Molina Clinical Policy
Implantable Intrathecal Pain Pump
Policy No. 160

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Next Review Due By: August 2026

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Chronic pain is commonly defined by three key parameters: persistence beyond the expected period of healing or recovery, inadequate response to conventional pain control strategies or surgical interventions, and a significant negative impact on the individual's functional ability or overall well-being. Management typically beings with the least invasive options, such as physical therapy, relaxation techniques, and nonprescription analgesics or anti-inflammatory drugs. If these approaches fail to provide sufficient relief, treatment may escalate to include prescription medications, adjuvant pharmacotherapies, or interventional techniques such as nerve blocks, transcutaneous electrical nerve stimulation (TENS), or spinal cord stimulation.

Intrathecal therapy is an advanced pain management technique that involves the use of an implantable, programmable infusion pump to deliver analgesic or anti spasmodic medications directly into the cerebrospinal fluid (CSF). By bypassing the blood-brain barrier, intrathecal delivery allows for potent analgesic effects at significantly lower doses than systemic administration, thereby reducing systemic side effects. This route is typically considered for patients with refractory pain or severe spasticity due to conditions such as cancer, multiple sclerosis, cerebral palsy, amyotrophic lateral sclerosis, or spinal cord injury. While relatively uncommon for cancer-related pain, intrathecal therapy can be particularly effective in improving quality of life for patients with pelvic malignancies or mesothelioma, especially when pain relief enables continued oncologic treatment (Copenhaver et al. 2025).

Implantable infusion pump (IIP) – also referred to as intrathecal drug delivery systems (IDDS) – is a refillable device that continuously delivers medication through an intrathecal catheter. IIPs may be programmable or fixed-rate and are typically implanted subcutaneously in the abdomen, with the catheter tunneled to the spine. Medication regimens may include morphine (the only FDA-approved opioid), hydromorphone, clonidine, baclofen, or ziconotide. Common complications include infection, pump malfunction, cerebrospinal fluid leak, and catheter-related issues. Infections are reported in up to 3% of patients, and rare cases of granuloma formation at the catheter tip have been documented (Copenhaver et al. 2025). Despite risks, intrathecal therapy has been shown to significantly reduce pain scores and opioid use in appropriately selected patients.

Regulatory Status

The U.S. Food and Drug Administration FDA has approved several implantable pumps for the continuous intrathecal administration of opioid drug therapy. These devices are classified as Class III medical devices and require premarket approval (PMA). They are listed under FDA product code LKK (implanted programmable infusion pump).

COVERAGE POLICY

For coverage regarding implanted intrathecal infusion pump therapy for administration of intraspinal antispasmodic therapy for spasticity or dystonia refer to MCG policy A-0420.

Medically Necessary

Implanted intrathecal infusion pump therapy for administration of intraspinal opioid or non-opioid analgesic therapy is **considered medically necessary** in adults with severe, chronic, intractable pain for ONE of the following indications:

1. For treatment of **malignant pain** when ALL the following criteria are met:
    a. Diagnosis of severe, intractable pain of *cancer* origin affecting activity of daily living functional ability (>6 on the NRS Pain Rating Scale*)
    b. Life expectancy of at least 3 months
    c. Body size adequate to support pump device
    d. Documented failure of, or unacceptable side effects from, systemic opioid or other analgesic therapy to provide adequate pain relief
    e. Absence of ALL the following contraindications
        i. Active infection
        ii. Tumor encroachment of the thecal sac or epidural metastases confirmed via appropriate testing
        iii. Contraindications to implantation (i.e., coagulopathy, profound leukopenia, or pancytopenia, increased intracranial pressure)
    f. Prior to permanent implantation, a temporary trial of intrathecal opiates or non-opiate analgesics has been successful, as defined by a 50% reduction in pain and a self-reported improvement in daily functional ability
        i. *Note:* A temporary trial is only considered medically necessary when ALL criteria a–e is met

