Epidural Steroid Injections for Spinal Pain (for Nebraska Only)

Policy Number: CS039NE.Q
Effective Date: February 1, 2022

Instructions for Use

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Related Policies

- Ablative Treatment for Spinal Pain (for Nebraska Only)
- Occipital Neuralgia and Headache Treatment (for Nebraska Only)

Application

This Medical Policy only applies to the state of Nebraska.

Coverage Rationale

The following are proven and medically necessary:

- Epidural Steroid Injections (ESI) for treating radicular pain caused by spinal stenosis, disc herniation, degenerative changes in the vertebrae or for the short-term management of spine pain when the following criteria are met:
  - The pain is associated with symptoms of nerve root irritation and/or spine 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

The following are unproven and not medically necessary due to insufficient evidence of efficacy:

- The use of ultrasound guidance for ESIs
- ESI for all other indications of the spine not included above

Epidural Steroid Injection Limitations

- A maximum of three (3) ESI sessions (per region regardless of level, location, or side) in a calendar year when criteria (indications for coverage) are met for each injection
- A session is defined as one date of service in which ESI(s) is performed
- A region is defined by either the region of the cervical or thoracic spine or the region of the lumbar or sacral spine
- A calendar year is defined as the 12-month period from January 1st to December 31st

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. (Goertz et al. 2012)

Conservative Therapy: Consists of an appropriate combination of medication (for example, NSAIDs, analgesics, etc.) in addition to physical therapy, spinal manipulation therapy, cognitive behavioral therapy (CBT) or other interventions based on the individual's specific presentation, physical findings and imaging results. (AHRQ 2013; Qassem 2017; Summers 2013)

Epidural Steroid Injection (ESI): A nonsurgical treatment for managing Radiculopathy caused by disc herniation or degenerative changes in the vertebrae such as spondylosis. Medication is injected directly into the epidural space. The injection may also include a local anesthetic. The goal of ESI is to reduce inflammation, relieve pain, improve function, and reduce the need for surgical intervention. (Hayes, 2018)

Non-Radicular Back Pain: Pain which does not radiate along a dermatome (sensory distribution of a single root). Appropriate imaging does not reveal signs of spinal nerve root compression and there is no evidence of spinal nerve root compression seen on clinical exam. (Lenahan, 2018)

Radicular Back Pain: Pain which radiates from the spine into the extremity along the course of the spinal nerve root. The pain should follow the pattern of a dermatome associated with the irritated nerve root identified. (Lenahan, 2018)

Radiculopathy: Radiculopathy is characterized by pain which radiates from the spine to extend outward to cause symptoms away from the source of the spinal nerve root irritation. (Lenahan, 2018)

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 federal, state, or contractual requirements 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 Guidelines may apply.

CPT Code	Description
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) (e.g., 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) (e.g., 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 (i.e., fluoroscopy or CT)
64479	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, single level

