

IRO REVIEWER REPORT - WC



Notice of Independent Review Decision

June 19, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Caudal ESI Lumbar L5-S1 Under Fluoroscopy with IV Sedation

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

American Board of Anesthesiology

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

- 9-27-10 EMG/NCS of the lower extremities.

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- 11-30-11 CT Myelogram of the lumbar spine.
- 4-11-11 X-rays of the lumbar spine.
- 4-27-12, office visit.
- 11-30-12, office visit.
- 2-11-13, office visit.
- 3-4-13, office visit.
- 3-20-13 Adverse Determination notice.
- 5-6-13 Adverse Determination.
- 5-15-13, office visit.

PATIENT CLINICAL HISTORY [SUMMARY]:

9-27-10 EMG/NCS of the lower extremities showed significant abnormalities included fibrillations in the left L5 paraspinous, right L4 paraspinous and right L5 paraspinous muscles with positive sharp waves in the right L5 paraspinous muscles. These abnormalities suggest a bilateral L5 radiculopathy and an L4 radiculopathy on the right.

11-30-11 CT Myelogram of the lumbar spine shows status post remote discectomy and anterior interbody fusion at L3-L4 and L4-L5. There is hypertrophic bone fusion material at L3-L4 which fills the entirety of the right lateral recess causing mild spinal canal and severe right lateral recess stenosis. A 4 mm left paracentral disc protrusion at L5-S1 which mildly impinges upon the thecal sac and the left S1 nerve root sheath. The disc protrusion moderately narrows both of the lateral recesses, worse on the left than the right. A 4 mm left paracentral and foraminal disc protrusion at L2-L3 which mildly impinges upon the thecal sac, also moderately narrowing the left lateral recess and foramen. Non opacification of the L3, L4 L5 and S1 nerve root sheaths bilaterally.

4-11-11 X-rays of the lumbar spine show status post remote discectomy and anterior interbody fusion at L3-L4 and L4-L5. There is no solid bony fusion seen in either segment. Mild bilateral degenerative facet joint hypertrophy at L2-L3 and L5-S1. There has been no significant change in the appearance of the lumbar spine from 12-13-10.

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4-27-12, the claimant is a male who is being seen for consultation at the request of Patient reports a job related injury with twisting/ lifting trauma to the low back on xx/xx/xx. Injury resulted in lumbar fusion with laminectomy and artificial disc replacement in 2009. He indicates that approximately six months after surgery right leg and back pain persisted. Since then the patient is having constant , throbbing and aching low back pain radiating into the right leg lower extremity. Pain made worse with physical activity such as bending, twisting and turning. He indicates that his quality of life has severely been affected. He reports that he has not been able to work since injury and that he is undergoing divorce secondary to financial pressures due to injury. Patient gives a VRS pain score of 5/10 with medications. Current regimen includes the following medications: Flexeril and Ibuprofen. There is associated numbness, tingling and weakness of the right leg. Patient denies any bowel or bladder dysfunction. Patient has been treated with surgery, physical therapy and medications but continues to have moderate to severe pain on a daily basis. He indicates that he has completed physical therapy, work hardening, and lumbar ESI with limited benefit to his chronic back and leg pain. Recommendations:

1. This patient has failed to respond to conservative treatment in the form of physical therapy, rehabilitation, medication, and injection therapy. His/her pain is severe and the patient is requiring high doses of narcotics in order to make the pain tolerable and allow him/her to function at a minimum level. This patient has undergone surgery and has also failed to obtain significant relief of his/her symptoms. At this point I strongly feel that the patient is a good candidate for a Spinal Cord Stimulator trial. This will be done by placing a temporary percutaneous neuro-stimulator electrode under fluoroscopic control at the appropriate levels to be determined at the time of the surgery. The implanted neuro-stimulator will be analyzed electronically and programmed according to the patient's individual requirements. The patient will go home with this device and allowed to use it for no less than three days. After this trial period the neuro-stimulator electrode will be removed in the office and the patient will be evaluated regarding pain relief. If the patient experiences at least 50% of pain relief, this will be considered a positive trial and preauthorization for a permanent implant will be initiated. After careful evaluation of the patient and of his/her diagnostic studies I feel this is the most appropriate treatment. This procedure is reasonable and medically necessary. The risks, benefits, and alternatives of these procedures were discussed with the patient in detail using spine model, diagrams, and pictures. The risks of the procedure include but are not limited to bleeding, infection, no pain relief, increased pain, nerve injuries, spinal cord injury, spinal headache, need for further procedure, etc. Patients needs to avoid any blood thinners including Coumadin, Plavix, NSAIDs and all aspirin containing products for 5 days prior to the procedure to avoid the risk of bleeding. Written instructions were also given. The patient understands the possible complications and wants to proceed.

