Cohere Medicare Advantage Policy - Intrathecal Pain Pumps

Clinical Guidelines for Medical Necessity Review

Version: 3
Revision Date: June 26, 2025

Important Notices

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Policy Information:

Specialty Area: Musculoskeletal Care
Policy Name: Cohere Medicare Advantage Policy - Intrathecal Pain Pumps
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

Table of Contents

Medical Necessity Criteria

Service: Intrathecal Pain Pumps

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1-5]

- National Coverage Determination (NCD): Infusion pumps (280.14)
- Local Coverage Determination (LCD): Implantable infusion pumps (L33461)
  - Billing and Coding: Implantable infusion pump (A56695)
- Billing and Coding: Implantable infusion pumps for chronic pain (A55239)
- Billing and Coding: Implantable infusion pumps for chronic pain (A55323)

Description

An intrathecal drug delivery system (IDDS) involves a surgically implanted pump that delivers medication to The IDDS 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. Intrathecal drug therapies include opioid medications and nonopioid medications (e.g., baclofen, ziconotide, local anesthetics).[6]

Medical Necessity Criteria

Indications

An **intrathecal pain pump** to administer opiates, non-opiate analgesics, or antispasmodics for painful spasms is considered appropriate if **ANY** of the following is **TRUE**:

- Anti-spasmodic drugs (e.g., baclofen) for intractable spasticity with **ALL** of the following[1]:
  - Non-invasive methods of spasm control (e.g., oral anti-spasmodic drugs) are not effective due to **ANY** of the following:
    - Failure to adequately control the spasticity; **OR**
    - Intolerable side effects; **AND**
  - Before pump implantation, the patient must have responded favorably with a 50% improvement of function or spasticity to a trial intrathecal dose of the anti-spasmodic drug[7]; **OR**
- Opioid and non-opioid drugs for the treatment of chronic, intractable pain of malignant or non-malignant origin with **ALL** of the following[1,3,4,6,8-11]:
  - Any drug(s) used to fill the implantable infusion pump must be appropriate for the treatment of the patient's pain condition; **AND**
  - Origin of pain is **ANY** of the following:
    - Malignant with **ALL** of the following:
      - Life expectancy greater than 3 months; **AND**
      - History indicates there was not an adequate response to non-invasive methods of pain control; **OR**
    - Non-malignant and unresponsive to less invasive medical therapy as indicated by **ALL** of the following:
      - Duration of conservative care of greater than 3 months with **ALL** of the following:
        - Physical therapy; **AND**
        - Interventional pain injections if medically appropriate; **AND**
        - Medication including systemic opioids; **AND**
      - Evaluation with a multidisciplinary physician team that includes **ALL** of the following:
        - Psychological evaluation by a licensed mental health professional; **AND**
        - Surgery is not indicated; **OR**
- Permanent intrathecal pain pump with **ALL** of the following[3,4]:
  - Completion of a preliminary trial of intraspinal opioid or non-opioid drug administration with or without a temporary catheter (e.g., intrathecal, epidural); **AND**
  - Meets appropriate criteria above; **AND**
  - Evidence of at least 50% potential pain relief with the procedure (e.g., trial); **AND**
  - Minimal side effects and patient tolerance[12-13]; **OR**

- Replacement or revision of a covered device* is medically necessary with **ANY** of the following:
  - Device is not functioning, and the rationale is documented in the chart (e.g., pump interrogation report, imaging reports, pump flow study); **OR**
  - Device recalled by the manufacturer; **OR**
  - Notification was received from the pump indicating an impending failure.

*NOTE: A covered device includes the device-pump/battery, programmer, catheter, and extensions. Documentation should include which component(s) require replacement.

Non-Indications

An **intrathecal pain pump** to administer opiates or non-opiate analgesics is **NOT** considered appropriate if **ANY** of the following is **TRUE**:

- Presence of a known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.)[1-5]; **OR**
- Active infection[1-5]; **OR**
- The patient's body size is insufficient to support the weight and bulk of the device[1-5]; **OR**
- Replacement of a device for **ANY** of the following:
  - The entire implantable infusion system, including the catheter and/or programmer components, at the end of battery life, as it is not generally required); **OR**
  - Upgrade to newer technology when the current device is functional.

