

Subject: Implanted Intrathecal (Intraspinal) Infusion Therapy for Chronic Pain		Original Effective Date: 4/2/14
Guidance Number: MCG-160	Revision Date(s):	
Medical Coverage Guidance Approval Date: 4/2/14		

PREFACE

This Medical Guidance is intended to facilitate the Utilization Management process. 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 (i.e., 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 exclusions 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 following website: <http://www.cms.hhs.gov/center/coverage.asp>.

FDA INDICATIONS

The Food and Drug Administration (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.⁶

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

CMS has an NCD for Infusion Pumps (#280.14) and an implantable infusion pump is covered when used to administer opioid drugs (e.g., morphine) intrathecally or epidurally for treatment of severe chronic, intractable pain of malignant or nonmalignant origin in patients who have a life expectancy of at least 3 months, and who have proven unresponsive to less invasive medical therapy as determined by the following criteria: the patient's history must indicate that he/she would not respond adequately to noninvasive methods of pain control, such as systemic opioids (including attempts to eliminate physical and behavioral abnormalities, which may cause an exaggerated reaction to pain); and a preliminary trial of intraspinal opioid drug administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and degree of side effects (including effects on the activities of daily living) and patient acceptance.⁴

INITIAL COVERAGE CRITERIA

Implanted intrathecal infusion pump therapy for administration of intraspinal opioid or non-opioid analgesic therapy may be considered medically necessary and may be authorized for adults with severe chronic, intractable pain when ALL of the following criteria are met: ^{1-10 17 22} [ALL]

1. Treatment of Malignant pain (e.g., pain associated with cancer that includes tumor infiltration or metastases): [ALL]

- ☐ Prescriber and physician administering therapy is a Board certified Pain Management Specialist; and
- ☐ Diagnosis of severe, intractable pain of cancer origin affecting activity of daily living functional ability: > 6 on the NRS Pain Rating Scale* ¹⁷
- ☐ Life expectancy of at least 3 months; and ⁴
- ☐ History of systemic opioid or other analgesic therapy has failed to provide adequate pain relief; or
- ☐ Intolerable side effects to systemic methods of pain control have developed ¹⁷; and
- ☐ No contraindications are present (see coverage exclusions below); and
- ☐ A temporary trial of spinal (epidural or intrathecal) opiates or non-opiate analgesics has been successful as defined by a 50% reduction in pain, prior to permanent implantation** ¹⁰

2. Treatment of Non-Malignant Pain (e.g., pain not associated with cancer): [ALL]

- ☐ Prescriber and physician administering therapy is a Board certified Pain Management Specialist; and
- ☐ Diagnosis of severe, intractable pain of non-cancer origin affecting activity of daily living functional ability: > 6 on the NRS Pain Rating Scale* ⁴
- ☐ Documentation that a trial of conservative treatment modalities have been tried and failed for a minimum of six (6) months that includes (e.g., pharmacologic, surgical, psychologic or physical), if appropriate and not contraindicated ²²; and
- ☐ No further surgical interventions are indicated; and
- ☐ Psychological evaluation has been obtained and documentation states that the pain is not psychologic in origin; and
- ☐ No contraindications are present (see coverage exclusions below); and
- ☐ A temporary trial of spinal (epidural or intrathecal) opiates or non-opiate analgesics has been successful as defined by a 50% reduction in pain, prior to permanent implantation** ¹⁰

***The Numeric Rating Scale (NRS-11):** Rating Pain Level ⁵

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)

****Note: In order for the temporary trial to be authorized the above criteria must be met for treatment of malignant or non-malignant pain.**

CONTINUATION OF THERAPY

N/A

COVERAGE EXCLUSIONS

1. Epidural and Intrathecal Catheters are contraindicated and may not be authorized if any of the following circumstances are present: ^{2 4 10 17} [ALL]
 - ☐ Coagulopathy
 - ☐ Local infection at the catheter site
 - ☐ Increased intracranial pressure
 - ☐ Epidural metastases ¹⁷
 - ☐ Tumor encroachment on the thecal sac
 - ☐ Septicemia
 - ☐ Profound Leukopenia
 - ☐ Body size is insufficient to support the weight and bulk of the device ¹⁰
 - ☐ Presence of other implanted programmable devices
 - ☐ Known allergy or hypersensitivity to the drug being used
 - ☐ Untreated significant addiction
 - ☐ Active psychosis with delusional/hallucinatory components
 - ☐ Major uncontrolled depression/anxiety
 - ☐ Active suicidal or homicidal behavior
 - ☐ Serious cognitive deficits
 - ☐ Severe sleep disturbances

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Chronic Pain

Chronic pain is defined as, "pain that persists 6 months after an injury and beyond the usual course of an acute disease or a reasonable time for a comparable injury to heal, that is associated with chronic pathologic processes that cause continuous or intermittent pain for months or years, that may continue in the presence or absence of demonstrable pathologies; may not be amenable to routine pain control methods; and healing may never occur." In contrast, chronic pain syndrome has been defined as a complex condition with physical, psychological, emotional, and social components. ²² 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. The term "chronic pain syndrome" describes a chronic condition characterized by symptoms of pain and significant psychological dysfunction as evidenced by anger, anxiety, depression, loss of appetite, difficulty sleeping, and impaired interpersonal relationships. Chronic pain can be categorized as malignant or non-malignant. Pain, including non-malignant chronic pain, is classified as nociceptive, neuropathic, of mixed or undetermined pathology, or psychologically based. Causes of nociceptive pain include trauma, arthropathies, myalgias, visceral abnormalities, ischemic disorders, and systemic inflammatory disorders, such as polymyalgia rheumatica.

Neuropathic pain may result from a variety of conditions, including nerve injuries, postherpetic neuralgia, trigeminal neuralgia, diabetic neuropathy, the postamputation state, myelopathy, radiculopathy, arachnoiditis, and root sleeve fibrosis. Chronic recurrent headaches, painful vasculitis, fibromyalgia, and myofascial pain syndrome comprise the majority of chronic pain syndromes of mixed or undetermined pathology. Psychologically based pain syndromes include somatization disorders and hysterical reactions.¹

Treatment strategies for chronic pain generally begin with the least invasive and least expensive interventions such as exercise programs, meditation and relaxation, and nonprescription analgesics or anti-inflammatory drugs. If these treatments are ineffective, oral opioids may be used alone or with adjunctive medications such as antidepressants, calcium channel blockers, alpha- and beta-blockers, and steroids. 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 with any of these strategies or if the side effects are intolerable, intrathecal infusion of opioids may provide effective pain relief, while limiting the pharmacologic side effects of chronic systemic opioid administration. For this therapy, an implantable infusion pump delivers continuous infusions of the drug directly into the cerebrospinal fluid via a catheter placed in the intrathecal space.²

Implantable Infusion Pump

Implantable infusion pump (IIP) used for the delivery of intrathecal (intraspinal) opiates is a drug delivery system that provides continuous infusion of an agent at a constant and precise rate. The purpose of an IIP is to deliver therapeutic levels of a drug directly to a target organ or specific body region for a prolonged period of time. These pumps provide the long-term delivery of opioid (narcotic) medication in the management of malignant (cancer) pain and nonmalignant (non-cancer) pain. The drug reservoir can be refilled as needed through an external needle injection port in the pump. The infusion pump may be either nonprogrammable fixed-rate (ie, deliver a predetermined steady rate of infusion) and generate flow by fluorocarbon propellant or programmable (ie, variable delivery rates) and generate flow by direct electromechanical action. Fixed-rate infusion pumps allow the physician to change the dose by changing the concentration of the drug in the reservoir, whereas programmable infusion pumps allow the physician to alter the dose, give single doses, timed-specific doses, or change the continuous infusion rate with an external programmer.²³

