Epidural Steroid Injections

Spine, Pain, and Joint (SPJ) Utilization Management Policy

Effective Date: 06/13/2024

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Policy Statement

Diagnostic use of epidural steroid injections for back(leg) and neck(arm) pain is considered medically necessary when all of the following criteria are met:

- The patient has failed to improve after a minimum of 6 weeks of conservative care that includes (but is not limited to):
  - Physical therapy and/or chiropractic therapy
  - Pharmacotherapy such as NSAIDs or acetaminophen
  - Rest and modification of activity
- The patient's pain is radicular in nature both in its presentation and in the dermatomal distribution of pain. Also, the accompanying manifestations of weakness, numbness and pain are compatible with the underlying neuromuscular structures involved.
- Other significant, important clinical explanations for the symptoms and presentation have been evaluated and not seen to require immediate clinical attention.
- Pseudoradicular or somatic referred pain either from facet joints and/or myofascial/ligamentous structures associated with the spine have been excluded. This pain type is distinguished from radicular pain by its quality, pattern, distribution and depth.
- The injection is performed under fluoroscopic or CT guidance.

The diagnostic phase of patient care may consist of 1 or 2 injections at intervals of no sooner than 2 weeks. If the diagnostic phase is completed and unsuccessful because of insufficient expected clinical response to intervention, no further epidural injections are necessary.

Therapeutic use of epidural steroid injections is considered medically necessary following the completion of a diagnostic trial when all of the following criteria are met:

- Documentation of sustained relief of the treated radicular symptoms.
- At least 10 weeks have elapsed since the completion of the successful diagnostic trial.
- Patient has reported experiencing at least 50% pain relief.
- Functional improvement as measured by validated measurement tools.

In the therapeutic phase, no more than 4 epidural injection sessions per body region per year are considered medically necessary.

- A session is defined as one date of service in which the injection is performed.
- A region is defined as cervicothoracic or lumbosacral.
- A year is defined as the 12-month period starting from the date of service of the first approved injection.

Epidural steroid injections for all conditions and circumstances not listed above including but not limited to the following are considered unproven and not medically necessary:

- A pre-planned treatment program that does not involve reassessment of patient response following each injection and adjustment of the treatment plan if either excellent response is achieved with 1 or 2 injections or alternatively if little or no response is achieved after 1 or 2 injections.
- Repeat injections should only be performed upon return of pain and associated deterioration in functional status and after expected period of relief.
- Non-radicular pain.
- Therapeutic epidural injections in the absence of significant clinical improvement in pain and function after the initial 2 diagnostic injections.
- Chronic lumbar degenerative disc disease without radicular features.
- Cervical or lumbar central canal spinal stenosis without extremity symptoms.
- Cervical or lumber foraminal spinal stenosis without radicular features.

- Late-stage CRPS or CRPS with minimal skin sensitivity.
- Patient is unable to continue to make progress toward goals due to medical and/or psychosocial complications.
- Objective clinical data demonstrates that the patient is not benefitting from skilled therapeutic intervention as evidenced by minimal or no significant measurable change in a reasonable time frame. This will be related to appropriate clinical measures that are patient and diagnosis specific.
- The patient is significantly non-adherent with their specific therapeutic protocol. This includes, but is not limited to:
    - Insufficient attendance at therapy sessions as outlined by the therapist's plan of care.
    - Not appropriately involved during treatment.
    - Non-compliance with therapist instructions related to:
        - Home exercise program.
        - Activity and environmental modification to prevent re-injury or re-inflammation.
        - Self-management of symptoms or acute episodes.

The patient's specific contract language will govern all final determinations. Some common circumstances that are not eligible for coverage under many plans include therapy to return to specific vocational and/or occupational activities.

Additionally, the following are considered unproven and not medically necessary:

- The use of ultrasound guidance for epidural steroid injections.
- Monitored anesthesia care.