2. The patient advised to continue with therapy. This is very important to be able to maintain range of motion and lumbar spine strength and to avoid deconditioning. Patient needs to participate in both active and passive rehab modalities.

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3. The patient needs to be taking current medications. Patient was given a prescription for the following medications. The risk of narcotics includes but are not limited to sedation, respiratory depression, confusion, constipation, itching, nausea or vomiting, allergic reactions etc. If taken improperly or by an unauthorized person, they can cause serious accidents and even be fatal. The patient understands these risks. Narcotic agreement was reviewed with the patient. Patient advised to call me if any of these problems are experienced.
4. Patient may be able to return to work on a modified duty status. The pt. advised to discuss this with his treating physician.
5. Return to clinic in for SCS trial with ANS.
6. Face to face consult with psychologist for SCS approval.

11-30-12, the claimant is seen to discuss treatment options since denial of spinal cord stimulator trial. He has increasing low back pain associated with right leg pain, right foot pain numbness and tingling. The evaluator recommended resubmitting for spinal cord stimulator trial.

2-11-13, the claimant is male who presents with persistent chronic back pain, left buttock and left leg pain associated with numbness, weakness and tingling. The claimant was in good standing history of work reinjured himself on the job while twisting and heavy lifting. He subsequently underwent a lumbar disk fusion and anterior replacement in 2009 at the L3-4 and L4-5 levels. Repeat MRI, however, showed a paracentral disk herniation above at L2-3 and below at L5-S1. The patient's back pain continues moderate-to-severe in grade as he has become progressively desponded and depressed. In fact, the pain-related stress inventory filled out today was remarkable for 12 of 22 responses suggestive of moderate reactive depression, insomnia, and feelings of helplessness and worthlessness associated with this pain complaint. He has undergone sundry evaluations and treatments. Unfortunately, these have all failed, EMG nerve conduction testing is positive for radiculopathy at the L5-S1, at the L5 level bilaterally. The patient was referred there for medical management as well as potentially interventional pain care. The patient currently grades his pain at 7/10, aggravated 10/10 with most routine daily activities. He admits to sleep loss, headaches, and pain with sitting, bending, and standing. On exam, cervical spine revealed increased paraspinal muscle tone, trigger point tenderness throughout the cervical, mid thoracic and lumbar regions. He had a positive straight leg raising sign on the right at 60 degrees. He had moderate right greater than left sciatic notch tenderness with a positive contralateral straight leg raising sign On the left at 70 degree lumbosacral flexion, The patient's lumbar spine with moderate lumbar interspinous tenderness. He had mild decreased pinprick sensation at the L5 distribution on the right. Deep tendon reflexes are 1+ Achilles and patellae bilaterally. Toes were downgoing. No ankle clonus was elicited. Patrick tests at the hip were unremarkable. Diagnosis: Post lumbar laminectomy pain syndrome with recurrent radiculopathy L5 bilaterally. Status post interdisk fusion with failure to relieve pain at L3-4, L4-5. Moderate reactive depression, generalized deconditioning and chronic pain syndrome. Plan: Medication management, spinal cord stimulator for recalcitrant pain. The evaluator

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recommended Amitriptyline with Gabapentin, Ultram for moderate pain, and discontinue Ibuprofen as it is causing gastritis.

