INTRODUCTION

An implantable infusion pump (IIP), also referred to as an implantable drug delivery system (IDDS), is a device for the delivery of medication to manage severe, chronic, intractable pain and/or chronic intractable spasm. The purpose of this guideline is to address criteria for the permanent placement of an implantable infusion pump.

FOR THE TREATMENT OF CHRONIC INTRACTABLE PAIN  Appropriate when ALL of the following criteria are met:

1. Severe, chronic, intractable malignant or nonmalignant pain that has not responded to at least 12 weeks of standard nonsurgical therapies (e.g., systemic medications, physical and psychological therapies, or cognitive behavioral, etc.):  AND

2. Documentation of completion of a satisfactory trial *of intraspinal (intrathecal/epidural) opioid drugs with acceptable pain relief, acceptable degree of side effects and patient acceptance of mode of treatment
   - IIP provides ≥ 50% pain relief:  AND
   - Side effects are tolerable:  AND
   - *Satisfactory trials may vary from 2 weeks—12 weeks depending upon clinical response (dosage and catheter placement may be manipulated).

3. Drug is FDA approved for delivery via by Infusion Pump:
   - Opioids (e.g., morphine), ziconotide, and/or clonidine:  AND

4. Patient must have a life expectancy of at least 3 months or more:  AND

5. Documentation of completed psychological assessment prior to IIP, including the patient’s cognitive ability, willingness, and ability to participate in IIP therapy.

FOR THE TREATMENT OF SPASTICITY  Appropriate when ALL of the following criteria are met:

1. Evidence of intractable spasticity that results in the patient’s inability to maintain an upright posture, balance in ambulation or increased function related to one of the following conditions:
   - Spinal Cord Injury:  OR
   - Multiple Sclerosis:  OR
   - Stiff person syndrome:  OR
2. Other medical conditions causing intractable spasms: AND
3. Severe, uncontrollable spasms that have not responded to at least 12 weeks of standard therapies (e.g. oral medications, physical therapy etc): AND
4. Documentation of completion of a satisfactory* intrathecal trial of the antispasmodic drug defined as:
   o IIP provides ≥ 50% spasm relief; AND
   o Side effects are tolerable: AND
   o *Satisfactory trials may vary from 2 weeks—12 weeks depending upon clinical response (dosage and catheter placement may be manipulated).
5. Drug is FDA approved for delivery via by Infusion Pump:
   o anti-spasmodic drugs (e.g., baclofen): AND
6. Patient must have a life expectancy of at least 3 months: AND
7. Documentation of completed psychological assessment prior to IIP, including the patient's cognitive ability, willingness, and ability to participate in IIP therapy.

CONTRAINDICATED FOR ANY OF THE FOLLOWING:

- There are no other medical indications for other intrathecal treatments except for pain and spasticity.
- Patients with an active infection.
- Patients with a known allergy or hypersensitivity to the drug being used (e.g., morphine, etc.).
- Patients with a body size that is insufficient to support the weight and bulk of the device.

ADDITIONAL INFORMATION:

Devices must be Food and Drug Administration (FDA) approved for infusion of the specific medication that is to be administered (i.e., some pumps may be specifically designed for the delivery of antispasmodics, etc.)

Other implanted programmable devices where the crosstalk between devices may inadvertently change the prescription.

Overview: An implanted pump releases medication through a catheter directly to the epidural or intrathecal space, which interrupts pain signals before they reach the brain. This mode of drug delivery provides pain relief with less medication than oral dosing and helps to minimize the side effects associated with oral medications. An IIP consists of a programmable pump, an epidural or intrathecal catheter, and an external programmer. Under general anesthesia, the pump is surgically implanted subcutaneously in the abdominal area, the catheter tip is inserted in the epidural or intrathecal space, often with fluoroscopic guidance, and the catheter is connected to the pump. A screening or trial period (usually a minimum of 3 days in length) is required to assess pain relief and to determine whether the patient is a candidate for pump implantation.

Evidence Review:
Chronic pain is pain that continues or recurs ≥ 90 days. It may result from an initial injury or illness; however, there may be no apparent cause. Chronic pain may limit movement and
A limited number of trials suggest that pain pumps may be of benefit to patients with severe chronic pain that is malignant or nonmalignant in origin. Paice et al. (1996) reported that the majority of patients with chronic, intractable, nonmalignant pain in a large (n=245) retrospective multicenter survey were very satisfied to moderately satisfied with intrathecal morphine therapy, with a mean 61% reduction in pain. The mean dosage required for pain control exhibited a gradual increase, suggesting that tolerance to the drug develops over time. Device-related complications occurred in 22% of patients during the follow-up period, which ranged from 8 to 94 months, with a mean of 14.6 months. Survey data was limited, as only approximately 50% of queried physicians responded. No data was available on dropouts.

Thimineur et al. (2004) performed a small nonrandomized prospective study of 69 patients with chronic intractable nonmalignant pain who met inclusion criteria for implantation of an IIP. An IIP was implanted in 39 patients while 31 patients served as the comparison group. The authors reported that pain intensity, mood, and function all improved significantly in the IIP recipient group compared with pretreatment and with the comparison-group patients. Minimal complications were reported.

In consideration of the paucity of randomized controlled trials (RCTs), Hayek et al. (2011) conducted a systematic review of intrathecal infusion through IDDS for chronic malignant and nonmalignant pain. The authors evaluated the available evidence for the efficacy and safety of intrathecal infusions used in long-term management (>6 months) of chronic pain. The authors’ “moderate” recommendation for intrathecal infusion systems for malignant-related pain is based on Level II-2 evidence (i.e., well-designed cohort and case-control analytic studies) and their recommendation is “limited to moderate” based on Level II-3 evidence of moderate quality from nonrandomized studies for nonmalignant-related pain.

**U.S. Preventive Services Task Force (USPSTF) Evidence Criteria:**

Authors based their recommendations on level of evidence criteria developed by the USPSTF, which rates the quality of evidence on a scale of I to III as follows:

**I:** Evidence obtained from at least one properly randomized controlled trial.

**II-1:** Evidence obtained from well-designed controlled trials without randomization.

**II-2:** Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

**II-3:** Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

affect the ability to carry out activities of daily living (ADL). It may lead to disability. Psychological effects may include anger, anxiety, depression, and fear of reinjury. Common chronic pain complaints include arthritis pain, back pain, headache, nerve pain (neurogenic), phantom pain, and psychogenic pain (no apparent cause). Chronic pain usually cannot be cured. The goal of treatment is to reduce pain and improve function. Treatment may include acupuncture, behavior modification, biofeedback, electrical stimulation, medications, nerve blocks, physical therapy, psychotherapy, relaxation therapy, or surgery.
III:  Opinions of respected authorities, based on clinical experience, descriptive studies, and case reports or reports of expert committees.

Complications and side effects of IIP may include catheter dislodgement or occlusion, pump malfunction, arthralgia, decreased libido, erectile dysfunction, hematoma, infection, leakage, menstrual abnormalities, nausea and vomiting, nerve root irritation, peripheral edema, pruritus, decreased cognition, concentration, or memory, and other complications associated with seating of the device and changes in weight.
REFERENCES


Reviewed/Approved by Michael Pentecost, MD, Chief Medical Officer

6—Implantable Infusion Insertion Pump