

**Intrathecal Drug Delivery Systems**  
**DRAFT RULES – FOR DISCUSSION PURPOSES ONLY: 04/17/08**

**5221.6200 Low Back Pain**

Subp. 6. Surgery, including decompression procedures and arthrodesis. Surgery may only be performed if it also meets the specific parameters specified in subparts 11 to 13 and part 5221.6500. The health care provider must provide prior notification of nonemergency inpatient surgery according to part 5221.6050, subpart 9.

A. In order to optimize the beneficial effect of surgery, postoperative therapy with active and passive treatment modalities may be provided, even if these modalities had been used in the preoperative treatment of the condition. In the postoperative period the maximum treatment duration with passive treatment modalities in a clinical setting from the initiation of the first passive modality used, except bedrest or bracing, is as follows:

- (1) eight weeks following lumbar decompression or implantation of a ~~dorsal column stimulator or morphine pump~~ spinal cord stimulator or intrathecal drug delivery system;
- or
- (2) 12 weeks following arthrodesis.

B. Repeat surgery must also meet the parameters of subparts 11 to 13 and part 5221.6500, and is not indicated unless the need for the repeat surgery is confirmed by a second opinion obtained before surgery, if a second opinion is requested by the insurer.

C. The following surgical therapies Spinal cord stimulators have very limited application as provided in subitems (1) and (2). And require a second opinion that confirms that the treatment is indicated and within the parameters listed, and a personality or psychosocial evaluation that indicates that the patient is likely to benefit from the treatment.

- (1) A trial screening period of these devices is indicated only if the treating health care provider determines and a second opinion confirms that:
  - (a) the patient has intractable pain;
  - (b) the patient is not a candidate for another surgical therapy; and
  - (c) the patient has no psychological contraindications to this treatment. The treating health care provider may refer the patient for a consultation if the provider feels unable to assess the patient for psychological contraindications.

(2) Long term use of a spinal cord stimulator is indicated if the treating health care provider documents that there has been at least a 50% improvement in pain during a trial screening period of at least three days.

~~(1) Dorsal column stimulator is indicated for a patient who has neuropathic pain, and is not a candidate for any other surgical therapy, and has had a favorable response to a trial screening period.~~

~~(2) Morphine pump is indicated for a patient who has somatic pain, and is not a candidate for any other surgical therapy, and has had a favorable response to a trial screening period.~~

D. Intrathecal drug delivery systems have very limited application as provided in subitems (1) and (2).

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(2) Long term use of a intrathecal drug delivery systems is indicated if the treating health care provider documents that there has been at least a 50% improvement in pain during a trial screening period of at least XXXX days.

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## Comments Received and Recommendations Re: Proposed Rules for Intrathecal Drug Delivery Systems

	<b>Comment</b>	<b>Recommendation</b>
	<b>Added by Department</b>	
p. 2, l. 13	What constitutes an appropriate trial period?	A minimum trial period of 24 hours
	Which intrathecal medications are allowed?	Only morphine and hydromorphone for spinal conditions; only morphine, hydromorphone and ziconotide for CRPS. Other medications can be used only with prior approval by the insurer.

<u>reference</u>	<u>type</u>	<u>trial period</u>	<u>trial success</u>		
<u>Treatment in Workers' Compensation 2006</u>	Guide	The specific criteria include ... a temporary trial has been successful prior to permanent implantation.	Defined by a 50-70% reduction in pain		
<u>Intrathecal drug delivery for the management of pain and spasticity in adults: recommendations for best clinical practice</u>	Guide	A trial of intrathecal therapy should always be performed. This can be by means of bolus or infusion but the former give limited information. There is no ideal screening method.			
<u>Neuromodulation 2007 10(4) 300-328</u>	Guide	The panelists felt that trial procedure should be left up to the physician performing them. The panelists felt that until there are data that suggest that trials are unnecessary, trials should be performed before placing IT delivery agents through an IDDS. Trials can be performed with monotherapy or with polyanalgesia.			
<u>Pain Med 2004 5 6-13.</u>	Registry	Trialing methodologies were: Continuous epidural infusion (53%), continuous intrathecal infusion (25%), single intrathecal bolus injection (14%), and multiple intrathecal bolus injections (8%). The majority of patients (81.1%) were trialed with morphine only. The mean duration of the trial was $3.5 \pm 5.4$ days.			

