

CASEREVIEW

8017 Sitka Street
Fort Worth, TX 76137
Phone: 817-226-6328
Fax: 817-612-6558

Notice of Independent Review Decision

October 13, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Cervical epidural steroid injection under fluoroscopy with IV sedation at C5-6

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

This physician has over eight years of experience in Pain Management and as a Board Certified Anesthesiologist.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female who was injured on xx/xx/xx while xxxxx. She noted a sudden pull in her armpit down to her elbow and hand. She was initially treated with conservative physical therapy and rehabilitative efforts.

On April 10, 2014, MRI C-Spine, Impression: Multilevel midcervical degenerative hypertrophic changes above with resultant mild to moderate central stenosis and multilevel foraminal stenosis, most pronounced at the C5-6 level.

On February 4, 2015, Cervical Spine Series, Impression: 1. Grade 1 retrolisthesis at C5-6. 2. Moderate degenerative spondylosis and disc space narrowing at C5-6.

On February 17, 2015, the claimant presented for neck and shoulder pain. She was not doing any therapy yet. She indicated the medicine regimen was helping. On physical exam there was several trigger points along the medial border of the scapula ranging from T3-T7 as well some in the upper trapezius at the level of T1. This caused a positive jump sign with pain radiating to the shoulder and some of the lower ones caused pain radiating to the shoulder and into the triceps. Impression: 1. Thoracic myofascial pain in the area the patient reports her shoulder pain. 2. Possible cervical radiculopathy. Plan: Trigger point injections to try to decrease her pain and increase her tolerance of therapy. She may also benefit from cervical epidural steroid injections. Continue on Mobic for inflammation, Zanaflex in the afternoon for muscle spasm, Elavil 25 mg at bedtime and gabapentin 100 mg to take once at night for 5 days and then twice a day as tolerated with a burning pain sensation. Her Hydrocodone 7.5 mg was refilled.

On March 27, 2015, the claimant presented with a chief complaint of chronic persistent left neck, shoulder, arm and hand pain associated with numbness, tingling, sensitivity to touch and swelling about her left arm and hand. She described her pain as sharp, throbbing, burning, also with numbness in the first and second digits of her hand. On physical examination she was in moderate distress with trigger points throughout the cervical, interscapular, rhomboid regions. Her left arm and hand were cold as compared to the unaffected limb. She had mild hyperesthesia. She had notable decreased grip strength, decreased pinprick sensation at C5-6 distribution. She had decreased range of motion about the left shoulder with a mild positive apprehension test internal and external rotation however was preserved with pain on resistance. She had pain with light touch throughout the left upper extremity. Diagnoses: 1. Chronic neck, left shoulder, arm and hand pain consistent with cervical radiculopathy following work related injury. 2. Secondary complex regional pain syndrome of the left arm and hand. 3. Moderate-to-severe reactive depression and anxiety. 4. Cannot rule out rotator cuff tear or supraspinatus inflammation of the left shoulder. Plan: institute Effexor 75 mg XR to be increased to 150 mg q.a.m., amitriptyline at night will improve her sleep, pain tolerance and mood control. Institute gabapentin, a neuropathic pain medicine Neurontin 400 mg t.i.d. to be taking with her Hydrocodone.

On April 13, 2015, the claimant presented with her MRI results. She reported pain radiating to the left arm and hand and stated she often dropped things and had coordination deficits. She did report the use of prescribed medication had stabilized her symptoms. C5-6 ESIs were discussed.

On May 26, 2015, Operative Report Postoperative Diagnosis: 1. Left neck pain with left cervical radiculopathy. 2. Cervical herniated disk at C5-6 with C5 radiculopathy. Procedures Performed: 1. Introduction of cervical epidural catheter under fluoroscopy. 2. Injection of contrast for performance of epidurogram. 3. Injection of corticosteroid and local anesthetic solution.

June 8, 2015, the claimant presented with complete resolution of her neck, shoulder and arm pain complaints. Her pain was then at least 70% to 80% improved, some 2 weeks after injection therapy. She felt it had come back somewhat particularly the numbness and tingling in her left arm. However, the swelling, sensitivity, and burning pain had gotten much better. Her amitriptyline was raised to 75 mg and would consider her on gabapentin with Norco now down to just one or two tablets per day.

