EPIDURAL STEREROID AND FACET INJECTIONS FOR SPINAL PAIN

Policy Number: 2018T0004DD

Effective Date: February 1, 2018

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Note: Epidural steroid injections in this policy apply to the lumbar spine only. This section does not address cervical or thoracic injections.

The facet joint injections section of this policy addresses multiple sites, and is not limited to the lumbar spine.
Ultrasound Guidance
The use of ultrasound guidance for epidural steroid injection(s) and facet joint injection(s) is unproven and/or not medically necessary.
There is insufficient clinical evidence regarding its safety and/or efficacy in published peer-reviewed medical literature.

Epidural Steroid Injections
Epidural steroid injection is proven and/or medically necessary for treating acute and sub-acute sciatica or radicular pain of the low back caused by spinal stenosis, disc herniation or degenerative changes in the vertebrae.
Epidural steroid injections have a clinically established role in the short-term management of low back pain when the following two criteria are met:
- The pain is associated with symptoms of nerve root irritation and/or low back pain due to disc extrusions and/or contained herniations; and
- The pain is unresponsive to conservative treatment, including but not limited to pharmacotherapy, exercise or physical therapy.

Epidural steroid injection is unproven and/or not medically necessary for ALL other indications of the lumbar spine.
There is a lack of evidence from randomized controlled trials indicating that epidural steroid injections effectively treat patients with lumbar pain not associated with sciatica or radicular pain.

Note: This policy does not apply to obstetrical epidural anesthesia utilized during labor and delivery.

Facet Joint Injections
Diagnostic facet joint injection and/or facet nerve block (e.g., medial branch block) is proven and/or medically necessary to localize the source of pain to the facet joint in persons with spinal pain.

Therapeutic facet joint injection is unproven and/or not medically necessary for treating chronic spinal pain.
Clinical evidence about the very existence of facet joint syndrome is conflicting, and evidence from studies is inadequate regarding the superiority of periodic facet joint injections compared to placebo in relieving chronic spinal pain (pain lasting more than 3 months).

For additional information on facet joint injections as a diagnostic procedure prior to radiofrequency ablation, see Clinical Evidence.

DEFINITIONS
Acute Low Back Pain: Low back pain present for up to six weeks. The early acute phase is defined as less than two weeks and the late acute phase is defined as two to six weeks, secondary to the potential for delayed-recovery or risk phases for the development of chronic low back pain. Low back pain can occur on a recurring basis. If there has been complete recovery between episodes, it is considered acute recurrent.

Sub-Acute Low Back Pain: Low back pain with duration of greater than six weeks after injury but no longer than 12 weeks after onset of symptoms. (Goertz et al. 2012)

APPLICABLE CODES
The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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**Epidural**

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**Facet**

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Epidural Steroid and Facet Injections for Spinal Pain

UnitedHealthcare Commercial Medical Policy

DESCRIPTION OF SERVICES

Pain in the lower back is a common concern, affecting up to 90% of Americans at some point in their lifetime. The vast majority of episodes are mild and self-limited (Chronic nonmalignant back pain is defined as pain lasting 3 - 6 months or more that is not due to cancer). Up to 50% of affected persons will have more than one episode. Low back pain is not a specific disease; rather it is a symptom that may occur from a variety of different processes, including but not limited to spinal stenosis, disc herniation or degenerative changes in the vertebrae. Management of back pain that is persistent and disabling despite the use of recommended conservative treatment is challenging. Epidural steroid injections, and facet joint injections and blocks are among the treatments that have been employed as an alternative to more invasive interventions.

