



**CLAIMS EVAL**

*Utilization Review and  
Peer Review Services*

Notice of Independent Review Decision-WC

**DATE OF REVIEW: 6-7-10**

**IRO CASE #:**

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

Epidural steroid injection L3-L4 bilaterally (62311 x 2; 77003)

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

American Board of Orthopaedic Surgery-Board Certified

**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 or not medical necessity exists for each of the health care services in dispute.

### **INFORMATION PROVIDED TO THE IRO FOR REVIEW**

- MD/ OPAC, office visits 4-23-10.
- 4-21-10 request for selective epidural steroid injection L3-L4 bilaterally was provided by Dr..
- 4-26-10, MD., performed a Utilization Review.
- 5-13-10 Dr. provided a reconsideration request for selective epidural steroid injection L3-L4 bilaterally.
- On 5-20-10, MD., performed a Utilization Review.

### **PATIENT CLINICAL HISTORY [SUMMARY]:**

On xx/xx/xx, MD., evaluated the claimant. He presents with his wife complaining of significant ongoing low back pain. His low back pain was not affected by Lyrica. He is asking if "pain therapy" would be helpful (last done with Dr. that included a "series of 3" injections). Claimant states his knee surgeon suggested he try it and claimant wants to know if this would be a good idea. Claimant and wife both express his deteriorating condition and makes particular note that he has reverted back to ambulating with a walker if he has to get out of the house, but did not bring it today because wife states, "He tries to look good when he comes in here." And claimant states, "I hate lugging that thing around." Indoors, he ambulates minimally and usually only makes trips from his recliner to the restroom and back. He rates his low back pain as 4-8/10, averaging 6, described as sharp across his low back and when he is up for 10 minutes or less it changes to burning that creeps up both sides of his low back to between the shoulder blades. He also reports numbness of the left leg from the proximal thigh to toes 1-4, particularly at toe #1; also, partial foot drop that gets worse when he is on his feet for 10 minutes-or less. The claimant states he has not smoked in almost 1 year. Pulmonologist, Dr. had given him Spiriva and asthma nex that lead to pneumonia and kidney infection and he was hospitalized for 6 days. Claimant states his appetite has been restored. Claimant states he had cyanosis of his right great toe and Dr. his new primary care doctor ordered venous Doppler ultrasound of his lower extremities and he is not aware of what his results are; notes the big toe is "not as blue" as it was. On 1-27-10, he had a Functional Capacity Evaluation, which showed the claimant continues to be limited with walking, but it has improved some; states walking with a cane helps and states his tolerance of 100-125 steps has tripled at least. Physical exam shows he ambulates with a forward-flexed posture and with right lateral torso translation. In the standing position, the claimant flexes to 50 degrees without discomfort. Lateral bending reveals paraspinal spasms on the right. Extension and rotation is positive, left > right

with ipsilateral low back pain. Tenderness is sharp on the left and moderate on the right. There are well-healed scars. In the seated position, deep tendon reflexes are intact at the knees and intact at the ankles. Straight leg raise is negative. Lesague is negative. Motor strength is 5/5 of the hip flexors, 5/5 of the EHL, and 5/5 with breakaway (because of inability to sustain the contraction) of the left dorsi everters. Feet are symmetrically warm to touch. Pedal pulses are indiscernible. Peripheral edema is not present. Dermatomal pattern is numb at the left lower leg from the knee to across the dorsum of the left foot. The evaluator recommended bilateral selective ESIs at the L3-4 level. The claimant was informed of the potential benefits of supplementing the diet with 2,500 mg Calcium Citrate and 5,000 IU Vitamin D maintenance dose.

On 4-21-10 a request for selective epidural steroid injection L3-L4 bilaterally was provided by Dr..

4-23-10 OPAC/, MD., the evaluator reported he had peer review with Dr., occupational medicine and internal medicine, regarding recommendations for bilateral selective ESIs L3-4. He repeatedly interrupted me when trying to answer his questions. The reviewing doctor could not understand why the procedure was being recommended "his last MRI was in 2007." I attempted to convey the rationale for the blocks and he wanted to refer to the Official Disability Guidelines (ODG). As taken from the 2010 online ODG: Epidural steroid injections, diagnostic recommended as indicated below. Diagnostic epidural steroid transforaminal injections are also referred to as selective nerve root blocks, and they were originally developed as a diagnostic technique to determine the level of radicular pain. In studies evaluating the predictive value of selective nerve root blocks, only 5% of appropriate claimants did not receive relief of pain with injections. No more than 2 levels of blocks should be performed on one day. The response to the local anesthetic is considered an important finding in determining nerve root pathology. (CMS, 2004) (Benzon, 2005) When used as a diagnostic technique a small volume of local is used (<1.0 ml) as greater volumes of injectate may spread to adjacent levels. When used for diagnostic purposes the following indications have been recommended: 1) To determine the level of radicular pain, in cases where diagnostic imaging is ambiguous, including the examples below: 2) To help to evaluate a pain generator when physical signs and symptoms differ from that found on imaging studies; 3) To help determine pain generators when there is evidence of multi-level nerve root compression; 4) To help to determine pain generators when clinical findings are consistent with radiculopathy (e.g., Dermatomal distribution) but imaging studies are inconclusive; 5) To help to identify the origin of pain in claimants who have had previous spinal surgery. According to the ODG, it does appear recommendations are heavily weighted toward having imaging studies (does not appear to have to be advanced imaging) prior to having diagnostic blocks. Dr. did say he wanted to re-review ODG prior to submitting his opinion before the deadline which is Monday, 4-26-10. Conversation recorded. Repeat physical exam showed He ambulates with a forward-flexed posture and with right lateral torso translation. In the standing position, the claimant flexes to 50 degrees without discomfort. Lateral bending reveals paraspinal spasms on the right. Extension and rotation is positive, left > right with ipsilateral low back pain. Tenderness is sharp on the left and moderate on the right. There are well-healed scars. In the

