Molina Clinical Policy
Implantable Intrathecal Pain Pump: Policy No. 160

Last Approval: 8/09/2023
Next Review Due By: August 2024

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 defined by three general parameters: persistence beyond an expected time frame for healing or recovery, non-responsiveness to routine pain control methods or to appropriate surgical interventions, and adversely affecting functional ability or wellbeing. Treatment strategies for chronic pain begin with the least invasive such as exercise programs, meditation, relaxation, and nonprescription analgesics or anti-inflammatory drugs. If these treatments are ineffective additional pharmacotherapy may be used alone or with adjunctive medications. Local or regional nerve blocks, transcutaneous electrical stimulation, or electrical stimulation of the spinal cord may also be used to provide pain relief. If adequate pain relief is not achieved or intolerable side effects manifest with the previously mentioned strategies, intrathecal infusion of opioids may provide effective pain relief.

Implantable infusion pump (IIP) is a drug delivery system that provides continuous infusion of an agent at a constant and precise rate over a prolonged period of time directly into the cerebrospinal fluid via a catheter placed in the intrathecal space. The infusion pump may be either nonprogrammable at a fixed-rate (e.g., deliver a predetermined steady rate of infusion) or programmable (e.g., variable delivery rates) and is refillable via an external needle injection port in the pump. IIP for administration of intraspinal (neuraxial) non opioid and opioid therapy may be appropriate for patients who continue to suffer from severe pain despite aggressive attempts at management. This route of administration, as compared with other routes, provides increased analgesia at a lower dose of drug which causes fewer systemic side effects. Long-term complications following spinal catheter implantation include infection, epidural abscess, and catheter dislodgement or occlusion.

Regulatory Status

The FDA has approved several implantable miniature pumps that are suitable for continuous intrathecal administration of opioid drug therapy. Programmable, implantable infusion pumps are regulated by the FDA as Class III devices under the product code LKK (implanted programmable infusion pump).

COVERAGE POLICY

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 the following indications:

1. For treatment of **malignant pain** when **ALL** of 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. Documented failure of, or presence of unacceptable side effects from, systemic opioid or other analgesic therapy to provide adequate pain relief.
    d. Body size adequate to support pump device.
    e. No active infection
    f. No tumor encroachment of the thecal sac or epidural metastases confirmed via appropriate testing.
    g. Documented absence of contraindications to implantation (such as coagulopathy, profound

leukopenia, or pancytopenia, increased intracranial pressure)
h. 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** of criteria a – g is met.

2. For treatment of **non-malignant pain** when **ALL** of 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. Failure of interventions to treat underlying cause of pain.
    c. Documented failure of, or presence of 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 with accompanying documentation of member compliance with attempted pharmacological management.
    d. Documented failure of conservative treatment (such as pharmacologic, surgical, psychological, and/or physical therapy) for a minimum of six (6) months, if appropriate and not contraindicated.
    e. Documented psychological evaluation and confirmed absence of acute psychiatric instability and/or suicide risk with accompanying documentation of member as a favorable candidate for permanent intrathecal pump by a license mental health professional.
    f. Body size adequate to support pump device.
    g. No active infection.
    h. Documented absence of contraindications to implantation (such as coagulopathy, profound leukopenia, or pancytopenia, increased intracranial pressure)
    i. 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** of criteria a – h is met.

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

Implanted intrathecal infusion pump therapy for any indication other than those listed above are considered **experimental, investigational, and unproven** based on insufficient evidence.

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 are a well-studied technology with an abundance of 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
Stearns LM et al. (2020) conducted a long term multicenter prospective analysis of a product surveillance registry to augment the existing safety and efficacy data surrounding intrathecal opioid therapy in cancer patients. The registry began in 2003 to monitor the performance of SynchroMed Infusion Systems, with patient reported outcomes added beginning in 2013. The data collected from 1403 cancer patients implanted with an intrathecal IIP was 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.