*NOTE: If the patient has another implanted programmable device, and due to crosstalk between devices that may inadvertently change the prescription, all devices should be checked for possible crosstalk at the time of implantation of the infusion pump, with appropriate continued surveillance for such interactions.[2]

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
62323	Injection(s), of diagnostic or therapeutic substance(s) (e.g., 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 (i.e., 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)

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for a permanent intrathecal pain pump may include:

- Adverse effects from delayed or denied treatment, such as increased symptoms and complications, especially in patients with chronic, pain or cancer-related pain. According to Stearns et al. (2020), improved pain levels and higher quality of life scores were demonstrated in patients with cancer-related pain treated with an intrathecal drug delivery system (IDDS).[8] Schultz et al. (2021) 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.[9]

The clinical benefits of using these criteria for a permanent intrathecal pain pump may include:

- Improved patient selection results in better long-term outcomes. Enhanced diagnostic accuracy is crucial for complex pain conditions such as chronic, non-malignant pain and cancer-related pain. Stearns et al. (2020) stated that an IDDS may significantly improve pain levels and quality of life in patients with cancer-related pain.[8] Proper use of intrathecal pain pump criteria helps to avoid unnecessary interventions and associated risks, thus safeguarding patient health. Carvajal et al. (2018) highlighted the importance of long-term intrathecal drug delivery systems in managing refractory pancreatic cancer pain, with significant reductions in pain scores post-implantation.[14] Patient outcomes and higher satisfaction rates are reported with effective treatment. According to Schultz et al. (2021), targeted drug delivery for

chronic, nonmalignant pain significantly improves patient outcomes and quality of life.[9] Aman et al. (2021) 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.[15] In addition, Hayek et al. (2011) and Deer et al. (2010) cited multiple trials that demonstrated fewer adverse effects and an improvement of pain relief by 50% or greater.[12,13]

- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Schultz et al. (2021) also analyzed data from the Product Surveillance Registry (PSR). The study included 4646 patients with chronic, non-malignant pain who received a drug delivery system. Adverse events, product performance, and device replacement were discussed. The literature supports the use of drug delivery systems as an option instead of systemic opioids.[9]

Stearns et al. (2020) analyzed data from a prospective, long-term, multicenter registry of patients who received an intrathecal drug delivery system (IDDS) for cancer-related pain. The 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, including patients with late-stage cancer. Efficacy was demonstrated in randomized controlled clinical trials (RCTs), yet overall utilization is low.[8]

Carvajal et al. (2018) performed an observational study of patients diagnosed with pancreatic cancer; prevalence rates of pain range from 47% to 82%. The Results from 11 years of data were analyzed using an IDDS. A total of 10,300 IDDS days were analyzed. Before IDDS implantation, severe pain was reported (median presurgical numeric rating scale [NRS], 8 [interquartile range, 7-9]) despite receiving a daily dose of oral morphine of 360 mg. Concerning 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 complications were low and aligned with existing literature findings. The authors suggest that a long-term IDDS is effective and safe for managing refractory pancreatic cancer pain.[14]

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Clinical Guideline Revision History/Information

Original Date: May 31, 2024		
Review History		
Version 2	06/10/2024	422.101 disclaimer added.
Version 3	06/26/2025	Annual review. Rewrote the indications for “anti-spasmodic drugs“ to align with CMS NCD 280.14. Revised the section for “opioid and non-opioid drugs” to align with CMS NCD 280.14. Added an indication for “opioid and non-opioid drugs” for conservative care for non-malignant pain, (“physical therapy, interventional pain injections if medically appropriate, and medication including systemic opioids”). Added an indication for “opioid and non-opioid drugs” for “evaluation with a multidisciplinary physician team” including a “psychological evaluation by a licensed mental health professional” and when “surgery is not indicated.” Included a note regarding covered devices (“device-pump/battery, programmer, catheter, and extensions.”