Implanted Spinal Drug Delivery Systems

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➲ Instructions for Use

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Related Policies

- Ablative Treatment for Spinal Pain
- Epidural Steroid Injections for Spinal Pain
- Facet Joint and Medial Branch Block Injections for Spinal Pain

Coverage Rationale

Cancer-Related Pain

Epidural or intrathecal drug infusion trial or catheter pump placement for cancer-related pain is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Epidural or Intrathecal Catheter Placement.

Click here to view the InterQual® criteria.

Spasticity

Epidural or intrathecal drug infusion trial or catheter pump placement for severe spasticity is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Epidural or Intrathecal Catheter Placement.

Click here to view the InterQual® criteria.

Chronic Nonmalignant Pain

Epidural or intrathecal catheter drug infusion trial for nonmalignant pain is proven and medically necessary for the following:

- Chronic, intractable pain of a nonmalignant origin (e.g., failed back surgery syndrome, complex regional pain syndrome, neuropathic pain) when all the following criteria are met:
  - Age > 18 years*; and
  - Etiology of pain is known and clearly documented; and
  - Further treatment or surgical intervention for underlying condition is not indicated or refused; and
  - Documentation of treatment failure due to intolerable side effects or failure to provide analgesia safely after a minimum of a 6-month trial of conservative methods of pain management (e.g., pharmacological, physical therapy, behavioral health treatment); and
  - Documentation of the absence of underlying untreated psychological or psychosocial issues that will interfere with successful pain treatment

Epidural or intrathecal catheter pump placement for nonmalignant pain is proven and medically necessary when all the following criteria are met:

- Completion of drug infusion trial that met the above criteria; and
- Documentation of a ≥ 50% reduction in pain during the trial

Replacement of Device

Replacement of the device is considered medically necessary when the individual has met all the criteria for initial placement and the existing device is nonfunctional and either cannot be repaired or is no longer under warranty.

*This policy does not address individuals who are younger than 18 years of age.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

CPT Code	Description
62320	Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62321	Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (i.e., fluoroscopy or CT)
62322	Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62324	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62325	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (i.e., fluoroscopy or CT)
62326	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62327	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (i.e., fluoroscopy or CT)
62350	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy
62360	Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir
62361	Implantation or replacement of device for intrathecal or epidural drug infusion; non-programmable pump
62362	Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming

Description of Services

Implanted drug delivery systems for intrathecal (IT) drug administration consist of a catheter and a constant-flow or a programmable pump that delivers the drug directly into the cerebrospinal fluid within the IT space of the spinal column. The implantation of a pump is preceded by an IT or epidural trial infusion to determine whether the individual exhibits an adequate response. If the trial is successful, the drug infusion system is implanted under general anesthesia. Implanted drug delivery systems can be used to treat pain or spasticity. The U.S. Food and Drug Administration has approved morphine and ziconotide (a nonopioid drug) for IT analgesia (Hayes, 2019. Updated, 2022) and baclofen for spasticity. (Deer et al., 2017)

Clinical Evidence

In a Health Technology Assessment for intrathecal drug delivery systems (IDDSs) for cancer pain, Ontario Health (2024) indicated that although evidence is uncertain, intrathecal drug delivery vs other delivery methods for pain medication "likely reduces pain intensity and decreases the use of systemic opioids in adults with cancer pain who have a life expectancy greater than 6 months. It may also improve health-related quality of life, functional outcomes, and survival."

Sánchez-García et al. (2024) conducted a retrospective, single-center, cross-sectional, observational study to evaluate patients with refractory chronic noncancer pain (CNCP) using intrathecal drug delivery. The aim of this study was to assess the patients' health-related quality of life (HRQOL), satisfaction with treatment, and changes in pain magnitude over time. Adult patients with CNCP and IDDSs were included. The study population was divided into two groups: less than and more than 15 years of treatment. HRQOL was analyzed using validated questionnaires. Pain reduction was assessed using the visual analog scale, and treatment satisfaction was evaluated using the Patient Global Impression of Improvement scale. The results indicate poor HRQOL in intrathecal drug delivery patients, with better scores in the group with ≥ 15 years of treatment. Pain reduction was similar in both groups, and patients reported a positive satisfaction level with the treatment. The authors concluded that HRQOL in patients with CNCP is severely affected. Long-term intrathecal drug delivery patients have a similar or even better HRQOL in some respects than those with shorter follow-ups. Intrathecal drug delivery patients experienced pain reduction, with most feeling better or much better. Limitations include the retrospective nature of this study, single-center design, and limited sample size, possibly preventing the authors from detecting differences in study variables.

