

**Independent Reviewers of Texas
2150 S Central Expressway Suite 200
McKinney TX 75070**

Notice of Independent Review Decision

[Date notice sent to all parties]:

10/16/2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: Left C2-3 and C3-4 facet blocks medial branch of the dorsal ramus and appeal for the left L5-S1 ESI x1.

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

Board Certified PM&R, Board Certified Pain Medicine

REVIEW OUTCOME:

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

X 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 patient is a female whose date of injury is xx/xx/xx. The x had a hard landing causing neck and back pain. The patient underwent a course of physical therapy. MRI of the cervical spine dated 07/28/15 revealed at C2-3 there is mild left facet degenerative changes with no significant spinal canal or neural foraminal narrowing. At C3-4 there is a mild left facet degenerative change as well as minimal degenerative disc disease with central posterior protrusion-subligamentous disc herniation measuring 1 mm in AP dimension resulting in mild anterior impression of the thecal sac; however, there is no significant neural foraminal narrowing. There is greater than 1 cm AP dimension of the spinal canal. MRI of the lumbar spine dated 07/28/15 revealed at L5-S1 there is moderate to marked predominantly anterior sided degenerative disc disease with mild acute endplate

bony reactive changes and circumferential disc bulge extending 5 mm from its expected peripheral margin, as well as mild facet degenerative changes, right side greater than left resulting in bilateral neural foraminal narrowing with questionable minimal impingement or at least abutment of both exiting L5 nerve roots. There is no significant spinal canal narrowing. Follow up evaluation dated 08/13/15 indicates that she has had 6 sessions of physical therapy. On physical examination cervical range of motion is improved. Spurling's is negative. Deep tendon reflexes, sensation and muscle strength are normal in the upper extremities. Lumbar range of motion is decreased. Deep tendon reflexes, sensation and muscle strength are normal in the lower extremities. Straight leg raising is negative bilaterally. Physical examination on 08/14/15 notes positive straight leg raising on the left and a sensory deficit in the left L5-S1 dermatome. Behavioral evaluation dated 08/24/15 indicates that current medications are naproxen, Xanax, Flexeril, Simpone, Arava, Cymbalta, Ambien and Restasis. BDI is 37 and BAI is 29. Diagnosis is pain disorder associated with both psychological factors and a general medical condition. Follow up evaluation dated 08/27/15 indicates that deep tendon reflexes, sensation and muscle strength are normal in the lower extremities. Straight leg raising is negative bilaterally. Note dated 09/15/15 indicates that neurological exam is non-focal. Cervical and lumbar spine show paraspinal tenderness and spasm left greater than right, mild right upper extremity and lower extremity weakness against fixed resistance.

Initial request for left C2-3 and C3-4 facet blocks medial branch of the dorsal ramus and appeal for the left L5-S1 ESI x1 was non-certified on 08/20/15 noting that records indicate only 6 sessions of physical therapy have been tried and there is no documentation of any other forms of conservative treatment tried and failed. With only 6 sessions of physical therapy, evidence based guideline criteria for facet injections of conservative therapy for at least 4-6 weeks has not been met. The denial was upheld on appeal dated 09/11/15 noting that the medical necessity for the cervical medial branch nerve blocks cannot be established on the basis of the current physical findings and response to treatment as there appears to be a substantial soft tissue component that persists in the face of what is likely to be pre-existing multilevel diffuse degenerative spine changes. Regarding the performance of one or more lumbar epidural steroid injections, there are no objective findings to support the presence of active nerve root irritation of the lumbar region; hence, the medical necessity cannot be established based upon the clinical guidelines and/or clinical data submitted at this time.

