



**Clinical Review Criteria
Implanted Infusion Pumps**

For **Insulin Pumps** See Separate Criteria

- Intra-Arterial Infusion Pump
- Intraspinal Pump
- Intrathecal Pump

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Infusion Pumps (280.14)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Implanted Infusion Pump for Chronic Pain (A55323)

For Non-Medicare Members

The following criteria must be met for each specific type of treatment:

1. Chemotherapy for Liver Cancer must meet **ALL of the following**:
 - a. Is receiving intra-arterial infusion of 5-FUdR for the treatment of liver cancer.
 - b. Must meet **ONE of the following**:
 - Liver cancer for patients with primary hepatocellular carcinoma.
 - Duke's Class D colorectal cancer, in whom the metastases are limited to the liver, and where (1) the disease is unresectable or (2) the patient refuses surgical excision of the tumor.
2. Anti-Spasmotic Drugs for Severe Spasticity must meet **ALL of the following**:
 - a. Use to administer anti-spasmotic drugs intrathecally (e.g., baclofen).
 - b. The patient has chronic intractable spasticity with a baseline average Ashworth Scale* score of at least 3 (or a Modified Ashworth Scale* score of 2), and a Spasm Frequency score** of at least 2.
 - c. The spasticity is unresponsive to less invasive medical therapy as determined by the following criteria:
 - A 6-week trial, the patient cannot be maintained on noninvasive methods of spasm control, such as oral anti-spasmotic drugs, either because these methods fail to control adequately the spasticity or produce intolerable side effects.
 - The patient has responded favorably to a trial intrathecal dose of the anti-spasmotic drug, e.g., demonstrates at least a 2-point reduction in the Ashworth Scale or Spasm Frequency score for 4 hours following an intrathecal bolus of baclofen.

*[Ashworth and Modified Ashworth Scale](#) (scale appears in middle of document)

**[Spasm Frequency Score](#)

3. Opioid Drugs for Treatment of Chronic Intractable Pain must meet **ALL of the following**:
 - a. Used to administer opioid drugs intrathecally or epidurally.
 - b. Patient has severe chronic intractable pain of malignant or nonmalignant origin with a life expectancy of at least 3 months.
 - c. Patient agrees to a 50% reduction in systemic opiates prior to undergoing an intrathecal opiate trial.
 - d. Are proven unresponsive to one or more of the following less invasive medical therapies:

- Trial of neuropathic pain medication
 - Trial of nonsteroidal anti-inflammatory drugs (NSAIDs)
 - Trial of physical therapy
 - Trial of behavioral health treatments (e.g., CBT, ACT)
 - The patient's history indicates that he/she would not respond adequately to non-invasive methods of pain control, such as systemic opioids (documentation should include attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain)
- e. No acute psychiatric instability or uncontrolled suicide risk
- f. No diagnosed substance-related disorder (other than nicotine) or patient currently receiving active treatment for disorder
- g. A preliminary trial of intraspinal opioid drug administration has been undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and degree of side effects (i.e. patient has experienced > 50% reduction in pain and concomitant increase in function) and patient acceptance.

In addition to meeting the appropriate above criteria the patient does not have one of the following contraindications:

1. A known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.);
2. An infection;
3. Body size at the implant site is insufficient to support the weight and bulk of the device;
4. Other implanted programmable devices since crosstalk between devices may inadvertently change the prescription.

If requesting this service, please send the following documentation to support medical necessity:

- Last 3 months of clinical notes from requesting provider &/or consulting specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Implantable pumps are designed to provide a continuous infusion of medication to a specific body site. The pumps are used with morphine for malignant pain management, and the drug 5-FUdR for liver cancer chemotherapy and Baclofen for intractable spasticity.

About two-thirds of metastatic cancer patients experience moderate-to-severe pain (Smith et al., 2002). Chronic non-malignant pain is also common. One type of non-malignant pain, chronic low back pain, is the second most frequent cause of hospital admissions in the United States (Deer et al., 2004).

