



MEDICAL COVERAGE POLICY

SERVICE: Implantable Intrathecal Drug Delivery System

Policy Number:	046
Effective Date:	05/01/2018
Last Review:	03/06/2018
Next Review Date:	03/06/2019

Important note:

Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website.

SERVICE: Implantable Intrathecal Drug Delivery System

PRIOR AUTHORIZATION: Required.

POLICY: The use of implantable intrathecal drug delivery systems may be considered medically necessary for members with one of the following conditions:

1. Chronic intractable pain in members who have a life expectancy of at least three months, and who are intolerant of or unresponsive to less invasive medical therapy, including but not limited to pharmacologic, surgical, psychological, or physical treatment modalities
2. Intractable spasticity of cerebral or spinal cord origin in patients who are unresponsive to or cannot tolerate oral anti-spasticity agents

There are two steps in the process of authorizing an implantable intrathecal drug delivery:

Step one: for members potentially eligible for an implantable intrathecal drug delivery system, a trial using an external pump is required.

Step two: authorization for a permanent implantable intrathecal drug pump may be requested following a trial during which there has been at least a 50% reduction in pain or spasticity.

OVERVIEW: 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 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 patients, it should be used as part of a program to facilitate restoration of function and return to activity, and not just for pain reduction.

MANDATES: There are no mandated benefits or regulatory requirements for SWHP to provide coverage for these services.

Food and Drug Administration (FDA): Implantable drug delivery systems used for the intrathecal administration of opioids are regulated by the FDA as Class III medical devices and can be found in the FDA Premarket Approval (PMA) Database by entering *intrathecal* in the Quick Search field at: [click here](#).



MEDICAL COVERAGE POLICY

SERVICE: Implantable Intrathecal Drug Delivery System

Policy Number:	046
Effective Date:	05/01/2018
Last Review:	03/06/2018
Next Review Date:	03/06/2019

Intrathecal drug delivery performed with the use non-FDA approved devices is **not covered**.

CMS: There is a National Coverage Determination (NCD) for Infusion Pumps (280.14) effective December 17, 2004. There is also an LCD, L35112 with an effective date of 01/01/2016. Please refer to those documents for Medicare lines of business.

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	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; non-programmable pump
	62362	Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming
	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
	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 physician's skill)
	95990	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular);
	95991	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular); administered by physician
	96522	Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (e.g., intravenous, intra-arterial)
HCPCS codes	E0782	Infusion pump, implantable, nonprogrammable (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)
	C1772	Infusion pump, programmable (implantable)
	C1891	Infusion pump, nonprogrammable, permanent (implantable)
	C2626	Infusion pump, nonprogrammable, temporary (implantable)
	A4220	Refill kit for implantable infusion pump
	A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code



MEDICAL COVERAGE POLICY

SERVICE: Implantable Intrathecal Drug Delivery System

Policy Number: 046

Effective Date: 05/01/2018

Last Review: 03/06/2018

Next Review Date: 03/06/2019

ICD10 codes:	G24.1 Genetic torsion dystonia
	G80.3 Athetoid cerebral palsy
	G24.2 Idiopathic nonfamilial dystonia
	G24.2 Other dystonia
	G89.0 Central pain syndrome
	G89.21 - G89.29 Chronic pain due to trauma
	G89.3 Neoplasm related pain (acute) (chronic)
	G89.4 Chronic pain syndrome
	G90.50 - G90.9 Complex regional pain syndrome I

CMS: NCD for Infusion Pumps 280.14

POLICY HISTORY:

Status	Date	Action
New	6/1/2010	New policy
Reviewed	12/28/2010	Reviewed only
Reviewed	12/6/2011	Reviewed only
Reviewed	9/5/2012	Extensively revised and updated
Reviewed	5/23/2013	No significant changes.
Reviewed	4/24/2014	No significant changes.
Reviewed	4/30/2015	Updates added.
Reviewed	5/12/2016	Minor clarifications
Reviewed	4/18/2017	No significant changes
Reviewed	3/06/2018	Changed criteria – aligned with LCD

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

- Ackerman LL, Follett KA, Rosenquist RW. Long-term outcomes during treatment of chronic pain with intrathecal clonidine or clonidine/opioid combinations. *J Pain Symptom Manage.* 2003 Jul;26(1):668-77.
- Aldrete JA, Couto da Silva JM. Leg edema from intrathecal opiate infusions. *Eur J Pain.* 2000;4(4):361-365.
- American College of Occupational and Environmental Medicine. *Occupational Medicine Practice Guideline*, 2nd Ed. 2008. Accessed 12/1/2008.
- American Medical Association. *Current Procedural Terminology – Professional Edition.*
- Anderson VC, Burchiel KJ. A prospective study of long term intrathecal morphine in the management of chronic nonmalignant pain. *Neurosurgery.* 1999;44:289 - 300.
- Anderson VC, Cooke B, Burchiel KJ. Intrathecal hydromorphone for chronic nonmalignant pain: a retrospective study. *Pain Med.* 2001;2(4):287-297.
- Angel IF, Gould HJ Jr, Carey ME. Intrathecal morphine pump as a treatment option in chronic pain of nonmalignant origin. *Surg Neurol.* 1998 Jan;49(1):92-8; discussion 98-9.
- Bedder MD, Burchiel K, Larson A. Cost analysis of two implantable narcotic delivery systems. *J Pain Symptom Manage.* 1991;6:368-373.
- Bedder MD. Epidural opioid therapy for chronic nonmalignant pain: critique of current experience. *J Pain Symptom Manage.* 1996;11:353-356.

