

# Health Decisions, Inc.

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## Notice of Independent Review Decision

September 9, 2015

### IRO CASE #:

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:** Cervical Epidural Steroid Injections at C2-3

**A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:** American Board Certified Orthopedic Surgeon 13 years' experience.

### 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]:

This patient is a female who reported an injury on xx/xx/xx. She reported to have slipped and fell where water was on the floor at work. She was diagnosed with cervical herniated nucleus pulposus, myofascial pain, radicular syndrome, and spondylosis. The request is for Cervical ESI at C2-3.

11/12/14: Injury note: Pt reports that she fell at work xx/xx/xx injuring her neck and her left shoulder. History: HTN, High Cholesterol, CABG, 2 neck fusions, takes blood thinners and sleeping medication. Pt was referred to an orthopedic surgeon.

12/12/14: New office Visit note: Pt presents with neck and arm pain going on for 1-3 months that was caused by a fall. Theresa is here for further evaluation of her neck and right shoulder; she also reports some low back pain and leg pain that started after the fall as well. Her cervical spine and her shoulder are the compensable injuries however. She was previously seen 3 weeks after her fall at work. She states that the event occurred on 9/22/14 when slipping on a wet floor and landing on her side. She had not had any treatment for this other than medications. She has had 2 ACDF procedures. One was in 2011 and the second in 2012. Prior to her fall in September of this year, she had complete resolution of her neck and upper extremity symptoms. She was doing quite well. She now rates her neck pain as an 8/10. Her pain radiates into the right trapezius and shoulder region. She denies any new neurologic bowel or bladder changes. There are no alleviating factors. Physical exam: Pt is sitting comfortably and does not have difficulty acquiring an upright position, her gait is balanced, and her pelvis is level with the floor. Cervical spine alignment is neutral. Levator scapulae, trapezius, scalenus muscles are tender bilateral. Occipital area is non-tender. Spinous processes are non-tender. No adenopathy or masses in the neck areas, carotids are palpable bilaterally and the thyroid is normal and in consistency. Cervical range of motion is painful and restricted to the following: flexion is painful at 25% of normal, extension is painful at 25% of normal, rotation on the right is painful at 25% of normal, and

rotation on the left is painful at 25% of normal. Hoffman's sign is absent; Babinski's Test is negative bilaterally. Spurlings is negative on the right and negative on the left. Tinel's wrist is negative on the right and negative of the left. Waddell's test shows non-specific tenderness, stimulation / axil loading, distraction: Seated SLR, Regional disturbance and overreaction absent. The Thoracic spine is tender bilateral. Spinous processes are non-tender. Scapula area is non-tender. Scapular winging is negative on the right and negative on the left. Paravertebral muscles are tender bilateral. Lumbar range of motion is painful and restricted to the following: flexion is painful at 75% of normal, extension is painful at 25% of normal, rotation on the right is non-painful, and rotation on the left is non-painful. Spinous processes are non-tender. Straight leg raises are normal bilateral with no issues. Femoral stretch is negative on the right and left. I recommend a CT myelogram for further evaluation. Pt was diagnosed with Myofascial pain, Cervical Radicular syndrome, Cervical Spondylosis without Myelopathy, and Hypertension.

12/30/14: Report of CT Cervical Myelogram with Contrast: Impression: 1. Status post discectomy and anterior interbody fusion at C3-C4, C4-C5 and C5-C6. There are small degenerative hypertrophic spurs along the posterior surface at C5-C6, which moderately narrow the right foramen and lateral recess. 2. 3mm Left Paracentral disc protrusion at C2-C3, which moderately effaces the thecal sac and contacts the anterior surface of the cervical spinal cord. 3. 3mm Left paracentral disc protrusion at C6-C7, which mildly impinges upon the thecal sac and moderately narrows the left foramen and lateral recess.

01/15/15: Follow up visit: Pt here for follow up of her CT myelogram. Pains in her neck, shoulders, and headaches have not improved over the last 3-4 months. She is unable to work. There is significant pain with ROM cervical spine especially extension and tenderness to palpation over the paraspinal cervical musculature and the trapezius bilaterally. I agree with the radiologist findings. I believe that the new disc protrusion at C2-C3 is likely a result of her on the job injury on 9/22/14. This contributes to significant neck pain and myofascial spasms. She also has significant facet syndrome due to her fall. I recommend epidural steroid injection and facet blocks as well as trigger point blocks in the cervical region. We'll recommend ESI and facet blocks as well trigger point blocks in the cervical region. We'll refill her anti-inflammatory pain cream. I will give her a prescription for Soma and hydrocodone and Celebrex to be used for symptomatic treatment.

