National Imaging Associates, Inc.*

2024 NIA Clinical Guidelines For Medical Necessity Review

INTERVENTIONAL PAIN MANAGEMENT GUIDELINES

Effective January 1, 2024 – December 31, 2024

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Guidelines for Clinical Review Determination

Preamble

NIA is committed to the philosophy of supporting safe and effective treatment for patients. The medical necessity criteria that follow are guidelines for the provision of diagnostic imaging. These criteria are designed to guide both providers and reviewers to the most appropriate diagnostic tests based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice will be used when applying the guidelines. Determinations are made based on both the guideline and clinical information provided at the time of the request. It is expected that medical necessity decisions may change as new evidence-based information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient.

Guideline Development Process

These medical necessity criteria were developed by National Imaging Associates, Inc. (NIA) for the purpose of making clinical review determinations for requests for therapies and diagnostic procedures. The developers of the criteria sets included representatives from the disciplines of radiology, internal medicine, nursing, cardiology, and other specialty groups. NIA's guidelines are reviewed yearly and modified when necessary following a literature search of pertinent and established clinical guidelines and accepted diagnostic imaging practices.

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TABLE OF CONTENTS

***National Imaging Associates, Inc.**	
Clinical guidelines: **EPIDURAL SPINE INJECTIONS**	**Original Date: October 2012**
CPT Codes: **Cervical Thoracic Region:** **62320, 62321, 64479 (+64480)** **Lumbar Sacral Region:** **62322, 62323, 64483 (+64484)**	**Last Revised Date: May 2023**
Guideline Number: NIA_CG_300	**Implementation Date: January 2024**

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.

Note: Any injection performed at least two years from prior injections in the same region will be considered a new episode of care and the **INITIAL** injection requirements must be met for approval. Events such as surgery on the same spinal region or any new pathology would also prompt a new episode of care.

INDICATIONS FOR EPIDURAL SPINE INJECTIONS OR SELECTIVE NERVE BLOCKS (Caudal, Interlaminar, Transforaminal)

See LEGISLATIVE REQUIREMENTS for specific mandates in the State of Washington

For the treatment of acute pain or exacerbation of chronic radicular pain[1] ALL of the following must be met:

- Neck or back pain with acute radicular symptoms[2]
- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10 [2-5]
- Duration of pain < 3 months
- Failure to respond to non-operative conservative therapy targeting the requested spinal region for a minimum of 2 weeks unless the medical reason this treatment cannot be done is clearly documented (active therapy components not required)[2, 3]

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For the treatment of spinal stenosis causing axial or radicular pain[1] ALL of the following must be met:

- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10 [2-5]
- Failure to respond to non-operative conservative therapy* targeting the requested spinal region for a minimum of 6 weeks in the last 6 months unless the medical reason this treatment cannot be done is clearly documented; OR details of engagement in ongoing non-operative conservative therapy* if the individual has had prior spinal injections in the same region[2, 3]

For the treatment of failed back surgery syndrome or epidural fibrosis causing axial[6, 7] or radicular pain[1] ALL of the following must be met:

- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10 [2-5]
- Documentation of a medical reason that clearly indicates why an injection is needed (not typically done immediately post-surgery)[3]
- Failure to respond to non-operative conservative therapy* targeting the requested spinal region for a minimum of 6 weeks in the last 6 months unless the medical reason this treatment cannot be done is clearly documented; OR details of engagement in ongoing non-operative conservative therapy* if the individual has had prior spinal injections in the same region[2, 3]

For a diagnostic transforaminal injection to identify the pain generator for surgical planning ALL of the following must be met:

- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10 [2-5]
- Documentation of a pre-operative evaluation and plan for surgery

NOTE: No more than 2 levels of transforaminal blocks should be done in one day.[8]

INDICATIONS FOR REPEAT INJECTIONS

Epidural injections may be repeated only as medically necessary. **Each** epidural injection requires an authorization, and the following criteria must be met for repeat injections:

- Up to 3 epidural injections may be performed in the initial treatment phase, no sooner than 2 weeks apart, provided that at least 30% pain relief or significant documented functional improvement is obtained[5]
- If an injection during the initial treatment phase is unsuccessful, another injection may be performed at a different level in the **same spinal region** or with a change in technique given there is a question about the pain generator or evidence of multi-level pathology
- Epidural injections may only be repeated after the initial treatment phase if the individual has had at least 50% pain relief or significant documented functional improvement for a **minimum of 2 months** after each therapeutic injection[3]

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- The individual continues to have pain causing functional disability or average pain level ≥ 6 on a scale of 0 to 10 [2, 3, 5]
- The individual is engaged in ongoing active conservative therapy*, unless the medical reason this treatment cannot be done is clearly documented[2, 9]
- In the first year of treatment, a total of 6 epidural injections may be performed **per spinal region** (this includes a series of 3 injections in the initial treatment phase and 3 additional therapeutic injections).[3]
- After the first year of treatment, a maximum of 4 epidural injections may be performed in a 12-month period **per spinal region**.[3, 5] If special circumstances are documented (e.g., elderly individual with severe spinal stenosis and not an operative candidate), then repeat injections are limited to a maximum of 6 epidural injections in a 12-month period per spinal region.[5]
- If different spinal regions are being treated, injections should be administered at intervals of no sooner than 7 days unless a medical reason is provided to necessitate injecting multiple regions on the same date of service (see NOTE).[3]

NOTE: It is generally considered **not medically necessary** to perform multiple interventional pain procedures on the same date of service. Documentation of a medical reason to perform injections in different regions on the same day can be provided and will be considered on a case-by-case basis (e.g., holding anticoagulation therapy on two separate dates creates undue risk for the patient). Different types of injections in the same spinal region (cervical, thoracic, or lumbar) should not be done on the same day with the exception of a facet injection and ESI performed during the same session for a synovial cyst confirmed on imaging.

EXCLUSIONS

These requests are excluded from consideration under this guideline:

- Intrathecal injections for pain or spasticity prior to permanent pump insertion
- Implantation of intrathecal catheters or ports for chemotherapy
- Post-operative pain control
- Caudal or spinal anesthesia for surgery

CONTRAINDICATIONS FOR EPIDURAL INJECTIONS

- Active systemic or spinal infection
- Skin infection at the site of needle puncture
- Severe spinal stenosis resulting in intraspinal obstruction

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Washington

- **Washington State Health Care Authority Technology Assessment**
  20160318B – Spinal Injections[10, 11]
  Limitations of Coverage*:
    - Therapeutic epidural injections in the lumbar or cervical-thoracic spine for chronic pain are a covered benefit when all of the following conditions are met:
        - For treatment of radicular pain
        - With fluoroscopic guidance or CT guidance
        - After failure of conservative therapy
        - No more than two without clinically meaningful improvement in pain and function; and
        - Maximum of three in six months.
    - Washington State Health Care Authority oversees the Apple Health (Medicaid) program and the Public Employees Benefits Board (PEBB) Program[12]

* This coverage policy does not apply to those with a known systemic inflammatory disease such as: ankylosing spondylitis, psoriatic arthritis or enteropathic arthritis

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BACKGROUND

Therapeutic Spinal Epidural Injections or Select Nerve Root Blocks (Transforaminal) are types of interventional pain management procedures. The therapeutic use of epidural injections is for short-term pain relief associated with acute back pain or exacerbation of chronic back pain. With therapeutic injections, a corticosteroid is injected close to the target area with the goal of pain reduction. Epidural injections should be used in combination with other active conservative treatment* modalities and not as stand-alone treatment for long-term back pain relief. Different approaches used when administering spinal epidural injections[13] include:

- **Interlaminar** epidural injections, with steroids, access the epidural space between two vertebrae (Interlaminar) to treat cervical, lumbar, or thoracic pain with radicular pain.[14] These procedures should be performed using fluoroscopic guidance.[15, 16] Interlaminar epidural injections are the most common type of epidural injection.
- **Transforaminal** epidural injections (also called selective nerve root blocks) access the epidural space via the intervertebral foramen where the spinal nerves exit (cervical, lumbar/sacral, or thoracic region). It is used both diagnostically and therapeutically. Some studies report lack of evidence and risks of transforaminal epidural injections.[17] These procedures are always aided with fluoroscopic guidance.[1, 16, 18-21]
- **Caudal** epidural injections, with steroids, are used to treat back and lower extremity pain, accessing the epidural space through the sacral hiatus, providing access to the lower nerve roots of the spine. These procedures should be performed using

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fluoroscopic guidance. Failed back surgery syndrome is the most common reason for the caudal approach.[3, 16, 21-23]

The rationale for the use of spinal epidural injections is that the sources of spinal pain, e.g., discs and joints, are accessible and amendable to neural blockade.

Medical necessity management for epidural injections includes an initial evaluation including history and physical examination as well as a psychosocial and functional assessment. The following must be determined: nature of the suspected organic problem; non-responsiveness to active conservative treatment*; level of pain and functional disability; conditions which may be contraindications to epidural injections; and responsiveness to prior interventions.

