Implantable Infusion Pumps for Non-Cancer Pain

Implantable infusion pumps are battery powered devices that are surgically implanted to provide continuous drug delivery for pain management in patients with non-cancer pain. The pump, which has a fluid reservoir, is placed under the skin in the abdomen. The catheter is inserted into the intrathecal or epidural space of the spine, tunneled under the skin, and connected to the pump. The drug is delivered to the spinal cord where pain signals travel, interrupting pain signals before they reach the brain. The ability to deliver the drug directly into the spine provides pain relief with significantly smaller opioid doses, which can help to minimize side effects (e.g., drowsiness, dizziness, dry mouth, nausea, vomiting and constipation) that can accompany systemic pain medications that might be delivered orally, transdermally, or through an IV.

The New York State Department of Health currently covers implantable infusion pumps for patients with a cancer diagnosis. The Department will make a determination whether or not to expand coverage of this technology within the Medicaid benefit package.

Dossier sources of evidence already submitted:

The following evidence was recently submitted to the Department:

1. Anderson Valerie, C, J Burchiel Kim and B Cooke. A prospective, randomized trial of intrathecal injection vs. Epidural infusion in the selection of patients for continuous intrathecal opioid therapy. Neuromodulation: journal of the International Neuromodulation Society. 2003;6(3):142-152.

2. Anderson, VC and KJ Burchiel. A prospective study of long-term intrathecal morphine in the management of chronic nonmalignant pain. Neurosurgery. 1999;44(2):289-300; discussion 300-281.

3. Atli, A, BR Theodore, DC Turk and JD Loeser. Intrathecal opioid therapy for chronic nonmalignant pain: A retrospective cohort study with 3-year follow-up. Pain medicine (Malden, Mass.). 2010;11(7):1010-1016.

4. Bolash, R, B Udeh, Y Saweriset al. Longevity and cost of implantable intrathecal drug delivery systems for chronic pain management: A retrospective analysis of 365 patients. Neuromodulation : journal of the International Neuromodulation Society. 2014;23(23):1525-1403.

5. Coffey, RJ, ML Owens, SK Brosteet al. Mortality associated with implantation and management of intrathecal opioid drug infusion systems to treat noncancer pain. Anesthesiology. 2009;111(4):881-891.

6. Coffey, RJ, ML Owens, SK Brosteet al. Medical practice perspective: Identification and mitigation of risk factors for mortality associated with intrathecal opioids for non-cancer pain. Pain medicine (Malden, Mass.). 2010;11(7):1001-1009.

7. Corrado, P, B Alperson and M Wright. Perceived success and failure of intrathecal infusion pump implantation in chronic pain patients. Neuromodulation. 2008;11(2):98-102.

8. de Lissovoy, G, RE Brown, M Halpern, SJ Hassenbusch and E Ross. Cost-effectiveness of long-term intrathecal morphine therapy for pain associated with failed back surgery syndrome. Clinical therapeutics. 1997;19(1):96-112; discussion 184-115.

9. Deer, T, I Chapple, A Classenet al. Intrathecal drug delivery for treatment of chronic low back pain: Report from the national outcomes registry for low back pain. Pain medicine (Malden, Mass.). 2004;5(1):6-13.

10. Deer, TR, R Levy, J Prageret al. Polyanalgesic consensus conference-2012: Recommendations to reduce morbidity and mortality in intrathecal drug delivery in the treatment of chronic pain. Neuromodulation,. 2012;15(5):467-482.

11. Deer, TR, J Prager, M Jacobset al. Polyanalgesic consensus conference-2012: Recommendations on trialing for intrathecal (intraspinal) drug delivery: Report of an interdisciplinary expert panel. Neuromodulation,. 2012;15(5):420-435.

12. Deer, TR, J Prager, MS Jacobset al. Polyanalgesic consensus conference 2012: Recommendations for the management of pain by intrathecal (intraspinal) drug delivery: Report of an interdisciplinary expert panel. Neuromodulation,. 2012;15(5):436-464.

13. Deer, TR, J Prager, MS Jacobset al. Polyanalgesic consensus conference-2012: Consensus on diagnosis, detection, and treatment of catheter-tip granulomas (inflammatory masses). Neuromodulation,. 2012;15(5):483-495.

14. Dewilde, S, L Verdian and GD Maclaine. Cost-effectiveness of ziconotide in intrathecal pain management for severe chronic pain patients in the uk. Current medical research and opinion. 2009;25(8):2007-2019.

15. Doleys, DM, JL Brown and T Ness. Multidimensional outcomes analysis of intrathecal, oral opioid, and behavioral-functional restoration therapy for failed back surgery syndrome: A retrospective study with 4 years' follow-up. Neuromodulation : journal of the International Neuromodulation Society. 2006;9(4):270-283.

