

**Policy: MP293**

**Section: Medical Benefit Policy**

**Subject: Intrathecal Infusion Pump**

### Applicable Lines of Business

<b>Commercial</b>	<b>X</b>	<b>CHIP</b>	<b>X</b>
<b>Medicare</b>	<b>X</b>	<b>ACA</b>	<b>X</b>
<b>Medicaid</b>	<b>X</b>		

### I. Policy: Intrathecal Infusion Pump

### II. Purpose/Objective:

To provide a policy of coverage regarding Intrathecal Infusion Pump

### III. Responsibility:

- A. Medical Directors
- B. Medical Management

### IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

### V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

### Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

**DESCRIPTION:**

An implantable infusion pump that is intended to provide long-term, continuous or intermittent infusion of pain medication or anti-spasmodic medication.

**Implantable Infusion Pump for the Treatment of non-malignant Chronic Intractable Pain**

**INDICATIONS: Requires Prior Authorization by a Plan Medical Director or designee**

The intrathecal infusion pump is used as a last resort to treat chronic intractable non-malignant pain. An intrathecal infusion pump for administration of opioid or other non-opiate analgesic medication for long term use is considered medically necessary when **all** of the following criteria are met:

1. For the treatment of severe, chronic, intractable and disabling pain with one of the following diagnoses:
  - a. Advanced primary or metastatic carcinoma
  - b. CRPS Type I or Type II refractory to other treatments
  - c. Postherpetic neuralgia
  - d. Failed back surgery
  - e. Phantom limb pain
  - f. Arachnoiditis
  - g. Spinal cord myopathy/ myelopathy
  - h. Complex/severe vertebral compression fractures

**And**

2. An evaluation must be done by a multi-disciplinary team, which must include a psychological evaluation that states there are no behavioral health contraindications; **and**
3. Documented failure or contraindication to physical therapy or chiropractic care. There must be documentation of a minimum of 4 weeks of physical therapy or chiropractic care at least 2 times per week for the four weeks (minimum of 8 visits) within one year of the request for injections. The therapy **MUST** be associated with the body area that will be treated with the requested injections. A home exercise program is not an adequate substitute for formal physical therapy or chiropractic care. If the provider indicates the member cannot do physical therapy or chiropractic care due to pain, the provider must submit documentation from an evaluating physical therapist or chiropractor dated within 4 weeks of the request indicating the member cannot tolerate therapy services. Please note that one visit for injection to allow the member to attend therapy is not considered medically necessary. Please also note that completion of less than the minimum number of therapy or chiropractor visits due to non-compliance is not an acceptable alternative to this requirement in the absence of documentation the member was unable to tolerate therapy services; **and**
4. Documented failure or contraindication to pharmacologic therapy. There must be documentation of the use of at least three (3) classes of medications from the following list of medication classes must be submitted for review: NSAIDs, opiates, non-opioid analgesics, anti-epileptic medications used for treatment of chronic pain, antidepressant medications used for treatment of chronic pain, ASA or ASA derivatives, muscle relaxants, steroids, such as prednisone or Medrol or documented contraindication to each of these drug classes; **and**
5. Documented failure or contraindication to nerve blocks/ epidural injections; **and**
6. Documented failure or contraindication to surgical intervention; **and**
7. A preliminary trial of opioid administration via intrathecal/epidural catheter or via epidural injections with opioids with a noted reduction of at least 50% of the pain symptoms with minimal side effects. **NOTE:** The preliminary trial also requires prior authorization and must meet criteria 1, 2 and 3.

**CONTRAINDICATIONS:**

1. Severe spinal stenosis with intraspinal obstruction
2. Physical addiction to opioid medications
3. Infection
4. Pain that is primarily psychogenic in nature

**EXCLUSIONS:**

The Plan does **NOT** provide coverage for intrathecal infusion pump for any other indication not listed because it is considered **experimental, investigational or unproven.**

## **Implantable Infusion Pump for the Treatment of Malignant Intractable Pain**

### **INDICATIONS: Requires Prior Authorization by a Plan Medical Director or designee**

An intrathecal infusion pump for administration of opioid or other non-opiate fixed-dose analgesic medication is considered medically necessary when all of the following criteria are met:

- Opioids or other analgesics in adequate fixed schedule systemic dosing have not provided adequate pain relief or have resulted in intolerable side effects
- A temporary trial of opiates or non-opiate analgesics has been documented as providing a reduction of at least 50% of the pain symptoms
- Life expectancy is greater than 3 months\*
- There are no contraindications to the implantation of the pump

\*For shorter life expectancy, less invasive external infusion pumps provide comparable pain relief in the short term and are considered to be standard of care.