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 left C2-3 and C3-4 facet blocks medial branch of the dorsal ramus and appeal for the left L5-S1 ESI x1 is not recommended as medically necessary, and the two previous denials are upheld. In regards to cervical facet blocks, the patient's physical examination fails to establish the presence of cervical facet-mediated pain. The Official Disability Guidelines note that clinical presentation should be consistent with facet joint pain, signs

and symptoms. In regards to the lumbar epidural steroid injection, the Official Disability Guidelines require documentation of radiculopathy on physical examination corroborated by imaging studies and/or electrodiagnostic results. The patient's physical examination fails to establish the presence of active radiculopathy with follow up evaluation dated 08/27/15 indicating that deep tendon reflexes, sensation and muscle strength are normal in the lower extremities. Straight leg raising is negative bilaterally. 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

Facet joint diagnostic blocks

Recommended prior to facet neurotomy (a procedure that is considered "under study"). Diagnostic blocks are performed with the anticipation that if successful, treatment may proceed to facet neurotomy at the diagnosed levels. Current research indicates that a minimum of one diagnostic block be performed prior to a neurotomy, and that this be a medial branch block (MBB). Although it is suggested that MBBs and intra-articular blocks appear to provide comparable diagnostic information, the results of placebo-controlled trials of neurotomy found better predictive effect with diagnostic MBB. In addition, the same nerves are tested with the MBB as are treated with the neurotomy. The use of a confirmatory block has been strongly suggested due to the high rate of false positives with single blocks (range of 27% to 63%) but this does not appear to be cost effective or to prevent the incidence of false positive response to the neurotomy procedure itself.

Technique: The described technique of blocking the medial branch nerves in the C3-C7 region (C3-4, C4-5, C5-6, and C6-7) is to block the named medial branch nerves (two injections). Authors have described blocking C2-3 by blocking the 3rd occipital nerve. Another technique of blocking C2-3 is to block at three injection points (vertically over the joint line, immediately above the inferior articular facet at C2 and immediately below the superior articular facet at C3).

(Barnsley, 1993) The medial branch nerve innervates the facet joint, facet capsular ligaments, the interspinous and supraspinous ligaments, spinous processes and paraspinal muscles. Relief of pain could be due to blockade of nociceptive input from any combination of these. It is suggested that the volume of injectate for diagnostic medial branch blocks be kept to a minimum (a trace amount of contrast with no more than 0.5 cc of injectate) as increased volume may anesthetize these other potential areas of pain generation and confound the ability of the block to accurately diagnose facet pathology. A recent study has recommended that the volume be limited to 0.25 cc.

Epidemiology of involved levels: Using cadaver evidence facet arthrosis most commonly affects the upper cervical levels, and increased with age, and was very rare in patients less than 40 years of age. C4-5 is the most common level followed by C3-4 and C2-3. This study did not attempt to identify number of levels of involvement. (Lee, 2009) Number of levels of involvement: In a randomized controlled trial of therapeutic cervical medial branch blocks it was stated that 48% of patients had 2 joints involved and 52% had three joints involved. (Manchikanti, 2008) These levels were identified by the pain pattern, local or paramedian tenderness over the area of the facet joint, and reproduction of pain to deep pressure. (Manchikanti, 2004) Other prevalence studies from this group also indicated that the majority of patients with cervical involvement were treated at three joints. Target joints were identified as noted above. (Manchikanti, 2004). There are no studies that have actually tested levels of involvement using individual injections for diagnostic verification.

(Lord 1996) (Washington, 2005) (Manchikanti , 2003) (Dreyfuss, 2003) (Falco, 2009) (Nordin, 2009) (Cohen, 2010) See the Low Back Chapter for further references.

Complications: See Facet joint therapeutic steroid injections.

Criteria for the use of diagnostic blocks for facet nerve pain:

Clinical presentation should be consistent with facet joint pain, signs & symptoms.

1. One set of diagnostic medial branch blocks is required with a response of $\geq 70\%$. The pain response should be approximately 2 hours for Lidocaine.
2. Limited to patients with cervical pain that is non-radicular and at

no more than two levels bilaterally.

3. There is documentation of failure of conservative treatment (including home exercise, PT and NSAIDs) prior to the procedure for at least 4-6 weeks.

4. No more than 2 joint levels are injected in one session (see above for medial branch block levels).

5. Recommended volume of no more than 0.5 cc of injectate is given to each joint, with recent literature suggesting a volume of 0.25 cc to improve diagnostic accuracy.

6. No pain medication from home should be taken for at least 4 hours prior to the diagnostic block and for 4 to 6 hours afterward.

7. Opioids should not be given as a “sedative” during the procedure.

8. The use of IV sedation may be grounds to negate the results of a diagnostic block, and should only be given in cases of extreme anxiety.