2. For treatment of **non-malignant pain** when ALL the following criteria are met:
    a. Diagnosis of severe, intractable pain of *non-cancer* origin affecting activity of daily living functional ability (>6 on the NRS Pain Rating Scale*)
    b. Body size adequate to support pump device
    c. Documentation of ALL the following:
        i. Failure of interventions to treat underlying condition
        ii. Failure of, or unacceptable side effects from, systemic opioid or other analgesic therapy to provide adequate pain relief administered *on a fixed prescribed schedule*, NOT on an 'as needed' basis
        iii. Member compliance with attempted pharmacological management
        iv. Failure of conservative pain management (i.e., pharmacologic, surgical, psychological, and/or physical therapy) for a minimum of six (6) months, if appropriate and not contraindicated
        v. Psychological evaluation with confirmed absence of acute psychiatric instability and/or suicide risk
        vi. Confirmation by a licensed mental health professional that Member is a favorable candidate for permanent intrathecal pump
    d. Absence of active infection
    e. Absence of contraindications to implantation (i.e., coagulopathy, profound leukopenia, or pancytopenia, increased intracranial pressure)
    f. Prior to permanent implantation, a temporary trial of intrathecal opiates or non-opiate analgesics has been successful, as defined by a 50% reduction in pain and a self-reported improvement in daily functional ability
        i. *Note*: A temporary trial is only medically necessary when ALL criteria a–e is met

Refer to supplemental information section for details on NRS Pain Rating Scale

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Intrathecal implantable infusion pumps, sometimes called intrathecal drug delivery systems (IDDS), are well-studied with much evidence supporting its indications, safety, and efficacy. Below are a few of the most recent and relevant studies used to support this policy.

Malignant (Cancer) Pain

Systematic Reviews and Meta-Analyses

Perruchoud et al. (2023) conducted a systematic review and meta-analysis examining the use of intrathecal drug delivery systems (IDDS) for the management of chronic pain in individuals with cancer. The review included studies published between 1990 and 2019 that assessed the safety and efficacy of IDDS in oncology settings. Key data were extracted to evaluate mean changes in pain intensity, daily opioid consumption, and infection rates. On a 0-10 pain scale, mean differences were -4.34 ($p < 0.001$) at 4-5 weeks; -4.34 ($p < 0.001$) at 6 to 12 weeks; and -3.32 ($p < 0.001$) beyond 6 months. Additionally, mean oral morphine equivalent consumption decreased by 308.24 mg/day (SE = 22.72). The average infection rate was approximately 3% for both external and fully implanted systems – consistent with IDDS use in other clinical settings. The authors concluded that this approach offers a safe and effective strategy for achieving sustained reductions in cancer-related chronic pain.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Stearns LJ et al. (2019) conducted an economic analysis using claims data from 536 patients in a large U.S. payer database. The study found that patients who received implantable targeted drug delivery therapy alongside conventional medical management incurred over $63,000 USD per patient compared to those managed with conventional therapy alone. Additionally, the use of an implantable intrathecal pump was associated with fewer inpatient admissions, shorter hospital stays, and reduced emergency department utilization.

Brogan et al. (2020) conducted a prospective observational study evaluating the impact of intrathecal implantable infusion pump therapy (IIP) on serum opioid levels, pain control, systemic side effects, and survival in cancer in patients with cancer-related pain. While opioids remain a cornerstone in cancer pain management, their systemic use is often limited by significant side effects toxicity. The study aimed to assess whether intrathecal opioid administration could reduce systemic opioid exposure and associated adverse effects without compromising analgesia. Researchers collected data on daily morphine equivalent doses (OME), serum opioid concentrations, pain and symptom inventory scores, and constipation severity a baseline (time of implantation), 4 weeks, and 8 weeks post-implant. At baseline, the average daily OME 375 mg, mean serum morphine and oxycodone concentrations were 53.7 ng/mL and 73.7 ng/mL, By week 4, 87.5% of patients had discontinued systemic opioids and 53% had undetectable serum opioid levels. At 8 weeks, 92% remained off all systemic opioids and 59% had undetectable serum levels. Significant reductions in reported “worst pain,” “average pain,” and overall symptom severity were observed at both 4 and 8 weeks. Interestingly, pain relief was not correlated with serum opioid levels; patients with undetectable serum concentrations experienced similar analgesic benefits to those with detectable levels. Additionally, reports of constipation rated as “quite a bit” or “very much” decreased from 58.7% at baseline to 19.2% at week 4 ($p < .001$), and to 37.5% at week 8 ($p = .23$). The therapy was associated with a low complication rate.

Stearns LM et al. (2020) conducted a long-term, multicenter, prospective analysis using data from a product surveillance registry to enhance the evidence base on the safety and efficacy of intrathecal opioid therapy in cancer patients. The registry, initiated in 2003 to track the performance of SynchroMed Infusion Systems, began collecting patient-reported outcomes in 2013. The data from 1,403 cancer patients who received an IIP were analyzed. to reveal a significant improvement in quality of life and pain reduction from baseline to 6 months. Adverse events, such as infection, replacement, and/or pocket revision, were reported in 3.2% of patients.

