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Policy Effective Date	**02/01/2025**
Policy End Date	**12/31/2025**

Implantable Infusion Pump for Pain and Spasticity

Table of Contents

Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Implantable infusion pumps **may be considered medically necessary** when used to deliver drugs that are United States (U.S.) Food and Drug Administration (FDA) approved for this route of access and for the related indication for the treatment of intractable pain or spasticity.

Criteria A - Trial Period
Prior to permanent implantation of an infusion pump, a trial period using an external pump for continuous infusion, or a single bolus intra-spinal (epidural or intrathecal) injection **may be considered medically necessary** when used for the intrathecal administration of drugs for the treatment of:

1. Severe spasticity of cerebral or spinal cord origin in individuals who are unresponsive to or who cannot tolerate oral baclofen therapy; OR

2. Severe, chronic, intractable pain in patients who are intolerant of, or unresponsive to, less invasive medical therapy, including but not limited to pharmacologic, surgical, psychological, or physical treatment modalities; this includes administration of single drugs that are FDA approved, or compounded drugs whose ingredients are FDA approved; **and**
    - Documentation of an evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) that confirms no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of an implantable pain pump or contraindicate its placement.

NOTE 1: A trial with a percutaneous intrathecal or epidural drug delivery system for cancer-related pain is not required in the presence of advanced disease, when survival time is limited, and when the individual is considered at high risk for procedures. Evaluation by a mental health provider is also not required.

Criteria B - Permanent Implantation

Permanent implantation of an infusion pump **may be considered medically necessary** in individuals who meet ALL of the following criteria:

1. Criteria A (1 or 2) above for the intrathecal administration of drugs was met; AND
2. A trial period with the proposed agent demonstrated a greater than 50% reduction in pain with minimal side effects and improvement in function (**EXCEPTION: see NOTE 1**).

Implantable infusion pumps **are considered experimental, investigational, and/or unproven** for all other uses related to pain and spasticity.

NOTE 2: Replacement, revision or removal of catheter, reservoir, and/or pump will not require additional medical necessity review.

Policy Guidelines

None.

Description

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 2012, the MedStream™ Programmable Infusion System (Codman and Shurtleff, a division of DePuy), which includes an implantable pump, was approved by the FDA through the premarket approval process for intrathecal delivery of baclofen in patients with spasticity.

FDA 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). (1)

Rationale

Medical policies 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 with 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.

Duarte et al. (2023) published the results of a systematic review and meta-analysis looking at the effectiveness and safety of intrathecal drug delivery systems (IDDS) for the management of cancer pain. (3) From 1988 to March 2021, a total of 22 studies (24 reports) included a total of 3043 participants who received either IDDS or spinal cord stimulation (SCS) for cancer pain. Eight studies reporting data for 405 participants with an IDDS could be included in the meta-analysis of pain intensity that showed a statistically significant reduction at the latest posttreatment follow-up time compared with baseline (mean difference [MD], −3.31; 95% confidence interval [CI], −4.18 to −2.45; p< 0.001). Six studies reporting data for 325 participants with an IDDS could be included in the meta-analysis of pain intensity that showed a statistically significant reduction up to one month after treatment compared with baseline (MD, −3.53; 95% CI, −4.06 to −3.00; p < 0.001). A meta-analysis including studies of participants with either an IDDS or an SCS device showed similar results. Improvements in other outcomes

following implantation of IDDS also were observed. Post-dural puncture headache was the most reported complication, whereas urinary retention, nausea, and vomiting were commonly reported side effects.

Section Summary: Cancer Pain
Systematic reviews on the use of implantable infusion pumps for cancer pain find it to be equally or more effective than conventional pain management and is a safe and effective option for managing cancer pain.

Noncancer Pain
Falco et al. (2013) published a systematic review of intrathecal infusion for the treatment of chronic noncancer pain. (4) 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 (e.g., outcomes not related to pain relief; sample size <50; minimum quality assessment). All 7 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 is limited. Suggested contraindications to intrathecal opioid therapy (e.g., active infection) and indications to proceed with therapy (e.g., oral opioid therapy contraindicated) are provided.