CPT Code	Description
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

Diagnosis Code	Description
All Regions	
M47.25	Other spondylosis with radiculopathy, thoracolumbar region
M51.15	Intervertebral disc disorders with radiculopathy, thoracolumbar region
M96.1	Postlaminectomy syndrome, not elsewhere classified
Cervical/Thoracic	
G54.2	Cervical root disorders, not elsewhere classified
G54.3	Thoracic root disorders, not elsewhere classified
M47.21	Other spondylosis with radiculopathy, occipito-atlanto-axial region
M47.22	Other spondylosis with radiculopathy, cervical region
M47.23	Other spondylosis with radiculopathy, cervicothoracic region
M47.24	Other spondylosis with radiculopathy, thoracic region
M50.10	Cervical disc disorder with radiculopathy, unspecified cervical region
M50.11	Cervical disc disorder with radiculopathy, high cervical region
M50.121	Cervical disc disorder at C4-C5 level with radiculopathy
M50.122	Cervical disc disorder at C5-C6 level with radiculopathy
M50.123	Cervical disc disorder at C6-C7 level with radiculopathy
M50.13	Cervical disc disorder with radiculopathy, cervicothoracic region
M51.14	Intervertebral disc disorders with radiculopathy, thoracic region
M54.11	Radiculopathy, occipito-atlanto-axial region
M54.12	Radiculopathy, cervical region
M54.13	Radiculopathy, cervicothoracic region
M54.14	Radiculopathy, thoracic region
M54.15	Radiculopathy, thoracolumbar region
S24.2XXA	Injury of nerve root of thoracic spine, initial encounter
Lumbar/Sacral	
G54.4	Lumbosacral root disorders, not elsewhere classified
M47.26	Other spondylosis with radiculopathy, lumbar region
M47.27	Other spondylosis with radiculopathy, lumbosacral region
M47.28	Other spondylosis with radiculopathy, sacral and sacrococcygeal region
M48.062	Spinal stenosis, lumbar region with neurogenic claudication
M51.16	Intervertebral disc disorders with radiculopathy, lumbar region
M51.17	Intervertebral disc disorders with radiculopathy, lumbosacral region
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region
M54.18	Radiculopathy, sacral and sacrococcygeal region

Diagnosis Code	Description
Lumbar/Sacral	
M54.30	Sciatica, unspecified side
M54.31	Sciatica, right side
M54.32	Sciatica, left side
M54.40	Lumbago with sciatica, unspecified side
M54.41	Lumbago with sciatica, right side
M54.42	Lumbago with sciatica, left side
S34.21XA	Injury of nerve root of lumbar spine, initial encounter
S34.22XA	Injury of nerve root of sacral spine, initial encounter

Description of Services

Spine pain, in particular, 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 in the treatment of back pain as an alternative to more invasive interventions. (Hayes, 2018)

Epidural steroid injection (ESI) is a nonsurgical treatment for managing 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; Archived 2018)

Clinical Evidence

Ultrasound Guidance

There is no evidence in the peer-reviewed literature demonstrating the overall health benefit of the use of ultrasonic guidance during spinal injections over the use of fluoroscopy or CT-guidance.

Ultrasound-guided spine injection therapy is a comparatively new technique in the management of axial and radicular pain from degenerative lumbar spinal conditions and may be a reasonable alternative to conventional methods of injection guidance. In 2020, Tay et al. completed a retrospective clinical audit of 42 patients who underwent ultrasound-guided lumbar spinal injection at a single institution for chronic axial and radicular pain in an acute public hospital sports medicine center between June 1, 2018 and June 1, 2019. 27 patients (64.3%) receiving facet joint injections and 18 patients (42.9%) receiving nerve root injections. The majority (90.5%) of patients experienced an improvement of >30% in pain intensity at 3 months post-injection, using the Numerical Rating Scale pain score ($p < 0.001$); with 40 patients (95.2%) reporting a reduction in Oswestry Disability Index score ($p < 0.001$). No complications were reported. It was concluded that the experience of this institution confirms the safety, feasibility, and effectiveness of ultrasound-guided lumbar spinal injection for the treatment of axial and radicular pain. The authors also note that ultrasound-guided spinal injection remains technically challenging and requires a steep learning phase, as well as careful patient selection, and that the study was not designed to directly compare outcomes for ultrasound-guided injection against the conventional standard of care. A larger dataset is required to confirm the efficacy of ultrasound-guided spine injection and the rate of adverse events, and a prospective study would be useful to determine clinical factors predicting success. This study is also limited by lack of comparison group and a small number of participants standard of care. A larger dataset is required to confirm the efficacy of ultrasound-guided spine injection and the rate of adverse events, and a prospective study would be useful to determine clinical factors predicting success. This study is also limited by lack of comparison group and a small number of participants

Epidural Steroid Injections

Overall, the volume of evidence for the use of therapeutic epidural injections in the treatment of acute and chronic back pain is large. Clinical studies have shown 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 however insufficient evidence to demonstrate that epidural steroid injections are effective in the treatment of back pain in the absence of radicular symptoms.