Scope

All in and out of network programs where utilization review determinations are rendered. This policy also serves as a resource for peer-to-peer interactions in describing the position of Optum on the reporting of interventions for the treatment of SIJ pain.

Universal Minimum Eligibility and Documentation Requirements

Along with disease indications, the patient's performance status and comorbidities are critical considerations for epidural steroid injection eligibility. Important eligibility evaluation elements include:

- In patients with low back pain, substantial imaging abnormalities such as:
    - A central disc herniation.
    - Severe degenerative disc disease.
    - Central spinal stenosis.
- In patients with low back pain only, a simple disc bulge or annular tear/fissure is insufficient to justify lumbar ESI, unless other indications are present.
- Documented Visual Analog Scale (VAS) for pain or Numeric Pain Rating Scale (NPRS) ≥ 3/10 (moderate to severe pain) with functional impairment in activities of daily living (ADLs).
- Documented failure of six weeks of non-surgical, non-injection care along with documented rationale for interventional treatment. NOTE: Exceptions to the six week wait, beginning at the onset of pain and prior to ESI should be documented. Such exceptions include, but may not be limited to the following:
    - At least moderate pain with significant functional loss at work and/or home.
    - Severe pain unresponsive to outpatient medical management.
    - Inability to tolerate non-surgical, non-injection care due to a documented co-existing medical condition(s).

    - Prior successful lumbar ESI for the same specific condition.
- Imaging
    - Plain films, at a minimum, to rule out contraindications.
    - Advances imaging (MRI, CT) as indicated.
- All patients, whether new or established, should have a history and focused physical exam sufficient to establish the indication for ESI and exclude contraindications.
    - Documentation should include other conditions (i.e., trochanteric bursitis, subacromial bursitis) and whether the patient has received treatments such as steroid trigger point injections and intra-articular steroid injections.
    - Patient's primary care physician must be notified if the current treatment plan involves prolonged, repeat steroid use including ESIs for more than 12 months.
- When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity of the services, such services will be denied as not reasonable and necessary.

Functional Outcomes

Improved functional outcomes are a key desired goal of ESIs. These outcomes will be affected by individual patient variables (e.g. age, anthropometric characteristics, and pre-morbid status) and the nature of the condition (previous history of injury or surgery to the affected region). Functional assessment will, therefore, be individually meaningful and measured, where relevant, using an appropriate, valid, and reliable assessment tool.

- Functional scales will be considered in utilization review, however, given the diverse nature of these scales, no arbitrary threshold can translate into an absolute endpoint for an episode of care. In general, regular, significant measurable changes should be seen in a reasonable time frame in relation to baseline performance.
- Given the above parameters describing pain, range of motion and function, some of the following activities may be demonstrated as applicable:
    - Basic ADLs such as positioning, mobility, self-maintenance tasks, communication.
    - Instrumental ADLs such as home management, community living skills and occupational activities.

Universal Contraindications

The following are considered contraindications to ESIs regardless of the approach until or unless there is documentation of evaluation by the appropriate clinical specialty:

- Rapidly progressing neurological deficit.
- New onset of low back pain in a patient with a history of cancer, multiple risk factors for cancer or strong clinical suspicion for cancer.
- Spinal infection. Risk factors for spinal infection include:
    - New onset of low back pain with fever.
    - History of intravenous drug use.
    - History of recent bacterial or fungal infection.
    - Immunosuppression.
- Risk factors for or signs of cauda equina syndrome including:
    - New onset urine retention, fecal incontinence, or saddle anesthesia.
    - Rapidly progressing (or other) neurological deficits.
- A co-existing medical condition that would preclude the safe performance of the procedure.
- A co-existing medical or other condition that contraindicates the intervention including, but not limited to the following:
    - Epidural hematoma.
    - Subarachnoid hematoma.
    - Epidural mass.
    - Spinal cord ischemia.

