Epidural steroid injections 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.

Related Policies

- Facet Joint Injections and Facet Joint Nerve Blocks
- Regional Sympathetic Blocks
- Artificial Intervertebral Disc: Lumbar Spine
- Artificial Intervertebral Disc: Cervical Spine
- Lumbar Spinal Fusion

Policy

The determination of medical necessity for the use of epidural steroid injections is always made on a case-by-case basis.

Epidural steroid injections performed with fluoroscopic guidance may be considered medically necessary for the treatment of radicular cervical or lumbar pain when all the following criteria are met:

- Lumbar or cervical radiculopathy that is not responsive to at least 4 weeks of conservative management (see Policy Guidelines section)
- Persistent pain is present of at least moderate-severe intensity
- Short-term relief of pain is the anticipated outcome
- Evidence of nerve root compression documented by Magnetic resonance imaging (MRI) or computerized tomography (CT) performed within the previous 12 months

Repeat treatment of persistent pain due to lumbar radiculopathy may be considered medically necessary when both of the following conditions are met:

- Previous epidural steroid injections were successful at relieving pain
- At least 30 days have elapsed since the prior injection (see Policy Guidelines for maximum number of injections).

NOTE: No more than 4 injections may be performed over a 12 month period
Repeat treatment is considered **not medically necessary** if the initial treatment did not result in substantial pain relief (see policy guidelines).

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

Simultaneous treatment of more than two 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, thoracic pain, and nonspecific low back pain.

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

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**Policy Guidelines**

The diagnosis of 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 (e.g.: L4, L5, or S1). For the purpose of this policy, radiculopathy is defined as the presence of any of the following:

1. Loss of strength of specific named muscle(s) or myotomal distribution(s) demonstrated on detailed neurologic examination (within the prior 3 months) concordant with nerve root compression of the involved named spinal nerve root(s).

2. Altered sensation to light touch, pressure, pin prick or temperature demonstrated on a detailed neurologic examination (within the prior 3 months) in the sensory distribution concordant with nerve root compression of the involved named spinal nerve root(s).

3. Diminished, absent or asymmetric reflex(es) within the prior 3 months concordant with nerve root compression of the involved named spinal nerve root(s).

4. Pain or other dysaesthesia/paraesthesia reported by the patient in a sensory distribution(s) (specific dermatone(s)) of the involved named spinal nerve root(s) with either of the following:
   a. A concordant radiologist’s interpretation of an advanced diagnostic imaging study (MRI or CT) of the spine demonstrating compression of the involved named spinal nerve root(s). (Performed within the past 12 months)
   b. Electrodiagnostic studies (EMG/NCV’s) diagnostic of nerve root compression of the involved named spinal nerve root(s). (Performed within the past 12 months)

The optimal time for assessing a response to epidural steroid injections is 1 to 2 weeks after injection.

The definition of successful relief of pain:

- At least a 20-point improvement on a 0-100 VAS*, or
• At least a 50% improvement of functional status assessed 1-2 weeks after injection.

Note: A maximum of 4 injections per year may be allowed regardless of the location.

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
  o 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

* A Visual Analogue Scale (VAS) is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. For example, the amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. From the patient’s perspective this spectrum appears continuous. Their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. It was to capture this idea of an underlying continuum that the VAS was devised.

The simplest VAS is a straight horizontal line of fixed length, usually 100 mm. The ends are defined as the extreme limits of the parameter to be measured (symptoms, pain, health) orientated from the left (worst) to the right (best). In some studies, horizontal scales are orientated from right to left, and many investigators use vertical VAS.

Using a ruler, the score is determined by measuring the distance (mm) on the 10-cm line between the “no pain” anchor and the patient’s mark, providing a range of scores from 0-100. A higher score indicates greater pain intensity. Based on the distribution of pain VAS scores in postsurgical patients (knee replacement, hysterectomy, or laparoscopic myomectomy) who described their postoperative pain intensity as none, mild, moderate, or severe, the following cut points on the pain VAS have been recommended: no pain (0-4 mm), mild pain (5-44 mm), moderate pain (45-74 mm), and severe pain (75-100 mm). Normative values are not available. The scale has to be shown to the patient otherwise it is an auditory scale not a visual one.

