

# Cigna Medical Coverage Policies – Musculoskeletal Implantable Intrathecal Drug Delivery System

Effective July 1, 2021



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## Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

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# CMM-210: Implantable Intrathecal Drug Delivery System

## Definitions

- **An implantable intrathecal drug delivery system** (Pain pump or Baclofen pump) is a device used for the continuous infusion of a drug directly into the cerebrospinal fluid via a catheter placed in the intrathecal or epidural space. A pump is placed in the subcutaneous tissue of the abdomen and connected to the catheter. The pump reservoir holds the medication(s), and the pump is programmed to give a set dose of medication over time. For most individuals, it should be used as part of a program to facilitate restoration of function and return to activity, and not just for pain reduction. An intrathecal drug delivery trial can be accomplished by either a single intrathecal bolus injection or an intrathecal catheter infusion.

## General Guidelines

This guideline does not apply to epidural injections administered for obstetrical or surgical epidural anesthesia.

- The determination of medical necessity for the performance of an implantable intrathecal or epidural drug delivery system is always made on a case-by-case basis.

## Indications

- The use of an implantable intrathecal or epidural drug delivery system is considered **medically necessary** for **ANY** of the following indications when the associated criteria are met:
  - ◆ Nonmalignant, chronic intractable pain (e.g., failed back surgery syndrome with low back pain and/or radicular pain, post-herpetic neuralgia, complex regional pain syndrome)
  - ◆ Severe, refractory spasticity or chronic intractable dystonia in individuals who are unresponsive to or cannot tolerate oral anti-spasticity agents (i.e., baclofen [Lioresal®]) (i.e., intrathecal injection of Baclofen)
  - ◆ Cancer-related pain

## Nonmalignant, Chronic Intractable Pain

- A trial with a percutaneous intrathecal or epidural drug delivery system for nonmalignant chronic intractable pain is considered **medically necessary** when **ALL** of the following criteria have been met:
  - ◆ There is a documented pathology (i.e., an objective basis for the pain complaint)
  - ◆ Failure of at least six (6) months of noninvasive pain management, including active rehabilitative exercises and fixed schedule dosing of opioids or other analgesics unless contraindicated and the reason(s) for the contraindication(s) is/are documented in the medical record
  - ◆ Further surgical intervention or other treatment is not indicated or likely to be effective

- ◆ An attestation from a primary care physician, neurologist, physiatrist, psychiatrist, psychologist, or other licensed behavioral and/or medical health care provider (i.e., face-to-face or virtual assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of inadequately controlled mental and/or behavioral health conditions/issues (e.g., substance use disorders, depression, or psychosis) as a major contributor to chronic pain.
- ◆ Individual agrees to a 50% reduction in systemic opiates prior to undergoing an intrathecal opiate trial.
- A permanent implantable intrathecal or epidural drug delivery system for the above listed pain conditions is considered **medically necessary** if the individual has met the above criteria for a preliminary trial and has experienced > 50% reduction in pain for eight (8) hours and concomitant increase in function during an appropriate trial.

### **Severe, Refractory Spasticity/Chronic Intractable Dystonia**

- A trial with a percutaneous intrathecal drug delivery system for severe, refractory spasticity or chronic intractable dystonia is considered **medically necessary** for **EITHER** of the following indications:
  - ◆ There is failure, contraindication or intolerance to at least a six (6) week trial of oral antispasmodic drugs and physical therapy
  - ◆ Individual has a baseline average Ashworth score of at least 3 (or a Modified Ashworth score of 2), and a Spasm Frequency score of at least 2
    - An Ashworth score of 3 represents a considerable increase in muscle tone when testing resistance to passive movement about a joint with varying degrees of velocity.
    - A Modified Ashworth score of 2 represents a slight increase in muscle tone followed by minimal resistance of the range of motion.
    - A Spasm Frequency Score of 2 represents a patient's self-report of between 1 to 5 spasms per day.
  - ◆ A permanent implantable infusion for the treatment of chronic intractable spasticity or chronic intractable dystonia is considered **medically necessary** when a preliminary trial of intrathecal antispasmodic drug administration, that meets the above medical necessity criteria, demonstrates a beneficial clinical response (e.g., demonstrates at least a 2-point reduction in the Ashworth or Spasm Frequency score for four (4) hours following an intrathecal trial bolus of Baclofen)