Interventional pain management specialists do not agree on how to diagnose and manage spinal pain; there is a lack of consensus with regards to the type and frequency of spinal interventional techniques for treatment of spinal pain. The American Society of Interventional Pain Physicians (ASIPP) guidelines recommend an algorithmic approach which provides a step-by-step procedure for managing chronic spinal pain based upon evidence-based guidelines.[1, 3] This approach is based on the structural basis of spinal pain and incorporates acceptable evidence of diagnostic and therapeutic interventional techniques available in managing chronic spinal pain.

The guidelines and algorithmic approach referred to above include the evaluation of evidence for diagnostic and therapeutic procedures in managing chronic spinal pain and recommendations for managing spinal pain. The Indications and Contraindications presented within this document are based on the guidelines and algorithmic approach. Prior to performing this procedure, shared decision-making between patient and physician must occur, and the patient must understand the procedure and its potential risks and results (moderate short-term benefits, and lack of long-term benefits).

OVERVIEW

***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.[2, 9, 24]

****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[9, 25, 26] ; **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,

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closure of therapy offices, patient inconvenience, or noncompliance without explanation does not constitute "inability to complete" HEP.[2, 9]

Terminology - Interlaminar Epidural; Selective Nerve Root Injection (transforaminal only); Transforaminal Injection; Injections of Spinal Canal

Hip-spine syndrome[27-29] - Hip-spine syndrome is a condition that includes both debilitating hip osteoarthritis and low back pain. Abnormal spinal sagittal alignment and difficulty in maintaining proper balance, as well as a wobbling gait, may be caused by severe osteoarthritis of the hip joint. Epidural injections are used to determine a primary pain generator in this condition.

Spondylolisthesis and nerve root irritation[13, 30-33] - Degenerative lumbar spondylolisthesis is the displacement of a vertebra in the lower part of the spine; one lumbar vertebra slips forward on another with an intact neural arch and begins to press on nerves. The most common cause, in adults, is degenerative disease; although, it may also result from bone diseases and fractures. Degenerative spondylolisthesis is not always symptomatic. Epidural injections may be used to determine a previously undocumented nerve root irritation because of spondylolisthesis.

Lumbar spinal stenosis with radiculitis[13, 34, 35] - Spinal stenosis is narrowing of either the spinal column or of the neural foramina where spinal nerves leave the spinal column, causing pressure on the spinal cord. The most common cause is degenerative changes in the lumbar spine. Neurogenic claudication is the most common symptom, with leg symptoms including the buttock, groin, and anterior thigh; however, symptoms may also radiate down along the posterior leg to the foot. In addition to pain, leg symptoms can include fatigue, heaviness, weakness, or paresthesia. Some individuals may also suffer from accompanying back pain. Symptoms are worse when standing or walking and are relieved by sitting. Lumbar spinal stenosis is often a disabling condition, and it is the most common reason for lumbar spinal surgery in adults over 65 years. The most common levels of stenosis are L3 through L5, but it may occur at multilevel in some individuals. Radiculitis is the inflammation of a spinal nerve root that causes pain to radiate along the nerve paths. Epidural injections help to ascertain the level of the pain generator in this condition.

Lumbar herniated disc[36-39] - Epidural steroid injections have been proven to be effective at reducing symptoms of lumbar herniated discs. Observation and epidural steroid injection are effective nonsurgical treatments for this condition.

Postoperative epidural fibrosis[40-42] - Epidural fibrosis is a common cause of failed back surgery syndrome. With the removal of a disc, the mechanical reason for pain may be removed, but an inflammatory condition may continue after the surgery and may cause pain. Epidural corticosteroids, with their anti-inflammatory properties, are used to treat postoperative fibrosis and may be used along with oral Gabapentin to reduce pain.

Failed back surgery syndrome (FBSS)[21, 43] - Failed back surgery syndrome is characterized by persistent or recurring low back pain, with or without sciatica, following lumbar surgery. The most common cause of FBSS is epidural fibrosis triggered by a surgical procedure such as

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discectomy. The inflammation resulting from the surgical procedure may start the process of fibrosis and cause pain. Epidural steroid injections are administered to reduce pain.

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POLICY HISTORY

Date	Summary
May 2023	• Added in references • Removed Additional Resources • Added Legislative language for Washington State

May 2022	• Added note to clarify when **INITIAL** injection requirements must be met for approval
	• Reorganized indications for clarity and uniformity
	• Added region-specific wording to conservative treatment requirement (e.g., conservative therapy targeting the requested spinal region)
	• Clarified acute pain as duration less than 3 months
	• Updated Frequency of Repeat Injections section and Removed 'Therapeutic' from Section Title (since up to 3 diagnostic injections are allowed by GL)
	• Exclusions section:
	  ○ Added caudal or spinal anesthesia for surgery
	  ○ Updated intrathecal injections for pain or spasticity prior to permanent pump insertion
	• Updated and simplified contraindications list for epidural injections

January 2022	• Off-cycle change: Changed pain relief period after initial injection: At least 50% or more pain relief obtained for a minimum of 6 weeks 2 months after initial injections (Manchikanti, 2013)

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Reviewed / Approved by NIA Clinical Guideline Committee

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Clinical guidelines: **EPIDURAL SPINE INJECTIONS AND SINGLE INJECTION TRIALS FOR INTRATHECAL PUMPS**	**Original Date: May 2022**
CPT Codes: **Cervical Thoracic Region:** **62320, 62321, 64479 (+64480)** **Lumbar Sacral Region:** **62322, 62323, 64483 (+64484)**	**Last Revised Date: May 2023**
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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.

Note: Any injection performed at least two years from prior injections in the same region will be considered a new episode of care and the **INITIAL** injection requirements must be met for approval. Events such as surgery on the same spinal region or any new pathology would also prompt a new episode of care.

INDICATIONS FOR EPIDURAL SPINE INJECTIONS OR SELECTIVE NERVE BLOCKS (Caudal, Interlaminar, Transforaminal)

See LEGISLATIVE REQUIREMENTS for specific mandates in the State of Washington

For the treatment of acute pain or exacerbation of chronic radicular pain[1] ALL of the following must be met:

- Neck or back pain with acute radicular symptoms[2]
- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10 [2-5]
- Duration of pain < 3 months

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- Failure to respond to non-operative conservative therapy targeting the requested spinal region for a minimum of 2 weeks unless the medical reason this treatment cannot be done is clearly documented (active therapy components not required)[2, 3]

For the treatment of spinal stenosis causing axial or radicular pain[1] ALL of the following must be met:

- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10 [2-5]
- Failure to respond to non-operative conservative therapy* targeting the requested spinal region for a minimum of 6 weeks in the last 6 months unless the medical reason this treatment cannot be done is clearly documented; **OR** details of engagement in ongoing non-operative conservative therapy* if the individual has had prior spinal injections in the same region[2, 3]

For the treatment of failed back surgery syndrome or epidural fibrosis causing axial[6, 7] or radicular pain[1] ALL of the following must be met:

- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10 [2-5]
- Documentation of a medical reason that clearly indicates why an injection is needed (not typically done immediately post-surgery)[3]
- Failure to respond to non-operative conservative therapy* targeting the requested spinal region for a minimum of 6 weeks in the last 6 months unless the medical reason this treatment cannot be done is clearly documented; **OR** details of engagement in ongoing non-operative conservative therapy* if the individual has had prior spinal injections in the same region[2, 3]

For a diagnostic transforaminal injection to identify the pain generator for surgical planning ALL of the following must be met:

- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10 [2-5]
- Documentation of a pre-operative evaluation and plan for surgery

NOTE: No more than 2 levels of transforaminal blocks should be done in one day.[8]

INDICATIONS FOR REPEAT INJECTIONS

Epidural injections may be repeated only as medically necessary. **Each** epidural injection requires an authorization, and the following criteria must be met for repeat injections:

- Up to 3 epidural injections may be performed in the initial treatment phase, no sooner than 2 weeks apart, provided that at least 30% pain relief or significant documented functional improvement is obtained[5]
- If an injection during the initial treatment phase is unsuccessful, another injection may be performed at a different level in the **same spinal region** or with a change in technique given there is a question about the pain generator or evidence of multi-level pathology

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- Epidural injections may only be repeated after the initial treatment phase if the individual has had at least 50% pain relief or significant documented functional improvement for a **minimum of 2 months** after each therapeutic injection[3]
- The individual continues to have pain causing functional disability or average pain level ≥ 6 on a scale of 0 to 10 [2, 3, 5]
- The individual is engaged in ongoing active conservative therapy*, unless the medical reason this treatment cannot be done is clearly documented[2, 9]
- In the first year of treatment, a total of 6 epidural injections may be performed **per spinal region** (this includes a series of 3 injections in the initial treatment phase and 3 additional therapeutic injections) .[3]
- After the first year of treatment, a maximum of 4 epidural injections in a 12-month period may be performed **per spinal region**.[3, 5] If special circumstances are documented (e.g., elderly individual with severe spinal stenosis and not an operative candidate) then repeat injections are limited to a maximum of 6 epidural injections in a 12-month period per spinal region.[5]
- If different spinal regions are being treated, injections should be administered at intervals of no sooner than 7 days unless a medical reason is provided to necessitate injecting multiple regions on the same date of service (see **NOTE**).[3]

NOTE: It is generally considered **not medically necessary** to perform multiple interventional pain procedures on the same date of service. Documentation of a medical reason to perform injections in different regions on the same day can be provided and will be considered on a case-by-case basis (e.g., holding anticoagulation therapy on two separate dates creates undue risk for the patient). Different types of injections in the same spinal region (cervical, thoracic, or lumbar) should not be done on the same day with the exception of a facet injection and ESI performed during the same session for a synovial cyst confirmed on imaging.