Note: If another spinal procedure (e.g., facet joint injection/nerve block, sacroiliac joint injection, regional sympathetic block) is performed on the same day of service as an epidural steroid injection, both procedures will be reviewed for medical necessity based on applicable Blue Shield Medical Policy criteria. (See Index/Cross Reference Section of Related BSC Medical Policies in the Appendix).

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the
contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Rationale

Background

Back pain is an extremely common condition. Most episodes are self-limited and will resolve within 1 month, but a small percentage will persist and become chronic. Patients with chronic back pain may suffer from serious disability and may use a high volume of medical services. Despite high utilization, many patients with chronic back pain do not improve with available treatments including surgical interventions. Therefore, there is a high unmet need to determine the efficacy of different treatments for chronic back pain and to determine specific patient populations who may benefit from specific interventions. Along with this unmet need for efficacious treatments in patients with chronic back pain, there has been a proliferation of new technologies, and large increases in the number of patients treated and in the intensity of treatment. Therefore, there is a concern for overtreatment of patients who may not benefit from interventions for back pain.

Back pain can result from a variety of underlying causes. Sciatica is a subset of low back pain that is associated with irritation of 1 or more lumbar spinal nerve roots, which results in symptoms of radiculopathy. Symptoms of radiculopathy include pain that radiates down the leg to below the knee, numbness, muscle weakness, and lack of reflexes in a dermatomal distribution. Most patients with sciatica respond to conservative care with resolution of their symptoms between several weeks and several months following onset. In a subset of patients, symptoms and signs of progressive muscle weakness prompt a more aggressive intervention to prevent permanent dysfunction. In other patients, symptoms persist, despite conservative management, without progression of neurologic signs, and further treatment options are sought for pain relief.

Spinal stenosis is another common source of back pain. Spinal stenosis is caused by narrowing of the spinal canal due to degenerative changes, leading to impingement of the spinal cord and the spinal nerve roots. Symptoms of spinal stenosis can include back pain, leg pain with exertion (neurogenic claudication), muscle weakness, and sensory deficits. Definitive treatment for spinal stenosis is surgery, which includes decompression of the spinal canal with or without spinal fusion. Epidural steroids may reduce inflammation from pressure on the spinal cord, and thus reduce symptoms of compression.

Nonspecific low back pain, sometimes called mechanical low back pain, is diagnosed when no specific etiology of pain can be identified. While the origin of nonspecific low back pain is not certain, many experts feel that the pain is of discogenic origin or due to painful movement of the vertebrae. In these instances, epidural steroid injections may reduce swelling of the vertebral disc and/or surrounding structures, leading to pain relief.

Regardless of specific etiology, conservative management is the first-line treatment for most patients with back pain. Nonsteroidal anti-inflammatory drugs (NSAIDs) or other
analgesics are used for symptom relief. These agents should be used at a sufficient dose to induce a therapeutic response for at least several weeks. Modification of activity in conjunction with some form of exercise therapy, often involving a physical therapist, is usually also prescribed early in the course of symptoms. For patients with persistent nonradicular back pain, current guidelines recommend interdisciplinary rehabilitation, which is defined as an integrated approach using physical rehabilitation in conjunction with a psychological or psychosocial intervention.1

For patients who fail conservative therapy, there are a number of interventional techniques available, ranging from minimally invasive procedures such as injections to major surgeries such as spinal decompression with fusion. Injections can be given in different locations (soft tissues, intraspinal, SI joints, etc.) and can use different therapeutic agents (e.g., botulinum toxin, steroids, proteolytic enzymes). Other interventional techniques include radiofrequency ablation, prolotherapy, and chemonucleolysis. Most of these nonsurgical interventions do not have high-quality evidence demonstrating efficacy.4 Numerous different surgical interventions are available, such as discectomy and spinal fusion, each of which can be performed by a variety of different techniques. The decision to undertake surgery is best made in the setting of shared decision making between the patient and surgeon, with thorough considerations of the risks and benefits of surgery.

