IMED, INC.
11625 Custer Road • Suite 110-343 • Frisco, Texas 75035
Office 972-381-9282 • Toll Free 1-877-333-7374 • Fax 972-250-4584
e-mail: imeddallas@msn.com

Notice of Independent Review Decision

DATE OF REVIEW: 02/19/10

IRO CASE NO.:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Item in dispute: Right L5 Transforaminal ESI.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
Texas Board Certified Physical Medicine & Rehabilitation and Pain Management

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

Denial Overturned

INFORMATION PROVIDED TO THE IRO FOR REVIEW
1. Clinical note D.C., 12/23/08
2. MRI lumbar spine dated 01/13/09
3. EMG/NCV study dated 01/20/09
4. Utilization review determination dated 01/27/09
5. Treatment records Injury and Rehabilitation Center, 1/29/08
6. Procedure report right L5 transforaminal epidural steroid injection dated 03/23/09
7. Clinical notes Dr. 03/23/09 thru 06/08/09
8. Procedure note right L5 transforaminal epidural steroid injection dated 05/01/09
9. Utilization review determination dated 06/09/09
10. Procedure report right L5 transforaminal epidural steroid injection dated 07/21/09
11. Utilization review determination dated 01/18/10
12. **Official Disability Guidelines**

PATIENT CLINICAL HISTORY (SUMMARY):
The employee is a male who has a date of injury of xx/xx/xx. He was reported to have tried to sit in a chair but it moved forward, causing him to fall on his back and his elbow very hard.

The employee was taken to Hospital by ambulance. He subsequently underwent x-rays of his low back and elbow and was provided oral medications and discharged.

On 12/23/08, the employee was seen by, D.C. The employee complained of constant pain in his thoracic and lumbar spine regions and had difficulty when getting up from a seated position. He reported having back pain that radiated into the right thigh and knee and reported experiencing tingling sensation in the lateral upper thigh. On physical examination, he was reported to have a hard time getting up from a seated and supine position due to low back pain. His gait was irregular and antalgic, and he had tenderness and spasm in the mid low back, paraspinal muscles and spinous process. He had tenderness over both SI joints. He was reported to have moderately weak bilateral iliopsoas muscles, right hamstrings, quadriceps, tibialis anterior, and gastroc soleus was reported to be mildly weak. He was reported to have hypoesthesia along his right thigh and right leg and his reflexes were 1+ at the Achilles and patella. He was reported to have difficulty with heel toe walk, eliciting pain in his right leg. Supine straight leg raise was positive and caused pain in the lumbar spine which radiated to the posterior right thigh. Eli and Yeoman's maneuvers elicited pain across the lumbar spine. The employee was diagnosed with possible lumbar disc displacement, thoracic myositis, and contusion of the elbow. He subsequently was started on chiropractic treatment.

The employee was referred for MRI on 01/13/09. This study reported a shallow posterior subligamentous disc displacement that was non-compressive in character at L1-L2. At L2-L3, there was degenerative facet arthropathy of mild severity without substantive foraminal stenosis. There was a left sided extra foraminal disc protrusion identified without evidence of neural compression. At L3-L4, there was degenerative facet arthropathy of mild severity demonstrated without substantive foraminal stenosis, and there was a right sided extraforaminal disc protrusion demonstrated abutting the L3 right exiting nerve. At L4-L5, there was a left sided extra foraminal disc protrusion noted which was non-compressive in character. There was degenerative facet arthropathy producing bilateral foraminal canal narrowing of a mild severity. At L5-S1, there was disc dehydration accompanied by a loss of disc height. There was no evidence of disc displacement, and there was degenerative facet arthropathy of mild severity demonstrated without substantive foraminal stenosis.

The employee was referred for EMG/NCV study on 01/29/09. The employee was noted to have EMG abnormalities suggestive of a right L4 radiculopathy.

Records indicate that the employee was subsequently referred to Dr., and on 03/23/09, the employee underwent a right sided L5 transforaminal epidural steroid injection. Post procedurally, the employee reported 50 percent improvement but he continued to experience pain. He was reported to be utilizing ibuprofen on an as-needed basis and is no longer taking any other pain medications. On physical examination, the employee was able to get on and off of the examination table without difficulty. He had paravertebral muscle spasm L3-L5 with continued paresthesia following the L5 dermatome.

The employee was subsequently recommended to undergo a repeat epidural steroid injection. This was performed on 05/01/09. The employee was reported to overall have 70 percent improvement after two injections. He had gone from taking pain medications three to four times per day to taking it as-needed and not on a daily basis. He reported

that he has back pain with tingling down the back and right leg. He was subsequently recommended to get an additional epidural steroid injection.

A clinic note dated 06/08/09 indicated that a peer-to-peer was conducted with Dr. A third epidural steroid injection was requested and not approved. The reviewer's opinion reported that it was not indicated by ***Official Disability Guidelines***.