## **Intrathecal Infusion Pump for Administration of Anti-Spasmodic Agents**

### **INDICATIONS: Requires Prior Authorization by a Plan Medical Director or designee**

An intrathecal infusion pump for administration of anti-spasmodic agents, such as but is not limited to Baclofen, for long-term use is considered medically necessary when **all** of the following criteria are met:

1. Diagnosis of chronic intractable spasticity; **and**
2. At least 1 year after traumatic brain injury; **and**
3. Unresponsive to conservative treatment; **and**
4. Documented trial and failure to control spasms or intolerant side effects to 3 or more anti-spasmodic agents; **and**
5. Documented failure or contraindication to physical therapy or chiropractic care. There must be documentation of a minimum of 4 weeks of physical therapy or chiropractic care at least 2 times per week for the four weeks (minimum of 8 visits) within one year of the request for injections. The therapy **MUST** be associated with the body area that will be treated with the requested injections. A home exercise program is not an adequate substitute for formal physical therapy or chiropractic care. If the provider indicates the member cannot do physical therapy or chiropractic care due to pain, the provider must submit documentation from an evaluating physical therapist or chiropractor dated within 4 weeks of the request indicating the member cannot tolerate therapy services. Please note that one visit for injection to allow the member to attend therapy is not considered medically necessary. Please also note that completion of less than the minimum number of therapy or chiropractor visits due to non-compliance is not an acceptable alternative to this requirement in the absence of documentation the member was unable to tolerate therapy services; **and**

A favorable response to a trial of the planned anti-spasmodic medication that is planned to be administered via intrathecal infusion pump

**NOTE:** The preliminary trial also requires prior authorization and must meet criteria.

## **Elastomeric Infusion Pumps**

### **Prior Authorization is NOT required for peri-operative or post-operative use.**

Elastomeric pumps are intended for intermittent or continuous delivery of local anesthetics or narcotics to surgical wound sites or close proximity to nerves for regional anesthesia and pain management.

- Continuous local delivery of anesthesia to operative sites using an elastomeric infusion pump is considered medically necessary when narcotics or other analgesia for postoperative pain management are required.

## **FOR MEDICARE LINE OF BUSINESS**

**NOTE:** Disposable drug delivery systems, including elastomeric infusion pumps (A4305, A4306, and A9274) are not covered because they do not meet the Medicare definition of DME.

## **EXCLUSIONS:**

The Plan does **NOT** provide coverage for intrathecal infusion pump for any other indication not listed because it is considered **experimental, investigational or unproven**.

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

### **Medicaid Business Segment:**

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

#### **CODING ASSOCIATED WITH: Intrathecal Infusion Pump**

***The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

- 62324 Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, 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) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic;with imaging guidance (ie, fluoroscopy or CT)
- 62326 Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, 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) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal)with imaging guidance (ie, 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
- 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
- 62355 Removal of previously implanted intrathecal or epidural catheter
- 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
- 62368 Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation or reservoir status, alarm status, drug prescription status); with reprogramming
- 62369 Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation or 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 or reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified healthcare professional)
- 95990 Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular)
- C1772 Infusion pump, programmable (implantable)
- C1891 Infusion pump, nonprogrammable, permanent (implantable)
- C2626 Infusion pump, nonprogrammable, temporary (implantable)
- E0782 Infusion pump, implantable, non-programmable (includes all components, e.g., pump, catheter, connectors, etc.)
- E0783 Infusion pump, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)
- E0785 Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement

**LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

**REFERENCES:**

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

Australian Safety and Efficacy Register of New Interventional Procedures; Surgical Implantable Spinal Infusion Devices for Chronic Pain and Spasticity. 2003; 1-46.

