

<b>MEDICAL POLICY</b>	<b>Back: Epidural Steroid Injections (All Lines of Business Except Medicare)</b>
<b>Effective Date: 10/1/2021</b>	Medical Policy Number: 14
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**See Policy CPT/HCPCS CODE section below for any prior authorization requirements**

**SCOPE:**

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

All Lines of Business except Medicare

**BENEFIT APPLICATION**

Medicaid Members

*Oregon:* Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**DOCUMENTATION REQUIREMENTS**

The following information must be submitted in order to determine if medical necessity criteria are met:

- Indication for the requested procedure
- Clinical notes documenting that the individual has been evaluated at least once by the requesting provider before submitting a request for injection
- Medical records must document that a detailed neurological examination, conducted in-office or via video televisit, has been performed by, or reviewed by the provider performing the injection, within 3 months prior to procedure.
- Clinical documentation of extent and response to conservative care (see [Policy Guidelines](#) for all requirements), as applicable to the policy criteria, including outcomes of any procedural interventions, medication use and physical therapy notes

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- Evaluation and documentation of the extent and specifics of one or more of the functional impairments or disabilities
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues if and when present
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months or at the time of onset of symptoms
  - Imaging must be performed and read by an independent radiologist
  - If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede.

### POLICY CRITERIA

#### Initial Injection(s)

- I. Epidural steroid injections performed with imaging guidance (e.g., CT, fluoroscopy) may be considered **medically necessary and covered** when **all** of the following criteria (A.- G.) are met:
  - A. A detailed neurologic examination, performed in-office or via video televisit, within the last 3 months documents radiculopathy (see [Policy Guidelines](#)); **and**
  - B. Persistent, debilitating, radicular pain (see [Policy Guidelines](#)) and at least one of the following criteria are met (1.-3.):
    1. Documented moderate to severe interference of radicular pain with age-appropriate activities of daily living (see [Policy Guidelines](#)); **or**
    2. For thoracic/lumbar ESIs, severe disability as measured by the Oswestry Disability Index (see [Policy Guidelines](#)); **or**
    3. For cervical ESIs, moderate to severe disability as measured by the Neck Disability Index (i.e. 15 points or higher on Neck Disability Index) (see [Policy Guidelines](#) for complete definition); **and**
  - C. Patient meets **at least one** of the following (1.-2.) criteria:
    1. Advanced imaging (MRI or CT) identifying **either** of the following (1.-2.):
      - a. Foraminal or lateral recess stenosis which may be causing nerve root impingement and/or demonstrated nerve contact; **or**
      - b. Disc protrusion which may be causing nerve root impingement and/or demonstrated nerve contact; **or**
    2. Electrodiagnostic study showing radiculopathy (see [Policy Guidelines](#)); **and**
  - D. There is corresponding dermatomal distribution of the radicular pain; **and**
  - E. Symptoms have failed to respond to 6 weeks of conservative treatment (see [Policy Guidelines](#) for all requirements and exceptions) *within* the last 6 months, including both of the following( 1.-2.):
    1. Physical therapy including either one the following (a.-b.)
      - a. At least 3 physical therapy visits (including active muscle conditioning) over a course of 6 weeks or less; **or**

- b. Physical therapist's notes, or a physician's statement in the documentation explaining why physical therapy is contraindicated (e.g. progressively worsening pain and disability); **and**
  - 2. Documented medication usage (e.g. narcotic analgesics, muscle relaxants, non-steroidal anti-inflammatory drugs) or participation in an interdisciplinary pain management program; **and**
  - F. The injection is targeted to the documented impingement and/or contact point; **and**
  - G. No more than the maximum number of nerve root levels per session is performed (1.-2.):
    - 1. Caudal and interlaminar: No more than 1 level per session may be performed and not in conjunction with an transforaminal injection.
    - 2. Transforaminal: No more than 2 transforaminal ESIs may be performed at a single setting (e.g. single level bilaterally or two nerve root levels unilaterally)
- II. Epidural steroid injections are considered **not medically necessary and are not covered** when criterion I. above is not met.

Repeat Injection(s)

- III. Repeat epidural steroid injection(s) (see [Policy Guidelines](#) for definition) may be considered **medically necessary and covered** when **all** of the following criteria are met (A.-C.):
- A. Criterion I. above is met; **and**
  - B. Documentation that the initial injection(s) resulted in **all** of the following (1.-3.):
    - 1. Greater than 50% radicular pain relief as measured by a standardized rating scale (e.g. Visual Analogue Scale; see [Policy Guidelines](#)); **and**
    - 2. Decreased medication use; **and**
    - 3. Improvement in the patient's activities of daily living (see e.g. [Oswestry Disability Index](#), [Neck Disability Index](#); see Policy Guidelines); **and**
  - C. Documentation of a formal evaluation, performed in-office or via video televisit, which includes a physical exam and reasons for repeating the injection (see [Documentation Requirements](#)).
- IV. Repeat epidural steroid injections are considered **not medically necessary and are not covered** when criterion III. above is not met.

Frequency Limitations

- V. No more than 3 sessions per spinal region (cervical, thoracic, lumbar) per 12-month period may be considered **medically necessary and covered**.
- VI. No more than 4 ESIs in a 6-month period may be considered **medically necessary and covered**.

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VII. No more than 6 ESIs per 12-month period, regardless of the number of levels involved, may be considered **medically necessary and covered**.

### Other Medically Necessary Indications

VIII. Epidural steroid injections for the treatment of post-herpetic neuralgia may be considered **medically necessary and covered** when there is documentation of recent shingles.