<i>reference</i>	<i>type</i>	<i>sources</i>	<i>comments</i>	<i>results</i>	<i>complications</i>	<i>study design issues</i>	<i>author's conclusions</i>
<a href="#">Pain Physician. 2007 Jan;10(1):7-111</a>	Guide				The complications include post-dural puncture headache, infection, nausea, urinary retention, pruritus, catheter and pump failure, pedal edema, hormonal changes, granuloma formation, and decreased libido.	Retrospective reports dominate the literature on intrathecal pain management (1294-1298). Among the retrospective evaluations, the reports provided significant improvement at short-term and long-term follow-up.	The evidence for implantable intrathecal infusion systems is strong for short-term improvement in pain of malignancy or neuropathic pain. The evidence is moderate for long-term management of chronic pain.
<a href="#">Assessment and management of chronic pain.</a>	Guide					Supporting evidence is of class: B (cohort study)	Intrathecal Medication Delivery Systems can provide an excellent therapeutic effect for nonmalignant and cancer pain. However, it should be reserved only for patients who have failed other conservative approaches for the treatment of pain, and should be used cautiously. The best candidates are patients who respond well to oral opioids but who cannot tolerate the side effects (e.g., sedation, nausea, constipation).
<a href="#">Complex Regional Pain Syndrome type 1 Guidelines</a>	Guide				The main side-effects of the screening process and continuous administration of ITB are post-puncture headache, diminished consciousness and urine retention.	There is insufficient evidence that intrathecal baclofen (ITB) is effective in treating dystonia in CRPS-I patients. [Level 3 (of 4) evidence based on two non-comparative trials.]	Intrathecal baclofen has no place in the treatment of patients with CRPS-I. Intrathecal baclofen can only be considered for patients with CRPS-I if dystonia is a major problem and conventional therapy has proven ineffective. This treatment must be administered in the context of a trial.
<a href="#">Treatment in Workers' Compensation 2006</a>	Guide						Recommended only as an end-stage treatment alternative for selected patients. This treatment should only be used relatively late in the treatment continuum, when there is little hope for effective management of chronic intractable pain from other therapies. The specific criteria in these cases include the failure of at least 6 months of other conservative treatment modalities, intractable pain secondary to a disease state with objective documentation of pathology, further surgical intervention is not indicated, psychological evaluation unequivocally states that the pain is not psychological in origin, and a temporary trial has been successful prior to permanent implantation as defined by a 50-70% reduction in pain.
<a href="#">Evidence-based clinical practice guideline for interdisciplinary rehabilitation of chronic non-malignant pain syndrome patients</a>	Guide						Given the continued absence of quality research, however, the current guidelines do not recommend using implantable infusion pumps or spinal cord stimulators with chronic non-malignant pain syndrome patients.

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<u>Intrathecal drug delivery for the management of pain and spasticity in adults; recommendations for best clinical practice</u>	Guide			There have been a variety of economic studies of intrathecal pumps ranging from cost modeling to cost utility analyses. It appears that this therapy is more cost effective than systemic medication beyond 11-22 months for non-cancer pain.	Minor complications are common. In a population of cancer patients, catheter, procedure, device-related and illness-associated adverse incidents occurred at a rate of 0.45 events per patient year. Neurological deficits can occur from the procedure and from inflammatory mass development at catheter tip. There are reports of neurotoxicity and permanent neurologic al damage following intrathecal infusions of local anaesthetics. Possible infections include meningitis, epidural abscess, pump pocket infection or pump reservoir infection. Cerebrospinal fluid leaks, hygromas and post dural puncture headaches have all been reported. Device-related complications include catheter kinking, disconnection, dislodgement or pump failure, program error and overflow or incorrect refill.		Intrathecal drug delivery can be an effective method of pain control. Patient selection is important, particularly when used for CNMP. It must be carried out by a multi-professional team with a comprehensive understanding of the physical, psychological and rehabilitation aspects of the patient's condition.
<u>Neuromodulation 2007 10(4) 300-328</u>	Guide					First-line medications are supported by extensive clinical experience and published preclinical and clinical data and are typically used as starting IT therapies. Morphine and ziconotide are the only medications approved by the FDA for IT therapy. Medications listed below Line 1 are supported by a smaller amount of published preclinical evidence, fewer published clinical studies, less clinical anecdotal experience, or a combination thereof.	The first-line agents are morphine, hydromorphone, and ziconotide. Second line agents include 1) the combination of morphine or hydromorphone and bupivacaine or clonidine; 2) the combination of morphine or hydromorphone and ziconotide; or 3) fentanyl alone. Third-line approaches are: 1) clonidine alone; 2) a combination of morphine/ hydromorphone/ fentanyl/ bupivacaine plus clonidine and ziconotide.
<u>Clin J Pain 2007 Feb 23(2) 180-95</u>	SysRev	6 on effectiveness and complications, and 4 others on complications only.		All 6 articles reviewed for effectiveness reported improvement in pain and functioning on average among patients who received a permanent IDDS. Two articles reported the proportion of patients with Z50% improvement in pain at 6 months (38%, 56%) and 2 at longer follow-ups (30%, 44%). Intrathecal morphine-equivalent doses increased over time.	The most commonly reported permanent IDDS drug side effects were nausea/vomiting (mean rate weighted by sample size=33%), urinary retention (24%), and pruritus (26%). Catheter problems were also reported commonly. Rare but serious complications included intrathecal catheter tip granulomas.	None of the studies were randomized trials, or of ziconotide	The studies reviewed found improvement in pain and functioning on average among patients with chronic noncancer pain who received permanent IDDS. However, their methodologic limitations preclude conclusions concerning the effectiveness of this technology long-term and as compared with other treatments.

