MEDICAL CONTESTED CASE HEARING NO. 09181
M6-09-17145-01

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and Rules of the Division of Workers' Compensation adopted thereunder.

ISSUE

A medical pre-hearing was set on February 9, 2008 and continued at Claimant's request, then held on March 10, 2009, with the medical contested case hearing held on April 9, 2009, to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that the Claimant is not entitled to referral to a pain management doctor for evaluation for either facet or ESI injections for the compensable injury of _____?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by JBT, ombudsman. Respondent/Carrier appeared and was represented by PS, attorney.

BACKGROUND INFORMATION

The Petitioner/Claimant testified that she was a Load Agent (Weight and Balance) for the Employer for over 36 years. She sustained a compensable injury to her low back on _____ and underwent conservative treatment to include a series of three epidural steroid injections (ESIs) that provided pain relief for a few months. On June 3, 1999 Dr. K performed surgery to the Petitioner/Claimant's lumbar spine at L4-L5. The Petitioner/Claimant stated that gave her pain relief for one and one-half years. However, the pain returned and in 2001 she underwent a second series of ESIs with concomitant pain relief for several years. Again, the pain returned and a third series of ESIs was performed between December 2005 and February 2006. The Petitioner/Claimant had relief from pain until January 2008, sought treatment for that pain, and requested from Dr. T, another series of ESIs because of their past efficacy. Dr. T made the request for the referral to a pain management doctor for evaluation for either facet or ESI injections.

The first utilization reviewer denied the request because there was no documentation that the pain symptoms were referable to a lumbar radiculopathy or lumbar facet mediated pain syndrome. The reviewer also stated the *OFFICIAL DISABILITY GUIDELINES* (*ODG*) do not support therapeutic injections for symptoms of a chronic pain syndrome.

The second utilization reviewer mistakenly stated the Petitioner/Claimant had not had any spinal surgery, but, none the less, pointed out the injury was over 11 years old. The reviewer noted that the *ODG* does not support treatment this far removed from the original injury.

The IRO reviewer upheld the Respondent/Carrier's denial of the referral to a pain management doctor for evaluation for either facet or ESI injections. This reviewer agreed with the second utilization reviewer that ESI or facet blocks, 11 years post injury, were not supported by the *ODG*. The IRO reviewer also stated that the treating physician noted the radiculopathy, in terms of a neurological examination, was not documented.[1] The IRO reviewer concluded the proposed treatment did not meet medical necessity.

DISCUSSION

Texas Labor Code Section 408.021 provides that an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. **Section 401.011(22-a)** defines health care reasonably required as "health care that is clinically appropriate and considered effective for the injured employee's injury and provided in accordance with best practices consistent with: (A) evidence based medicine; or (B) if that evidence is not available, generally accepted standards of medical practice recognized in the medical community." "Evidence based medicine" is further defined, by **Section 401.011(18-a)** as the use of the current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts, and treatment and practice guidelines in making decisions about the care of individual patients.

The Division of Workers' Compensation has adopted treatment guidelines under Division **Rule 137.100**. That rule requires that health care providers provide treatment in accordance with the current edition of the *Official Disability Guidelines (ODG),* and treatment provided pursuant to those guidelines is presumed to be health care reasonably required as mandated by the above-referenced sections of the **Texas Labor Code**.

Therefore, in any dispute regarding medical necessity, the initial inquiry is whether the proposed treatment is consistent with the *ODG*.

On the date of this medical contested case hearing, the ODG provides the following with regard to facet joint intra-articular injections (therapeutic blocks) for the treatment of the low back:

> "Under study. Current evidence is conflicting as to this procedure and at this time no more than one therapeutic intra-articular block is suggested. If successful (pain relief of at least 50% for a duration of at least 6 weeks), the recommendation is to proceed to a medial branch diagnostic block and subsequent neurotomy (if the medial branch block is positive). If a therapeutic facet joint block is undertaken, it is suggested that it be used in consort with other evidence based conservative care (activity, exercise, etc.) to facilitate functional improvement. (Dreyfuss, 2003) (Colorado, 2001) (Manchikanti , 2003) (Boswell, 2005) See Segmental rigidity (diagnosis). In spite of the overwhelming lack of evidence for the long-term effectiveness of intra-articular steroid facet joint injections, this remains a popular treatment modality. Intra-articular facet joint injections have been popularly utilized as a therapeutic procedure, but are not currently recommended as a treatment modality in most evidence-based reviews