Ding et al. (2024) conducted a retrospective observational study to evaluate the effectiveness and safety of a cancer pain information platform combined with semi-implantable IDDSs among patients with refractory cancer pain under a home analgesia model. A total of 49 patients received semi-implantable IDDSs with patient-controlled analgesia in conjunction with the establishment of a cancer pain information platform. Numeric rating scales (NRSs), Bruggrmann Comfort Scale (BCS), high-quality sleep duration, and opioid-related adverse effects were recorded at various time points and analyzed: the day on admission (T0), the day of discharge (T1), 30 days post discharge (T2), 60 days post discharge (T3), 90 days post discharge (T4), 120 days post discharge (T5), 150 days post discharge (T6), 180 days post discharge (T7), and the day before death (T8). Compared with T0, the NRS decreased and BCS increased at the T1 to T8 time points ($p < 0.05$). However, the NRS and BCS did not show differences at the T1 to T8 time points ($p > 0.05$). The duration of high-quality sleep was extended, and the incidence of opioid-related adverse effects was reduced. Postoperative complications included one case of cerebrospinal fluid leakage, three cases of infection at the butterfly needle insertion site, six cases of hospital readmission for equipment malfunction, and no cases of respiratory depression. Eleven patients continued standardized antitreatment after IDDS surgery. The mean survival time in all patients was 135.51 ±102.69 days, and the survival rate at T7 was 30.61%. The authors concluded that the cancer pain information platform, combined with a semi-implantable IDDS, is beneficial for pain management in individuals with refractory cancer under the home analgesia model; this improves individuals' quality of life. This study has limitations. This study requires long-term tracking and observation, with a long research cycle, resulting in high research costs. At the same time, the research results may be affected by time factors. A large sample size is still required to avoid inaccuracy and bias in the research results.

A prospective observational study by Giglio et al. (2022) was conducted to report the effects on pain, mood, and quality of life of an intrathecal combination therapy delivered by an IDDS connected to a subcutaneous port in malignant refractory pain. Adult participants in whom intrathecal therapy was recommended were recruited. Following study approval in October 2021, 50 participants (16 female; 34 male), with a life expectancy of less than 3 months, were enrolled (age 69 ±12 years). All had advanced cancer with metastasis. An intrathecal therapy with morphine and levobupivacaine was started. Visual Analog Scale of Pain Intensity (VASPI) score, depression and anxiety (evaluated by the Edmonton Symptom Assessment System), the Pittsburgh Sleep Quality Index (PSQI), the 5-level EQ-5D version (EQ-5D-5L), and the requirements of breakthrough cancer pain (BTCP) medications were registered, with adverse event rate and the satisfaction of participants scored as Patient Global Impression of Change. The median daily VASPI score was 75,

median depression score was 6, median anxiety score was 4, and median PSQI was 16. At 28 days, a reduction in VASPI score was registered as well as in the depression and anxiety item. Regarding PSQI decrease, the EQ-5D-5L showed improvement in all components at 14 and 28 days. Patient Global Impression of Change scores showed a high level of satisfaction. A low incidence of adverse events and a reduction in BTCP episodes were also registered. The authors concluded that intrathecal combination therapy delivered by an IDDS connected to a subcutaneous port could ensure adequate control of cancer-related symptoms, including pain, depression, anxiety, and sleep disturbances. These effects, with a low rate of adverse events (defined as drug intolerance) and reduced BTCP episodes, could explain the improvement in quality of life and the overall high levels of participants' satisfaction. This nonrandomized study has several limitations, including the study design and the difficult-to-treat category of the participants enrolled, which do not permit the authors to reach a firm conclusion. In addition, the short life expectancy due to cancer progression limited the time of observation. Further research that includes randomized controlled trials (RCTs) is needed to validate these findings.