Helm et al. (2021) conducted a systematic review and meta-analysis of the efficacy and safety of transforaminal epidural steroid injections for 4 indications: radicular pain from spinal stenosis and failed back surgery syndrome; and for axial low back pain. The available literature on transforaminal injections was reviewed and the level of evidence was classified on a 5-point scale based on the quality of evidence developed by the US Preventive Services Task Force (USPSTF) and modified by the American Society of Interventional Pain Physicians (ASIPP). Data sources included relevant literature from 1966 to April 2020, and manual searches of the bibliographies of known primary and review articles. Pain relief and functional improvement were the primary outcome measures. A minimum of 6 months pain relief follow-up was required. Eighteen randomized controlled trials met the inclusion criteria. Eleven randomized controlled trials dealt with various aspects of transforaminal injections for radicular pain due to disc herniation and show Level 1 evidence supporting the use of transforaminal injections for this condition. A meta-analysis showed that at both 3 and 6 months, there was highly statistically significant improvement in both pain and function with both particulate and nonparticulate steroids. For radicular pain from central stenosis there is one moderate quality study, with Level IV evidence. For radicular pain caused by failed back surgery syndrome there is one moderate quality study, with Level IV evidence. For radicular pain from foraminal stenosis and for axial pain there is Level V evidence, opinion-based/consensus, supporting the use of transforaminal injections. The authors concluded that Level I evidence indicates transforaminal injections are generally safe but have been associated with major neurological complications related to spinal cord infarction. Due to concern over the role of particulate steroids, multiple other injectates have been evaluated, including nonparticulate steroids, tumor necrosis factor alpha (TNF-a) inhibitors, and local anesthetics without steroids, and none have been proven superior. This review is limited by the paucity of literature for some indications.

In a 2020 meta- analysis of randomized controlled trials, Yang et al. compared the clinical effectiveness of epidural steroid injections (ESI) versus conservative treatments for patients with lumbosacral radicular pain. A search was conducted on relevant studies published between 2000 and January 10, 2019 and randomized controlled trials directly comparing the efficacy of ESI with conservative treatment were selected. Primary Outcomes included pain relief, functional improvement using the Oswetry disability index, or successful events. 6 randomized controlled trials (249 patients with ESI and 241 patients with conservative treatment) were identified and included in this meta-analysis. The results showed that ESI was beneficial for pain relief at short-term (1-3 months) and intermediate-term (3-6 months) when compared with conservative treatment, but this effect was not maintained at long-term (6 months to one year) follow-up. In terms of functional improvement, the overall outcome of meta-analysis showed that ESI did not have any advantage over conservative treatment at short-term and intermediate-term follow-up. Successful event rates were significantly higher in patients who received ESI than in patients who received conservative treatment. There were no statistically significant differences in functional improvement after ESI and conservative treatment at short-term and intermediate-term follow-up. The authors concluded that the use of ESI is more effective for alleviating lumbosacral radicular pain than conservative treatments in terms of short-term and intermediate term. Patients also reported more successful outcomes after receiving ESI when compared to conservative treatment. However, this effect was not maintained at long-term follow-up. The limitations of this meta-analysis resulted from the variation in types of interventions and small sample size.

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. Placebo controlled RCTs, pragmatic studies, and observational studies were included in the analysis. Utilizing a threshold of ≥50% reduction in pain, treatment success rates across studies were 63% (Range: 58 to 68%) at 1-month, 74% (Range: 68-80%) at 3-months, 64% (59-69%) at 6-months, and 64% (57-71%) at 1year. The authors concluded that there is strong evidence that lumbar transforaminal injection of steroids is an effective treatment for radicular pain due to disc herniation.

In a systematic review, Manchikanti et al (2015) reported on the long-term efficacy of cervical intralaminar and transforaminal epidural injections, focusing on cervical disc herniation, spinal stenosis, and discogenic pain. Based on 7 randomized controlled trials of different types of injections, none of which included comparison to a placebo group or to non-invasive treatment, the authors concluded that the evidence demonstrated Level II evidence for efficacy of cervical interlaminar epidural injections, in spite of the scant available clinical literature specific to conditions other than disc herniation. The findings are

limited by lack of relevant comparison group that would allow to estimate the benefit of cervical epidural injection as compared to other treatment approaches.

