

 <p>POLICY LIBRARY: MEDICAL</p>	Effective Date:	Approval Date:	Approved By:
	02/18/2009	02/18/2009	MQIC/SLT
	Doc. Control #: PRV.MQ.MP.066.001		
Title/Subject:			
TMMP 210 - IMPLANTABLE INTRATHECAL DRUG DELIVERY SYSTEMS (62318, 62319, 62350, 62351, 62362, 62367, 62368, 96521, 96522)			

1. Purpose

The purpose of this policy is to establish the criteria for the medical necessity of implantable intrathecal drug delivery systems.

2. 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 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.

3. Statement of Policy

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

3.2. The use of implantable intrathecal drug delivery systems **may be considered medically necessary** for a patient with chronic intractable pain and/or spasticity due to:

- Failed back surgery syndrome with low back pain and/or radicular pain
- Complex regional pain syndrome (also known as reflex sympathetic dystrophy)
- Primary or metastatic cancer
- Post-herpetic neuralgia
- Severe, refractory spasticity of cerebral or spinal cord origin in patients who are unresponsive to or cannot tolerate oral anti-spasticity agents (i.e., Baclofen [Lioresal®]) (a.k.a. Intrathecal injection of Baclofen).

3.3. There may be other chronic pain conditions for which the use of implantable intrathecal drug delivery systems **may be considered medically necessary**.

3.4. A trial of percutaneous intrathecal drug delivery systems for pain **may be considered medically necessary** when the following criteria have been met:

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- There is documented pathology (i.e., an objective basis for the pain complaint); and
- The patient with non-malignant pain has demonstrated a sufficient trial of at least six (6) months of all reasonable treatment options for pain management which could potentially provide benefit with a reasonable expectation that the treatment could possibly render the need for the intrathecal pain pump medically unnecessary; and
- The patient has participated in a reasonable trial of aggressive active rehabilitative exercises; and
- Patient has had a sufficient trial of strong opioids or other analgesics in adequate doses, with a fixed schedule (not on a PRN basis) dosing which have failed to relieve pain or the patient has developed intolerable side effects to systemic opioids or other analgesics; and
- Further surgical intervention or other treatment is not indicated or likely to be effective; and
- Patient has a life expectancy of greater than three (3) months, and
- The patient has received appropriate psychiatric care and has obtained psychiatric clearance.

3.5. An implantable intrathecal drug delivery system for pain **is considered medically necessary** if the patient met the criteria in section 3.4 and experienced at least a 50% reduction in pain during an appropriate trial.

3.6. The use of percutaneous intrathecal drug delivery systems for spasticity without pain will be reviewed on a case-by-case basis.

4. References

4.1. Scientific:

The following scientific references were utilized in the formulation of this medical policy. Triad Healthcare, Inc. will continue to review clinical evidence surrounding intrathecal pain pumps and may modify this policy 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 Triad Healthcare, Inc. so the information can be reviewed by the Academic Advisory Committee (AAC)

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and the Medical Quality Improvement Committee (MQIC) 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.
- 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
- 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.
- 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.

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- 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.
- 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.
- 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.
- Deer TR. Current and future trends in spinal cord stimulation for chronic pain. *Curr Pain Headache Rep*. 2001 Dec;5(6):503-9.
- Du Pen S, Du Pen A, Hillyer J. Intrathecal hydromorphone for intractable nonmalignant pain: a retrospective study. *Pain Med*. 2006;7(1):10-15.
- 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.
- 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.
- Krames ES. Intraspinal opioid therapy for chronic nonmalignant pain: current practice and clinical guidelines. *J Pain Symptom Manage*. 1996;11(6):333-352.
- 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.
- Miele VJ, Price KO, Bloomfield S, Hogg J, Bailes JE. A review of intrathecal morphine therapy related granulomas. *EurJPain*. 2006;10(3):251-261.
- Nguyen H, Garber J, Hassenbusch S. Spinal analgesics. *Anesth Clin of NA*. 2003;21(4).

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- 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.
- Paice JA, Penn RD, Shott S. Intraspinal morphine for chronic pain: a retrospective, multicenter study. *J Pain Symptom Manage.* 1996;11:71-80.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- Valentino L, Pillay KV, Walker J. Managing chronic nonmalignant pain with continuous intrathecal morphine. *J Neurosci Nurs.* 1998;30:233-239.
- 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.

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- 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.
- 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.
- Winkelmuller M, Winkelmuller W. Long-term effects of continuous intrathecal opioid treatment in chronic pain of nonmalignant etiology. *J Neurosurg.* 1996;85:458-467.
- Workloss Data Institute. Official Disability Guidelines 2008. www.worklossdata.com. Accessed 1/13/09.
- 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.

4.2. Related Triad Medical Policies:

- [TMMP 18 – Medical Necessity](#)

5. Attachments

- [Provider Manual](#)

Table of Revisions

Revision Date	Modified By	Description
02/18/2009	Level 1, 2, 3	New medical policy.