Options for initial treatment of chronic pain include exercise, physical therapy, individual counseling, pain education classes, medications such as NSAIDs and complementary/alternative treatments such as massage or acupuncture. Opioids are an option as part of a comprehensive treatment plan if patients fail other therapies (GHC chronic non-malignant pain guideline). A meta-analysis of studies on oral morphine by the Cochrane Collaboration found it to be an effective analgesic for cancer pain (Wiffen et al., 2003). Another Cochrane review on chronic low-back pain found a lack of high-quality evidence and concluded that the benefits of opioids for this type of pain remain uncertain (Deshpande et al., 2007). Disadvantages of opioid analgesics include potential side effects such as nausea and vomiting, constipation, itching and respiratory depression. Moreover, during long-term opioid therapy patients may develop a tolerance leading to a need for higher doses, and patients may become physically dependent on opioids, and experience withdrawal symptoms if the medication is suddenly stopped (Wiffen et al., 2003).

The delivery of pain medication in directly into the fluid that surrounds the spinal cord (intrathecal analgesia) began in the 1970s following the discovery of opioid receptors in the central nervous system. Potential advantages of intrathecal analgesia include the ability to relieve pain in patients with previously intractable pain; the need for a lower milligram dose of opioids compared to systemic administration which may result in fewer side effects; and the ability to easily adjust the dose of opioids. Spinal analgesia was first used to treat chronic cancer-related pain. The use of intrathecal pain pumps for non-malignant pain is more controversial due to the limited

evidence on the ability of opioids to relieve non-malignant pain over the long-term. As with oral opioids, there are concerns about tolerance, dependence and addiction (Williams et al., 2000; Cohen & Dragovich, 2007). Side effects that have been associated with long-term intrathecal morphine therapy include nausea, vomiting, itching urinary retention, constipation, sexual dysfunction and edema (Ruan, 2007).

Chronic pain is a major public health problem in the United States and across the world. It has significant negative effects on patients' functional capacity and quality of life, as well as high direct and indirect costs for the health care system. In a Gallup Survey of "Pain in America" more than 4 out of 10 adults indicated that they experience pain on a daily basis. Chronic pain is a complex phenomenon that is difficult to define. The American Society of Interventional Pain Physicians (ASIPP) defined it as:

1. Pain that persists beyond the usual course of an acute disease or a reasonable time for any injury to heal that is associated with chronic pathologic processes that cause continuous pain or pain at intervals for months or years.
2. Persistent pain that is not amenable to routine pain control methods, and
3. Pain where healing may never occur (Boswell 2007).

Chronic non-cancer pain (CNCP) has also been defined as ongoing pain that lasts over six months, that is due to non-life-threatening causes, and does not respond to available treatment methods (Ghafoor 2007).

A key to successful management of chronic pain is a multidisciplinary approach that optimizes medication use in conjunction with other nonpharmacological therapies including exercise, physical therapy, individual counseling, pain education classes, and complementary/alternative treatments such as massage or acupuncture. When conservative treatments fail, surgery to correct underlying causes is considered. These conservative and surgical therapies provide adequate pain relief for most but not all CNCP patients (Ghafoor 2007).

Intrathecal (IT) analgesia was introduced in the 1970s following the discovery of opioid receptors in the central nervous system and was initially used for malignant pain in patients who have failed to obtain adequate pain relief, or those with adequate analgesia but with intolerable side effects to drug therapy. Currently, it is being used for other indications such as chronic back pain, neuropathy, mixed neuropathic-nociceptive pain, and radicular pain from failed back syndrome. IT analgesia involves the delivery of pain medication directly into the fluid that surrounds the spinal cord to target the pre- and post-synaptic receptors in the dorsal horn of the cord (Koulousakis 2007, Smith 2008, Patel 2009).

