Cohere Medicare Advantage Policy - Intrathecal Pain Pumps

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
Guideline Name: Cohere Medicare Advantage Policy - Intrathecal Pain Pumps

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Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Intrathecal Pain Pumps

Benefit Category

Durable medical equipment

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.[1]

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.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of intrathecal pain pump procedures. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Adverse effects from delayed or denied treatment: Delays or denials in intrathecal pain pump procedures can lead to increased symptoms and complications, especially in patients with chronic pain or cancer-related pain. According to Stearns et al., improved pain levels and higher quality of life scores were demonstrated in patients with cancer-related pain treated with intrathecal drug delivery systems.[4]
- Risks with inappropriate surgical procedures: This includes infection, bleeding, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to complications. Carvajal

et al. noted that long-term intrathecal drug delivery systems are effective and safe for managing refractory pancreatic cancer pain, with significant pain relief reported.[12]
- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. Schultz et al. reported that adverse events, product performance, and device replacement data support the use of drug delivery systems as an option in lieu of systemic opioids.[10]

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to intrathecal pain pump procedures for the patients selected for best outcomes. The goal is to provide accurate diagnostics and effective treatment planning, reducing the risk of complications and improving overall patient health. Aman et al. emphasized that the American Society of Pain and Neuroscience (ASPN) Best Practices and Guidelines support the interventional management of cancer-associated pain with intrathecal drug delivery systems.[2]
- Enhanced diagnostic accuracy: This is crucial for complex pain conditions such as chronic non-malignant pain and cancer-related pain. Stearns et al. stated that intrathecal drug delivery systems significantly improve pain levels and quality of life in patients with cancer-related pain.[4]
- Reduction in complications and adverse effects: Proper use of intrathecal pain pump criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Carvajal et al. highlighted the importance of long-term intrathecal drug delivery systems in managing refractory pancreatic cancer pain, with significant reductions in pain scores post-implantation.[12]
- Enhanced overall patient satisfaction: Ensuring that intrathecal pain pumps are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. According to Schultz et al., targeted drug delivery for chronic nonmalignant pain demonstrates significant improvements in patient outcomes and quality of life.[10]

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are

employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Intrathecal pain pumps** to administer opiates, non-opiate analgesics, or antispasmodics for painful spasms are considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ **Malignant cancer-related pain** as evidenced by **ANY** of the following[1-4]:
    - **ALL** of the following are **TRUE**:
      - Presence of cancer-related pain; **AND**
      - Documented life expectancy of three months or more; **AND**
      - Oral, transdermal, or subcutaneous opioids failed or side effects are not tolerable[5]; **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 demonstrates adequate pain relief 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**
- **Chronic, non-malignant pain** as evidenced by **ANY** of the following[9-11]:
    - **ALL** of the following are **TRUE**:
        - Severe chronic, intractable pain of non-malignant origin; **AND**
        - Failure of conservative management (e.g., rest, analgesics, physical therapy, oral or injectable corticosteroids) must be documented. Documentation should include detailed evidence of the measures taken, rather than solely a physician's statement; **AND**
        - The patient's history must indicate that he/she would not respond adequately to noninvasive methods of pain control, such as systemic opioids (oral, transdermal, or subcutaneous opioids failed or side effects are not tolerable)[4]; **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 demonstrates an improvement of at least 50% pain relief (including effects on the activities of daily living) 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 was received from the pump indicating an impending failure; **OR**
- **Painful spasticity** as evidenced by **ANY** of the following[1,6-7]:

- Chronic intractable painful spasticity in patients who have proven unresponsive to less invasive medical therapy as determined by **ANY** of the following criteria:
    - There must be at least a 6-week trial; the patient cannot be maintained on non-invasive methods of spasm control, such as oral anti-spasmodic drugs, either because these methods fail to control adequately the spasticity; **OR**
    - Non-invasive anti-spasmotics produce intolerable side effects; **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 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]:

◆ **ANY** of the following contraindications:

- Presence of a known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.); **OR**
- Patients with an active infection; **OR**
- Whose body size is insufficient to support the weight and bulk of the device; **OR**
- With other implanted programmable devices since crosstalk between devices may inadvertently change the prescription; **OR**

◆ Requests for a replacement or upgrade if the current device is functional despite newer technology being available.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Codes	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)

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

	(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

	catheter)

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 levels and higher quality of life scores were demonstrated in the literature, including patients with late-stage cancer. Efficacy is reported in randomized controlled clinical trials (RCTs) yet overall utilization is low.[4]

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.[10]

Carvajal et al. (2018) performed an observational study of patients diagnosed with pancreatic cancer. Prevalence rates of pain range from 47% to 82%. Results from 11 years of data were analyzed based on the utilization of intrathecal drug delivery systems (IDDS). A total of 10,300 IDDS days were included. Prior to IDDS implantation severe pain was reported (median presurgical NRS, 8 [interquartile range, 7-9]) despite receiving a daily dose of oral morphine of 360 mg. With respect to the median overall survival (OS), post-intrathecal treatment initiation was 82 days (95% confidence interval, 59-95). After implant surgery the median OS was 91 days (83-111) for implanted pumps and 27 days (20-49) for external pumps ($P < .0001$). Patients reported significant pain relief as evidenced by a notable reduction in pain scores at 1 week, 1 month, and 3 months post-implantation ($P < .001$). Severe pain (NRS score, ≥7) also decreased from 89.2% before surgery to 4.5% after 1 week, 6.7% after 1 month, and 10.3% after 3 months of IDDS implantation ($P < .01$). Rates of complication were low and align with existing literature findings. The authors suggest that long-term IDDS are effective and safe for managing refractory pancreatic cancer pain.[12]

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