous Approach
	0RHP43Z	Insertion of Infusion Device into Left Wrist Joint, Percutaneous Endoscopic Approach
	0RHQ03Z	Insertion of Infusion Device into Right Carpal Joint, Open Approach
	0RHQ33Z	Insertion of Infusion Device into Right Carpal Joint, Percutaneous Approach
	0RHQ43Z	Insertion of Infusion Device into Right Carpal Joint, Percutaneous Endoscopic Approach
	0RHR03Z	Insertion of Infusion Device into Left Carpal Joint, Open Approach
	0RHR33Z	Insertion of Infusion Device into Left Carpal Joint, Percutaneous Approach
	0RHR43Z	Insertion of Infusion Device into Left Carpal Joint, Percutaneous Endoscopic Approach
	0RHS03Z	Insertion of Infusion Device into Right Metacarpocarpal Joint, Open Approach
	0RHS33Z	Insertion of Infusion Device into Right Metacarpocarpal Joint, Percutaneous Approach
	0RHS43Z	Insertion of Infusion Device into Right Metacarpocarpal Joint, Percutaneous Endoscopic Approach
	0RHT03Z	Insertion of Infusion Device into Left Metacarpocarpal Joint, Open Approach
	0RHT33Z	Insertion of Infusion Device into Left Metacarpocarpal Joint, Percutaneous Approach
	0RHT43Z	Insertion of Infusion Device into Left Metacarpocarpal Joint, Percutaneous Endoscopic Approach
	0RHU03Z	Insertion of Infusion Device into Right Metacarpophalangeal Joint, Open Approach
	0RHU33Z	Insertion of Infusion Device into Right Metacarpophalangeal Joint, Percutaneous Approach
	0RHU43Z	Insertion of Infusion Device into Right Metacarpophalangeal Joint, Percutaneous Endoscopic Approach
	0RHV03Z	Insertion of Infusion Device into Left Metacarpophalangeal Joint, Open Approach
	0RHV33Z	Insertion of Infusion Device into Left Metacarpophalangeal Joint, Percutaneous Approach
	0RHV43Z	Insertion of Infusion Device into Left Metacarpophalangeal Joint, Percutaneous Endoscopic Approach
	0RHW03Z	Insertion of Infusion Device into Right Finger Phalangeal Joint, Open Approach
	0RHW33Z	Insertion of Infusion Device into Right Finger Phalangeal Joint, Percutaneous Approach

Type	Code	Description
	0RHW43Z	Insertion of Infusion Device into Right Finger Phalangeal Joint, Percutaneous Endoscopic Approach
	0RHX03Z	Insertion of Infusion Device into Left Finger Phalangeal Joint, Open Approach
	0RHX33Z	Insertion of Infusion Device into Left Finger Phalangeal Joint, Percutaneous Approach
	0RHX43Z	Insertion of Infusion Device into Left Finger Phalangeal Joint, Percutaneous Endoscopic Approach
	0SH003Z	Insertion of Infusion Device into Lumbar Vertebral Joint, Open Approach
	0SH033Z	Insertion of Infusion Device into Lumbar Vertebral Joint, Percutaneous Approach
	0SH043Z	Insertion of Infusion Device into Lumbar Vertebral Joint, Percutaneous Endoscopic Approach
	0SH203Z	Insertion of Infusion Device into Lumbar Vertebral Disc, Open Approach
	0SH233Z	Insertion of Infusion Device into Lumbar Vertebral Disc, Percutaneous Approach
	0SH243Z	Insertion of Infusion Device into Lumbar Vertebral Disc, Percutaneous Endoscopic Approach
	0SH303Z	Insertion of Infusion Device into Lumbosacral Joint, Open Approach
	0SH333Z	Insertion of Infusion Device into Lumbosacral Joint, Percutaneous Approach
	0SH343Z	Insertion of Infusion Device into Lumbosacral Joint, Percutaneous Endoscopic Approach
	0SH403Z	Insertion of Infusion Device into Lumbosacral Disc, Open Approach
	0SH433Z	Insertion of Infusion Device into Lumbosacral Disc, Percutaneous Approach
	0SH443Z	Insertion of Infusion Device into Lumbosacral Disc, Percutaneous Endoscopic Approach
	0SH503Z	Insertion of Infusion Device into Sacrococcygeal Joint, Open Approach
	0SH533Z	Insertion of Infusion Device into Sacrococcygeal Joint, Percutaneous Approach
	0SH543Z	Insertion of Infusion Device into Sacrococcygeal Joint, Percutaneous Endoscopic Approach
	0SH603Z	Insertion of Infusion Device into Coccygeal Joint, Open Approach
	0SH633Z	Insertion of Infusion Device into Coccygeal Joint, Percutaneous Approach
	0SH643Z	Insertion of Infusion Device into Coccygeal Joint, Percutaneous Endoscopic Approach
	0SH703Z	Insertion of Infusion Device into Right Sacroiliac Joint, Open Approach
	0SH733Z	Insertion of Infusion Device into Right Sacroiliac Joint, Percutaneous Approach
	0SH743Z	Insertion of Infusion Device into Right Sacroiliac Joint, Percutaneous Endoscopic Approach
	0SH803Z	Insertion of Infusion Device into Left Sacroiliac Joint, Open Approach
	0SH833Z	Insertion of Infusion Device into Left Sacroiliac Joint, Percutaneous Approach
	0SH843Z	Insertion of Infusion Device into Left Sacroiliac Joint, Percutaneous Endoscopic Approach

