

## FEP 2.01.94 Epidural Steroid Injections for Back Pain

**Effective Date:** April 15, 2018

**Related Policies:**

- 7.01.87 Artificial Intervertebral Disc: Lumbar Spine
- 7.01.107 Interspinous and Interlaminar Stabilization/Distraktion Devices (Spacers)
- 7.01.108 Artificial Intervertebral Disc: Cervical Spine
- 7.01.126 Image-Guided Minimally Invasive Lumbar Decompression for Spinal Stenosis
- 7.01.138 Interspinous Fixation (Fusion) Devices

## Epidural Steroid Injections for Back Pain

### Description

Epidural steroid injections (ESIs) are a treatment for back pain that has not responded to conservative measures. Local steroid injections may improve pain by reducing inflammation, thus relieving pressure on nerve roots or other structures that may be the origin of pain.

### FDA REGULATORY STATUS

Steroids are not approved by the U.S. Food and Drug Administration for use as epidural injections; such use represents off-label use of an U.S. Food and Drug Administration–approved medication. The specific preparations used for epidural injections are steroids added to a sterile saline solution, which are prepared by a compounding pharmacy.

### POLICY STATEMENT

Epidural steroid injections performed with fluoroscopic guidance may be considered **medically necessary** for the treatment of back pain when the following criteria are met:

- Lumbar radiculopathy (sciatica) or cervical radiculopathy that is not responsive to at least 4 weeks of conservative management (see Policy Guidelines section); AND
- Persistent pain is present of at least moderate-to-severe intensity; AND
- Short-term relief of pain is the anticipated outcome.

Repeat treatment of persistent pain due to radiculopathy/sciatica may be considered **medically necessary** under the following conditions:

- Previous epidural steroid injections were successful at relieving pain; AND
- At least 30 days have elapsed since the prior injection (see Policy Guidelines section for maximum number of injections); AND
- No more than 6 injections were given over a 12-month period.

Repeat treatment is considered **not medically necessary** in the absence of documentation of benefit from epidural steroid injections.

## FEP 2.01.94 Epidural Steroid Injections for Back Pain

Simultaneous treatment of 2 vertebral levels may be considered **medically necessary** if criteria are met at each level.

Simultaneous treatment of more than 2 vertebral levels is considered **not medically necessary**.

Epidural steroid injections are considered **investigational** in all other situations, including but not limited to treatment of spinal stenosis and nonspecific low back pain.

The use of fluorography (imaging of the epidural space) as a component of epidural steroid injections is considered **investigational**.

### POLICY GUIDELINES

The diagnosis of lumbar radiculopathy is typically made by a combination of suggestive signs and symptoms in conjunction with imaging that demonstrates compression of a spinal nerve root. Symptoms are due to irritation of the spinal nerve root at L4, L5, or S1, and may include posterior leg pain that extends past the knee, a loss of sensation in a dermatomal pattern, and/or loss of deep tendon reflexes. However, all of these symptoms may not be present. On exam, provocative tests such as the straight leg maneuver are positive. Magnetic resonance imaging is the most useful imaging modality and can confirm or exclude the presence of nerve root compression, most commonly due to a herniated disc.

Several aspects of epidural steroid injection therapy are not standardized. Expert opinion was sought through clinical vetting on the following issues:

- The optimal time for assessing a response to epidural steroid injections. Expert opinion supports that response can be assessed anytime from immediately to several weeks after the procedure, with the most popular time to assess response being 1 to 2 weeks after injection.
- The definition of a clinically significant response to injections. Expert opinion supports that a reasonable definition of response is at least a 20-point improvement on a 0-to-100 visual analog scale, or an improvement of at least 50% in functional status when measured using a validated scale.
- The maximum number of injections in 1 year. There is no agreement on the maximum number of injections that should be given in 1 year. Some experts recommend that no more than 3 injections should be given in 1 year, but other experts believe that more than 3 per year can be used safely. None of the expert opinions supported more than 6 injections given over a 12-month period.

Conservative nonsurgical therapy for at least 4 weeks should include the following:

- Use of prescription-strength analgesics for several weeks at a dose sufficient to induce a therapeutic response
  - Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants AND
- Participation in at least 4 weeks of physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy, AND
- Evaluation and appropriate management of associated cognitive and behavioral issues

### BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

### RATIONALE

#### Summary of Evidence

For individuals who have lumbar or cervical radiculopathy who receive ESI, the evidence includes many small RCTs and a number of systematic reviews of these RCTs. Relevant outcomes are symptoms,

---

## FEP 2.01.94 Epidural Steroid Injections for Back Pain

---

functional outcomes, health status measures, quality of life, medication use, and treatment-related morbidity. The evidence base lacks large-scale, high-quality trials and has a high degree of variability among the available trials in terms of patient populations, epidural injection techniques, and comparison treatments. The results of individual trials are mixed, with some reporting significant benefits for the ESI group and others reporting no benefit. Most systematic reviews do not perform pooled analyses due to the heterogeneity of trials. In the 2 reviews that reported quantitative results, short-term pain relief at up to 6 months follow-up was superior in patients treated with epidural steroids. None of the analyses reported long-term benefits for treatment with ESIs. Adverse events were generally mild but were not well reported in these trials. Serious adverse events can occur, but their rate is unknown. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have spinal stenosis who receive ESIs, the evidence includes a moderately large RCT, a few small RCTs, and systematic reviews of these RCTs. Relevant outcomes include symptoms, functional outcomes, health status measures, quality of life, medication use, and treatment-related morbidity. The largest RCT and the majority of smaller trials do not report a benefit for ESIs. The evidence is insufficient to determine the effects of technology on health outcomes.

For individuals who have nonspecific low back pain who receive ESIs, the evidence includes a number of small RCTs and systematic reviews of these RCTs. Relevant outcomes include symptoms, functional outcomes, health status measures, quality of life, medication use, and treatment-related morbidity. The majority of trials are of low quality and did not report a benefit for ESIs. The evidence is insufficient to determine the effects of the technology on health outcomes.

### SUPPLEMENTAL INFORMATION

#### Practice Guidelines and Position Statements

##### American Association of Neurological Surgeons

The 2014 update of the guidelines on the performance of fusion procedures for degenerative disease of the lumbar spine from the American Association of Neurological Surgeons stated that lumbar epidural steroid injections (ESIs) are an option for short-term relief of chronic low back pain without radiculopathy in patients with degenerative disease of the lumbar spine (level III evidence).<sup>23</sup> Caudal ESIs are an option for reducing low back pain without radiculopathy of greater than 6 weeks in duration in patients with degenerative disease of the lumbar spine (level III evidence).

##### Agency for Healthcare Research and Quality

The Agency for Healthcare Research and Quality issued an evidence-based practice center systematic review protocol in 2014.<sup>24</sup> The protocol indicated that systematic reviews of injection therapies have come to conflicting conclusions regarding the benefits of injection therapies, and clinical practice guidelines provide discordant recommendations regarding their use. Important challenges in conducting a review of this topic include sparse data from randomized trials for most injection therapies (with the exception of epidural steroids), inconsistency of results across trials, as well as variability across studies in the methods used to select patients for inclusion, the specific techniques used, the comparisons evaluated, and the outcomes assessed."

##### North American Spine Society

The 2012 North American Spine Society (NASS) clinical guidelines on multidisciplinary spine care diagnosis and treatment of lumbar disc herniation with radiculopathy stated there were no studies available which directly addressed the role of ESIs or selective nerve root blocks in the diagnosis of patient selection for subsequent surgical treatment of a lumbar disc herniation with radiculopathy.<sup>25</sup>

In 2011, NASS revised its clinical guidelines on multidisciplinary spine care diagnosis and treatment of degenerative lumbar spinal stenosis.<sup>26</sup> NASS made the following recommendation: a multiple injection

---

## FEP 2.01.94 Epidural Steroid Injections for Back Pain

---

regimens of radiographically-guided transforaminal ESI or caudal injections is suggested to produce medium-term (3 to 36 months) relief of pain in patients with radiculopathy or neurogenic intermittent claudication from lumbar spinal stenosis (grade C recommendation).