[1] Responding to the first utilization review, on September 9, 2008, Dr. T wrote, "I do believe that the patient has a neurologic examination which is basically unremarkable, without evidence of overt radiculopathy or evidence of nerve damage."

as their benefit remains controversial. The therapeutic facet joint injections described here are injections of a steroid (combined with an anesthetic agent) into the facet joint under fluoroscopic guidance to provide temporary pain relief. (Dreyfuss, 2003) (Nelemans-Cochrane, 2000) (Carette, 1991) (Nelemans, 2001) (Slipman, 2003) (van Tulder, 2006) (Colorado, 2001) (ICSI, 2004) (Bogduk, 2005) (Resnick, 2005) (Airaksinen, 2006) 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)

Systematic reviews endorsing therapeutic intra-articular facet blocks:

Pain Physician, 2005: In 2005 there were two positive systematic reviews published in *Pain Physician* that stated that the evidence was moderate for short-term and limited for long-term improvement using this intervention. (Boswell, 2005) (Boswell, 2005) These results were based, in part, on five observational studies. These non-controlled studies were confounded by variables such as lack of confirmation of diagnosis by dual blocks and recording of subjective pain relief, or with measures that fell under verbal rating and/or pain relief labels (measures that have been reported to have problems with validity). (Edwards, 2005)

Pain Physician, 2007: Pain Physician again published a systematic review on this subject in 2007 and added one additional randomized trial comparing intra-articular injections with sodium hyaluronate to blocks with triamcinolone acetonide. The diagnosis of facet osteoarthritis was made radiographically. (Fuchs, 2005) Two randomized trials were not included, in part, as they failed to include controlled diagnostic blocks. These latter articles were negative toward the use of therapeutic facet blocks. (Lilius, 1989) (Marks, 1992) An observational non-controlled study that had positive results was included that made the diagnosis of lumbar facet syndrome based on clinical assessment of “pseudoradicular” lumbar pain, including evidence of an increase of pain in the morning and with excessive stress and exercise (no diagnostic blocks were performed). (Schulte, 2006) With the inclusion of these two articles the conclusion was changed so that the evidence for lumbar intra-articular injections was “moderate” for both short-and long-term improvement of low back pain. (Boswell2, 2007)

Complications: These included suppression of the hypothalamic-pituitary-adrenal axis for up to 4 weeks due to steroids with resultant elevated glucose levels for less than a week. (Ward, 2002) There have been rare cases of infection (septic arthritis, epidural abscess and meningitis). (Cohen, 2007) Complications from needle placement include dural puncture, spinal cord trauma, intraartierial and intravenous injection, spinal anesthesia, neural trauma, pneumothorax, and hematoma formation. (Boswell2, 2007)

Single photon emission computed tomography: (bone scintigraphy, SPECT scan): Not recommended although recent research is promising. This technique is recommended based on the ability of radionuclide bone scintigraphy to detect areas of increased function, depicting synovial areas of inflammation as well as degenerative changes. Thirteen of 15 patients had a > 1 standard deviation pain score improvement at 1 month versus 7 of 32 patients with a negative or no scan. The benefit of the injection lasted for approximately 3 months and did not persist to 6 months. (Pneumaticos2, 2006) See also Facet joint diagnostic blocks (injections); Facet joint pain, signs & symptoms; Facet joint radiofrequency neurotomy; Facet joint medial

branch blocks (therapeutic injections); & Segmental rigidity (diagnosis). Also see Neck Chapter and Pain Chapter."

"Criteria for use of therapeutic intra-articular and medial branch blocks, are as follows:

1. No more than one therapeutic intra-articular block is recommended.
2. There should be no evidence of radicular pain, spinal stenosis, or previous fusion.
3. If successful (initial pain relief of 70%, plus pain relief of at least 50% for a duration of at least 6 weeks), the recommendation is to proceed to a medial branch diagnostic block and subsequent neurotomy (if the medial branch block is positive).
4. No more than 2 joint levels may be blocked at any one time.
5. There should be evidence of a formal plan of additional evidence-based activity and exercise in addition to facet joint injection therapy."