INTRASPINAL DRUG TRIALS FOR CHRONIC INTRACTABLE PAIN OR SPASTICITY CAN BE CONSIDERED USING THIS GUIDELINE.

An intraspinal drug trial for the treatment of chronic intractable pain in non-terminal individuals is appropriate when <u>ALL</u> the following criteria 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.

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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[10]:
  - 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.)

EXCLUSIONS

These requests are excluded from consideration under this guideline:

- Implantation of intrathecal catheters or ports for chemotherapy
- Post-operative pain control
- Caudal or spinal anesthesia for surgery

CONTRAINDICATIONS

- Active systemic or spinal infection
- Skin infection at the site of needle puncture
- Severe spinal stenosis resulting in intraspinal obstruction
- Body habitus that is insufficient to support the weight and bulk of the device

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Washington

- **Washington State Health Care Authority Technology Assessment**
  20160318B – Spinal Injections[11, 12]
  Limitations of Coverage*:
    - Therapeutic epidural injections in the lumbar or cervical-thoracic spine for chronic pain are a covered benefit when all of the following conditions are met:
      - For treatment of radicular pain
      - With fluoroscopic guidance or CT guidance
      - After failure of conservative therapy
      - No more than two without clinically meaningful improvement in pain and function; and
      - Maximum of three in six months.

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- Washington State Health Care Authority oversees the Apple Health (Medicaid) program and the Public Employees Benefits Board (PEBB) Program[13]

* This coverage policy does not apply to those with a known systemic inflammatory disease such as: ankylosing spondylitis, psoriatic arthritis or enteropathic arthritis

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BACKGROUND

Therapeutic Spinal Epidural Injections or Select Nerve Root Blocks (Transforaminal) are types of interventional pain management procedures. The therapeutic use of epidural injections is for short-term pain relief associated with acute back pain or exacerbation of chronic back pain. With therapeutic injections, a corticosteroid is injected close to the target area with the goal of pain reduction. Epidural injections should be used in combination with other active conservative treatment* modalities and not as stand-alone treatment for long-term back pain relief. Different approaches used when administering spinal epidural injections[14] include:

- **Interlaminar** epidural injections, with steroids, access the epidural space between two vertebrae (Interlaminar) to treat cervical, lumbar, or thoracic pain with radicular pain.[15] These procedures should be performed using fluoroscopic guidance.[16] Interlaminar epidural injections are the most common type of epidural injection.
- **Transforaminal** epidural injections (also called selective nerve root blocks) access the epidural space via the intervertebral foramen where the spinal nerves exit (cervical, lumbar/sacral, or thoracic region). It is used both diagnostically and therapeutically. Some studies report lack of evidence and risks of transforaminal epidural injections.[17] These procedures are always aided with fluoroscopic guidance.[1, 18-21]
- **Caudal** epidural injections, with steroids, are used to treat back and lower extremity pain, accessing the epidural space through the sacral hiatus, providing access to the lower nerve roots of the spine. These procedures should be performed using fluoroscopic guidance. Failed back surgery syndrome is the most common reason for the caudal approach.[3, 21-23]
- **Intraspinal Drug Trial** in anticipation of implanted infusion pump for spinal drug administration.

The rationale for the use of spinal epidural injections is that the sources of spinal pain, e.g., discs and joints, are accessible and amendable to neural blockade.

Medical necessity management for epidural injections includes an initial evaluation including history and physical examination as well as a psychosocial and functional assessment. The following must be determined: nature of the suspected organic problem; non-responsiveness to active conservative treatment*; level of pain and functional disability; conditions which may be contraindications to epidural injections; and responsiveness to prior interventions.

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Interventional pain management specialists do not agree on how to diagnose and manage spinal pain; there is a lack of consensus with regards to the type and frequency of spinal interventional techniques for treatment of spinal pain. The American Society of Interventional Pain Physicians (ASIPP) guidelines recommend an algorithmic approach which provides a step-by-step procedure for managing chronic spinal pain based upon evidence-based guidelines.[1, 3] This approach is based on the structural basis of spinal pain and incorporates acceptable evidence of diagnostic and therapeutic interventional techniques available in managing chronic spinal pain.

The guidelines and algorithmic approach referred to above include the evaluation of evidence for diagnostic and therapeutic procedures in managing chronic spinal pain and recommendations for managing spinal pain. The Indications and Contraindications presented within this document are based on the guidelines and algorithmic approach. Prior to performing this procedure, shared decision-making between patient and physician must occur, and the patient must understand the procedure and its potential risks and results (moderate short-term benefits, and lack of long-term benefits).

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, 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.

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

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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.[24]

OVERVIEW

***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.[2, 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[9, 25, 26] ; **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.[2, 9]

Terminology - Interlaminar Epidural; Selective Nerve Root Injection (transforaminal only); Transforaminal Injection; Injections of Spinal Canal

Hip-spine syndrome[27-29] - Hip-spine syndrome is a condition that includes both debilitating hip osteoarthritis and low back pain. Abnormal spinal sagittal alignment and difficulty in maintaining proper balance, as well as a wobbling gait, may be caused by severe osteoarthritis of the hip joint. Epidural injections are used to determine a primary pain generator in this condition.

Spondylolisthesis and nerve root irritation[14, 30-33] - Degenerative lumbar spondylolisthesis is the displacement of a vertebra in the lower part of the spine; one lumbar vertebra slips forward on another with an intact neural arch and begins to press on nerves. The most common cause, in adults, is degenerative disease; although, it may also result from bone diseases and fractures. Degenerative spondylolisthesis is not always symptomatic. Epidural injections may be used to determine a previously undocumented nerve root irritation because of spondylolisthesis.

Lumbar spinal stenosis with radiculitis[14, 34, 35] - Spinal stenosis is narrowing of either the spinal column or of the neural foramina where spinal nerves leave the spinal column, causing pressure on the spinal cord. The most common cause is degenerative changes in the lumbar spine. Neurogenic claudication is the most common symptom, with leg symptoms including the buttock, groin, and anterior thigh; however, symptoms may also radiate down along the posterior leg to the foot. In addition to pain, leg symptoms can include fatigue, heaviness,

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weakness, or paresthesia. Some individuals may also suffer from accompanying back pain. Symptoms are worse when standing or walking and are relieved by sitting. Lumbar spinal stenosis is often a disabling condition, and it is the most common reason for lumbar spinal surgery in adults over 65 years. The most common levels of stenosis are L3 through L5, but it may occur at multilevel in some individuals. Radiculitis is the inflammation of a spinal nerve root that causes pain to radiate along the nerve paths. Epidural injections help to ascertain the level of the pain generator in this condition.

Lumbar herniated disc[36-39] - Epidural steroid injections have been proven to be effective at reducing symptoms of lumbar herniated discs. Observation and epidural steroid injection are effective nonsurgical treatments for this condition.

Postoperative epidural fibrosis[40-42] - Epidural fibrosis is a common cause of failed back surgery syndrome. With the removal of a disc, the mechanical reason for pain may be removed, but an inflammatory condition may continue after the surgery and may cause pain. Epidural corticosteroids, with their anti-inflammatory properties, are used to treat postoperative fibrosis and may be used along with oral Gabapentin to reduce pain.

Failed back surgery syndrome (FBSS)[21, 43] - Failed back surgery syndrome is characterized by persistent or recurring low back pain, with or without sciatica, following lumbar surgery. The most common cause of FBSS is epidural fibrosis triggered by a surgical procedure such as discectomy. The inflammation resulting from the surgical procedure may start the process of fibrosis and cause pain. Epidural steroid injections are administered to reduce pain.

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POLICY HISTORY

Date	Summary
May 2023	• Added references • Removed Additional Resources • Added Legislative Language for Washington State
May 2022	New policy

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Reviewed / Approved by NIA Clinical Guideline Committee

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***National Imaging Associates, Inc.**	
Clinical guidelines: **PARAVERTEBRAL FACET JOINT INJECTIONS OR BLOCKS**	**Original Date: October 2012**
CPT Codes: **Cervical Thoracic Region: 64490 (+ 64491, +64492) 0213T, +0214T, +0215T** **Lumbar Region: 64493 (+64494, +64495) 0216T, +0217T, +0218T**	**Last Revised Date: May 2023**
Guideline Number: NIA_CG_301	**Implementation Date: January 2024**

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

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Note: Any injection performed at least two years from prior injections in the same region will be considered a new episode of care and the **INITIAL** injection requirements must be met for approval. Events such as surgery on the same spinal region or any new pathology would also prompt a new episode of care.

