National Imaging Associates, Inc.*	
Clinical guidelines: **IMPLANTABLE INFUSION PUMP INSERTION**	**Original Date: July 2015**
CPT Codes: **62350, 62351, 62355, 62360, 62361, 62362**	**Last Revised Date: ~~June~~ May 2021~~1~~**
Guideline Number: NIA_CG_310	**Implementation Date: January 2023~~2~~**

INDICATIONS FOR IMPLANTABLE INFUSION PUMP INSERTION

~~**For the Treatment of Chronic Intractable Pain**~~

An intraspinal drug trial for the treatment of chronic intractable pain is appropriate when ALL the following criteria are met:

~~**NOTE**: Intrathecal trials are not indicated in opiate-naïve patients.~~

- Pain causing functional disability that significantly interferes with activities of daily living including ability to work and overall quality of life; ~~or~~ **OR** persistent pain levels of ≥ 6 on a scale of 0 to 10 despite treatment
- **Failure to respond to non-operative conservative therapy* for a minimum of 12 weeks, including a combination of both active and inactive components**
- ~~At least 12 weeks of conservative therapy*~~
  - ~~Including both inactive and active components~~
  - ~~Including 12 weeks of oral or transdermal opiate pain medications~~
- A life expectancy of at least 3 months

- **NOTE: Intrathecal trials are not indicated in opiate-naïve individuals.**

A permanently implanted infusion pump for the treatment of chronic intractable pain is appropriate when ALL the following criteria are met:

* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

- **Pain causing functional disability that significantly interferes with activities of daily living, including ability to work and overall quality of life; OR persistent pain levels of ≥ 6 on a scale of 0 to 10 despite treatment**
- **Failure to respond to non-operative conservative therapy* for a minimum of 12 weeks including a combination of both active and inactive components**
- **At least 12 weeks of oral or transdermal opiate pain medications**
- **A life expectancy of at least 3 months**
- **Documentation of a successful trial of intraspinal (intrathecal or epidural) opioid medication administered as a bolus or by continuous infusion providing at least 50% pain relief with tolerable side effects**
- **Documentation of a completed psychological assessment prior to permanent pump insertion that documents the individual's cognitive ability, willingness, and ability to participate in implanted infusion pump therapy**

- ~~Severe, chronic, intractable malignant or nonmalignant pain that significantly interferes with activities of daily living including ability to work and overall quality of life that has not responded to **at least 12 weeks** of standard nonsurgical therapies (e.g., systemic medications including oral opioid therapy unless contraindicated, physical and psychological therapies, or cognitive behavioral, etc.); **AND**~~
- ~~Documentation of completion of a satisfactory trial (see Note) of intraspinal (intrathecal or epidural) opioid drugs, administered as a bolus or by continuous infusion, with acceptable pain relief, acceptable degree of side effects and patient acceptance of mode of treatment~~
  - ~~Intraspinal drug trial provides ≥ 50% pain relief; **AND**~~
  - ~~Side effects are tolerable; **AND**~~

  ~~**NOTE**: Satisfactory trials include a bolus dose or continuous dosing depending upon clinical response (dosage and catheter placement may be manipulated).~~
- ~~Patient must have a life expectancy of at least 3 months; **AND**~~
- ~~Documentation of completed psychological assessment prior to IIP implantation, including the patient's cognitive ability, willingness, and ability to participate in IIP therapy.~~

~~**For the Treatment of Spasticity**~~

An intraspinal drug trial for the treatment of spasticity is appropriate when ALL ~~of~~ the following criteria are met:

- I~~Evidence of i~~ntractable spasticity that results in the ~~patient~~**individual**'s inability to maintain an upright posture, **severely impairs** balance in ambulation, or ~~increased function~~**significantly interferes with activities of daily living** related to **one** of the following conditions[1] ~~(McIntyre, 2014)~~:
  - Spinal cord injury~~; **OR**~~
  - Multiple sclerosis~~; **OR**~~
  - Stiff person syndrome~~; **OR**~~

- Other medical conditions causing intractable spasms~~.~~
- Severe, uncontrollable spasms that have **failed to respond to a minimum of 12 weeks** ~~not responded to **at least 12 weeks**~~ of standard therapies (e.g., oral medications, physical therapy, etc.)~~.~~
- ~~Patient~~**A** ~~must have a~~ life expectancy of at least 3 months~~.~~

A permanently implanted infusion pump for the treatment of spasticity is appropriate when ALL of the following criteria are met:

- ~~Evidence of intractable~~**Intractable** spasticity that results in the ~~patient~~**individual's** inability to maintain an upright posture, **severely impairs** balance in ambulation, or ~~increased function~~**significantly interferes with activities of daily living** related to **one** of the following conditions[1] ~~(McIntyre, 2014)~~:
  - Spinal cord injury~~; **OR**~~
  - Multiple sclerosis~~; **OR**~~
  - Stiff person syndrome~~; **OR**~~
  - Other medical conditions causing intractable spasms~~; **AND**~~
- Severe, uncontrollable spasms that ~~have not responded~~**failed to respond to a minimum of** ~~to at least~~ 12 weeks of standard therapies (e.g., oral medications, physical therapy, etc.)~~; **AND**~~
- **A life expectancy of at least 3 months**
- **Documentation of a successful trial of intraspinal (intrathecal or epidural) antispasmodic medication administered as a bolus or by continuous infusion providing at least 50% spasm relief with tolerable side effects**
- **Documentation of a completed psychological assessment prior to permanent pump insertion that documents the individual's cognitive ability, willingness, and ability to participate in implanted infusion pump therapy**
- ~~Documentation of completion of a satisfactory intrathecal trial (see Note) of the antispasmodic drug defined as:~~
  - ~~Intraspinal drug trial provides ≥ 50% spasm relief; **AND**~~
  - ~~Side effects are tolerable; **AND**~~

  ~~**NOTE**: Satisfactory trials include a bolus dose or continuous dosing depending upon clinical response (dosage and catheter placement may be manipulated).~~
- ~~Patient must have a life expectancy of at least 3 months; **AND**~~
- ~~Documentation of completed psychological assessment prior to IIP implantation, including the patient's cognitive ability, willingness, and ability to participate in IIP therapy~~

INDICATIONS FOR PUMP REPLACEMENT

Replacement of an Implanted Infusion Pump is indicated with one of the following:

- **Documentation of a pump malfunction impairing function or safety**
- **Battery depletion**

NOTE: If the pump is programmable, the pump analysis report should accompany the request for replacement.

CONTRAINDICATIONS FOR IMPLANTED INFUSION PUMP

- **Active systemic or spinal infection**
- **Body habitus that is insufficient to support the weight and bulk of the device**

NOTE: There are no other medical indications for other intrathecal treatments except chronic pain and intractable spasticity.

- ~~Documentation of a pump malfunction impairing function or safety~~
  - ~~Documentation must clearly state it is the pump that is defective;~~ ~~**AND**~~
  - ~~If the pump is programmable, the pump analysis report must accompany the request;~~ ~~**AND**~~
  - ~~Absence of contraindications to anesthesia and surgery.~~
- ~~Battery depletion~~
  - ~~Documentation of both safety and efficacy of this treatment for this patient.~~
    - ~~Degree of pain relief;~~ ~~**AND**~~
    - ~~Functional improvement;~~ ~~**AND**~~
    - ~~Side effects;~~ ~~**AND**~~
  - ~~If the pump is programmable, the pump analysis report must accompany the request;~~ ~~**AND**~~
  - ~~Absence of contraindications to anesthesia and surgery.~~

~~**CONTRAINDICATED FOR ANY OF THE FOLLOWING**~~

- ~~There are no other medical indications for other intrathecal treatments except for pain and spasticity~~
- ~~Patients with an active infection~~
- ~~Patients with a known allergy or hypersensitivity to a drug being used (e.g., morphine, etc.)~~
- ~~Patients with a body size that is insufficient to support the weight and bulk of the device~~

BACKGROUND

An implantable infusion pump (IIP), also referred to as an implantable drug delivery system (IDDS), is a device for the delivery of medication to manage severe, chronic, intractable pain and/or chronic intractable spasm. The purpose of this guideline is to address criteria for the permanent placement of an implantable infusion pump.