Epidural Steroid Injections

Epidural injection therapy is one of several second-line therapies available for patients who fail conservative treatment and is one of the most common modalities used for patients who fail initial conservative treatment.5 Epidural injections are performed by inserting a needle into the space between the dura and ligamentum flavum and injecting a steroid preparation. There is considerable variability in the technical aspects of epidural injections. There are several different approaches possible for entering the epidural space (translaminar, transforaminal, caudal). In addition, the procedure may be performed with or without fluoroscopic guidance. A national survey published in 20026 reported that 30% of academic institutions and 77% of private practices use fluoroscopy. Other authors have estimated that lack of correct needle position in the epidural space may occur in 25% of more of injections.2 Further variability of technique may involve factors such as the depth of injection into the epidural space, volume of injectate, and the filling patterns of the injectate.5

Treatment is generally given as 1 to 3 injections, each performed at least 1 month apart. Treatment is generally limited to no more than 3 injections in a 12-month period, owing to concerns about the AEs of chronic steroid administration, both locally and systemically.

Regulatory Status

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

Rationale

Assessment of efficacy for therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies
and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

The evidence base on the efficacy of epidural steroid injections for back pain is large, with many RCTs published. In addition to the RCTs, there have been numerous systematic reviews of RCTs published. This literature review will therefore concentrate on a representative sample of the available systematic reviews of RCTs, emphasizing the most recently published systematic reviews.

**Sciatica/Radiculopathy**

**Lumbar Radiculopathy/Sciatica**

A systematic review of epidural injections for sciatica was published by Pinto et al in 2012. This review included RCTs that included information on at least 1 of the outcomes of overall pain, leg pain, back pain, or disability status. There were a total of 25 publications included in the review, representing 23 unique trials. The sample size in the trials ranged from 23 to 325, with most studies enrolling fewer than 100 patients. Using the GRADE classification, the level of quality was determined to be high for each outcome.

Pooled results for each of the outcomes are summarized in Table 1. The magnitude of the between-group differences is small, and statistically significant only for the outcomes of short-term leg pain and short-term disability. The greatest magnitude of difference was 6.2 units on a 0 to 100 visual analog scale (VAS) for short-term leg pain. This magnitude of difference is below the minimally important difference for a 0 to 100 pain scale, which is generally considered to be in the range of 10 to 30 units.

<table>
<thead>
<tr>
<th>Outcome (0-100 Scale)</th>
<th>Weighted Mean Difference Between Groups (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Leg pain</strong></td>
<td>Short Term: -6.2 (-9.0 to -3.0)</td>
</tr>
<tr>
<td></td>
<td>Long Term: -4.8 (-10.2 to 0.7)</td>
</tr>
<tr>
<td><strong>Back pain</strong></td>
<td>Short Term: 0.5 (-3.9 to 4.8)</td>
</tr>
<tr>
<td></td>
<td>Long Term: 3.4 (-2.4 to 9.2)</td>
</tr>
<tr>
<td><strong>Disability</strong></td>
<td>Short Term: -3.1 (-5.0 to -1.2)</td>
</tr>
<tr>
<td></td>
<td>Long Term: -2.7 (-6.8 to 1.3)</td>
</tr>
</tbody>
</table>

CI: confidence interval.

Benyamin et al published a systematic review that included RCTs and non-RCTs of epidural injections in patients with low back pain and/or leg pain. There were 19 studies that met the inclusion criteria. Most of these trials (13/19) compared epidural steroids with an active control and 5 of 19 used a placebo control. A qualitative summary of studies was performed, without any quantitative meta-analysis. Subgroup analysis was performed on studies that included patients with disc herniation and radiculopathy. The authors also separated the intervention into studies that used fluoroscopic guidance. Of the 8 studies that used fluoroscopic guidance, all reported short-term results that favored epidural steroid injections. Among 4 trials that reported longer term follow-up at 1 year, 2 were positive and 2 were negative.

Chou et al included epidural steroid injection for low back pain with radiculopathy as part of their systematic review of nonsurgical interventional therapies for low back pain. These authors identified 17 RCTs reporting on short-term benefit, and 4 RCTs reporting on longer term benefit. For short-term benefits, the results were mixed. A total of 10 of 17 trials reported no benefit, and 7 of 17 reported a statistically significant benefit. Of the 7 trials that were rated higher quality, 4 of 7 reported a benefit and 3 of 7 reported no benefit. Subgroup analysis by type of placebo control (epidural or soft tissue injection) revealed that most trials using a soft tissue control injection (5/6) reported a benefit, while
most of these trials using an epidural control injection (9/11) reported no benefit. Other subgroup analyses based on duration of symptoms, use of imaging to confirm prolapsed disc, and study quality did not show any significant differences.

