

INDEPENDENT REVIEWERS OF TEXAS, INC.

2150 S. Central Expressway · Suite 200-264 · McKinney, Texas 75070

Office 214-533-2864 Fax 214-380-5015

e-mail: independentreviewers@hotmail.com

[Date notice sent to all parties]:

8/24/2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: Outpatient left C4-5 Transforaminal ESI w Fluoroscopy and Monitored Anesthesia

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

REVIEW OUTCOME:

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

XUpheld (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 patient is a male whose date of injury is XX/XX/XXXX. The patient tripped over a metal doorstop, lost his balance and fell against the wall hitting his left shoulder and then fell directly on the pavement landing on his right knee. MRI of the cervical spine dated 10/29/14 revealed at C4-5 there is moderate spondylosis and disc bulging narrowing the AP dimension of the thecal sac to 9-10 mm. No cord compression is identified. The neural foramina appear only slightly narrowed due to uncovertebral osteoarthritis. Note dated 11/11/14 indicates that the patient has completed extensive physical therapy. The patient underwent cervical epidural steroid injection at C6 on 03/26/15 and reported 100% relief for 3 weeks. Note dated 05/05/15 documents 60-75% relief of symptoms. The patient underwent repeat epidural steroid injection on 05/29/15. Follow up note dated 07/16/15 indicates that pain level is 2-3/10. The patient reported 60-70% relief of symptoms for 4-6 weeks after the injection. Current medications are clonazepam,

glipizide and metformin. On physical examination there is hypalgesia in the left C4 and C5 dermatomes. There is no evidence of weakness. Deep tendon reflexes are 2+/5 with the exception of 0+/5 left biceps. Spurling's is positive on the left.

The initial request for outpatient left C4-5 transforaminal epidural steroid injection with fluoroscopy was non-certified on 07/27/15 noting that although the current request is for a different nerve root level than that previously injected, it appears the pain generator has already been identified at the left C6 level with previous 100% pain relief documented after 2 prior epidural steroid injections. The denial was upheld on appeal dated 08/04/15 noting that while criteria for the use of ESIs for diagnostic purposes are to help determine pain generators when there is evidence of multilevel nerve root compression and the patient's exam and MRI findings support multilevel radiculopathy, the request was for an epidural steroid injection at higher than a C6-7 level.

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

Based on the clinical information provided, the request for outpatient left C4-5 transforaminal epidural steroid injection with fluoroscopy is not recommended as medically necessary, and the two previous denials are upheld. The Official Disability Guidelines note that cervical epidural steroid injections are 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. It appears that the patient's pain generator has been identified given the positive response to two prior epidural steroid injections performed at the C6 level. Therefore, medical necessity is not established in accordance with current evidence based guidelines.

IRO REVIEWER REPORT TEMPLATE -WC

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

X MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

ODG Neck and Upper Back Chapter

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.