American Society of Anesthesiologists, Inc. Practice guidelines for chronic pain management: An updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology*. 2010; 112(4) - 810-833.

Azouvi, P, Mane, M, et. al. Intrathecal baclofen administration for control of severe spinal spasticity: functional improvement and long-term follow-up. *Archives of Physical Medicine & Rehabilitation*. January 1996; 77(1):35-9.

Middel, B, Kuipers-Umppeijer, H, et. al. Effect of intrathecal baclofen delivered by an implanted programmable pump on health related quality of life in patients with severe spasticity. *Journal of Neurology, Neurosurgery & Psychiatry*. August 1997; 63(2):204-9.

Ordia J, Fischer E, et. al. Chronic intrathecal delivery of baclofen by a programmable pump for the treatment of severe spasticity. *Journal of Neurosurgery*. 1996, 85: 452-57.

Pohl M, Rockstroh G, Ruckriem S, et al. Time course of the effect of a bolus dose of intrathecal baclofen on severe cerebral spasticity. *J Neurol*. 2003; 250(10):1195-1200

Gooch JL, Oberg WA, Grams B, et al. Care provider assessment of intrathecal baclofen in children. *Dev Med Child Neurol*. 2004; 46(8):548-552

Albright AL, Gilmartin R, Swift D, et al. Long-term intrathecal baclofen therapy for severe spasticity of cerebral origin. *J Neurosurg*. 2003; 98(2):291-295

Falco FJ, Patel VB, Hayek SM, et al. Intrathecal infusion systems for long-term management of chronic noncancer pain: an update of assessment of evidence. *Pain Physician*. Apr 2013;16(2 Suppl):SE185-216

Hamza M, Doleys D, Wells M et al. Prospective study of 3-year follow-up of low-dose intrathecal opioids in the management of chronic nonmalignant pain. *Pain Med* 2012; 13(10):1304-13.

Smith TJ, Staats PS, Deer T, et al. Implantable Drug Delivery Systems Study Group. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain: impact on pain, drug-related toxicity, and survival. *J Clin Oncol*. 2002; 20(19):4040-4049

Gilmer-Hill HS, Boggan JE, Smith KA, Wagner FC Jr. Intrathecal morphine delivered via subcutaneous pump for intractable cancer pain: a review of the literature. *Surg Neurol*. 1999; 51(1):12-15.

Myers J, Chan V, Jarvis V, et al. Intraspinal techniques for pain management in cancer patients: a systematic review. *Support Care Cancer*. Feb 2010;18(2):137-149

J. H. Raphael, R. V. Duarte, J. L. Southall, P. Nightingale, and G. D. Kitas, Randomised, double-blind controlled trial by dose reduction of implanted intrathecal morphine delivery in chronic non-cancer pain, *BMJ open*, vol. 3, p. e003061, 2013.

Malheiro L, Gomes A, Barbosa P, et al. Infectious complications of intrathecal drug administration systems for spasticity and chronic pain: 145 patients from a tertiary care center. *Neuromodulation*. Jul 2015; 18(5):421-427.

Deer TR, Pope JE, Hayek SM, et al. The polyanalgesic consensus conference (PACC): recommendations on intrathecal drug infusion systems best practices and guidelines. *Neuromodulation*. 2017;20(2):96 – 132.

Centers for Medicare & Medicaid Services. Novitas Solutions, Inc. Local Coverage Determination (LCD): Implantable Infusion Pump (L35112) - **RETIRED**

Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Infusion Pumps (280.14)

National Comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology: adult cancer pain. V2.2023

Hu L, Zheng Y, Lin J, et al. Does adjuvant hepatic artery infusion chemotherapy improve patient outcomes for hepatocellular carcinoma following liver resection? A meta-analysis. World J Surg Oncol. 2023; 21(1):121.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 01/15

**Revised:** 2/17 (combined policies)

**Reviewed:** 3/18, 3/19, 3/20, 3/21, 3/22, 3/23, 3/24

**CMS UM Oversight Committee Approval:** 12/23, 5/24

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.