Type	Code	Description
	0SH903Z	Insertion of Infusion Device into Right Hip Joint, Open Approach
	0SH933Z	Insertion of Infusion Device into Right Hip Joint, Percutaneous Approach
	0SH943Z	Insertion of Infusion Device into Right Hip Joint, Percutaneous Endoscopic Approach
	0SHB03Z	Insertion of Infusion Device into Left Hip Joint, Open Approach
	0SHB33Z	Insertion of Infusion Device into Left Hip Joint, Percutaneous Approach
	0SHB43Z	Insertion of Infusion Device into Left Hip Joint, Percutaneous Endoscopic Approach
	0SHC03Z	Insertion of Infusion Device into Right Knee Joint, Open Approach
	0SHC33Z	Insertion of Infusion Device into Right Knee Joint, Percutaneous Approach
	0SHC43Z	Insertion of Infusion Device into Right Knee Joint, Percutaneous Endoscopic Approach
	0SHD03Z	Insertion of Infusion Device into Left Knee Joint, Open Approach
	0SHD33Z	Insertion of Infusion Device into Left Knee Joint, Percutaneous Approach
	0SHD43Z	Insertion of Infusion Device into Left Knee Joint, Percutaneous Endoscopic Approach
	0SHF03Z	Insertion of Infusion Device into Right Ankle Joint, Open Approach
	0SHF33Z	Insertion of Infusion Device into Right Ankle Joint, Percutaneous Approach
	0SHF43Z	Insertion of Infusion Device into Right Ankle Joint, Percutaneous Endoscopic Approach
	0SHG03Z	Insertion of Infusion Device into Left Ankle Joint, Open Approach
	0SHG33Z	Insertion of Infusion Device into Left Ankle Joint, Percutaneous Approach
	0SHG43Z	Insertion of Infusion Device into Left Ankle Joint, Percutaneous Endoscopic Approach
	0SHH03Z	Insertion of Infusion Device into Right Tarsal Joint, Open Approach
	0SHH33Z	Insertion of Infusion Device into Right Tarsal Joint, Percutaneous Approach
	0SHH43Z	Insertion of Infusion Device into Right Tarsal Joint, Percutaneous Endoscopic Approach
	0SHJ03Z	Insertion of Infusion Device into Left Tarsal Joint, Open Approach
	0SHJ33Z	Insertion of Infusion Device into Left Tarsal Joint, Percutaneous Approach
	0SHJ43Z	Insertion of Infusion Device into Left Tarsal Joint, Percutaneous Endoscopic Approach
	0SHK03Z	Insertion of Infusion Device into Right Metatarsal-Tarsal Joint, Open Approach
	0SHK33Z	Insertion of Infusion Device into Right Metatarsal-Tarsal Joint, Percutaneous Approach
	0SHK43Z	Insertion of Infusion Device into Right Metatarsal-Tarsal Joint, Percutaneous Endoscopic Approach
	0SHL03Z	Insertion of Infusion Device into Left Metatarsal-Tarsal Joint, Open Approach
	0SHL33Z	Insertion of Infusion Device into Left Metatarsal-Tarsal Joint, Percutaneous Approach
	0SHL43Z	Insertion of Infusion Device into Left Metatarsal-Tarsal Joint, Percutaneous Endoscopic Approach

Type	Code	Description
	0SHM03Z	Insertion of Infusion Device into Right Metatarsal-Phalangeal Joint, Open Approach
	0SHM33Z	Insertion of Infusion Device into Right Metatarsal-Phalangeal Joint, Percutaneous Approach
	0SHM43Z	Insertion of Infusion Device into Right Metatarsal-Phalangeal Joint, Percutaneous Endoscopic Approach
	0SHN03Z	Insertion of Infusion Device into Left Metatarsal-Phalangeal Joint, Open Approach
	0SHN33Z	Insertion of Infusion Device into Left Metatarsal-Phalangeal Joint, Percutaneous Approach
	0SHN43Z	Insertion of Infusion Device into Left Metatarsal-Phalangeal Joint, Percutaneous Endoscopic Approach
	0SHP03Z	Insertion of Infusion Device into Right Toe Phalangeal Joint, Open Approach
	0SHP33Z	Insertion of Infusion Device into Right Toe Phalangeal Joint, Percutaneous Approach
	0SHP43Z	Insertion of Infusion Device into Right Toe Phalangeal Joint, Percutaneous Endoscopic Approach
	0SHQ03Z	Insertion of Infusion Device into Left Toe Phalangeal Joint, Open Approach
	0SHQ33Z	Insertion of Infusion Device into Left Toe Phalangeal Joint, Percutaneous Approach
	0SHQ43Z	Insertion of Infusion Device into Left Toe Phalangeal Joint, Percutaneous Endoscopic Approach

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
03/05/2012	New Policy Adoption TRIAD Healthcare Inc., Musculoskeletal Health Services Medical Policy	Medical Policy Committee
07/14/2014	Policy revision with position change	Medical Policy Committee
01/30/2015	Policy title change from Implantable Intrathecal Drug Delivery Systems Policy revision without position change	Medical Policy Committee
02/01/2017	Coding update	Administrative Review
04/01/2017	Policy title change from "Implantable Infusion Pump" Policy revision without position change	Medical Policy Committee
04/01/2018	Policy revision without position change	Medical Policy Committee
05/01/2019	Policy revision without position change	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.