MEDICAL POLICY  

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

Effective Date: 3/1/2020

Section: MED  
Policy No: 123

Technology Assessment Committee Approved Date: 10/10; 12/15
Medical Policy Committee Approved Date: 8/94; 7/96; 8/97; 4/98; 4/99; 4/00; 8/01; 12/02; 2/03; 8/03; 7/04; 7/06; 9/08; 10/10; 11/12/13; 10/14; 11/2014; 1/15; 3/15; 4/15; 9/15; 9/16; 6/17; 6/18; 8/19; 2/2020

Medical Officer  
Date

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.

POLICY CRITERIA

Note: Neither conscious sedation nor Monitored Anesthesia Care (MAC) is routinely necessary for epidural steroid injections and are not routinely reimbursable. Individual consideration may be given for payment in rare unique circumstances if the medical necessity of sedation is unequivocal and clearly documented.

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.–E.) are met:

A. A detailed neurologic examination within the last 3 months documents radiculopathy; and
B. 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; and
C. There is corresponding dermatomal distribution of the pain; and
D. The injection is targeted to the documented impingement and/or contact point; and
E. There has been a failure of less invasive interventions including physical therapy and/or chiropractic care and at least one of the following (1.-2.) within the last 6 months:
   1. Medications such as: narcotic analgesics, muscle relaxants, non-steroidal anti-inflammatory drugs; or
   2. Interdisciplinary pain management program.

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) may be considered medically necessary and covered when all of the following criteria are met (A.-C.):

   A. Symptoms of radiculopathy return; and
   B. Documentation that the initial injection(s) resulted in all of the following (1.-3.):
      1. Clinically relevant sustained pain reduction; and
      2. Decreased medication use; and
      3. Improvement in the patient’s functional abilities; and
   C. Documentation that the patient is concurrently participating in an active rehabilitation program/home exercise program/functional restoration program.

IV. Repeat epidural steroid injections are considered not medically necessary and are not covered when criterion III. above is not met.

Frequency Limitations

V. A maximum of 3 sessions per spinal region (cervical, thoracic, lumbar) per 12-month period.

Other Medically Necessary Indications

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

VIII. Epidural steroid injections with ultrasound guidance (0228T-0231T) are considered investigational and are not covered for any indication.

IX. Epidural steroid injections are considered investigational and are not covered for the following indications (A.-D.):

   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

Link to Policy Summary

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.

CPT/HCPCS CODES

All Lines of Business Except Medicare

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<th>Prior Authorization Required</th>
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<td>Cervical/Thoracic Region</td>
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| Lumbar Region |

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**Not Covered**

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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).\(^1\)

**Low Back Pain**

Per a 2010 Hayes review:\(^2\)

“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.³

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.⁴

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.\textsuperscript{5,6}

**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 April 2019.

**Medically Necessary Indications**

**Cervical Radiculopathy**

In 2019, Hayes evaluated the safety and efficacy of epidural steroid injections (ESIs) for the treatment of cervical radiculopathy.\textsuperscript{7} 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. 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.

**Thoracic Radiculopathy**

In 2018, Hayes conducted a “search and summary” of abstracts evaluating the safety and efficacy of epidural steroid injections for thoracic radiculopathy. 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**

- In 2013 (updated 2017; archived 2018), Hayes conducted a systematic review evaluating the safety and efficacy of ESIs for the treatment of low back pain (LBP) and sciatica. Searching the literature through December 2016, Hayes assessed 18 RCTs comparing ESI with epidural placebo or an active control. Sample sizes varied from 48 to 228 patients; follow-up periods ranged from 3 weeks to 2 years. Outcomes of interest were pain reduction, disability and surgery, comparative effectiveness and safety.

  While 3 studies found that ESIs temporarily reduced pain compared with placebo, 7 of 8 studies found that epidural anesthetics reduced pain at least as well as ESIs. Three studies found that epidural steroid injections plus anesthetic reduced pain more than intramuscular injections; however, 4 out of 5 studies found that ESI did not improve disability or reduce the need for...
surgery. Hayes assessed the overall quality of evidence as “low.” Limitations in reviewed studies included small sample sizes, inadequate follow-up, and heterogeneity in patient populations, underlying cause of back pain and injection procedures.

Hayes concluded that while ESIs may transiently reduce LBP and sciatica, the effect appears attributable to the anesthetic that is administered with the steroids, rather than to the steroids themselves. Hayes ultimately assigned a “C” rating (potential but unproven benefit) for ESIs for patients with chronic LBP and/or sciatica for whom conservative therapy has failed. “D1” ratings (no proven benefit) were assigned for ESIs for patients with LBP and/or sciatica who have not tried at least 6 months of conservative therapy and for whom conservative therapy has failed when a steroid is given without an anesthetic.

- 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.12-15

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.16 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.17 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. Another found that ESI’s reduced pain and improved quality of life more effectively than patients receiving oral antivirals and analgesics alone. 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. 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.
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). 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. One study assessing 12 trials (n=1,006) found that ESI’s reduced post-operative morphine consumption for conventional surgeries, but not for discectomy. Another study, 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.

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. The guidance stated that ESIs required contrast enhanced fluoroscopy or CT guidance, regardless of indication or injection approach. The following recommendations were also made:
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- 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.  

- 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.

- In 2011, the North American Spine Society issued a clinical practice guideline on the diagnosis and treatment of degenerative lumbar spinal stenosis. The NASS issued a grade “A” recommendation for contrast-enhanced fluoroscopy to guide ESIs to improve the accuracy of medication delivery.

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. 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. This recommendation was made of 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. 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).”

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:

- 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 ≥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
  - 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. 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. 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.
In 2007, the “Therapeutics and Technology Assessment Subcommittee” of the AAN issued a guidance addressing the use of ESI to treat lumbosacral pain. 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 2014, NASS issued a coverage recommendation addressing lumbar epidural injections. 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
    - 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. 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:
### MEDICAL POLICY

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

- 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. 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, transforminal, caudal).

- In 2011, NASS issued an evidence-based clinical practice guideline addressing the diagnosis and treatment of degenerative lumbar spinal stenosis. 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. 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. On the basis of “moderate” quality evidence, the ISCSI 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.\textsuperscript{38} 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.\textsuperscript{35} 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)*

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.\textsuperscript{39}

**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. 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.” 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.

REFERENCES