### Non-Covered Indications

IX. Conscious sedation, Monitored Anesthesia Care (MAC), and intraoperative neuromonitoring (IONM) is considered **not medically necessary and not covered** when performed with an epidural steroid injection.

X. Epidural steroid injections performed without imaging guidance (62320, 62322) are considered **not medically necessary and not covered**.

XI. Interlaminar epidural steroid injections performed above C7-T1 are considered **not medically necessary and are not covered**.<sup>1</sup>

XII. Epidural steroid injections with ultrasound guidance (0228T-0231T) are considered **not medically necessary and are not covered** for any indication.

XIII. Epidural steroid injections are considered **not medically necessary and are not covered** for the following indications (A.- I.):

- A. Back or neck pain without radiculopathy
- B. Isolated central spinal stenosis
- C. Chemical radiculitis caused by annular tears
- D. Post-operative pain relief from spinal fusion and/or discectomy/laminectomy
- E. Axial low back pain without leg dominant symptoms originating in the nerve roots
- F. Axial or nonspecific pain without radiating pain, unless involving a nerve root that does not refer to a limb
- G. Cancer-related pain
- H. Infection
- I. Compressive lesions of the spinal cord, conus medullaris or cauda equina.

Link to [Policy Summary](#)

## POLICY GUIDELINES

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*Activities of daily living:* The activities of daily living (ADLs) is a term used to describe essential skills that are required to independently care for oneself.<sup>2</sup> Examples may include, but are not limited to, the following:

- Ambulating
- Feeding
- Dressing
- Personal hygiene
- Transportation and shopping
- Meal preparation
- Housecleaning and home maintenance

*Conservative treatments:* According to the North American Spine Society, the majority of acute back, neck and radicular pain will improve over 4 weeks.<sup>1</sup> Conservative care must be recent (within the last year) and include all of the following:

- Participation in a physical therapy program for the duration of conservative management, including at least 3 physical therapy visits
- Oral analgesics (including anti-inflammatory medications, if not contraindicated)
- Oral corticosteroids (if not contraindicated)
- Exceptions to waiting 4 weeks should be documented and reviewed on a case-by-case basis. Reasonable exceptions may include but are not limited to the following:<sup>1</sup>
  - At least moderate to severe pain, with functional loss at work and/or home
  - Pain unresponsive to outpatient medical management
  - Inability to tolerate nonsurgical, noninjection care due to coexisting medical condition(s) (e.g. cardiac disease), or severe pain
  - Prior successful injection therapy for the same condition that achieved greater than 50% pain relief with documented functional improvement, reduced impairment or decrease in analgesic medication.

Additional indications for which conservative care **may be waived** include the following:

- Spinal cord compression with corresponding neurological symptoms
- Stenosis causing cauda equina syndrome
- Stenosis causing myelopathy
- Stenosis causing severe weakness (graded 4 minus or less on Medical Research Council (MRC) Scale\*)
- Severe stenosis associated with instability (dynamic excursion of greater than 1mm translation or greater than 5 degrees angulation at interspace)
- Progressive neurological deficit on serial examinations
- Discharge note from a physical therapist documenting lack of utility of further physical therapy

\*

<b>Medical Research Council (MRC) Scale</b>	
<i>Grade</i>	<i>Description</i>

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0	No contraction
1	Flicker or trace of contraction
2	Active movement with gravity eliminated
3	Active movement against gravity
4 minus	Active movement against gravity and slight resistance
4	Active movement against gravity and moderate resistance
4 plus	Active movement against gravity and strong resistance
5	Normal power

*Maximum number of nerve root levels that may be performed in one session:*

- **Caudal and interlaminar:** No more than 1 level per session may be performed and **not** in conjunction with an transforaminal injection.
- **Transforaminal:** No more than 2 transforaminal ESIs may be performed at a single setting (e.g. single level bilaterally or two nerve root levels unilaterally)

*Neck Disability Index:* The Neck Disability Index (NDI) is a modification of the Oswestry Disability Index, and is used by clinicians and researchers to quantify neck pain.<sup>3</sup> Patients self-report scores across 10 categories, including pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation. Each section is scored on a 6-point scale ranging from 0 (“no pain”) to 5 (“worst imaginable pain”).

- Scoring
  - 0-4 points (0-8%) no disability,
  - 5-14 points ( 10 – 28%) mild disability,
  - 15-24 points (30-48% ) moderate disability,
  - 25-34 points (50- 64%) severe disability,
  - 35-50 points (70-100%) complete disability

*Oswestry Disability Index:* The Oswestry Disability Index (ODI) is an index derived from the Oswestry Low Back Pain Questionnaire used by clinicians and researchers to quantify disability for low back pain.<sup>4</sup> The questionnaire contains ten topics concerning intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel. Each question is scored by the patient on a scale of 0-5 (least amount of disability to most severe disability). Scores are then added and then doubled to obtain the index (range 0 to 100).

- Scoring
  - 0%–20%: Minimal disability
  - 21%–40%: Moderate disability
  - 41%–60%: Severe disability
  - 61%–80%: Crippling back pain
  - 81%–100%: Patients are either bed-bound or have an exaggeration of their symptoms

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*Persistent, debilitating pain:* Persistent, debilitating (or disabling) pain is defined as significant level of pain on a daily basis defined on a Visual Analog Scale as greater than “5” (moderate). The scale ranges from “0” (no pain) to “10” (as bad as it could be).

