Kansas City
An Independent Licensee of the Blue Cross and Blue Shield Association

Epidural Steroid Injections for Neck or Back Pain

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Blue KC has developed medical policies that serve as one of the sets of guidelines for coverage decisions. Benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in the medical policies. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and/or federal law. Medical policy does not constitute plan authorization, nor is it an explanation of benefits.

When reviewing for a Medicare beneficiary, guidance from National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) supersede the Medical Policies of Blue KC. Blue KC Medical Policies are used in the absence of guidance from an NCD or LCD.

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Epidural Steroid Injections for Back Pain when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

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

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

Repeat treatment of persistent pain due to radiculopathy or 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 Considerations for maximum number of injections); AND
- No more than 6 injections given over a 12 month period.

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

When Policy Topic is not covered

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

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 and nonspecific low back pain.

The use of fluorography (imaging of the epidural space) as a component of epidural steroid injections is considered **incidental** and is not separately payable.

Considerations

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.

Description of Procedure or Service

Populations	Interventions	Comparators	Outcomes
Individuals: ▪ With lumbar or cervical radiculopathy	**Interventions of interest are:** ▪ Epidural steroid injections	**Comparators of interest are:** ▪ Conservative care (eg, physical therapy, medications, other nonpharmacologic measures)	**Relevant outcomes include:** ▪ Symptoms ▪ Functional outcomes ▪ Health status measures ▪ Quality of life ▪ Medication use ▪ Treatment-related morbidity
Individuals: ▪ With spinal stenosis	**Interventions of interest are:** ▪ Epidural steroid injections	**Comparators of interest are:** ▪ Conservative care (eg, physical therapy, medications, other nonpharmacologic measures)	**Relevant outcomes include:** ▪ Symptoms ▪ Functional outcomes ▪ Health status measures ▪ Quality of life ▪ Medication use ▪ Treatment-related morbidity
Individuals: ▪ With nonspecific low back pain	**Interventions of interest are:** ▪ Epidural steroid injections	**Comparators of interest are:** ▪ Conservative care (eg, physical therapy, medications, other nonpharmacologic measures)	**Relevant outcomes include:** ▪ Symptoms ▪ Functional outcomes ▪ Health status measures ▪ Quality of life ▪ Medication use ▪ Treatment-related morbidity

Epidural steroid injections (ESIs) are a treatment for neck or 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.

For individuals who have lumbar or cervical radiculopathy who receive ESIs, the evidence includes randomized controlled trials (RCTs) and a number of systematic reviews and meta-analyses of these RCTs. Relevant outcomes are symptoms, 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. Meta-analyses have found reduced pain in the short- and intermediate-term (up to 6 months) with ESI compared with conventional therapy. None of the analyses reported long-term benefits for treatment with ESIs. Adverse events were generally mild but 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 an improvement in the net health outcome.

For individuals who have spinal stenosis who receive ESIs, the evidence includes a moderately large RCT (N=400) and systematic reviews of 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 in the systematic reviews did not report a benefit for ESIs. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have nonspecific low back pain who receive ESIs, the evidence includes systematic reviews of RCTs and nonrandomized studies. Relevant outcomes include symptoms, functional outcomes, health status measures, quality of life, medication use, and treatment-related morbidity. Most trials were of low quality and did not report a benefit for ESIs. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Input was received from 5 academic medical centers and 6 specialty societies while this policy was in development in 2014. Consensus was reached among reviewers that: treatment of cervical radiculopathy is medically necessary with the same criteria as for lumbar radiculopathy; the minimum period of time for conservative therapy should be 4 weeks or less; fluoroscopic guidance should be used in all cases of ESIs; and, fluorography imaging of the epidural space is investigational. There was mixed input on the optimal timing to assess response, the number of levels that should be treated at one time, and the maximum number of injections to be given in 1 year.

Background

Back Pain

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.[1,] Patients with chronic back pain may suffer from a 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 which patient populations may benefit from specific interventions. In addition, there has been a proliferation of new technologies, combined with large increases in the number of patients treated and in the intensity of treatment. Therefore, there is a concern for the over-treatment of patients who may not benefit from interventions for back pain.[2,]

Lumbar or Cervical Radiculopathy

Back pain can result from a variety of underlying causes. Radiculopathy is a subset of back pain that is associated with irritation of 1 or more spinal nerve roots. Symptoms of lumbar radiculopathy, which is sometimes known as sciatica, include pain that radiates down the leg to below the knee, numbness, muscle weakness, and lack of reflexes in a dermatomal distribution.[3,] Most patients with radiculopathy respond to conservative care with a resolution of their symptoms within several weeks to 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

Spinal stenosis is another common source of back pain. Spinal stenosis is caused by the 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. The 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

Nonspecific low back pain, sometimes called mechanical low back pain, is diagnosed when no specific etiology of pain can be identified. Although the etiology of nonspecific low back pain is uncertain, many experts feel that the pain is of discogenic origin or due to the 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.

