Implanted Spinal Drug Delivery Systems

Policy Number: 2025T0626L
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➲ Instructions for Use

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Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

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 Non-Malignant Pain

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

- Chronic intractable pain of a non-malignant origin (e.g., failed back surgery syndrome, complex regional pain syndrome, neuropathic pain) when all of 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 non-malignant pain is proven and medically necessary when all of the following criteria are met:

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

Replacement of Device

Replacement of the device is considered medically necessary when the individual has met all of the criteria for initial placement and the existing device is non-functional 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.

Medical Records Documentation Used for Reviews

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. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the protocol titled Medical Records Documentation Used for Reviews.

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
62323	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); with imaging guidance (i.e., fluoroscopy or CT)
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)

CPT Code	Description
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 patient 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 Food and Drug Administration has approved morphine and ziconotide (a non-opioid drug) for IT analgesia (Hayes Intrathecal Opioids for Noncancer Pain, July 2019. Updated July 2022) and baclofen for spasticity (Deer et al., 2017).

Clinical Evidence

In a health technology assessment for intrathecal drug delivery systems (IDDS) for cancer pain, Ontario Health (2024) indicates that while evidence is uncertain, “compared with other ways of delivering pain medication, intrathecal drug delivery 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 participants with refractory chronic non-cancer pain (CNCP) using intrathecal drug delivery (IDD). 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 IDDS systems 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 (VAS), and treatment satisfaction was evaluated using the Patient Global Impression of Improvement scale. The results indicate a poor HRQoL in IDD participants, with better scores in the group with ≥ 15 years of treatment. Pain reduction was similar in both groups, and participants reported a positive satisfaction level with the treatment. The authors concluded that HRQoL in CNCP patients is severely affected. Long-term IDD patients have a similar or even better HRQoL in some respects compared to those with shorter follow-ups. IDD patients experienced pain reduction, with most feeling better or much better. Limitations include the retrospective nature of this study, being a single-center study, and a 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 intrathecal drug delivery systems (IDDS) among participants with refractory cancer pain under a “home analgesia” model. A total of 49 participants underwent semi-implantable IDDS with patient-controlled analgesia in conjunction with the establishment of a cancer pain information platform. Numeric rating

scales (NRS), 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, NRS decreased and BCS increased at T1 to T8 time points ($p < .05$). However, NRS and BCS did not show differences at T1 to T8 time points ($p > .05$). 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 (CSF) 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 participants continued standardized antitreatment after IDDS surgery. The mean survival time for all participants 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 semi-implantable IDDS is beneficial for the pain management of refractory cancer patients under the “home analgesia” model, improving their 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 (QoL) of an intrathecal (IT) combination therapy delivered by an intrathecal (IT) drug delivery system connected to a subcutaneous port (IDDS-SP) in malignant refractory pain. Adult patients in which IT therapy was recommended were recruited. Following study approval in October 2021, 50 patients, (16 F/34 M) with a life expectancy of less than 3 months were enrolled (age 69 ±12). All had advanced cancer with metastasis. An IT therapy with morphine and levobupivacaine was started. VASPI score, depression and anxiety (evaluated by the Edmonton Symptom Assessment System -ESAS-), the Pittsburgh Sleep Quality Index (PSQI), the 5-level EuroQol 5D version (EQ-5D-5L) and the requirements of breakthrough cancer pain (BTcP) medications were registered, with adverse events rate and the satisfaction of patients scored as Patient Global Impression of Change (PGIC). The median daily VASPI score was 75, the median depression score was 6, and the median anxiety score was 4, median PSQI was 16. At 28 days, a reduction in VASPI score was registered as well as in depression and anxiety item. PSQI decrease. The EQ-5D-5 L showed improvement in all components at 14 and 28 days. Patient Global Impression of Change scores showed 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-SP could ensure adequate control of cancer related symptoms including pain, depression, anxiety, and sleep disturbances. These effects, with low rate of AEs (defined as drug intolerance) and reduced BTcP episodes, could explain the improvement in QoL and the overall high levels of patients’ satisfaction. This non-randomized study has several limitations including study design and the difficult-to-treat category of patients enrolled which does 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 with randomized controlled trials is needed to validate these findings.

A systematic review and meta-analysis by Duarte et al. (2022) were performed to evaluate the effectiveness and safety of intrathecal drug delivery systems (IDDS) and spinal cord stimulation (SCS) for cancer pain. Electronic databases were searched from 1988 to March 2021. Randomized controlled trials (RCTs) and observational studies of 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 (VAS) or numerical rating scale. A total of 22 studies (24 reports) included a total of 3043 participants who received either IDDS or 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% 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. Postdural puncture headache was the most reported complication, whereas urinary retention, nausea, and vomiting were commonly reported side effects. The authors concluded their findings suggest that IDDS is effective in reducing pain intensity for patients with cancer pain when compared with pretreatment. This study is limited by the availability of only one RCT and the remaining nonrandomized studies providing mostly 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 with treatment for cancer. Furthermore, it was not possible to evaluate outcomes considering whether the patients had recovered from cancer or had cancer progression. Further research with RCTs is needed to validate these findings.