9. The patient should document pain relief with an instrument such as a VAS scale, emphasizing the importance of recording the maximum pain relief and maximum duration of pain. The patient should also keep medication use and activity logs to support subjective reports of better pain control.

10. Diagnostic facet blocks should not be performed in patients in whom a surgical procedure is anticipated.

11. Diagnostic facet blocks should not be performed in patients who have had a previous fusion procedure at the planned injection level.

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

ODG Low Back Chapter

Epidural steroid injections (ESIs), therapeutic

Recommended as a possible option for short-term treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy) with use in conjunction with

active rehab efforts. Not recommended for spinal stenosis or for nonspecific low back pain. See specific criteria for use below. Radiculopathy symptoms are generally due to herniated nucleus pulposus or spinal stenosis, but ESIs have not been found to be as beneficial a treatment for the latter condition. According to SPORT, ESIs are associated with less improvement in spinal stenosis. (Radcliff, 2013)

Short-term symptoms: The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular 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. (Armon, 2007) Epidural steroid injection can offer short-term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program. There is little information on improved function or return to work. There is no high-level evidence to support the use of epidural injections of steroids, local anesthetics, and/or opioids as a treatment for acute low back pain without radiculopathy. (Benzon, 1986) (ISIS, 1999) (DePalma, 2005) (Molloy, 2005) (Wilson-MacDonald, 2005)

Use for chronic pain: Chronic duration of symptoms (> 6 months) has also been found to decrease success rates with a threefold decrease found in patients with symptom duration > 24 months. The ideal time of either when to initiate treatment or when treatment is no longer thought to be effective has not been determined. (Hopwood, 1993) (Cyteval, 2006) Indications for repeating ESIs in patients with chronic pain at a level previously injected (> 24 months) include a symptom-free interval or indication of a new clinical presentation at the level.

For spinal stenosis: The use of epidural steroid injection (ESI) in patients with lumbar spinal stenosis is common, but there is little evidence in the literature to demonstrate its long-term benefit. Despite equivalent baseline status, ESIs are associated with significantly less improvement at 4 years among all patients with spinal stenosis. Furthermore, ESIs were associated with longer duration of surgery and longer hospital stay. There was no improvement in outcome with ESI whether patients were treated surgically or nonsurgically. There was no distinct surgical avoidance noted with ESI. (Radcliff, 2013) This systematic review found the data was limited to suggest that ESI is effective in lumbar spinal stenosis. (Bresnahan, 2013) An RCT addressed the use of ESIs for treatment of spinal stenosis, and there was no statistical difference except in pain intensity and Roland Morris Disability Index and this was at two weeks only. (Koc, 2009) According to the APS/ ACP

guidelines, ESIs are not for nonspecific low back pain or spinal stenosis. (Chou, 2008) According to a high quality RCT, in the treatment of symptoms of lumbar spinal stenosis, epidural injections of glucocorticoids plus lidocaine offered minimal or no benefit over epidural injections of lidocaine alone at 6 weeks. At 3 weeks, the glucocorticoid-lidocaine group had greater improvement than the lidocaine-alone group, but the differences were clinically insignificant. Despite a rapid increase in the use of epidural glucocorticoid injections for lumbar spinal stenosis, there is little evidence of effectiveness from clinical trials. (Friedly, 2014)

Transforaminal approach: Some groups suggest that there may be a preference for a transforaminal approach as the technique allows for delivery of medication at the target tissue site, and an advantage for transforaminal injections in herniated nucleus pulposus over translaminar or caudal injections has been suggested in the best available studies. (Riew, 2000) (Vad, 2002) (Young, 2007) This approach may be particularly helpful in patients with large disc herniations, foraminal stenosis, and lateral disc herniations. (Colorado, 2001) (ICSI, 2004) (McLain, 2005) (Wilson-MacDonald, 2005) Two recent RCTs of caudal injections had different conclusions. This study concluded that caudal injections demonstrated 50% pain relief in 70% of the patients, but required an average of 3-4 procedures per year. (Manchikanti, 2011) This higher quality study concluded that caudal injections are not recommended for chronic lumbar radiculopathy. (Iversen, 2011) Transforaminal epidural steroid injections, despite being generally regarded as superior to interlaminar injections, are not significantly better in providing pain relief or functional improvement, according to a new systematic review. (Chien, 2014)