Treatment

Regardless of specific etiology, conservative management is the first-line treatment for most patients with neck or back pain. Nonsteroidal anti-inflammatory drugs or other analgesics are used for symptom relief. These agents should be used for at least several weeks at a dose sufficient to induce a therapeutic response. Duloxetine or tramadol are recommended second-line pharmacologic therapies by the American College of Physicians.[4,] Additionally, modification of activity in conjunction with some form of exercise therapy is frequently prescribed early in the course of symptoms and typically involves a physical therapist. For patients with persistent nonradicular back pain, 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, a number of interventional therapies are available, which range from minimally invasive procedures, such as injections, to major surgeries, such as spinal decompression with fusion. Injections can be given in different locations (eg, soft tissues, intraspinal, sacroiliac joints) and can use different therapeutic agents (eg, 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 their efficacy.[5,] A number of surgical interventions are available, such as discectomy and spinal fusion, each of which can be performed by a variety of techniques. The decision to undertake surgery is best made in the setting of shared decision making between the patient and surgeon, with thorough consideration given to the risks and benefits of surgery.

Epidural Steroid Injections

Epidural injection therapy is one of several therapies available for patients who fail conservative treatment and is one of the most common modalities used in this group of patients.[6,] Epidural steroid 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. Several different approaches may be used for entering the epidural space (translaminar, transforaminal, caudal). In addition, epidural steroid injections may be administered with or without fluoroscopic guidance. Some investigators have estimated that lack of correct needle position in the epidural space may occur in 25% or more of injections administered.[2,] Variability of the technique may also involve factors such as the depth of injection into the epidural space, the volume of injectate, and the filling patterns of the injectate.[6,]

Treatment is generally given as 1 to 3 injections, each performed at least 1 month apart. Some experts recommend no more than 3 injections in a 12-month period, owing to concerns about the adverse events of chronic steroid administration, both locally and systemically. Others contend that up to 6 injections per year are safe.

Regulatory Status

Steroids are not approved by the U.S. Food and Drug Administration (FDA) for use as epidural injections; such use represents an off-label administration of a 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

This evidence review was created in October 2014 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through October 4, 2021.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

The evidence base on the efficacy of epidural steroid injections (ESIs) for neck or back pain is large, with many RCTs and numerous systematic reviews or meta-analyses of RCTs published. This literature review, therefore, concentrates on a representative sample of the available systematic reviews and meta-analyses of RCTs, emphasizing those published most recently.

Lumbar Radiculopathy or Sciatica and Cervical Radiculopathy

Clinical Context and Therapy Purpose

The purpose of ESI for patients who have lumbar or cervical radiculopathy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of ESIs improve the net health outcome for those who suffer from lumbar or cervical radiculopathy?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with lumbar or cervical radiculopathy.

Interventions
The therapy being considered is ESI.

Comparators
The following practice is currently being used to treat lumbar or cervical radiculopathy : conservative care, which can include physical therapy, medications, and other nonpharmacologic measures.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, health status measures, QOL, medication use, and treatment-related morbidity. Specifically, outcomes of interest include reductions in pain and medication usage, and improvement in functional outcomes and QOL. Reductions in pain and medication use can be observed within a week. The duration of pain relief with corticosteroids is rarely longer than 3 months, so outcomes should be measured within this window.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Lumbar Radiculopathy or Sciatica

Systematic Reviews
Verheijen et al (2021) conducted a meta-analysis of 17 RCTs comparing ESI to epidural or nonepidural placebo in patients with sciatica.[7,] Studies were eligible for inclusion in the meta-analysis if they provided data on sciatica patients (any level of pain, any duration of symptoms, and any prior therapy). For back pain, ESI was not significantly more effective than epidural placebo at 6 weeks (mean difference,