*Radiculopathy:* Dysfunction of a nerve root associated with pain, sensory impairment, weakness, or diminished deep tendon reflexes in a nerve root distribution.<sup>5</sup> Signs and symptoms of radiculopathy must be confirmed by imaging studies and may include any of the following:

- Pain that radiates into the distal portion of the extremities following the nerve root distribution for the proposed intervention
- Numbness and tingling in a dermatomal distribution
- Muscular weakness in a pattern associated with spinal nerve root compression
- Increased or abnormal reflexes corresponding to affected nerve root level
- Loss of sensation in a dermatomal pattern.

*Repeat injections:* Repeat injections refer to injections performed via the same method (e.g. interlaminar, caudal) and at the same location as a prior injection. Injections performed via a different method and/or at a different location are considered “initial injections.”

## BILLING GUIDELINES

Convenience kits, such as Dyural 80, are not covered. Physicians are to bill for the steroid medication only. All other costs are procedural expenses.

The following codes for monitored anesthesia and moderate sedation will deny when billed with an epidural steroid injection (CPT: 62321, 64479, 64480, 62323, 64483, 64484):

- 00300
- 00600
- 00620
- 00630
- 00640
- 01992
- 99152
- 99153
- 99156
- 99157

## CPT/HCPCS CODES

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Prior Authorization Required

**Cervical/Thoracic Region**

62321	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)
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)

**Lumbar Region**

62323	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)
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)

Not Covered

62320	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
62322	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
<del>0228T</del>	<b>TERMED 12/31/2020</b> <del>Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; single level</del>
<del>0229T</del>	<b>TERMED 12/31/2020</b> <del>Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; each additional level (List separately in addition to code for primary procedure)</del>
<del>0230T</del>	<b>TERMED 12/31/2020</b> <del>Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level</del>



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<b>0231T</b>	<b>TERMED 12/31/2020</b> <del>Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; each additional level (List separately in addition to code for primary procedure)</del>
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**DESCRIPTION**

Epidural Steroid Injections

Epidural steroids injections (ESIs) involve the placement of steroids into the epidural space to decrease lower back pain or neck pain associated with radicular symptoms. Epidural injections can be performed by the translaminar approach (via the interlaminar space in the spine), the transforaminal approach (through the neuroforamen dorsal to the nerve root), or the caudal approach (through the sacral hiatus at the sacral canal).<sup>6</sup>

Low Back Pain

Per a 2010 Hayes review:<sup>7</sup>

“Low back pain is a major cause of disability in adults, occurring in 15% to 20% of the working-age population annually and 80% of adults at some point in their lives. While most occurrences of low back pain resolve without intervention, approximately 10% of the cases do not respond to conservative treatment and are associated with chronic and disabling pain. The most prevalent cause of low back pain is intervertebral disc disease (IDD). Intervertebral discs consist of an outer component known as the annulus fibrosus, and an inner component known as the nucleus pulposus. IDD results in discogenic pain, which is persistent and disabling. When involving discs of the lower back, the resulting pain is characterized by chronic and disabling pain in the low back, may involve lesser pain in the groin or legs, and typically worsens with sitting or standing and subsides with lying down.”

Radiculopathy

Radiculopathy, often referred to as a “pinched nerve,” is a pathologic process wherein a nerve in the cervical, lumbar or thoracic spine is compressed or irritated. This often occurs as a result of degenerative changes, which may lead to bone spurs or herniated discs. Symptoms include pain, numbness, or weakness radiating from anywhere from the neck into the shoulder, arm, hand or fingers.<sup>8</sup>

Spinal Stenosis

Spinal stenosis is predominantly caused by degeneration in the intervertebral discs, ligaments and bone structures of the spine, and is characterized by a narrowing of the spinal canal, lateral spinal recesses and compressed neural elements in the lower back, resulting in pain and disability. Symptoms are typically provoked by upright exercise, including walking, and relieved with forward flexion at the waist, sitting or reclining. While conservative treatments improve symptoms in one-third of patients (e.g.

physical therapy, nonsteroidal anti-inflammatory drugs), surgical options for those refractory to these therapies range from minimally invasive decompression techniques to traditional surgical laminectomy with or without spinal fusion, laminotomy, or hemilaminotomy.<sup>9</sup>

### Sciatica

Sciatica refers to pain that radiates along sciatic nerve, branching from the lower back through the hips, buttocks and legs. Sciatica most commonly occurs as the result of a herniated disc, degenerative disc disease of spinal stenosis compressing part of the nerve. Symptoms include inflammation, pain and numbness in the affected leg.

### Post-herpetic neuralgia

Post-herpetic neuralgia is the most common complication of shingles, occurring when nerve fibers are damaged during an outbreak of shingles, resulting in chronic pain.

### Chemical radiculitis caused by annular tears

The annulus refers to the outer ring of fibers surrounding intervertebral discs, which connect vertebral bones. An annular tear occurs when the annulus is torn or ruptured, with no accompanying rupture to the disc material itself. Chemical radiculitis refers to the inflammation of the nerve root due to an annular tear and the dissemination of disc fluid along the nerve root sheath, evoking antibody response and an auto-immune reaction. It has been suggested that symptoms of low back pain and radiating leg pain, not identifiable by MRI or CT, could be explained by the irritating effects of chemical mediators leaking through annular tears.<sup>10,11</sup>

### Post-operative pain relief from spinal fusions or discectomy/laminectomy

Spinal fusion refers to surgery that eliminates motion between two or more vertebrae in the spine by fusing them together. Bone grafts are placed around the spine during surgery, around which the body heals, thereby joining the vertebrae together. Discectomy refers to the surgical removal of part, or the entirety of an intervertebral disc that is pressing on a nerve root or the spinal cord. Before the disc material is removed, a small piece of bone (the lamina) from the affected vertebra may also be removed, allowing access to the spinal cord, and/or to relieve pressure on nerves (i.e. laminectomy).