The 2013 NASS issued a review and recommendation statement on lumbar transforaminal ESIs (LTFESI).<sup>27</sup> The following recommendations were made:

“Patients with lumbar scoliotic stenosis and radiculopathy experience significantly higher success rates if their symptoms were present for less than three months. Level of evidence IV.”

“There is no significant difference between EMG [electromyography] positive and negative groups in terms of pain difference, but a mild functional improvement in an EMG positive patient undergoing LTFESI. Level of evidence V.”

In 2011 NASS issued a review and recommendation statement for cervical ESIs.<sup>28</sup> The following recommendation was made: Both transforaminal and interlaminar ESIs may be considered to provide short- and long-term relief of cervical radiculitis (grade C recommendation).

### American Society of Anesthesiologists

The 2010 guidelines on chronic pain management from the American Society of Anesthesiologists recommended that transforaminal epidural injections should be performed with appropriate image guidance to confirm correct needle position and spread of contrast before injecting therapeutic substances.<sup>29</sup> Image guidance might be considered for interlaminar epidural injections to confirm correct needle position and spread of contrast before injecting therapeutic substance.

### American College of Physicians

The American College of Physicians issued a 2007 guidelines on the diagnosis and treatment of low back pain that stated: “*Patients with persistent low back pain and signs and symptoms of radiculopathy or spinal stenosis should be evaluated with MRI (preferred) or CT [computed tomography] only if they are potential candidates for surgery or ESI. (Strong recommendation, moderate-quality evidence)*”<sup>30</sup>

### American Pain Society

The American Pain Society published guidelines on the use of interventional therapies for low back pain in 2009,<sup>1</sup> based on a systematic review of the evidence published in the same year.<sup>4</sup> These guidelines made the following recommendations regarding ESIs:

- In patients with persistent radiculopathy due to herniated lumbar disc, it is recommended that clinicians discuss risks and benefits of ESIs as an option (weak recommendation, moderate-quality evidence). It is recommended that shared decision making regarding ESI include a specific discussion about inconsistent evidence showing moderate short-term benefits and lack of long-term benefits.
- There is insufficient evidence to adequately evaluate benefits and harms of ESI for spinal stenosis.
- There is insufficient evidence to adequately evaluate benefits of local injections, botulinum toxin injection, ESI, intradiscal electrothermal therapy, therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, or intrathecal therapy with opioids or other medications for nonradicular back pain.

### American Society of Interventional Pain Physicians

In 2013, the American Society of Interventional Pain Physicians updated its guidelines on interventional techniques in chronic spinal pain.<sup>31</sup> The following recommendations were made regarding ESIs of the lumbar spine:

## FEP 2.01.94 Epidural Steroid Injections for Back Pain

- “The evidence is good in managing disc herniation or radiculitis for caudal, interlaminar, and transforaminal epidural injections;
- [the evidence] is fair for axial or discogenic pain without disc herniation, radiculitis or facet joint pain with caudal, and interlaminar epidural injections, and limited for transforaminal epidural injections;
- [the evidence] is fair for spinal stenosis with caudal, interlaminar, and transforaminal epidural injections; and
- [the evidence] is fair for post surgery syndrome with caudal epidural injections and limited with transforaminal epidural injections.”

The following recommendations were made regarding ESIs of the cervical spine:

- The evidence is good for cervical interlaminar epidural injections for cervical disc herniation or radiculitis; and
- [the evidence] is fair for axial or discogenic pain, spinal stenosis, and post- surgery cervical syndrome.

### American Academy of Neurology

The American Academy of Neurology published guidelines in 2007 on the use of epidural steroids for lumbosacral radiculopathy.<sup>32</sup> These guidelines made the following recommendations:

- “[E]pidural steroid injections may result in some improvement in radicular lumbosacral pain when determined between 2 and 6 weeks following the injection, compared to control treatment (Level C, Class I-III). The average magnitude of effect is small, and the generalizability of the observation is limited by the small number of studies, limited to highly selected patient populations, the few techniques and doses studied, and variable comparison treatments.”
- “[I]n general, epidural steroid injections for radicular lumbosacral pain have shown no impact on average impairment of function, on need for surgery, or on long-term pain relief beyond 3 months. Their routine use for these indications is not recommended (Level B, Class I-III).”
- “[T]here is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain (Level U).”