Brogan et al. (2020) conducted a prospective observational study to assess serum opioid levels, pain control, reduced systemic side effects, and improved survival rates in cancer patients implanted with an intrathecal IIP. Opioids are a staple of cancer pain management but often result in harsh side effects and systemic toxicity, the goal of this study was to collect data validating that intrathecal opioid use decrease systemic opioid levels and their associate toxicity system side effects. Daily oral morphine equivalency dose, serum opioid levels, pain and symptom inventory, and a constipation questionnaire were obtained at time of implantation, 4 weeks, and 8 weeks post implantation. Average baseline daily oral morphine equivalency was 375 mg (median, 240; interquartile range, 150-405; range, 0-3160), mean serum morphine concentration was 53.7 ng/mL (n = 17), and mean oxycodone concentration was 73.7 ng/mL (n = 20). At 4 weeks, 87.5% of patients had discontinued non-intrathecal opioids, and 53% had undetectable (<2 ng/mL) serum opioid concentrations. At 8 weeks, 92% remained off all non-intrathecal opioids and 59% had undetectable serum opioid levels. Statistically significant decreases in the mean "worst pain," "average pain," and symptom severity were reported at 4 and 8 weeks. The pain and symptom decrease reported were independent of serum opioid levels; when analyzed separately, there was no difference in the pain scores of subjects with detectable serum opioid levels compared to those with undetectable levels at 4 and 8 weeks. Constipation ranked as "quite a bit" or "very much" decreased from 58.7% to 19.2% of subjects at week 4 (P < .001) and to 37.5% at 8 weeks (P = .23). A low complication rate was observed.

Stearns LJ et al. (2019) conducted an economic evaluation of claims data on 536 patients from a large US payer database. The analysis revealed a cost savings of over $63k USD per patient when implantable targeted drug delivery therapy was utilized in conjunction with conventional medical management versus conventional medication management alone. Patients with an IIP also saw a reduction in fewer inpatient visits, shorter inpatient length of stay, and fewer emergency department visits.

Non-Malignant Pain
Wilkes et al. (2018) conducted a retrospective medical record review of 60 noncancer chronic pain patients who received an intrathecal infusion pump and completed a morphine microdose monotherapy regimen. Fifty eight percent of patients' pain was successfully managed with intrathecal microdose morphine alone without additional oral therapy. Overall pain reduction occurred in all patients with mean pain scores from 7.4 ± 0.32 before microdose therapy to 4.8 ± 0.3 after microdose therapy. Microdosing morphine showed promise in achieving effective analgesia, reducing side effects, and being cost effectively managed in the outpatient setting.

Kleinmann and Wolter (2017) conducted a chart review on patients treated with an intrathecal infusion pump for non-malignant pain at a single institution between 1990-2014. Thirty-six patients were included in the review with a mean duration of intrathecal opioid therapy of 11.8 years. Pain levels prior to pump implantation were 7.98 utilizing the Numeric Pain Rating Scale. Pain levels directly after pump implantation were 4.87 and at time of follow-up 4.44 reported. Adverse events recorded were typically unwanted clinical side effects such as fatigue, obstipation, urinary retention, and sexual dysfunction; however, there was no life-threatening complication or permanent neurological deficits reported.

Grider et al. (2016) conducted a 36-month prospective cohort study evaluating 58 participants with intrathecal infusion pumps on a low dose morphine regimen. The mean opioid intrathecal opioid dose less than 350 µg per day of morphine equivalent utilized without oral supplementation. Improved visual analog scale pain rating and improved pain severity and interference on the Multidimensional Pain Inventory with lower intrathecal opioid doses.