Previously, Patel et al. (2009) published a systematic review of intrathecal infusion pumps used to treat chronic noncancer pain. (5) 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 4 studies showed positive results for pain relief, 1 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), (6) 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. (7) 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 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 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 nontraumatic spinal cord injury identified 8 studies (N=162). (8) 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 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. (9) Reviewers identified 16 uncontrolled studies (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. (10) This study found a statistically significant increase in GMFM score after 1 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 non-ambulatory children with severe spastic cerebral palsy. (11) Patients who responded to a one-time test intrathecal baclofen dose of 50 mcg 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 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. (12) 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. (13) 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 (AE) within 12 months of surgical insertion of the pump. (14) Most AEs (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 2-year outcomes for 14 ambulatory adults with hereditary spastic paraplegia. (15) 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 (1.7) (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 2 patients. Ghosh et al. (2013) reported on the 3-year experience of 119 children (mean age, 13 years) at a single U.S. center. (16) 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 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. (17) 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. (18) 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). (19)

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 randomized controlled trials (RCTs) and a systematic review. The relevant outcomes are symptoms, quality of life (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 sufficient to determine that the technology results in an improvement in the net health outcome.

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 sufficient to determine that the technology results in an improvement in the net health outcome.

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.

Practice Guidelines and Position Statements

Cancer Pain

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network guidelines (v.3.2024) for the treatment of adult cancer pain recommend placement of epidural or intrathecal infusion pumps to deliver analgesic or anesthetic drugs. (19)

Noncancer Pain

American Society of Interventional Pain Physicians' (ASIPP)

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. (21) In 2013, the ASIPP issued updated evidence-based practice guidelines on interventional techniques in the management of chronic spinal pain (22, 23). The review did not identify any randomized controlled trials for the treatment of chronic noncancer pain with intrathecal (IT) opioids and was based on 7 observational studies, which they concluded showed a long-term benefit from IT infusion devices. Thus, although the evidence base was rated as "limited," ASIPP guidelines recommended the use of IT infusion systems for recalcitrant noncancer pain.

American Society of Regional Anesthesia and Pain Medicine and American Society of Anesthesiologists (ASRA-ASA)

The ASRA-ASA issued practice guidelines pertaining to chronic pain management in 2010 to update a previous version of the guidelines from 1997. These guidelines indicate that observational studies report that IT opioid injections can provide effective pain relief for 1 to 12 months for patients with neuropathic pain. The recommendation arising from this guideline is that IT opioid administration may be used for patients with neuropathic pain. However, shared decision making regarding this procedure should involve a discussion of potential

complications. In addition, a neuraxial opioid trial should be conducted prior to permanent implantation of IT drug delivery systems (24).

North American Spine Society (NASS)
In 2017, NASS published coverage recommendations on spinal intrathecal drug delivery systems for treatment of chronic nonmalignant pain. Per NASS, the implantable infusion may benefit a small subgroup of patients with chronic nonmalignant pain and a clear spinal pathology. These patients should have failed or could not tolerate other treatment methods, including but not limited to nonopioid medications, physical therapy, and appropriate interventional (nonsurgical) treatments, in addition to a successful treatment trial with at least 50% improvement in symptoms and a psychological evaluation to rule out drug and alcohol disorders and other psychological conditions. (25)

Spasticity
National Institute for Health and Care Excellence (NICE)
The NICE (2016) updated its guidance on the management of spasticity in children and young people with nonprogressive brain disorders. (26) 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. (27) 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.

Medicare National Coverage
Medicare's National Coverage Determination on Infusion Pumps (NCD 280.14) provides coverage for implantable infusion pumps for the following indications (28):

- "…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."

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	36260, 36261, 36262, 36563, 36576, 36583, 36590, 61215, 62320, 62321, 62322, 62323, 62324, 62325, 62327, 62350, 62351, 62360, 62361, 62362, 62365, 62367, 62368
HCPCS Codes	A4220, A4300, A4301, E0782, E0783, E0785, E0786