A randomized, double-blind controlled trial was conducted by Manchikanti et al (2014). The objective of this trial was to assess the effect on pain relief and functional improvement using thoracic interlaminar epidural injections in patients with chronic mid back pain and/or upper back pain. Two groups of 55 patients each were randomized to receive injections with local anesthetic alone, or injections with local anesthetic plus steroids. After two years both groups of patients saw significant improvement (71% using anesthetic alone, and 80% using anesthetic plus steroids). The authors concluded that chronic thoracic pain (not originating in the facet joint) could be managed with both types of thoracic epidural injections. This study was limited by lack of a placebo group.

Rosas et al, (2010) performed a retrospective case series to evaluate fluoroscopically directed thoracic transforaminal epidural injections. One hundred and ninety-eight foraminal nerve blocks and foraminal epidural injections to the thoracic spine were performed between 1997 and 2007. This new technique was reviewed to evaluate improved safety, as this approach should decrease the change of inadvertently injuring surrounding structures. There were no major complications when this new technique was properly performed. The authors concluded that this new technique of performing thoracic transforaminal epidural injections under fluoroscopy allows the ability to gauge needle depth, thereby decreasing potential injury to surrounding structures, including the pleura, dura mater, and vasculature. The findings are limited by lack of outcome data other than safety data and lack of comparison group.

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.

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.

A retrospective case series by Botwin et al. (2006) assessed thoracic interlaminar epidural steroid injections, done under fluoroscopy, for the incidence of adverse effects or complications. The study included 21 patients who received the injections over a five year period who were experiencing thoracic radicular pain from herniated nucleus pulposus or thoracic spondylosis. The authors concluded that there were no major complications, and there was no difference in the complication rate between the two diagnoses. The findings are limited by lack of outcome data other than safety data and lack of comparison 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. (Everett, 2004)

Clinical Practice Guidelines/Technology Assessments

Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program

The 2015 AHRQ comparative effectiveness study on injection therapies for low back pain (LBP) concluded that ESIs for radiculopathy were associated with immediate improvements in pain and might be associated with immediate improvements in function, but benefits were small and not sustained, and there was no effect on long-term risk of surgery. Evidence did not suggest that effectiveness varies based on injection technique, corticosteroid, dose, or comparator. Limited evidence

suggested that epidural corticosteroid injections are not effective for spinal stenosis or nonradicular back pain. (Chou et al. 2015)

American Society of Anesthesiologists (ASA)

As of 2010, the ASA had 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 ASIPP published updated evidence-based guidelines regarding interventional techniques in the management of chronic spinal pain in 2013 (Manchikanti et al.). The ASIPP maintains a comprehensive guideline for epidural steroid injections including indications, limitations and therapy frequencies. Specifically, these guidelines make the following conclusion or recommendations, among others:

- Disc herniation: Based on relevant, high-quality 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.
- Spinal stenosis: The evidence 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.
- 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.
- Post-surgery syndrome: The evidence for lumbar and cervical post-surgery syndrome based on one relevant, high-quality RCT with fluoroscopic guidance for caudal and cervical interlaminar epidural injections, with or without steroids, is Level II with moderate to strong recommendation for long-term improvement.

The authors also observe that in “the therapeutic phase (after the diagnostic phase is completed), the suggested frequency of interventional techniques should be 2½ to 3 months or longer between each injection, provided that > 50% relief is obtained for 2½ to 3 months, not exceeding 4 per year, per region.”