Facet blocks can be considered a diagnostic or therapeutic procedure. Facet blocks using short-acting local anesthetics can be used to diagnose facet (zygapophyseal) joint syndrome as the cause of chronic back pain. Facet blocks utilizing long acting local anesthetics, anti-inflammatory agents such as corticosteroids, or nerve ablating techniques such as radiofrequency lesioning have been investigated for treatment of chronic back pain attributed to facet joint syndrome. (Hayes, 2010, Archived 2011)

Epidural steroid injection (ESI) is a nonsurgical treatment for managing low back pain and sciatica caused by disc herniation or degenerative changes in the vertebrae. An epidural steroid injection is an injection of long lasting steroid in the epidural space; that is the area which surrounds the spinal cord and the nerves coming out of it. The goal of ESI is to relieve pain, improve function, and reduce the need for surgical intervention. (Hayes, 2007, Updated 2016)

CLINICAL EVIDENCE

Ultrasound Guidance

Wu et al (2016) conducted a meta analysis of controlled trials (randomized and non-randomized) to assess the comparative effectiveness of ultrasound-guided (USG) versus computed tomography (CT)/fluoroscopy-guided lumbar facet joint injections in adults. Databases were searched for controlled trials comparing the clinical effectiveness between USG and CT/fluoroscopy-guided injection techniques in patients with facet syndrome were included. Two reviewers independently screened abstracts and full texts. The results of the mean procedure duration, decreased pain score, and Modified Oswestry Disability score after treatment were extracted and presented in the form of mean. Of 103 records screened, 3 studies were included, with a total of 202 adults with facet joint pain. There was no statistically significant difference between the 2 groups in pain score and Modified Oswestry Disability score after injection .There was also no statistically significant difference in the mean procedure duration between the 2 groups. The authors concluded that while USG injection is feasible, and minimizes exposure of radiation to patients and practitioners in the lumbar facet joint injection process. This review suggested no significant differences in pain and functional improvement were noted between the USG and CT-/fluoroscopy-guided techniques in facet joint injection.

Facet Injections

Manchikanti et al (2016) conducted a systematic evidence-based assessment methodology of controlled trials of diagnostic validity and randomized controlled trials to investigate the diagnostic validity and therapeutic value of lumbar facet joint interventions in managing chronic low back pain. The literature search was extensive utilizing various types of electronic search media, and inclusion criteria encompassed all facet joint interventions performed in a controlled fashion. Across all databases, 16 high quality diagnostic accuracy studies were identified and multiple studies assessed the influence of multiple factors on diagnostic validity. In contrast to diagnostic validity studies, therapeutic efficacy trials were limited to a total of 14 randomized controlled trials, assessing the efficacy of intraarticular injections, facet or zygapophysial joint nerve blocks, and radiofrequency neurotomy of the innervation of the facet joints. The pain relief of greater than 50% was the outcome measure for diagnostic accuracy assessment of the controlled studies with ability to perform previously painful movements, whereas, for randomized controlled therapeutic efficacy studies, the primary outcome was significant pain relief and the secondary outcome was a positive change in functional status. For the inclusion of the diagnostic controlled studies, all studies must have utilized either placebo controlled facet joint blocks or comparative local anesthetic blocks. In assessing therapeutic interventions, short-term and long-term reliefs were defined as either up to 6 mo or greater than 6 mo of relief. The evidence for the diagnostic validity of lumbar facet joint nerve blocks with at least 75% pain relief with ability to perform previously painful movements was level I, based on a range of level I to V derived from a best evidence synthesis. For
therapeutic interventions, the evidence was variable from level II to III, with level II evidence for lumbar facet joint nerve blocks and radiofrequency neurotomy for long-term improvement (greater than 6 mo), and level III evidence for lumbosacral zygapophysial joint injections for short-term improvement only. The authors concluded that this review provides significant evidence for the diagnostic validity of facet joint nerve blocks, and moderate evidence for therapeutic radiofrequency neurotomy and therapeutic facet joint nerve blocks in managing chronic low back pain.