Fluoroscopic guidance: Fluoroscopic guidance with use of contrast is recommended for all approaches as needle misplacement may be a cause of treatment failure. (Manchikanti, 1999) (Colorado, 2001) (ICSI, 2004) (Molloy, 2005) (Young, 2007)

Factors that decrease success: Decreased success rates have been found in patients who are unemployed due to pain, who smoke, have had previous back surgery, have pain that is not decreased by medication, and/or evidence of substance abuse, disability or litigation. (Jamison, 1991) (Abram, 1999) Research reporting effectiveness of ESIs in the past has been contradictory, but these discrepancies are felt to have been, in part, secondary to numerous methodological flaws in the early studies, including the lack of imaging and contrast administration. Success rates also may depend on the technical skill of the interventionalist. (Carette, 1997) (Bigos, 1999) (Rozenberg, 1999) (Botwin, 2002) (Manchikanti ,

2003) (CMS, 2004) (Delpont, 2004) (Khot, 2004) (Buttermann, 2004) (Buttermann2, 2004) (Samanta, 2004) (Cigna, 2004) (Benzon, 2005) (Dashfield, 2005) (Arden, 2005) (Price, 2005) (Resnick, 2005) (Abdi, 2007) (Boswell, 2007) (Buenaventura, 2009) Also see Epidural steroid injections, “series of three” and Epidural steroid injections, diagnostic. ESIs may be helpful with radicular symptoms not responsive to 2 to 6 weeks of conservative therapy. (Kinkade, 2007) Epidural steroid injections are an option for short-term pain relief of persistent radiculopathy, although not for nonspecific low back pain or spinal stenosis. (Chou, 2008) As noted above, injections are recommended if they can facilitate a return to functionality (via activity & exercise). If post-injection physical therapy visits are required for instruction in these active self-performed exercise programs, these visits should be included within the overall recommendations under Physical therapy, or at least not require more than 2 additional visits to reinforce the home exercise program.

With discectomy: Epidural steroid administration during lumbar discectomy may reduce early neurologic impairment, pain, and convalescence and enhance recovery without increasing risks of complications. (Rasmussen, 2008) Not recommended post-op. The evidence for ESI for post lumbar surgery syndrome is poor. (Manchikanti, 2012)

Patient selection: Radiculopathy must be documented, as indicated in the ODG criteria. In addition, ESIs are more often successful in patients without significant compression of the nerve root and, therefore, in whom an inflammatory basis for radicular pain is most likely. In such patients, a success rate of 75% renders ESI an attractive temporary alternative to surgery, but in patients with significant compression of the nerve root, the likelihood of benefiting from ESI is low (26%). This success rate may be no more than that of a placebo effect, and surgery may be a more appropriate consideration. (Ghahreman, 2011) Injections for spinal pain have high failure rates, emphasizing the importance of patient selection. Individuals with centralized pain, such as those with fibromyalgia and chronic widespread pain, and poorly controlled depression, may be poor candidates. (Brummett, 2013)

MRIs: According to this RCT, the use of MRI before ESIs does not improve patient outcomes and has a minimal effect on decision making, but the use of MRI might have reduced the total number of injections required and may have improved outcomes in a subset of patients. Given these potential benefits as well as concerns related to missing important rare contraindications to epidural steroid injection, plus the small benefits of ESIs themselves, ODG continues to recommend that radiculopathy be corroborated by imaging studies

and/or electrodiagnostic testing. (Cohen, 2012)

Fracture risk: Lumbar ESIs are associated with an increased risk for spinal fracture. Each single additional ESI increased the risk for fracture by 21%, with an increasing number of ESIs associated with an increasing likelihood of fracture. Use of ESIs seems to promote deterioration of skeletal quality. This definable fracture risk should be balanced with the best available evidence regarding the long-term efficacy of ESIs, which is limited. Clinicians should consider these findings before prescribing ESIs for elderly patients. (Mandel, 2013)