## **REVIEW OF EVIDENCE**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of epidural steroid injection (ESI) as a diagnostic tool or treatment for back and neck pain. Below is a summary of the available evidence identified through July 2020.

### Medically Necessary Indications

#### *Cervical Radiculopathy*

In 2020, Hayes evaluated the safety and efficacy of epidural steroid injections (ESIs) for the treatment of cervical radiculopathy.<sup>12</sup> Searching the literature through January 2019, Hayes included 7 publications (including 6 RCTs) for review. Sample sizes ranged from 38 to 120. Follow-up times ranged from 3 weeks to 2 years. Outcomes of interest were pain, function, opioid use and symptom relief duration.

Three studies reported no difference in pain between ESIs and anesthetic injection alone at up to 2-year follow-up. Across individual studies, patients receiving autologous conditioned serum (ACS) injections and percutaneous epidural neuroplasty (PEN) reported superior pain outcomes compared to patients receiving ESI. No difference in pain was reported between ESI patients and patients receiving pulsed radiofrequency (RF). No difference in function was found between patients receiving ESI and either anesthetic injection alone, PEN or pulsed RF, although ACS patients experienced comparatively superior outcomes. Two studies assessed opioid use in patients receiving ESI or anesthetic injection alone and found no differences. One study found greater duration of symptom relief in PEN patients compared to ESI patients. While adverse events (AEs) across studies were typically minor, serious AEs outside of the reviewed studies have occurred, including paraplegia, meningitis, and epidural abscess.

Hayes assessed the overall quality of evidence as “low.” Limitations among reviewed studies included the lack of placebo-controlled trials, lack of follow-up beyond 2 years, lack of patient selection criteria and treatment parameters (e.g. injection route, type of steroid, type of anesthetic), and the difficulty of definitively establishing efficacy given the variation in the underlying causes of radicular pain and in ESI approaches. Hayes concluded that alternative “poorly investigated” treatments, such as ACS and PEN, may improve long-term pain and function outcomes compared to ESI. Hayes ultimately assigned a “D1” rating (no proven benefit) for ESI use in adults with cervical radiculopathy noting the low-quality but consistent evidence indicating ESI’s lack of beneficial effect on pain or disability stemming from cervical radiculopathy compared with epidural injections of anesthetic alone.

### *Lumbar Radiculopathy*

In 2011 (updated 2016), the Washington State Health Care Authority conducted a systematic review and meta-analysis evaluating the safety and efficacy of spinal injections for the treatment of back and neck pain.<sup>13</sup> Independent investigators systematically searched the literature through July 2015, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 124 publications were included for review, including 72 RCTs appearing in 95 publications.

The quality of evidence across all included studies was assessed to be “low.” For indications of lumbar radiculopathy, lumbar spinal stenosis, failed back surgery syndrome, facet joint pain, and sacroiliac joint pain, investigators found no difference for pain, function and risk of surgery outcomes for patients receiving either ESI injections, control injections or placebos. For cervical radiculopathy due to disc and/or foraminal narrowing, investigators found no difference between ESI patients and conservative care patients in outcomes of arm pain, and surgery; however, functionality was better for conservative care patients. For indications of cervical radiculopathy and spinal stenosis, ESI patients and patients receiving control injections experienced no difference in pain, function, and disability outcomes. In its “final findings and decision” document, investigators recommended, over a 6-month span, no more

than 3 fluoroscopic or CT-guided ESIs in the lumbar or cervical-thoracic spine for the treatment of patients with radicular pain who have failed conservative therapy.<sup>14</sup>

#### *Thoracic Radiculopathy*

In 2018, Hayes conducted a “search and summary” of abstracts evaluating the safety and efficacy of epidural steroid injections for thoracic radiculopathy.<sup>15</sup> Searching the literature through August 2018, Hayes retrieved five abstracts for review (1 systematic review, 1 RCT, 1 retrospective uncontrolled study, 1 case report, and 1 literature review.) Despite positive results reported in the abstracts, Hayes concluded that published evidence was insufficient to assess the safety and efficacy for ESI’s for the treatment of thoracic radiculopathy.

#### *Sciatica*

Several older systematic reviews and meta-analyses have indicated that epidural steroid injections more effectively reduce pain from sciatica at short- and medium-term follow-up compared to placebo injections.<sup>16-19</sup>

#### Injection Route

- In 2018, Lee and colleagues conducted a systematic review and meta-analysis comparing the clinical efficacy of transforaminal (TFESI) and caudal epidural steroid injections (CESI) for the treatment of lumbar and lumbosacral disc herniation.<sup>20</sup> Independent investigators systematically searched the literature through July 2017, identified eligible studies, assessed study quality, extracted data and pooled results. Outcomes of interest were pain (measured by visual analogue scale [VAS] and numeric rating scale) and disability (measured by Oswestry disability index). In total, 6 studies were included for qualitative review. Outcomes were analyzed using a random effects model to obtain effect size and statistical significance.

Of the 6 studies, 4 supported the superiority of TFESI over CESI, compared to 1 study supporting the superiority of CESI to TFESI, while 1 article reported no significant difference. TFESI patients experienced insignificantly improved pain and functionality at 1- and 6-months follow-up compared to CESI patients. Meta-analysis indicated insignificantly superior clinical efficacy with TFESI compared to CESI. Limitations in reviewed studies included small sample sizes (four of the six studies included fewer than 100 subjects), a high degree of heterogeneity of patients’ baseline characteristics and treatment parameters. As such, the overall quality of evidence was assessed as “low.” Investigators “weakly recommended” TFESI over CESI, despite noting the results’ inconclusiveness.