There are two types of implantable intrathecal drug delivery systems (IDDS) available in the US. The fixed rate pump allows continuous infusion and bolus dose administration but does not have the option of changing the flow rate. The other, and most common implantable pump is a programmable infusion system which is available in different reservoir sizes. The infusion pumps are typically implanted in the lower abdomen, just beneath the skin. A catheter is inserted into the intrathecal space of the spine, tunneled under the skin and connected to the implanted pump for medication delivery, and to an external programmer that controls infusion rate and records medication concentration, volume, and dosage. A drug is infused over an extended period and may be delivered at a constant or variable rate by calibrating the infusion pump according to the physicians' specification. The pump requires refilling regularly via subcutaneous port injections. A variety of analgesic/co-analgesic agents have been utilized to provide spinal analgesia however, morphine remains the gold standard and is the only opioid approved by the FDA for intrathecal delivery to treat chronic pain. The FDA approved the use of ziconotide, for patients unresponsive to intrathecally delivered morphine. It also approved the use baclofen with the use of implantable infusion pumps for patients with severe spasticity of spinal origin. However, off-label use of other drugs in IT pumps is common (Ghafoor 2007, Koulousakis 2007, Turner 2007).

The implantable infusion pump is an invasive alternative for medication delivery and requires ongoing maintenance and surgeries to periodically replace the pump. It has the potential benefit of providing more effective pain control by administering the analgesic drug directly to the target area, using lower doses of opioids compared to systemic administration, and the ability to adjust the dose of opioids. However, there are many risks and potential harms associated with IT drug therapy. These involve the problems related to the intrathecal drug delivery systems (IDDS), and the adverse events of the medications used. Serious complications that may occur after the intrathecal catheter placement include postoperative subarachnoid hemorrhage, meningitis, catheter tip inflammatory masses, infection, root irritation, reactive arachnoiditis, catheter dislocation, and pump failure. Drug-related side effects consist of dose-independent effects as urinary retention, pruritis, pain due to bolus injection, perspiration, and sedation; and dose-dependent side effects as nausea, constipation, dysphoria, euphoria, sedation, respiratory depression, hypotension, central depression, and tachyphylaxis. As with oral opioids, there are concerns about tolerance, dependence, and addiction. Drug overdose could take place if the pump is

inappropriately used or monitored; and drug withdrawal symptoms may occur with mechanical problems as pump failure or catheter blockage and kinking. There are also reports that patients with CNCP treated with intrathecal opioid therapy experience increased mortality compared to others with similar conditions treated with other therapies. It is thus recommended that pumps for chronic IT opioid application should only be implanted in specialized center. Before implantation the therapeutic effect of IT application should be assessed by a bolus trial or continuous injection via an external pump, connected to the intrathecal catheter through an implanted port (Cohen 2007, Koulousakis 2007, Smith 2008, Pasutharnchat 2009, Rathmell 2009, Coffey 2009).

In 1991, the Medtronic SynchroMed infusion system was approved by the FDA for the intrathecal delivery of morphine to treat malignant and non-malignant pain. The system consists of a pump that is generally implanted subcutaneously in the lower abdominal wall, a spinal catheter implanted into the lumbar intrathecal space between L1 and L4 and a programmer. The pump can be programmed via telemetry to control infusion modes and flow rates. SynchroMed is the only commercially available pump system that can be programmed outside the body. There are various models that differ in the size of the reservoir and the presence of a side catheter access port. Other implantable infusion pumps that have received FDA premarket approval include the Codman 3000 (Codman), Model 300 Constant Flow Implantable Infusion Pump (Arrow international) and the infused implantable Infusion Pump (Strato/infusaid).

Assessment objectives:

- To determine whether implanted infusion pumps for delivering intrathecal opioids are effective for the control of chronic noncancer pain (CNCP).
- To determine whether the use of implanted infusion pumps for delivering intrathecal opioids improves the quality of life and functioning in patients with CNCP.
- To determine whether the use of implanted infusion pumps for delivering intrathecal opioids are more effective than other non-invasive alternative therapies for pain control in patients with CNCP.
- To determine whether the technology is safe for use in patients with CNCP.