On June 25, 2015, MRI of the Cervical Spine, Impression: 1. 5 mm left paracentral and foraminal disc protrusion at C6-7, which impinges upon the thecal sac, the anterior surface of the cervical spinal cord and the proximal left C7 nerve root. The protrusion causes mild central spinal canal and severe left foraminal and lateral recess stenosis. 2. 3 mm disc bulge at C5-6, which moderately effaces the thecal sac and moderately narrows the foramina and lateral recesses. The disc bulge also results in mild central spinal canal stenosis as well. 3. 2 mm posterior central disc protrusions at C3-4 and C4-5. 4. Mild degenerative spondylosis at C5-6.

On July 8, 2015, the claimant presented with moderate left shoulder, arm and hand pain with numbness and weakness into the fifth digit of her left hand. She still reports more than 70% pain relief and improved function following the last injection. She is waiting for approval of a second ESI. It was explained that after injection therapy and rehabilitative efforts with that cervical discectomy should be explore. In the meantime, her medication had to be increased. On examination she continued to have decreased neck ROM and moderate mid cervical interspinous tenderness.

On July 10, 2015, UR. Rationale for Denial: Not recommended based on recent evidence, given the serious risks of this procedure in the cervical region, and the lack of quality evidence for sustained benefit. However, in this case, the claimant has had a prior injection at the same level on 5/26/15, 6 weeks ago. But the most recent/updated clinical note dated 6/8/15 documented that at that time, the claimant was 2 weeks post-injection with 70% to 80% improvement. Per the guideline, if an ESI will be administered based on documented exceptions, the repeat blocks should only be offered if there is at least 50% pain relief for six to eight weeks. Medical necessity has not been established based on the clinical notes submitted for review and the guidelines cited above.

On August 6, 2015, the claimant presented who reported she responded with near 100% relief over 1 week and now more than 6 weeks later she still had at least 70% improvement. Additionally, the swelling, sensitivity and burning pain in her left arm and hand consistent with secondary CRPS resolved following the first ESI. On exam she had decreased neck ROM. Decreased grip strength on the left with mild decreased pinprick in the C6-7 distribution consistent with cervical disk injury at C5-6, C6-7.

On August 27, 2015, UR. Rationale for Denial: The history and documentation do not objectively support the request for a repeat cervical epidural steroid injection (ESI) at this time. The ODG do not support ESIs in the cervical region due to potentially serious complications that may occur. In addition, there is no clear evidence of radiculopathy at level C5-6 on physical examination (PE) and no electromyography (EMG) has been submitted. The medical necessity of this request has not been clearly demonstrated.

On September 4, 2015, the claimant presented for further care regarding her shoulder, neck and upper back pain, complaints associated with reactive depression, and cervical disk protrusion. xxx was going to titrate neuropathic pain medicine Topamax 50 mg t.i.d. as she was gaining weight on gabapentin and trazodone to help her with her sleep. She was clearly suffering from the reactive depression and anxiety. To help get that under control before interventional pain care, Prozac 20 daily was begun and helping somewhat.

On September 11, 2015, UR. Rationale for Denial: The ODG Treatment Index does not recommend the use of cervical epidural steroid injections because of its high number of catastrophic neurological complications and because of the lack of published efficacy of cervical epidural steroid injections.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The previous adverse determinations are upheld. Per ODG, does not recommend the use of cervical epidural steroid injections because of its high number of catastrophic neurological complications and because of the lack of published efficacy of cervical epidural steroid injections. Therefore, this request for Cervical epidural steroid injection under fluoroscopy with IV sedation at C5-6 is non certified.

PER ODG:

Epidural steroid injection (ESI)

Not recommended based on recent evidence, given the serious risks of this procedure in the cervical region, and the lack of quality evidence for sustained benefit. These had been recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy), with specific criteria for use below. In a previous Cochrane review, there was only one study that reported improvement in pain and function at four weeks and also one year in individuals with radiating chronic neck pain. ([Peloso-Cochrane, 2006](#)) ([Peloso, 2005](#)) Other reviews have reported moderate short-term and long-term evidence of success in managing cervical radiculopathy with interlaminar ESIs. ([Stav, 1993](#)) ([Castagnera, 1994](#)) Some have also reported moderate evidence of management of cervical nerve root pain using a transforaminal approach. ([Bush, 1996](#)) ([Cyteval, 2004](#)) A previous retrospective review of interlaminar cervical ESIs found that approximately two-thirds of patients with symptomatic cervical radiculopathy from disc herniation were able to avoid surgery for up to 1 year with treatment. Success rate was improved with earlier injection (< 100 days from diagnosis). ([Lin, 2006](#)) There have been case reports of cerebellar infarct and brainstem herniation as well as spinal cord infarction after cervical transforaminal injection. ([Beckman, 2006](#)) ([Ludwig, 2005](#)) Quadriplegia with a cervical ESI at C6-7 has also been noted ([Bose, 2005](#)) and the American Society of Anesthesiologists Closed Claims Project database revealed 9 deaths or cases of brain injury after cervical ESI (1970-1999). ([Fitzgibbon, 2004](#)) These reports were in contrast to a retrospective review of 1,036 injections that showed that there were no catastrophic complications with the procedure. ([Ma, 2005](#)) The American Academy of