INDICATIONS FOR FACET JOINT INJECTIONS OR MEDIAL BRANCH NERVE BLOCKS[1-4]

See Legislative Requirements for specific mandates in the State of Washington

To confirm non-radicular pain suggestive of facet joint or pars interarticularis origin ALL of the following must be met:

- History of mainly axial or non-radicular pain unless stenosis is caused by synovial cyst[5-7]
- Lack of evidence that the primary source of pain being treated is from sacroiliac joint pain, discogenic pain, disc herniation, or radiculitis[5-7]
- For chronic lumbar spondylolysis, imaging studies that confirm the presence of a pars interarticularis fracture/defect are required
- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10 [6-8]

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- Duration of pain of at least **3 months**[6, 7]
- Failure to respond to non-operative conservative therapy* targeting the requested spinal region for a minimum of 6 weeks in the last 6 months unless the medical reason this treatment cannot be done is clearly documented; OR details of engagement in ongoing non-operative conservative therapy* if the individual has had prior spinal injections in the same region[6, 8, 9]

NOTE: All procedures must be performed under imaging guidance.[10-14]

INDICATIONS FOR REPEAT INJECTIONS

Facet joint injections and medial branch nerve blocks may be repeated only as medically necessary. **Each** injection requires an authorization, and the following criteria must be met for repeat injections:

- Up to 2 injections may be performed in the initial diagnostic phase, no sooner than 2 weeks apart, provided at least 50% pain relief or significant documented functional improvement is obtained[6]
    - If the most recent injection was a diagnostic block with local anesthetic only, there must be at least 7 days between injections
- If the first injection is unsuccessful, a second injection may be performed at a different spinal level or with a change in technique (~~i.e~~. e.g., from an intra-articular facet injection to a medial branch nerve block) given there is a question about the pain generator or evidence of multi-level pathology
- Facet joint injections may only be repeated after the initial diagnostic phase if the individual has had at least 50% pain relief or significant documented functional improvement for a **minimum of 2 months** after each therapeutic injection[6]
- The individual continues to have pain causing functional disability or average pain level ≥ 6 on a scale of 0 to 10[6, 8]
- The individual is engaged in ongoing active conservative therapy*, unless the medical reason this treatment cannot be done is clearly documented[6, 8, 9]
    - Diagnostic injections within 1 month of the previous injection do not require documentation of ongoing active conservative therapy
- In the diagnostic phase, a maximum of 2 procedures may be performed. Repeat diagnostic injections after successful radiofrequency neurolysis are allowable if there is a question about the pain generator, different levels are to be targeted, or if there is surgery in the same spinal region.
- A maximum of 4 facet injections may be performed in a 12-month period **per spinal region** (except under unusual circumstances, such as a recurrent injury).[6]
    - Unilateral injections performed at the same level on the right vs. left within 1 month of each other would be considered as one procedure toward the total number of facet procedures allowed per 12 months.[6]

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- If different spinal regions are being treated, injections should be administered at intervals of no sooner than 7 days unless a medical reason is provided to necessitate injecting multiple regions on the same date of service (see NOTE)[6]

Radiofrequency neurolysis procedures should be considered in individuals with a successful medial branch nerve block (at least 70% pain relief or improved ability to function), but with insufficient sustained relief (less than 2-3 months improvement).[6, 8]

NOTE: It is generally considered **not medically necessary** to perform multiple interventional pain procedures on the same date of service. Documentation of a medical reason to perform injections in different regions on the same day can be provided and will be considered on a case-by-case basis (e.g., holding anticoagulation therapy on two separate dates creates undue risk for the patient). Different types of injections in the same spinal region (cervical, thoracic, or lumbar) should not be done on the same day with the exception of a facet injection and ESI performed during the same session for a synovial cyst confirmed on imaging.

EXCLUSIONS

These requests are excluded from consideration under this guideline:

- Sacral lateral branch blocks (S1, S2, S3)
- Atlantoaxial joint injections (C1-2)
- Occipital nerve blocks
- Hardware injection or block for diagnosis or treatment of post-surgical or other spine pain

CONTRAINDICATIONS FOR FACET JOINT INJECTIONS

- Active systemic or spinal infection
- Skin infection at the site of needle puncture
- Inability to obtain percutaneous access to the target facet joint

LEGISLATIVE REQUIREMENTS

- Washington
  - Washington State Health Care Authority Health Technology Assessment 20160318B – Spinal Injections[15, 16]
    - Therapeutic medial branch nerve block injections, intradiscal injections and facet injections are not a covered benefit.[15]
    - Washington State Health Care Authority oversees the Apple Health (Medicaid) program and the Public Employees Benefits Board (PEBB) Program.[17]

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BACKGROUND

Facet joints, (also called zygapophyseal joints or z-joints), posterior to the vertebral bodies in the spinal column and connecting the vertebral bodies to each other, are located at the junction of the inferior articular process of a more cephalad vertebra and the superior articular process of a more caudal vertebra. These joints provide stability and enable movement, allowing the spine to bend, twist, and extend in different directions. They also restrict hyperextension and hyperflexion.[6, 18]

Facet joints are clinically important spinal pain generators in individuals with chronic spinal pain. In 15 – 45% of individuals with chronic low back pain, facet joints have been implicated as a cause of the pain. Facet joints are considered as the cause of chronic spinal pain in 48% of individuals with thoracic pain and 54 – 67% of individuals with chronic neck pain.[19] Facet joints may refer pain to adjacent structures, making the underlying diagnosis difficult as referred pain may assume a pseudoradicular pattern. Lumbar facet joints may refer pain to the back, buttocks, and lower extremities while cervical facet joints may refer pain to the head, neck, and shoulders.

Imaging findings are of little value in determining the source and location of 'facet joint syndrome', a term originally used by Ghormley[20] in 1933, referring to back pain caused by pathology at the facet joints. Imaging studies may detect changes in facet joint architecture, but correlation between radiologic findings and symptoms is unreliable. Although clinical signs are also unsuitable for diagnosing facet joint-mediated pain, they may be of value in selecting individuals for controlled local anesthetic blocks of either the medial branches or the facet joint itself.[21]

Medical necessity management for paravertebral facet injections includes an initial evaluation including history and physical examination and a psychosocial and functional assessment. The following must be determined: nature of the suspected organic problem; non-responsiveness to conservative treatment*; level of pain and functional disability; conditions which may be contraindications to paravertebral facet injections; and responsiveness to prior interventions.

The most common source of chronic pain is the spine, and up to 80% of the U.S. population suffers from spinal pain sometime during their life span.[22] Facet joint interventions are used in the treatment of pain in certain individuals with a confirmed diagnosis of facet joint pain. Interventions include intraarticular injections and medial branch nerve blocks in the lumbar, cervical, and thoracic spine. Prior to performing this procedure, shared decision-making between patient and physician must occur, and the patient must understand the procedure and its potential risks and results. Facet joint injections or medial branch nerve blocks require guidance imaging.

OVERVIEW

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***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.[8, 23]

****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[23-25] ; **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.[8, 23]

Terminology: Facet Injections; Facet Joint Blocks; Paravertebral Facet Injections; Paravertebral Facet Joint Injections; Paravertebral Facet Joint Nerve Injections; Zygapophyseal injections; Lumbar Facet Blockade; Medial Branch blocks

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POLICY HISTORY

Date	Summary

May 2023	• Expanded indication for pars interarticularis
	• Added to exclusions
	  ○ Sacral lateral branch block (S1, S2, S3)
	  ○ Atlantoaxial joint injections (C1-2)
	  ○ Hardware injection or block for dx or treatment of post-surgical or other spine pain
	• Added references

May 2022	• Added note to clarify when INITIAL injection requirements must be met for approval • Reorganized indications for clarity and uniformity • Added region-specific wording to conservative treatment requirement (e.g., conservative therapy targeting the requested spinal region) • Simplified indications by combining two "lack of evidence" indications • Clarified "average" pain levels • Add US guidance for procedure as option (in addition to fluoroscopic or CT guidance) • Extended the interval from 2 weeks to 1 month • Clarified that repeat diagnostic injections are allowable after an unsuccessful rf denervation under certain conditions • Updated Contraindications section • Added an Exclusions section, including lateral branch blocks and occipital nerve blocks • Updated Frequency of Repeat Injections section • Clarified lack of medical necessity of performing multiple pain procedures on same DOS

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Reviewed / Approved by NIA Clinical Guideline Committee

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Clinical guidelines: **PARAVERTEBRAL FACET JOINT DENERVATION (RADIOFREQUENCY NEUROLYSIS)**	**Original Date: October 2012**
CPT Codes: **Cervical Thoracic Region: 64633, +64634** **Lumbar Region: 64635, +64636**	**Last Revised Date: May 2023**
Guideline Number: NIA_CG_302	**Implementation Date: January 2024**

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.

