

Intrathecal Opioid Infusion Pump Therapy for Management of Chronic Pain

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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, 09/2019, 10/2020, 10/2021, 09/2022,

10/2023

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 device must have FDA approval and be used specifically for the FDA-approved purpose
 - b. The drugs used to fill the implantable pump must be appropriate for treating the individual
 - c. The administration of the medication must reasonably be expected to alleviate or reduce the pain effects
 - d. Administration of the opioid drugs, singly or in combination with other opioid or nonopioid drugs must require the intrathecal or epidural route and be effective on a long-term basis
 - e. The patient has demonstrable pathology found through diagnostic testing that is related to their pain complaints; and
 - f. 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
- g. Patient has completed a psychological evaluation with clearance for non-cancer related indications.
- h. Surgical intervention is not indicated; and
- i. 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 have 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 where the crosstalk between devices may inadvertently change the prescription
 - 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 active infection that may increase the risk associated with the implantable infusion pump
 - 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 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)
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	

V. Annual Review History

Review Date	Revisions	Effective Date
01/2014	Annual Review: Added table with a review date, revisions, and effective	01/22/2014
	date.	
01/2015	Annual Review: No change	01/28/2015
10/15	Annual Review: Revised to be consistent with CMS guidelines. Added	10/28/2015
	ICD-10 codes	
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
09/26/2018	Annual Review: No change	09/26/2018
09/25/2019	Annual Review: No change	10/01/2019
10/28/2020	Annual Review: Removed indication; - minimum life expectancy of 3-	11/02/2020
	months; grammar updates	
10/27/2021	Annual Review: added 'Infusion pump' wording to title	11/1/2021
09/28/2022	Annual Review: no changes	10/1/2022
10/25/2023	Annual Review: no changes	11/1/2023

VI. References

- 1. Implantable Infusion Pump. Centers for Medicare & Medicaid Services. Retrieved from https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35112 09/2022
- 2. Wallace M. Treatment options for refractory pain: the role of intrathecal therapy. September 10, 2002, American Academy of Neurology Vol 59(5).
- 3. Practice guidelines for chronic pain management. 1997, National Guidelines Clearinghouse.
- 4. 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.
- 5. 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
- 6. 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.
- 7. 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.

- 8. Kaplan KM, Brose WG. Intrathecal methods. Neurosurg Clin N Am. 2004 Jul; 15(3):289-96, vi.
- 9. Miles J. Intrathecal therapy for chronic pain. Stereotact Funct Neurosurg. 2001; 77(1-4):156-8.
- 10. Centers for Medicare & Medicaid Services: Local Coverage Article: Implantable Infusion Pumps for Chronic Pain (A55323); Noridian Healthcare Solutions, LLC; Effective Date 09/01/2016.
- 11. 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

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)		
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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