IIP for administration of intraspinal (neuraxial) opioid therapy may be appropriate for patients who continue to suffer from severe pain despite aggressive attempts at oral and parenteral pain management, and for patients who have a large tumor in a deep abdominal or pelvic structure, who experience radicular lower extremity pain caused by a tumor. Intraspinal opioid therapy is also an early option when systemically administered opioids are not effective because of dose-limiting side effects, tolerance, or because the type of pain responds poorly to opioids. This route of administration, as compared with other routes, provides increased analgesia at a lower dose of drug and, therefore, causes fewer side effects. Drug delivery systems include placement of a short-term, external catheter, for terminal cancer patients, and as a trial for an implantable pump, and long-term implantable infusion pumps, for cancer patients with a life expectancy greater than 3 months, and for ambulatory patients with chronic pain. Placement of the trial catheter may be performed in an outpatient setting with successful

titration accomplished within 23 hours; however, patients receiving morphine should remain in observation the entire time in case of respiratory distress. Hospital admission may be indicated for patients with comorbid conditions or in cases of respiratory complications. For terminal cancer patients, the short-term epidural catheter can be implanted in the hospice or home environment with minimal risk of infection. Long-term complications following spinal catheter implantation include infection, epidural abscess, and catheter dislodgement or occlusion.³

GENERAL INFORMATION

Summary of Medical Evidence

Malignant (Cancer) Pain

Hayek et al (2011) published a systematic review of intrathecal infusion through implanted drug delivery devices for chronic pain. The purpose of this systematic review is to evaluate and update the available evidence for the efficacy and safety of intrathecal infusions used in long-term management (> 6 months) of chronic pain. Studies are assessed using the Agency for Healthcare Research and Quality (AHRQ) criteria for observational studies and the Cochrane Musculoskeletal Review Group criteria for randomized trials. The level of evidence was determined using 5 levels of evidence, ranging from Level I to III with 3 subcategories in Level II, based on the quality of evidence developed by the U.S. Preventive Services Task Force (USPSTF). The primary outcome measure for chronic non-cancer is pain relief (short-term relief \leq one-year and long-term > one-year), whereas it is 3 months for cancer. Secondary outcome measures of improvement in functional status, psychological status, return to work, and reduction in opioid intake. The level of evidence for this systematic review of non-cancer pain studies meeting the inclusion criteria of continuous use of an intrathecal drug delivery system (IDDS) for at least 12 months duration with at least 25 patients in the cohort, is Level II-3 based on USPSTF criteria. The level of evidence for this systemic review for cancer-related pain studies meeting the inclusion criteria of continuous use of IDDS for at least 3 months duration with at least 25 patients in the cohort is Level II-2 based on USPSTF criteria. Based on the available evidence, the recommendation for intrathecal infusion systems for cancer-related pain is moderate recommendation based on the high quality of evidence and the recommendation is limited to moderate based on the moderate quality of evidence from non-randomized studies for non-cancer related pain.¹⁵

Deer et al (2011) outlined consensus guidelines for the implementation of intrathecal therapy in patients with cancer-related pain and other end of life states causing pain. Evidence was compiled, ranked, and strength considered by an invited panel of well-published and innovative clinician research leaders in pain medicine. Based on that analysis, an accumulation of evidence from observational and randomized prospective trials supports the use of intrathecal (IT) drug delivery to provide effective analgesia for patients with cancer-related pain, including individuals at the end of life. Although not all patients are candidates for this invasive treatment modality, clinicians can determine the appropriateness of proceeding with device implantation by carefully evaluating the individual's overall medical status, psychological stability, social support system, and prognosis of disease. Further, consumption of health care resources and cost-effective treatment is becoming more of a priority; not only is this therapy appropriate medically, but also economically. This multifaceted approach to patient selection assists in maximizing treatment effect and avoiding unintended consequences of therapy. With

careful consideration of the patient's medical comorbidities and prior therapies, communication with the oncologist, proper psychological evaluation, and appropriate trialing technique, clinicians can effectively optimize the use of IT therapy for cancer pain. The panel advocates for a much wider application of IT therapy to provide meaningful analgesia for patients with cancer pain, including those at the end of life from a variety of causes.¹⁷