### **Cancer-Related Pain**

- A trial with a percutaneous intrathecal or epidural drug delivery system for cancer-related pain is considered **medically necessary** when there is failure, intolerance or contraindication to noninvasive methods of pain control including systemic opioids.
- A permanent implantable intrathecal or epidural drug delivery system for the above listed pain conditions is considered **medically necessary** if the individual has met the above criteria for a preliminary trial and has experienced at least a 50% reduction in pain during an appropriate trial.

- ◆ **Please Note:** A trial with a percutaneous intrathecal or epidural drug delivery system for cancer-related pain is not required in the presence of advanced disease, when survival time is limited, and when the individual is considered high risk for procedures.

### Non-Indications

- An intrathecal or epidural drug delivery system is considered **experimental, investigational or unproven (EIU)** for **ANY** other indication, including cancer-related pain, spastic/dystonic, or other pain conditions that do not meet the above criteria.

### Replacement

- Replacement of an implanted intrathecal or epidural drug infusion system is considered **medically necessary** when **BOTH** of the following criteria have been met:
  - ◆ The existing device is documented to be nearing end of battery life, will no longer be functional and cannot be repaired, or a built-in component provides notification of impending failure
  - ◆ There is no evidence to suggest the device has been abused or neglected.
- Replacement of an implantable/intrathecal infusion pump is considered **not medically necessary** when the existing infusion pump and/or components remain functional.

## Procedure (CPT®) Codes

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

CPT®	Code Description/Definition
62320	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, cervical or thoracic; without imaging guidance.
62321	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, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)
62322	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); without imaging guidance.
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) (eg, 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) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)
62326	Injection (s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, 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) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, 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
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

This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.