A systematic review by Manchikanti et al identified 13 RCTs that evaluated epidural steroid injections for the treatment of lumbar radiculopathy. Two of these trials compared epidural steroids with placebo and the remaining compared epidural steroids with an active control. No pooled analysis was performed. The authors reported that most of the trials reported positive effects for both short-term and long-term pain relief.

An earlier systematic review and meta-analysis was published in 1995 by Watts and Silagy. This review included 11 trials of epidural steroids that were judged to be of good quality, enrolling a total of 907 patients. The odds of pain relief (defined as at least 75% reduction in pain scores) at 60 days posttreatment for the epidural steroid group compared with control was 2.61 (95% CI, 1.90 to 3.77). At 12-month follow-up, there was also a statistically significant improvement in the odds of pain relief (odds ratio [OR]=1.87; 95% CI, 1.31 to 2.68).

Cervical Radiculopathy

There are a smaller number of published trials on the use of epidural steroids for cervical radiculopathy. Two systematic reviews were identified that summarized the literature on cervical epidural injections for cervical radiculopathy.

Benyamin et al included studies of epidural injections for neck pain that was present for more than 3 months, with or without radiculopathy. The authors identified 3 RCTs that met their inclusion criteria, all of which treated patients with cervical radiculopathy, but only 1 of which compared epidural steroids with a control condition. One of the other trials compared 2 different preparations of steroids, and the third trial compared steroids plus morphine with steroids alone. In the single trial comparing steroids with control, 42 patients were randomized to epidural steroid injections (n=24) or to steroid injections in the adjacent neck muscle. One week after the last epidural injection, more patients in the epidural group reported good pain relief compared with control (76% vs 36%, p not reported), and at 1-year follow-up, the difference in the percent of patients reporting good pain improvement persisted in favor of the epidural steroid group (68% vs 12%, p not reported).

Diwan et al performed a systematic review of epidural steroid injections for chronic neck and upper extremity pain and reported separately on the evidence for cervical radiculopathy. This analysis included 4 RCTs, 3 of which were included in the Benyamin 2009 review. The fourth RCT, which was the largest (n=120) and rated the highest in quality, randomized patients to epidural steroid plus local anesthetic versus local anesthetic alone, and reported on pain relief at 6 months and 12 months. At 6 months, the percent of patients experiencing pain relief was 82% for the steroid group versus 73% for the control group, a difference that was not statistically significant. At 12 months, outcomes were also not different between groups, with 72% of patients in the steroid group reporting pain relief compared with 68% in the control group.

Section Summary

There are a large number of small RCTs that evaluate epidural steroid injections for lumbar radiculopathy/sciatica, and numerous systematic reviews that summarize these trials. For short-term pain relief, the direction of benefit in virtually all trials is in favor of epidural injections, and the differences between groups reached statistical significance in some trials but not others. Most systematic reviews do not perform quantitative meta-analysis, thus limiting the ability to examine these small trials with increased power. In 1
meta-analysis that reported pooled results, there was a statistically significant improvement in pain at 6 months, but the mean difference was less than the minimally important clinical difference for a 0 to 100 VAS pain scale. For long-term pain relief at 1 year or longer, most trials report negative results, and no pooled analysis reports significant differences. For cervical radiculopathy, the evidence is less and the available studies do not generally report a benefit for epidural steroid treatment.

**Spinal Stenosis**

In the Benyamin 2012 systematic review, there were 6 RCTs identified that treated patients with spinal stenosis, 5 of which compared steroid injections with a local anesthetic alone. Two of the trials reported group differences in favor of the steroid group, 3 reported significant improvement in pain for the steroid group but did not report between-group differences, and the final trial reported no significant improvement for the steroid group.

The systematic review by Chou et al identified 3 small placebo controlled trials on treatment of spinal stenosis, but in 2 of these studies only a subset of treated patients had spinal stenosis. The authors rated the quality of this evidence poor and concluded that it was not possible to determine whether epidural steroids offer a benefit for spinal stenosis.

Manchikanti et al identified 4 RCTs of epidural steroid injections for treatment of lumbar spinal stenosis. Two of these trials compared epidural steroids with control and reported on pain relief and/or disability. Neither of the 2 included trials reported that pain relief with epidural steroids was superior to control, either short term or long term.