16. Duarte Rui, V, H Raphael Jon, L Southall Jane, C Baker and L Ashford Robert. Intrathecal granuloma formation as result of opioid delivery: Systematic literature review of case reports and analysis against a control group. Clinical neurology and neurosurgery. 2012;114(6):577-584.

17. Duarte Rui, V, H Raphael Jon, E Sparkes, L Southall Jane, K LeMarchand and L Ashford Robert. Long-term intrathecal drug administration for chronic nonmalignant pain. Journal of neurosurgical anesthesiology. 2012;24(1):63-70.

18. Dunn, KM, KW Saunders, CM Rutteret al. Opioid prescriptions for chronic pain and overdose: A cohort study. Annals of internal medicine. 2010;152(2):85-92.

19. Ellis, DJ, S Dissanayake, D McGuireet al. Continuous intrathecal infusion of ziconotide for treatment of chronic malignant and nonmalignant pain over 12 months: A prospective, open-label study. Neuromodulation : journal of the International Neuromodulation Society. 2008;11(1):40-49.

20. Falco, FJ, VB Patel, SM Hayeket al. Intrathecal infusion systems for long-term management of chronic non-cancer pain: An update of assessment of evidence. Pain physician. 2013;16(2 Suppl):SE185-216.

21. Fluckiger, B, H Knecht, S Grossmann and P Felleiter. Device-related complications of long-term intrathecal drug therapy via implanted pumps. Spinal cord. 2008;46(9):639-643.

22. Guillemette, S, S Witzke, J Leier, J Hinnenthal and P Prager Joshua. Medical cost impact of intrathecal drug delivery for noncancer pain. Pain medicine (Malden, Mass.). 2013;14(4):504-515.

23. Hamza, M, D Doleys, M Wellset al. Prospective study of 3-year follow-up of low-dose intrathecal opioids in the management of chronic nonmalignant pain. Pain medicine (Malden, Mass.). 2012;13(10):1304-1313.

24. Hayek, SM, TR Deer, JE Pope, SJ Panchal and VB Patel. Intrathecal therapy for cancer and non-cancer pain. Pain physician. 2011;14(3):219-248.

25. Hayek, SM, IE Veizi, SN Narouze and N Mekhail. Age-dependent intrathecal opioid escalation in chronic noncancer pain patients. Pain medicine (Malden, Mass.). 2011;12(8):1179-1189.

26. Hayes, C, MS Jordan, FJ Hodson and L Ritchard. Ceasing intrathecal therapy in chronic non-cancer pain: An invitation to shift from biomedical focus to active management. PloS one. 2012;7(11):e49124.

27. Ilias, W, B le Polain, E Buchser and L Demartini. Patient-controlled analgesia in chronic pain patients: Experience with a new device designed to be used with implanted programmable pumps. Pain practice : the official journal of World Institute of Pain. 2008;8(3):164-170.

28. Kamran, S and BD Wright. Complications of intrathecal drug delivery systems. Neuromodulation : journal of the International Neuromodulation Society. 2001;4(3):111-115.

29. Kumar, K, G Hunter and DD Demeria. Treatment of chronic pain by using intrathecal drug therapy compared with conventional pain therapies: A cost-effectiveness analysis. Journal of neurosurgery. 2002;97(4):803-810.

30. Kumar, K, S Rizvi and S Bishop. Cost effectiveness of intrathecal drug therapy in management of chronic nonmalignant pain. The Clinical journal of pain. 2013;29(2):138-145.

31. Maeyaert, J, E Buchser, JP Van Buyten, NG Rainov and R Becker. Patient-controlled analgesia in intrathecal therapy for chronic pain: Safety and effective operation of the model 8831 personal therapy manager with a pre-implanted synchromed infusion system. Neuromodulation : journal of the International Neuromodulation Society. 2003;6(3):133-141.

32. Martell, BA, PG O'Connor, RD Kernset al. Systematic review: Opioid treatment for chronic back pain: Prevalence, efficacy, and association with addiction. Annals of internal medicine. 2007;146(2):116-127.

33. Mekhail, N, R Mahboobi, A Farajzadeh Deroeeet al. Factors that might impact intrathecal drug delivery (idd) dose escalation: A longitudinal study. Pain practice : the official journal of World Institute of Pain. 2014;14(4):301-308.

34. Narouze, SN, SN Narouze, J Casanova and D Souzdalnitski. Patients with a history of spine surgery or spinal injury may have a higher chance of intrathecal catheter granuloma formation. Pain Practice,. 2014;14(1):57-63.

35. Neuman, SA, JS Eldrige, W Quet al. Post dural puncture headache following intrathecal drug delivery system placement. Pain Physician,. 2013;16(2):101-107.