## References

1. Ackerman L, Follett K, Rosenquist R. Long-term outcomes during treatment of chronic pain with intrathecal clonidine or clonidine/opioid combinations. *J Pain Symptom Manage*. 2003;26(1):668-677.
2. American College of Occupational and Environmental Medicine. *Occupational Medicine Practice Guideline*, 2nd Ed. 2008.
3. American Medical Association. *Current Procedural Terminology* –2016 Professional Edition.
4. Anderson V, Burchiel K. A prospective study of long term intrathecal morphine in the management of chronic nonmalignant pain. *Neurosurgery*. 1999;44:289-300.
5. Anderson V, Cooke B, Burchiel K. Intrathecal hydromorphone for chronic nonmalignant pain: a retrospective study. *Pain Med*. 2001;2(4):287-297.
6. Angel I, Gould H Jr, Carey M. Intrathecal morphine pump as a treatment option in chronic pain of nonmalignant origin. *Surg Neurol*. 1998;49(1):92-98.
7. Boswell M, Shah R, Everett C, et al. Interventional Techniques: Evidence-based Practice Guidelines in The Management of Chronic Spinal Pain: Evidence-Based Practice Guidelines. *Pain Physician*. 2005;8:1-47.
8. Brown J, Klapow J, Doleys D, et al. Disease-specific and generic health outcomes: a model for the evaluation of long-term intrathecal opioid therapy in noncancer low back pain patients. *Clin J Pain*. 1999;15:122-131.
9. Bottros M, Christo P. Current perspectives on intrathecal drug delivery. *J Pain Res*. 2014; 7; 615– 626.
10. Dahm P, Nitescu P, Appelgren L, Curelaru I. Efficacy and technical complications of long-term continuous intraspinal infusions of opioid and/or bupivacaine in refractory nonmalignant pain: a comparison between the epidural and the intrathecal approach with externalized or implanted catheters and infusion pumps. *Clin J Pain*. 1998;14:4-16.
11. Dario A, Scamoni C, Picano M, et al. The infection risk of intrathecal drug infusion pumps after multiple refill procedures. *Neuromodulation*. 2005;8(1):36-39.
12. Deer T. Current and future trends in spinal cord stimulation for chronic pain. *Curr Pain Headache Rep*. 2001;5(6):503-509.
13. Deer T, Chapple I, Classen A, et al. Intrathecal drug delivery for treatment of chronic low back pain: report from the National Outcomes Registry for Low Back Pain. *Pain Med*. 2004;5(1):6-13.
14. Deer T, Krames ES, Hassenbusch SJ, Burton A, Caraway D, Dupen S, et al. Polyanalgesic consensus conference 2007: Recommendations for the management of pain by intrathecal (intraspinial) drug delivery: Report of an interdisciplinary expert panel. *Neuromodulation*. 2007;10(4):300-328.
15. Deer TR, Hayek SM, Pope JE et al. Polyanalgesic Consensus Conference (PACC): Recommendations for Trialing of Intrathecal Drug Delivery Infusion Therapy. *Neuromodulation* 2017;20(2):133-154. DOI: 10.1111/ner.12543.
16. Deer TR, Kim C, Bowman R, Tolentino D, Stewart C, Tolentino W. Intrathecal ziconotide and opioid combination therapy for noncancer pain: an observational study. *Pain Physician*. 2009;12(4):E291-E296.
17. Deer TR, Smith HS, Burton AW, et al. Comprehensive Consensus Based Guidelines on Intrathecal Drug Delivery Systems in the Treatment of Pain Caused by Cancer Pain. *Pain Physician*. 2011; 14:E283-E312
18. Deer TR, Pope JE, Hayek SM, et al. The polyanalgesic consensus conference (PACC): recommendations on intrathecal drug infusion systems best practices and guidelines. *Neuromodulation*. 2017;20(2):96-132.
19. Deer TR, Prager J, Levy R, Rathmell J, Buchser E, Burton A, et al. Polyanalgesic Consensus Conference 2012: recommendations for the management of pain by intrathecal (intraspinial) drug delivery: report of an interdisciplinary expert panel. *Neuromodulation*. 2012a;15(5):436-464.
20. Deer TR, Prager J, Levy R, Burton A, Buchser E, Caraway D, et al. Polyanalgesic Consensus Conference--2012: recommendations on trialing for intrathecal (intraspinial) drug delivery: report of an interdisciplinary expert panel. *Neuromodulation*. 2012b;15(5):420-35.
21. Deer TR, Smith HS, Burton AW, Pope JE, Doleys DM, Levy RM, Staats PS, Wallace MS, Webster LR, Rauck RL, Cousins M; Center For Pain Relief, Inc. Comprehensive consensus based guidelines on intrathecal drug delivery systems in the treatment of pain caused by cancer pain. *Pain Physician*. 2011;14(3):E283-E312.
22. Du Pen S, Du Pen A, Hillyer J. Intrathecal hydromorphone for intractable nonmalignant pain: a retrospective study. *Pain Med*. 2006;7(1):10-15.
23. Guillaume D, Van Havenbergh A, Vloeberghs M, et al. A clinical study of intrathecal baclofen using a programmable pump for intractable spasticity. *Arch Phys Med Rehabil*. 2005;86:2165-2171.
24. Hamza M, Doleys DM, Saleh IA, Medvedovsky A, Verdolin MH, Hamza M. A Prospective, Randomized, Single-Blinded, Head-to-Head Long-Term Outcome Study, Comparing Intrathecal (IT) Boluses With Continuous Infusion Trialing Techniques Prior to Implantation of Drug Delivery Systems (DDS) for the Treatment of Severe Intractable Chronic Nonmalignant Pain. *Neuromodulation*. 2015 Oct;18(7):636-48.
25. Hassenbusch S, Portenoy R, Cousins M, et al. Polyanalgesic Consensus Conference 2003: an update on the management of pain by intraspinal drug delivery--report of an expert panel. *J Pain Symptom Manage*. 2004;27(6):540-563.
26. Intrathecal Drug Delivery Systems North American Spine Society Coverage Policy Recommendations 2017.