The systematic review by Diwan et al identified 1 RCT of 60 patients that treated cervical spinal stenosis. In this trial, there were no significant differences in the percent of patients reporting pain relief in the epidural group compared with control at 6 months (87% vs 80%) or at 12 months (73% vs 70%).

Since the publication of the systematic reviews, an additional moderately large-sized RCT of epidural steroid injections for spinal stenosis was published in 2014. This trial randomized 400 patients with lumbar central spinal stenosis and at least moderate to severe leg pain (≥4 on 0-10 VAS) or disability (≥7 on Roland Morris Disability Questionnaire, 0-24 scale) due to spinal stenosis to either epidural steroid injections plus lidocaine or lidocaine alone. One repeat injection could be given at 3 weeks at the discretion of the patient and treating physician. Both patients and treating physicians were blinded to treatment assignment. The primary outcomes were the patient’s rating of buttocks, hip or leg pain at 6 weeks following initial treatment, and the Roland Morris Disability Questionnaire score at 6 weeks. Secondary outcomes included the same outcome measures at 3 weeks posttreatment, measures of back pain, percent responders (defined either as ≥30% reduction in pain, or ≥50% reduction in pain), and scores on several quality-of-life scales.

At 6-week follow-up, there were no significant differences in the primary outcomes. The change in pain on the 0-10 VAS for the steroid group was -2.8 for the steroid group compared with -2.6 for the control group (adjusted between-group mean difference, -0.2 points; 95% CI, -0.8 to 0.4; p=0.48), and the change in the disability score was -4.2 points for the steroid group versus -3.1 points for the control group (adjusted between group mean difference, -1.0 points; 95% CI, -2.1 to 0.1; p=0.07). There were small, statistically significant differences in measures of pain and disability at 3 weeks, but these were less than the minimal clinical difference for the scales, and differences did not persist at 6 weeks. On the secondary outcomes at 6 weeks, there were generally no between-group differences except for 2 subscales of the QOL measures (symptoms of depression on PHQ-8 scale, and satisfaction on SSSQ scale).
Section Summary

There are only a few RCTs that evaluate epidural steroids for spinal stenosis, and the published systematic reviews do not perform pooled analysis of the available trials. Most published trials do not report significant benefit for epidural steroids, including a moderately large sized RCT published in 2014. This evidence does not support that epidural steroids improve outcomes for patients with spinal stenosis.

Nonspecific Low Back Pain

A Cochrane review was published in 2008 on injection therapy for subacute and chronic low back pain. This review included RCTs that enrolled patients with low back pain for at least 1 month and reported pain outcomes. A total of 18 studies met the inclusion criteria, 10 of which were considered to be at low risk for bias. Due to high levels of heterogeneity, pooled analysis was not performed. Of the 18 included studies, 5 reported a benefit for treatment with epidural steroids. There were 2 placebo-controlled studies of short-term outcomes of leg pain. Neither of these studies reported a significant improvement of pain associated with epidural injections. Three studies compared epidural steroids with nonsteroidal anti-inflammatory drug (NSAIDs), and none of these reported significant improvements for patients treated with epidural steroids.

The systematic review by Benyamin et al. identified 3 trials of epidural steroid injections for nonspecific low back pain, 1 randomized and 2 nonrandomized. The randomized trial reported a greater percentage of patients with pain relief following epidural steroid injection compared with local anesthetic alone (83% vs 73%), but this between-group difference was not statistically significant. The 2 nonrandomized studies reported improvements for patients treated with epidural steroids, but no between-group comparisons were done.

Manchikanti et al. addressed the indication of nonspecific low back pain (axial low back pain) in their systematic review. However, there were no RCTs identified that met their inclusion criteria, and only 3 nonrandomized studies were included. This evidence was insufficient to form conclusions on the efficacy of epidural steroids for nonspecific low back pain.

Section Summary

The evidence on epidural steroid injections for nonspecific low back pain is limited. Small RCTs have been published, but these have generally been judged to be of low quality, and most studies do not report significant improvements for the epidural steroid group. This evidence is not sufficient to determine whether epidural steroids improve outcomes for the treatment of nonspecific low back pain.

