



Evolut Clinical Guideline 1751 for Epidural Spine Injections and Single Injection Trials for Intrathecal Pumps

Guideline Number: Evolut_CG_1751	<u>Applicable Codes</u>	
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STATEMENT

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.*
- *The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.*

Purpose

This guideline describes indications, contraindications, and exclusions for the performance of epidural spine injections, based on The American Society of Interventional Pain Physicians (ASIPP) recommended algorithmic approach, ⁽¹⁾ and indications, contraindications and exclusions for single injection intraspinal drug trials for intrathecal pumps.

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

Scope

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.

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. An intrathecal/intraspinal drug trial utilizes a temporary implant to demonstrate efficacy and appropriateness of an IIP.

Special Note

New Episode of Care

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.

~~See Legislative Language for specific mandates in the State of Washington.~~

INDICATIONS FOR INITIAL EPIDURAL SPINAL INJECTIONS/NERVE BLOCKS

General to all Caudal, Interlaminar and Transforaminal Injections

- Fluoroscopic guidance should be used for caudal and interlaminar injections and is necessary for transforaminal injections.
- For all injections, patients must exhibit pain causing functional disability or average pain level of ≥ 6 on a scale of 0 to 10 ⁽²⁻⁴⁾ related to the requested spinal region.

Treatment Purposes

- Acute pain or exacerbation of chronic radicular pain (all ~~of~~ the following must be met) ⁽¹⁾:
 - Neck or back pain with acute radicular symptoms
 - Duration of pain < 3 months
 - Failure to respond to non-operative **conservative treatment*** 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⁾
- Spinal stenosis causing axial or radicular pain (all of the following must be met) ⁽¹⁾:
 - Failure to respond to non-operative conservative treatment* targeting the requested spinal region for a minimum of six (6) weeks in the last six (6) months unless the medical reason this treatment cannot be done is clearly documented
 - **OR** details of engagement in ongoing non-operative conservative treatment if the individual has had prior spinal injections in the same region ^(3,5)
- Failed back surgery syndrome or epidural fibrosis causing axial or radicular pain (all of the following must be met) ^(1,6):
 - 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 treatment*** targeting the requested spinal region for a minimum of six (6) weeks in the last six (6) months unless the medical reason this treatment cannot be done is clearly documented
 - **OR** details of engagement in ongoing non-operative conservative treatment if the individual has had prior spinal injections in the same region ⁽²⁾

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

- Lack of meaningful improvement after a full course of treatment; **OR**
- Progression or worsening of symptoms during treatment; **OR**
- Documentation of a medical reason the member is unable to participate in treatment

(Closure of medical or therapy offices, patient inconvenience, or noncompliance without explanation does not constitute “inability to complete” treatment)

Diagnostic Purposes ^(1,4)

- Transforaminal injection to identify the pain generator for surgical planning (all of the following must be met):
 - 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

Repeat Epidural Spinal 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.

Initial Treatment Phase

- 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 ⁽⁴⁾
 - 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

Therapeutic Phase

- 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** before each therapeutic injection ⁽³⁾
- The patient:
 - continues to have pain moderate to severe pain causing functional disability or average pain level ≥ 6 on a scale of 0 to 10 related to the requested spinal region. ^(3,4)
 - is engaged in ongoing active conservative treatment, unless the medical reason this treatment cannot be done is clearly documented
- In the first year of treatment, a total of 6 epidural injections may be performed **per spinal region**
 - (This includes up to 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**. ^(3,4)
 - 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. ⁽⁴⁾

- If different spinal regions are being treated, injections should be administered at intervals of at least 7 days unless a medical reason is provided to necessitate injecting multiple regions on the same date of service (see **Medical Necessity**). ⁽³⁾

Contraindications for Epidural Spinal Injections

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

INDICATIONS FOR INTRASPINAL DRUG TRIAL

Chronic Intractable Pain in Non-Terminal Individuals

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

- Pain causing functional disability that significantly interferes with activities of daily living, including ability to work and overall quality of life ⁽⁵⁾⁽⁶⁾ **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