American Association of Neurological Surgeons and Congress of Neurological Surgeons

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. (Resnick, 2005)

North American Spine Society (NASS)

In 2020, NASS revised its coverage policy recommendations for epidural steroid injections and selective spinal nerve blocks. They stated that the rationale for coverage is based on high-level evidence and what most practitioners would consider to be accepted practice patterns. Multiple randomized-controlled trials (RCTs) have demonstrated that lumbar epidural steroid injections (LESIs) are effective in the treatment of lumbar radiculitis caused by disc herniation. There is sufficient literature to suggest that a trial of ESIs for radicular pain caused by conditions other than disc herniation is appropriate prior to considering surgical intervention.

In their 2020 Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis & Treatment of Low Back Pain, the NASS states there is there is insufficient evidence to make a recommendation for or against the use of caudal epidural steroid injections and interlaminar epidural steroid injections in patients with low back pain.

In 2013 NASS had published a Review and Recommendation Statement entitled Lumbar Transforaminal Epidural Steroid Injections. A grade A recommendation (defined as good evidence) was given for the effectiveness of ESI at treating radicular pain related to lumbar disc herniation for at least 1 month in more than 50% of individuals. The review graded the evidence as insufficient for a recommendation to treat lumbar radicular pain in the presence of stenosis. There was insufficient evidence to provide an evidence-based recommendation on the maximum number of lumbar ESIs that are appropriate in any given timeframe or the amount of pain/functional improvement needed to justify repeat injections.

In 2011, NASS had 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)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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: https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder.
(Accessed January 12, 2021)

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Policy History/Revision Information

Date	Summary of Changes
02/01/2022	**Template Update** • Replaced content sub-heading titled “Professional Societies” with “Clinical Practice Guidelines” in *Clinical Evidence* section **Applicable Codes** • Added ICD-10 diagnosis codes G54.2, G54.3, M47.21, M47.22, M47.23, M47.24, M47.25, M50.10, M50.11, M50.121, M50.122, M50.123, M50.13, M54.11, M54.12, M54.13, and M54.18 • Removed ICD-10 diagnosis codes E08.41, E09.41, E10.41, E11.41, E13.41, G54.1, G57.00, G57.01, G57.02, G57.03, G57.70, G57.71, G57.72, G57.73, G57.80, G57.81, G57.82, G57.83, G57.90, G57.91, G57.92, G57.93, G58.8, G58.9, G59, G90.50, G90.521, G90.522, G90.523, G90.529, G90.59, M43.00, M43.01, M43.02, M43.03, M43.04, M43.05, M43.06, M43.07, M43.08, M43.09, M43.10, M43.11, M43.12, M43.13, M43.14, M43.15, M43.16, M43.17, M43.18, M43.19, M43.27, M43.28, M47.16, M47.816, M47.817, M47.818, M47.896, M47.897, M47.898, M48.00, M48.061, M48.07, M48.08, M51.06, M51.26, M51.27, M51.34, M51.35, M51.36, M51.37, M51.46, M51.47, M51.9, M53.2X7, M53.2X8, M53.3, M53.86, M53.87, M53.88, M99.23, M99.24, M99.25, M99.26, M99.27, M99.28, M99.29, M99.33, M99.34, M99.35, M99.36, M99.37, M99.38, M99.39, M99.43, M99.44, M99.45, M99.46, M99.47, M99.48, M99.49, M99.53, M99.54, M99.55, M99.56, M99.57, M99.58, M99.59, M99.63, M99.64, M99.65, M99.66, M99.67, M99.68, M99.69, M99.73, M99.74, M99.75, M99.76, M99.77, M99.78, M99.79, S32.000A, S32.001A, S32.002A, S32.008A, S32.009A, S32.010A, S32.011A, S32.012A, S32.018A, S32.019A, S32.020A, S32.021A, S32.022A, S32.028A, S32.029A, S32.030A, S32.031A, S32.032A, S32.038A, S32.039A, S32.040A, S32.041A, S32.042A, S32.048A, S32.049A, S32.050A, S32.051A, S32.052A, S32.058A, S32.059A, S34.4XXA, S74.00XA, S74.01XA, and S74.02XA **Supporting Information** • Archived previous policy version CS039NE.P

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