Vekaria et al (2016). Evidence supporting the use of therapeutic intra-articular facet joint injections for patients with suspected facet joint pain is sparse. The authors conducted a systematic review, including a narrative synthesis to determine if intra-articular facet joint injections with active drug are more effective in reducing back pain and back pain-related disability than a sham procedure or a placebo/inactive injection. The authors also evaluated if intra-articular facet joint injections with active drug or placebo/inactive injection are more effective in reducing back pain and back pain-related disability than conservative treatment. Electronic databases were searched through April 2015. Data were screened and single extraction with independent verification and risk of bias assessment was performed. A total of 391 records were screened, and six trials were included. The trials included were small (range 18-109 participants) and overall in terms of pain and disability outcomes most were inconclusive. Only two of the trials report any significant between-group differences in pain or disability outcomes. The authors addressed limitations and flaws in these trials that were clinically diverse and precluded any meta-analysis. A number of methodological issues were identified. The positive results are interpreted with caution, and suggest that there is a need for further high-quality work in this area. Further randomised controlled trials of higher methodological standard comparing facet joint injection with a sham/placebo control or conservative treatment are needed from which to base any conclusion on the effectiveness of facet joints in improving pain and disability outcomes.

Manchicanti et al. (2010a) conducted a double-blind randomized controlled trial of facet joint nerve blocks to manage chronic low back pain. One hundred twenty patients were equally randomized to receive either a local anesthetic only (group I) or a local anesthetic mixed with a steroid (group II). Outcomes were measured at baseline, 3, 6, 12, 18 and 24 months post-treatment with the Numeric Rating Scale (NRS), the Oswestry Disability Index 2.0 (ODI), work status, and opioid intake. Significant pain relief (≥ 50%) and functional improvement of ≥ 40% were observed in 85% in Group 1, and 90% in Group II, at 2-year follow-up. The authors found that both groups had equal relief with or without the addition of steroids to the treatment.

A systematic review by Boswell et al. (2007) evaluated the effectiveness of 3 types of facet joint interventions (intra-articular injections, medial branch nerve blocks, and neurotomy) in managing chronic spinal pain. The primary outcome measure was pain relief. For intra-articular facet joint injections and medial branch blocks, short-term pain relief was defined as relief lasting less than 6 weeks and long-term relief as 6 weeks or longer. For medial branch blocks, repeated injections at defined intervals provided long-term pain relief. For medial branch radiofrequency neurotomy, short-term pain relief was defined as relief lasting less than 3 months and long-term relief as lasting 3 months or longer. Other outcome measures included functional improvement, improvement of psychological status, and return to work. The authors concluded that for intra-articular facet joint injections, the evidence for short- and long-term pain relief is limited for cervical pain and moderate for lumbar pain. For medial branch blocks, the evidence is moderate for short- and long-term pain relief. For medial branch neurotomy, the evidence is moderate for short- and long-term pain relief. The evidence for thoracic medial branch neurotomy is indeterminate.

Manchikanti (2006) also investigated 55 consecutive patients with thoracic facet joint pain treated with medial branch blocks. Significant pain relief was achieved in 71% of patients at 3 and 6 months, 71% at 24 months, and 69% at 36 months. The investigators concluded that thoracic medial branch blocks were an effective treatment for managing thoracic facet joint pain.

In a prospective, randomized, double-blind trial by Manchikanti et al. (2007), data from a total of 60 patients were included, with 15 patients in each of 4 groups. Thirty patients were in a non-steroid group consisting of Groups I (control, with lumbar facet joint nerve blocks using bupivacaine) and II (with lumbar facet joint nerve blocks using bupivacaine and Sarapin); another 30 patients were in a steroid group consisting of Groups III (with lumbar facet joint nerve blocks using bupivacaine and steroids) and IV (with lumbar facet joint nerve blocks using bupivacaine, Sarapin, and steroids). Significant improvement in pain and functional status were observed at 3 months, 6 months, and 12 months, compared to baseline measurements. The average number of treatments for 1 year was 3.7 with no significant differences among the groups. Duration of average pain relief with each procedure was 14.8 +/- 7.9 weeks in the non-steroid group and 12.5 +/- 3.3 weeks in the steroid group, with no significant differences among the groups. Therapeutic lumbar facet joint nerve blocks with local anesthetic, with or without Sarapin or steroids, may be effective in the treatment of chronic low back pain of facet joint origin.