Non-Malignant Pain

Randomized Controlled Trials

Pope et al. (2022) conducted a randomized controlled trial (RCT) comparing drug delivery systems (IDDS) with conventional medical management (CMM) in patients with refractory, non-cancer-related chronic pain. A total of 54 participants were randomized 1:1 to receive either IDDS (n = 26) or CMM (n = 28) and were followed for 3, 6, 9, and 12 months. By the 3-month mark, patients in the IDDS group demonstrated statistically significant improvements in

pain from baseline, while the CMM group showed no measurable change. No adverse events were reported related to compounded intrathecal medications. The authors concluded that IDDS is a safe and effective option for managing chronic non-malignant pain.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Hamza et al. (2012) performed a small prospective cohort study to evaluate the long-term outcomes of low-dose intrathecal opioid therapy for the treatment of severe, intractable, chronic non-malignant pain. The study included 61 patients with a mean pain duration of 6.2 years prior to implantation. All patients underwent an intrathecal opioid trial; three did not respond and were excluded, while 58 proceeded to implantation. Patients were followed for 36 months, with assessments at 6, 12, 18, 24, and 36 months. The Brief Pain Inventory was used to assess outcomes, including self-reported worst and average pain scores, functional status, intrathecal and oral opioid doses, and behavioral improvements. Results demonstrated a statistically significant reduction in both the worst and average pain scores from baseline across all time points. Patients also experienced significant improvement in physical and behavioral function, along with marked reductions in oral opioid consumption. At baseline, the average oral morphine equivalent dose was 128.9 mg/day, which decreased to 3.8 mg/day by three months and remained stable throughout the study period. The intrathecal opioid dose remained consistently low, averaging 1.4 mg/day at six months and 1.48 mg/day at 36 months. The authors concluded that low-dose intrathecal opioid therapy offers sustained pain relief, functional improvement, and long-term opioid-sparing benefits in patients with chronic non-cancer pain.

Kleinmann and Wolter (2017) conducted a retrospective chart review of patients treated with intrathecal infusion pumps for chronic non-malignant pain at a single institution between 1990 and 2014. The analysis included 36 patients, with a mean duration of intrathecal opioid therapy of 11.8 years. Average pain scores, measured using the Numeric Pain Rating Scale, were 7.98 prior to implantation, decreasing to 4.87 immediately after implantation and 4.44 at long-term follow-up. Reported adverse events were generally non-life-threatening and included fatigue, constipation, urinary retention, and sexual dysfunction. No permanent neurological deficits or life-threatening complications were observed.

Wilkes et al. (2018) performed a retrospective review of medical records from 60 patients with chronic non-cancer pain who were treated with an intrathecal infusion pump and completed a microdose morphine monotherapy regimen. In 58% of cases, pain control was achieved using intrathecal microdosing alone, eliminating the need for supplemental oral opioid therapy. All patients experienced a reduction in pain, with mean pain scores decreasing from 7.4 ± 0.32 at baseline to before to 4.8 ± 0.3 after treatment. The findings support microdose intrathecal morphine as a promising option for effective analgesia, reduced side effects, and cost-effective outpatient care.

National and Specialty Guidelines

The American Society of Pain and Neuroscience (ASPN) has published two key guidelines outlining best practices for the use of intrathecal drug delivery systems (IDDS) in the management of chronic pain.

- The *Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain* includes recommendations for the use of IDDS in patients with chronic intractable lower back pain. The guidelines support the use of intrathecal therapy in individuals who have undergone a comprehensive evaluation to determine the underlying pain generator, have addressed contributing psychological factors, and have not achieved adequate relief despite multiple, evidence-based biomedical and interventional treatments. It emphasizes that careful patient selection—including confirmation of diagnosis, psychological stability, and demonstrated treatment adherences essential for the safe and effective application of IDDS (Sayed et al. 2022).
- The *Best Practices and Guidelines for the Interventional Management of Cancer-Associated Pain* recommends intrathecal analgesia for patients with malignancy-related pain that is severe and refractory to conventional systemic therapies. The guidelines highlight that intrathecal drug delivery can lead to substantial reductions in pain and systemic side effects, including sedation, nausea, and constipation, which are commonly associated with high-dose oral or parenteral opioids (Aman et al. 2021). In addition to clinical benefits, the therapy has been shown to be cost-effective from a U.S. payer perspective, particularly in patients with longer expected survival. The guideline also supports earlier consideration of IDDS in cancer pain pathways, rather than reserving the intervention solely as a last resort (Aman et al. 2021).