A systematic review and meta-analysis by Duarte et al. (2022) was performed to evaluate the effectiveness and safety of IDDSs and spinal cord stimulation (SCS) for cancer pain. Electronic databases were searched from 1988 to March 2021. RCTs and observational studies in adults with pain related to cancer or its treatment who received an implantable IDDS or SCS were eligible for inclusion. The primary outcome of the review was change in pain intensity from baseline to the last available follow-up, measured using a visual analog scale or NRS. A total of 22 studies (24 reports) included a total of 3,043 individuals who received either an IDDS or SCS for cancer pain. Eight studies that reported data from 405 individuals 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, -3.31; 95% CI, -4.18 to -2.45; $p < 0.001$). Six studies reporting data from 325 individuals with an IDDS could be included in the meta-analysis of pain intensity that showed a statistically significant reduction up to 1 month after treatment compared with baseline (mean difference, -3.53; 95% CI, -4.06 to -3.00; $p < 0.001$). A meta-analysis that included studies in individuals with either an IDDS or an SCS device showed similar results. Improvements in other outcomes following implantation of an IDDS were also observed. Postdural puncture headache was the most reported complication, and urinary retention, nausea, and vomiting were commonly reported side effects. The authors concluded that their findings suggest that IDDS is effective in reducing pain intensity in individuals with cancer pain compared with pretreatment. This study is limited by the availability of only one RCT and the remaining nonrandomized studies that mostly provided data from single centers. In addition, because of limitations in study reporting, a preplanned subgroup analysis could not be performed to consider cancer-related pain or pain related to treatment for cancer. Furthermore, it was not possible to evaluate outcomes considering whether the individuals had recovered from cancer or had cancer progression. Further research that includes RCTs is needed to validate these findings.

In a Health Technology Assessment for intrathecal opioids for CNCP, Hayes indicated that there is a large but low-quality body of evidence that suggests that intrathecal opioids alone or combined with a nonopioid drug appear to be safe, consistently reduce CNCP, and improve function for several months or years. The evidence base for the Hayes report included 21 studies (22 publications). Of these, there were two RCTs (Raphael et al., 2013; Hamza et al., 2015) and two comparative prospective studies (Thimineur et al., 2004; Hamza et al., 2012). The other studies were prospective noncomparative studies or retrospective studies. Intrathecal opioid therapy improved pain in the majority of individuals in 20 studies, which compared pain measures before and after pump implantation, although the amount of improvement was variable. Of the 19 studies in which a result for percentage reduction in pain was calculated, four found reductions of ≥ 50%, five found reductions of ≥ 40% to < 50%, two found reductions of ≥ 30% to < 40%, and eight found reductions of ≥ 20% to < 30% with intrathecal opioid therapy only. In all the studies, individuals were required to undergo a screening trial to evaluate clinical response to an epidural or intrathecal opioid prior to pump implantation. Individuals with a successful screening trial, defined in most studies as a clinically significant pain reduction of ≥ 50% from baseline, with no adverse effects of treatment, were implanted with constant-flow or programmable pumps. The Hayes report indicated that there is a need for additional, larger, well-designed, controlled trials to better determine benefits over the long term and to define selection criteria for individuals. (Hayes, 2019. Updated July 2022)

Sommer et al. (2019) evaluated the efficacy of and surgical and pharmacological complications with intrathecal pumps for refractory nonmalignant pain syndromes beyond a time span of 10 years. In this retrospective, single-center cohort study, 27 patients were identified. Pain intensity using the NRS, pain and intrathecal pump characteristics, and complications were analyzed. The overall time of intrathecal therapy from first implantation to the last follow-up was 20.4 ±6.0 years. Time to implantation of the second pump (n = 18) was 10.0 ±5.3 years and between the second and third pump (n = 6) was 6.5 ±2.7 years; two patients received their fourth pump 6 years later. The NRS score was 9.0 ±0.9 before implantation, 7.0 ±1.8 one year after implantation, and 4.0 ±2.3 at the last follow-up. Intrathecal drug dose remained stable after 3 years. Opioid intoxications occurred in three patients (10%). One patient (3%) underwent revision surgery due to a catheter infection. Drug side effects occurred in four patients (14%). The patient group had pain-related

restrictions in physical activities, with minimal impact regarding mental and emotional stress. The authors indicated that even after a time span of over 15 years and several exchanges of pump systems, pain intensity was still reduced.

Herring et al. (2019) conducted a single-center retrospective study to evaluate the long-term efficacy of IDDSs in patients with complex regional pain syndrome (CRPS). Patients with CRPS who were implanted with an IDDS between 2000 and 2013 and had 4 or more years of continuous follow-up were included in the analysis. The outcome variables of interest were pain intensity and oral opioid intake. The primary predictor of interest was dose of intrathecal opioids, with ziconotide, bupivacaine, and clonidine characterized as binary secondary predictors. Of the 1,653 IDDSs identified, 62 were implanted primarily for CRPS-related pain. Of these, 26 had 4 or more years of complete follow-up data. Pain scores did not decrease over time, and there was no correlation between pain intensity and use of any intrathecal medication. Although oral opioid intake decreased over time, intrathecal opioid dose did not affect oral opioid consumption. Ziconotide was associated with a hastening of the decrease in oral opioid intake, whereas the presence of bupivacaine unexpectedly increased oral opioid intake. Intrathecal opioid dose was not associated with long-term decreases in oral opioid intake. Ziconotide was associated with a decrease in oral opioid intake over the 4-year follow-up, and bupivacaine was associated with an increase in oral opioid intake. The authors concluded that the findings suggest that intrathecal opiates may not be effective in reducing oral opiate intake; ziconotide may hasten a decrease in intake; and bupivacaine may lead to an increase in intake. This study is limited by its retrospective observations and small sample size, making it difficult to determine whether these conclusions can be generalized to a larger population.

