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| Origination Date: 01/00                  | Revision Date(s): 11/02, 12/03, 12/04, 12/05,<br>12/06, 12/07, 1/09 |
| Developed By: Medical Criteria Committee |   |

*Csaba Mera MD*

Approved: Csaba Mera, MD

Date: 01/13/09

**Description:**

Opioids delivered via an intrathecal implantable infusion pump provide effective pain relief of chronic intractable pain while limiting the adverse effects associated with long-term systemic administration of potent analgesics. Due to the invasive nature of this treatment and the potentially serious complications associated with the implanted infusion pumps and catheters, intrathecal opioid therapy is generally undertaken only as a last resort after other forms of pain management have been tried and proven ineffective.

**Criteria**

- I. ODS will cover a **trial** of an implantable infusion pump for pain management to plan limitations when **all** of the following criteria are met:
  - A. The patient has a life expectancy of at least 6 months; and
  - B. The device must have FDA approval and be used specifically for the FDA approved purpose; and
  - C. The patient has demonstrable pathology found through diagnostic testing that is related to their pain complaints; and
  - D. All other appropriate methods of pain control/pain management have been tried and proven ineffective, including but not limited to the following:
    - i. Physical therapy or exercise programs
    - ii. Rest and relaxation
    - iii. Oral/transdermal pain medications are ineffective or patient is intolerant due to side effects
    - iv. Non-prescription analgesics and anti-inflammatories
    - v. Injectable pain medications (IM, SQ, or IV injections)
    - vi. Local/regional blocks or epidural steroid injections; and
  - E. Surgical intervention is not indicated; and
  - F. No known obstruction to cerebral spinal fluid flow
- II. ODS will cover the permanent placement of an implantable infusion pump when the above criteria has been met and a positive response to an intrathecal opioid infusion trial is shown by documentation of the ability to conduct usual daily activities with a 50% reduction in pain.
- III. Contraindications to implantable infusion pumps:
  - A. Patients with other implanted programmable devices, such as cardiac pacemakers
  - B. Patients whose body size is insufficient to support the bulk and weight of the device
  - C. Patients with a known allergy or hypersensitivity to the drug being used
  - D. Patients who have an infection
  - E. Patients with a history of drug abuse or addiction; active psychosis or suicidality; untreated major depression or mood disorder; or patients with compromised reasoning, judgment, or memory

**Information to be Submitted with Pre-Authorization Request:**

- Complete history and physical from treating physician
- Medical records from the treating physician outlining conservative therapy trials, duration, and results
- Documentation of patient's current activity level
- For permanent pump placement, documentation of the results of the patient's response to the intrathecal opioid trial

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