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: ~~June~~ May 2022~~1~~**
Guideline Number: NIA_CG_300	**Implementation Date: January 2023~~2~~**

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 (Cc~~c~~audal, I~~i~~nterlaminar, T ~~and~~ t~~t~~ransforaminal) *~~(Injection of local anesthetics with corticosteroids)~~*

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 levels 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]**

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 levels 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**

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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 radicular pain[1]
ALL of the following must be met:

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

- ~~Pain causing functional disability or average pain levels of ≥ 6 on a scale of 0 – 10[1-4] (Manchikanti, 2013; NASS, 2013, 2012; Summers, 2013); **AND**~~
  - ~~Diagnostic transforaminal injection to identify the pain generator for surgical planning[2] (Manchikanti, 2013); **OR**~~
  - ~~Conservative therapy~~
- ~~Acute pain or exacerbation of chronic radicular pain with the following clinical timeframes:~~
  - ~~Neck or back pain with acute radicular pain[1] (Summers, 2013):~~
  - ~~After 2 weeks or more of acute radicular pain that has failed to respond or poorly responded to conservative management unless the medical reason this conservative treatment cannot be done is clearly documented, (active components not required)[1, 2] (Manchikanti, 2013; Summers, 2013); **OR**~~
- ~~Failed back surgery syndrome or epidural fibrosis causing radicular pain[2] (Manchikanti, 2013):~~
  - ~~Typically, not done immediately post-surgery. Documentation requires a medical reason that clearly indicates why an injection is needed (Manchikanti, 2013).[2]~~
  - ~~Patient must engage in some form of other active conservative treatment* for a minimum of 6 weeks in the last 6 months; OR details of engagement in other forms of active conservative non-operative treatment, if the patient had any prior spinal injections prior to epidural injections, unless the medical reason this conservative treatment cannot be done is clearly documented[1, 2] (Manchikanti, 2013; Summers, 2013); **OR**~~
- ~~Spinal stenosis (foraminal, central or disc disease) causing axial or radicular pain[2, 5] (Lee, 2009; Manchikanti, 2013):~~

- ~~Patient must engage in some form of other active conservative treatment* for a minimum of 6 weeks in the last 6 months; **OR** details of engagement in other forms of active conservative non-operative treatment, if the patient had any prior spinal injections prior to epidural injections, unless the medical reason this conservative treatment cannot be done is clearly documented[1, 2]; (Manchikanti, 2013; Summers, 2013);~~

NOTE: No more than 2 levels of transforaminal blocks should be done in one day.[6]

FREQUENCY OF REPEAT INJECTIONS ~~REPEAT THERAPEUTIC 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 the first injection is unsuccessful, a second injection may be performed at a different spinal level 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 symptoms return, and 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]**
- ~~Documented proof that the prior injection had a positive response by significantly decreasing the patient's pain (at least 30% reduction in pain after initial injections **or** significant documented functional improvement) (NASS, 2013).[5] Or a second injection may be performed at a different spinal level or with a different epidural technique, if there is documentation of a question about the pain generator or there is evidence of multilevel pathology (ODG, 2017); **AND**~~
- ~~No more than 3 procedures in a 12-week period of time per region, with at least 14 days between injections in the initial phase. At least 50% or more pain relief obtained for a minimum of 2 months after initial injections[3] (Manchikanti, 2013); **AND**~~
- The ~~patient~~**individual** continues to have ~~documented~~ **pain causing** functional disability or **average** pain level**s** ≥ 6 on a scale of 0 to 10[2, 3, 5] ~~(Manchikanti, 2013; NASS, 2013; Summers, 2013); **AND**~~
- **The individual is engaged in ongoing active conservative therapy*, unless the medical reason this treatment cannot be done is clearly documented[2, 7]**
- **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 phase and 3 additional therapeutic injections) .[3]**
- **Repeat therapeutic injections should not be done more frequently than every 2 months with a maximum of 4 epidural injections 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]**