The employee was seen in follow up on 06/15/09. At that time, it was reported that the employee was 70 percent better than when he started. He was taking less medications and only took it as-needed. On physical examination, the employee was in no acute distress. He had paravertebral muscle spasm and hypertonicity primarily on the right L3-L5. His paresthesias fell in an L5 nerve root distribution. A request for third epidural steroid injection was resubmitted.

On 07/21/09, the employee underwent a right L5 transforaminal injection. It was reported that a third epidural steroid injection virtually eliminated the employee's leg pain. He continued to have a small amount. He was still taking medication but that was primarily due to pain in the lower thoracic area. Physical examination showed him to have no gait disorder. He had minimal pain over the lumbar spine to palpation. He had a trigger point versus rib dislocation at T10 on the right hand side. Pain was specific and exacerbated by taking a deep breath. He had palpable muscle spasms in the area.

The employee was reported to have a lumbar radiculopathy 90 percent improved after epidural steroid injections. The employee was subsequently returned for additional chiropractic treatment and recommended to undergo trigger point injection if his thoracic pain did not improve. He was provided a refill prescription for Hydrocodone and ibuprofen.

The employee was seen in follow up on 08/10/09. He presented regarding thoracic pain and was reported to have done well with injections for his lumbar pain. He had increased pain when he moved his arm and shoulder. On examination, he had pain over the T8 and T10 area. The employee was subsequently recommended to undergo therapeutic trigger point injections at T8 on the right.

The employee was seen in follow up on 12/16/09. It was reported that he had been back at work for a few weeks and his right leg pain had returned. He reported feeling like he had his hands crawling on his legs with some tingling and burning sensation down the back of his right hamstring. He continued to experience pain in the lower thoracic area on the right side only. On physical examination, he was reported to have tingling following the L5 and S1 nerve root distributions in the right leg. He had some pain to palpation of the lower paraspinal muscles as well as approximately T8-L1 on the right hand side. The employee was subsequently provided the oral medications Hydrocodone, Motrin, and Lidoderm Patches. He was scheduled for a right L5 transforaminal epidural steroid injection.

The employee was subsequently seen in follow up on 01/06/10. It was reported that he was denied a repeat epidural steroid injection. It was reported that he had difficulty getting up from the seated position and did not push off with his right leg. He continued to have paravertebral muscle spasm and tingling sensation following L4 and L5

distributions that did not go below his knee. He was subsequently again submitted for epidural steroid injection.

On 01/18/10, the case was reviewed by D.C. This was an extremely small and poorly reproduced document. The reviewer reported epidural steroid injections were appropriate when there is documentation of radiculopathy on examination. The reviewer further reported repeat injection should be based on continued objective documentation of pain relief noting decreased need for pain medications and increased functional response.

A clinical note dated 01/22/10 indicated that the employee was scheduled for transforaminal epidural steroid injections which was denied. The first denial reported that the employee did not get significant relief on the first two injections. The second review contained the same data. The first review was completed by a D.C. speaking with the doctor who was also a D.C.

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

The request for a right L5 transforaminal epidural steroid injection is medically necessary. The available clinical records indicate that the employee has a history of low back pain with radiation to the right lower extremity status post fall. Records indicate that the employee has a right sided extraforaminal disc protrusion at L3-L4 abutting the right L3 exiting nerve root. He has undergone EMG/NCV study which identifies a right L4 radiculopathy.

The records indicate that the employee has undergone a total of three lumbar epidural steroid injections in the past. The first, performed on 03/23/09, performed on the right at L5 resulted in 50 percent improvement. A second lumbar epidural steroid injection was performed on 05/01/09 and reports overall 70 percent improvement with clear documentation of reduced need for oral medications and improved functional status. The employee subsequently underwent a third lumbar epidural steroid injection on 07/21/09 with complete resolution of his right lower extremity symptoms. He subsequently did not develop recurrent symptoms until 12/16/09. The employee's subjective complaints are clinically associated with previously treated pathology. While the employee's physical examination does not indicate a floored radiculopathy, there is electrodiagnostic evidence and objective documentation of the efficacy of lumbar epidural steroid injections on the right at L5. This is fully within ***Official Disability Guides***, and the request for lumbar epidural steroid injections at L5 on the right is medically necessary.

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

The 2010 ***Official Disability Guidelines***, 15th Edition, The Work Loss Data Institute. Online Edition.

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. 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) This recent RCT concluded that both ESIs and PT seem to be effective for lumbar spinal stenosis for up to 6 months. Both ESI and PT groups demonstrated significant improvement in pain and functional parameters compared to control and no significant difference was noted between the 2 treatment groups at 6 months, but the ESI group was significantly more improved at the 2nd week. (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 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) (Delport, 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 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)

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.)