Clinical Practice Guidelines

American Society of Interventional Pain Physicians (ASIPP)

The ASIPP has issued updated evidence-based practice guidelines on interventional techniques in the management of chronic spinal pain (Manchikanti et al., 2013a; Manchikanti et al., 2013b; Manchikanti et al., 2021). The review did not identify any RCTs for the treatment of CNCP with intrathecal opioids and was based on seven observational studies, which they concluded showed long-term benefit with intrathecal infusion devices. Thus, although the evidence base was rated as limited, the ASIPP guidelines recommend the use of intrathecal infusion systems for recalcitrant noncancer pain.

American Society of Pain and Neuroscience (ASPN)

A clinical guideline published by the ASPN (2022) on interventional treatments for low back pain states that although review methodologies vary, all the reviews report a gap in current literature that supports IDDSs for noncancer pain, including chronic low back pain. Evidence of IDDSs for chronic noncancer back pain is moderate. Based on 2001 U.S. Preventive Services Task Force criteria, which were republished in March 2020 and modified for interventional spine procedures, the ASPN states that therapy grading for IDDSs is limited to grade B for noncancer back pain. (Sayed et al., 2022)

American Society of Regional Anesthesia and Pain Medicine (ASRA)/American Society of Anesthesiologists (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 intrathecal opioid injections can provide effective pain relief for 1 to 12 months in patients with neuropathic pain. The recommendation arising from this guideline is that intrathecal opioid administration may be used in 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 IDDSs. (ASRA-ASA, 2010)

British Pain Society (BPS)

In an updated evidence review that includes recommendations for best clinical practice published in 2015, a working group convened by the BPS stated that there is mounting evidence of the effectiveness of intrathecal drug administration in patients with chronic nonmalignant pain. Large-scale RCTs of this therapy have shown limited short-term efficacy of ziconotide (Eldabe et al., 2024; Wallace et al., 2006; Rauck et al., 2006). Small RCTs support the efficacy of intrathecal opioids at 3 months of follow-up and in long-term patients, while numerous prospective studies show long-term efficacy. The place of low-dose intrathecal drug delivery opioids (microdosing) and low flow rates in practice is yet to be established (Eldabe et al., 2024). Regarding pain in patients with cancer, the BPS working group believes that there is reasonable evidence supporting the use of intrathecal drug delivery in those with cancer pain that is not controlled by systemic analgesia or for which systemic analgesia causes intolerable side effects. (Eldabe et al., 2024)

National Comprehensive Cancer Network® (NCCN®)

The 2025 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for adult cancer pain (v2.2025) state the following: “Regional analgesics techniques potentially allow for targeted delivery of local anesthetics when pain control is

required for specific (limited) areas of pain which can be addressed by neural blockade of appropriate peripheral nerves or nerve plexus. For broader areas of pain, epidural or intrathecal routes of administration of analgesics solutions (containing local anesthetic, opioid, and/or other analgesics suitable for neuraxial administration) may be considered. Percutaneous catheters with external infusion pumps may be used for prolonged administration (days to a few weeks) for selected peripheral nerve/regional plexus blocks as well as epidural/intrathecal analgesics administration. For clinical settings requiring longer-term administration of epidural/intrathecal analgesics, implanted spinal pump systems are typically used to minimize the concern of catheter migration (displacement) and the risk of infection". (Swarm et al., 2025)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Implantable drug delivery systems used for intrathecal administration of opioids are regulated by the FDA as Class III medical devices under the product code LKK (implanted programmable infusion pump). More than 500 device approvals are listed in the FDA Premarket Approval database when LKK is entered into the Product Code search field. For specific device information, enter the manufacturer, device name, and/or Premarket Approval number into the corresponding search fields. (Accessed March 12, 2026)

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Policy History/Revision Information

Date	Summary of Changes
07/01/2026	**Applicable Codes** • Removed CPT code 62323 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Removed *Medical Records Documentation Used for Reviews* section • Archived previous policy version 2026T0626M

Instructions for Use

This Medical Policy provides assistance in interpreting benefit plans. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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