- ~~The patient is actively engaged in other forms of active conservative non-operative treatment, unless pain prevents the patient from participating in conservative therapy[2, 6]* (Qassem, 2017; Summers, 2013); **AND**~~
- ~~In the first year of treatment, which may include an initial series of 3 injections in the initial therapeutic phase and additional injections in the maintenance phase, a total of 6 epidural injections, per region, may be performed (Manchikanti, 2013).[3]~~
- ~~Repeat injections after the initial therapeutic phase should be done at intervals of at least 2 months, provided that previous injections resulted in at least 50% relief or functional improvement for at least 2 months and are limited to a maximum total of 4 therapeutic procedures per region per 12 months (Manchikanti, 2013; NASS, 2013).[3, 5] If special circumstances are documented (e.g., elderly patient with severe spinal stenosis and not an operative candidate) then repeat injections are limited to a maximum of 6 procedures in 12 months (NASS, 2013).[5]~~
  ~~**NOTE:** Each epidural injection requires an authorization.~~
- If ~~the neural blockade is applied for~~ different **spinal** regions **are being treated**, injections ~~may~~ **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)**~~for most types of procedures (Manchikanti, 2013)~~.[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 (i.e., 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 in the same session for a synovial cyst.

- ~~Injecting multiple regions or performing multiple procedures during the same visit may be deemed medically **unnecessary** unless documentation is provided outlining an unusual situation (ODG, 2017).~~
- ~~No more than 2 levels of transforaminal blocks should be done in one day (Singh, 2017).[7]~~
- ~~An intraspinal injection* of opioid or other substance for the purpose of completing a trial for an implantable infusion pump is approvable using NIA_CG_310.~~

~~**NOTE**: See Background section~~

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
- ~~Intrathecal injections for muscular dystrophy~~

- 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**
- ~~Bleeding diathesis and full anticoagulation (risk of epidural hematoma)~~
- ~~Severe spinal stenosis resulting in intraspinal obstruction~~
- ~~Local infection at injection site~~
- ~~Predominantly psychogenic pain~~
- ~~Sepsis~~
- ~~Hypovolemia~~
- ~~Uncontrolled diabetes~~
- ~~Uncontrolled glaucoma~~
- ~~High concentrations of local anesthetics in patients with multiple sclerosis~~
- ~~For diagnosis or treatment of facet mediated pain~~
- ~~Known or suspected allergic reaction to steroid medications; OR~~
- ~~Spinal infection~~

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. ~~There are~~ ~~D~~different approaches used when administering spinal epidural injections[8] **include**:

- **Interlaminar** epidural injections, with steroids, access the epidural space between two vertebrae (Interlaminar) to treat cervical, lumbar, or thoracic pain with radicular pain.[9] These procedures should be performed using fluoroscopic guidance ~~(AHRQ, 2013)~~.[10, 11] 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.[12] These procedures are always aided with fluoroscopic guidance ~~(AHRQ, 2013)~~.[1, 11, 13-16]

- **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 ~~(AHRQ, 2013)~~.[11] ~~–~~ Failed back surgery syndrome is the most common reason for the caudal approach.[3, 11, 16-18]
- ~~**Intraspinal Drug Trial** in anticipation of implanted infusion pump for spinal drug administration.~~

  ~~**NOTE**: There is a separate Clinical Guideline for Implanted Infusion Pumps, see: NIA_CG_310. Because the CPT code for the intraspinal drug trial is the same CPT Code as other intraspinal injections covered by this clinical guideline, this guideline is used for the intraspinal drug trial. It is advised that the Clinical Guideline for Implanted Infusion Pumps be consulted prior to performing the intraspinal drug trial. If the patient is unlikely to meet the other requirements for an implanted infusion pump, an intraspinal drug trial should not be done.~~