Spasticity in Non-Terminal Individuals

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

- Intractable spasticity that results in the individual's inability to maintain an upright posture, severely impairs balance in ambulation, or significantly interferes with activities of daily living related to **ONE** of the following conditions ^(7,8):
 - Spinal cord injury
 - Multiple sclerosis
 - Stiff person syndrome
 - Other medical conditions causing intractable spasms
- Failure to respond to a minimum of 12 weeks of non-operative conservative therapy (e.g., oral medications, physical therapy, etc.)

Additional Trials

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

- Less than 50% pain relief
- Intolerable side effects

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

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

Contraindications for Intraspinal Drug Trial

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

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

LEGISLATIVE LANGUAGE

Washington

- ~~20160318B—Spinal Injections⁽⁹⁾~~

~~Number and Coverage Topic:~~

~~20160318B—Spinal Injections~~

-

~~HTCC Coverage Determination:~~

~~Spinal injections are a covered benefit with conditions.~~

-

~~HTCC Reimbursement Determination:~~

~~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: f~~
 - ~~For treatment of radicular pain; f~~
 - ~~With fluoroscopic guidance or CT guidance; f~~
 - ~~After failure of conservative therapy; f~~
 - ~~No more than two without clinically meaningful improvement in pain and function; and~~
 - ~~Maximum of three in six months. f~~
- ~~Therapeutic sacroiliac joint injections for chronic pain is a covered benefit when all of the following conditions are met: f~~
 - ~~With fluoroscopic guidance or CT guidance; f~~
 - ~~After failure of conservative therapy; and f~~
 - ~~No more than one without clinically meaningful improvement in pain and function, subject to agency review.~~

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

~~Non-Covered Indicators:~~

~~Therapeutic medial branch nerve block injections, intradiscal injections and facet injections are not a covered benefit.~~

CODING AND STANDARDS

Coding

CPT Codes

<u>CPT</u>	
<u>Code</u>	<u>Description</u>
<u>Cervical/Thoracic Interlaminar Epidural</u>	
<u>62320</u>	<u>Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance</u>

<u>CPT</u>	
<u>Code</u>	<u>Description</u>
<u>62321</u>	<u>Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)</u>
<u>Cervical/Thoracic Transforaminal Epidural</u>	
<u>64479</u>	<u>Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), cervical or thoracic, single level</u>
<u>+64480</u>	<u>Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), cervical or thoracic, each additional level (List separately in addition to code for primary procedure)</u>
<u>Lumbar/Sacral Interlaminar Epidural</u>	
<u>62322</u>	<u>Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance</u>
<u>62323</u>	<u>Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)</u>
<u>Lumbar/Sacral Transforaminal Epidural</u>	
<u>64483</u>	<u>Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), lumbar or sacral, single level</u>
<u>+64484</u>	<u>Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), lumbar or sacral, each additional level (List separately in addition to code for primary procedure)</u>

Cervical Thoracic Region:

~~62320, 62321, 64479, +64480~~

Lumbar Sacral Region:

~~62322, 62323, 64483, +64484~~

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children’s Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

BACKGROUND

Medical Necessity

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
- Responsiveness to prior interventions

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 (Epidural Spine Injection) performed during the same session for a synovial cyst confirmed on imaging.

Conservative Treatment

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

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

****Home Exercise Program (HEP)****

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

- Documentation of an exercise prescription/plan provided by a physician, physical therapist, or chiropractor **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).