-2.9; 95% confidence interval [CI], -6.8 to 0.9; p=.14; I^2=0%), 3 months (mean difference, -0.7; 95% CI, -23.5 to 25; p=.95; I^2=94%), or 6 months (mean difference, -4.9; 95% CI, -19.9 to 10.2; p=.53; I^2=84%). However, only 3, 2, and 2 studies were included in the 6-week, 3-month, and 6-month back pain analyses, respectively; the Grading of Recommendations Assessment, Development and Evaluation (GRADE) quality of evidence was moderate at 6 weeks, very low at 3 months, and low at 6 months. When compared to nonepidural placebo, ESI resulted in greater relief of back pain at 3 months (mean difference, 6.9; 95% CI, 1.3 to 12.5; p=.02; I^2=42%) but not at 6 weeks or 6 months (quality of evidence: moderate; 2 trials were included in the analysis at each time point). Based on low-quality evidence, leg pain was significantly improved with ESI compared to epidural placebo at 6 weeks (mean difference, -8.6; 95% CI, -13.4 to -3.9; p<.01; I^2=70%) and 3 months (mean difference, -5.2; 95% CI, -10.1 to -0.2; p=.04; I^2=83%), but not at 6 months (mean difference, -2.7; 95% CI, -8 to 2.6; p=.31; I^2=75%). In a sensitivity analysis adjusting for heterogeneity, leg pain was significantly improved with ESI compared to epidural placebo at all time points. Compared to nonepidural placebo, ESI did not significantly improve leg pain at any time point (quality of evidence: low to moderate). Functional status was significantly improved with ESI versus epidural placebo at 6 weeks (mean difference, −4.1; 95% CI, −6.5 to −1.6; p<.01; I^2=35), but between-group differences were not significant at 3 months or 6 months (quality of evidence: moderate at 6 weeks, low at 3 months, and very low at 6 months). Compared to nonepidural placebo, ESI did not significantly improve functional status at any time point (quality of evidence: moderate). The patient population included in this review was not well-defined; therefore, it is unclear whether certain subpopulations may obtain greater benefit from ESI. Other limitations of the review include the relatively small number of studies available (particularly for the back pain outcome analyses and all comparisons between ESI and nonepidural placebo), the unclear clinical importance of the outcomes, and the variation in treatment success definitions across studies.

Yang et al (2020) conducted a meta-analysis of 6 RCTs comparing ESI (n=249) and conservative treatment (n=241) in patients with lumbosacral radiculopathy.[8,] Pain scores on visual analog scale (VAS) or numeric rating scale (NRS) were reduced with ESI compared with conservative treatment at up to 1 month of follow up (mean difference, 1.24; 95% CI, 0.58 to 1.91; p=.0002; I^2=67%) and also at 1 to 3 months of follow up (mean difference, 0.87; 95% CI, 0.48 to 1.26; p<.0001; I^2=0%). There was no difference between conservative treatment and ESI in the analysis of 2 studies that evaluated long-term efficacy from 6 months up to 1 year (mean difference, 2.43; 95% CI, 0.47 to 4.38; p=.02; I^2=87%). There was no significant difference in functional outcomes between groups at either short-term or intermediate-term follow up.

Smith et al (2019) published the results of a systematic review of 19 studies assessing the efficacy of lumbar transforaminal steroid injection for radicular pain due to lumbar disc herniation.[9,] Placebo-controlled RCTs, pragmatic studies, and observational studies were included in the analysis. Utilizing a threshold of ≥50% reduction in pain, treatment success rates (ranges) across studies were 63%

(58% to 68%) at 1 month, 74% (68% to 80%) at 3 months, 64% (59% to 69%) at 6 months, and 64% (57% to 71%) at 1 year.

Arirachakaran et al (2018) conducted a systematic review comparing treatment with ESI (n=502) and placebo (n=504) in patients with moderate-to-severe back pain and radicular leg pain following discectomy for lumbar disc herniation.[10,] A total of 12 studies were pooled for the meta-analysis. The mean difference in VAS pain score for back pain at 1 week and 1 month was -0.53 (95% CI, -1.42 to 0.36) and -0.89 (95% CI, -1.36 to -0.42) lower compared to placebo. The mean difference in VAS pain score for leg pain at 1 week and 1 month was -0.63 (95% CI, -0.75 to -0.50) and -0.47 (95% CI, -0.78 to -0.15) lower, respectively, compared to placebo. Morphine consumption decreased by -8.47 mg (95% CI, -16.16 to -0.78 mg) compared to placebo. As included studies utilized mean follow-up durations ranging from 1 week to 1 month, this review did not evaluate long-term outcomes.

Bhatia et al (2016) published the results of a systematic review and meta-analysis of 8 RCTs including 771 patients (366 in steroid and 405 in comparator groups) that evaluated transforaminal ESIs to treat lumbosacral radicular pain secondary to herniated intervertebral discs.[11,] The control groups received local anesthetic with saline or saline alone. The strength of evidence for each included study was classified with the GRADE system. Of the 8 studies included, 2 were rated as high risk of bias, 2 with unclear risk of bias, and 4 with low risk of bias. Although this review minimized variability by including studies that used only transforaminal administration of steroid as opposed to interlaminar and caudal administration, reviewers acknowledged variability on account of steroid dose, frequency, and the number of procedures. Reported results indicated that 3 months of ESI resulted in a statistically significant but clinically modest reduction of 0.97 points in mean pain scores (0 to 10 scale) (95% CI, -1.42 to -0.51; p<.001, I^2=90%) compared with local anesthetic or saline with a GRADE weak recommendation based on moderate-quality evidence. Epidural steroids did not decrease physical disability at 1 to 3 months after the intervention (GRADE strong recommendation based on high-quality evidence) or incidence of surgery at 12 months after the intervention (GRADE strong recommendation based on moderate-quality evidence) compared with local anesthetic or saline. Reviewers concluded that well-designed, large RCTs would be required to evaluate appropriate dosages, adverse events, number of procedures, and effect on psychological disability and QOL.