Hamza et al. (2012) performed a small prospective, cohort long-term outcome study with the use of low-dose opioids in intrathecal drug delivery system for the treatment of intractable, severe chronic nonmalignant pain. A total of 61 patients with a mean duration of symptoms prior to implant of 6.2 years were included in the study. After adequate patient evaluation, each underwent a trial with intrathecal opioids. Three patients failed the trial, and 58 patients were implanted. Follow-up was 36 months, with intervals at 6, 12, 18, 24, and 36 months. The Brief Pain Inventory was used at baseline prior to implantation and at follow up for the duration of the study. Outcome measures included self-reported pain scores (worst and average), functional improvement, intrathecal dose, and oral opioid consumption. A statistically significant reduction in both worst and average pain from baseline throughout the duration of the study was observed, as well as a statistically significant improvement in physical and behavioral function. All subjects showed a significant reduction in the oral opioid consumption. The dose of IT opioids remained low and unchanged for 36 months of follow-up: 1.4 morphine equivalent/day at 6 months and 1.48 at 36 months. Oral opioid averaged 128.9mg of morphine

equivalent/patient/day at baseline to 3.8 at 3 month and remained at the same level throughout the study. The authors concluded that low-dose IT opioid can provide sustained significant improvement in pain and function for long-term follow-up in chronic non-cancer pain.

Hayes (2022) updated their Health Technology Assessment evaluating *Intrathecal Opioids for Chronic Noncancer Pain.* Hayes assigned a C rating for this technology based on a substantial but low-quality body of evidence evaluating efficacy and safety, which indicates that the administration of intrathecal opioids alone or in combination with a non-opioid medication appears to be safe and consistently reduces chronic pain and improves function in patients who respond to the treatment with a decrease in pain and few to no side effects prior to permanent implantation. This rating also implies that more extensive, well-designed clinical trials are required to more accurately assess long-term risks and benefits, and establish patient eligibility standards.

Health Quality Ontario conducted a Health Technology Assessment of *Intrathecal Drug Delivery Systems for Noncancer Pain* in 2016 which concluded that while intrathecal drug delivery systems significantly reduce pain and morphine consumption, they were not superior in patient reported well-being or quality of life; and therefore the evidence could not speak to the superiority of intrathecal drug delivery systems over oral opioids in global pain improvement in non-cancer pain patients.

National and Specialty Guidelines

The American Society of Pain and Neuroscience (ASPN) issued best practices and guidelines for the interventional management of cancer – associated pain in 2021. The guideline states that intrathecal analgesia is indicated in cancer patients with severe pain where conventional medication regimens have failed. The therapy has been proven to be effective in pain reduction with accompanying side effect reduction, as well as cost effective for the US payer.

The American Society of Anesthesiologists and The American Society of Regional Anesthesia and Pain Medicine (**ASA-ASRA)** issued updated practice guidelines for chronic pain management in 2010. According to these guidelines, observational studies show that intrathecal opioid injections can provide effective pain relief for 1 to 12 months in patients with neuropathic pain. A discussion of potential complications should be included in shared decision making regarding this procedure. Furthermore, a neuraxial opioid trial should be performed prior to the permanent installation of IT drug delivery systems (ASRA-ASA, 2010).

The American Society of Interventional Pain Physicians (ASIPP) (2013) issued updated evidence-based practice guidelines on interventional techniques in the management of chronic spinal pain. The review was based on seven observational studies, which they concluded showed a long-term benefit from intrathecal infusion devices. As a result, the ASIPP guidelines recommended the use of intrathecal infusion systems for recalcitrant noncancer pain.

The Polyanalgesic Consensus Conference (PACC) developed a drug selection algorithm for intrathecal therapy based on evidence and expert opinion. Failure of conservative therapies, psychological evaluation, medical history evaluation, and an intrathecal IIP screening trial are all part of the behavioral algorithm for considering patients for intrathecal IIP pain therapy. The algorithm also stipulates which drugs are best as first line agents for different types of chronic pain.

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) Codes

CPT	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) Codes

HCPCS	Description
E0782	Infusion pump, implantable, non-programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0783	Infusion pump, 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

08/09/2023	Policy reviewed. Coverage criteria changes made. IRO reviewed July 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.