**Additional Information**

Facet joint injection, as a diagnostic procedure prior to radiofrequency ablation, is not recommended in patients with:

- Neurologic abnormalities
- More than one pain syndrome
• Definitive clinical and/or imaging findings pointing to a specific diagnosis other than facet joint syndrome
• Previous spinal surgery at the clinically suspected levels

**Professional Societies**

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

*The Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain Update 2013*

The ASIPP maintains a comprehensive guideline for facet injections including indications, limitations and therapy frequencies.

**Epidural Steroid Injections**

Overall, the evidence for the use of diagnostic and therapeutic injections in the treatment of acute and chronic back pain is limited. Clinical studies have demonstrated that epidural steroid injections have provided short-term improvement and may be considered in the treatment of selected patients with radicular pain as part of an active therapy program. There is insufficient evidence to demonstrate that epidural steroid injections are effective in the treatment of back pain in the absence of radicular symptoms.

Manchikanti et al (2014) sought to assess the effectiveness of transforaminal epidural injections of local anesthetic with or without steroids in managing chronic low back and lower extremity pain in patients with disc herniation and radiculitis. One hundred twenty patients were randomly assigned to 2 groups: Group I received 1.5 mL of 1% preservative-free lidocaine, followed by 0.5 mL of sodium chloride solution. Group II received 1% lidocaine, followed by 3 mg, or 0.5 mL of betamethasone. The sodium chloride solution and betamethasone were either clear liquids or were provided in opaque-covered syringes. The primary outcome measure was significant improvement (at least 50%) measured by the average Numeric Rating Scale (NRS) and the Oswestry Disability Index 2.0 (ODI). Secondary outcome measures were employment status and opioid intake. At 2 years there was significant improvement in all participants in 65% who received local anesthetic alone and 57% who received local anesthetic and steroid. When separated into non-responsive and responsive categories based on initial relief of at least 3 weeks with 2 procedures, significant improvement (at least 50% improvement in pain and function) was seen in 80% in the local anesthetic group and 73% in the local anesthetic with steroid group. Presumed limitations of this evaluation include the lack of a placebo group. The authors concluded transforaminal epidural injections of local anesthetic with or without steroids might be an effective therapy for patients with disc herniation or radiculitis. The present evidence illustrates the lack of superiority of steroids compared with local anesthetic at 2-year follow-up.

Friedly et al (2014) reported that rigorous data are lacking regarding the effectiveness and safety of epidural glucocorticoid injections for the treatment of lumbar spinal stenosis. In a double-blind, multisite trial, the authors randomly assigned 400 patients who had lumbar central spinal stenosis and moderate-to-severe leg pain and disability to receive epidural injections of glucocorticoids plus lidocaine or lidocaine alone. The patients received one or two injections before the primary outcome evaluation, performed 6 weeks after randomization and the first injection. The primary outcomes were the score on the Roland-Morris Disability Questionnaire (RMDQ, in which scores range from 0 to 24, with higher scores indicating greater physical disability) and the rating of the intensity of leg pain (on a scale from 0 to 10, with 0 indicating no pain and 10 indicating "pain as bad as you can imagine"). At 6 weeks, there were no significant between-group differences in the RMDQ score (adjusted difference in the average treatment effect between the glucocorticoid-lidocaine group and the lidocaine-alone group, -1.0 points; 95% confidence interval [CI], -2.1 to 0.1); or the intensity of leg pain (adjusted difference in the average treatment effect, -0.2 points; 95% CI, -0.8 to 0.4). A prespecified secondary subgroup analysis with stratification according to type of injection (interlaminar vs. transforaminal) likewise showed no significant differences at 6 weeks. The authors concluded in the treatment of lumbar spinal stenosis, epidural injection of glucocorticoids plus lidocaine offered minimal or no short-term benefit as compared with epidural injection of lidocaine alone.

Novak and Nemeth (2008) conducted a literature review to evaluate the effect of repeat epidural injections and/or the timing of injections to treat low back pain. Of the 91 articles identified, 15 were included in the review. The authors found little evidence to suggest that repeat epidural steroid injections are beneficial. The authors also found little evidence to suggest guidelines for frequency and timing of epidural steroid injections. The authors suggest that further studies with at least a 1 year follow-up are necessary to evaluate the timing and number of repeat injections.