Description: An implanted pump releases medication through a catheter directly to the epidural or intrathecal space, which interrupts pain signals before they reach the brain. This mode of drug

delivery provides pain relief with less medication than oral dosing and helps to minimize the side effects associated with oral medications. An IIP consists of a programmable pump, an epidural or intrathecal catheter, and an external programmer. The pump is surgically implanted subcutaneously**; often with fluoroscopic guidance,** ~~,~~ the catheter tip is inserted in the epidural or intrathecal space, ~~often with fluoroscopic guidance,~~ and the catheter is connected to the pump. A screening or trial period is required to assess pain relief and to determine whether the ~~patient~~**individual** is a candidate for pump implantation.

Complications and side effects of IIP may include catheter dislodgement or occlusion, pump malfunction, arthralgia, decreased libido, erectile dysfunction, hematoma, infection, leakage, menstrual abnormalities, nausea and vomiting, nerve root irritation, peripheral edema, pruritus, decreased cognition, concentration or memory loss, and other complications associated with seating of the device and changes in weight.

Evidence Review[2] ~~(Chou, 2013)~~: Chronic pain is pain that continues or recurs ≥ 90 days. It may result from an initial injury or illness; however, there may be no apparent cause. Chronic pain may limit movement and affect the ability to carry out activities of daily living (ADL). It may lead to disability. Psychological effects may include anger, anxiety, depression, and fear of reinjury. Common chronic pain complaints include arthritis pain, back pain, headache, nerve pain (neurogenic), phantom pain, and psychogenic pain (no apparent cause). Chronic pain usually cannot be cured. The goal of treatment is to reduce pain and improve function. Treatment may include acupuncture, behavior modification, biofeedback, electrical stimulation, medications, nerve blocks, physical therapy, psychotherapy, relaxation therapy, or surgery.

Thimineur, et al. (2004)[3] performed a small nonrandomized prospective study of 69 ~~patient~~**individual**s with chronic intractable nonmalignant pain who met inclusion criteria for implantation of an IIP. An IIP was implanted in 39 ~~patient~~**individual**s while 31 ~~patient~~**individual**s served as the comparison group. The authors reported that pain intensity, mood, and function all improved significantly in the IIP recipient group compared with pretreatment and with the comparison-group ~~patient~~**individual**s. Minimal complications were reported.[3]

In consideration of the paucity of randomized controlled trials (RCTs), Hayek, et al. (2011)[4] conducted a systematic review of intrathecal infusion through IDDS for chronic malignant and nonmalignant pain. The authors evaluated the available evidence for the efficacy and safety of intrathecal infusions used in long-term management (> 6 months) of chronic pain. The authors' "moderate" recommendation for intrathecal infusion systems for malignant-related pain is based on Level II-2 evidence (i.e.**,** well-designed cohort and case-control analytic studies) and their recommendation is "limited to moderate" based on Level II-3 evidence of moderate quality from nonrandomized studies for nonmalignant-related pain.

Perruchoud, et al. (2022)[5] performed a meta-analysis of studies published between 1990 and 2019 to evaluate the efficacy of intrathecal drug delivery in individuals with cancer-related pain. The authors note that pain levels statistically dropped (-4.34 on a 10-scale after 4 – 5 weeks and -3.32 after 6 months) as compared to baseline. Infection rates were comparable between external pumps, internal pumps, and other indications; moreover, opioid consumption decreased, on average, more than 50%.