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

## REFERENCES

1. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine (Phila Pa 1976)*. May 1 2009;34(10):1066-1077. PMID 19363457
2. Benyamin RM, Manchikanti L, Parr AT, et al. The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. *Pain Physician*. Jul-Aug 2012;15(4):E363-404. PMID 22828691
3. Pinto RZ, Maher CG, Ferreira ML, et al. Epidural corticosteroid injections in the management of sciatica: a systematic review and meta-analysis. *Ann Intern Med*. Dec 18 2012;157(12):865-877. PMID 23362516
4. Chou R, Atlas SJ, Stanos SP, et al. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. *Spine (Phila Pa 1976)*. May 1 2009;34(10):1078-1093. PMID 19363456

---

## FEP 2.01.94 Epidural Steroid Injections for Back Pain

---

5. Manchikanti L, Buenaventura RM, Manchikanti KN, et al. Effectiveness of therapeutic lumbar transforaminal epidural steroid injections in managing lumbar spinal pain. *Pain Physician*. May-Jun 2012;15(3):E199-245. PMID 22622912
6. Cluff R, Mehio AK, Cohen SP, et al. The technical aspects of epidural steroid injections: a national survey. *Anesth Analg*. Aug 2002;95(2):403-408, table of contents. PMID 12145061
7. Bhatia A, Flamer D, Shah PS, et al. Transforaminal epidural steroid injections for treating lumbosacral radicular pain from herniated intervertebral discs: a systematic review and meta-analysis. *Anesth Analg*. Mar 2016;122(3):857-870. PMID 26891397
8. Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. *J Pain*. Feb 2008;9(2):105-121. PMID 18055266
9. Cohen SP, Hanling S, Bicket MC, et al. Epidural steroid injections compared with gabapentin for lumbosacral radicular pain: multicenter randomized double blind comparative efficacy study. *BMJ*. Apr 16 2015;350:h1748. PMID 25883095
10. Spijker-Huiges A, Winters JC, van Wijhe M, et al. Steroid injections added to the usual treatment of lumbar radicular syndrome: a pragmatic randomized controlled trial in general practice. *BMC Musculoskelet Disord*. Oct 11 2014;15:341. PMID 25304934
11. Manchikanti L, Cash KA, Pampati V, et al. Transforaminal epidural injections in chronic lumbar disc herniation: a randomized, double-blind, active-control trial. *Pain Physician*. Jul-Aug 2014;17(4):E489-501. PMID 25054399
12. Benyamin RM, Singh V, Parr AT, et al. Systematic review of the effectiveness of cervical epidurals in the management of chronic neck pain. *Pain Physician*. Jan-Feb 2009;12(1):137-157. PMID 19165300
13. Diwan S, Manchikanti L, Benyamin RM, et al. Effectiveness of cervical epidural injections in the management of chronic neck and upper extremity pain. *Pain Physician*. Jul-Aug 2012;15(4):E405-434. PMID 22828692
14. Cohen SP, Hayek S, Semenov Y, et al. Epidural steroid injections, conservative treatment, or combination treatment for cervical radicular pain: a multicenter, randomized, comparative-effectiveness study. *Anesthesiology*. Nov 2014;121(5):1045-1055. PMID 25335172
15. Friedly JL, Comstock BA, Turner JA, et al. A randomized trial of epidural glucocorticoid injections for spinal stenosis. *N Engl J Med*. Jul 3 2014;371(1):11-21. PMID 24988555
16. Friedly JL, Comstock BA, Turner JA, et al. Long-term effects of repeated injections of local anesthetic with or without corticosteroid for lumbar spinal stenosis: a randomized trial. *Arch Phys Med Rehabil*. Aug 2017;98(8):1499-1507.e1492. PMID 28396242
17. Staal JB, de Bie R, de Vet HC, et al. Injection therapy for subacute and chronic low-back pain. *Cochrane Database Syst Rev*. Jul 16 2008(3):CD001824. PMID 18646078
18. Choi HJ, Hahn S, Kim CH, et al. Epidural steroid injection therapy for low back pain: a meta-analysis. *Int J Technol Assess Health Care*. Jul 2013;29(3):244-253. PMID 23769210
19. Koes BW, Scholten RJ, Mens JM, et al. Efficacy of epidural steroid injections for low-back pain and sciatica: a systematic review of randomized clinical trials. *Pain*. Dec 1995;63(3):279-288. PMID 8719528
20. Rathmell JP, Benzon HT, Dreyfuss P, et al. Safeguards to prevent neurologic complications after epidural steroid injections: consensus opinions from a multidisciplinary working group and national organizations. *Anesthesiology*. May 2015;122(5):974-984. PMID 25668411
21. US Food and Drug Administration. Epidural Corticosteroid Injection: Drug Safety Communication - Risk of Rare But Serious Neurologic Problems. 2014; <https://naidw.org/groups/viewdiscussion/1595-fda-fda-medwatch-epidural-corticosteroid-injection-drug-safety-communication-risk-of-rare-but-serious-neurologic-problems?groupid=277>. Accessed November 6, 2017.
22. Centers for Disease Control Prevention. Multistate outbreak of fungal infection associated with injection of methylprednisolone acetate solution from a single compounding pharmacy - United States, 2012. *MMWR Morb Mortal Wkly Rep*. Oct 19 2012;61(41):839-842. PMID 23076093
23. Watters WC, 3rd, Resnick DK, Eck JC, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 13: injection therapies, low-back pain, and lumbar fusion. *J Neurosurg Spine*. Jul 2014;21(1):79-90. PMID 24980590
24. Chou R, Hashimoto R, Friedly J, et al. *Pain management injection therapies for low-back pain (Technology Assessment No. ESIB0813)*. Rockville, MD: Agency for Healthcare Research and Quality; 2015.
25. North American Spine Society (NASS). Clinical guidelines for multidisciplinary spine care diagnosis and treatment of lumbar disc herniation with radiculopathy. 2012; <https://www.spine.org/Portals/0/Documents/ResearchClinicalCare/Guidelines/LumbarDiscHerniation.pdf>. Accessed September 29, 2017.