INDICATIONS FOR PARAVERTEBRAL FACET JOINT DENERVATION/RADIOFREQUENCY NEUROLYSIS

See Legislative Requirements for specific mandates in the State of Washington

For the treatment of facet-mediated pain ALL of the following must be met:

- Lack of evidence that the primary source of pain being treated is from sacroiliac joint pain, discogenic pain, disc herniation or radiculitis[1, 2]
- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10 [1-3]
- Duration of pain of at least **3 months**[1, 3]
    - Positive response to at least one local anesthetic block of the facet joint nerves (medial branch blocks), with at least 70% pain relief or improved ability to function for a minimal duration at least equal to that of the local anesthetic, but with insufficient sustained relief (less than 2-3 months relief) [1-3]
    - Failure to respond to non-operative conservative therapy* targeting the requested spinal region for a minimum of 6 weeks in the last 6 months unless the medical reason this treatment cannot be done is clearly documented[1-3]

NOTE: All procedures must be performed using fluoroscopic or CT guidance[6, 7]

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INDICATIONS FOR REPEAT PROCEDURES

Facet joint denervation procedures may be repeated only as medically necessary. **Each** denervation procedure requires an authorization, and the following criteria must be met for repeat procedures:

- Positive response to prior radiofrequency denervation procedures with at least 50% pain relief or improved ability to function for at least 4 months[1, 3-5]
- The individual continues to have pain causing functional disability or average pain level ≥ 6 on a scale of 0-10[1-3]
- The individual is engaged in ongoing non-operative conservative therapy* unless the medical reason this treatment cannot be done is clearly documented.[1, 3-5]
- A maximum of 2 facet denervation procedures maybe be performed in a 12-month period **per spinal region**[1]
    - Unilateral radiofrequency denervation's performed at the same level(s) on the right vs left within 1 month of each other would be considered as one procedure toward the total number of radiofrequency procedures allowed per 12 months. There is no minimum timeframe required between these procedures on the right vs left. Opposite side denervation procedures performed at the same level(s) within 1 month of the first side do not require follow-up information to be submitted.

NOTE: It is generally considered **not medically necessary** to perform multiple interventional pain procedures on the same date of service. Documentation of a medical reason to perform injections in different regions on the same day can be provided and will be considered on a case-by-case basis (e.g., holding anticoagulation therapy on two separate dates creates undue risk for the patient).

EXCLUSIONS

These requests are excluded from consideration under this guideline:

- Radiofrequency denervation of the sacroiliac joint and/or sacral lateral branches (S1, S2, S3)

CONTRAINDICATIONS FOR FACET JOINT DENERVATION

- Active systemic or spinal infection
- Skin infection at the site of needle puncture

LEGISLATIVE REQUIREMENTS

- Washington
    - Washington State Health Care Authority Health Technology Assessment – 20140321B – Facet Neurotomy[8-10]

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- Lumbar Facet Neurotomy is a **covered benefit** with the following conditions:
    - Patient(s) must be over 17 years of age, and:
    - Has at least six months of continuous low back pain referable to the facet joint
    - The pain is non-radicular pain
    - Condition is unresponsive to other therapies including conservative care
    - There are no other clear structural cause of back pain
    - There is no other pain syndrome affecting the spine.
    - For identification, diagnosis, and treatment:
        - Patient must be selected by at least 80% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting
        - One or two joints per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.
- Cervical Facet Neurotomy for cervical pain is a **covered benefit** with the following conditions:
    - Limited to C3 - 4, through C6 -7
    - Patient(s) over 17 years of age, and:
    - Has at least six months of continuous neck pain referable to the facet joint
    - The pain is non-radicular
    - Condition is unresponsive to other therapies including conservative care
    - There are no other clear structural cause of neck pain
    - No other pain syndrome affecting the spine
    - For identification, diagnosis, and treatment:
        - Patient must be selected by 100% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting
        - One joint per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.
- Non-Covered Indicators
    - Facet Neurotomy for the thoracic spine is **not covered**.
    - Facet Neurotomy for headache is **not covered**.

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- Washington State Health Care Authority oversees the Apple Health (Medicaid) program and the Public Employees Benefits Board (PEBB) Program.[11]

BACKGROUND

Facet joints, (also called zygapophyseal joints or z-joints), posterior to the vertebral bodies in the spinal column and connecting the vertebral bodies to each other, are located at the junction of the inferior articular process of a more cephalad vertebra and the superior articular process of a more caudal vertebra. These joints provide stability and enable movement, allowing the spine to bend, twist, and extend in different directions. They also restrict hyperextension and hyperflexion.[1, 12]

Facet joints are clinically important spinal pain generators in individuals with chronic spinal pain. In 15 – 45% individuals with chronic low back pain, facet joints have been implicated as a cause of the pain. Facet joints are considered as the cause of chronic spinal pain in 48% of individuals with thoracic pain and 54 – 67% of individuals with chronic neck pain.[13] Facet joints may refer pain to adjacent structures, making the underlying diagnosis difficult as referred pain may assume a pseudoradicular pattern. Lumbar facet joints may refer pain to the back, buttocks, and lower extremities while cervical facet joints may refer pain to the head, neck, and shoulders.

Imaging findings are of little value in determining the source and location of 'facet joint syndrome', a term originally used by Ghormley[14] in 1933, referring to back pain caused by pathology at the facet joints. Imaging studies may detect changes in facet joint architecture, but correlation between radiologic findings and symptoms is unreliable. Although clinical signs are also unsuitable for diagnosing facet joint-mediated pain, they may be of value in selecting individuals for controlled local anesthetic blocks of either the medial branches or the facet joint itself.[15]

Facet joints are known to be a source of pain with definitive innervations. Interventions used in the treatment of individuals with a confirmed diagnosis of facet joint pain include medial branch nerve blocks in the lumbar, cervical, and thoracic spine; and radiofrequency neurolysis (*see additional terminology*). The medial branch of the primary dorsal rami of the spinal nerves has been shown to be the primary innervations of facet joints. Substance P, a physiologically potent neuropeptide considered to play a role in the nociceptive transmission of nerve impulses, is found in the nerves within the facet joint.[1, 16, 17]

Radiofrequency neurolysis is a minimally invasive treatment for cervical, thoracic, and lumbar facet joint pain. It involves using energy in the radiofrequency range to cause necrosis of specific nerves (medial branches of the dorsal rami), preventing the neural transmission of pain.

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The objective of radiofrequency neurolysis is to both provide relief of pain and reduce the likelihood of recurrence.[18]

Members of the American Society of Anesthesiologists (ASA) and the American Society of Regional Anesthesia and Pain Medicine (ASRA) have agreed that conventional or thermal radiofrequency ablation of the medial branch nerves to the facet joint should be performed for neck or low back pain.[19] Radiofrequency neurolysis has been employed for over 30 years to treat facet joint pain. Prior to performing this procedure, shared decision-making between patient and physician must occur, and the patient must understand the procedure and its potential risks and results.

OVERVIEW

THERAPEUTIC PARAVERTEBRAL FACET JOINT DENERVATION (RADIOFREQUENCY NEUROLYSIS): Local anesthetic block is followed by the passage of radiofrequency current to generate heat and coagulate the target medial branch nerve. Traditional radiofrequency and cooled radiofrequency are included by this definition. Pulsed radiofrequency, cryo-ablation, or laser ablation are not included in this definition.

***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.[3, 4, 20]

****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[4, 5, 21] ; **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.[3, 4]

Terminology: Paravertebral Facet Joint Denervation, Radiofrequency Neurolysis, Destruction Paravertebral Facet Joint Nerve, Facet Joint Rhizotomy, Facet Neurolysis, Medial Branch Radiofrequency Neurolysis, Medial Branch Radiofrequency Neurotomy or Radiofrequency Denervation.

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POLICY HISTORY

Date	Summary
May 2023	• Moved RFA to RFA requirements to "Repeat Procedure" section
May 2022	• Added note to clarify when INITIAL injection requirements must be met for approval • Added region-specific wording to conservative treatment requirement (e.g., conservative therapy targeting the requested spinal region) • Clarified average pain levels • Added Exclusions section, including Denervation of any nerves other than medial branch nerves (i.e., sacroiliac joint denervation, sacral lateral branch denervation, etc.) • Increased interval time frame from 2 weeks to 1 month for unilateral rf denervation's performed at same level • Increased interval time from 2 weeks to 1 month for 2nd side denervation procedures • Updated Contraindication Section • Clarified lack of medical necessity of performing multiple pain procedures on same DOS

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Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guidelines: **SACROILIAC JOINT INJECTIONS**	**Original Date: January 2014**
CPT Codes: 27096	**Last Revised Date: May 2023**
Guideline Number: NIA_CG_305	**Implementation Date: January 2024**

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.

Note: Any injection performed at least two years from prior injections in the same region will be considered a new episode of care and the **INITIAL** injection requirements must be met for approval. Events such as surgery on the same spinal region or any new pathology would also prompt a new episode of care.