- In 2016, Liu and colleagues conducted a systematic review and meta-analysis comparing the efficacy of transforaminal and caudal epidural steroid injections for the treatment of lumbosacral radicular pain.<sup>21</sup> Independent investigators systematically searched the literature through June 2015, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 8 studies were included for review (6 prospective and 2 retrospective). The

combined sample size was 942 patients, although only the 664 patients from the prospective studies were included for meta-analysis. Follow-up periods ranged from 2 weeks to 2 years. The primary outcome of interest was “degree of pain relief” (visual or verbal analog pain score); the secondary outcome measure was functional improvement, as measured by the Oswestry Disability Index. Meta-analysis indicated that TFESI patients experienced insignificantly superior improvements in pain and function compared to CESI patients at 2-week follow-up, although the clinical significance of these improvements was unclear. These differences disappeared at 3-, 6-, and 12-months follow-up. TFESI and CESI patients also experienced no difference in function at any follow-up period.

Limitations included the lack of RCTs, small sample sizes, and high degree of heterogeneity in patient characteristics and treatment parameters among included studies. Investigators concluded that both TFESI and CESI appear to effectively improve pain and function for patients with lumbosacral radicular pain. While TFESI patients’ radicular pain was slightly superior to CESI patients’ at up to 6-month, CESI patients’ pain and function were slightly better than TFESI patients’ at 12-months follow-up. Authors called for additional studies to validate these findings and further guide clinical decision-making.

#### Post-Herpetic Neuralgia

Studies assessing the safety and efficacy of ESI’s for the treatment of post-herpetic neuralgia is limited, but indicates significant pain reduction at 1- and 3-months follow-up. One RCT assessing 40 patients found significantly improved pain scores at 1- and 3- months follow-up compared to baseline.<sup>22</sup> Another found that ESI’s reduced pain and improved quality of life more effectively than patients receiving oral antivirals and analgesics alone.<sup>23</sup> Limitations include studies’ small sample sizes (n=40 to 100), and the lack of studies including groups receiving placebo injections.

#### Investigational Indications

##### *Low Back Pain without Radiculopathy*

In 2015, AHRQ conducted a systematic review evaluating the safety and efficacy of pain management injection therapies for the treatment of low back pain.<sup>24</sup> Investigators systematically searched the literature for randomized trials of patients with lumbosacral radiculopathy, spinal stenosis, non-radicular back pain or chronic postsurgical back pain. The safety and efficacy of epidural, facet joint or sacroiliac corticosteroid injections were evaluated in placebo-controlled trials for the above indications. In total, 78 RCTs evaluating epidural injections were included for review. Investigators found low-quality evidence suggesting that epidural corticosteroid injections were not effective for spinal stenosis or non-radicular back pain. Results did not clearly demonstrate effectiveness for ESI versus placebos in the treatment of radiculopathy, spinal stenosis and non-radicular back pain in outcomes of pain, function or likelihood of surgery. Significant improvements were observed in the following: pain at immediate-term follow-up (WMD -7.55 on a 0 to 100 scale, 95% CI -11.4 to -3.74); function at intermediate-term follow-up when an outlier trial was excluded (SMD -0.33, 95% CI -0.56 to -0.09); and risk of surgery at short-

term follow-up (RR 0.62, 95% CI 0.41 to 0.92); however, these benefits were small and not sustained at long-term follow-up.

#### *Degenerative Spondylolisthesis*

In 2020, Gerling and colleagues published a retrospective cohort study, using 4-year prospective data from the degenerative spondylolisthesis cohort of the Spine Patient Outcomes Research Trial (SPORT).<sup>25</sup> Authors intended to measure the effect of ESI on both patient-reported outcomes and perioperative complications and assess the relationship between ESI treatment and rates of crossover from nonoperative to operative management. In total, 266 patients who never received ESIs prior to enrollment in the study and 74 patients who received ESIs within 3 months of enrollment were compared with 192 patients who did not receive ESIs at any time during 4 years of follow-up. At follow-up, patient-reported pain and function were similar between ESI and no-ESI groups. Of the patients who were initially treated nonsurgically, those who received ESI and those who did not receive ESI did not differ with regard to surgical crossover rates. The rates of crossover to nonoperative treatment by patients who initially chose or were assigned to surgery also did not differ between the ESI and no-ESI groups. Investigators concluded that there was no relationship between ESI and improved clinical outcomes over a 4-year study period for patients who underwent surgery for degenerative spondylolisthesis. Due to this lack of long-term efficacy, ESI treatment was judged to have limited impact on patient decisions to avoid surgery.

#### *Spinal Stenosis*

In 2016, Cochrane conducted a systematic review comparing the safety and efficacy of surgical versus non-surgical interventions for the treatment of lumbar spinal stenosis (LSS).<sup>26</sup> Investigators searched the literature through February 2015, identified eligible studies, assessed study quality and extracted data. Outcomes of interest included pain, function, disability and quality of life. In total, 26 articles were included for review, including 5 RCTs (n = 643). Follow-up times ranged from 6 weeks to 10 years. Of the 26 studies, one small, low-quality study (n=38) included for review reported no difference in disability for patients treated with minimally invasive mild decompression versus those treated with ESI at 6-week follow-up (MD 5.70, 95% CI 0.57 to 10.83). Pain results, as assessed by the Zurich Claudication Questionnaire, were better for epidural injection at six weeks (MD -0.60, 95% CI -0.92 to -0.28), and visual analogue scale (VAS) improvements were better in the mild decompression group (MD 2.40, 95% CI 1.92 to 2.88). Investigators concluded that all studies provided conflicting, low-quality evidence on the efficacy of surgery versus conservative treatments for LSS.