Mixed Indications

A systematic review by Choi et al. published in 2012 included trials of epidural steroids for back pain, regardless of specific indication. There were a total of 29 studies included in the review, of which 23 of 29 met at least 5 of 11 quality criteria. The authors noted evidence for noncomparability of groups (selection bias) at baseline, particularly for the baseline pain levels. For pain outcomes, combined analysis revealed a statistically significant difference in favor of epidural steroids at 6 months (weighted mean difference, -0.41; 95% CI, -0.66 to -0.16) but a nonsignificant result at 12 months. For disability level, there were no statistically significant differences between groups at either 6- or 12-month follow-up. There was also no difference reported in the need for future surgery for patients receiving epidural steroid injections.
Safety

Potential adverse effects of epidural steroid injections can include complications of the injection itself, such as inadvertent puncture of the dura, bleeding, and infections. Additional complications may be related to the administration of steroids, including suppression of the hypothalamic-pituitary axis and the immune system.

The adverse effects (AEs) of epidural steroid injections are not well-reported in the treatment trials. In 1 systematic review, only 4 of 15 included trials reported on adverse events. In addition to the lack of systematic reporting of AEs, the available trials are generally small and therefore not adequate for determining rates of uncommon AEs. Therefore, the rate of AEs is mostly uncertain.

In the systematic review by Chou et al, it was noted that while there were case reports of serious adverse events (SAEs) such as paralysis and infection due to epidural injections in the literature, SAEs were rarely reported in the clinical trials. Of the 17 trials included in the treatment of low back pain with radiculopathy, 10 of 17 did not report AEs at all, and the AEs reported in the other trials were generally transient and mild. In 1 high-quality trial with systematic reporting of AEs, 3.3% of patients (4/120) experienced a postinjection headache, 0.8% (1/120) experienced postdural puncture headache, 1.7% (2/120) experienced postinjection nausea, and 4.2% (5/120) experienced other AEs.

In 2014, FDA issued a drug safety communication on rare but serious neurologic problems associated with epidural steroid injections. This communication stated that the safety of epidural injections has not been established and that FDA has not approved corticosteroids for this use. Potential serious adverse neurologic events include loss of vision, stroke, paralysis, and death. FDA has assembled an expert panel to develop recommendations, and plans to convene an Advisory Committee in late 2014 to determine whether further regulatory action is warranted.

Epidural steroids are generally compounded medications, i.e., the specific preparations for clinical use are prepared at a pharmacy rather than by the manufacturer of the drug. In 2012, there were several hundred patients who developed fungal meningitis complications due to contaminated medication obtained from a single pharmacy. CDC obtained preliminary data on 137 patients. Of those, 12 of 137 patients (9%) died, 3 of 137 (2%) had stroke, and 3 of 137 (2%) had osteomyelitis or epidural abscess. The contamination was attributed to faulty sterilization procedures at the pharmacy that compounded the medications.

Section Summary

AEs, both minor and serious, can occur following epidural steroid injections, but the rate of AEs is uncertain. There are few SAEs reported in the RCTs, but there is also a lack of systematic reporting in the available trials. Minor AEs that are self-limited, such as headache, occur more commonly, but the evidence is not sufficient to determine the actual rate of such events. Further research is needed to determine true rate of AEs. The occurrence of SAEs is currently a topic of investigation by FDA.

Ongoing and Unpublished Clinical Trials

A search of online site ClinicalTrials.gov in September 2014 found 3 ongoing trials.
(NCT01495923) Steroids versus Gabapentin is a randomized study with an estimated enrollment of 142 and an estimated completion date of December 2014.
(NCT01934868) Prolotherapy versus epidural steroid injections for lumbar pain radiating to the leg is a randomized study with an estimated enrollment of 160 and completion date of May 2016.
(NCT02196883) Steroid injections given at the “level of MRI pathology” versus at the “level
of clinical symptoms” to see if one is more effective than the other. This study has a completion date of May 2015. An estimated enrollment was not provided.

Summary of Evidence

Epidural steroid injections are used to treat low back pain that has not responded to conservative measures and that is due to various etiologies including lumbar radiculopathy/sciatica, cervical radiculopathy, lumbar spinal stenosis, and nonspecific low back pain. The evidence base consists of many small randomized controlled trials (RCTs) and a number of systematic reviews of these RCTs. Limitations of the evidence base include a lack of large-scale, high-quality trials, and a high degree of variability among the available trials in terms of patient populations, techniques of epidural injections, and comparison treatments.