INDICATIONS FOR SACROILIAC JOINT (SIJ) INJECTIONS (Intraarticular or ligamentous injections only)

See Legislative Requirements for specific mandates in the State of Washington

For the treatment of Sacroiliac Joint (SIJ) pain ALL of the following must be met:

- Primarily axial low back pain (below level of L5) which may radiate to the groin or lower extremity[1]
- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10[1-3]
- Positive exam findings to suggest the diagnosis, which include the pelvic (SI) distraction test, pelvic (SI) compression test, thigh thrust test, FABER (Patrick's test), posterior shear test, Yeoman's test, or Gaenslen's test[4, 5]
- Duration of pain of at least **3 months**
- Failure to respond to non-operative conservative therapy* targeting the requested spinal region for a minimum of 6 weeks in the last 6 months unless the medical reason this treatment cannot be done is clearly documented; **OR** details of active engagement in ongoing non-operative conservative non-operative therapy* if the individual has had prior spinal injections in the same region[1, 2]

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For the treatment of spondyloarthropathy[6] ALL of the following must be met:

- The individual has experienced ≥ 3 months of low back pain
- Age of onset < 45 years
- Comprehensive pain management program is in place including physical therapy, home exercise, patient education, psychosocial support, and/or oral medication
- Prior history of evidence of sacroiliitis on imaging (i.e., active inflammation on magnetic resonance imaging [MRI] or definite radiographic sacroiliitis grade > 2 bilaterally *or* grade 3-4 unilaterally)
- ***1 or more*** spondyloarthropathy features:
    - Inflammatory back pain with **at least 4** of the following criteria present:
        - Age at onset < 45 years
        - Insidious onset
        - Improvement with exercise
        - No improvement with rest
        - Pain at night (with improvement upon getting up)
    - Arthritis
    - Enthesitis of the heel (irritability of muscles, tendons, or ligaments where they enter the bone)
    - Uveitis (inflammation of the uvea, the middle layer of the eye)
    - Dactylitis (inflammation of a finger or toe)
    - Psoriasis
    - Crohn's/colitis
    - Good response to NSAIDs
    - Family history of spondyloarthropathy
    - Positive testing for HLA-B27
    - Elevated C-reactive protein (CRP)

NOTE: All procedures must be performed under imaging guidance[7-10]

INDICATIONS FOR REPEAT INJECTIONS

Sacroiliac joint injections may be repeated only as medically necessary. **Each** sacroiliac joint injection requires an authorization, and the following criteria must be met for repeat injections:

- Up to 2 sacroiliac joint injections may be performed in the initial treatment phase, no sooner than 2 weeks apart, provided that at least 50% pain relief or significant documented functional improvement is obtained[1]
- Sacroiliac joint injections may only be repeated after the initial treatment phase if the individual has had at least 50% pain relief or significant documented functional improvement for a **minimum of 2 months** after each therapeutic injection[1]
- The individual continues to have pain causing functional disability or average pain level ≥ 6 on a scale of 0 to 10[1-3, 11]

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- The individual is engaged in ongoing active conservative therapy*, unless the medical reason this treatment cannot be done is clearly documented[2, 11, 12]
- For individuals that have received other interventional pain injections in the lumbar/sacral region (e.g., epidural steroid injection or facet joint injection) since the last SIJ injection, repeat positive provocative exam findings are required (pelvic distraction test, pelvic compression test, thigh thrust test, FABER (Patrick's test), posterior shear test, Yeoman's test, or Gaenslen's test).[4, 5]
- A maximum of 4 sacroiliac joint injections may be performed in a 12-month period[1]

NOTE: It is generally considered **not medically necessary** to perform multiple interventional pain procedures on the same date of service. Documentation of a medical reason to perform injections in different regions on the same day can be provided and will be considered on a case-by-case basis (e.g., holding anticoagulation therapy on two separate dates creates undue risk for the patient).

EXCLUSIONS

These requests are excluded from consideration under this guideline:

- Sacral lateral branch blocks (S1, S2, S3)
- Radiofrequency denervation of the sacroiliac joint

CONTRAINDICATIONS FOR SACROILIAC JOINT INJECTIONS

- Active systemic or spinal infection
- Skin infection at the site of needle puncture

LEGISLATIVE REQUIREMENTS

Washington

- **Washington State Health Care Authority Technology Assessment**
- 20160318B – Spinal Injections[13, 14]
  Limitations of Coverage*:
  - Therapeutic sacroiliac joint injections for chronic pain is a covered benefit when all of the following conditions are met:
    - With fluoroscopic guidance or CT guidance
    - After failure of conservative therapy; and
    - No more than one without clinically meaningful improvement in pain and function, subject to agency review
  - Washington State Health Care Authority oversees the Apple Health (Medicaid) program and the Public Health Employees Benefits Board (PEBB) Program[15]

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* This coverage policy does not apply to those with a known systemic inflammatory disease such as: ankylosing spondylitis, psoriatic arthritis or enteropathic arthritis.

BACKGROUND

This guideline addresses the use of sacroiliac joint injections for the treatment of low back pain that originates in the region of the sacroiliac joint (SIJ). An injection of anesthetic or steroid may be used for the diagnosis and treatment of SIJ pain syndrome disorders (such as degenerative joint disease, postsurgical injuries, or traumatic injuries), or for treatment of spondyloarthropathy (inflammatory disorders of the joints and ligaments of the spine).

Sacroiliac joint injections are typically used for the following conditions:

- **Sacroiliac joint (SIJ) syndrome** may be caused by various events, including pain secondary to postsurgical or traumatic injury, degeneration (wear and tear), or pregnancy. Physical examination (history and physical, provocative maneuvers) and diagnostic injection help to identify the source of pain as the SIJ.[16-18]
- **Diagnostic SIJ injections** are used to determine if the SIJ pain originates with the SIJ. Diagnostic blocks can reveal (or fail to reveal) that the source of pain is originating from the SIJ, and then an appropriate treatment plan can be developed.[1, 19]
- **Therapeutic SIJ injections** may be used to treat SIJ pain once it has been determined that the SIJ is the origin of the pain. A therapeutic injection typically includes a corticosteroid and a local anesthetic that can be injected directly into the joint (intra-articular) or into the tissues surrounding the joint (periarticular).[20, 21]
- **Spondyloarthropathy** (also known as spondyloarthritis) is the name for a family of rheumatic diseases that cause arthritis. Sacroiliitis is a key indicator of spondyloarthritis and is diagnosed with imaging. Individuals with spondyloarthropathy are generally managed by rheumatologists and account for only a small percentage of the cases that present in interventional pain management settings.[22-24]

OVERVIEW

***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 and consist of physical therapy, a physician-supervised home exercise program**, or chiropractic care.[2, 12, 25]

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

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- Documentation of an exercise prescription/plan provided by a physician, physical therapist, or chiropractor[12, 26, 27] ; **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.[2, 12]

Telehealth visits have become routine in modern medical practice. However, sacroiliac joint injections cannot be performed via telehealth encounters. Individuals who can schedule an in-person encounter for injection are expected to also schedule an in-person encounter for provocative physical examination, prior to injection, in order to document the medical necessity of the joint injection.

Low back pain is one of the most common of all spinal pain problems. According to the Centers for Disease Control and Prevention (CDC), the prevalence of low back pain in adults 18 years of age and older is 28.4% and may range as high as 32.1% in adults ≥ 75 years.[28] Symptoms of low back pain may arise from multiple sites, including lumbar intervertebral discs, facet joints, sacroiliac joints, ligaments, fascia, muscles, and nerve root dura. The sacroiliac joint has been shown to be a source of pain in 10 – 30% of chronic low back pain.[1, 29-31]

The sacroiliac joint (SIJ) is located between the sacrum (located at the base of the spine) and the pelvis and supports the weight of the upper body in the standing position. SIJs are in both the right and left side of the lower back with strong ligaments holding the joints in place. The SIJ is well-innervated and is capable of being a source of low back pain and referred pain in the lower extremity. Low back pain originating from the SIJ can result from inflammatory conditions such as sacroiliitis, spondyloarthropathy (e.g., ankylosing spondylitis, rheumatoid spondylitis), or from postsurgical or traumatic injury, degeneration (wear and tear), or pregnancy. SIJ pain most often occurs in the buttocks and lower back and may radiate down through the buttocks and the leg. Physical examination and radiographic techniques may confirm a diagnosis related to spondyloarthropathy. Physical examination, including provocative maneuvers to elicit pain response, and controlled SIJ injections can help diagnose noninflammatory pain arising from the SIJ.[29, 32-34]

To confirm correct placement of the injectable medication into the intra-articular space, fluoroscopic or computed tomography (CT) guidance is used.[9, 35, 36] A periarticular injection into the soft tissue may be used if ligamentous or muscular attachments are suspected to be involved. The goal of the therapeutic injection is to reduce inflammation or pain and provide longer pain relief. Long-term relief is generally defined as 6 weeks or longer, but positive responders generally have a much longer duration of response; serial injections may be required in order to maintain therapeutic effectiveness.[29, 37]

Spinal injections for the treatment of SIJ pain syndrome are typically performed as one part of a comprehensive treatment program, which will nearly always include an exercise program to

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improve or maintain spinal mobility.[17, 38] Potential candidates for SIJ injections include those with low back pain originating from the SIJ that is unresponsive to conservative treatments.