Cervical Radiculopathy

Systematic Reviews

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 the treatment of cervical radiculopathy.

Diwan et al (2012) performed a systematic review of ESIs for chronic neck and upper-extremity pain and reported separately on the evidence for cervical

radiculopathy.[12,] This analysis included 4 RCTs, 3 of which were included in the review by Benyamin et al (2009), discussed next.[13,] The fourth RCT, which was the largest (N=120) and rated the highest in quality, randomized patients to epidural steroid plus local anesthetic or local anesthetic alone, and reported on pain relief at 6 and 12 months. At 6 months, the percentage 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 similar, with 72% of patients in the steroid group reporting pain relief compared with 68% in the control group.

A review by Benyamin et al (2009) included studies of epidural injections for neck pain that was present for more than 3 months, with or without radiculopathy.[13,] Reviewers identified RCTs that met 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 ESIs (n=24) or to steroid injections in the adjacent neck muscle (n=18). 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 percentage of patients reporting good pain improvement persisted in favor of the epidural steroid group (68% vs. 12%, p not reported).

Randomized Controlled Trials

Since these systematic reviews were published, Cohen et al (2014) reported the results of an RCT that compared ESI, conservative treatment, and a combination of both for patients with cervical radiculopathy.[14,] A total of 169 patients were randomized to conservative care (physical therapy plus medications), ESIs, or a combination of both treatments. The primary outcomes were neck and arm pain measured at 1 and 3 months posttreatment. There were no differences noted between ESI and conservative care on any of the outcome measures. The group receiving combination therapy had a greater reduction in arm pain at 1 month compared with the 2 individual treatments and had a greater success rate at 3 months (56.9% vs. 26.8%, p=.006).

Section Summary: Lumbar Radiculopathy or Sciatica and Cervical Radiculopathy

For individuals who have lumbar radiculopathy who receive ESI, the evidence includes RCTs and a number of systematic reviews or meta-analyses of these RCTs. Although large-scale, high-quality trials are lacking, several recent systematic reviews and meta-analyses of smaller trials indicate improved pain with ESI compared with conservative treatment or placebo. There are fewer trials in individuals with cervical radiculopathy, but a 2014 RCT reported ESI efficacy similar to conservative treatment and improved pain when a combination of ESI and conservative treatment was used. Epidural steroid injections appear to improve pain in the short- and intermediate-term (up to 6 months) without long-

term benefit. Adverse events were generally mild but not well reported in these analyses. Serious adverse events can occur, but their rate is unknown.

Spinal Stenosis

Clinical Context and Therapy Purpose
The purpose of ESI for patients who have spinal stenosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of ESIs improve the net health outcome for those who suffer from spinal stenosis?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with spinal stenosis.

Interventions
The therapy being considered is ESI.

Comparators
The following practice is currently being used to treat spinal stenosis: conservative care, which can include physical therapy, medications, and other nonpharmacologic measures.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, health status measures, QOL, medication use, and treatment-related morbidity. Specifically, outcomes of interest include pain and medication usage, and improvement in functional outcomes and QOL. Reductions in pain and medication use can be observed within a week. The duration of pain relief with corticosteroids is rarely longer than 3 months, so outcomes should be measured within this window.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Smith et al (2019) identified 11 studies assessing the efficacy of transforaminal ESI in patients with radicular pain due to spinal stenosis.[9,] Utilizing a threshold of ≥50% reduction in pain, treatment success rates (ranges) across studies were 49% (43% to 55%) at 1 month, 48% (35% to 61%) at 3 months, 43% (33% to 53%) at 6 months, and 59% (45% to 73%) at 1 year. However, the authors noted that these results lacked adequate corroboration from appropriately controlled RCTs.

In the systematic review by Benyamin et al (2012), 6 RCTs assessed patients with spinal stenosis, 5 of which compared steroid injections with a local anesthetic alone.[2,] Two trials reported between-group differences in favor of steroid injections, 3 reported significant improvement in pain for the steroid group but did not report between-group differences, and the other reported no significant improvement for the steroid group.

Manchikanti et al (2012) identified 4 RCTs of ESIs for the treatment of lumbar spinal stenosis.[6,] Although 2 compared epidural steroids with control and reported on pain relief and/or disability, neither reported that pain relief with epidural steroids was superior to control, either in the short- or the long-term.

The systematic review by Diwan et al (2012) identified 1 RCT that treated cervical spinal stenosis in 60 patients.[12,] In this trial, there were no significant differences in the percentages 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%).