Neurology concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. (Armon, 2007) In other studies, there was evidence for short-term symptomatic improvement of radicular symptoms with epidural or selective root injections with corticosteroids, but these treatments did not appear to decrease the rate of open surgery. (Haldeman, 2008) (Benyamin, 2009) Some have said epidural steroid injections should be reserved for those who may otherwise undergo open surgery for nerve root compromise. (Bigos, 1999) There is limited evidence of effectiveness of epidural injection of methyl prednisolone and lidocaine for chronic MND with radicular findings. (Peloso-Cochrane, 2006) The FDA is warning 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. (FDA, 2014)

Recent evidence: ESIs should not be recommended in the cervical region, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee concluded. Injecting a particulate steroid in the cervical region, especially using the transforaminal approach, increases the risk for sometimes serious and irreversible neurological adverse events, including stroke, paraplegia, spinal cord infarction, and even death. The FDA has never approved an injectable corticosteroid product administered via epidural injection, so this use, although common, is considered off-label. Injections into the cervical region, as opposed to the lumbar area, are relatively risky, and the risk for accidental injury in the arterial system is greater in this location. (FDA, 2015) An AMA review suggested that ESIs are not recommended higher than the C6-7 level; no cervical interlaminar ESI should be undertaken at any segmental level without preprocedural review; & particulate steroids should not be used in therapeutic cervical transforaminal injections. (Benzon, 2015) According to the American Academy of Neurology (AAN), ESIs do not improve function, lessen need for surgery, or provide long-term pain relief, and the routine use of ESIs is not recommended. They further said that there is in particular a paucity of evidence for the use of ESIs to treat radicular cervical pain. (AAN, 2015) In this comparative-effectiveness study, no significant differences were found between ESI and conservative treatments. (Cohen, 2014) See the [Low Back Chapter](#), where ESIs are recommended as a possible option for short-term treatment of radicular pain in conjunction with active rehab efforts, but they are not recommended for spinal stenosis or for nonspecific low back pain.

While not recommended, cervical ESIs may be supported using [Appendix D](#), Documenting Exceptions to the Guidelines, in which case:

Criteria for the use of Epidural steroid injections, therapeutic:

Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.

- (1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing.
- (2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).
- (3) Injections should be performed using fluoroscopy (live x-ray) for guidance
- (4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections.
- (5) No more than two nerve root levels should be injected using transforaminal blocks.
- (6) No more than one interlaminar level should be injected at one session.
- (7) In the therapeutic phase, repeat blocks should only be offered if there is at least 50% pain relief for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year.
- (8) Repeat injections should be based on continued objective documented pain and function

response.

(9) Current research does not support a “series-of-three” injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections.

(10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or stellate ganglion blocks or sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.

(11) Cervical and lumbar epidural steroid injection should not be performed on the same day;

(12) Additional criteria based on evidence of risk:

(a) ESIs are not recommended higher than the C6-7 level;

(b) Cervical interlaminar ESI is not recommended; &

(c) Particulate steroids should not be used. ([Benzon, 2015](#))

Criteria for the use of Epidural steroid injections, diagnostic:

To determine the level of radicular pain, in cases where diagnostic imaging is ambiguous, including the examples below:

(1) To help to evaluate a pain generator when physical signs and symptoms differ from that found on imaging studies;

(2) To help to determine pain generators when there is evidence of multi-level nerve root compression;

(3) To help to determine pain generators when clinical findings are suggestive of radiculopathy (e.g. dermatomal distribution), and imaging studies have suggestive cause for symptoms but are inconclusive;

(4) To help to identify the origin of pain in patients who have had previous spinal surgery.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)