#### *Chemical radiculitis caused by annular tears*

No clinical trials were identified addressing the safety or efficacy of ESI's to treat chemical radiculitis caused by annular tears.

#### *Post-operative pain relief from spinal fusions or discectomy/laminectomy*

Evidence from two systematic reviews concluded that evidence was insufficient to support the use of ESIs for the treatment of pain following discectomy/laminectomy procedures.<sup>27,28</sup> One study assessing 12 trials (n=1,006) found that ESI's reduced post-operative morphine consumption for conventional surgeries, but not for discectomy.<sup>27</sup> Another study,<sup>28</sup> assessing 17 RCTs (n=1,727), reported that while ESIs significantly improved pain control and morphine use at short-term follow-up, the low-quality of articles included for meta-analysis necessitated "significantly more research" before ESIs could be recommended for routine use. One small RCT has been published since the above systematic reviews conducted literature searches. The study reported that found that 30 discectomy patients receiving ESIs experienced no statistically significant improvement in pain, morphine intake or disability compared to patients receiving placebo injections at short and mid-term follow-ups.<sup>29</sup>

No studies were identified addressing the safety or efficacy of ESI's to treat post-operative pain from spinal fusion surgery or discectomy/laminectomy.

## **CLINICAL PRACTICE GUIDELINES**

### Imaging Guidance

- In 2014, the North American Spine Society (NASS) issued a coverage guidance addressing lumbar ESIs.<sup>30</sup> The guidance stated that ESIs required contrast enhanced fluoroscopy or CT guidance, regardless of indication or injection approach. The following recommendations were also made:
  - For transforaminal ESIs, live contrast-enhanced fluoroscopy or digital subtraction angiography is preferred, though contrast-enhanced CT guidance may be performed with the understanding that this form of visualization might not detect intravascular flow leading to potential complications, especially if particulate steroids are used.
  - Exceptions to the use of contrast are considered in patients who have a significant history and/or are at high risk for an adverse event if contrast material is used (e.g. contrast allergy).
    - In these cases, physicians should consider using a test-dose injection prior to injecting any particular steroids and/or use only non-particulate steroid solutions.
    - The reasons for not using contrast should be documented in the procedure report.<sup>30</sup>
- In 2012, the North American Spine Society issued a clinical practice guideline on the diagnosis and treatment of lumbar disc herniation with radiculopathy. The NASS issued a "grade A" recommendation for contrast-enhanced fluoroscopy to guide ESIs to improve the accuracy of medication delivery.<sup>31</sup>
- In 2011, the North American Spine Society issued a clinical practice guideline on the diagnosis and treatment of degenerative lumbar spinal stenosis.<sup>31</sup> The NASS issued a grade "A" recommendation for contrast-enhanced fluoroscopy to guide ESIs to improve the accuracy of medication delivery.

## MEDICAL POLICY

## Back: Epidural Steroid Injections (All Lines of Business Except Medicare)

### Radicular Pain (Cervical, Thoracic, Lumbar)

#### *Department of Veteran Affairs/Department of Defense (VA/DoD)*

In 2017, a multidisciplinary panel of experts conducted a systematic review evaluating interventions for the diagnosis and treatment of low back pain.<sup>32</sup> The VA/DoD strongly recommended against the use of ESI's for the long-term reduction of radicular low back pain, non-radicular low back pain, or spinal stenosis. The guideline issued a "weak" recommendation for the use of ESI's for the very short-term reduction of radicular low back pain.

#### *American Academy of Family Physicians (AAFP)*

In 2016, the AAFP issued clinical recommendations for the non-operative management of cervical radiculopathy, stating that ESIs should be considered among patients that experienced no improvement after 4 to 8 weeks of non-operative treatment.<sup>33</sup> This recommendation was made on the basis of expert opinion, not a systematic evidence review.

#### *Colorado Division of Worker's Compensation (CDWC)*

- The 2014 Colorado Division of Workers' Compensation evidence-based clinical practice guideline for low back pain medical treatment stated "there is strong evidence that epidural steroid injections have a small average short term benefit for leg pain and disability for those with sciatica."<sup>34</sup> The guideline also concluded there is good evidence that the addition of steroids to a transforaminal injection has a small effect on patient reported pain and disability. Lastly, the guideline stated "there is strong evidence that epidural steroid injections do not, on average, provide clinically meaningful long-term improvements in leg pain, back pain, or disability in patients with sciatica (lumbar radicular pain or radiculopathy)."<sup>34</sup>
- In 2014, the CDWC issued medical treatment guidelines on cervical spine injury, stating that ESI should not be used for non-radicular cervical pain, and should only be used in a small subset of patients who meet the following criteria:<sup>35</sup>
  - Radicular findings or herniated disc and meet all of the indications for surgery at approximately 6 to 8 weeks' post-active therapy
  - Rare acute ruptured (herniated) disc with clear objective radiculopathy if, after 1 to 2 weeks of initial oral analgesic and conservative treatment there is:
    - Continued pain interfering with most activities of daily living
    - An inability to tolerate the required movements to participate in therapy
    - Pain greater in the arm than in the neck (generally of  $\geq 7$  on the VAS scale of 10)
    - Pain following a correlated radicular dermatome
    - A herniated disc on magnetic resonance imaging at the level of subjective and objective findings