Meyers et al. (2010) performed a systematic review of the literature to evaluate the effectiveness of intraspinal techniques in the setting of cancer pain. 12 RCTs were identified on intraspinal techniques for managing pain in cancer patients. To be included in the review studies are required to report pain as an outcome measure using a validated scale. The investigators did not identify the type or types of cancer addressed in individual studies and did not pool study findings. Two RCTs specifically addressed implantable infusion pumps. One compared intrathecal morphine delivered via an implantable infusion pump plus medical management (n=101) to medical management alone (n=99) in patients with refractory cancer pain. The difference between groups in clinical success (defined as at least 20% reduction in pain score and at least 20% reduction in drug toxicity at 4 weeks) reached borderline statistical significance, favoring the implantable pump group over the control group (85% vs. 71%, respectively, $p=0.05$). The proportion of patients who experienced pain score reduction was 52% in the implantable pain pump group and 39% in the control group; this was not a statistically significant difference ($p=0.55$). The other RCT on implantable pumps compared epidural morphine delivered as a continuous infusion by the Infusaid pump to intermittent delivery by a Port-a-Cath® (Deltec, Saint Paul, MN). The 2 groups did not differ significantly in their pain scores; scores were low in both groups and the study, which had only 29 participants, was likely underpowered. The authors of the systematic review concluded that intraspinal techniques may be appropriate for selected cancer patients with intractable cancer pain and that intraspinal analgesia is equally or more effective than conventional medical management and often associated with fewer side effects.²⁴

Non-Malignant Pain

Raphael et al. (2013) performed a small randomised, double-blind, controlled, parallel group trial to investigate the efficacy of intrathecal morphine in the long term by hypothesising that a reduction of the intrathecal opioid dose following long-term administration would increase the level of pain intensity. Participants included 24 patients with non-cancer pain implanted with morphine reservoirs that were assessed for eligibility. Primary outcomes were visual analogue scale (VAS) pain score change and withdrawal from the study due to lack of efficacy. 9 of the patients assessed for eligibility declined to participate in the study. 15 patients were randomised to control (n=5) or intervention (n=10) and included in an intention-to-treat analysis. Owing to worsening of pain, seven patients withdrew from the study prematurely. None knew prior to withdrawal which arm of the study they were in, but all turned out to be in the dose-reduction arm. The calculation of dropout rates between groups indicated a significant statistical difference ($p=0.026$) and recruitment was ceased. The VAS change between baseline and the last observation was smaller in the control group (median, Mdn=11) than in the intervention group (Mdn=30.5), although not statistically significant, $Z=-1.839$, $p=0.070$; $r=-0.47$. Within groups, VAS was significantly lower at baseline (Mdn=49.5) than at the last observation (Mdn=77.5) for the

reduction group, $Z=-2.805$, $p=0.002$; $r=-0.627$ but not for the control group ($p=0.188$). In conclusion, this double-blind randomised controlled trial of chronic intrathecal morphine administration suggests the effectiveness of this therapy for the management of chronic non-cancer pain.¹⁶

Hamza et al. (2012) performed a small prospective, cohort long-term outcome study with the use of low-dose opioids in intrathecal (IT) drug delivery system (DDS) for the treatment of intractable, severe chronic nonmalignant pain. A total of 61 consecutive patients (60% females, 40% males) with a mean age of 59.2 years and a mean duration of symptoms prior to implant of 6.2 years were referred for implant of DDS for severe intractable non-cancer pain. After adequate patient evaluation, each underwent a trial with IT 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 for follow-up assessment criteria at baseline prior to implant as well as throughout the duration of the study. Outcome measures included self-reported pain scores (worst and average), functional improvement, and IT 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. Also documented was 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 virtually 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.²⁰

Duarte and colleagues (2012) published a case series with long-term follow-up on 20 patients with chronic nonmalignant pain who received intrathecal delivery of opioid analgesics. Patients were followed for a mean of 13.5 years (range: 10.4 to 17.9 years). At 4-year and 13-year assessments, outcomes were significantly improved compared to baseline. However, outcomes did not significantly improve between 4 and 13 years. For example, mean pain intensity (measured on an 11-point scale where 0 represents no pain and 10 represents the worst pain) was 8.65 (SD: 0.29) at baseline, 4.95 (SD: 0.53) at 4 years post-treatment, and 5.30 (SD: 0.35) at 13 years post-treatment. Similarly, the mean quality-of-life score (0 represents no interference with quality of life and 10 represents maximum interference) was 8.45 (SD: 0.49) at baseline, 4.95 (SD: 0.69) at 4 years, and 4.45 (SD: 0.48) at 13 years.²⁶

