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Intrathecal Pump for Chronic Nonmalignant Pain

Туре	Technology Assessment	
Category	Surgical	
Sub-Category	Neurosurgery	
Number	2005T0060C	
Approved By		Approval Date
Medical Technology Assessment Committee		11/17/2005

After evaluating relevant benefit document language (exclusions
or limitations), refer to Coverage sections of this document to
determine coverage.

This policy describes the use of the implantable infusion pump for delivery of pain medication into the space around the spinal cord in patients with chronic intractable pain of nonmalignant origin.

Medical Products	InfusAid (R), M-3000 Implantable Drug Delivery Pump with Bolus Safety
	Valve, SynchroMed (R), APT (SM)

Background

Description

Chronic nonmalignant pain is a complex condition involving neurophysiologic, cognitive, behavioral, cultural, social and economic factors. It is usually defined as pain of at least 6 months' duration and can include pain from a chronic condition, prolonged healing from an injury or an unknown cause.

Treatment options usually begin with the least invasive interventions such as exercise programs, meditation, relaxation and nonprescription analgesics or anti-inflammatory drugs. If these measures are ineffective, opioids may be used along with antidepressants, steroids and muscle relaxants. Nerve blocks (local or regional) and electrical stimulation may also be used to provide pain relief. If these methods fail, intrathecal infusion of opioids or other medications may provide effective relief while limiting the side effects of systemic drug use.

Intrathecal therapy involves the continuous infusion of the drug directly into the cerebrospinal fluid via a catheter placed in the intrathecal space. A pump is placed in the subcutaneous tissue of the abdomen and connected to the catheter. Usually a trial of the system is completed before the pump is inserted into the abdominal tissue. The pump reservoir holds the medication(s) and the pump is programmed to give a set dose of medication over time. There is also a bolus option for break through pain that can be self administered.

Audience	
Targeted Population	Enrollees, in all benefit plans, with severe intractable chronic pain of nonmalignant origin.
Coverage	All reviewers must first identify member eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of <u>this policy.</u>
Medicare Coverage	 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 patients 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.

	Determinations may be made on coverage of other uses of implanted infusion pumps if the contractors medical staff verifies that:
	 The drug is reasonable and necessary for the treatment of the individual patient:
	• It is medically necessary that the drug be administered by an implanted infusion pump; and,
	• The Food and Drug Administration (FDA)-approved labeling for the pump must specify that the drug being administered and the purpose for which it is administered is an indicated use for the pump.
	The implantation of an infusion pump is contraindicated in the following patients:
	• With a known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.);
	 Who have an infection; Whose body size is insufficient to support the weight and bulk of the devices and
	 With other implanted programmable devices since crosstalk between devices may inadvertently change the prescription.
	Payment may also be made for drugs necessary for the effective use of an implantable infusion pump as long as the drug being used with the pump is
	itself reasonable and necessary for the patients treatment. ¹
Corrora Dationala	

Coverage Rationale

Intrathecal Administration of Analgesic Medication is proven when delivered by a FDA-approved implantable infusion pump and all of the following situations apply:

- Life expectancy of greater than 3 months
- Unsatisfactory response to less invasive methods of pain control, including oral opioid trials and inadequate response to therapy to eliminate physical and behavioral abnormalities, which may cause an exaggerated reaction to pain.
- Positive response to intrathecal drug administration prior to pump implantation.
- The pain is not primarily of psychological origin.
- Patient is not an active abuser of chemicals or chemically dependent.

Clinical Information

Clinical Recommendations

Note: This section provides detailed information about the clinical intended use for the treatment that is the topic of this Technology Assessment. The detailed information provided in this section is NOT used to decide whether or not a service is paid for. Rather, it provides background information and rationale about the scientifically appropriate use of the treatment, for discussion purposes with providers. See "Coverage" section to determine what procedure(s) are covered/non-covered (i.e., paid for where such benefits are available).