The systematic review by Chou et al (2009) identified 3 placebo-controlled trials on the treatment of spinal stenosis, but in 2 of them, only a subset of treated patients had spinal stenosis.[5,] Reviewers rated the quality of this evidence as poor and concluded that it was not possible to determine whether epidural steroids offer a benefit for spinal stenosis.

Randomized Controlled Trials

Schneider et al (2019) published the results of a 3-arm RCT comparing the clinical effectiveness of medical care (n=88), group exercise (n=84), and manual therapy/individualized exercise (n=87) in patients with lumbar spinal stenosis.[15,] Treatment in the medical care group consisted of medications and/or ESI provided by a physiatrist. Study limitations include failure to disclose the proportion of patients in the medical care group receiving ESI during the course of the study, excluding patients <60 years of age, and no direct reporting of pain outcomes. The primary outcomes were symptoms and physical function as measured by the patient-reported Swiss Spinal Stenosis (SSS) score. The SSS score ranges from 12 to 55 points, with higher scores indicating higher levels of self-reported disability. Analyses at 2 months indicated that manual therapy/individualized exercise demonstrated greater reduction in SSS score compared to medical care (-2.0; 95% CI, -3.6 to -0.4) or group exercise (-2.4; 95% CI, -4.1 to -0.8). The magnitude of the difference in the reduction of SSS score between groups did not reach the level of a minimal clinically important difference of 3.02 points.

A moderately large RCT of ESIs for the treatment of spinal stenosis was published by Friedly et al (2014).[16,] This double-blind trial randomized 400 patients with lumbar central spinal stenosis and at least moderate-to-severe leg pain (≥4 on 0 to 10 VAS) or disability (≥7 on Roland-Morris Disability Questionnaire [RMDQ], 0 to 24 scale) due to spinal stenosis to treatment with ESIs plus lidocaine or lidocaine alone. One repeat injection could be given at 3 weeks at the discretion of the patient and treating physician. The primary outcomes were the patient's rating of pain in the buttocks, hip, or leg at 6 weeks following the initial treatment and the RMDQ 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 QOL scales. At the 6-week follow-up, there were no significant differences in the primary outcomes between groups. The change in pain scores on the VAS for the steroid group was -2.8 compared with -2.6 for the control group (adjusted between-group mean difference, -0.2 points; 95% CI, -0.8 to 0.4; p=.48), and the change in the RMDQ scores 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=.07). There were small, statistically significant differences in measures of pain and disability at 3 weeks, but these changes 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 8-item Patient Health Questionnaire, and satisfaction on the SSS questionnaire). Friedly et al (2017) published 12-month follow-up data because the trial protocol offered participants the option to crossover to the alternative treatment after 6 weeks while remaining masked to treatment assignment.[17,] Results showed that ESIs offered no benefits from 6 weeks to 12 months beyond that of injections of lidocaine alone in terms of self-reported pain and function or reduction in the use of opioids and spine surgery. At 12 months, the adjusted mean difference from baseline between groups was -0.4 for RMDQ score (95% CI, -1.6 to 0.9) and was 0.1 for leg pain (95% CI, -0.5 to 0.7).

Section Summary: Spinal Stenosis
For individuals who have spinal stenosis who receive ESIs, the evidence includes a moderately large RCT (N=400) and systematic reviews of RCTs. The largest RCT and the majority of smaller trials in the systematic reviews did not report a benefit for ESIs.

Nonspecific Low Back Pain

Clinical Context and Therapy Purpose
The purpose of ESI for patients who have nonspecific low back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of ESIs improve the net health outcome for those who suffer from nonspecific low back pain?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with nonspecific low back pain.

Interventions
The therapy being considered is ESI.

Comparators
The following practice is currently being used to treat nonspecific low back pain: conservative care, which can include physical therapy, medications, and other nonpharmacologic measures.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, health status measures, QOL, medication use, and treatment-related morbidity. Specifically, outcomes of interest include reductions in pain and medication usage, and improvement in functional outcomes and QOL. Reductions in pain and medication use can be observed within a week. The duration of pain relief with corticosteroids is rarely longer than 3 months, so outcomes should be measured within this window.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews
A Cochrane review by Staal et al (2008) assessed injection therapy for subacute and chronic low back pain.[18,] This review included RCTs that enrolled patients with low back pain for at least 1 month and reported pain outcomes. Eighteen studies met the inclusion criteria, 10 of which were considered to be at low risk for bias. Due to high levels of heterogeneity, a pooled analysis was not performed. Of the 18 selected studies, 5 reported a benefit for treatment with epidural steroids. There were 2 placebo-controlled studies of short-term outcomes of leg pain. Neither study reported a significant reduction of pain associated with epidural injections. Three studies compared epidural steroids with nonsteroidal anti-inflammatory drugs, and none of them reported significant improvements for patients treated with epidural steroids.