Abdi et al. (2007) conducted a systemic review of published trials and abstracts of scientific meetings, published between January 1966 and October 2006, to determine the efficacy and safety of ESIs. The primary outcome measure was pain relief. Other outcome measures were functional improvement, improvement of psychological status, and return to work. They identified 11 randomized trials of lumbar interlaminar ESI. Of these studies, 8 had favorable results for short-term (< 6 weeks) relief and 1 was positive for long-term (6 weeks) relief. The level of evidence for interlaminar ESIs was considered strong for short-term pain relief and limited for long-term pain relief. There were 7 randomized trials of lumbar transforaminal ESI (TFESI), 5 of which had favorable results for both short- and long-term pain relief. The level of evidence for TFESI was considered strong for short-term pain relief and moderate for long-term pain relief. Of the 8 randomized trials of caudal ESIs, 5 had favorable results for short-term pain relief and 4 had...
favorable results for long-term pain relief. The level of evidence for caudal epidural injections was considered strong for short-term relief and moderate for long-term relief.

Manchicanti et al. (2010b) conducted a double-blind randomized controlled trial of interlaminar epidural steroid injections, with and without steroids, in managing chronic pain of lumbar disc herniation or radiculitis. Seventy patients were equally randomized to receive either a local anesthetic only (group I) or a local anesthetic mixed with a steroid (group II). Outcomes were measured at baseline, 3, 6, and 12 months post-treatment with the Numeric Rating Scale (NRS), the Oswestry Disability Index 2.0 (ODI), employment status, and opioid intake. Significant pain relief (≥ 50%) was seen at 12 months in 74% of patients in group I and 86% in group II, and 69% and 83% in ODI scores respectively. Patients in group II also had more improvement in functional status at 12 months (83% vs. 69%) and required less opioid intake.

A total of 206 patients with a diagnosis of "postlaminectomy syndrome" were enrolled in Aldrete's (2003) randomized, blinded, comparative study of indomethacin or methylprednisolone. The results of the study suggested that epidural injection of indomethacin and methylprednisolone were equally effective at reducing back pain.

Buttermann (2004) conducted a randomized comparative study of epidural betamethasone injections or discectomy for the treatment of herniated nucleus pulposus. Initially the patients were treated with either epidural injections of betamethasone (n=50) or discectomy (n=50). Patients who failed to obtain relief with steroid injections were entered into a crossover group (n=27) and treated with discectomy. The discectomy group had earlier motor recovery than the steroid group; however, there were no other significant differences between groups. The results suggested that epidural betamethasone injections were not as effective as discectomy. However, steroid injections were effective for up to 3 years in nearly half of the patients who had not responded to conservative treatment.

Khot et al. (2004) performed a single-blind, randomized, placebo-controlled study of epidural steroid injection for patients with low back pain of discogenic origin. In this study, 60 patients were randomly assigned to receive epidural methylprednisolone, while 60 patients received a placebo epidural injection. After 1 year, there was no difference in outcome between the treatment and placebo groups.

In one of the largest recent double-blind, randomized studies, Price et al. (2005) evaluated the effect of epidural steroid injection on 228 patients with either acute or chronic sciatica. Patients received either epidural steroid or placebo injection, up to 3 injections, and were then evaluated periodically for a 12-month period. At 3 weeks after injection, more patients in the steroid group reported reduction in pain and showed improvement in the Oswestry Disability Index score than did patients in the placebo group; however, at all other follow-up times, there were no significant differences in any outcomes between the treatment and control group. This suggested that any effect of epidural steroid was transient.