seated position, deep tendon reflexes are intact at the knees and intact at the ankles. Straight leg raise is negative. Lesague is negative. Motor strength is 5/5 of the hip flexors, 5/5 of the EHL, and 5/5 with breakaway (because of inability to sustain the contraction) of the left dorsi/everters. Feet are symmetrically warm to touch. Pedal pulses are indiscernible. Peripheral edema is not present. Dermatomal pattern is numb at the left lower leg from the knee to across the dorsum of the left foot. Recommendations: Bilateral selective ESIs at the L3-4 level. The claimant was informed of the potential benefits of supplementing the diet with 2,500 mg Calcium Citrate and 5,000 IU Vitamin D maintenance dose.

On 4-26-10, MD., performed a Utilization Review. Dr. spoke with, PA for Dr. at 16:00 Eastern on 4-23-2010., PA, indicated that the claimant has radicular symptoms. He feels that the claimant would respond to L3-4 epidural steroid injections. The L3-4 level would be the level above the prior surgical fusion. However, the claimant's symptoms do not corroborate with the MRI findings which are 3 years old. There is no objective evidence of L3-4 radiculopathy. The claimant's problem appeared to be symptomatic only. Hence, the necessity of the injections is not substantiated.

5-13-10 Dr. provided a reconsideration request for selective epidural steroid injection L3-L4 bilaterally. Diagnosis: Increased resorption above intact fusion/adjacent segment disease, partial foot drop, and unremitting back pain.

On 5-20-10, MD., performed a Utilization Review. The requested selective epidural steroid injection L3-4 bilaterally times two is not medically necessary based on review of this medical records and phone conversation with physician assistant for Dr.. James explains that this is a gentleman who has had five previous back operations. He has an anteroposterior fusion L4 through S1 and a posterolateral fusion at L3-4. He has undergone two rhizotomies, and nothing done so far has helped his pain. James explains that Dr. believes there may be micro-motion at the L3-4 level and wants to do a selective epidural steroid injection L3-4 to determine whether or not he may need further surgery such as revision of his L3-4 fusion since there was only a posterolateral fusion and not an anteroposterior fusion as well. This reviewer has discussed with the fact that ODG guidelines on epidural steroid injections indicate that claimants should have a radiculopathy documented. explains to this reviewer by telephone that the claimant has numbness down the anterior aspect of his leg from his knee out to the dorsum of his foot, and he has a subjective footdrop with ambulation. This reviewer has discussed with that the nerve root that is present at the L3-4 interspace would not give someone footdrop or numbness out into their toes, and so, therefore, the neurologic deficit that is being used as a justification for the injection is not anatomically related to the level that is being requested for injection. explains that they are just trying to take care of this claimant and determine any pain generators so they can fix him if possible. This reviewer does not understand, from an anatomic point of view, how an epidural steroid injection is going to determine whether or not there is micro-motion and thereby a pain generator that may need to be fixed. explained to this reviewer that this reviewer is misreading the ODG guidelines and that Dr. has a long history of experience in taking care of back claimants, and this is what he wants to do, and he should be allowed to do

this series of injections. In light of the fact that the level of injection does not correlate with the neurologic changes documented in the medical record, coupled with the fact that this reviewer does not believe that a selective epidural steroid injection would give any information as to whether or not the claimant had micro-motion and/or facet-mediated pain at a junctional level, then the requested epidural steroid injections are not necessarily medically necessary. A long conversation was held with, and this reviewer's opinions were clearly discussed. This reviewer asked multiple questions and explained to this reviewer's concerns and opinions. Recommend adverse determination.

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

After reviewing the records, the exam findings used as support for these injections do not correlate with the known anatomy of the spine. Claimant had prior L4/S1 fusion and posterior L3/L4 fusion. Clinical examinations provided do not support an L3/L4 radiculopathy. This claimant has clinical symptoms which would not benefit from epidural injections. Therefore, the request for bilateral L3-L4 epidural steroid injection is not reasonable or medically necessary.

**ODG-TWC, last update 5-18-10 Occupational Disorders of the Low Back – 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.

*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) (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 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)

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.)

**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)