

SENT VIA EMAIL OR FAX ON  
Dec/12/2008

## **P-IRO Inc.**

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### **NOTICE OF INDEPENDENT REVIEW DECISION**

**DATE OF REVIEW:**

Dec/12/2008

**IRO CASE #:**

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

Lumbar ESI at L3/4

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

Board Certified Orthopedic Surgeon

**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)

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

OD Guidelines

Radiology report, 07/25/08

Office note, 07/30/08

MRI lumbar spine, 07/31/08

Office notes, Dr. , 08/13/08, 10/07/08

Procedure note, 08/28/08, 09/16/08

Discussion with claimant, 09/02/08, 09/25/08

Note, 09/18/08, 10/03/08, 10/14/08

Pre-authorization decision and rationale, 10/06/08, 10/21/08, 11/19/08

RTW note, 0/24/08

**PATIENT CLINICAL HISTORY SUMMARY**

This claimant is a xx year-old male who was injured on xx/xx/xx while lifting. A radiology report on 07/25/08 showed no acute disease and a possible sixth lumbar vertebrae. The claimant was seen on 07/30/08 for left low back and left buttock pain with spasms, giving way of the left leg, tingling of the right leg and numbness of the left toes greater than the right foot.

He was taking Prednisone, Celebrex and Skelaxin. He had a straight leg raise on the left at 20 degrees with radiculopathy symptoms on the left and straight leg raise on the right at 45 degrees with radiculopathy symptoms on the left. A lumbar MRI on 07/31/08 showed at L3-4 a left posterior paramedian broad-based disc herniation and caudal extrusion of disc material causing left parasagittal and lateral recess stenosis impinging on the central descending left L4 nerve root. It did not extend through the left neural foramen. Sequestration of disc material was possible. Both exit foramina mildly encroached in conjunction with posterior element hypertrophy. There was a milder concentric spondylotic bulge at L4-5 with posterior element hypertrophy encroaches upon the central canal but no overt central stenosis. The foramina were mildly encroached. The distal thecal sac congenitally smoothly tapered.

Dr. evaluated the claimant on 08/13/08 noting a positive straight leg raise on the left with paresthesias on the left and mildly cross straight leg raise on the left. He was noted to have a clear herniated extruded disc at L3-4 on the left with left leg sciatica. His pain started in the left sciatic notch and went down the left posterior hamstring area. He had tingling and paresthesias in the left foot, 4/5 dorsiflexion of left foot and stated that when he walked his quadriceps was 5-/5. An L3-4 herniated disc was diagnosed. On 08/28/08 the claimant underwent a left L3-4 epidural steroid injection with approximately 2 weeks of good pain relief. On 09/16/08 he underwent an L2-3 epidural steroid injection. A third epidural steroid injection was denied. He was seen on 10/07/08 at which time it was indicated that the first injection lasted 3 weeks and the 2nd injection was still working. He wanted to do a third injection and avoid surgery. Dr. stated that out of the first two injections the claimant was at least 50 percent better and wanted to have the third injection and then may attempt to return to work. The injection was denied two other times and is now under dispute. ?

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

The request is for a third lumbar ESI. The claimant appears to have an L3-4 left disc herniation with radiculopathies. He has had two ESI with short term, but not lasting benefit. ODG guidelines were used. They state that a series of three is not recommended. There is no guarantee in the current literature to suggest the basis for recommending a third ESI. With two ESI's resulting only in short term benefit, a third would not be approved. ODG suggests it may be prudent to proceed with surgery at this time.

Official Disability Guidelines Treatment in Worker's Comp 2007 Updates, (i.e. Low Back-Epidural Steroid Injections and a Series of 3 Epidural Steroid Injections)

Epidural Steroid Injections - 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.

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.

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)

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) 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)

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, 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. For unequivocal evidence of radiculopathy, see AMA Guides, 5th Edition, page 382-383. (Andersson, 2000)

(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 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 required. This is generally referred to as the “therapeutic phase.” Indications for repeat blocks include acute exacerbation of pain, or new onset of 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.)

Series of 3 Epidural Steroid Injections - Not recommended. Original recommendations that suggested a “series of three injections” generally did so prior to the advent of fluoroscopic guidance. These previous recommendations were based primarily on case studies and anecdotal evidence (Class IV and V data). (Abram, 1999) (Warr, 1972) (Hickey, 1987) There does not appear to be any evidence to support the current common practice of a series of injections. (Novak, 2008) Contemporary research studies with higher levels of evidence (including two controlled trials) have suggested that on average, two or less ESIs are required in patients with successful outcomes from the use of ESIs to treat disc related lumbar radiculopathy. (Lutz, 1998) (Vad, 2002) (Riew, 2000) While all of these latter studies have utilized repeat injections, there has been no evidence-based research to explain why this practice is required, or the mechanism for possible action. Since the introduction of fluoroscopically guided ESIs, it has been suggested that there is little evidence to repeat an accurately placed epidural injection in the presence of mono-radiculopathy, regardless of whether there is partial or no response. (McLain, 2005) A recent randomized controlled trial of blind ESIs found no evidence to support repeat injections, because at six weeks there was no significant difference found between the ESI group and a placebo controlled group in terms of any measured parameter. (Price, 2005) A repeat injection has been suggested if there is question of accurate dermatomal diagnosis, if pain may be secondary to a different generator, or in the case of multilevel pathology. (McLain, 2005) There is a lack of support for 2nd epidural steroid injection if the 1st is not effective. (Cuckler, 1985) With fluoroscopic guidance, there is little support to do a second epidural if there is no response to the first injection. There is little to no guidance in current literature to suggest the basis for the recommendation of a third ESI, and the routine use of this practice is not recommended.

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

ACOEM-AMERICA 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 ERVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)