The review by Benyamin et al (2012) identified 3 trials of ESIs for nonspecific low back pain, 1 randomized and 2 nonrandomized.[2,] The randomized trial reported a greater percentage of patients with pain relief following ESI (83%) compared with local anesthetic alone (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 (2012) addressed the indication of nonspecific low back pain (axial low back pain) in their systematic review.[6,] However, no RCTs met their inclusion criteria, and only 3 nonrandomized studies were included. This evidence was insufficient to inform conclusions on the efficacy of epidural steroids for nonspecific low back pain.

Section Summary: Nonspecific Low Back Pain
For individuals who have nonspecific low back pain who receive ESIs, the evidence includes systematic reviews of RCTs and nonrandomized studies. Most trials were of low quality and did not report a benefit for ESIs.

Safety
Potential adverse events of ESIs 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.

In the systematic review by Chou et al (2009), it was noted that while case reports have reported serious adverse events such as paralysis and infection due to epidural injections, serious adverse events were rarely reported in the clinical trials.[5,] Of the 17 trials included in the review that reported on the use of epidural injections for treatment of low back pain with radiculopathy, 10 of 17 did not report adverse events at all, and the adverse events reported in the other trials were generally transient and mild. In 1 high-quality trial with systematic reporting of adverse events, 3.3% (4/120) of patients experienced a postinjection headache, 0.8% (1/120) experienced post-dural puncture headache, 1.7% (2/120) experienced postinjection nausea, and 4.2% (5/120) experienced other adverse events.

Adverse events of ESIs are not well reported in treatment trials. In a systematic review by Koes et al (1995), only 4 of 15 included trials reported on adverse events.[19,] In addition to this lack of reporting, the available trials are generally small and therefore inadequate for determining rates of uncommon adverse events. A consensus panel (2015) convened in part by the U.S. Food and Drug Administration (FDA) reviewed the literature on serious neurologic complications following ESI.[20,] The evidence was restricted to case reports and reports of malpractice claims. Reports included direct needle injury to the spinal cord, arterial injury, swelling of an unrecognized epidural lesion, and paraplegia/stroke. Based on the pattern of reports, the report concluded that stroke and paraplegia were

likely caused by intraarticular injection of particulate steroids. Therefore, the rate of adverse events is mostly uncertain.

The FDA (2014) issued a drug safety communication on rare but serious neurologic problems associated with ESIs.[21,] This communication stated that the safety of ESIs has not been established and that the FDA has not approved corticosteroids for this use. Potential serious adverse neurologic events include loss of vision, stroke, paralysis, and death. The FDA subsequently assembled an expert panel that issued a report in 2015.[20,] This report included a series of recommendations regarding the ESI technique, including clinically relevant issues related to its performance, such as the use of particulate steroids, use of contrast, and the use of sedation.

Epidural steroids are generally compounded medications because the specific preparations for clinical use are prepared at a pharmacy rather than by the manufacturer of the drug. In 2012, several patients were identified who developed fungal meningitis complications following ESI due to contaminated medication obtained from a single pharmacy.[22,] The U.S. Centers for Disease Control and Prevention subsequently obtained preliminary data on 137 patients across 10 states affected by this outbreak. Of those, 12 (9%) of 137 patients died, 3 (2%) of 137 had suffered a stroke, and 3 (2%) of 137 had osteomyelitis or epidural abscess. The contamination was attributed to faulty sterilization procedures at the pharmacy that compounded the medications.

Due to reports that transforaminal anterolateral ESI approaches may be associated with rare but serious complications, Bise et al (2019) compared the efficacy of transforaminal anterolateral against 2 recently described, potentially safer methods: transforaminal posterolateral and transfacet indirect approaches.[23,] The efficacy of transforaminal anterolateral, transforaminal posterolateral, and transfacet indirect ESI approaches was assessed in patients with cervical radicular pain (N=104). The decrease in VAS did not differ between the 3 types of ESI at 6 weeks (p=.635) or 6 months (p=.529) and no complications were reported.

Section Summary: Safety

Adverse events, both minor and serious, can occur following ESIs. For serious neurologic events, the evidence consists of case reports and, as a result, the rate of serious adverse events is uncertain. Few serious adverse events have been reported in the RCTs, but there is also a lack of systematic reporting in the available trials. Minor adverse events that are self-limited (eg, headache) are more common, but the evidence is not sufficient to determine actual event rates. Further research is needed to determine the true rate of adverse events attributable to ESIs. An FDA consensus panel has issued guidelines for the technical performance of ESI with the goal of reducing potential serious neurologic events.