02/17/15: Treatment plan evaluation: The treatment plan supports cervical ESI and also trigger point injections. will coordinate referral to a provider in. The team is also recommending post injection PT. Follow up date at DSRC has been set for 3/17/15.

02/17/15: TPE Evaluation: Pt has decreased sensation across the shoulders. She has no evidence of scapular winging. She does have positive trigger points in the bilat trapezius, supraspinatus, and parascapular muscles. Assessment: Cervical radiculopathy, cervical disk injury. Plan: Would recommend cervical ESI, and post injection physical therapy.

02/17/15: Psychological Interview: Initial clinical impression was good. seemed open to discussing any issues that were pursued. She was oriented x 4 with no indication of delusion or confusion. She was able to discuss issues in an abstract and concrete manner. She did not reflect any dramatic anxiety or depression during evaluation. At this time pursuit of the injections and physical therapy will began. will be reevaluated at the completion of those treatments and at the time further plans can be developed.

02/17/15: Physical Performance Evaluation: At this time this pt has not participated in lower level of care in terms of physical therapy. The patient states that an ESI of the cervical spine had been recommended yet not performed. At this time the DSRC team recommends that she participate in injections as recommended by her physician as well as begin outpatient physical therapy when appropriate. If this patient attends physical therapy here the goal would be to get her to material handle 7 lbs. From floor to waist x 5 reps. We would like to see a 20% increase in range of motion as well. She will be independent with a home program.

03/04/15: Office Visit with: Discussed findings and recommendations with patient. Pt presents with 6 month history of neck, upper shoulders, thoracic, and mid back pain. Pt states she has old hx of cervical fusion that is non-industrial. Pt is approved to be treated for c-spine at this time. Pt states 9/2014 she slipped on concrete at work causing injury. Pt has had x-rays and cervical myelogram showing 3mm disc displacement at C2-C3 and C6-C7 with

otherwise stable fusion. Pt presents for F/U- states she saw a neurosurgeon who is specifically requesting CESI at this time. Pt advised to quit smoking and not to drink etoh with pain medication. Recommend formal PT. Continue Celebrex 200mg QD. F/U week of 5/4/15.

03/04/15: Follow up note: Pt comes today only for a referral for pain management physician for evaluation of cervical ESI and trigger point injections. Pt saw on 2/17/15, however due to being out of network she had to be seen by me for that referral. This patient is well developed, well-nourished white female alert and oriented x 4 in no apparent distress and gait is normal. Referral was made for cervical ESI and trigger point injections.

03/13/15: Radiology Report X-ray Lumbosacral ap/lat 2-3 views: The L1 vertebral segment shows approximately 10% Volume loss with chronic appearing anterior wedging. No other definite findings to suggest thoracic or lumbar vertebral compression fracture are noted; however, for further evaluation MRI may be helpful. Degenerative changes are noted within the Lumbar spine from T12-L1 to L2-3 and at L5-S1. Degenerative changes are noted in the thoracic spine from T6-7 to T12-L1.

04/03/15: Office Visit note: Pt was last seen on March 4, 2015 TPI into the cervical paraspinals, upper trapezius last visit. Pt states TPI into the cervical paraspinals did not help at all. Pt is doing PT, Celebrex no helping, wants to proceed with CESI/ nerve block recommended.

04/16/15: Office Visit note: Pt is here for follow up. She continues to Have severe left sided headaches. She denies neurologic or bowel/bladder changes. Her pain management doctor Requested an epidural which has not been approved yet. Current medications: Soma 350mg 1 tab QD, Celebrex 200mg 1 cap QD, Norco 10-325 1-2 Tabs Q6-8hrs PRN, Tizanidine HCL 2mg 1 TID PRN, Tylenol with codeine #3 1-2 tab Q6hrs PRN. Plan: Pt has a new disc protrusion at C2-C3 and she is having left sided C3 radicular type pain. This corresponds to her CT myelogram. I would request for a C2-C3 epidural steroid injection. Her only other option is a C2-C3 fusion. I feel that the new disc protrusion at C2-C3 is a result of her on-the-job injury on 9/22/14 which contributes to her neck pain and radiating C3 left sided pain.