Treatment for SIJ pain depends upon the signs and symptoms, as well as the underlying cause for the pain. Medications, such as over-the-counter analgesics, a short course of narcotics, muscle relaxants or tumor necrosis factor (TNF) inhibitors, such as etanercept (Enbrel), adalimumab (Humira), or infliximab (Remicade), may be prescribed. Therapy sessions with a physical therapist involving range-of-motion, stretching, and strengthening exercises may be used to maintain joint flexibility and strengthen the muscles. Other interventional procedures used to treat SIJ pain include corticosteroid injections to reduce inflammation and pain, radiofrequency denervation, electrical stimulation, or in rare cases, joint fusion.[32]

The indications for coverage for the treatment of spondyloarthropathy have been established through use of the reviewed clinical studies and through criteria developed by the Assessment of SpondyloArthritis International Society (ASAS) for the classification of axial spondyloarthritis.[39] They are in keeping with the benefit guidelines developed by the Centers for Medicare & Medicaid Services (CMS).[40]

While evidence supports that SIJ injection is an effective method of determining the source of pain, evidence supporting the efficacy of SIJ in the treatment of SIJ pain syndrome is considerably limited. There are limited controlled or prospective clinical studies to support SIJ injection for therapeutic purposes. Despite the limited quality of the clinical studies supporting SIJ injection for the treatment of SIJ pain, the procedure is recommended by the American Society of Anesthesiologists (ASA) and the American Society of Regional Anesthesia and Pain Management (ASRAPM) Practice Guidelines.[41] The indications for coverage have been established from the 2009 *Comprehensive Evidence-Based Guidelines for Interventional Techniques in the Management of Chronic Spinal Pain*[3] and updated with the 2013 *An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part II: Guidance and Recommendations.*[1]

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POLICY HISTORY

Date	Summary
May 2023	• Adjusted time interval for repeat injections from minimum of 6 weeks to 2 months after each injection • Added Washington State Legislative Language
May 2022	• Added note to clarify when **INITIAL** injection requirements must be met for approval • Reorganized indications for clarity and uniformity • Added region-specific wording to conservative treatment requirement (e.g., conservative therapy targeting the requested spinal region) • For consistency among guidelines, changed wording and order of contraindications to injections • Add US guidance for injections as option (in addition to fluoroscopic or CT guidance) • Under treatment of spondyloarthropathy, replaced 'or' with 'and' in list of required components of a comprehensive pain management program • Updated Frequency of Repeat Injections section • Clarified lack of medical necessity of performing multiple pain procedures on same DOS • Updated Contraindications

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Clinical guidelines: **IMPLANTABLE INFUSION PUMP INSERTION**	**Original Date: July 2015**
CPT Codes: **62350, 62351, 62355, 62360, 62361, 62362**	**Last Revised Date: May 2023**
Guideline Number: NIA_CG_310	**Implementation Date: January 2024**

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.

INDICATIONS FOR IMPLANTABLE INFUSION PUMP INSERTION

An intraspinal drug trial for the treatment of chronic intractable pain in non-terminal individuals is appropriate when ALL the following criteria 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.

A permanently implanted infusion pump for the treatment of chronic intractable pain in non-terminal individuals is appropriate when ALL the following criteria 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
- At least 12 weeks of oral or transdermal opiate pain medications

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- 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

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.)

A permanently implanted infusion pump for the treatment of spasticity in non-terminal individuals is appropriate when ALL of 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.)
- 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

INDICATIONS FOR PUMP REPLACEMENT

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

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- 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.

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, 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.

Evidence Review[2]: 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,

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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 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%.

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]:

- I: Evidence obtained from at least one properly randomized controlled trial (RCT)
- IIa (or II-1): Evidence obtained from well-designed controlled trials without randomization
- IIb (or II-2): Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- 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
- III: Opinions of respected authorities, based on clinical experience, descriptive studies, and case reports or reports of expert committees[6]

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***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]

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POLICY HISTORY

Date	Summary
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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Clinical guidelines: **Spinal Cord Stimulation**	**Original Date: August 2020**
CPT Codes: **63650, 63655, 63661, 63662, 63663, 63664, 63685, 63688**	**Last Revised Date: May 2023**
Guideline Number: NIA_CG_405	**Implementation Date: January 2024**

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.

INDICATIONS FOR SPINAL CORD STIMULATION (SCS)

A spinal cord stimulation trial is appropriate when ALL the following criteria are met[1]:

- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10
- Failure to respond to non-operative conservative therapy* for a minimum of 6 months unless the medical reason this treatment cannot be done is clearly documented
- A completed psychological assessment that documents the following[2]:
  - Pain is not psychologic in origin
  - Management of any Axis II findings
  - No evidence of existing or untreated addiction
  - Demonstration of cognitive ability to manage the stimulator
- Pain caused by at least **ONE** of the following:
  - Failed spine surgery syndrome (FSSS)[3, 4] or post-laminectomy syndrome
  - Complex regional pain syndrome (CRPS),[5, 6] type I or type II, characterized by **ALL** of the following:
    - Unilateral vasomotor changes
      - Changes in skin color; cyanotic, or mottled;
      - Changes in skin temperature; **OR**
      - Unilateral edema
    - Unilateral sudomotor changes
      - Skin is dry; **OR**
      - Skin is moist

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        - Unilateral trophic changes
            - Skin is smooth or shiny;
            - Soft issue atrophy;
            - Joint stiffness, with decreased passive ROM;
            - Nail changes; **OR**
            - Hair growth changes
    - Chronic neuropathic pain of certain origins[7] that falls into **ONE** of the following diagnoses:
        - Lumbosacral arachnoiditis
        - Post herpetic neuralgia[8, 9]
        - Radiculopathy
        - Chronic ischemic leg pain[10]
        - Diabetic peripheral neuropathy[11-13]
        - Phantom limb syndrome (stump pain)
        - Peripheral neuropathy
        - Chronic back pain (neuropathic pain) and not a surgical candidate
        - Chronic, refractory angina pectoris, characterized by **ALL** the following:
            - Continued angina after percutaneous coronary intervention or coronary artery bypass graft
            - Not a candidate for further revascularization
            - Angina is NYHA (New York Heart Association) III (less than ordinary physical activity causes symptoms) or IV (symptoms present at rest)
            - Optimal pharmacotherapy for at least one month with failure to tolerate medications in indicated dosage or failure to respond adequately to indicated medications

A permanent spinal cord stimulator is appropriate when ALL the following criteria are met:

- Documentation of a successful trial of the temporary SCS device providing at least 50% reduction in pain and significant functional improvement for a minimum duration of 3 days[14]
- The same type of stimulator device will be used

Revision or removal of a spinal cord stimulator device is indicated with ONE of the following:

- Migration of lead(s)
- Loss of effectiveness
- Intolerance by the individual
- Infection
- Painful generator site
- Development of neurological deficits
- Patient demand

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CONTRAINDICATIONS FOR SPINAL CORD STIMULATION

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

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BACKGROUND

In the United States, the most common indication for spinal cord stimulator (SCS) placement is chronic pain from failed spine surgery syndrome.[15] For more than 30 years, SCS has successfully alleviated patient suffering and enhanced the lives of individuals with refractory pain conditions.[1] SCS is a minimally invasive, non-opioid alternative therapy used for the treatment of chronic neuropathic pain[16] or ischemic pain and is a safe and effective alternative therapy to other medications. SCS has been well established as a safe and effective treatment of pain derived from a wide variety of etiologies.[17] For individuals with chronic pain who have failed conservative approaches, SCS should be considered among other options before prescribing long-term opioids.[18]

SCS is used to treat some common indications to include, but not limited to, failed spine surgery syndrome (FSSS), complex regional pain syndrome, painful peripheral vascular disease, and intractable angina. Limited literature suggests that SCS may also be beneficial for individuals with visceral abdominal and perineal pain[19-21] and for painful diabetic neuropathy.[22]

Based primarily on differences in clinical observations, SCS therapies can be categorized into at least two modalities to include paresthesia SCS (classical SCS) and sub-perception SCS (e.g., burst, kHz). Paresthesia SCS is generally characterized by programming stimulation parameters (including electric field configuration) between metal contacts residing in the epidural space[16] such that the individual experiences paresthesia and the paresthesia topography overlaps the pain topography as much as possible.[23]

It is reported that the applied fields change the electrical potential across membranes based on the properties of tissues near the electrode, such as the dura, layer of cerebrospinal fluid, and white matter.[23] In the case of excitable membranes, such as those found in nearby dorsal column axons,[23] the electric field can trigger one or more action potentials, depending on the bioelectrical properties of the axon (diameter, myelination status, and electrical threshold). This modality of stimulation typically results in analgesia in minutes to hours and in many cases notable decreases in pain are reported during post-op recovery.[23]

In contrast, sub-perception SCS is characterized by programming parameters that do not cause the individual to feel paresthesia. This modality of stimulation tends to have longer wash-in and wash-out times and typically results in analgesia in several hours to days.[23]

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A 2019 meta-analysis of 12 randomized trials including approximately 1000 individuals with intractable spine or limb pain related to various disorders (e.g., FSSS; chronic back, leg or trunk pain; diabetic neuropathy; peripheral vascular disease; complex regional pain syndrome [CRPS]) found that SCS was associated with increased odds of >50 percent pain reduction, compared with continued medical therapy.[24]

Overall complications of SCS range from 5.3 to 40 percent and are most commonly due to hardware-related issues. The majority of complications are not life-threatening (e.g., lead migration), but they do often require lead revision or explanation.[7, 25]

***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.[26-28]

****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[26, 29, 30] ; **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.[26, 27]

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POLICY HISTORY

Date	Summary
May 2023	• No Change
May 2022	• Reorganized and reworded indications for clarity and uniformity • Clarified average pain on 10-point scale • Clarified pain causing functional disability • Added Contraindications section

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Clinical guideline: **SYMPATHETIC NERVE BLOCKS**	**Original Date: November 2020**
CPT Codes: 64510, 64517, 64520, 64530	**Last Revised Date: May 2023**
Guideline Number: NIA_CG_404	**Implementation Date: January 2024**

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.