36. Noble, M, JR Treadwell, SJ Tregearet al. Long-term opioid management for chronic noncancer pain. The Cochrane database of systematic reviews. 2010(1):1-68.

37. Patel, VB, L Manchikanti, V Singh, DM Schultz, SM Hayek and HS Smith. Systematic review of intrathecal infusion systems for long-term management of chronic non-cancer pain. Pain physician. 2009;12(2):345-360.

38. Paulozzi, LJ and GW Ryan. Opioid analgesics and rates of fatal drug poisoning in the United States. American journal of preventive medicine. 2006;31(6):506-511.

39. Raffaeli, W, D Righetti, A Caminitiet al. Implantable intrathecal pumps for the treatment of noncancer chronic pain in elderly population: Drug dose and clinical efficacy. Neuromodulation: Journal of the International Neuromodulation Society. 2008;11(1):33-39.

40. Raphael, JH, RV Duarte, JL Southall, P Nightingale and GD Kitas. Randomised, double-blind controlled trial by dose reduction of implanted intrathecal morphine delivery in chronic non-cancer pain. BMJ open. 2013;3(7). pii(7):e003061.

41. Raphael, JH, JL Southall, TV Gnanadurai, GJ Treharne and GD Kitas. Long-term experience with implanted intrathecal drug administration systems for failed back syndrome and chronic mechanical low back pain. BMC musculoskeletal disorders. 2002;3:17.

42. Rauck, RL, MS Wallace, MS Leonget al. A randomized, double-blind, placebo-controlled study of intrathecal ziconotide in adults with severe chronic pain. Journal of pain and symptom management. 2006;31(5):393-406.

43. Reig, E and D Abejon. Continuous morphine infusion: A retrospective study of efficacy, safety, and demographic variables. Neuromodulation : journal of the International Neuromodulation Society. 2009;12(2):122-129.

44. Roberts, LJ, PM Finch, CR Goucke and LM Price. Outcome of intrathecal opioids in chronic non-cancer pain. European journal of pain (London, England). 2001;5(4):353-361.

45. Saltari Maria, R, A Shaladi, B Pivaet al. The management of pain from collapse of osteoporotic vertebrae with continuous intrathecal morphine infusion. Neuromodulation : journal of the International Neuromodulation Society. 2007;10(2):167-176.

46. Shaladi, A, MR Saltari, B Pivaet al. Continuous intrathecal morphine infusion in patients with vertebral fractures due to osteoporosis. The Clinical journal of pain. 2007;23(6):511-517.

47. Siegler, A, E Tuazon, D Bradley O'Brien and D Paone. Unintentional opioid overdose deaths in new york city, 2005-2010: A place-based approach to reduce risk. International Journal of Drug Policy. 2014;25(3):569-574.

48. Staats, PS, T Yearwood, SG Charapataet al. Intrathecal ziconotide in the treatment of refractory pain in patients with cancer or aids: A randomized controlled trial. Jama. 2004;291(1):63-70.

49. Thimineur, MA, E Kravitz and MS Vodapally. Intrathecal opioid treatment for chronic non-malignant pain: A 3-year prospective study. Pain. 2004;109(3):242-249.

50. Turner, JA, JM Sears and JD Loeser. Programmable intrathecal opioid delivery systems for chronic noncancer pain: A systematic review of effectiveness and complications. The Clinical journal of pain. 2007;23(2):180-195.

51. Tutak, U and DM Doleys. Intrathecal infusion systems for treatment of chronic low back and leg pain of noncancer origin. Southern medical journal. 1996;89(3):295-300.

52. Wallace, MS, SG Charapata, R Fisheret al. Intrathecal ziconotide in the treatment of chronic nonmalignant pain: A randomized, double-blind, placebo-controlled clinical trial. Neuromodulation : journal of the International Neuromodulation Society. 2006;9(2):75-86.

53. Wallace, MS, R Rauck, R Fisher, SG Charapata, D Ellis and S Dissanayake. Intrathecal ziconotide for severe chronic pain: Safety and tolerability results of an open-label, long-term trial. Anesthesia and analgesia. 2008;106(2):628-637.

54. Wallace, MS, RL Rauck and T Deer. Ziconotide combination intrathecal therapy: Rationale and evidence. The Clinical journal of pain. 2010;26(7):635-644.

55. Wesemann, K, RJ Coffey, Y Tan, S Broste, MS Wallace and A Buvanendran. Clinical accuracy and safety using the synchromed ii intrathecal drug infusion pump. Regional Anesthesia and Pain Medicine. 2014;39(4):341-346.

56. Willis, KD and DM Doleys. The effects of long-term intraspinal infusion therapy with noncancer pain patients: Evaluation of patient, significant-other, and clinic staff appraisals. Neuromodulation : journal of the International Neuromodulation Society. 1999;2(4):241-253.