

Clear Resolutions Inc.

An Independent Review Organization
7301 RANCH RD 620 N, STE 155-199A
Austin, TX 78726
Phone: (512) 772-4390
Fax: (512) 519-7316
Email: resolutions.manager@cri-iro.com

NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Nov/02/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

C5-C6 ESI, Transforaminal under fluoroscopic and IV Sedation;

Right L4-L5, L5-S1 transforaminal ESI, under fluoroscopic and IV sedation

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

MD, Board Certified in Physical Medicine and Rehabilitation
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 Guidelines and Treatment Guidelines
Adverse Determination Letters, 8/14/09, 8/27/09
MD, 9/25/09, 7/27/09
MRI Lumbar Spine, 12/22/08
MRI Cervical Spine, 12/22/08
MD, 9/22/09, 8/11/09, 7/7/09, 6/23/09, 12/30/08
MD, 1/29/09

PATIENT CLINICAL HISTORY SUMMARY

According to the records, this female patient was injured on xx/xx/xx. She developed neck and low back pain. She had cervical and lumbar MRIs on 12/22/08. The cervical study showed spondylosis with a C6/7 protrusion with severe left foraminal stenosis. There was a disc bulge and right foraminal narrowing at C5/6. The lumbar MRI showed a small L4/5 disc herniation and spinal stenosis at L3/4. Dr. 's exam on 7/27/09 described pain with cervical motion and a positive Spurling sign to the left C5/6 dermatome. He also described right L4/5 dermatomal symptoms on SLR. He did not describe any further neurological findings. He requested an EMG. Dr. noted pain with motion, a positive Spurling sign, and pain with SLR.

He noted on 7/7/09 and 8/11/09 that the “lower extremities are neurologically intact.” There were no upper extremity reports made available for this review. Dr. (1/19/09) described normal motor strength in the upper and lower extremities, symmetrical reflexes, and negative SLR.

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

The requests for the cervical and epidural injections are based on the patient’s symptoms and radiological findings. The ODG, based upon evidence-based medicine, has certain requirements. While the symptoms of radiculitis and radiculopathy can be similar, only the radiculopathy can be approved for ESIs under select circumstances. There first must be a dermatomal distribution of the symptoms. This may be considered positive based upon the SLR and Spurling maneuvers even if it was not clear that the dermatomal symptoms were present before the provoking maneuvers.

The physical examination of this patient did not demonstrate any neurological findings in the cervical spine. There were no electrodiagnostic studies. In the absence of any objective neurological loss, a cervical radiculopathy is not present. Therefore, the reviewer finds that medical necessity is not met for C5-C6 ESI, Transforaminal under fluoroscopic and IV Sedation.

The lumbar study also requires the presence of a dermatomal distribution of the pain and abnormal radiological findings and abnormal neurological exam. The latter, as described in the AMA guides, includes abnormal EMG, atrophy, abnormal motor and sensory examinations. The physical examinations, other than a positive SLR, were reported as normal. An EMG was requested, but apparently was not performed. Abnormal SLR is not an accepted criteria for the diagnosis of a radiculopathy. In the absence of the required neurological findings, the diagnosis of a lumbar radiculopathy has not been established. Therefore, a lumbar ESI does not meet the ODG criteria in this patient’s case. The reviewer finds that medical necessity is not met for Right L4-L5, L5-S1 transforaminal ESI, under fluoroscopic and IV sedation.

The reviewer finds that medical necessity does not exist for C5-C6 ESI, Transforaminal under fluoroscopic and IV Sedation; Right L4-L5, L5-S1 transforaminal ESI, under fluoroscopic and IV sedation.

Cervical, Epidural steroid injection (ESI)

Recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy). See specific criteria for use below. In a recent Cochrane review, there was one study that reported improvement in pain and function at four weeks and also one year in individuals with chronic neck pain with radiation. (Peloso-Cochrane, 2006) (Peloso, 2005) Other reviews have reported moderate short-term and long-term evidence of success in managing cervical radiculopathy with interlaminar ESIs. (Stav, 1993) (Castagnera, 1994) Some have also reported moderate evidence of management of cervical nerve root pain using a transforaminal approach. (Bush, 1996) (Cyteval, 2004) A recent retrospective review of interlaminar cervical ESIs found that approximately two-thirds of patients with symptomatic cervical radiculopathy from disc herniation were able to avoid surgery for up to 1 year with treatment. Success rate was improved with earlier injection (< 100 days from diagnosis). (Lin, 2006) There have been recent case reports of cerebellar infarct and brainstem herniation as well as spinal cord infarction after cervical transforaminal injection. (Beckman, 2006) (Ludwig, 2005) Quadriplegia with a cervical ESI at C6-7 has also been noted (Bose, 2005) and the American Society of Anesthesiologists Closed Claims Project database revealed 9 deaths or cases of brain injury after cervical ESI (1970-1999). (Fitzgibbon, 2004) These reports were in contrast to a retrospective review of 1,036 injections that showed that there were no catastrophic complications with the procedure. (Ma, 2005)

The American Academy of Neurology recently concluded that epidural steroid injections may

lead to an improvement in radicular lumbosacral 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, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. (Armon, 2007) There is evidence for short-term symptomatic improvement of radicular symptoms with epidural or selective root injections with corticosteroids, but these treatments did not appear to decrease the rate of open surgery. (Haldeman, 2008) (Benyamin, 2009) See the Low Back Chapter for more information and references

Criteria for the use of Epidural steroid injections, therapeutic

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 by physical examination and 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) for guidance
- (4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at 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) In the therapeutic phase, repeat blocks should only be offered if there is at least 50% pain relief for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year
- (8) Repeat injections should be based on continued objective documented pain and function response
- (9) Current research does not support a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections
- (10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or stellate ganglion blocks or 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

Criteria for the use of Epidural steroid injections, diagnostic

To determine the level of radicular pain, in cases where diagnostic imaging is ambiguous, including the examples below:

- (1) To help to evaluate a pain generator when physical signs and symptoms differ from that found on imaging studies
- (2) To help to determine pain generators when there is evidence of multi-level nerve root compression
- (3) To help to determine pain generators when clinical findings are suggestive of

radiculopathy (e.g. dermatomal distribution) but imaging studies are inconclusive

(4) To help to identify the origin of pain in patients who have had previous spinal surgery.

Lumbar

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....

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 of 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. “

Page 382-382. 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)

Page 382-382. AMA Guides to the Evaluation of Permanent Impairment. 5th edition