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<u>J Pain Symptom Manage</u> 2000 Aug 20(2) S12-36	SysRev					Clinical efficacy in large-scale randomized controlled trials utilizing intrathecal delivery of most compounds has not been demonstrated, and variations between study designs make useful comparisons of existing studies difficult. Generally, the scientific quality of the published studies is variable, with results obtained from limited numbers of prospective controlled studies (many with inadequate patient group size), uncontrolled clinical studies, case reports, retrospective studies, and anecdotes.	Intrathecal morphine appears to be safe at clinical concentrations, and has favorable efficacy data. Limited information on the other opioid classes also appears favorable, although published literature supporting this is very limited. Based on the currently available literature, both clinical efficacy and toxicology for bupivacaine and clonidine appear favorable. The efficacy of combinations of different drug classes such as opioids/local anesthetics, opioids/ clonidine, and opioids/local anesthetics/ clonidine appears favorable, but is based largely on case studies and retrospective analysis. No information is available on the long-term compatibility of these combinations.
<u>Pain Physician</u> 2007 Mar 10(2) 357-66	Sysrev				Most side effects of intrathecal morphine therapy are dose dependent and mediated by opioid receptors. Common ones include nausea, vomiting, pruritus, urinary retention, constipation, sexual dysfunction, and edema. Less common ones include respiratory depression, and hyperalgesia. Catheter tip inflammatory mass formation is a less common complication that may not be mediated by opioid receptors. Treatment usually involves the utilization of opioid receptor antagonist, such as naloxone.		Patients considering intrathecal opioid pump therapy should be informed and advised about the possible side effects associated with longterm intrathecal morphine administration prior to placement of a permanent morphine infusion pump.
<u>Eur J Anaesthesiol</u> 2006 Jul 23(7) 605-10	RCT	Opioid-naive patients suffering from non-cancerous chronic back-pain.  Patients with gastroenteric, urinary or respiratory tract disease, allergy to opioid drugs, sensory deficit, or use of drugs with a central effect or any effect on the urinary and gastrointestinal functions were excluded.	Clinically significant pain relief was observed in all patients receiving intrathecal morphine but only six patients (25%) of the control group { $P = 0.0005$ ). The incidence of pruritus was lower in patients of Groups III (6%) and IV (3%) than in Groups I (12%) and II (20%) ( $P = 0.002$ ).	The incidence of nausea and vomiting was higher at 2- and 4-h observation times, and decreased 24 h after intrathecal injection. Nausea was more frequent in Groups I (56%) and II (50%) than in Groups III (33%) and IV (24%) ( $P = 0.0005$ ). Vomiting was higher in patients receiving morphine than in control group, but without differences among the four doses. No urinary retention was observed in the control group, while 2 h after intrathecal injection urinary retention was observed in 20—40% of cases, and decreased to less than 10% 24 h after spinal injection without differences among the four doses.	N = 144.  Randomly allocated to receive one of four doses of intrathecal morphine: 0.015 mg (Group I), 0.03 mg (Group II), 0.06 mg (Group III) and 0.25 mg (Group IV). And a placebo group receiving paraspinous administration of normal saline (2 mL). A blinded observer recorded the occurrence of pruritus, nausea, vomiting, urinary retention and respiratory depression (respiratory rate < 6bpm) at 2, 4 and 24 h after injection.	The onset and incidence of minor opioid-related side-effects after intrathecal morphine administration do not depend on its dose, occurring with even very small doses of morphine. Accordingly, they can be considered as a patient-dependent effect of the drug.	