27. Krames E. Intraspinal opioid therapy for chronic nonmalignant pain: current practice and clinical guidelines. *J Pain Symptom Manage*. 1996;11(6):333-352.
28. Kumar K, Hunter G, Demeria D. Treatment of chronic pain by using intrathecal drug therapy compared with conventional pain therapies: a cost-effectiveness analysis. *J Neurosurg*. 2002;97(4):803-810.
29. Miele V, Price K, Bloomfield S, et al. A review of intrathecal morphine therapy related granulomas. *Eur J Pain*. 2006;10(3):251-261.
30. Manchikanti L1, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician*. 2013 Apr;16(2 Suppl):S49-283.
31. Manchikanti L, Falco FJ, Singh V, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part I: introduction and general considerations. *Pain Physician*. 2013 Apr;16(2 Suppl):S1-48.
32. McIntyre A, Mays R, Mehta S, et al. Examining the effectiveness of Intrathecal baclofen on spasticity in individuals with chronic spinal cord injury: a systemic review. *J Spinal Cord Med*. 2014 Jan;37(1):11-8.
33. Modified Ashworth scale and spasm frequency score in spinal cord injury: reliability and correlation. *Spinal Cord*. 2016; 54:702–708.
34. North American Spine Society (NASS). NASS Coverage Policy Recommendations: Intrathecal Drug Delivery Systems. Burr Ridge, IL: North American Spine Society. March 2017.
35. Nguyen H, Garber J, Hassenbusch S. Spinal analgesics. *Anesth Clin of NA*. 2003;21(4).
36. Osenbach R, Harvey S. Neuraxial infusion in patients with chronic intractable cancer and noncancer pain. *Curr Pain Headache Rep*. 2001;5(3):241-9.
37. Penn RD et al. Intrathecal baclofen for severe spinal spasticity. *N Engl J Med*. 1989; 320: 1517–1521.
38. Raffaelli W, Marconi G, Fanelli G, et al. Opioid-related side-effects after intrathecal morphine: a prospective, randomized, double-blind dose-response study. *Eur J Anaesthesiology*. 2006;23:605-10.
39. Rauck R, Wallace M, Leong M, et al; Ziconotide 301 Study Group. A randomized, double-blind, placebo-controlled study of intrathecal ziconotide in adults with severe chronic pain. *J Pain Symptom Manage*. 2006;31(5):393-406.
40. Staal C, Arends A, Ho S.A self-report of quality of life of patients receiving intrathecal baclofen therapy. *Rehabil Nurs*. 2003 Sep-Oct;28(5):159-63.
41. Thimineur M, Kravitz E, Vodapally M. Intrathecal opioid treatment for chronic non-malignant pain: a 3-year prospective study. *Pain*. 2004;109(3):242-249.
42. Turner J, Sears J, Loeser J. Programmable intrathecal opioid delivery systems for chronic noncancer pain: a systematic review of effectiveness and complications. *Clin J Pain*. 2007;23(2):180-95.
43. van Hilten B, van de Beek W, Hoff J, et al. Intrathecal baclofen for the treatment of dystonia in patients with reflex sympathetic dystrophy. *N Engl J Med*. 2000;343(9):625-630.
44. Waara-Wolleat K, Hildebrand K, Stewart G. A review of intrathecal fentanyl and sufentanil for the treatment of chronic pain. *Pain Med*. 2006;7:251-259.
45. Winkelmuller M, Winkelmuller W. Long-term effects of continuous intrathecal opioid treatment in chronic pain of nonmalignant etiology. *J Neurosurg*. 1996;85:458-467.
46. Workloss Data Institute. Official Disability Guidelines.
47. Yoshida G, Nelson R, Capen D, Nagelberg et al. Evaluation of continuous intraspinal narcotic analgesia for chronic pain from benign causes. *Am J Orthop*. 1996;25(10):693-694.