Note: Any injection performed at least two years from prior injections in the same region will be considered a new episode of care and the **INITIAL** injection requirements must be met for approval. Events such as surgery on the same spinal region or any new pathology would also prompt a new episode of care.

INDICATIONS FOR SYMPATHETIC NERVE BLOCK

For the treatment of Post-Traumatic Stress Disorder (PTSD)[1-6]

- Stellate ganglion block can be performed for treatment of PTSD

For the treatment of acute pain[7]

- Duration of pain < 3 months[8]
- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10
- Failure to respond to non-operative conservative therapy for a minimum of 2 weeks unless the medical reason this treatment cannot be performed is clearly documented

For the treatment of chronic pain[9-12]

- Duration of pain ≥ 3 months
- Pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10
- Pain characterized by at least **ONE** of the following:

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    - Pain in one upper extremity with or without associated pain on the same side in the upper trunk, head, or neck
    - Pain in one lower extremity with or without associated pain on the same side in the buttock, pelvis, or groin
    - Ischemic limb pain with at least one of the following:
        - Intractable pain at rest
        - Non-healing ulcers
        - Failed surgical revascularization
- At least **THREE** of the following must be present when treating non-ischemic, extremity pain:
    - Allodynia or hyperalgesia
    - Trophic bone changes on imaging
    - Unilateral osteoporosis on imaging
    - Bone scan consistent with complex regional pain syndrome (CRPS)[13]
    - Unilateral vasomotor changes, including:
        - Changes in skin color (e.g., cyanotic, or mottled)
        - Changes in skin temperature
    - Unilateral edema
    - Unilateral sudomotor changes, including:
        - Skin is asymmetrically dry
        - Skin is asymmetrically moist
    - Unilateral trophic changes, including:
        - Skin is smooth or shiny
        - Soft issue atrophy
        - Joint stiffness, with decreased passive ROM
        - Nail changes
        - Hair growth change
- Failure to respond to non-operative conservative therapy which may include physical and occupational therapies (e.g., desensitization, mirror therapy, graded motor imagery, range of motion exercises), transcutaneous electrical nerve stimulation (TENS), ultrasound, laser, and/or cognitive behavioral therapy

NOTE: All procedures must be performed using imaging guidance[17-21]

Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. This criterion is supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.

FREQUENCY OF REPEAT INJECTIONS

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Sympathetic nerve blocks may be repeated only as medically necessary. Each sympathetic nerve block requires an authorization, and the following must be met for repeat injections:

- For the treatment of pain:
    - The previous sympathetic nerve block resulted in at least 50% pain relief or significant documented functional improvement for at least the duration of the local anesthetic
    - The individual continues to have pain causing functional disability or average pain levels ≥ 6 on a scale of 0 to 10
    - The individual is engaged in ongoing active conservative therapy* unless the medical reason this treatment cannot be done is clearly documented or is not indicated.
    - It has been at least one week since the prior sympathetic nerve block
    - For acute pain, no more than 6 sympathetic block procedures per region per year
    - For chronic pain, no more than 4 sympathetic block procedures per region per year
- For the treatment of PTSD:
    - The previous stellate ganglion block resulted in at least 50% reduction in symptoms or significant documented functional improvement for at least the duration of the local anesthetic
    - It has been at least one week since the prior sympathetic nerve block
    - No more than three blocks in the first 12 weeks, with no more than 6 blocks per year

NOTE: It is generally considered **not medically necessary** to perform multiple interventional pain procedures on the same date of service. Documentation of a medical reason to perform injections in different regions on the same day can be provided and will be considered on a case-by-case basis (e.g., holding anticoagulation therapy on two separate dates creates undue risk for the patient).

CONTRAINDICATIONS FOR SYMPATHETIC NERVE BLOCKS

- Active systemic or spinal infection
- Skin infection at the site of needle puncture

BACKGROUND

The sympathetic autonomic nervous system (SANS) is involved in both acute and chronic pain. Selective interventional blockade of specific sympathetic pathways can be used to treat ischemic pain. Due to the anatomical separation of the sympathetic ganglia and plexi from

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somatic nerves in prevertebral and paravertebral regions, sympathetic blocks can be used to provide analgesic effects without somatic sensory deficits. These sympathetic nerve blocks may be used to treat visceral, vascular, and neuropathic pain, including pain associated with a wide range of conditions, such as cancer, post-traumatic stress disorder (PTSD), and complex regional pain syndrome (CRPS).[2, 22-25]

McLean (2015)[1] noted that multiple case series have been conducted evaluating the potential impact of stellate ganglion block (SGB) for PTSD symptom management as well as the safety of image-guided procedures. The author conducted a review of single center data on 250 SGBs performed over an 18-month period (November 2013 – April 2015). The goal of this study was to perform a quality assurance and performance improvement project on the safety and individual acceptability of the SGB procedure for the relief of symptoms related to chronic PTSD, including detection of any potential complications or unanticipated side effects. Post-procedural individual satisfaction survey results (n=110 individuals) show 100% "overall satisfied" with the procedure, and 95% of respondents indicated a willingness to repeat the procedure. The author concluded that in the study center "the SGB procedure for PTSD is a safe, well-tolerated, and acceptable treatment adjunct in the management of severe symptoms associated with chronic treatment-refractory PTSD."[1] The author also noted that further studies are necessary to determine the optimal treatment regimen and efficacy.

Ya Deau et al (2018)[7] compared spinal and general anesthesia as supplements to nerve blocks in a randomized controlled trial to determine the effect on early patient release following foot and ankle surgery. Without using intraoperative opioids, all individuals received popliteal and adductor canal nerve blocks (bupivacaine and dexamethasone), but the individuals were randomized to either the spinal anesthesia group or general anesthesia group. Time until ready for discharge and pain scores at rest were both recorded. The individuals receiving general anesthesia were discharged earlier than the spinal anesthesia individuals (median of 39 minutes earlier; 95% CI, 2-75; P=0.0380); however, their pain scores at rest one-hour post-procedure were higher (adjusted difference in means, 2.1; $P < 0.001$). The authors conclude, "The choice of spinal or general anesthesia as an adjunct to peripheral nerve blockade can reflect patient, clinician, and institutional preferences."[7]

Makharita et al (2012)[8] conducted a randomized, controlled, double-blind trial (n=64) to determine whether SGB, performed under fluoroscopy, can reduce postherpetic neuralgia (PHN). Individuals were divided into two groups: a control group receiving saline and an experimental group receiving bupivacaine and dexamethasone. The amounts of post-operative analgesic (acetaminophen) and pain (using a visual analog scale) were recorded at baseline, weekly (for six weeks), and after 2, 3, and 6 months. The experimental group recorded a significantly shorter duration of pain after both 3 and 6 months ($P = 0.043$ and 0.035,

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respectively) as well as a significant reduction in total doses of analgesics (P < 0.001). The authors conclude that SGB, in combination with an antiviral agent, is effective at treating PHN.[8]

Yoo et al (2011)[9] stated that the sympathetic nervous system has important roles in mediating many neuropathic pain conditions. They noted that thoracic sympathetic block (TSB) is a useful therapeutic procedure for neuropathic pain in the upper extremities and thorax, but that no studies have examined the factors related to an improved therapeutic effect of TSB. This study was designed to evaluate the influence of potential prognostic factors for a better TSB effect and identified clinically important prognostic factors in 51 individuals under fluoroscopic guidance. Regarding incorporation of TSB, only symptom duration was statistically relevant, with percutaneous TSB being more efficacious in individuals with symptom durations one year or less as compared to individuals with symptoms of more than one year (P = 0.006; odds ratio, 8.037; 95% confidence interval, 1.808-35.729). However, TSB effectiveness was not affected by either the individual's age, gender, BMI, diagnosis, or pre-procedural pain intensity. The authors concluded that these "results showed that an earlier TSB produced a better outcome for patients with chronic pain syndrome. Thus, early TSB should be performed in patients with chronic pain in the upper extremities."[9]

Cohen et al (2014)[13] conducted a randomized control trial (n=73) to study the effects of sedation during diagnostic injections since the use of sedation may be a potential cause of an inaccurate diagnostic block. 46 individuals within the study were considered good candidates for a repeat injection within three months. All individuals maintained a pain diary. The individuals who had blocks performed with sedation reported statistically larger reduction in pain diary score and less procedure-related pain than individuals without sedation. However, no statistical difference in either increased satisfaction or in outcomes one month post-procedure were observed between the two groups.[13]

****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[26, 28, 29] ; **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.~~,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.[15, 26]

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POLICY HISTORY

Date	Summary
May 2023	• Statement added for clinical indication • Adjusted treatment for chronic pain • Adjusted non-operative conservative therapy • Adjusted frequency of repeat injections • Adjusted background (conservative therapy removed) • Types of sympathetic nerve blocks covered was removed
May 2022	• Added note to clarify when **INITIAL** injection requirements must be met for approval • Reorganized and reworded indications for clarity and uniformity • Under treatment for chronic pain, updated non-operative conservative therapy • Clarified frequency of injections for treatment of PTSD versus other indications • Clarified lack of medical necessity of performing multiple pain procedures on same DOS • Added Contraindications section • Added region-specific wording to conservative treatment requirement (e.g., conservative therapy targeting the requested spinal region)

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