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 ~~and~~ **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 ~~and International Spine Intervention Society (SIS) guidelines provide~~ **recommend** an algorithmic approach which provides a step-by-step procedure for managing chronic spinal pain based upon evidence-based guidelines.[1, 3] ~~It~~ **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** ~~Conservative Therapy:** (Spine) should include a multimodality approach consisting of a combination of active and inactive components. Inactive components, such as rest, ice, heat, modified activities, medical devices, acupuncture or stimulators, medications, injections (including trigger point), and diathermy can be utilized. Active modalities consist of physical therapy, a physician supervised home exercise program**, or chiropractic care (Qassem, 2017; Summers, 2013).~~[2, 7, 19]

****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, 20, 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 (i.e., increased pain or inability to physically perform exercises). Closure of medical offices, closure of therapy offices, patient inconvenience, or noncompliance without explanation does not constitute "inability to complete" HEP. ~~****Home Exercise Program - (HEP)** – the following **two elements are required** to meet guidelines for completion of conservative therapy:~~

- ~~Documentation provided of an exercise prescription/plan[7, 19, 20] (Qassem, 2017; Sculco, 2001)~~
- ~~Follow up with member with documentation provided regarding completion of HEP, (after suitable 6-week period) or inability to complete HEP due to physical reason- i.e., increased pain, inability to physically perform exercises. (Closure of medical offices, closure of therapy offices, patient inconvenience or noncompliance without explanation does not constitute "inability to complete" HEP)~~[2, 7] ~~(Qassem, 2017; Summers, 2013).~~

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

Hip-spine syndrome[22-24] **-** 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[8, 25-28] **-** 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 ~~as a result of~~**because of** spondylolisthesis.

Lumbar spinal stenosis with radiculitis[8, 29, 30] **-** 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.** ~~referring to "leg symptoms encompassing the buttock, groin and anterior thigh, as well as radiation down the posterior part of the leg to the feet."~~ In addition to pain, leg symptoms can include fatigue, heaviness, weakness, or paresthesia. Some ~~patients~~ **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 multilevels in some ~~patient~~**individual**s. 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.

~~**Postoperative epidural fibrosis**[30-33] - 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.~~

Lumbar herniated disc[31-34] **-** Epidural steroid injections have been proven to be effective at reducing symptoms of lumbar herniated discs. ~~Evidence shows that they can be successful in 42% to 56% of patients who do not improve after 6 weeks of conservative treatment.~~ Observation and epidural steroid injection are effective nonsurgical treatments for this condition.

Postoperative epidural fibrosis[35-37] - 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)[16, 38] **-** 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 ~~which be~~ 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.

POLICY HISTORY

Date	Summary

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)
June 2021	• No changes
November 2020	• Removed CPT codes 0228T; 0229T; 0230T; 0231T
October 2020	• Updated background information
October 2019	• Added 'axial' to specify radicular pain for spinal stenosis • Added section on Exclusions • For 'frequency of repeat therapeutic injections' • Changed diagnostic to therapeutic • Removed: ~~ongoing pain or~~ documented functional disability or pain level ≥6 on a scale of 0 to 10
November 2018	• Epidural injections or selective nerve blocks: Added language "active components are not required" to indication: 'After 2 weeks or more of acute radicular pain…' • Added text to specify that the time limitation on multiple ESIs is 'per region'. See indication: "In the first year of treatment, which may include an initial series of 3 injections in the initial diagnostic phase and additional injections in the treatment phase, a total of 6 epidural injections, per region, may be performed" • Frequency of repeat therapeutic injections: Changed 'an injection of opioid' to an 'intraspinal injection of opioid' to clarify

	• Background section: Added content “Intraspinal Drug Trial in anticipation of implanted infusion pump for spinal drug administration”; Added content on Intraspinal Drug Trials • Overview section: removed examples for ‘Home Exercise Program’, including ‘Yoga, Tai Chi, Aerobic Exercise’ • Added and updated references

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Reviewed / Approved by NIA Clinical Guideline Committee

~~**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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ADDITIONAL RESOURCES

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Reviewed / Approved by NIA Clinical Guideline Committee

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.