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<u>Anesth Analg 2000 Dec 91(6) 1493-8</u>	RCT	Patients who had neuropathic pain after SCI and who were unresponsive to other treatment. Patients were not considered for the study <4 wk after their injury and until they had undergone a trial of other drugs used for the treatment of neuropathic pain after SCI. Patients who had SCI at or above C-4 were excluded from the study because of the risk of respiratory arrest. Other exclusion criteria included preexisting hypertension, angina, congestive cardiac failure, active urinary tract infection, and age >80 yr.		Intrathecal morphine resulted in a mean reduction in pain to 80% of the baseline pain before drug administration. Intrathecal administration of clonidine resulted in a mean reduction in pain levels to 83% of the baseline pain. These reductions in pain levels were not significantly different from the relief obtained after saline administration. Intrathecal administration of the mixture of morphine and clonidine resulted in a mean reduction in pain levels to 63% of the baseline pain. There was a significant difference in the relief obtained with the mixture of morphine and clonidine compared with placebo ( $P = 0.0084$ ).	The most common side effects after morphine administration in those with SCI were pruritus, oxygen desaturation, sedation, nausea, and hypotension (>15% decrease in blood pressure). The most common side effects after clonidine administration were hypotension, nausea, sedation, oxygen desaturation, and dry mouth. Of those who received saline, 13% experienced sedation and 13% had oxygen desaturation. The most common side effects after the administration of the mixture were hypotension, oxygen desaturation, pruritus, dry mouth, and sedation. Using the mixture did not result in a marked reduction in the incidence of side effects.	N = 15. A double-blinded, randomized, controlled trial of intrathecal morphine or clonidine, alone or combined, in the treatment of neuropathic pain after spinal cord injury	The combination of morphine and clonidine produced significantly more pain relief than placebo 4 h after administration; either morphine or clonidine alone did not produce as much pain relief.
<u>J Clin Oncol 2002 Oct 1 20(19) 4040-9</u>	RCT	All patients had a documented average pain VAS > 5 at two measurements within a week of randomization, despite 200 mg/d of oral morphine or the equivalent. All patients had advanced cancer, pain expected to continue throughout life, age > 18 years, an expected life span > 3 months, and were suitable for the IDDS (no mechanical barriers, obstruction of CSF flow, or active infection).		Sixty of 71 IDDS patients (84.5%) achieved clinical success compared with 51 of 72 CMM patients (70.8%, $P = .05$ ). IDDS patients more often achieved >20% reduction in both pain VAS and toxicity (57.7% [41 of 71] v 37.5% [27 of 72], $P = .02$ ). The mean CMM VAS score fell from 7.81 to 4.76 (39% reduction); for the IDDS group, the scores fell from 7.57 to 3.67 (52% reduction, $P = .055$ ). The mean CMM toxicity scores fell from 6.36 to 5.27 (17% reduction); for the IDDS group, the toxicity scores fell from 7.22 to 3.59 (50% reduction, $P = .004$ ). The IDDS group had significant reductions in fatigue and depressed level of consciousness ( $P < .05$ ).		N = 202.  A RCT of CMM versus IDDS plus CMM.	IDDSs improved clinical success in pain control, reduced pain, and significantly relieved common drug toxicities in patients with refractory cancer pain.
<u>J Pain Symptom Manage 2006 May 31(5) 393-406</u>	RCT	Patients were required to have severe chronic pain that was inadequately controlled by systemic and/or IT analgesics, a Visual Analogue Scale of Pain Intensity (VASPI) score >50 mm, and pain of any etiology that warranted the use of IT therapy. Exclusion criteria included pregnancy or lactation, investigational drug or device use within 30 days prior to screening, known sensitivity to ziconotide, and contraindications to IT therapy		Intention to treat analysis: VASPI scores improved from baseline to Week 3 by a mean of 14.7% in the ziconotide-treated group and 7.2% in the placebo group ( $P = 0.036$ ).	Significant adverse events reported in the ziconotide group were dizziness, confusion, ataxia, abnormal gait, and memory impairment. Discontinuation rates for AEs and serious AEs were comparable for both groups.	N=220. A double-blind, placebo-controlled, two arm, randomized study consisted of an initial screening visit, a three-week weaning period from all IT drugs, a one-week stabilization period, and a three-week double-blind treatment period. Patients randomized to ziconotide (n = 112) or placebo (n = 108).	Slow titration of ziconotide, a nonopioid analgesic, to a low maximum dose resulted in significant improvement in pain and was better tolerated than in two previous controlled trials that used a faster titration to a higher mean dose.