Cyteval et al. (2006) prospectively followed 229 patients with lumbar radiculopathy (herniated disc and degenerative lesions) at 2 weeks and 1 year after percutaneous periradicular (transforaminal) steroid infiltration. The aim of the study was to find predictive factors of efficacy of the steroid injection procedure. ESIs were performed under fluoroscopic guidance, and periradicular flow was confirmed with contrast medium. Short- and long-term pain relief was demonstrated. The only predictive factor of pain relief was symptom duration before the procedure. The authors concluded that periradicular (transforaminal) infiltration was a simple, safe, and effective (short- and long-term relief) nonsurgical procedure with an improved benefit when performed early in the course of the illness. The primary limitation of the study was the lack of a control group.

Complications associated with epidural injections include steroid side effects, dural puncture, transient increased pain, transient paresthesias, aseptic and/or bacterial meningitis, neurological dysfunction or damage, epidural abscess, intracranial air, allergic reaction, epidural hematoma, persistent dural leak, nausea, headache, paraplegia, tetraplegia, seizure, stroke, and death. (Derby, 2004; Everett, 2004)

Epidural steroid injections should not be performed at the site of congenital anatomic anomalies or in persons who have had previous surgery in which the epidural space is absent, altered, or eliminated. The treatment is contraindicated in patients with systemic infections or bleeding tendencies; infection at the injection site; patients undergoing active anticoagulation therapy; patients at risk for medical decompensation from fluid retention, such as those with severe congestive heart failure or poorly controlled hypertension; and patients with other unstable medical conditions. Steroid injections may lower resistance to infection and should be used with caution in patients with poorly controlled diabetes, since the corticosteroid injection may transiently increase the blood glucose levels. In addition, fluoroscopy should not be used to guide epidural injections for pregnant women to avoid radiation exposure of the fetus. (McLain, 2005)
Clinical Trials

There are several clinical trials recruiting and in process for Facet and Epidural Steroid Injections. Please see (search by procedure name for specific opportunities): https://clinicaltrials.gov/ct2/home. (Accessed November 8, 2017)

Professional Societies/Technology Assessments

Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program
Pain Management Injection Therapies for Low Back Pain (2015)

For this technology assessment, the authors used predefined criteria, and selected randomized trials of patients with lumbosacral radiculopathy, spinal stenosis, nonradicular back pain, or chronic postsurgical back pain that compared effectiveness or harms of epidural, facet joint, or sacroiliac corticosteroid injections versus placebo or other interventions. Also included were randomized trials that compared different injection techniques and large (sample sizes >1000) observational studies of back injections that reported harms. Seventy-eight randomized trials of epidural injections, 13 trials of facet joint injections, and one trial of sacroiliac injections were included. Limited evidence suggested that epidural corticosteroid injections are not effective for spinal stenosis or nonradicular back pain and that facet joint corticosteroid injections are not effective for presumed facet joint pain. There was insufficient evidence to evaluate effectiveness of sacroiliac joint corticosteroid injections. (Chou et al 2015)

American Society of Anesthesiologists (ASA)
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

As of 2010, the ASA has not issued a statement specifically on the use of epidural steroids for the management of low back pain and/or sciatica. However, the ASA Task Force on Pain Management issued more general practice guidelines for chronic pain management. The 2010 ASA guidelines recommended that: Epidural steroid injections with or without local anesthetics may be used as part of a multimodal treatment regimen to provide pain relief in selected patients with radicular pain or radiculopathy. Transforaminal epidural injections should be performed with appropriate image guidance to confirm correct needle position and spread of contrast before injecting a therapeutic substance.

American Academy of Neurology (AAN)
In 2007 (Armon, 2007), the Therapeutics and Technology Assessment Subcommittee of the AAN released an assessment addressing the use of epidural steroid injections (ESIs) to treat radicular lumbosacral pain.

- Epidural 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 to III evidence). 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 3 months. Their routine use for these indications is not recommended (Level B, Class I to III evidence).
- Data on use of epidural steroid injections to treat cervical radicular pain are inadequate to make any recommendation (Level U).

American Society of Interventional Pain Physicians (ASIPP)
The Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain Update 2013

The ASIPP maintains a comprehensive guideline for epidural steroid injections including indications, limitations and therapy frequencies.