04/22/15: Office Visit note : Pt expresses frustration and feels she is not getting treatment. Pt states she tried to continue to work but was officially terminated 11/14 from Ogle Beauty School as the registrar. Pt presents today for the follow up with history of cervical pain. Pt complains of headache. Pain is localized in the neck, upper back. Pain is throbbing in nature. Pain is better lying down. Pt c/o numbness in the cervical region and left arm muscle weakness. Pt rates pain 9/10. Pt is independent of all ADL's . Cervical ROM spine: Flexion 30, extension 50, lateral bending 10R/5L, rotation 50R/35L ROM of B UE's; shoulder abduction 180 with pain on left during AROM, ER and IR 90. Full ROM of (B) LE's. Motor: age appropriate B UE's. Sensation: Intact to pinprick/light touch in B UE's and LE's w/patchy discrepancy at this time L>R dermatomes in C5, C6, C7. PE consistent with DX: Neck pain, Left arm pain and numbness, Cervical radiculopathy, Cervical disc displacement, Cervical DDD, Cervical spondylosis, Cervical stenosis, Left shoulder pain, Left shoulder tendonitis?, L1 compression wedging 10%, Muscle spasms / MFP

06/10/15: Office Visit note Pt presents today for follow up with history of cervical pain. Pt states when she takes medication it only takes the edge off. Pt states last dosage of Norco was this morning. Pt states the pain is interrupting sleep, she cannot move her neck and the pain shoots up to her head. Pt complains of numbness in the cervical region. Pt is independent with all ADL's and gait w/o AD. Discussed findings and recommendations with pt; Pt presents with 6 months history of pain of the neck and upper shoulder. Per work compensation- pt to have PT prior to Cervical ESI which was recommended per neurosurgery prior to PT. Per WC, will have patient complete therapy though Dallas Back institute. Per surgical advisement I have requested CESI at C7-T1 with catheter. Patient has combination of pathology with intermittent SX radiating into occipital region as well as down L>R arm. I will place catheter at C3 level for injection to address Sx. Pt does demonstrate depressed reflexes B/L UE.

06/15/15: Physical Therapy Note: Pt presents for therapy today. She is somewhat discouraged by her condition. She states little progress has been made. Pt is cooperative with therapy and performed ROM with physical therapist as requested. Pt did give good effort. This pt does appear to be a good candidate for physical therapy. Plan to continue authorized sessions.

07/02/15: Office Visit note: Pt is here for follow up her injection was denied she continues to have significant neck pain and radiating shoulder pain. She denies neurologic or bowel/bladder changes. There is significant pain with cervical ROM especially extension. Positive Spurling sign 4 periauricular pain. I recommend ESI. She has been going to physical therapy and doing this on her own with minimal results. I will try and have our worker's compensation department preauthorize the epidural at c2-3 injection. She will follow up in 3 months.

07/16/15: UR: Based on the clinical information submitted for this review and using the evidence-based, peer reviewed guidelines referenced above, this request is non-certified. The requested cervical epidural steroid injections at the C2-3 level are not recommended per the referenced guidelines as this level is higher than the C6-7.

08/20/15: UR: The ODG does not recommend cervical ESI's based on recent evidence, given the serious risks of this procedure in the cervical region, and the lack of quality evidence for sustained benefit. In addition, cervical ESI's are not recommended higher than the C6-C7 level. Given these issues, the medical necessity of this request is not established, and the previous denial is upheld.

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

The request for cervical epidural steroid injection (ESI) C2-3 is denied.

The Official Disability Guidelines (ODG) does not support cervical ESI above C6-7. Patients considered for cervical ESI should have evidence of radiculopathy, which correlates to imaging studies and/or electrodiagnostic testing.

This patient is currently dealing with pain in the neck and upper shoulders. She has radiation of pain into the occipital region as well as down both arms. The left arm is more affected. She has a history of anterior cervical fusions C3-C6. Her 2014 CT myelogram demonstrated adjacent segment disc disease at C2-3 and C6-7. Moderate left sided foraminal stenosis is noted at C6-7. It is unclear from the record whether her primary pain generator is the C2-3 or C6-7 level. An EMG-NC study is recommended to determine the pain generator in this patient before consideration of any invasive procedures in the cervical region.

The Cervical Epidural Steroid Injections at C2-3 is not medically necessary at this point in time.

#### **Per ODG:**

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](#)) Quadriparesis 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)**