Summary of Evidence

For individuals who have lumbar or cervical radiculopathy who receive ESIs, the evidence includes RCTs and a number of systematic reviews and meta-analyses of these RCTs. Relevant outcomes are symptoms, 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. Meta-analyses have found reduced pain in the short- and intermediate-term (up to 6 months) with ESI compared with conventional therapy. None of the analyses reported long-term benefits for treatment with ESIs. Adverse events were generally mild but 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 an improvement in the net health outcome.

For individuals who have spinal stenosis who receive ESIs, the evidence includes a moderately large RCT (N=400) and systematic reviews of 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 in the systematic reviews did not report a benefit for ESIs. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have nonspecific low back pain who receive ESIs, the evidence includes systematic reviews of RCTs and nonrandomized studies. Relevant outcomes include symptoms, functional outcomes, health status measures, quality of life, medication use, and treatment-related morbidity. Most trials were of low quality and did not report a benefit for ESIs. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 5 academic medical centers and 6 specialty societies while this policy was in development in 2014. Consensus was reached among reviewers that: treatment of cervical radiculopathy is medically necessary with the same criteria as for lumbar radiculopathy; the minimum period

of time for conservative therapy should be 4 weeks or less; fluoroscopic guidance should be used in all cases of epidural steroid injections (ESI); and, fluorography imaging of the epidural space is investigational. There was mixed input on the optimal timing to assess response, the number of levels that should be treated at one time, and the maximum number of injections to be given in 1 year.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Neurology
In 2007, the American Academy of Neurology published guidelines on the use of epidural steroids for lumbosacral radiculopathy.[24,] 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)."

American Association of Neurological Surgeons
In 2014, 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 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).[25,] 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).

American College of Physicians et al
In 2007, the American College of Physicians and the American Pain Society issued guidelines on the diagnosis and treatment of low back pain, which 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)."[26,] Portions of these guidelines were updated in 2017, but there was no discussion on ESI use.[4,]

American Pain Society
In 2009, the American Pain Society published guidelines on the use of interventional therapies for low back pain,[1,] based on a systematic review of the evidence published in the same year.[5,] These guidelines made the following recommendations on ESIs:

- "In patients with persistent radiculopathy due to herniated 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 ESI include a specific discussion about inconsistent evidence showing moderate short-term benefits, and lack of long-term benefits."
- There is "insufficient evidence … to reliably judge 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 (IDET), 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 Anesthesiologists
In 2010, the 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.[27,] Image guidance might be considered for interlaminar epidural injections to confirm correct needle position and spread of contrast before injecting therapeutic substance.

American Society of Interventional Pain Physicians
In 2021, the American Society of Interventional Pain Physicians published an updated guideline on the use of epidural injections in the management of chronic spinal pain.[28,]

For patients with disc herniation, the following recommendations were made:

- Based on relevant, high-quality trials of fluoroscopically guided epidural injections, with or without steroids, and results of previous systematic reviews, "the evidence is Level I for caudal epidural injections, lumbar interlaminar epidural injections, lumbar transforaminal epidural injections, and cervical interlaminar epidural injections with strong recommendation for long-term effectiveness."
- "For thoracic disc herniation, based on one relevant, high-quality RCT of thoracic epidural with fluoroscopic guidance, with or without steroids, the evidence is Level II with moderate to strong recommendation for long-term effectiveness."

For patients with spinal stenosis, the following recommendations were made: "based on one high-quality RCT in each category the evidence is Level III to II for fluoroscopically guided caudal epidural injections with moderate to strong recommendation and Level II for fluoroscopically guided lumbar and cervical interlaminar epidural injections with moderate to strong recommendation for long-term effectiveness. The evidence for lumbar transforaminal epidural injections is Level IV to III with moderate recommendation with fluoroscopically guided lumbar transforaminal epidural injections for long-term improvement."

For patients with axial discogenic pain, "The evidence for axial discogenic pain without facet joint pain or sacroiliac joint pain in the lumbar and cervical spine with fluoroscopically guided caudal, lumbar and cervical interlaminar epidural injections, based on one relevant high quality RCT in each category is Level II with moderate to strong recommendation for long-term improvement, with or without steroids."

North American Spine Society

The North American Spine Society (NASS) has released multiple clinical guidelines for the management of back pain. In 2020, the NASS released comprehensive guidelines on the diagnosis and treatment of low back pain.[29,] The NASS concluded there is insufficient evidence for or against the use of caudal ESI for discogenic low back pain or interlaminar ESI for axial low back pain based on a review of the literature (grade I recommendation).

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in October 2021 did not identify any ongoing or unpublished trials that would likely influence this review.