    - Trauma.
- Potential presence of a central nervous system (CNS) process resulting in the presenting symptoms (e.g., transverse myelitis, central demyelination)
    - Patient must be thoroughly evaluated and a CNS process ruled out as the source of pain or neurologic deficit prior to ESI.
    - If CNS process is present, but the pain or neurologic deficit is clearly unrelated, an ESI may be indicated if one of the medically necessary indications identified above is present.
    - Numbness and/or weakness without paresthesia/dysesthesia or pain.

Procedural Requirements

All Methods

- All elective (non-emergent) ESIs should be performed with image-guidance. Fluoroscopy and CT are the only validated imaging methods.
- Contrast medium should be injected during epidural procedures. Exception to the use of contrast include:
    - Significant history and or are at high risk for an adverse event if contrast material is used (e.g., allergy). Reason for not using contrast must be documented in the procedure report.
- Films that adequately document final needle position and injectate flow must be retained and made available upon request.
- For each session, no more than 80 mg triamcinolone, 80mg methylprednisolone, 12 mg betamethasone, 15mg dexamethasone, or equivalent corticosteroid dosing may be used.

Transforaminal Lumbar ESIs

- Diagnostic selective nerve root blocks (anesthetic only), performed in a manner similar to transforaminal ESIs may be considered to further evaluate the anatomical level of radicular pain.
- When a diagnostic spinal nerve block is performed, post-block assessment of percentage pain relief must be documented.
    - Any additional documentation such as post-injection focused neurologic exam to assess for nerve root anesthetization or myotomal weakness is optional but can be included in the physician's report.

Utilization Levels per Session

- No more than 2 transforaminal injections may be performed at a single setting (e.g., single spinal level bilaterally or two spinal levels unilaterally).
- One cervical/thoracic or lumbar/sacral interlaminar injection per session and not in conjunction with a transforaminal injection.

Frequency Criteria

- No more than 2 ESIs may be performed in the diagnostic phase per region (cervical/thoracic region or lumbar/sacral region).
- With documentation of at least 10 weeks of improvement with the first 2 epidural injections in the diagnostic phase, therapeutic epidural injections may be performed not exceeding 4 per year with the documentation of at least 10 weeks of pain relief > 50% with documentation of improvement in functional status for repeat injections. NOTE: Therapeutic phase starts with the first therapeutic injection.
- For transforaminal epidural injections, a maximum of 2 levels will be reimbursed (e.g., single spinal level bilaterally or 2 spinal levels unilaterally), irrespective of the levels utilized and irrespective of the nerves blocked in 1 region.

Sedation

- Local anesthesia or minimal to moderate conscious sedation may be appropriate options.

- Monitored anesthesia care may be considered on very rare occasions with clear documentation of the need for such sedation.

Background

The primary indication for an epidural steroid injection (ESI) involves the etiologies that cause radicular pain. Radicular pain can be caused by the compression, inflammation, or irritation of a nerve root, leading to the radiation of pain and numbness along the distribution of the affected spinal nerve root. The radicular pain is often due to neurogenic inflammation and/or membrane instability of a spinal nerve or nerves (William et al., 20222). First-line treatment of radicular pain typically consists of conservative measures including motion-based therapy progressing to formal exercise and oral medications for symptom relief (Kennedy et al., 2011). If conservative treatments do not lead to clinical improvements, or are not tolerated by the patient, this may indicate the need for an interventional treatment such as ESI (William et al., 2022).

An ESI involves the injection of a solution of anti-inflammatory corticosteroid, typically paired with a local anesthetic or preservative-free normal saline injected into the epidural space to support pain relief. Corticosteroids are believed to reduce pain by blocking prostaglandin synthesis and the conduction of pain signals though nociceptive c fibers that mediate dull, aching pain (Oliveira et al., 2020). The standard of care for ESIs is the use of fluoroscopic or CT guidance to verify the injection is being delivered to the correct site. There are several approaches to injecting the epidural space: transforaminal, interlaminar, and caudal (William et al., 2022).

