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Notice of Independent Review Decision

DATE OF REVIEW: October 2, 2007

IRO CASE #:

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

This case was reviewed by a Pain Management Doctor, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

L4-5 epidural steroid injection

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

Upheld (Agree)

REVIEW OF RECORDS

- o Submitted medical records were reviewed in their entirety.
- o July 31, 2007 utilization review letter from
- o August 28, 2007 utilization review letter from
- o July 26, 2007 chart notes by, M.D.
- o June 7, 2007 designated doctor evaluation report by, M.D.
- o June 7, 2007 work status report by, M.D.
- o June 8, 2007 lumbar MRI report by -, M.D.
- o June 6, 2007 report by, D.C.
- o June 20, 2007 referral letter by, D.C.

CLINICAL HISTORY SUMMARY

The patient sustained an industrial injury on xx/xx/xx involving the lumbar spine. An August 31, 2007 utilization review report regarding a request for L4-5 epidural steroid injection states the following: The patient is a male who complains of mid back pain that developed after twisting. He had completed six sessions of physical therapy. A July 26, 2007 report indicates a visual analog scale score of 9/10 with documentation of limited range of motion, pain primarily in the midthoracic spine, and pain radiating to the feet and tailbone. The reviewer stated that there is no documentation of objective findings indicative of neuro-compromise or radiculopathy. The report provides an opinion that the patient had not had the benefit of sufficient conservative management with physical therapy, self-care, and a home exercise program. The report states that there is a discrepancy/inconsistency between the anatomical location of the pain and the anatomical location chosen for the injection. Therefore, a non-certification was rendered for the request of L4-5 epidural steroid injection.

The request was again reviewed on August 28, 2007 by another reviewer. This report also renders a non-certification. This report notes that the claimant's neurologic exam is noted to be negative. An MRI dated June 8, 2007 is essentially negative. The reflexes are noted to be within normal limits and palpation of the claimant is within normal limits. The reviewer stated that there is no clinical evidence of radiculopathy to support the medical necessity of a lumbar epidural steroid injection.

A lumbar spine MRI was performed on June 8, 2007 and was found to be normal. He was examined on June 6, 2007 with relevant findings of positive Valsalva test, positive straight leg raise on the right at 35°, pain worsened over the right sacrum with palpation, symmetric lower extremity deep tendon reflexes, L4-5 hypoesthesia on the right, and normal muscle strength.

A designated doctor evaluation was performed on June 7, 2007. Relevant examination findings included normal reflexes, heel/toe walk with difficulty, bilateral 65° straight leg raise, decreased sensation in the right lower extremity throughout compared to the left, and 5/5 motor strength in the lower extremity. It was deemed that the patient had not yet achieved maximum medical improvement.

On July 26, 2007 the patient was examined and was found to demonstrate limited active range of motion and spasm of the left and right lumbar paraspinal muscles. It is not clear if a lower extremity neurologic examination was performed.

ANALYSIS AND EXPLANATION OF DECISION

According to the Official Disability Guidelines, criteria for lumbar epidural steroid injections include documentation of radiculopathy. Upon examination on June 6, 2007, the patient demonstrated L4-5 hypoesthesia on the right. In the designated doctor examination of June 7, 2007, the patient subjectively reported that he has decreased sensation in the entire right lower extremity. The designated doctor recommended an electrodiagnostic study to further investigate this hypoesthesia. Although the records reflect that the patient has possible hypoesthesia in the right lower extremity, the lumbar spine MRI was entirely normal. The MRI did not demonstrate evidence of central canal stenosis or neural foraminal stenosis to cause concern for lumbar nerve root impingement. The medical records fail to document results of an EMG/NCV that could help clarify the discrepancy between imaging findings and examination findings. Without a clear correlation between imaging, examination, and/or EMG/NCV, radiculopathy has not been established. Without concern for true lumbar radiculopathy, lumbar epidural steroid injections are not indicated. In addition, the patient is not yet a surgical candidate for which the ACOEM guidelines recommend prior to consideration for epidural steroid injections. Therefore, my determination is to uphold the decision to non-certify the request for an L4-5 epidural steroid injection.

The IRO's decision is consistent with the following guidelines:

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

- _x_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
- _x_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

According to ACOEM guidelines, page 309, epidural steroid injections are an option to treat patients with low back pain who demonstrate evidence of radiculopathy on physical examination in order to avoid surgery. Although epidural steroid injections may afford short-term improvement in patients with radicular symptoms, these injections offer no significant long-term functional benefit, nor do they reduce the need for surgery." Epidural injections for back pain without radiculopathy are not recommended.

Epidural steroid injections (ESIs) are recommended as a possible option for short-term treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy). 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. 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)

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. (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) 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)

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.

Criteria for the use of Epidural steroid injections:

Note: The purpose of ESI is to reduce pain and inflammation, restoring range of motion and 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) 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 two injections should be performed. A second block is not recommended if there is inadequate response to the first block. 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. To be considered successful after this initial use of a block/blocks there should be documentation of at least 50-70% relief of pain from baseline and evidence of improved function for at least six to eight weeks after delivery.

(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 (the phase after the initial block/blocks were given and found to produce pain relief), repeat blocks should only be offered if there is at least 50-70% pain relief for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. (CMS, 2004) (Boswell, 2007)

(8) Repeat injections should be based on continued objective documented pain 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 as this may lead to improper diagnosis or unnecessary treatment.

ODG Epidural injections - Series of three injections

Not recommended. Original recommendations that suggested a "series of three injections" generally did so prior to the advent of fluoroscopic guidance. These previous recommendations were based primarily on case studies and anecdotal evidence (Class IV and V data). (Abram, 1999) (Warr, 1972) (Hickey, 1987) Contemporary research studies with higher levels of evidence (including two controlled trials) have suggested that on average, two or less ESIs are required in patients with successful outcomes from the use of ESIs to treat disc related lumbar radiculopathy. (Lutz, 1998) (Vad, 2002) (Riew, 2000) While all of these latter studies have utilized repeat injections, there has been no evidence-based research to explain why this practice is required, or the mechanism for possible action. Since the introduction of fluoroscopically guided ESIs, it has been suggested that there is little evidence to repeat an accurately placed epidural injection in the presence of mono-radiculopathy, regardless of whether there is partial or no response. (McLain, 2005) A recent randomized controlled trial of blind ESIs found no evidence to support repeat injections, because at six weeks there was no significant difference found between the ESI group and a placebo controlled group in terms of any measured parameter. (Price, 2005) A repeat injection has been suggested if there is question of accurate dermatomal diagnosis, if pain may be secondary to a different generator, or in the case of multilevel pathology. (McLain, 2005) With fluoroscopic guidance, there is little support to do a second epidural if there is no response to the first injection. There is little to no guidance in current literature to suggest the basis for the recommendation of a third ESI, and the routine use of this practice is not recommended.