*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: ~~May~~ January 2024~~3~~**
Guideline Number: NIA_CG_310	**Implementation Date: July ~~anuary~~ 2024**

Table Of Contents

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

STATEMENT

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.

PURPOSE

The purpose of this guideline is to address criteria for intraspinal drug trials as well as the permanent placement of an implantable infusion pump.

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

INDICATIONS FOR IMPLANTABLE INFUSION PUMP INSERTION

INTRASPINAL DRUG TRIAL~~For chronic intractable pain~~

~~An intraspinal drug trial F~~For the treatment of chronic intractable pain in non-terminal individuals (**ALL** ~~is appropriate when ALL~~ the following criteria must be ~~are~~ met):

- Pain causing functional disability that significantly interferes with activities of daily living including ability to work and overall quality of life; **OR** persistent pain level of ≥ 6 on a scale of 0 to 10 despite treatment
- Failure to respond to non-operative conservative therapy* targeting the requested spinal region for a minimum of 12 weeks unless the medical reason this treatment cannot be done is clearly documented

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

F~~An intraspinal drug trial f~~or the treatment of spasticity in non-terminal individuals ~~is appropriate when ALL~~(**ALL** the following must be~~criteria are~~ met):

- Intractable spasticity that results in the individual's inability to maintain an upright posture, severely impairs balance in ambulation, or significantly interferes with activities of daily living related to **ONE** of the following conditions [1]:
    - Spinal cord injury
    - Multiple sclerosis
    - Stiff person syndrome

- Other medical conditions causing intractable spasms
- Failure to respond to a minimum of 12 weeks of ~~standard~~non-operative conservative therap~~ies~~y (e.g., oral medications, physical therapy, etc.)

Additional Trials

A second intraspinal drug trial is indicated when documentation of the first trial of intraspinal (intrathecal or epidural) medication administered as a bolus or by continuous infusion resulted in one of the following:

- Less than 50% pain relief
- Intolerable side effects

Limit of two intraspinal drug trials for preliminary consideration of chronic intractable pain or spasticity management with permanent implantable device in non-terminal individuals.

NOTE: Intrathecal trials are not indicated in ~~opiate~~opioid-naïve individuals

PERMANENTLY IMPLANTED INFUSION PUMP

For the treatment of chronic intractable pain in non-terminal individuals (**ALL** the following must be met):

- Pain causing functional disability that significantly interferes with activities of daily living, including ability to work and overall quality of life; **OR** persistent pain level of ≥ 6 on a scale of 0 to 10 despite treatment
- Failure to respond to non-operative conservative therapy* targeting the requested spinal region for a minimum of 12 weeks unless the medical reason this treatment cannot be done is clearly documented
- At least 12 weeks of oral or transdermal ~~opiate pain~~opioid or nonopioid pain medications
- 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, physical capability, and willingness to participate in implanted infusion pump therapy
- ~~For spasticity~~

~~**An intraspinal drug trial for the treatment of spasticity in non-terminal individuals is appropriate when ALL the following criteria are met:**~~

- ~~Intractable spasticity that results in the individual's inability to maintain an upright posture, severely impairs balance in ambulation, or significantly interferes with activities of daily living related to **one** of the following conditions[1]:~~
  - ~~Spinal cord injury~~
  - ~~Multiple sclerosis~~
  - ~~Stiff person syndrome~~
  - ~~Other medical conditions causing intractable spasms~~

- ~~Failure to respond to a minimum of 12 weeks of standard therapies (e.g., oral medications, physical therapy, etc.)~~

For the treatment of spasticity in non-terminal individuals (**ALL** of the following must be met):

- Intractable spasticity that results in the individual's inability to maintain an upright posture, severely impairs balance in ambulation, or significantly interferes with activities of daily living related to **one** of the following conditions [1];
  - Spinal cord injury
  - Multiple sclerosis
  - Stiff person syndrome
  - Other medical conditions causing intractable spasms
- Failure to respond to a minimum of 12 weeks of ~~standard~~ conservative therapy ~~therapies~~ (e.g., oral medications, physical therapy, etc.)
- 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, physical capability, and willingness to participate in implanted infusion pump therapy

NOTE: Failure of conservative treatment is defined as one of the following:

- Lack of meaningful improvement after a full course of treatment; **OR**
- Progression or worsening of symptoms during treatment; **OR**
- Documentation of a medical reason the member is unable to participate in treatment (*Closure of medical or therapy offices, patient inconvenience, or noncompliance without explanation does not constitute "inability to complete" treatment*)

PUMP REPLACEMENT, REVISION AND REMOVAL

Replacement, revision, or removal of an Implanted Infusion Pump is indicated with one of the following:

- Loss of effectiveness (e.g., battery depletion)
- Intolerance by the individual
- Infection
- Painful generator site
- Patient demand

Documentation of pump or catheter malfunction impairing function or safety ~~Battery depletion~~~~Documentation of a pump malfunction impairing function or safety~~

- ~~Battery depletion~~
-
-
- **Other medical reason deemed appropriate for replacement, revision, or removal**

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

~~BACKGROUND~~

~~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, and the catheter is connected to the pump. A screening or trial period is required to assess pain relief and to determine whether the 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.~~

~~Thimineur, et al. (2004)[3] performed a small nonrandomized prospective study of 69 individuals with chronic intractable nonmalignant pain who met inclusion criteria for implantation of an IIP. An IIP was implanted in 39 individuals while 31 individuals 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 individuals. 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 (e.g., 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%.

***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 (e.g., 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 TREATMENT**

Non-operative conservative treatment should include a multimodality approach consisting of at least one (1) active and one (1) inactive component targeting the affected spinal region.

- Active components
  - Physical therapy
  - Physician-supervised home exercise program (HEP)**
  - Chiropractic care [2, 3]
- Inactive components
  - Medications (e.g., NSAIDs, steroids, analgesics)
  - Injections (e.g., epidural steroid injection, selective nerve root block)
  - Medical devices (e.g., TENS unit, bracing)

**** HOME EXERCISE PROGRAM (HEP)**

The following two elements are required to meet conservative therapy guidelines for HEP:

- Documentation of an exercise prescription/plan provided by a physician, physical therapist, or chiropractor [2]

  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)

POLICY HISTORY

Date	Summary
January 2024	• Added criteria for additional intrathecal trials • Expanded pump criteria to include non-opioid medical trials • Expanded replacement indications to also include revision and removal • Edited background
May 2023	Removed language 'A life expectancy of at least 3 months'

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

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Reviewed / Approved by NIA Clinical Guideline Committee

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