Clinical Evidence

There is an abundance of evidence supporting the use of ESIs in the evaluation and treatment of acute and chronic back pain. The data on efficacy can be challenging due to the wide variety of study designs, the variable inclusion criteria, and the outcomes reported (Kennedy & Schneider, 2017). The majority of evidence demonstrates efficacy in short-term improvement. There is insufficient evidence demonstrating that ESIs are effective in the treatment of back pain in the absence of radicular symptoms.

Boswell et al. (2023) conducted a systematic review is to determine the effectiveness of epidural injections in the treatment of chronic spinal pain. Both randomized and non-randomized studies were included in the review. The evidence was evaluated for three approaches (transforaminal, caudal, and interlaminar) separately. Multiple randomized and non-randomized trials of transforaminal epidural injections provided strong evidence for short-term and long-term relief on managing lumbar nerve root pain. Their effectiveness in post lumbar laminectomy syndrome and disc extrusions is inconclusive. The combined overall evidence of caudal ESIs, based on randomized and nonrandomized trials (prospective and retrospective) is strong for short-term relief and moderate for long-term relief with two of three randomized trials and four of four non-randomized trials demonstrating positive results in radicular pain. The evidence for chronic low back pain and spinal stenosis appears to be limited due to a lack of randomized or double-blind trials evaluating this effect. For laminar epidural injections, of the eight randomized trials reviewed, six demonstrated positive evidence for short-term relief, and three of eight showed positive evidence for long-term relief. The overall effectiveness of interlaminar ESIs in managing chronic spinal pain is moderate for short-term relief and limited for long-term relief in managing lumbar radicular pain. There was no significant evidence based on randomized trials of effectiveness of intralaminar ESIs in managing cervical radicular pain.

An evidence review published by Hayes, Inc. (2021) assessed the use of ESI for the treatment of thoracic spine pain and found that thoracic disc herniation is rare and patients may present with thoracic axial pain, but not with radicular pain. The review cited one randomized controlled trial (RCT) suggesting that ESI for chronic thoracic pain in patients who most commonly had disc-associated pain provides clinical benefit and symptom relief for up to two years.

Verheijen et al. (2021) conducted a systematic review and meta-analysis comparing ESIs with placebo injections in patients with sciatic pain. Seventeen out of 732 articles were included. ESI was superior compared to epidural placebo at 6 weeks (- 8.6 [- 13.4; - 3.9]) and 3 months (- 5.2 [- 10.1; - 0.2]) for leg pain and at 6 weeks for functional

status (- 4.1 [- 6.5; - 1.6]), though the minimally clinical important difference (MCID) was not met. There was no difference in ESI and placebo for back pain, except for non-epidural placebo at 3 months (6.9 [1.3; 12.5]). Proportions of treatment success were not different. ESI reduced analgesic intake in some studies and complication rates are low. While ESIs demonstrated safety and efficacy for short-term pain management when compared to placebo, no additional value of ESI was observed at three and six months.

A systematic review and meta-analysis by Conger et al. (2020) sought to determine the effectiveness of fluoroscopically-guided cervical transforaminal ESI for the treatment of radicular pain in patients aged ≥18 years with cervical radicular pain due to disc herniation or degenerative spondylosis when compared to sham, placebo procedure, or active standard of care treatment, excluding alternative versions of ESI. Randomized or nonrandomized comparative studies and nonrandomized studies without internal control were included. The primary outcome measure was patient-reported improvement in pain of at least 50% from baseline, assessed four or more weeks after the treatment intervention. Secondary outcomes included validated functional assessment tools and avoidance of spinal surgery. The Grades of Recommendation, Assessment, Development and Evaluation (GRADE) system was used to evaluate risk of bias and overall quality of evidence. A meta-analysis was conducted for comparative measures of effect and for within-group response rates if applicable. There were no studies with an internal comparison group (control group) meeting the review's definition of comparison group. Therefore, comparative measures of effect were not calculated. In cohort studies, pooled response rates were 48% (95% confidence interval [CI] = 34-61%) at one month and 55% (95% CI = 45-64%) at three months. Approximately 50% of patients experience ≥50% pain reduction at short- and intermediate-term follow-up after ESI. However, the literature is very low quality according to the GRADE criteria, primarily due to a lack of studies with placebo/sham or active standard of care control comparison groups.