References

1. FDA. Use Caution with Implanted Pumps for Intrathecal Administration of Medicines for Pain Management: FDA Safety Communication (November 14, 2018). Available at <https://www.fda.gov> (accessed December 17, 2024).
2. Myers J, Chan V, Jarvis V, et al. Intraspinal techniques for pain management in cancer patients: a systematic review. Support Care Cancer. Feb 2010; 18(2):137-149. PMID 19943068
3. Duarte R, Copley S, Nevitt S, et al. Effectiveness and safety of intrathecal drug delivery systems for the management of cancer pain: A systematic review and meta-analysis. Neuromodulation 2023; 26:1126-1141. PMID 35422368
4. Falco FJ, Patel VB, Hayek SM, et al. Intrathecal infusion systems for long-term management of chronic non- cancer pain: an update of assessment of evidence. Pain Physician. Apr 2013; 16(2 Suppl):SE185-216. PMID 23615891
5. Patel VB, Manchikanti L, Singh V, et al. Systematic review of intrathecal infusion systems for long-term management of chronic non-cancer pain. Pain Physician. 2009; 12(2):345-360. PMID 19305484
6. Guyatt G, Gutterman D, Baumann MH, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: report from an American College of Chest Physicians task force. Chest. Jan 2006; 129(1):174-181. PMID 16424429
7. Hamza M, Doleys D, Wells M, et al. Prospective study of 3-year follow-up of low-dose intrathecal opioids in the management of chronic nonmalignant pain. Pain Med. Oct 2012; 13(10):1304-1313. PMID 22845187
8. McIntyre A, Mays R, Mehta S, et al. Examining the effectiveness of intrathecal baclofen on spasticity in individuals with chronic spinal cord injury: a systematic review. J Spinal Cord Med. Jan 2014; 37(1):11-18. PMID 24089997
9. Pin TW, McCartney L, Lewis J, et al. Use of intrathecal baclofen therapy in ambulant children and adolescents with spasticity and dystonia of cerebral origin: a systematic review. Dev Med Child Neurol. Oct 2011; 53(10):885-895. PMID 21635230
10. Motta F, Antonello CE, Stignani C. Intrathecal baclofen and motor function in cerebral palsy. Dev Med Child Neurol. May 2011; 53(5):443-448. PMID 21480874
11. Morton RE, Gray N, Vloeberghs M. Controlled study of the effects of continuous intrathecal baclofen infusion in non-ambulant children with cerebral palsy. Dev Med Child Neurol. Aug 2011; 53(8):736-741. PMID 21707598
12. Stokic DS, Yablon SA. Effect of concentration and mode of intrathecal baclofen administration on soleus H-reflex in patients with muscle hypertonia. Clin Neurophysiol. Nov 2012; 123(11):2200-2204. PMID 22595326
13. Malheiro L, Gomes A, Barbosa P, et al. Infectious complications of intrathecal drug administration systems for spasticity and chronic pain: 145 patients from a tertiary care center. Neuromodulation. Jul 2015; 18(5):421-427. PMID 25580571
14. Borrini L, Bensmail D, Thiebaut JB, et al. Occurrence of adverse events in long-term intrathecal baclofen infusion: a 1-year follow-up study of 158 adults. Arch Phys Med Rehabil. Jun 2014; 95(6):1032-1038. PMID 24407102
15. Margetis K, Korfias S, Boutos N, et al. Intrathecal baclofen therapy for the symptomatic treatment of hereditary spastic paraplegia. Clin Neurol Neurosurg. Aug 2014; 123:142-145. PMID 24973568