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 01 2009; 34(10): 1066-77. 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): 865-77. PMID 23362516

4. Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. Ann Intern Med. Apr 04 2017; 166(7): 514-530. PMID 28192789
5. 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 01 2009; 34(10): 1078-93. PMID 19363456
6. 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
7. Verheijen EJA, Bonke CA, Amorij EMJ, et al. Epidural steroid compared to placebo injection in sciatica: a systematic review and meta-analysis. Eur Spine J. Nov 2021; 30(11): 3255-3264. PMID 33974132
8. Yang S, Kim W, Kong HH, et al. Epidural steroid injection versus conservative treatment for patients with lumbosacral radicular pain: A meta-analysis of randomized controlled trials. Medicine (Baltimore). Jul 24 2020; 99(30): e21283. PMID 32791709
9. Smith CC, McCormick ZL, Mattie R, et al. The Effectiveness of Lumbar Transforaminal Injection of Steroid for the Treatment of Radicular Pain: A Comprehensive Review of the Published Data. Pain Med. Mar 01 2020; 21(3): 472-487. PMID 31343693
10. Arirachakaran A, Siripaiboonkij M, Pairuchvej S, et al. Comparative outcomes of epidural steroids versus placebo after lumbar discectomy in lumbar disc herniation: a systematic review and meta-analysis of randomized controlled trials. Eur J Orthop Surg Traumatol. Dec 2018; 28(8): 1589-1599. PMID 29845327
11. 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
12. 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): E405-34. PMID 22828692
13. 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): 137-57. PMID 19165300
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): 1045-55. PMID 25335172
15. Schneider MJ, Ammendolia C, Murphy DR, et al. Comparative Clinical Effectiveness of Nonsurgical Treatment Methods in Patients With Lumbar Spinal Stenosis: A Randomized Clinical Trial. JAMA Netw Open. Jan 04 2019; 2(1): e186828. PMID 30646197
16. Friedly JL, Comstock BA, Turner JA, et al. A randomized trial of epidural glucocorticoid injections for spinal stenosis. N Engl J Med. Jul 03 2014; 371(1): 11-21. PMID 24988555
17. 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.e2. PMID 28396242
18. 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
19. Koes BW, Scholten RJPM, Mens JMA, 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): 974-84. PMID 25668411
21. US Food and Drug Administration. Epidural Corticosteroid Injection: Drug Safety Communication - Risk of Rare But Serious Neurologic Problems. 2014; https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-requires-label-changes-warn-rare-serious-neurologic-problems-after. Accessed October 4, 2021.

22. Centers for Disease Control and Prevention (CDC). 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): 839-42. PMID 23076093
23. Bise S, Pesquer L, Feldis M, et al. Comparison of three CT-guided epidural steroid injection approaches in 104 patients with cervical radicular pain: transforaminal anterolateral, posterolateral, and transfacet indirect. Skeletal Radiol. Dec 2018; 47(12): 1625-1633. PMID 30032466
24. 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 October 5, 2021.
25. Watters WC, 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
26. 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): 478-91. PMID 17909209
27. Benzon HT, Connis RT, De Leon-Casasola OA, et al. 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): 810-33. PMID 20124882
28. Manchikanti L, Knezevic NN, Navani A, et al. Epidural Interventions in the Management of Chronic Spinal Pain: American Society of Interventional Pain Physicians (ASIPP) Comprehensive Evidence-Based Guidelines. Pain Physician. Jan 2021; 24(S1): S27-S208. PMID 33492918
29. North American Spine Society (NASS). Evidence-based clinical guidelines for multidisciplinary spine care: Diagnosis and treatment of low back pain. 2020; https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LowBackPain.pdf. Accessed October 4, 2021.

Billing Coding/Physician Documentation Information

62320 Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance

62321 Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)

62322 Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance

62323 Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)

64479 Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, single level
64480 Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional level (List separately in addition to code for primary procedure)
64483 Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level
64484 Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level (List separately in addition to code for primary procedure)

ICD-10 Codes:
M47.22-M47.27 Other spondylosis with radiculopathy code range
M48.00-M48.08 Spinal stenosis code range
M50.10-M50.13 Cervical disc disorders with radiculopathy code range
M51.14-M51.17 Thoracic, thoracolumbar or lumbosacral intervertebral disc disorders with radiculopathy code range
M54.12 Radiculopathy, cervical region
M54.13 Radiculopathy, cervicothoracic region
M54.16 Radiculopathy, lumbar region
M54.17 Radiculopathy, lumbosacral region
M54.30-M54.42 Sciatica code range
M54.50-M54.59 Low back pain code range (eff 10/01/2021)

Additional Policy Key Words

N/A

Policy Implementation/Update Information

12/1/14 New Policy. 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
12/1/15 No policy statement changes.
4/1/16 Added CPT's: 64479, 64480, 64483, 64484. No policy statement changes.
12/1/16 No policy statement changes.
12/1/17 No policy statement changes.
12/1/18 No policy statement changes.

12/1/19 No policy statement changes.
12/1/20 "Neck" added to policy title. First medically necessary indication updated to include neck.
12/1/21 No policy statement changes.
12/1/22 No policy statement changes.