Deer et al (2010) published consensus guidelines for intrathecal therapy as an invasive alternative for the long-term management of select patients with intractable pain associated with various disease states, including those of non-cancer origin. It is commonly accepted that proper patient selection is essential to optimizing treatment outcomes, yet the practice of candidate selection for device implantation varies widely. A multifaceted approach--with consideration of preexisting medical comorbidities; psychological status; associated social, technical, and economic issues; and response to intrathecal trialing--enables practitioners to fully evaluate the appropriateness of implanting a patient with an intrathecal drug delivery system. Yet, to date no standard set of

guidelines have been developed to aid practitioners in navigating this evaluation process. Using experience- and knowledge-based expert opinion to systematically evaluate the available evidence, this article provides consensus guidelines aimed at optimizing the selection of patients with noncancer pain for intrathecal therapy. In conclusion, complete assessment of a patient's physical, psychological, and social characteristics, can guide practitioners in determining the appropriateness of initiating intrathecal therapy. These consensus guidelines are intended to assist with weighing this risk/benefit ratio of intrathecal therapy, thereby minimizing the potential for treatment failure, unacceptable adverse effects, and excess mortality.¹⁰

Webster et al. (2009) performed an open-label multicenter study to evaluate the long-term safety and efficacy of intrathecal ziconotide. Participants included 78 patients with chronic pain who had completed one of two previous ziconotide clinical trials. Each patient's initial ziconotide dose was based on his or her dose from the study of origin and was adjusted as necessary on the basis of adverse events and analgesic effect. The median ziconotide dose was 6.48 mcg/day (range, 0.00-120.00 mcg/day) at the Initial Visit and ranged from 5.52 to 7.20 mcg/day across all study visits. The most commonly reported new adverse events that were considered ziconotide related were memory impairment (11.3%); dizziness, nystagmus, and speech disorder (8.5% each); nervousness and somnolence (7.0% each); and abnormal gait (5.6%). There was no evidence of increased adverse event incidence at higher cumulative ziconotide doses. Elevations in creatine kinase were noted, but the proportion of patients with creatine kinase elevations did not change from the Initial Visit to the Termination Visit (4.1% each). Stable mean Visual Analog Scale of Pain Intensity scores during the three years of the study suggested no evidence of increased pain intensity with increased duration of ziconotide exposure. Long-term treatment with ziconotide appeared to be well tolerated and effective in patients whose response to ziconotide and ability to tolerate the drug had been previously demonstrated.²¹

Patel et al. (2009) performed a systematic review on intrathecal infusion pumps used to treat chronic non-cancer pain. To be included in the review, studies needed to evaluate an intrathecal device (programmable or fixed infusion rate), state a specific indication and the drug that was injected, follow patients for at least 12 months, and include at least 25 patients. In addition, the investigators rated study quality and, to be included, studies needed to score at least 50 out of 100 on a methodologic quality scale. The primary outcome of interest to the systematic review was pain relief. A total of 15 studies on intrathecal infusion for non-cancer pain were identified; however, 6 did not have sufficient follow-up, 4 included fewer than 25 patients, and 1 had unacceptably low quality, leaving 4 eligible studies. All of the studies were observational and involved intrathecal opioid administration; sample sizes ranged from 69 to 120. Most patients experienced lumbospinal pain. Two of the 4 studies showed positive results for pain relief, one study had negative results, and results were not available for the fourth study. The authors of the systematic review acknowledged the paucity of literature and lack of RCTs. The level of evidence for intrathecal infusion systems indicated either Level II-3 or Level III (limited) based on U.S. Preventive Services Task Force (USPSTF) criteria.²⁵

Hayes, Cochrane, UpToDate

Hayes does not have a current Medical Technology Directory Report for the topic of implantable intrathecal infusion pump therapy in the management of malignant pain. There is one report from 2014 on the topic of non-malignant pain.²

Cochrane:

A 2013 Cochrane review called “Opioids for neuropathic pain” was published to reassess the efficacy and safety of opioid agonists for the treatment of neuropathic pain. The review included randomized controlled trials (RCTs) in which opioid agonists were given to treat central or peripheral neuropathic pain of any etiology. Pain was assessed using validated instruments, and adverse events were reported. Thirty-one trials met inclusion criteria, studying 10 different opioids: 23 studies from the original 2006 review and eight additional studies from this updated review. Seventeen studies (392 participants with neuropathic pain, average 22 participants per study) provided efficacy data for acute exposure to opioids over less than 24 hours. Sixteen reported pain outcomes, with contradictory results; 8/16 reported less pain with opioids than placebo, 2/16 reported that some but not all participants benefited, 5/16 reported no difference, and 1/16 reported equivocal results. Six studies with about 170 participants indicated that mean pain scores with opioid were about 15/100 points less than placebo. Fourteen studies (845 participants, average 60 participants per study) were of intermediate duration lasting 12 weeks or less; most studies lasted less than six weeks. Most studies used imputation methods for participant withdrawal known to be associated with considerable bias; none used a method known not to be associated with bias. The review concluded that since the last version of this review, new studies were found providing additional information. Data were reanalyzed but the results did not alter any of our previously published conclusions. Short-term studies provide only equivocal evidence regarding the efficacy of opioids in reducing the intensity of neuropathic pain. Intermediate-term studies demonstrated significant efficacy of opioids over placebo, but these results are likely to be subject to significant bias because of small size, short duration, and potentially inadequate handling of dropouts. Analgesic efficacy of opioids in chronic neuropathic pain is subject to considerable uncertainty. Reported adverse events of opioids were common but not life-threatening. Further randomized controlled trials are needed to establish unbiased estimates of long-term efficacy, safety (including addiction potential), and effects on quality of life.¹¹

UpToDate:

In a report called “Overview of the treatment of chronic pain”, intrathecal administration of opioids (i.e. morphine) may be appropriate for patients who require particularly large doses of opioids because the systemic effect may become intolerable. The report describes that the advantage of this route of administration is the ability to get the opioid directly to the opioid receptors in the spinal cord, thereby reducing the systemic concentration and minimizing side effects and patients may need to continue to use oral analgesics on a rescue basis.⁷

Professional Organizations

The American Society of Anesthesiologists (ASA) (2010) published practice guidelines for chronic pain management. Within the guidelines chronic pain is defined as pain of any etiology not directly related to neoplastic involvement, associated with a chronic medical condition or extending in duration beyond the expected temporal boundary of tissue injury and normal healing, and adversely affecting the function or well-being of the individual. Studies with observational findings indicate that intrathecal opioid injections can provide pain relief for assessment periods ranging from one to 12 months for patients with neuropathic pain. The guidelines indicate that intrathecal opioid injection or infusion may be used for patients with neuropathic pain and collective decision making regarding intrathecal opioid injection or infusion should include a specific discussion of potential complications. Neuraxial opioid trials should be performed before considering permanent implantation of intrathecal drug delivery systems. The ASA practice guideline for cancer pain management (1996) indicates there is sufficient literature to support the efficacy neuraxial analgesic delivery (i.e., epidural, subarachnoid, intraventricular) for the management of cancer pain.^{12 13 14}

The Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain (2010) state the following:⁸

- Before initiating opioid therapy, consider the evidence related to effectiveness in patients with chronic non-cancer pain. (Grade A).
- For patients experiencing unacceptable adverse effects or insufficient opioid effectiveness from one particular opioid, try prescribing a different opioid or discontinuing therapy. (Grade B).
- When initiating a trial of opioid therapy for patients at higher risk for misuse, prescribe only for well-defined somatic or neuropathic pain conditions (Grade A), start with lower doses and titrate in small-dose increments (Grade B).
- For patients experiencing unacceptable adverse effects or insufficient opioid effectiveness from one particular opioid, try prescribing a different opioid or discontinuing therapy. (Grade B).
- Opioids present hazards for adolescents (Grade B)
- Opioid therapy for elderly patients can be safe and effective (Grade B)

The Institute of Clinical Systems Improvement (ICSI) Guidelines (2011) called “Assessment and Management of Chronic Pain” describe that treatment approaches for the management of chronic pain are divided into two levels. Level I treatment involves the standard approaches to the treatment of chronic pain including pharmacologic management, intervention management, non-pharmacologic management and complementary medicine management. These treatment approaches should be implemented as first steps towards rehabilitation before Level II treatments are considered. Level II treatment includes referral for multidisciplinary pain rehabilitation or surgery for placement of a spinal cord stimulator or intrathecal pump. Level II treatments may be effective interventions for patients with chronic pain who have failed more conservative treatment options. Level II treatments are designed for the most complex and challenging patients with chronic pain. The treatment options included in Level II are expensive and require a significant investment on the part of the patient to be effective with either level of management. This should ideally be coordinated by the primary care provider.⁹