American Association of Neurological Surgeons and the Congress of Neurological Surgeon

A guideline from the American Association of Neurological Surgeons and the Congress of Neurological Surgeons states: There is no meaningful evidence in the medical literature that the use of epidural injections is of any long-term value in the treatment of patients with chronic low-back pain. The literature does indicate that the use of lumbar epidural injections can provide short-term relief in selected patients with chronic low-back pain. There is evidence that suggests that facet joint injections can be used to predict outcome after RF ablation of a facet joint. The predictive ability of facet joint injections does not appear to apply to lumbar fusion surgery. No evidence exists to support the effectiveness of facet injections in the treatment of patients with chronic low-back pain. (Resnick, 2005)

North American Spine Society (NASS)
The 2012 North American Spine Society (NASS) clinical guidelines for multidisciplinary spine care diagnosis and treatment of lumbar disc herniation with radiculopathy stated there were no studies available which directly addressed the role of ESIs or selective nerve root blocks in the diagnosis of patient selection for subsequent surgical treatment of a lumbar disc herniation with radiculopathy.
In 2011, NASS revised its clinical guidelines for multidisciplinary spine care diagnosis and treatment of degenerative lumbar spinal stenosis with the following recommendation: that while there is evidence that nonfluoroscopically guided interlaminar and single radiographically guided transforaminal ESIs can result in short-term symptom relief in patients with neurogenic claudication or radiculopathy, there is conflicting evidence concerning long-term efficacy. The guidelines also note that there is some evidence that a multiple injection regimen of radiographically guided transforaminal ESIs or caudal injections can produce long-term relief of pain in patients with radiculopathy or neurogenic intermittent claudication from lumbar spinal stenosis. However, the evidence is of relatively poor quality, and therefore no strong recommendation in support of this therapy was made.

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Epidural Steroid Injection is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation. Injectable corticosteroids include methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and dexamethasone, and are approved by the FDA, however, the effectiveness and safety of the drugs for Epidural Steroid Injection have not been established, and FDA has not approved corticosteroids for such use.

In April 2014, the U.S. Food and Drug Administration (FDA) warned, that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. They noted the effectiveness and safety of epidural administration of corticosteroids have not been established, and the FDA has not approved corticosteroids for this use. FDA is requiring the addition of a warning to the drug labels of injectable corticosteroids to describe these risks. The FDA recommends that individuals should discuss the benefits and risks of epidural corticosteroid injections with their health care professionals, along with the benefits and risks associated with other possible treatments.

Additional information may be obtained from the U.S. Food and Drug Administration - Center for Drug Evaluation and Research (CDER) at: [http://www.fda.gov/cder/drug/default.htm](http://www.fda.gov/cder/drug/default.htm). (Accessed November 8, 2017)

**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Medicare does not have a National Coverage Determination (NCD) for epidural steroid injections for spinal pain. Local Coverage Determinations (LCDs) exist; refer to the LCDs for Category III CPT® Codes, Epidural, Lumbar Epidural Injections, Lumbar Epidural Steroid Injections (ESI), Epidural, Non-Covered Category III CPT Codes, Noncovered Services, Services That Are Not Reasonable and Necessary and Transforaminal Epidural, Paravertebral Facet and Sacroiliac Joint Injections.

Medicare does not have an NCD for facet injections for spinal pain. LCDs exist, refer to the LCDs for Category III CPT® Codes, Facet Joint Injections, Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy, Noncovered Services, Paravertebral Facet Joint Block, Services That Are Not Reasonable and Necessary, Surgery: Lumbar Facet Blockade and Transforaminal Epidural, Paravertebral Facet and Sacroiliac Joint Injections. (Accessed November 17, 2017)

**REFERENCES**


### POLICY HISTORY/REVISION INFORMATION

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| 02/01/2018 | - Updated coverage rationale; replaced language indicating:  
  o "[The listed services] are proven and medically necessary" with "[the listed services] are proven and/or medically necessary"  
  o "[The listed services] are unproven and not medically necessary" with "[the listed services] are unproven and/or not medically necessary"  
- Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references  
- Archived previous policy version 2018T0004CC |