MEDICAL COVERAGE POLICY

SERVICE: Implantable Intrathecal Drug Delivery System

Policy Number: 046

Effective Date: 05/01/2018

Last Review: 03/06/2018

Next Review Date: 03/06/2019

10. Boswell MV, Shah RV, Everett CR, Sehgal N, McKenzie-Brown AM, Abdi S, Bowman RC, Deer TR, Datta S, Colson JD, Spillane WF, Smith HS, Lucas LF, Burton AW, Chopra P, Staats PS, Wasserman RA, Manchikanti L. Interventional Techniques in The Management of Chronic Spinal Pain: Evidence-Based Practice Guidelines. *Pain Physician*. 2005;8:1-47
11. 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.
12. Cherry DA, Gourlay GK, Eldredge KA. Management of chronic intractable angina - spinal opioids offer an alternative therapy. *Pain*. 2003 Mar;102(1-2):163-6.
13. 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.
14. 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.
15. 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.
16. Deer TR. Current and future trends in spinal cord stimulation for chronic pain. *Curr Pain Headache Rep*. 2001 Dec;5(6):503-9.
17. Du Pen S, Du Pen A, Hillyer J. Intrathecal hydromorphone for intractable nonmalignant pain: a retrospective study. *Pain Med*. 2006;7(1):10-15.
18. Guillaume D, Van Havenbergh A, Vloeberghs M, Vidal J, Roeste G. A clinical study of intrathecal baclofen using a programmable pump for intractable spasticity. *Arch Phys Med Rehabil*. 2005;86:2165-71.
19. Hassenbusch SJ, Portenoy RK, Cousins M, Buchser E, Deer TR, Du Pen SL, Eisenach J, Follett KA, Hildebrand KR, Krames ES, Levy RM, Palmer PP, Rathmell JP, Rauck RL, Staats PS, Stearns L, Willis KD. 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 Jun;27(6):540-63.
20. Krames ES. Intraspinal opioid therapy for chronic nonmalignant pain: current practice and clinical guidelines. *J Pain Symptom Manage*. 1996;11(6):333-352.
21. Kumar K, Hunter G, Demeria DD. Treatment of chronic pain by using intrathecal drug therapy compared with conventional pain therapies: a cost-effectiveness analysis. *J Neurosurg*. 2002 Oct;97(4):803-10.
22. Miele VJ, Price KO, Bloomfield S, Hogg J, Bailes JE. A review of intrathecal morphine therapy related granulomas. *EurJPain*. 2006;10(3):251-261.
23. Nguyen H, Garber J, Hassenbusch S. Spinal analgesics. *Anesth Clin of NA*. 2003;21(4).
24. Osenbach RK, Harvey S. Neuraxial infusion in patients with chronic intractable cancer and noncancer pain. *Curr Pain Headache Rep*. 2001 Jun;5(3):241-9.
25. Paice JA, Penn RD, Shott S. Intraspinal morphine for chronic pain: a retrospective, multicenter study. *J Pain Symptom Manage*. 1996;11:71-80.
26. Paice JA, Winkelmuller W, Burchiel K, Racz GB, Prager JP. Clinical realities and economic considerations: efficacy of intrathecal pain therapy. *J Pain Symptom Manage*. 1997 Sep;14(3 Suppl):S14-26.
27. 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.
28. Rauck RL, Wallace MS, Leong MS, 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.
29. 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.
30. Thimineur MA, Kravitz E, Vodapally MS. Intrathecal opioid treatment for chronic non-malignant pain: a 3-year prospective study. *Pain*. 2004;109(3):242-249.



Scott & White
HEALTH PLAN
PART OF BAYLOR SCOTT & WHITE HEALTH

MEDICAL COVERAGE POLICY

SERVICE: Implantable Intrathecal Drug Delivery System

Policy Number: 046

Effective Date: 05/01/2018

Last Review: 03/06/2018

Next Review Date: 03/06/2019

31. Turner JA, Sears JM, Loeser JD. Programmable intrathecal opioid delivery systems for chronic noncancer pain: a systematic review of effectiveness and complications. *Clin J Pain*. 2007;23(2):180-95.
32. Tutak U, Doleys DM. Intrathecal infusion systems for treatment of chronic low back and leg pain of noncancer origin. *South Med J*. 1996 Mar;89(3):295-300.
33. Valentino L, Pillay KV, Walker J. Managing chronic nonmalignant pain with continuous intrathecal morphine. *J Neurosci Nurs*. 1998;30:233-239.
34. van Hilten BJ, van de Beek WJ, Hoff JI, Voormolen JH, Delhaas EM. Intrathecal baclofen for the treatment of dystonia in patients with reflex sympathetic dystrophy. *N Engl J Med*. 2000;343(9):625-30.
35. Waara-Wolleat KL, Hildebrand KR, Stewart GR. A review of intrathecal fentanyl and sufentanil for the treatment of chronic pain. *Pain Med*. 2006;7:251-9.
36. Winkelmuller M, Winkelmuller W. Long-term effects of continuous intrathecal opioid treatment in chronic pain of nonmalignant etiology. *J Neurosurg*. 1996 Sep;85(3):458-67.
37. Winkelmuller M, Winkelmuller W. Long-term effects of continuous intrathecal opioid treatment in chronic pain of nonmalignant etiology. *J Neurosurg*. 1996;85:458-467.
38. Workloss Data Institute. Official Disability Guidelines 2008. www.worklossdata.com. Accessed 1/13/09.
39. Yoshida GM, Nelson RW, Capen DA, Nagelberg S, Thomas JC, Rimoldi RL, Haye W. Evaluation of continuous intraspinal narcotic analgesia for chronic pain from benign causes. *Am J Orthop*. 1996 Oct;25(10):693-4.
40. Novitas-Solutions LCD L35112, accessed 02/22/2018.