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- The presence of either (1) dural tension, Spurling sign, traction/distraction, or upper limb tension test and/or (2) decreased reflexes, radicular sensation deficits, or motor weakness on testing
- Spinal stenosis

### *American Society of Interventional Pain Physicians (ASIPP)*

In 2014, ASIPP issued an update to its evidence-based guidelines on interventional techniques in chronic spinal pain.<sup>36</sup> For managing disc herniation or radiculitis in the lumbar spine, ASIPP concluded that evidence, ranging in quality from “fair” to “good,” supported the use of ESI’s for managing disc herniation, radiculitis, discogenic pain without disc herniation, and spinal stenosis. In the cervical spine, ASIPP concluded that “fair” to “good” quality evidence supported the use of ESI for disc herniation, radiculitis, axial pain, discogenic pain, spinal stenosis and post cervical surgery syndrome. ASIPP also concluded that fair quality evidence supported the use of ESI for managing thoracic pain.

### *American Society of Regional Anesthesiologists (ASRA)/ American Society of Regional Anesthesia and Pain Medicine (ASRA/ASRAPM)*

In 2010, ASRA and ASRA/ASRPM issued a joint practice guideline for chronic pain management.<sup>37</sup> The guidance described ESI as a single-modality intervention for pain and noted that ESI may be used with or without local anesthetics as part of a multimodal treatment regimen for select patients with radicular pain or radiculopathy.

### *American Academy of Neurology (AAN)*

In 2007, the “Therapeutics and Technology Assessment Subcommittee” of the AAN issued a guidance addressing the use of ESI to treat lumbosacral pain.<sup>38</sup> The AAN concluded that ESIs may result in some improvement in radicular lumbosacral pain when assessed between 2 and 6 weeks following the injection, compared to control treatments. The body clarified that the benefit is small and generalizability is limited by the low-quality of evidence. Moreover, ESI’s for radicular lumbosacral pain does not impact average function, need for surgery or provide pain relief beyond 3 months. Evidence was assessed to be insufficient to establish the efficacy of ESI to treat radicular cervical pain.

### *North American Spine Society (NASS)*

- In 2020, NASS issued a coverage recommendation addressing epidural steroid injections and selective spinal nerve blocks.<sup>1</sup> On the basis of an evidence review conducted through July 2018, investigators stated the following:
  - Therapeutic ESIs are indicated for the treatment of radicular or referred pain in which 2 of 4 of the following criteria are met:<sup>1</sup>
    - The pain is severe enough to cause a degree of functional and/or vocational impairment or disability.

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- Pain duration of at least 4 weeks, and/or inability to tolerate or failure to respond to 4 weeks of noninvasive care
- Objective findings of radiculopathy or sclerotomal referred pain pattern are present and documented on examination
- Advanced imaging (CT or magnetic resonance imaging [MRI]) demonstrates a correlative region of nerve involvement

Investigators also listed the following contraindications to ESIs:<sup>1</sup>

- Axial or nonspecific pain without radiating pain (unless it involves a nerve root that does not refer to a limb)
- Cancer
- Infection
- Compressive lesions of the spinal cord, conus medullaris or cauda equina
- Relative contraindications: uncontrolled bleeding disorders, poorly controlled diabetes, immune system impairment, and history of severe allergic reaction to components

Additional recommendations included the following:<sup>1</sup>

- To minimize the risk of direct spinal cord injury, interlaminar ESIs should not be performed above C8
  - The ultimate choice of what approach or technique (interlaminar versus transforaminal) to use should be made by the treating physician
  - Injections are performed independently based on the patient's symptoms and response to prior injections and approach (if performed). There is no role for a routine "series of 3" ESIs.
  - No more than 4 ESIs should be performed in a 6-month period of time
  - No more than 6 ESIs should be performed in a 12-month period of time regardless of the number of levels involved.
  - No more than 2 transforaminal ESIs should be performed at a single setting (e.g. single level bilaterally or two levels).
  - For caudal or interlaminar ESIs, only one level per session may be performed and not in conjunction with a transforaminal injection.
  - Local anesthesia is sufficient for a majority of ESIs. Occasionally minimal to moderate conscious sedation is an appropriate option on a case-by-case basis in consultation with patients who understand the risk benefit ratio. If monitored anesthesia care is utilized, the need for such sedation should be clearly documented in the medical records.
- In 2014, NASS issued a coverage recommendation addressing lumbar epidural injections.<sup>30</sup> The recommendation indicated therapeutic lumbar ESIs for the following diagnoses with qualifying criteria, when appropriate:
    - Lumbar radicular pain in which the following criteria are met:
      - the pain is severe enough to cause some degree of functional deficit
      - failure of at least four weeks of noninvasive care