The largest amount of evidence is for treatment of lumbar radiculopathy/sciatica. The results of individual trials are mixed, with some reporting significant benefits for the epidural steroid group and others reporting no benefit. Most systematic reviews do not perform pooled analyses due to heterogeneity of trials. In the 2 reviews that report quantitative results, short-term pain relief at up to 6-month follow-up is superior for patients treated with epidural steroids. However, in 1 review, the mean difference in pain on a 0 to 100 visual analog scale was less than the minimal important clinical difference for that scale. None of the analyses report long-term benefits for steroid treatment. Adverse events are generally mild, but are not well reported in these trials. Serious adverse events can occur, but the rate of serious adverse events is unknown. Based on the available evidence, epidural steroid injections may be considered medically necessary for the treatment of lumbar radiculopathy when conservative measures are unsuccessful and short-term pain relief is the goal of treatment.

For other conditions causing back pain, including spinal stenosis and nonspecific low back pain, the quantity of evidence is less and most of available studies do not report a benefit for epidural steroid injections. As a result, epidural steroid injections are considered investigational for the treatment of conditions other than lumbar radiculopathy/sciatica.

Supplemental Information

Practice Guidelines and Position Statements

The 2014 update of the guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine from the American Association of Neurological Surgeons states that lumbar epidural steroid injections 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.) Caudal epidural steroid injections are an option for reducing low back pain without radiculopathy of greater than 6 weeks’ duration in patients with degenerative disease of the lumbar spine. (Level III evidence).

The Agency for Healthcare Research and Quality issued an evidence-based practice center systematic review protocol in 2014. Project title: Pain management injection therapies for low back pain stated that between 1994 and 2001, the use of epidural injections increased by 271 percent and face joint injections increased by 231 percent among Medicare beneficiaries. Despite these dramatic increases, use of injection therapies for low back pain remains controversial. 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."

The 2012 North American Spine Society clinical guidelines for multidisciplinary spine care diagnosis and treatment of lumbar disc herniation with radiculopathy\(^ {19}\) stated there were no studies available which directly addressed the role of epidural steroid injections or selective nerve root blocks in the diagnosis of patient selection for subsequent surgical treatment of a lumbar disc herniation with radiculopathy.

In 2011, the North American Spine Society revised their clinical guidelines for multidisciplinary spine care diagnosis and treatment of degenerative lumbar spinal stenosis.\(^ {20}\) They made the following recommendation: a multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injections is suggested to produce medium-term (3-36 months) relief of pain in patients with radiculopathy or neurogenic intermittent claudication from lumbar spinal stenosis. Grade C recommendation.

The North American Spine Society issued 2010 clinical guidelines for multidisciplinary spine care diagnosis and treatment of degenerative lumbar spinal stenosis.\(^ {21}\) The following grade C recommendation was made: Transforaminal epidural steroid injections using fluoroscopic or CT guidance may be considered when developing a medical/interventional treatment plan for patients with cervical radiculopathy from degenerative disorders. Due consideration should be given to the potential complications.

The 2013 North American Spine Society issued a review and recommendation statement for lumbar transforaminal epidural steroid injections (LTFESI).\(^ {22}\) The following recommendations were made:

- Transforaminal epidural steroid injections using fluoroscopic or CT guidance may be considered when developing a medical/interventional treatment plan for patients with cervical radiculopathy from degenerative disorders. Due consideration should be given to the potential complications. Level of evidence III.
- 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-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.

The 2011 North American Spine Society issued a review and recommendation statement for cervical epidural steroid injections.\(^ {23}\) The following recommendation was made: Both transforaminal and interlaminar epidural steroid injections may be considered to provide short- and long-term relief of cervical radiculitis. Recommendation level C.