The Polyanalgesic Consensus Conference (PACC)(2012) published recommendations for the proper methods of trialing for long-term intrathecal drug delivery. A preliminary trial of intrathecal opioid administration is often used to determine an individual's response to therapy prior to implantation of a permanent device and consists of intrathecal or epidural administration over a few days , a few hours or over multiple weeks using either single injections, multiple injections, or continuous infusion. Several factors were noted to be important considerations in trialing, including goals for pain relief and functional improvement, reduction in systemic opioid use, management of adverse events and complications, and potential mental status changes. Most patients who undergo trialing should be monitored for at least 24 hours, regardless of whether this monitoring occurs in an inpatient setting or in another appropriate environment. ¹⁹

The Polyanalgesic Consensus Conference (PACC) (2012) published updated recommendations for the management of pain by intrathecal drug delivery. These guidelines are based on evidence published between 2007 and 2011 relevant to opioid and nonopioid intrathecal analgesics, in addition to expert opinion. The panelists developed recommendations divided into three arms; neuropathic, nociceptive and mixed pain states using a hierarchy based on evidence of safety and efficacy. First line drug therapy for each arm includes the following recommendations: ²⁰

- Neuropathic pain: morphine, ziconitide, and combination of morphine and bupivacaine.
- Nociceptive pain: morphine, hydromorphone, ziconitide and fentanyl. Hydromorphone is based on widespread use and clinical safety; fentanyl has been upgraded to a first line based on consensus conference as a result of long-term safety profile, most notable lack of granuloma formation with long-term use.
- Mixed pain states: clinical scenario should drive the decision making process to determine which algorithm should be used (neuropathic or nociceptive) noting algorithms may need to be changed pending response to therapy.

CODING INFORMATION

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
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
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
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 physician's skill)
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	Requiring skill of a physician or other qualified health care professional

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)

ICD-9	Description
86.06	Insertion of totally implantable infusion pump (procedure code)
338.21-338.29	Chronic pain
338.3	Neoplasm related pain
338.4	Chronic pain syndrome

ICD-10	Description
G89.21-G89.29	Chronic pain
G89.3	Neoplasm related pain
G89.4	Chronic pain syndrome

RESOURCE REFERENCES

1. McKesson InterQual Clinical Evidence Summary. Chronic Pain Syndrome. 2013 McKesson Corporation.
2. Hayes Medical Technology Directory. Intrathecal Opioid Therapy for Chronic Nonmalignant Pain. Winifred Hayes Inc. Lansdale, Pa. Nov 14, 2011. Updated March 27, 2014.
3. McKesson InterQual Clinical Evidence Summary. Chronic Cancer Pain. 2013 McKesson Corporation.
4. Centers for Medicare & Medicaid (CMS). National Coverage Determination (NCD) for Infusion Pumps. #280.14. Effective date 12/17/04. Accessed at: <http://www.cms.hhs.gov/center/coverage.asp>.