3-4-13, the claimant has moderate back, left buttock and left leg pain below the level of the knee associated with radiculopathy and failed back pain syndrome. The evaluator recommended a caudal epidural steroid injection due to the persistent radicular symptoms otherwise, he was going to go ahead right away with trial for spinal cord stimulator.

3-20-13 Adverse Determination notice. UR performed, the doctor was not available; spoke with. Request for caudal ESI L5-S1. Clinical reviewed includes: office visit 314, 2/11/13, CT myelogram 11/30/11, EMG/NCS 9/27/10, office visit 11/4/11. Claimant is status post L3-5 fusion on 10/19/09. He has had prior treatment with physical therapy, work hardening, chronic pain management program, ESI on 10/20/11 note from 11/11 states ESI helped only "briefly." Most current CT myelogram fails to reveal any evidence of neurocompressive pathology. EMG/NCS showed abnormalities suggestive of bilateral L5 radiculopathy, and right L4 radiculopathy. is requesting ESI at L5-S1. However, given his poor response to prior ESI, request for repeat is unlikely to be of any benefit. Request not medically necessary. Refer to ODG section 722.1 subsection under ESI.

5-6-13 Adverse Determination after reconsideration notice. UR performed, non-certification. Based on review of the medical records provided, the proposed treatment consisting of 1 Caudal ESI Lumbar L5-S1 under fluoroscopy with IV Sedation is not appropriate and medically necessary for this diagnosis and clinical findings. The caudal ESI is indicated, but sedation is not. The claimant is completely healthy and on an NSAID only. There is no indication of any overt medical or psychiatric issues to require sedation for this relatively straightforward injection. The refused to discuss the case with the reviewer and per would not remove the sedation component so the entire request is denied.

5-15-13, the claimant is treating for failed back pain syndrome and persistent back, right buttock, and leg pain, associated numbness, weakness, and tingling. This gentleman has a positive straight leg raising sign. He has been placed on appropriate medication and is interested in spinal cord stimulation as a definitive treatment for his ongoing pain. He does want to try a caudal epidural block first, which is certainly a reasonable attempt to help him with his neuropathic leg pain as he is continuing working. He does admit to weakness and decreased range of motion. He has a positive straight leg raising sign again on the right at 60 degrees with decreased pinprick sensation in the L5 distribution. He has mild interspinous tenderness, pain with flexion, he did work a full work day today and he feels exhausted due to increasing pain. His sleep has improved with Amitriptyline 25 mg at night. He is getting fair analgesia with a combination of Neurontin and Ultram. He is taking the medicines compliantly void of side effects. Caudal epidural blockade will be authorized as soon as possible for his ongoing pain. Based on response to this care, further injection therapy versus spinal cord stimulation will be offered.

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5-31-13 Notice to Claims Eval of Case Assignment.

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

This claimant has evidence of a radiculopathy and MRI findings that support the diagnosis and EMG findings as well. Therefore, the caudal ESI is necessary and recommended. The claimant has 12 out of 22 positive responses on a depression scale. Since anxiety is coupled with that, sedation would be indicated as well. Therefore, the request for Caudal ESI Lumbar L5-S1 Under Fluoroscopy with IV Sedation is medically appropriate and necessary.

Per ODG 2013 epidural steroid injection: 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. See specific criteria for use below. Radiculopathy symptoms are generally due to herniated nucleus pulposus or spinal stenosis, although ESIs have not been found to be as beneficial a treatment for the latter condition. In fact, 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) A recent RCT of 29 patients divided into three groups addressed the use of ESIs for treatment of spinal stenosis. A control group with no treatment was compared to a group receiving passive physical therapy for two weeks and another receiving an interlaminar ESI at the stenotic level. At two weeks the group that received the ESI had significantly better pain relief than the other two groups. When the three groups were compared there was no statistical difference except in pain intensity and Roland Morris Disability Index and this was at two weeks only. The authors stated that improvement only appeared to be in the early phase of treatment. (Koc, 2009)

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

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chronic pain at a level previously injected (> 24 months) include a symptom-free interval or indication of a new clinical presentation at the level.

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)

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)

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

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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) 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) 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) 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)

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 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 and muscle relaxants).
- (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

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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.)

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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)**