In a health technology assessment for intrathecal opioids for chronic noncancer pain, Hayes indicates that there is a large-sized but low-quality body of evidence that suggests that intrathecal (IT) opioids alone or combined with a non-

opioid drug appear to be safe and consistently reduce chronic noncancer pain 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 2 comparative prospective studies (Thimineur et al., 2004; Hamza et al., 2012). The other studies were prospective non-comparative studies or retrospective studies. Intrathecal opioid therapy improved pain in the majority of patients in 20 studies, which compared pain measures before and after pump implantation, although the amount of improvement was variable. Of the 19 studies for which a result for percentage reduction in pain was calculated, 4 found reductions of ≥ 50%; 5 found reductions of ≥ 40% to < 50%, 2 studies found reductions of ≥ 30% to < 40%, and 8 studies found reductions of ≥ 20% to < 30% for IT opioid therapy only. In all of the studies, patients were required to undergo a screening trial to evaluate clinical response to an epidural or intrathecal opioid prior to pump implantation. Patients 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 patient selection criteria (Hayes, Intrathecal Opioids for Noncancer Pain, July 2019. Updated July 2022).

Sommer et al. (2019) evaluated the efficacy of and surgical and pharmacological complications of IT 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 numeric rating scale (NRS), pain and IT pump characteristics, and complications were analyzed. Overall time of IT therapy from first implantation to 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) 6.5 ±2.7 years; 2 patients received their fourth pump 6 years later. The NRS score was 9.0 ±0.9 before implantation, 7.0 ±1.8 1 year after implantation, and 4.0 ±2.3 at the last follow-up. IT drug dose remained stable after 3 years. Opioid intoxications occurred in 3 patients (10%). One patient (3%) underwent revision surgery due to a catheter infection. Drug side effects occurred in 4 patients (14%). The patient group had pain-related restrictions in physical activities with menial 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 intrathecal drug delivery systems (IDDS) in patients with complex regional pain syndrome (CRPS). Patients with CRPS implanted with an IDDS between 2000 and 2013 who had four 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 IDDS identified, 62 were implanted primarily for CRPS-related pain. Of these, 26 had four 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 four-year follow-up, and bupivacaine was associated with an increase in oral opioid intake. The authors concluded that 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)

In 2013, the ASIPP issued updated evidence-based practice guidelines on interventional techniques in the management of chronic spinal pain (Manchikanti et al., 2013a; Manchikanti et al., 2013b). The review did not identify any randomized controlled trials (RCTs) 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 Pain and Neuroscience (ASPN)

A clinical guideline published by the ASPN (2022) on interventional treatments for low back pain states although review methodologies vary, all of the reviews report a gap in current literature supporting IDDS for noncancer pain, including chronic LBP. Evidence of IDDS for chronic noncancer back pain is moderate. Based on 2001 USPSTF criteria, republished March 2020 and modified for interventional spine procedures, the ASPN states therapy grading for IDDS is limited to grade B for noncancer back pain (Sayed et al., 2022).

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 (ASRA-ASA, 2010).

British Pain Society (BPS)

In an updated evidence review that included 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 (CNMP). Large-scale randomized controlled trials (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 three-months follow-up and in long-term patients while numerous prospective studies show long-term efficacy. The place of low dose ITDD opioids (micro-dosing) and low flow rates in practice is yet to be established (Eldabe et al., 2024). For pain in patients with cancer, the BPS working group believes that there is reasonable evidence supporting the use of intrathecal drug delivery (ITDD) in patients with cancer pain that is not controlled by systemic analgesia or where systemic analgesia causes intolerable side effects (Eldabe et al., 2024).

National Comprehensive Cancer Network® (NCCN)

The 2025 NCCN Adult Cancer Pain Clinical Practice Guideline (v1.2025) states: “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.”

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 (IT) 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 (PMA) Database when LKK is entered into the Product Code search field at the Premarket Approval Database. For specific device information, enter the manufacturer, device name, and/or PMA number into the corresponding search fields. (Accessed March 18, 2025)

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Policy History/Revision Information

Date	Summary of Changes
09/01/2025	**Coverage Rationale** • Added language to indicate replacement of the device is considered medically necessary when the individual has met all of the criteria for initial placement and the existing device is non-functional and either cannot be repaired or is no longer under warranty **Medical Records Documentation Used for Review** • Updated list of Medical Records Documentation Used for Reviews; replaced: ○ "Treatments tried, failed, or contraindicated; include the dates and reason for discontinuation" with "treatments tried, failed, or contraindicated; include the dates, *duration*, and reason for discontinuation" ○ "*Other* applicable diagnostic tests" with "*all recent* applicable *imaging studies and* diagnostic tests"

Date	Summary of Changes
	Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version 2025T0626K

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.