16. Ghosh D, Mainali G, Khera J, et al. Complications of intrathecal baclofen pumps in children: experience from a tertiary care center. Pediatr Neurosurg. 2013; 49:138-144. PMID 24577095
17. Vles GF, Soudant DL, Hoving MA, et al. Long-term follow-up on continuous intrathecal Baclofen therapy in non- ambulant children with intractable spastic Cerebral Palsy. Eur J Paediatr Neurol. Nov 2013; 17(6):639-644. PMID 23871360
18. Motta F, Antonello CE. Analysis of complications in 430 consecutive pediatric patients treated with intrathecal baclofen therapy: 14-year experience. J Neurosurg Pediatr. Mar 2014; 13(3):301-306. PMID 24404968
19. Mathur SN, Chu SK, McCormick Z, et al. Long-term intrathecal baclofen: outcomes after more than 10 years of treatment. PM R. Jun 2014; 6(6):506-513. PMID 24355547
20. NCCN - Adult Cancer Pain - NCCN Clinical practice guidelines in Oncology (v3.2024). National Comprehensive Cancer Network. Available at <https://www.nccn.org> (accessed December 18, 2024).
21. Manchikanti L, Boswell MV, Singh V, et al. Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. Pain Physician. 2009; 12(4):699-802. PMID 19644537
22. Manchikanti L, Falco FJ, Singh V, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part I: introduction and general considerations. Pain Physician. Apr 2013; 16(2 Suppl):S1-S48. PMID 23615882
23. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. Pain Physician. Apr 2013; 16(2 Suppl):S49-S283. PMID 23615883
24. American Society of Regional Anesthesia and Pain Medicine and American Society of Anesthesiologists (ASRA-ASA). Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. Apr 2010; 112(4):810-833. PMID 20124882
25. North American Spine Society (NASS). NASS Coverage Policy Recommendations: Intrathecal Drug Delivery Systems. Burr Ridge, IL: North American Spine Society. March 2017.
26. National Institute for Health and Care Excellence (NICE). Spasticity in under 19s: management [CG145] (July 2012, updated November 2016). Available at <https://www.guidance.nice.org.uk> (accessed December 17, 2024).
27. Dan B, Motta F, Vles JS, et al. Consensus on the appropriate use of intrathecal baclofen (ITB) therapy in paediatric spasticity. Eur J Paediatr Neurol. Jan 2010; 14(1):19-28. PMID 19541514
28. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Infusion pumps (280.14) (2004). Available at <https://www.cms.gov> (accessed December 17, 2024).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
12/31/2025	Document became inactive.
02/01/2025	Document updated with literature review. Coverage unchanged. Reference 3 added; others removed or updated.
07/15/2023	Reviewed. No changes.
08/15/2022	Document updated with literature review. The following changes were made to Coverage: 1) Added NOTE 1: A trial with a percutaneous intrathecal or epidural drug delivery system for cancer-related pain is not required in the presence of advanced disease, when survival time is limited, and when the individual is considered at high risk for procedures. Evaluation by a mental health provider is also not required" to the Criteria A - Trial Period section and 2) Removed "(for non-cancer pain)" from the Criteria B - Permanent Implantation section. References 21-23 added; some updated and others removed.
12/15/2021	Document updated with literature review. The following changes were made to Coverage: NOTE 1 was incorporated in the coverage statement for the intrathecal administration of drugs, now including criteria for the trial period prior to permanent implantation and NOTE 2 was renumbered to NOTE 1. Reference 21 was added, and others updated.
04/01/2021	Reviewed. No changes.
03/01/2020	Document updated with literature review. The following changes were made to Coverage: Content modified to reflect narrowing of policy scope to address use of implantable infusion pumps in treatment of pain and spasticity only. Title changed from Implantable Infusion Pump to Implantable Infusion Pump for Pain and Spasticity. References 1 and 12 were added and some references were removed.
02/15/2017	Document updated with literature review. The following changes were made in Coverage: Added bone or soft tissue sarcoma or skin cancers to the following statement "Implantable infusion pumps are considered experimental, investigational, and/or unproven for all other uses (e.g., chemotherapy for patients with head and neck cancers, gastric cancer, bone

	or soft tissue sarcomas, or skin cancers; heparin for thromboembolic disease; insulin for diabetes; antibiotics for osteomyelitis)."
05/15/2015	Reviewed. No changes.
10/15/2014	Document updated with literature review. The following was changed in Coverage: 1) Implantable infusion pumps may be considered medically necessary when used to deliver drugs that are FDA approved for both the condition and the route of administration, for the treatment of primary epithelial ovarian cancer (intraperitoneal infusion as component of chemotherapy); 2) Implantable infusion pumps are considered experimental, investigational and/or unproven for chemotherapy for head and/or neck cancers (intra-arterial injection of chemotherapeutic agents).
07/15/2012	Document updated with literature review. Coverage unchanged. "This policy is no longer scheduled for routine literature review and update" has been removed from the document.
09/15/2010	CPT/HCPCS code(s) updated
06/01/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
09/15/2007	Coverage revised
03/01/2007	Revised/updated entire document
06/01/2001	CPT/HCPCS code(s) updated
03/01/2000	Revised/updated entire document
08/01/1999	CPT/HCPCS code(s) updated
07/01/1999	CPT/HCPCS code(s) updated
04/01/1999	CPT/HCPCS code(s) updated
05/01/1996	CPT/HCPCS code(s) updated
07/01/1995	CPT/HCPCS code(s) updated
12/01/1990	New medical document