Recent research: An updated Cochrane review of injection therapies (ESIs, facets, trigger points) for low back pain concluded that there is no strong evidence for or against the use of any type of injection therapy, but it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy. (Staal-Cochrane, 2009) Recent studies document a 629% increase in expenditures for ESIs, without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) There is fair evidence that epidural steroid injection is moderately effective for short-term (but not long-term) symptom relief. (Chou3, 2009) This RCT concluded that caudal epidural injections containing steroids demonstrated better and faster efficacy than placebo. (Sayegh, 2009) In this RCT there were no statistically significant differences between any of the three groups at any time points. This study had some limitations: only one type of steroid in one dose was tested; the approach used was caudal and transforaminal injections might provide superior results. (Weiner, 2012) Effects are short-term and minimal. At follow-up of up to 3 months, epidural steroids were associated with statistically significant reductions in mean leg pain and mean disability score, but neither of these short-term improvements reached the threshold for clinical significance. There were no significant differences in either leg pain or disability at 12 months follow-up. (Pinto, 2012) According to this systematic review, ESIs without the drug (epidural nonsteroid injections), often used as a placebo treatment, were as effective as ESIs and better than no epidural injections. (Bicket, 2013) This meta-analysis suggested that ESI did not improve back-specific disability more than a placebo or other procedure long-term (6 months), and did not significantly decrease the number of patients who underwent subsequent surgery. (Choi, 2013) 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) This study shows that ESIs had a significant beneficial effect as an additional treatment for lumbosacral radicular syndrome in general practice, but the effect was too small to be considered clinically relevant to patients, so the authors do not recommend ESIs as a regular

intervention in general practice. (Spijker-Huiges, 2014) A high quality RCT concluded that gabapentin and ESIs for radicular pain both resulted in modest improvements in pain and function, which persisted through three months. Some differences favored ESIs, but these tended to be small and transient. They recommended a trial with neuropathic drugs as a reasonable first line treatment option. (Cohen, 2015) The AHRQ comparative effectiveness study on injection therapies for LBP concluded that ESIs for radiculopathy were associated with immediate improvements in pain and might be associated with immediate improvements in function, but benefits were small and not sustained, and there was no effect on long-term risk of surgery. Evidence did not suggest that effectiveness varies based on injection technique, corticosteroid, dose, or comparator. Limited evidence suggested that epidural corticosteroid injections are not effective for spinal stenosis or nonradicular back pain. (Chou, 2015) In another systematic review, evidence was only robust for positive effects in patients with chronic radiculopathy, with statistically significant effects on immediate (5 days to ≤ 2 weeks) improvement in pain, and short-term (> 2 weeks to ≤ 3 months) surgery risk. (Chou, 2015b) See the Neck Chapter, where ESIs 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.

Criteria for the use of Epidural steroid injections:

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

(1) Radiculopathy (due to herniated nucleus pulposus, but not spinal stenosis) must be documented. Objective findings on examination need to be present. Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing.

(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs, muscle relaxants & neuropathic drugs).

(3) Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance.

(4) Diagnostic Phase: At the time of initial use of an ESI (formally referred to as the “diagnostic phase” as initial injections indicate whether success will be obtained with this treatment intervention), a maximum of one to two injections should be performed. A repeat

block is not recommended if there is inadequate response to the first block (< 30% is a standard placebo response). A second block is also not indicated if the first block is accurately placed unless: (a) there is a question of the pain generator; (b) there was possibility of inaccurate placement; or (c) there is evidence of multilevel pathology. In these cases a different level or approach might be proposed. There should be 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) Therapeutic phase: If after the initial block/blocks are given (see “Diagnostic Phase” above) and found to produce pain relief of at least 50-70% pain relief for at least 6-8 weeks, additional blocks may be supported. This is generally referred to as the “therapeutic phase.” Indications for repeat blocks include acute exacerbation of pain, or new onset of radicular symptoms. The general consensus recommendation is for no more than 4 blocks per region per year. (CMS, 2004) (Boswell, 2007)

(8) Repeat injections should be based on continued objective documented pain relief, decreased need for pain medications, and functional response.

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

(10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or sacroiliac blocks or lumbar 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. (Doing both injections on the same day could result in an excessive dose of steroids, which can be dangerous, and not worth the risk for a treatment that has no long-term benefit.)