Clinical evidence supports the use of intrathecal pump for chronic nonmalignant pain when delivered by a FDA-approved implantable infusion pump and all of the following situations apply:

- Life expectancy of greater than 3 months
- Unsatisfactory response to less invasive methods of pain control, including oral opioid trials and inadequate response to therapy to eliminate physical and behavioral abnormalities, which may cause an exaggerated reaction to pain.
- Positive response to the drug in intrathecal administration drug prior to pump implantation.
- The pain is not primarily of psychological origin.
- Patient not an active abuser of chemicals or chemically dependent.

An intrathecal pump should be used in caution in individuals with a past history of substance abuse.

Implantation of intrathecal pumps should be done by a physician and in a facility with experience and expertise in this procedure.

Clinical Precautions

Before patients begin long-term spinal analgesic infusion, they must

- 1. Undergo a comprehensive psychological evaluation
- 2. Have knowledge of the risks involved
- 3. Have been reviewed for efficacy of a definitive surgical surgical treatment
- 4. Have been reviewed for efficacy of oral pharmacotherapy and
- 5. Complete the McGill Pain Questionnaire to provide a complete description of their pain.⁷

Use of implantable intrathecal infusion pumps is contraindicated in the following situations:

- Patients who have another implanted device, such as cardiac pacemaker (due to lack of research in patients with other implanted devices)
- Infection at the pump site
- Patients in whom the pump cannot be implanted less than 2.5 cm from the surface of the skin
- Patients who are not large enough to accept pump bulk and weight
- Patients who have a contraindication to the drug

Intrathecal administration of morphine may result in a number of short-term side effects, including pruritus, dysphoria, histamine release, sedation, respiratory depression, gastrointestinal hypomotility, impotence abnormal body temperature regulation, nausea and vomiting, urinary retention, and constipation. These side effects are usually amenable to symptomatic treatment. A number of significant complications related to device failure or the implantation procedure have been reported

in up to 39% of patients with implanted infusion pumps; these include cessation or change in therapy due to battery depletion or pump failure, pocket seroma, hematoma, erosion or infection, complete or partial catheter occlusion, kinking, breakage, leakage or disconnection, catheter dislodgement or migration, bleeding, arachnoiditis, meningitis, and spinal headache. Device-related complications may require an additional surgical procedure to replace or remove the pump.

Although the development of tolerance to morphine can potentially limit the usefulness of intrathecal opioid therapy, most studies have shown only a gradual increase in effective dose, and many patients show no decrease in responsiveness to morphine over time. For those who do develop tolerance, pain can often be managed effectively by supplementation with oral nonnarcotic analgesics, or by use of intrathecal hydromorphone or hydromorphone plus bupivacaine combinations in place of morphine.

Setting(s)

Outpatient / Inpatient

Regulatory Requirements

According to the US Food and Drug Administration (FDA) Web site: SynchroMed® (Medtronic, Minneapolis, MN), InfusAid® (Infusaid Corp., Norwood, MA), M-3000 Implantable Drug Delivery Pump with Bolus Safety Valve (Arrow International, Walpole, MA) are approved for intrathecal delivery of morphine (FDA, 1999).²

The FDA is aware of a potential problem with intrathecal pumps. The problem arises because some models of this device have two ports. The first port refills the reservoir and the second one, which is used for myelography or removing CSF, leads directly into the catheter. These accidents occurred when the drug refill, instead of going into the reservoir port, was accidentally injected into the catheter access port. As a result, the drug intended for the reservoir went directly into the intrathecal space, and the patient received a massive overdose.

To help users locate the reservoir port when refilling the pump, the manufacturer provides a template. There's a different template that's used to find the catheter access port. ISMP points out that if this template is mistakenly used to try to locate the reservoir, the medication could be injected directly into the catheter, and then into the intrathecal space.³

Research Evidence

Staal et al. reported results of patient rating of quality of life as a result of intrathecal baclofen therapy. A total of 49 patients were surveyed about their experiences. An intrathecal pump was used for a year or more by 73% of the study participants. An improvement in quality of life was reported by 88% of the respondents. The most frequent reported quality of life measure was pain and spasticity control without the sedating effects of oral medications. Overall, 39% reported complications. The most common complications cited were infection and catheter breakage or disrupted connection.⁴