U.S. Preventive Services Task Force (USPSTF) Evidence Criteria~~:~~

- Authors based their recommendations on level of evidence criteria developed by the USPSTF, which rates the quality of evidence on a scale of I to III as follows[6]:

  - ~~o~~ I: Evidence obtained from at least one properly randomized controlled trial **(RCT)**
  - ~~o~~ IIa **(or II-1)**: Evidence obtained from well-designed controlled trials without randomization
  - ~~o~~ IIb **(or II-2)**: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
  - ~~o~~ IIc **(or II-3)**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence
  - ~~o~~ III: Opinions of respected authorities, based on clinical experience, descriptive studies, and case reports or reports of expert committees[6]
  -

~~Complications and side effects of IIP may include catheter dislodgement or occlusion, pump malfunction, arthralgia, decreased libido, erectile dysfunction, hematoma, infection, leakage, menstrual abnormalities, nausea and vomiting, nerve root irritation, peripheral edema, pruritus, decreased cognition, concentration, or memory, and other complications associated with seating of the device and changes in weight.~~

***Conservative Therapy - Non-operative treatment should include a multimodality approach consisting of a combination of active and inactive components. Inactive components can include rest, ice, heat, modified activities, medical devices, acupuncture, stimulators, medications, injections, and diathermy. Active modalities should be region-specific (targeting the cervical, thoracic, or lumbar spine) and consist of physical therapy, a physician-supervised home exercise program**, or chiropractic care.**[7-9]

****Home Exercise Program (HEP) - The following two elements are required to meet guidelines for completion of conservative therapy:**

- **Documentation of an exercise prescription/plan provided by a physician, physical therapist, or chiropractor[7, 10, 11] ; AND**

- **Follow-up documentation regarding completion of HEP after the required 6-week timeframe or inability to complete HEP due to a documented medical reason (i.e., increased pain or inability to physically perform exercises). Closure of medical offices, closure of therapy offices, patient inconvenience, or noncompliance without explanation does not constitute "inability to complete" HEP.**[7, 8]

~~***Conservative Therapy:** (Spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components such as rest, ice, heat, modified activities, medical devices, acupuncture or stimulators, medications, injections (including trigger point), and diathermy can be utilized. Active modalities consist of physical therapy, a physician supervised home exercise program**, or chiropractic care (Qassem, 2017; Summers, 2013).[7, 8]~~

~~****Home Exercise Program** - (HEP) – the following two elements are required to meet guidelines for completion of conservative therapy:~~

- ~~Documentation provided of an exercise prescription/plan[7, 10] (Qassem, 2017; Sculco, 2001); **AND**~~
- ~~Follow up with member with documentation provided regarding completion of HEP, (after suitable 6 week period) or inability to complete HEP due to physical reason i.e., increased pain, inability to physically perform exercises. Closure of medical offices, closure of therapy offices, patient inconvenience, or noncompliance without explanation does not constitute "inability to complete" HEP.~~

POLICY HISTORY

Date	Summary

May 2022	• **Reorganized and reworded indications for clarity and uniformity**
	• **Under permanent implanted infusion pump for treatment of chronic pain:**
	  ○ **Added OR persistent pain levels 6 or greater on a 10-point scale despite treatment**
	  ○ **Added requirement of minimum of 12 weeks of oral or transdermal opiate pain medications**
	• **Simplified indications for pump replacement**
	• **Updated Contraindications**

June 2021	No change
October 2020	• Added note: "Intrathecal trials are not indicated in opiate naïve patients".
October 2019	• Added: ○ Indications for the treatment of chronic intractable pain; and indications for pump replacement

	○ Specified method of delivery: Documentation of completion of a satisfactory trial *of intraspinal (intrathecal or epidural) opioid drugs, *administered as a bolus or by continuous infusion*, with acceptable pain relief, acceptable degree of side effects and patient acceptance of mode of treatment • Updated background information to include conservative therapy and home exercise program
November 2018	• Changed guideline title from 'Implantable Infusion Insertion Pump' to Implantable Infusion Pump Insertion' • For the treatment of chronic intractable pain, removed list of specified drugs • Deleted content: 'Drug is FDA approved' • In the description of an implantable pump, removed 'abdominal area' as the specified location of pump implantation; Removed the specified duration of "a minimum of 3 days in length' for the screening or trial period required to assess pain relief • Deleted an outdated study in the 'Evidence Review' • Added and updated references

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Reviewed / Approved by NIA Clinical Guideline Committee

~~**GENERAL INFORMATION**~~

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ADDITIONAL RESOURCES

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