Intrathecal Pain Pumps - Single Service

Clinical Guidelines for Medical Necessity Review

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Specialty Area: Diseases & Disorders of the Musculoskeletal System (M00-M99)
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Medical Necessity Criteria

Service: Intrathecal Pain Pumps

General Guidelines

- **Units, Frequency, & Duration:** One Unit
- **Criteria for Subsequent Requests:** For replacement when the device is not functioning, the technology requires an upgrade, or a notification is received from the device indicating impending failure.
- **Recommended Clinical Approach:** An intrathecal drug delivery system (IDDS) involves a surgically implanted pump that delivers medication to a patient with cancer-related pain, muscle spasticity, or chronic non-malignant pain. The IDD includes a pump, medication reservoir, and catheter. Once programmed, the pump delivers a set amount of medication via a catheter into the intrathecal space of the spinal canal. Administering medication in this manner allows irregular signals traveling through the nerves and spinal column to be interrupted. When the pump is no longer needed, it is removed.
- **Exclusions:** None.

Medical Necessity Criteria

Indications

➔ **Intrathecal Pain Pumps** to administer opiates or non-opiate analgesics are considered appropriate if **ANY** of the following is **TRUE**:

- ◆ **Malignant Cancer-Related Pain** as evidenced by **ANY** of the following:[1-3]
  - **ALL** of the following are **TRUE**:
    - Presence of metastatic lesion(s); **AND**
    - Documented life expectancy of three months or more; **AND**
    - Oral, transdermal, or subcutaneous opioids failed or side effects are not tolerable[4]; **AND**
    - **ANY** of the following is **TRUE**:
      - ◆ The request is for an intrathecal pain pump trial; **OR**
      - ◆ The request is for a permanent intrathecal pain pump, and the initial injection or infusion

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demonstrates an improvement of at least 50% prior to permanent implantation, minimal side effects, and patient tolerance; **OR**

- Replacement of an intrathecal pain pump is medically necessary when **ANY** of the following is **TRUE**:
    - The device is not functioning, and the rationale is documented in the chart (e.g., pump interrogation report, imaging reports, pump flow study, end of battery life); **OR**
    - Device recalled by the manufacturer; **OR**
    - Notification received from the pump indicating an impending failure; **OR**

◆ **Spasticity** as evidenced by **ANY** of the following:[5-6]

- **ALL** of the following are **TRUE**:
    - Symptoms that are uncontrolled by oral medication after at least a 6-week trial (or patient cannot tolerate prescribed medication) and **ANY** of the following:
        ◆ Painful spasticity; **OR**
        ◆ Spasticity or dystonia increases the patient's risk for contractures, pressure injuries, or other complications; **OR**
        ◆ Spasticity or dystonia impacts mobility and activities of daily living (ADLs); **AND**
    - The patient cannot be maintained on non-invasive methods of spasm control, such as oral anti-spasmodic drugs, for **ANY** of the following reasons:
        ◆ They fail to control adequately the spasticity; **OR**
        ◆ They produce intolerable side effects; **AND**
    - **ANY** of the following is **TRUE**:
        ◆ The request is for an intrathecal pain pump trial; **OR**
        ◆ The request is for a permanent intrathecal pain pump after completion of a successful trial of intrathecal injection of baclofen as evidenced by a drop of one point or more on the Ashworth Scale[7]; **OR**

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- Replacement of an intrathecal pain pump is medically necessary when **ANY** of the following is **TRUE**:
    - The device is not functioning, and the rationale is documented in the chart (e.g., pump interrogation report, imaging reports, pump flow study, end of battery life); **OR**
    - Device recalled by the manufacturer; **OR**
    - Notification received from the pump indicating an impending failure; **OR**

◆ **Chronic, Non-Malignant Pain** as evidenced by **ANY** of the following:[8-10]

- **ALL** of the following are **TRUE**:
    - Moderate to severe chronic, intractable pain of known etiology (e.g., advanced spinal osteoarthritis, complex regional pain syndrome, failed back surgery syndrome); **AND**
    - Failed treatment targeted at originating pain diagnosis; **AND**
    - Difficulty completing activities of daily living (ADLs) for at least six months; **AND**
    - Failed conservative treatment of at least six months within the last year, including **ALL** of the following:
        - ◆ Pharmacological modalities; **AND**
        - ◆ Combination for PT and home exercise program; **AND**
        - ◆ Interventional pain injections if indicated; **AND**
        - ◆ Cognitive behavioral therapy if suggested on psychological evaluation; **AND**
    - Oral, transdermal, or subcutaneous opioids failed or side effects are not tolerable[4]; **AND**
    - Additional treatment or surgery for the originating cause of the pain is not indicated or is refused; **AND**
    - Psychological evaluation and clearance has been performed (for non-malignant chronic pain); **AND**
    - **ANY** of the following:
        - ◆ The request is for an intrathecal pain pump trial; **OR**
        - ◆ The request is for a permanent intrathecal pain pump, and the initial injection or infusion