Medical Technology Assessment Committee (MTAC)

Implanted Pain Pumps for the Intrathecal Delivery of Opioids

08/06/2007: MTAC REVIEW

Evidence Conclusion: Cancer pain: The best evidence on the safety and effectiveness of implanted intrathecal pain pumps is an RCT with 200 patients. Of the 74% of patients with follow-up data at 4 weeks, there was a significantly greater reduction in toxicity, marginally significant reduction in pain and marginally significant increase in clinical success in the group assigned to receive a SynchroMed implantable pain pump in addition to comprehensive medical management (CMM) compared to CMM alone. Estimated survival at 6 months was higher in the group assigned to pain pumps, but the difference did not reach statistical significance. Limitations of the study include lack of blinding which could lead to biased estimates of self-report pain outcomes, funding by the device manufacturer and substantial cross-over (only 70% of the patients evaluated at 4 weeks in the pain pump group actually received implants and 5% of patients in the non-implant group received implants). Non-malignant pain: The evidence on safety and effectiveness is insufficient. There were case series and a cohort study that only compared pre- to post-implant changes, not between-group differences. The studies tended to find a reduction in self-reported pain after pump implantation and a reduction in oral morphine use (1 or 2 year follow-up). There were no comparison interventions and sample sizes were small. Device-related complications were relatively common.

Articles: The Medline search yielded one systematic review. This was published by the British Health Technology Assessment (HTA) group in 2000 and they did not identify any high-grade evidence. One randomized controlled trial was identified on malignant pain. Several articles were published based on this trial, the first on study outcomes in 2002. The article presenting the primary study outcomes (Smith et al., 2002) was critically appraised. No randomized controlled trials on non-malignant were identified. There was one non-randomized comparative trial which was critically appraised. (Thimineur et al., 2004). Two uncontrolled studies were also reviewed. Deer et al. (2004) reported data from the National Outcomes Registry for Low Back Pain. This registry was set up to prospectively collect data on patients with chronic low-back pain who underwent screening or a trial or an implanted pain pump. The other study was a prospective series using the Medtronic SynchroMed device (Anderson and Burchiel, 1999). There were other case series that had small sample sizes and/or did not mention whether a commercially available device was used. *Studies selected for critical appraisal were:* Smith TJ, Staats PS, Deer T et al. for the Implantable Drug Delivery Systems (IDDS) study. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain. J Clin Oncol 2002; 20: 4040-4049. See [Evidence Table](#). Thimineur MA, Kravitz E, Vodapally MS. Intrathecal opioid treatment for chronic non-malignant pain: a 3-year prospective study. Pain 2004; 109: 242-249. See [Evidence Table](#). Deer T, Chapple I, Classen A et al. Intrathecal drug delivery for treatment of chronic low

back pain. *Am Acad Pain Med* 2004; 5: 6-13. See [Evidence Table](#). Anderson VC, Burchiel KJ. A prospective study of long-term intrathecal morphine in the management of chronic nonmalignant pain. *Neurosurg* 1999; 44: 289-300 See [Evidence Table](#).

The use of implanted pain pumps for the intrathecal delivery of opioids in the treatment of malignant pain meets the *Kaiser Permanente Medical Technology Assessment Criteria*.

The use of implanted pain pumps for the intrathecal delivery of opioids in the treatment of non-malignant pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

10/18/2010: MTAC REVIEW

Implanted Pain Pumps for the Intrathecal Delivery of Opioids

Evidence Conclusion: This re-review of the implantable infusion pumps for delivering intrathecal opioids did not identify any studies that would change the conclusion from the 2007 MTAC review of the technology for the control of chronic noncancer pain (CNCP). There is still insufficient published evidence on the safety and effectiveness of the infusion pump for the control of CNCP and/or improving the QoL of the patients. The published studies for this indication were small case series and observational studies with no control groups. Comparisons were made between pre- and post-implant changes, not between differences among groups receiving different therapies or interventions. The studies had multiple threats to validity and may only provide low quality evidence; they are subject to selection and observation bias and did not take into account the placebo effect of the treatment or assess outcome for patients who had not received the therapy. Moreover, the studies did not compare characteristics of patients who completed the study to those who dropped out, did not adjust for the use of additional therapies or other confounding factors, and were funded by the manufacturer. Overall, the results of the published studies indicate a reduction in self-reported pain, reduction in oral morphine use, and /or improvement in quality of life and psychological function. However, there was a significant proportion of side effects associated with the implanted pump, the catheter, and the IT opioid use.

