

# Core 400 LLC

An Independent Review Organization

209 Finn St

Lakeway, TX 78734

Phone: (512) 772-2865

Fax: (530) 687-8368

Email: [manager@core400.com](mailto:manager@core400.com)

## NOTICE OF INDEPENDENT REVIEW DECISION

### DATE OF REVIEW:

Sep/13/2010

### IRO CASE #:

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

Outpatient Lumbar Epidural Steroid Injection

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

MD, Board Certified in Physical Medicine and Rehabilitation

Subspecialty Board Certified in Pain Management

### 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

ODG Treatment Guidelines

, 7/27/10, 8/24/10

Group 10/5/09 to 7/27/10

Memorial Hospital 8/20/09 to 10/1/09

3/4/09

ODG TWC article 8/31/10

1/12/10 to 7/26/10

12/31/09

R.N. 1/13/10

M.D. 1/29/10, 8/28/09

MD 2/19/09, 3/4/09

Associates 3/26/09, 4/6/09

Dr. 4/9/09

Spine Specialists, INC 5/7/09, 7/14/09

M.D. 6/8/09, 7/6/09, 7/24/09

### PATIENT CLINICAL HISTORY SUMMARY

This is a man injured on xx/xx/xx while carrying rheobar. He developed low back pain with pain down to the right leg, largely to the posterior thigh and inner leg above the ankle. The MRI on 3/4/09, 3 weeks post injury, showed generalized degenerative changes with mild to moderate stenosis and facet arthropathy in the lumbar spine. He was unable to work. He had a series of 3 lumbar ESIs from 6/8/09 to 7/24/09 that reportedly helped with the pain and numbness. He had a lumbar CT myelogram on 8/20/09 that showed a right paracentral moderate sized disc herniation at L3/4 that did affect the nerve root. This was 27 days after the last ESI. He had an IME by Dr. on 8/28/09, 5 weeks after the last ESI. He continued with pain. Dr. noted the pain interfered with sexual activity. He had 2.5cm atrophy of the right calf, but no other abnormal neurological findings. He was described in several notes as walking with a cane, but the hand used was not described. The request now is for a repeat ESI for pain (numbness).

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

The patient had a series of 3 ESIs in 2009. The ODG does not support this. While the ODG does approve the use of epidural injections in conjunction with active therapy, this was not described by the RSP Physiatry group. Further, lumbar ESIs are justified for radiculopathy based upon the AMA Guides. Repeat therapeutic blocks are only justified, per the ODG, if there is at least 50-70% relief for 6-8 weeks. The qualitative relief was not described in the records. The patient remained symptomatic at the IME which was held 5 weeks after the last of the "series of 3" ESIs." This showed he did not meet the minimum requirements for the ESIs to be repeated. Criteria for the use of Epidural steroid injections has not been met. The reviewer finds that there is no medical necessity for Outpatient Lumbar Epidural Steroid Injection.

#### 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) (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.)

#### The AMA Guides

“...For reflex abnormalities to be considered valid, the involved and normal limb(s) should show marked asymmetry...”

#### “Weakness and Loss of Sensation

“To be valid, the sensory findings must be in a strict anatomic distribution, i.e follow dermatomal patterns...Motor findings should be consistent with the affected nerve structures(s). Significant, long standing weakness is usually accompanied by atrophy.”

#### “Radiculopathy

Radiculopathy for the purposes of the Guides is defined as significant alteration in the function of a nerve root or nerve roots and is usually caused by pressure on one or several nerve roots. The diagnosis requires a dermatomal distribution of pain, numbness, and/or paresthesias in a dermatomal distribution. The diagnosis of herniated disc must be substantiated by an appropriate finding on the imaging study. The presence of findings on a imaging study in and of itself does not make the diagnosis of radiculopathy. There must also be evidence as described above. “

#### “Atrophy

Atrophy is measured with a tape measure at identical levels on both limbs. For reasons or reproducibility, the difference in circumference should be 2cm or greater in the thigh and 1cm or greater in the arm, forearm, or leg...”

#### “Electrodiagnostic verification of Radiculopathy

Unequivocal electrodiagnostic evidence of acute nerve root pathology includes the presence of multiple positive sharp waves or fibrillation potentials in muscles innervated by one nerve root. However the quality of the person performing and interpreting the study is critical. Electromyography should be performed only by a licensed physician qualified by reason of education, training and experience in these procedures. Electromyography does not detect all compressive radiculopathies and cannot determine the cause of the nerve root pathology. On the other hand, electromyography can detect noncompressive radiculopathies, which are not identified by imaging studies. “

AMA Guides to the Evaluation of Permanent Impairment. 5th edition.

#### **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 REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**  
**AMA Guides to the Evaluation of Permanent Impairment. 5th edition**