

October 5, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Medical Necessity: Interlaminar Epidural Steroid Injection Cervical C6-7 62310, 77009

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

The physician performing this review is Board Certified, American Board of Physical Medicine & Rehabilitation. The physician is certified in pain management. The physician has a private practice of Physical Medicine & Rehabilitation. The physician is a member of the Texas Medical Association and the Houston Physical Medicine and Rehabilitation Society. The physician is licensed and has been in practice for over 25 years.

REVIEW OUTCOME:

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

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

Upon independent review, the physician finds that the previous adverse determination should be ~ Upheld

PATIENT CLINICAL HISTORY [SUMMARY]:

This man reportedly injured his left upper extremity on. He has burning dyesthesias in the left upper extremity. The neurological examination showed no neurological loss in the left upper extremity. He had right deltoid weakness. He was identified as having a left rotator cuff tear, although details of this were not presented. An EMG done on 7/1/15 was interpreted as showing an acute radiculopathy based upon increased insertional activity in the left cervical paraspinal muscles at C6.

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(Conduction studies also showed bilateral CTS, and ulnar nerve involvement at the left elbow). The cervical MRI done on 5/18/15 showed widespread degenerative changes in the cervical spine.

This consisted of hypertrophic spondylosis and disc space narrowing from C3-7 with central stenosis from posterior osteophyte spurs at these levels. Uncinate hypertrophy was also found. There was right foraminal narrowing from the disc space narrowing at C3/4 and on the left at C4/5 and bilaterally at C5/6. There was no specific nerve root compromise described.

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

First, the ODG considers the indications for cervical ESI questionable to begin with due to dangers. It can be done, but requires a dermatomal pattern that was not identified. Second, there was no clear cut nerve root compromise on the MRI, but rather degenerative changes. The physical examination of the left upper extremity did not demonstrate any neurological loss. The EMG is being used as documentation of the presence of the radiculopathy. The report, however, is based upon increased insertional activities in the left paraspinal muscles. The ODG does not accept the presence of insertional activity as proof of a radiculopathy. It requires more spontaneous activity and in two muscles. So there has been no documentation that a radiculopathy was present to justify the cervical interlaminar ESI.

The procedure is uncertified.

ESI

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
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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

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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

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	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
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Electromyography (EMG)

Recommended (needle, not surface) as an option in selected cases. The American Association of Electrodiagnostic Medicine conducted a review on electrodiagnosis in relation to cervical radiculopathy and concluded that the test was moderately sensitive (50%-71%) and highly specific (65%-85%). ([AAEM, 1999](#)) EMG findings may not be predictive of surgical outcome in cervical surgery, and patients may still benefit from surgery even in the absence of EMG findings of nerve root impingement. This is in stark contrast to the lumbar spine where EMG findings have been shown to be highly correlative with symptoms.

Positive diagnosis of radiculopathy: Requires the identification of neurogenic abnormalities in two or more muscles that share the same nerve root innervation but differ in their peripheral nerve supply.

Timing: Timing is important as nerve root compression will reflect as positive if active changes are occurring. Changes of denervation develop within the first to third week after compression (fibrillations and positive sharp waves develop first in the paraspinals at 7-10 days and in the limb muscles at 2-3 weeks), and reinnervation is found at about 3-6 months

Acute findings: Identification of fibrillation potentials in denervated muscles with normal motor unit action potentials (usually within 6 months of symptoms: may disappear within 6 weeks in the paraspinals and persist for up to 1-2 years in distal limbs).

Chronic findings: Findings of motor unit action potentials with increased duration and phases that represent reinnervation. With time these become broad, large and polyphasic and may persist for years.

Anatomy: The test primarily evaluates ventral (anterior) root function (motor) and may be negative if there is dorsal root compression (sensory) only. Only C4-8 and T1 in the neck region have limb representation that can be tested electrodiagnostically. The anatomic basis for this lies in the fact that the cervical nerve roots have a motor and a sensory component. It is possible to impinge the sensory component with a herniated disc or bone spur and not affect the motor component. As a result, the patient may report radicular pain that correlates to the MRI without having EMG evidence of motor loss.

Paraspinal fibrillation potentials: May be seen in normal individuals and are nonspecific for etiology. The presence of these alone is insufficient to make a diagnosis of radiculopathy and they may be absent when there is a diagnosis of radiculopathy secondary to sampling error, timing, or because they were spared. They may support a diagnosis of radiculopathy when corresponding abnormalities are present in the limb muscles.

Indications when particularly helpful: EMG may be helpful for patients with double crush phenomenon, in particular, when there is evidence of possible metabolic pathology such as neuropathy secondary to diabetes or thyroid disease, or evidence of peripheral compression such as carpal tunnel syndrome.

H-reflex: Technically difficult to perform in the upper extremity but can be derived from the median nerve. The test is not specific for etiology and may be difficult to obtain in obese patients or those older than 60 years of age. ([Negrin, 1991](#)) ([Alrawi, 2006](#)) ([Ashkan, 2002](#)) ([Nardin, 1999](#)) ([Tsao, 2007](#)) See [Discectomy-laminectomy-laminoplasty](#). (Surface EMG and F-wave tests are not very specific and therefore are not recommended. For more information on surface EMG, see the [Low Back Chapter](#).)

While cervical electrodiagnostic studies are not necessary to demonstrate a cervical radiculopathy, they have been suggested to confirm a brachial plexus abnormality or some problem other than a cervical radiculopathy, but these studies can result in unnecessary over treatment. ([Plastaras, 2011](#)) ([Lo, 2011](#)) ([Fuglsang-Frederiksen, 2011](#))

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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)