A meta-analysis of RCTs comparing the clinical effectiveness of ESIs versus conservative treatment for patients with lumbosacral radicular pain was conducted by Yang and colleagues (2020). A systematic search was conducted for relevant studies published between 2000 and January 10, 2019. Six RCTs (249 patients with ESI and 241 patients with conservative treatment) were identified and included in this meta-analysis. Outcomes included visual analog scale, numeric rating scale, Oswestry disability index, or successful events. The outcome of the pooled analysis indicated that ESI is more effective for alleviating lumbosacral radicular pain than conservative treatments in terms of short-term and intermediate-term benefit when compared with conservative treatment, but this effect was not maintained at long-term follow-up. There were no statistically significant differences in functional improvement after ESI and conservative treatment at short-term and intermediate-term follow-up. The limitations of this meta-analysis resulted from the variation in types of interventions and small sample size.

A 2019 systematic review (Smith et al., 2019) of 19 studies assessed the efficacy of lumbar transforaminal steroid injection for radicular pain due to lumbar disc herniation. Placebo-controlled RCTs, pragmatic studies, and observational studies were included in the analysis. The primary outcome of interest was the proportion of individuals with reduction of pain by ≥50%. Additional outcomes of interest were a more-than-two-point reduction in pain score, patient satisfaction, functional improvement, decreased use of pain medication, and avoidance of spinal surgery. For patients with disc herniations, using the criterion of ≥50% reduction in pain, success rates across included studies (range) were 63% (58-68%) at one month, 74% (68-80%) at three months, 64% (59-69%) at six months, and 64% (57-71%) at one year. For patients with lumbar spinal stenosis, success rates across included studies (range) were 49% (43-55%) at one month, 48% (35-61%) at three months, 43% (33-53%) at six months, and 59% (45-73%) at one year, but there was a lack of corroboration from appropriately controlled studies. There is strong evidence that lumbar transforaminal injection of steroids is an effective treatment for radicular pain due to disc herniation. There is a lack of high-quality evidence demonstrating their effectiveness for the treatment of radicular pain due to spinal stenosis, though small studies suggest a possible benefit. Lumbar transforaminal injection of nonparticulate steroids is as effective as injections with particulate steroids.

Coding Information

Note: The Current Procedural Terminology (CPT) codes listed in this policy may not be all inclusive and are for reference purposes only. The listing of a service code in this policy does not imply that the service described by the code is a covered or non-covered health service. Coverage is determined by the member's benefit document.

CPT Code	Description
62320	Injection(s), of diagnostic or therapeutic substance(s) (e.g., 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
62321	Injection(s), of diagnostic or therapeutic substance(s) (e.g., 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 (i.e., fluoroscopy or CT)
62322	Injection(s), of diagnostic or therapeutic substance(s) (e.g., 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
62323	Injection(s), of diagnostic or therapeutic substance(s) (e.g., 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 (i.e., fluoroscopy or CT)
64479	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, single level
64480	Injection(s), anesthetic agent 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)
64483	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level
64484	Injection(s), anesthetic agent 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)

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Review and Approval History

Date	Description
4/27/2023	Quality Improvement Committee approved activation of the policy
6/12/2024	Annual review. Content transferred to new template. Approved by Optum Clinical Guideline Advisory Committee
6/13/2024	Approved by OrthoNet Quality Improvement Committee (QIC).