## FEP 2.01.94 Epidural Steroid Injections for Back Pain

26. North American Spine Society (NASS). Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis and treatment of degenerative lumbar spinal stenosis. 2011; <https://www.spine.org/Portals/0/Documents/ResearchClinicalCare/Guidelines/LumbarStenosis.pdf>. Accessed September 29, 2017.
27. North American Spine Society (NASS). Lumbar traforaminal epidural steroid injections: Review and recommendation statement. 2013; <https://www.spine.org/Documents/ResearchClinicalCare/LTFESIRReviewRecStatement.pdf>. Accessed November 6, 2017.
28. North American Spine Society (NASS). Cervical epidural steroid injections: Review & recommendation statement. 2011; <https://www.spine.org/Documents/ResearchClinicalCare/CESIRReviewRecStatement.pdf>. Accessed November 6, 2017.
29. American Society of Anesthesiologists Task Force on Chronic Pain Management, American Society of Regional Anesthesia Pain Medicine. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology*. Apr 2010;112(4):810-833. PMID 20124882
30. Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med*. Oct 02 2007;147(7):478-491. PMID 17909209
31. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician*. Apr 2013;16(2 Suppl):S49-283. PMID 23615883
32. American Academy of Neurology (AAN). AAN Summary of Evidence-Based Guidelines for Clinicians: Use of epidural steroid injections to treat lumbosacral radicular pain. 2007; <https://www.aan.com/Guidelines/Home/GetGuidelineContent/250>. Accessed November 6, 2017.

### POLICY HISTORY

Date	Action	Description
December 2014	New Policy	Policy created with literature review. Epidural steroid injections are medically necessary for treatment of lumbar sciatica/radiculopathy when criteria are met, not medically necessary if previous epidural injections were not successful, and investigational for all other situations.
June 2016	Update Policy	Policy updated with literature review through October 15, 2015; references 9-11, 14, and 19 added. Minor editorial changes to the policy statement with the intent unchanged.
March 2018	Update Policy	Policy updated with literature review through September 11, 2017; references 7 and 17 added; notes 23-24 and 29-30 updated. Policy statements unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.