

Intrathecal Opioid Therapy for Management of Chronic Pain

Date of Origin: 01/2000

Last Review Date: 09/26/2018

Effective Date: 09/27/2018

Dates Reviewed: 11/2002, 12/2003, 12/2004, 12/2005, 12/2006, 12/2007, 01/2009, 03/2011, 01/2012, 10/2012, 01/2014, 01/2015, 10/2015, 09/2016, 09/2017, 09/2018

Developed By: Medical Necessity Criteria Committee

I. Description

Opioids delivered via an intrathecal implantable infusion pump provide effective pain relief of chronic intractable pain while limiting the adverse effects associated with long-term systemic administration of potent analgesics. Due to the invasive nature of this treatment and the potentially serious complications associated with the implanted infusion pumps and catheters, intrathecal opioid therapy is generally undertaken only as a last resort after other forms of pain management have been tried and proven ineffective.

II. Criteria: CWQI HCS-0044A

- A. Moda Health will cover a **trial** of an implantable infusion pump for pain management to plan limitations when **All** of the following criteria are met:
- a. The patient has a life expectancy of at least 3 months; and
 - b. The device must have FDA approval and be used specifically for the FDA approved purpose; and
 - c. The drugs used to fill the implantable pump must be appropriate for the treatment of the individual patient.
 - d. The administration of the medication must reasonably be expected to alleviate or reduce the pain effects
 - e. Administration of the opioid drugs, singly or in combination with other opioid or non-opioid drugs must require the intrathecal or epidural route and be effective on a long-term basis
 - f. The patient has demonstrable pathology found through diagnostic testing that is related to their pain complaints; and
 - g. An evaluation by an orthopedic surgeon, neurologist, neurosurgeon, oncologist or other specialist familiar with the underlying disease is required to validate that other treatments have failed to alleviate the pain and no other reasonable options are available at the time of the evaluation and that all other appropriate methods of pain control/pain management have been tried and proven ineffective or complicated by unacceptable side effects, including but not limited to **ALL** of the following:
 - i. Physical therapy or exercise programs
 - ii. Rest and relaxation
 - iii. Oral/transdermal pain medications
 - iv. Non-prescription analgesics and anti-inflammatories

- v. Injectable pain medications (IM, SQ, or IV injections)
 - vi. Local/regional blocks or epidural steroid injections; and
 - h. Patient has completed a psychological evaluation with clearance for non-cancer related indications.
 - i. Surgical intervention is not indicated; and
 - j. No known obstruction to cerebral spinal fluid flow
- B. Moda Health will cover the permanent placement of an implantable infusion pump when the above criteria has been met and a positive response to an intrathecal opioid infusion trial is shown by documentation of the ability to conduct usual daily activities with a 50% reduction in pain.
- C. Contraindications to implantable infusion pumps:
- a. Patients with other implanted programmable devices, such as cardiac pacemakers
 - b. Patients whose body size is insufficient to support the bulk and weight of the device
 - c. Patients with a known allergy or hypersensitivity to the drug being used
 - d. Patients who have an infection
 - e. Patients with a history of drug abuse or addiction; active psychosis or suicidality; untreated major depression or mood disorder; or patients with compromised reasoning, judgment, or memory

III. Information Submitted with the Prior Authorization Request:

1. Complete history and physical from treating physician
2. Medical records from the treating physician outlining conservative therapy trials, duration, and results
3. Documentation of patient's current activity level
4. For permanent pump placement, documentation of the results of the patient's response to the intrathecal opioid trial

IV. CPT or HCPC codes covered:

| Codes | Description |
|-------|--|
| 36563 | Insertion of tunneled centrally inserted central venous access device with subcutaneous pump |
| 36576 | Repair of central venous access device, with subcutaneous port or pump, central or peripheral insertion site |
| 36578 | Replacement, catheter only, of central venous access device, with subcutaneous port or pump, central or peripheral insertion site |
| 36583 | Replacement, complete, of a tunneled centrally inserted central venous access device, with subcutaneous pump, through same venous access |
| 36590 | Removal of tunneled central venous access device, with subcutaneous port or pump, central or peripheral insertion |
| 62324 | Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic |

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| | 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) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, , interlaminar epidural or subarachnoid; cervical or thoracic, with imaging guidance (fluoroscopy or CT) |
| 62326 | Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including 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) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid; lumbar or sacral (caudal), with imaging guidance (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 |
| 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 |
| 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) |

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| 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) |
| E0785 | Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement |
| J0476 | Injection, baclofen, 50 mcg for intrathecal trial |
| J0735 | Injection, clonidine HCl, 1 mg |
| J1230 | Injection, methadone HCl, up to 10 mg |
| J2270 | Injection, morphine sulfate, up to 10 mg |
| J3490 | Injection, Bupivacaine or Sufentanil- drugs not otherwise classified |
| J7999 | Compounded drug, not otherwise classified |
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V. Annual Review History

| Review Date | Revisions | Effective Date |
|-------------|--|----------------|
| 01/2014 | Annual Review: Added table with review date, revisions, and effective date. | 01/22/2014 |
| 01/2015 | Annual Review: No change | 01/28/2015 |
| 10/15 | Annual Review: Revised to be consistent with CMS guideline. Added ICD-10 codes | 10/28/2015 |
| 09/2016 | Annual Review; updated CMS LCA guideline, updated codes, references | 09/28/2016 |
| 09/27/2017 | Annual Review: Added additional CPT codes, updated to new template | 09/27/2017 |
| 9/26/2018 | Annual Review: No change | 09/26/2018 |

VI. References

1. Wallace M. Treatment options for refractory pain: the role of intrathecal therapy. September 10, 2002, American Academy of Neurology Vol 59(5).
2. Practice guidelines for chronic pain management. 1997, National Guidelines Clearinghouse.
3. Anderson A, Burchiel K. A Prospective Study of Long-term Intrathecal Morphine in the Management of Chronic Nonmalignant Pain. February 1999, Neurosurgery, Vol 44(2) 289-301.
4. 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;14:283-312

5. Krames E, Olson K. Clinical realities and economic considerations: patient selection in intrathecal therapy. September 1997. J of Pain and Symptom Mgmt Vol 14(3) S3-12.
6. Paice J, Winkelmuller W, Burchiel K, et al. Clinical realities and economic considerations: efficacy of intrathecal pain therapy. September 1997. J of Pain and Symptom Mgmt. Vol 14(3) S14-26.
7. Kaplan KM, Brose WG. Intrathecal methods. Neurosurg Clin N Am. 2004 Jul; 15(3):289-96, vi.
8. Miles J. Intrathecal therapy for chronic pain. Stereotact Funct Neurosurg. 2001; 77(1-4):156-8.
9. Centers for Medicare & Medicaid Services: Local Coverage Article: Implantable Infusion Pumps for Chronic Pain (A55323); Noridian Healthcare Solutions, LLC; Effective Date 09/01/2016.
10. Physician Advisors

Appendix 1 – Applicable Diagnosis Codes including but not limited to:

| Codes | Description |
|--------|--|
| G89.0 | Central pain syndrome |
| G89.21 | Chronic pain due to trauma |
| G89.22 | Chronic post-thoracotomy pain |
| G89.28 | Other chronic postprocedural pain |
| G89.29 | Other chronic pain |
| G89.3 | Neoplasm related pain (acute) (chronic) |
| G89.4 | Chronic pain syndrome |
| R25.0 | Abnormal head movements |
| R25.1 | Tremor, unspecified |
| R25.2 | Cramp and spasm |
| R25.3 | Fasciculation |
| R25.9 | Unspecified abnormal involuntary movements |
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Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

| Jurisdiction(s): 5, 8 | NCD/LCD Document (s): |
|---|-----------------------|
| Noridian Local Coverage Article: Implantable Infusion Pumps for Chronic Pain (A55323) | |

<https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55323&ver=5&SearchType=Advanced&CoverageSelection=Local&ArticleType=Ed%7cKey%7cSAD%7cFAQ&PolicyType=Final&s=5%7c6%7c66%7c67%7c9%7c38%7c63%7c41%7c64%7c65%7c44&Keyword=infusion+pumps&KeywordLookup=Doc&KeywordSearchType=And&kq=true&bc=IAAAACAAAAAAA%3d%3d&>

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions

| Jurisdiction | Applicable State/US Territory | Contractor |
|--------------|--|------------------------------------|
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |