

**ReviewTex. Inc.**  
**1818 Mountjoy Drive**  
**San Antonio, TX 78232**  
**(phone) 210-598-9381 (fax) 210-598-9382**  
**reviewtex@hotmail.com**

**Date notice sent to all parties:**

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Cervical Epidural Steroid Injection under Fluoroscopy and with IV sedation at C 6-7 (62310, 77003, 01992)

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

Board Certified Anesthesiologist and Board Certified Pain Medicine.

**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]:**

Patient is a female. On XX/XX/XX, possibly an error due to poor copy quality, an MRI of the cervical spine was obtained. At C6-7 level, there was a central disc extrusion, with stenosis. The exam was of poor copy quality. XX/XX/XX, the patient was seen in clinic for complaints of neck pain. She also described arm pain right greater than left. Physical examination found reflexes 2+ in all extremities, sensation was intact, her gait was normal and she had bilateral biceps weakness rated at 4/5. Right hand intrinsic strength was also rated at 4/5. On 09/03/15, the patient was seen in clinic for initial pain evaluation. On exam, she had mild decreased pinprick sensation on the left in a C5-6 distribution as well as mild decreased grip strength on the left. A cervical epidural steroid injection was recommended. On 09/15/15, a utilization review determination letter stated the request was non-certified. On 09/17/15, the patient returned to clinic. It was noted she had decreased pinprick sensation and decreased grip strength. On 09/22/15, a

utilization review determination letter stated the request was non-certified. On 10/09/15, a progress note was submitted noting the patient had moderate to severe neck pain associated with cervical disc extrusion and cervical radiculopathy. She had decreased pinprick sensation at C5-6 and decreased grip strength.

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

On 09/15/15, a utilization review letter was submitted. It was noted that a request has been made for a cervical epidural steroid injection under fluoroscopy and with IV sedation at C6-7. The Official Disability Guidelines were cited as the reference source. It was noted that there was no indication for the need for sedation such as anxiety or needle phobia, and there was no corroboration from imaging although grip strength was associated with a C8 myotome and there was decreased pinprick sensation in a C5-6 distribution.

The Official Disability Guidelines neck chapter is utilized as well as Official Disability Guidelines pain chapter. The neck chapter indicates that epidural steroid injections are not recommended to the cervical spine based on recent evidence given the serious risk of the procedure in the cervical region, and the lack of quality evidence for sustained benefit. The provider has not given a rationale for exceeding guideline recommendations in regards to this procedure or to consider this patient an outlier per appendix D of the guidelines. Sedation is not indicated, except with documented anxiety or needle phobia, which was not documented.

Therefore it is the opinion of this reviewer that the request for a cervical epidural steroid injection under fluoroscopy and with IV sedation at C6-7 CPT codes 62310, 77003, and 01992 are not medically necessary.

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

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

**ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**  
Official Disability Guidelines (ODG), Treatment Index, 11th Edition (web), 2013, pain chapter, updated 06/16/15

Sedation: There is no evidence-based literature to make a firm recommendation as to sedation during an ESI. The use of sedation introduces some potential diagnostic and safety issues, making unnecessary use less than ideal. A major concern is that sedation may result in the inability of the patient to experience the expected pain and paresthesias associated with spinal cord irritation. This is of particular concern in the cervical region. (Hodges 1999) Routine use is not recommended except for patients with anxiety. The least amount of sedation for the shortest duration of effect is recommended. The general agent recommended is a benzodiazepine. (Trentman 2008) (Kim 2007) (Cuccuzzella 2006) While sedation is not recommended for facet

injections (especially with opioids) because it may alter the anesthetic diagnostic response, sedation is not generally necessary for an ESI but is not contraindicated. As far as monitored anesthesia care (MAC) administered by someone besides the surgeon, there should be evidence of a pre-anesthetic exam and evaluation, prescription of anesthesia care, completion of the record, administration of medication and provision of post-op care. Supervision services provided by the operating physician are considered part of the surgical service provided.

Official Disability Guidelines (ODG), Treatment Index, 11th Edition (web), 2013, neck and upper back chapter, updated 06/25/15

#### 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)