The 2010 guidelines on chronic pain management from the American Society of Anesthesiologists\(^ {24}\) state that transforaminal epidural injections should be performed with appropriate image guidance to confirm correct needle position and spread of contrast before injecting therapeutic substances. Image guidance may be considered for interlaminar epidural injections to confirm correct needle position and spread of contrast before injecting therapeutic substance.
The American College of Physicians issued a 2008 guideline for 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 only if they are potential candidates for surgery or epidural steroid injection. (Strong recommendation, moderate-quality evidence)

The American Pain Society published guidelines on the use of interventional therapies for low back pain in 2009, based on a systematic review of the evidence published in the same year. These guidelines made the following recommendations regarding epidural steroid injections:

- In patients with persistent radiculopathy due to hemiated lumbar disc, it is recommended that clinicians discuss risks and benefits of epidural steroid injections as an option (weak recommendation, moderate quality evidence). It is recommended that shared decision making regarding epidural steroid injection 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 epidural steroid injection for spinal stenosis.

- There is insufficient evidence to adequately evaluate benefits of local injections, botulinum toxin injection, epidural steroid injection, 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.

The American Society of Interventional Pain Physicians published updated guidelines for interventional techniques in chronic spinal pain. The following recommendations were made regarding epidural steroid injections of the lumbar spine:

- The evidence is good in managing disc hemiation or radiculitis for caudal, interlaminar, and transforaminal epidural injections;

- The evidence is fair for axial or discogenic pain without disc hemiation, 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;

- The evidence is fair for postsurgery syndrome with caudal epidural injections and limited with transforaminal epidural injections.

The following recommendations were made regarding epidural steroid injections of the cervical spine:

- The evidence is good for cervical interlaminar epidural injections for cervical disc hemiation or radiculitis.

- The evidence is fair for axial or discogenic pain, spinal stenosis, and postsurgery syndrome.

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

- Epidural steroid injections may result in some improvement in radicular lumbosacral pain when determined between two and six 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.

- In 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 three months. Their routine use for these indications is not recommended (Level B, Class I-III).

- Data on the use of epidural steroid injections to treat cervical radicular pain are inadequate to make any recommendation (Level U).

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

Epidural steroid injections is not a preventive service.

**Medicare National Coverage**

No national coverage determination (NCD) for epidural steroid injections was found. In the absence of and NCD coverage determination is left to the discretion of the local Medicare carrier.

**References**


**Documentation Required for Clinical Review**

- History and physical and/or consultation note including:
  - Conservative treatment(s), duration, and patient response
  - Diagnostic evaluation
  - Functional limitation(s)
  - Prior procedure(s) and response (if applicable)
  - Radiology report(s)
  - Electrodiagnostic studies (if applicable)

**Post Service**

- Procedure reports

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**MN/IE**

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.
<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0228T</td>
<td>Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; single level</td>
</tr>
<tr>
<td></td>
<td>0229T</td>
<td>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)</td>
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<td>0230T</td>
<td>Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level</td>
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<td></td>
<td>62310</td>
<td>Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic</td>
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<tr>
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<td>62311</td>
<td>Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)</td>
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<tr>
<td>HCPCS</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>ICD-9 Procedure</td>
<td>03.92</td>
<td>Injection of other agent into spinal canal</td>
</tr>
<tr>
<td>ICD-10 Procedure</td>
<td>For dates of service on or after 10/01/2015</td>
<td>3E0S33Z Introduction, epidural space, percutaneous, anti-inflammatory</td>
</tr>
<tr>
<td>ICD-9 Diagnosis</td>
<td>All Diagnoses</td>
<td></td>
</tr>
<tr>
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<td>For dates of service on or after 10/01/2015</td>
<td>All Diagnoses</td>
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**MN/ NMN**

The following services may be considered medically necessary when policy criteria are met. Services are considered not medically necessary when policy criteria are not met.

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<tbody>
<tr>
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<td>64479</td>
<td>Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, single level</td>
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<td></td>
<td>64480</td>
<td>Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, each</td>
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</tbody>
</table>
### Medical Policy

**64483**
Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level

**64484**
Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level (List separately in addition to code for primary procedure)

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### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/8/2012</td>
<td>Policy clarification</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>1/11/2013</td>
<td>Removed not medically necessary position statement and replaced with Note for review clarification purposes</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>12/15/2014</td>
<td>Policy Title change from Epidural Steroid Injections Policy revision with position change effective 2/15/2015</td>
<td>Medical Policy Committee</td>
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<tr>
<td>1/30/2015</td>
<td>Policy clarification</td>
<td>Administrative Review</td>
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<tr>
<td>2/15/2015</td>
<td>Policy revision with position change</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>

### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is
not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements**

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member’s health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member’s eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.