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- imaging demonstrating a correlative region of nerve impingement
  - Neurogenic claudication in which the following criteria are met:
    - the pain is severe enough to cause some degree of functional deficit
    - failure of at least four weeks of noninvasive care
    - imaging demonstrating a correlative region of nerve impingement
  - Low back pain without lower extremities symptoms ONLY in the following clinical scenarios:
    - High-level athletes during a competitive season
    - Pregnant women with intractable low back pain unresponsive to other treatments
  - NASS noted that exceptions to waiting 4 weeks should be reviewed on a case-by-case basis. Potential exceptions may include:
    - 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 co-existing medical condition(s) (e.g. cardiac disease)
    - Prior successful ESI for the same condition
- In 2014, NASS issued a coverage recommendation in which cervical ESI's were indicated for the treatment and/or evaluation of radiculopathy or radicular pain with a maximum of 4 diagnostic and/or therapeutic injections within a 6-month period.<sup>39</sup> NASS stated that injections should be performed with fluoroscopic or computed tomography (CT) image guidance. Cervical ESI's, either interlaminar or transforaminal, are indicated for the treatment of cervical radicular pain due to the following causes that meet the following criteria:
  - Cervical disc herniations, disc protrusions, disc bulges (e.g. disc osteophyte complexes), cervical spinal stenosis (central or foraminal stenosis) noted on an advanced imaging study (MRI or CT) that are consistent with and appear to be contributory to the patient's symptoms.
  - Failure of a course of supportive non-interventional care which can include observation, oral medications, physical therapy and/or activity modification
- In 2012, NASS issued an evidence-based clinical practice guideline addressing the diagnosis and treatment of lumbar disc herniation with radiculopathy.<sup>31</sup> NASS issued a grade "A" recommendation (i.e. good-quality evidence) for transforaminal ESI to provide short-term (2-4 weeks) pain relief in a proportion of patients with lumbar disc herniations with radiculopathy. Evidence was judged to be insufficient to recommend for or against the 12-month efficacy of transforaminal ESI. The body issued a grade "C" recommendation (poor-quality evidence) for interlaminar ESI in the treatment of patients with lumbar disc herniation with radiculopathy. Evidence was judged insufficient to recommend one injection approach over another (e.g. interlaminar, transforaminal, caudal).
- In 2011, NASS issued an evidence-based clinical practice guideline addressing the diagnosis and treatment of degenerative lumbar spinal stenosis.<sup>40</sup> NASS issued a grade "B" recommendation

(fair-quality evidence) for interlaminar ESIs to provide short-term (two weeks to six months) symptom relief in patients with neurogenic claudication or radiculopathy. The body issued a grade “C” recommendation (poor-quality evidence) for a multiple injection regimen of radiographically-guided transforaminal or caudal ESI to produce medium-term (3-36 months) pain relief in patients with radiculopathy or neurogenic intermittent claudication (NIC) from lumbar spinal stenosis.

- In 2010, NASS issued an evidence based clinical practice guideline addressing the diagnosis and treatment of cervical radiculopathy from degenerative disorders.<sup>41</sup> On the basis of poor quality evidence, NASS stated that transforaminal ESI using fluoroscopic or CT guidance may be considered as part of a treatment plan for patients with cervical radiculopathy from degenerative disorders.

#### *Institute for Clinical Systems Improvement (ICSI)*

In 2018, ICSI issued a clinical practice guideline for adult acute and subacute low back pain.<sup>42</sup> On the basis of “moderate” quality evidence, the ICSI issued a “strong recommendation” for epidural steroid injections as an adjunct treatment for acute and subacute low back pain with a radicular component to assist with pain relief.

#### Sciatica

#### *National Institute for Health and Care Excellence (NICE)*

In 2016, NICE issued a clinical practice guideline regarding the assessment and management of low back pain (LBP) and sciatica in adults.<sup>43</sup> The guideline recommended epidural injections of local anesthetic and steroid in people with acute and severe sciatica. NICE recommended against the use of epidural injections for neurogenic claudication in people who have central spinal canal stenosis.

#### Spinal Stenosis

#### *North American Spine Society (NASS)*

In 2011, NASS issued an evidence-based clinical practice guideline addressing the diagnosis and treatment of degenerative lumbar spinal stenosis.<sup>40</sup> The body issued a grade “C” recommendation (poor-quality evidence) for a multiple injection regimen of radiographically-guided transforaminal or caudal ESI to produce medium-term (3-36 months) pain relief in patients with neurogenic intermittent claudication (NIC) from lumbar spinal stenosis.

#### Low Back Pain without Radiculopathy

#### *Health Evidence Review Commission (HERC)*

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In 2017, HERC issued a coverage guidance in which the body strongly recommended against epidural corticosteroid for coverage for the treatment of low back pain without radiculopathy (e.g. spinal stenosis, non-radicular pain); and a “weak” recommendation against epidural corticosteroid injections for coverage for the treatment of low-back with radiculopathy.<sup>44</sup>

#### Other Indications

No clinical practice guidelines were identified addressing the use of ESI’s for the treatment of post-herpetic neuralgia, chemical radiculitis caused by annular tears, or post-operative pain from spinal fusion or discectomy/laminectomy.

## **POLICY SUMMARY**

Evidence is sufficient to support the short-term efficacy of epidural steroid injections as a treatment of a presumed radiculopathy. Evidence also demonstrates, however, that ESIs have no long-term efficacy. ESIs are widely considered standard of care treatment by professional societies. Large, randomized controlled trials are needed to further refine patient selection criteria and optimum treatment parameters (e.g. injection approach and regimen). Multiple clinical practice guidelines support the use of ESIs for short-term pain relief, but recommended against intermediate- or long-term use.

## **INSTRUCTIONS FOR USE**

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

## **REGULATORY STATUS**

#### U.S. Food and Drug Administration (FDA)

Injectable corticosteroids (e.g., prednisone, dexamethasone) are approved by the FDA; however, the safety and effectiveness of corticosteroids for injection into the epidural space has not been established or approved by the FDA.

In April 2014, the FDA warned that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events.<sup>45</sup> To raise awareness of the risks and in an ongoing effort to

investigate this issue, the FDA convened an Advisory Committee meeting of external experts. The committee published “Safeguards to prevent neurologic complications after epidural steroid injections: consensus opinions from a multidisciplinary working group and national organizations.”<sup>46</sup> This includes 17 statements and clinical considerations recommended and endorsed by the working group to prevent adverse events during ESI.

### Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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