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demonstrates an improvement of at least 50% prior to permanent implantation, minimal side effects, and patient tolerance; **OR**

- Replacement of an intrathecal pain pump is medically necessary when **ANY** of the following is **TRUE**:
    - The device is not functioning, and the rationale is documented in the chart (e.g., pump interrogation report, imaging reports, pump flow study, end of battery life); **OR**
    - Device technology requires an upgrade; **OR**
    - Notification was received from the pump indicating an impending failure.

Non-Indications

➔ **Intrathecal Pain Pumps** to administer opiates or non-opiate analgesics are **NOT** considered appropriate if **ANY** of the following is **TRUE**:[1]

- Spinal stenosis with intraspinal obstruction; **OR**
- Pain that has been diagnosed as psychogenic; **OR**
- Opioid addiction; **OR**
- Requests for a replacement or upgrade for ANY of the following:
    - Patient convenience; **OR**
    - The current device is functional despite newer technology; **OR**
- For infusion of heparins for thromboembolic disease or antibiotics (Vancomycin); **OR**
- Non-specific, generalized body pain
- Current mental disorder that is unstable or causes suicidal ideation; **OR**
- Substance use disorder (excluding nicotine); **OR**
- Known allergic reaction to analgesic to be infused; **OR**
- Tumor encroachment of the thecal sac; **OR**
- The patient's body size is insufficient to support the weight and bulk of the device.

Level of Care Criteria

Inpatient or outpatient.

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Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description
62323	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)
62324	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62325	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (i.e., fluoroscopy or CT)
62326	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62327	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (i.e., fluoroscopy or CT)

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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
62355	Removal of previously implanted intrathecal or epidural catheter
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; nonprogrammable pump
62362	Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming
62365	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 or refill
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

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	(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 skill of a physician or other qualified health care professional)
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	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular), includes electronic analysis of pump, when performed; requiring skill of a physician or other qualified health care professional
C1772	Infusion pump, programmable (implantable)
C1891	Infusion pump, non-programmable, permanent (implantable)
C2626	Infusion pump, non-programmable, temporary (implantable)
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

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	catheter)

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Medical Evidence

Stearns et al. (2020) analyzed data from a prospective, long-term, multicenter registry of patients who received intrathecal drug delivery systems (IDDSs) for cancer-related pain. The Product Surveillance Registry (PSR) included 1403 patients with cancer from 2003, when the registry began, through July 2017. Common cancer types were lung, breast, colon/rectal, pancreatic, and prostate. Improved pain level and higher quality of life scores were demonstrated in the literature, including patients late stage cancer. Efficacy is reported in randomized controlled clinical trials (RCTs) yet overall utilization is low.[3]

Schultz et al. (2021) also analyzed data from the PSR. A total of 4646 patients were included who had chronic, non-malignant pain and were treated with a drug delivery system. Adverse events, product performance, and device replacement are discussed. Literature supports the use of drug delivery systems as an option in lieu of systemic opioids.[9]

National and Professional Organizations

A selection of guidelines and criteria have been published - consult the Reference section for access.

- American Society of Anesthesiologists Task Force on Chronic Pain Management, American Society of Regional Anesthesia and Pain Medicine - *Practice Guidelines for Chronic Pain Management*[11]
- American Society of Interventional Pain Physicians (ASIPP) - *An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain*[12-13]
- American Society of Pain and Neuroscience (ASPN) - *Best Practices and Guidelines for the Interventional Management of Cancer-Associated Pain*[1]
- American Society of Pain and Neuroscience (ASPN) - *Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain*[14] · British Pain Society (BPS) - *Intrathecal Drug Delivery for the Management of Pain and Spasticity in Adults*[15]
- National Comprehensive Cancer Network (NCCN) - *Clinical Practice Guideline: Adult Cancer Pain*[4]

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- National Institute for Health and Care Excellence (NICE) - *Spasticity in Under 19s: Management [CG145]*[5]

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