5. UpToDate: Smith H. Evaluation of Chronic Pain in Adults. Literature review current through Nov. 2013.
6. Food and Drug Administration (FDA) [website]. Center for Devices and Radiological Health (CDRH). Information on Premarket Approval Applications. Available at: <http://www.fda.gov/cdrh/pmapage.htm>.
7. UpToDate: Rosenquist E. Overview of the treatment of chronic pain. Literature review current through Nov. 2013.
8. Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain© 2010 National Opioid Use Guideline Group (NOUGG). Version 5.6 April 30, 2010. Accessed at: <http://nationalpaincentre.mcmaster.ca/opioid/>
9. Institute of Clinical Systems Improvement (ICSI) Health Care Guidelines. Assessment and Management of Chronic Pain. 5th Edition; November, 2011. Accessed at: www.icsi.org
10. Deer TR, Smith HS, Cousins M, Doleys DM, et al. Consensus guidelines for the selection and implantation of patients with non-cancer pain for intrathecal drug delivery. Anesthesiology. 2010 May;112(5):1225-33. Accessed at: http://www.painphysicianjournal.com/linkout_vw.php?issn=1533-3159&vol=13&page=E175
11. McNicol ED, Midbari A, Eisenberg E. Opioids for neuropathic pain. Cochrane Database Syst Rev. 2013;8:CD006146.
12. American Society of Anesthesiologists. Practice guidelines for cancer pain management. Anesthesiology 1996;84:1243-57. (c) 1996 American Society of Anesthesiologists, Inc. Lippincott-Raven Publishers. Accessed April 29, 2013. Available at URL address; <http://www.asahq.org/publicationsAndServices/cancer.html>
13. American Society of Anesthesiologists Task Force on Chronic Pain Management; American Society of Regional Anesthesia and Pain Medicine. 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. Anesthesiology. 2010 Apr;112(4):810-33.
14. American Society of Anesthesiologists. Practice guideline for chronic pain management. Anesthesiology. 1997.;86:995-1004. Updated April 2010. Accessed April 29, 2013. Available at URL address: <http://www.asahq.org/publicationsAndServices/practiceparam.htm#cancer>
15. Hayek SM, Deer TR, Pope JE, Panchal SJ, Patel VB. Intrathecal therapy for cancer and non-cancer pain. Pain Physician. 2011 May-Jun;14(3):219-48. Accessed at: http://www.painphysicianjournal.com/linkout_vw.php?issn=1533-3159&vol=14&page=219
16. Raphael JH, Duarte RV, Southall JL et al. Randomised, double-blind controlled trial by dose reduction of implanted intrathecal morphine delivery in chronic non-cancer pain. BMJ Open. 2013 Jul 31;3(7). Accessed at: <http://bmjopen.bmj.com/content/3/7/e003061.long>
17. Deer TR, Smith HS, Burton AW, Pope JE et al. Comprehensive consensus based guidelines on intrathecal drug delivery systems in the treatment of pain caused by cancer pain. Pain Physician. 2011 May-Jun;14(3):E283-312. Accessed at: http://www.painphysicianjournal.com/linkout_vw.php?issn=1533-3159&vol=14&page=E283
18. Deer TR, Prager J, Levy R, Rathmell J, Buchser E, Burton A, et al. Polyanalgesic Consensus Conference 2012: recommendations for the management of pain by intrathecal (intraspinal) drug delivery: report of an interdisciplinary expert panel. Neuromodulation. 2012a Sep-Oct;15(5):436-64; discussion 464-6.

19. Deer TR, Prager J, Levy R, Burton A, Buchser E, Caraway D, et al. Polyanalgesic Consensus Conference--2012: recommendations on trialing for intrathecal (intraspinale) drug delivery: report of an interdisciplinary expert panel. *Neuromodulation*. 2012b Sep-Oct;15(5):420-35; discussion 435.
20. Hamza M, Doleys D, Wells M et al. Prospective study of 3-year follow-up of low-dose intrathecal opioids in the management of chronic nonmalignant pain. *Pain Med*. 2012 Oct;13(10):1304-13.
21. Webster LR, Fisher R, Charapata S, Wallace MS. Long-term intrathecal ziconotide for chronic pain: an open-label study. *J Pain Symptom Manage*. 2009 Mar;37(3):363-72.
22. Manchikanti L, Singh V, Datta S, Cohen SP, Hirsch JA,. Comprehensive review of epidemiology, scope, and impact of spinal pain. *Pain Physician*. Jul-Aug 2009;12(4):E35-70.
23. Shetty K. Implantable Drug Pump. [website]: MedScape WebMD. 2012, Feb 16. Accessed at: <http://emedicine.medscape.com/article/1983157-overview#a3>
24. Myers J, Chan V, Jarvis V et al. Intraspinale techniques for pain management in cancer patients: a systematic review. *Support Care Cancer* 2010; 18(2):137-49.
25. Patel VB, Manchikanti L, Singh V et al. Systematic review of intrathecal infusion systems for long-term management of chronic non-cancer pain. *Pain Physician* 2009; 12(2):345-60.
26. Duarte RV, Raphael JH, Sparkes E et al. Long-term intrathecal drug administration for chronic nonmalignant pain. *J Neurosurg Anesthesiol* 2012; 24(1):63-70.
27. Advanced Medical Review (AMR): Policy reviewed by a practicing MD board certified in Physical Med & Rehab, Pain Management. 12/23/13