The Washington State Health Technology Assessment (HTA) program reviewed the implantable infusion pump for drug administration to treat chronic non-cancer pain, in August 2008. After reviewing the evidence, the Health Technology Clinical Committee (HTCC) concluded, "The evidence on infusion pumps did not demonstrate net health benefit because weak or unproven evidence of some effectiveness for certain patients was undermined by significant evidence of serious harms and adverse events associated with the implantation of infusion pumps. The committee found that infusion pumps were not proven to be equally or more safe or effective, and the cost, while not a significant factor for this decision was likely equivalent. Based on these evidentiary findings, the committee voted 8 to 2 for non-coverage." Conclusion: There is insufficient published evidence to determine that the use of implanted infusion pumps for delivering intrathecal opioids is effective for the control of chronic non-cancer pain (CNCP). There is insufficient published evidence to determine that the use of implanted infusion pumps for delivering intrathecal opioids improves quality of life and functioning in patients with CNCP. There is insufficient published evidence to determine that the use of implanted infusion pumps for delivering intrathecal opioids is more effective than other non-invasive alternative therapies for pain control in patients with CNCP. There is insufficient published evidence to determine that the use of implanted infusion pumps for delivering intrathecal opioids is safe for use in patients with CNCP.

Articles: The available published literature on intrathecal (IT) opioid therapy delivered through implanted pumps for chronic noncancer pain is limited and consists of systematic reviews that did not pool the results in meta-analyses, small case series, and observational cohort studies with no control or comparison groups. The literature search did not identify any meta-analyses or randomized controlled trials that compared IT opioid therapy with other non-invasive therapies published since the 2007 MTAC review. There was one retrospective cohort study (Atli 2010) reporting on 3-years outcome of chronic pain patients receiving IT treatment through implanted pumps, one case series (Shaladi 2007) of 24 patients with osteoporotic vertebral fractures treated with intrathecal morphine infusion, and another series (Duse 2009) reporting on psychological functionality of 30 patients with CNCP. The larger cohort study with a long-term follow-up was selected for critical appraisal: Atli A, Theodore BR, Turk DC, et al. Intrathecal opioid therapy for chronic nonmalignant pain: a retrospective cohort study with 3-year follow-up. *Pain Medicine* 2010; 11:1010-1016. See [Evidence Table](#).

The use of implanted pain pumps for the intrathecal delivery of opioids in the treatment of non-malignant pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
36260	Insertion of implantable intra-arterial infusion pump (eg, for chemotherapy of liver)
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
HCPC Codes	Description
C1772	Infusion pump, programmable (implantable)
C1891	Infusion pump, nonprogrammable, permanent (implantable)
C2626	Infusion pump, nonprogrammable, temporary (implantable)
E0782	Infusion pump, implantable, nonprogrammable (includes all components, e.g., pump, catheter, connectors, etc.)
E0783	Infusion pump system, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0785	Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement
E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
11/23/1999	02/02/2010 ^{MDCRPC} , 12/07/2010 ^{MDCRPC} , 10/04/2011 ^{MDCRPC} , 08/07/2012 ^{MDCRPC} , 06/04/2013 ^{MDCRPC} , 04/01/2014 ^{MPC} , 02/03/2015 ^{MPC} , 12/01/2015 ^{MPC} , 10/04/2016 ^{MPC} , 08/01/2017 ^{MPC} , 07/10/2018 ^{MPC} , 07/09/2019 ^{MPC} , 07/07/2020 ^{MPC} , 07/06/2021 ^{MPC} , 07/05/2022 ^{MPC} , 07/11/2023 ^{MPC}	07/24/2023

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

Revision History	Description
04/10/2017	Added Coverage Article A55323
07/07/2020	Removed CPT code 36563 and added 36260
09/01/2020	MPC approved to adopt updates to clinical criteria for non-Medicare. Indications added under spasticity and chronic pain sections. Requires 60-day notice, effective 02/01/2021.
04/03/2023	Updating Medicare links.
07/24/2023	Updated Medicare links.