The American Society of Anesthesiologists and The American Society of Regional Anesthesia and Pain Medicine (ASA-ASRA) jointly issued the *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 (2010). These guidelines recognize that observational studies support the use of intrathecal opioid injections for providing pain relief lasting from 1 to 12 months in patients with neuropathic pain. They emphasize that intrathecal therapy should be considered as part of a comprehensive, multimodal approach to chronic pain management in carefully selected patients. The guidelines also recommend that potential risks, including infection, catheter-related complications, and systemic side effects, be thoroughly discussed with patients as part of shared decision-making. Shared decision-making should also incorporate consideration of treatment goals, patient expectations, and long-term therapy planning. A trial of neuraxial opioid administration is advised prior to the permanent implantation of an intrathecal drug delivery system, to assess patient response and tolerance.

The Polyanalgesic Consensus Conference (PACC) developed an evidence- and expert-based algorithm to guide drug selection for intrathecal therapy. The PACC guidelines recommend that patients considered for intrathecal therapy undergo a structured assessment that includes documentation of failed conventional therapies, thorough psychological and medical evaluation, and a successful screening trial using an implantable infusion pump (IIP). The algorithm further outlines preferred first-line agents based on pain type—recommending morphine and ziconotide for nociceptive and neuropathic pain, respectively, while also considering adjuvants such as bupivacaine, clonidine, and baclofen when appropriate. These guidelines underscore the importance of individualized therapy, safety monitoring, and ongoing re-evaluation to ensure optimal patient outcomes (Deer et al. 2017).

SUPPLEMENTAL INFORMATION

The Numeric Rating Scale (NRS-11) Rating Pain Level

0: No Pain
1 – 3: Mild Pain (nagging, annoying, interfering little with ADLs)
4 – 6: Moderate Pain (interferes significantly with ADLs)
7 – 10: Severe Pain (disabling; unable to perform ADLs)

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
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
62355	Removal of previously implanted intrathecal or epidural catheter
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
62365	Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion
62367	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming
62369	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill
62370	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)
95990	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular), includes electronic analysis of pump, when performed;
95991	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural)

	or brain (intraventricular), includes electronic analysis of pump, when performed, requiring skill of a physician or other qualified health care professional

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
A4300	Implantable access catheter, (e.g., venous, arterial, epidural subarachnoid, or peritoneal, etc.) external access
A4301	Implantable access total catheter, port/reservoir (e.g., venous, arterial, epidural, subarachnoid, peritoneal, etc.)
E0782	Infusion pump, implantable, non-programmable (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)
C1772	Infusion pump, programmable (implantable)
C1755	Catheter, intraspinal

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

08/13/2025	Policy reviewed. No changes to coverage criteria. Updated Overview, Summary of Medical Evidence, and References.
08/14/2024	Policy reviewed. No changes to coverage criteria. Updated references.
08/09/2023	Policy reviewed. Coverage criteria updated to include more details surrounding psychological evaluation for non-malignant pain candidates. IRO reviewed by a practicing physician board certified in Pain Management on July 26, 2023.
08/10/2022	Policy reviewed. No changes to coverage criteria. Updated references. Updated name of policy from 'Implantable Infusion Pump For Pain' to 'Implantable Intrathecal Pain Pump.'
08/11/2021	Policy reviewed. No changes to coverage criteria. Updated references.
06/17/2020	Policy reviewed. No changes to coverage criteria. Updated references.
06/19/2019	Policy reviewed. No changes to coverage criteria. Updated references.
07/10/2018	Policy reviewed. No changes to coverage criteria. Updated references.
06/14/2017	Policy reviewed. No changes to coverage criteria. Updated references.
03/06/2017	Policy reviewed. No changes to coverage criteria. Updated references.
06/15/2016	Policy reviewed. No changes to coverage criteria. Updated references.
12/16/2015	Policy reviewed. No changes to coverage criteria. Updated references.
04/02/2014	New policy.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Washington

For Medicaid reviews, consider and apply the following state-specific criteria: Health Technology Assessment (HTA) “Implantable Drug Delivery System” Washington State Healthcare Authority, November 14, 2008.