ANALYSIS OF EVIDENCE

Epidural Interventions in the Management of Chronic Spinal Pain: American Society of Interventional Pain Physicians (ASIPP) Comprehensive Evidence-Based Guidelines ⁽¹⁾:

- **Study Design:** This document is a comprehensive review and guideline update by the American Society of Interventional Pain Physicians (ASIPP) on epidural interventions for managing chronic spinal pain. It includes a systematic review of the literature, best evidence synthesis, and recommendations based on the evidence.
- **Target Population:** Patients with chronic spinal pain, including those with disc herniation, spinal stenosis, axial discogenic pain, and post-surgery syndrome.
- **Key Factors:** The guidelines are based on a review of 47 systematic reviews and 43 randomized controlled trials (RCTs). The evidence is categorized by the type of epidural intervention (caudal, interlaminar, transforaminal) and the specific spinal condition. The guidelines provide recommendations for the effectiveness of these interventions, with evidence levels ranging from Level I (strong) to Level IV (limited) depending on the condition and type of intervention.

An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part II: Guidance and Recommendations⁽³⁾:

- **Study Design:** This document is an update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain by ASIPP. It includes systematic reviews, evidence synthesis, and recommendations for various interventional techniques.
- **Target Population:** Patients with chronic spinal pain, including those with lumbar, cervical, and thoracic spine conditions.
- **Key Factors:** The guidelines cover diagnostic and therapeutic interventions, including epidural injections, facet joint interventions, sacroiliac joint injections, and percutaneous adhesiolysis. The evidence is categorized by the type of intervention and spinal condition, with recommendations based on the strength of the evidence. The guidelines emphasize the importance of evidence-based practice and the need for high-quality studies to support clinical decision-making.

The American Society of Pain and Neuroscience (ASPN) Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain⁽⁵⁾:

- **Study Design:** This document is an evidence-based clinical guideline by the American Society of Pain and Neuroscience (ASPN) for interventional treatments of low back pain. It includes a comprehensive review of the literature, evidence synthesis, and recommendations for various interventional treatments.
- **Target Population:** Patients with low back pain, including those with lumbar radiculopathy, spinal stenosis, and discogenic pain.
- **Key Factors:** The guidelines cover a wide range of interventional treatments, including epidural steroid injections, facet interventions, trigger point injections, and intradiscal regenerative therapies. The evidence is graded using the United States Preventive Services Task Force (USPSTF) criteria, with recommendations based on the strength of the evidence. The guidelines aim to provide clinicians with the most comprehensive and up-to-date information on the effectiveness and safety of interventional treatments for low back pain.

SUMMARY OF EVIDENCE

Shared Findings^(1,3,5):

- All three articles agree on the effectiveness of ESIs in managing chronic spinal pain, with varying levels of evidence supporting their use.
- The articles emphasize the importance of using high-quality, evidence-based guidelines to inform clinical practice.

Differing Findings:

- Manchikanti et al 2021 focuses on therapeutic epidural procedures and provides detailed guidelines for their use but does not address single injection trials for intrathecal pumps. ⁽¹⁾
- Manchikanti et al 2013 includes guidelines for various interventional techniques, including implantable devices like intrathecal pumps, but finds limited evidence for single injection trials. ⁽³⁾
- Sayed et al 2022 provides a broader review of interventional treatments, including ESIs, but does not focus on single injection trials for intrathecal pumps. ⁽⁵⁾

In summary, while all three articles support the use of ESIs for chronic spinal pain, they vary in their focus and the level of detail provided for single injection trials for intrathecal pumps. Manchikanti et al 2013 is the only one that addresses intrathecal pumps, albeit with limited evidence.

POLICY HISTORY

Date	Summary
<u>December 2025</u>	<ul style="list-style-type: none"> ● <u>Updated Disclaimer, General Information, and Legislative Language</u> ● <u>Added CPT code table to reflect new formatting.</u> ● <u>Removed Washington State regulatory language.</u> ● <u>Added Summary of Evidence and Analysis of Evidence</u>
December 2024	<ul style="list-style-type: none"> ● This guideline replaces Evolent Clinical Guideline 408 Epidural Spine Injections and Single Injection Trials For Intrathecal Pumps
January 2024	<ul style="list-style-type: none"> ● Added conservative tx language ● Added legislative language for WA state ● Added criteria for additional intrathecal trials

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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