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<a href="#">Pain Med 2004 5 6-13.</a>	Registry	Patients who were enrolled for IDDS trialing had chronic low back pain, with or without leg pain, but with greater back pain than leg pain.		The trialing success rate was 93% (154 patients). In all, 136 patients (82%) were implanted. In the implant group, numeric pain ratings dropped by more than 47% for back pain and more than 31% for leg pain at the 12-month follow-up. More than 65% of implanted patients reduced their Oswestry scores by at least one level at their 12-month follow-ups compared with baseline. At 12-month follow-ups, 80% of implanted patients were satisfied with their therapy and 87% said they would undergo the procedure again.	Adverse events were reported in 23 patients receiving an IDDS implant. Of these, 21 required some surgery to correct the problem. Adverse events included: Infection (2.2%), dislodgment/ migration (1.5%), and cerebrospinal fluid leak (0.7%). The most common adverse event over 12 months was reaction to medication, which occurred in 5.1% of patients. Other, rarely reported events included catheter kinking in 1.5% and catheter fracture in 0.7% of patients.	Thirty-six physicians enrolled 166 patients to be trialed for drug-delivery systems. Each participating center followed its standard clinical practice for patient selection, trialing methods, criteria for definition of a successful trial, implant methods, and postimplant therapy management. The registry protocol provided guidance regarding registry data requirements and ensured that standardized forms were used among all participating centers to solicit registry data at baseline, trialing, implant (or decision not to implant), and at 6- and 12-month follow-ups. Data were collected at all time points, regardless of implant status.	Current clinical practices related to trialing of drug-delivery systems resulted in the majority of patients successfully trialed. At 12-month follow-ups, implanted patients experienced reductions in numeric back and leg pain ratings, improved Oswestry scores, and high satisfaction with the therapy.
<a href="#">CLIN THER 1997 19(1) 96-112</a>	CE	A decision analytic study was conducted using computer simulation to project the outcomes in a simulated cohort of patients whose treatment for back surgery had failed. The objective of this study was to estimate the direct cost of intrathecal morphine therapy (IMT) delivered via an implantable pump relative to alternative therapy (medical management) over a 60-month course of treatment.		When both costs and adverse event rates were set at base case values, the expected cost (discounted at 5%) of IMT over 60 months was \$82,893 (\$1382 per month). With costs and adverse event rates at the best case values, the expected 60-month total cost was \$53,468 (\$891 per month), and when all the values were set at the worst case, the projected total cost rose to \$125,102 (\$2085 per month). By comparison, the cumulative 60-month total cost for medical management was \$85,186.		In general, the results of the simulation were robust to changes in the underlying assumptions. The model was most sensitive to changes in the cost of the pump/ catheter implant, ongoing monthly expenses for therapy, and pump replacement. A 100% change in the cost for each of these components of therapy translated into roughly a 20% change in the total 60-month cost of therapy.	
<i>only abstracts available</i>							
<a href="#">Ann Pharmacother 2006 Jul-Aug 40(7-8) 1293-300</a>	SysRev	Patients enrolled in clinical trials were intolerant of or refractory to other treatment modalities.		In double-blind, placebo-controlled studies, ziconotide significantly improved patient perception of pain from baseline to the end of the study periods, which ranged from 11 to 21 days.	Key ziconotide-related adverse events are neuropsychiatric, including depression, cognitive impairment, and hallucinations; depressed levels of consciousness; and elevation of creatine kinase levels. Ziconotide is also associated with a risk of meningitis due to possible contamination of the microinfusion.	There have been no studies that directly compared ziconotide with other intrathecal or systemic analgesics.	Ziconotide is a therapeutic option for treatment of severe chronic pain in patients who have exhausted all other agents, including intrathecal morphine, and for whom the potential benefit outweighs the risks of serious neuropsychiatric adverse effects and of having an implanted device.
<a href="#">Curr Pain Headache Rep 2005 Aug 9(4) 243-8</a>	CCT			Pain scores were reduced by 52% versus 39%, drug toxicity scores were reduced by 50% versus 17%. Even the most refractory pain patients--those failed by a month of comprehensive medical management by experts--when subsequently provided with IDDS, had a 27% reduction in pain scores and			IDDS should be considered as the best treatment for this population