A clinical trial by Ackerman et al. evaluated the effectiveness of intrathecal clonidine or opioids for the treatment of chronic pain. The authors concluded that in patients with complex regional pain syndrome, neuropathic pain and malignant pain, intrathecal clonidine was of limited utility for most patients. It was effective in a subset of patients, but the study indicated that duration of pain relief was less than 18 months. Intrathecal hydromorphone and morphine was effective for the majority of patients and resulted in a significant reduction in pain.⁵

A case series involving 7 patients was reported by Cherry et al. The participants had minimally controlled chronic intractable angina for 5 to 19 years prior to treatment with intrathecal opioids. Morphine or fentanyl was used and the dose ranges from 1.2 mcg to 16 mcg. All patients were pain free for 2-7 years with the treatment.⁶

Earlier retrospective studies by Paice et al., Winkelmuller, Bedder (the smallest study with 26 patients) and Brown et al. that involved a total of 429 patients concluded that intrathecal opioid therapy was effective in 75%, 74%, 54% and 89% of patients (respectively). While the retrospective study design has limitations, the authors concluded that intrathecal opioid therapy is effective but is also accompanied by a high complication rate.¹⁰⁻¹³

Several small prospective studies concluded intrathecal therapy was effective in selected patients. The small sample sizes, lack of control, potential areas of bias and heterogenous populations limits the usefulness of the results however.^{8,14-16}

Cost Analysis

Several studies which addressed cost-effectiveness issues involved with intrathecal therapy for chronic pain concluded that given the costly and debilitating nature of chronic nonmalignant pain and the significant adverse effects associated with oral morphine, intrathecal delivery of morphine via implanted pump can be cost-effective when other less invasive forms of pain control have failed.

The SynchroMed device from Medtronic carries a list price of about \$8000 to \$10,000, and the total cost of an implant procedure, including cost of device, and hospital and physician charges, has been estimated at about \$20,000 to \$25,000. The SynchroMed pump reservoir requires refilling every 1 to 3 months, depending on dosage levels selected; the annual cost for medication instillation and pump programming is about \$3000 to \$4000, depending on dose rates and complications. The battery on the SynchroMed pump generally lasts for 4 to 6 years before needing replacement.^{8,9}

While the initial costs of the pump, screening trial, and implantation procedure are higher with an implanted intrathecal infusion system than those associated with an external drug delivery system, there is some evidence that the implanted system may be more cost-effective for long-term intrathecal opioid administration. Bedder, et al. compared the costs of an exteriorized system with those of an implanted infusion pump. Using cost data from 5 patients with an exteriorized system and 15 patients with a SynchroMed pump, the authors concluded that both types of drug delivery systems have similar costs at 3 months of treatment, but the cost benefits accrue to the implanted system during longer treatments.⁹

Definitions	
СІРІ	Chronic Illness Problem Inventory
MPQ/VDS	McGill Pain Questionnaire, Verbal Descriptor Scale
MS	multiple sclerosis
QOL	Quality of life
VAS	Visual Analog Scale

References and Resources

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Resources

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History/Updates

11/17/2005	Policy update with coverage rationale reworded to conform to proven/unproven language with no change in coverage rationale. Policy (1999T0060B) archived.
10/18/2004	CPT and HCPCS codes added to Coding Section per direction from the Reimbursement Medical Policy Operations Manager.
2/19/2002	Policy Reformatted including Coverage and Clinical Recommendations sections

Coding

The Current Procedural Terminology (CPT) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document.

CPT Coding Section

Injection, including catheter placement, continuous infusion or intermittent bolus, not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or subarachnoid; cervical or thoracic
Injection, including catheter placement, continuous infusion or intermittent bolus, not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or subarachnoid; lumbar, sacral (caudal)
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
Removal of previously implanted intrathecal or epidural catheter
Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir
Implantation or replacement of device for intrathecal or epidural drug infusion; non- programmable pump
Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming
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
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
95990	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular);
HCPCS Coding Section	
A4220	Refill kit for implantable infusion pump
A4221	Supplies for maintenance of drug infusion catheter, per week (list drug separately)
E0782	Infusion pump, implantable, non-programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0783	Infusion pump system, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0785	Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement
E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)