

Notice of Independent Review Decision

**[Date notice sent to all parties]: 06/01/2012**

**IRO CASE #:**

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

Injection(s), Anesthetic Agent and/or Steroid Transforaminal Epidural, with Imaging Guidance (Fluoroscopy or CT); Lumbar or Sacral, Single Level

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

The physician performing this review is Board Certified, American Board of Orthopedic Surgery. He has been in practice since 1998 and is licensed in Texas, Oklahoma, Minnesota and South Dakota.

**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.

Upon independent review, I find the previous adverse determinations should be overturned. Most recent medical records made available dated 05/11/12 clearly describe objective evidence of radiculopathy, including weakness in ankle dorsiflexion on the right side. Earlier documentation, which was the basis of previous reviews, reportedly did not have this information available to them. As a consequence of this, as described below in the ODG guidelines, transforaminal epidural injections would be deemed appropriate.

Additionally, CT/myelogram also should be approved to further delineate the pathology of the L4-5 disk space suggested on previous MRI. Radiology reports indicate metallic artifact in this region on MRI, and *ODG* would support this additional diagnostic imaging with CT/myelogram under these circumstances.

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

Records Received: 26 page fax 05/18/12 Texas Department of Insurance IRO request, 61 pages of documents received via fax on 05/18/12 URA response to disputed services including administrative and medical, 424 pages of documents received via US Mail on 05/22/12 URA response to disputed services including administrative and medical, 4 pages of documents received via fax on 05/30/12 Provider response to disputed services including administrative and medical. Dates of documents range from 02/23/06 (DOI) to 05/18/12

**PATIENT CLINICAL HISTORY [SUMMARY]:**

is a female with back pain and right buttock and leg pain, apparently following an injury on xx/xx/xx. She had undergone an L4 to L5 fusion in 2009, following which she had apparently some improvement of her back pain but gradual worsening of pain into the right leg. Imaging studies and physical examination indicate pain reproduction with straight leg raise test on the right side with weakness of right ankle dorsiflexion motor strength and an absent ankle reflex on the right side. MRI study had shown previous L4-5 fusion with cage and bilateral pedicle screws. There is a question of metallic artifact in the right neural foramen at L4-5 along with the possibility of a large right foraminal disk herniation at that same location. There is previous EMG to suggest bilateral L5-S1 radiculopathy.

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

Upon independent review, I find the previous adverse determinations should be overturned. Most recent medical records made available dated 05/11/12 clearly describe objective evidence of radiculopathy, including weakness in ankle dorsiflexion on the right side. Earlier documentation, which was the basis of previous reviews, reportedly did not have this information available to them. As a consequence of this, as described below in the *ODG* guidelines, transforaminal epidural injections would be deemed appropriate.

Additionally, CT/myelogram also should be approved to further delineate the pathology of the L4-5 disk space suggested on previous MRI. Radiology reports indicate metallic artifact in this region on MRI, and *ODG* would support this additional diagnostic imaging with CT/myelogram under these circumstances.

As the more recent medical records available do document radiculopathy, and the previous MRI study is somewhat equivocal secondary to the presence of metallic artifact, the *ODG* guidelines are met for each of the requested procedures.

The recommendations included in this report are based purely upon review of the medical records made available to me. I have not personally had the opportunity to either meet or examine the patient or to personally view any imaging studies.

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](#)) 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 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](#))

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*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](#)) 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](#))

## 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 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.)

#### CT (computed tomography)

Not recommended except for indications below for CT. ([Slebus, 1988](#)) ([Bigos, 1999](#)) ([ACR, 2000](#)) ([Airaksinen, 2006](#)) ([Chou, 2007](#)) Magnetic resonance imaging has largely replaced computed tomography scanning in the noninvasive evaluation of patients with painful myelopathy because of superior soft tissue resolution and multiplanar capability. ([Seidenwurm, 2000](#)) The new ACP/APS guideline as compared to the old AHCPR guideline is more forceful about the need to avoid specialized diagnostic imaging such as computed tomography (CT) without a clear rationale for doing so. ([Shekelle, 2008](#)) A new meta-analysis of randomized trials finds no benefit to routine lumbar imaging (radiography, MRI, or CT) for low back pain without indications of serious underlying conditions, and recommends that clinicians should refrain from routine, immediate lumbar imaging in these patients. ([Chou-Lancet, 2009](#)) Primary care physicians are making a significant amount of inappropriate referrals for CT and MRI, according to new research published in the *Journal of the American College of Radiology*. There were high rates of inappropriate examinations

for spinal CTs (53%), and for spinal MRIs (35%), including lumbar spine MRI for acute back pain without conservative therapy. ([Lehnert, 2010](#))

**Indications for imaging -- Computed tomography:**

- Thoracic spine trauma: equivocal or positive plain films, no neurological deficit
- Thoracic spine trauma: with neurological deficit
- Lumbar spine trauma: trauma, neurological deficit
- Lumbar spine trauma: seat belt (chance) fracture
- Myelopathy (neurological deficit related to the spinal cord), traumatic
- Myelopathy, infectious disease patient
- Evaluate pars defect not identified on plain x-rays
- Evaluate successful fusion if plain x-rays do not confirm fusion ([Laasonen, 1989](#))

**ODG Criteria for Myelography and CT Myelography:**

1. Demonstration of the site of a cerebrospinal fluid leak (postlumbar puncture headache, postspinal surgery headache, rhinorrhea, or otorrhea).
2. Surgical planning, especially in regard to the nerve roots; a myelogram can show whether surgical treatment is promising in a given case and, if it is, can help in planning surgery.
3. Radiation therapy planning, for tumors involving the bony spine, meninges, nerve roots or spinal cord.
4. Diagnostic evaluation of spinal or basal cisternal disease, and infection involving the bony spine, intervertebral discs, meninges and surrounding soft tissues, or inflammation of the arachnoid membrane that covers the spinal cord.
5. Poor correlation of physical findings with MRI studies.
6. Use of MRI precluded because of:
  - a. Claustrophobia
  - b. Technical issues, e.g., patient size
  - c. Safety reasons, e.g., pacemaker
  - d. Surgical hardware

**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)**