On the date of this medical contested case hearing, the ODG provides the following with regard to epidural steroid injections (therapeutic injections) for the treatment of the low back:

"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)

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) (Delport, 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) 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)"

"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.)"

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) There does not appear to be any evidence to support the current common practice of a series of injections. (Novak, 2008) 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) There is a lack of support for 2nd epidural steroid injection if the 1st is not effective. (Cuckler, 1985) 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.

Petitioner/Claimant, as the party appealing the IRO decision, has the burden of overcoming the decision issued by the IRO by a preponderance of the evidence based medical evidence. The IRO decision is based on the ODG and notes both lack of propinquity between the date of injury and the proposed treatment and the lack of radiculopathy documented by neurological examination. The Petitioner/Claimant has failed to present any evidence based medical evidence from a competent source to overcome the IRO's decision. The preponderance of the evidence based medical evidence is not contrary to the IRO decision.

The rules requiring preauthorization are set out in Texas Department of Insurance, Division of Workers' Compensation (Division) Rule 134.600(p). Although Rule 134.600(p)(2) requires preauthorization for outpatient surgical or ambulatory surgical services as defined in subsection (a) of this section, there is no requirement for preauthorization for a referral to a pain management doctor for evaluation.

A referral by the treating doctor to a pain management doctor for evaluation is valid because the preauthorization procedures do not apply to that referral. After evaluation by a pain management doctor, there may well be some other type of treatment, other than facet or ESI injections, that would be beneficial to the Claimant; Therefore, the IRO decision must be bifurcated.

The preauthorization process and that part of the IRO decision pertaining to the referral to a pain management doctor for evaluation was improperly conducted and is hereby set aside. The preauthorization process and that part of the IRO decision pertaining to the facet and ESI injections was properly conducted, is valid, and is not contrary to the preponderance of the evidence based medicine.

Even though all the evidence presented was not discussed, it was considered. The Findings of Fact and Conclusions of Law are based on all of the evidence presented.

FINDINGS OF FACT

1. The parties stipulated to the following facts:

   A. Venue is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.

   B. On _____, Claimant/Petitioner was the employee of (Employer), and sustained a compensable injury..

   C. The IRO determined that the requested services were not reasonable and necessary health care for the compensable injury of _____.

2. Respondent/Carrier delivered to Petitioner/Claimant a single document stating the true corporate name of Respondent/Carrier, and the name and street address of Respondent/Carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.

3. That part of the IRO decision pertaining to the request for a referral to a pain management doctor for evaluation is not the proper subject of the preauthorization process and the IRO has no authority to review this request.

4. A referral to a pain management doctor for evaluation is health care reasonably required for the compensable injury of _____.

5. That part of the IRO decision pertaining to the facet or ESI injections is the proper subject of the preauthorization process and the IRO has authority to review this request.

6. The facet or ESI injections are not health care reasonably required for the compensable injury of _____.

CONCLUSIONS OF LAW

1. The Texas Department of Insurance, Division of Workers' Compensation, has jurisdiction to hear this case.

2. Venue is proper in the (City) Field Office.

3. That part of the IRO decision pertaining to a referral to a pain management doctor for evaluation is set aside, as it was not authorized by the Texas Workers' Compensation Act or the Division rules.

4. The preponderance of the evidence is not contrary to the decision of the IRO that facet and ESI injections are not health care reasonably required for the compensable injury of _____.

DECISION

The Petitioner/Claimant is entitled to a referral to a pain management doctor for evaluation for the compensable injury of _____. The Petitioner/Claimant is not entitled to facet or ESI injections for the compensable injury of _____.

ORDER

Carrier is ordered to pay benefits in accordance with this decision, the Texas Workers' Compensation Act, and the Commissioner's Rules. Accrued but unpaid income benefits, if any, shall be paid in a lump sum together with interest as provided by law.

The true corporate name of the insurance carrier is **THE INSURANCE COMPANY OF THE STATE OF PENNSYLVANIA** and the name and address of its registered agent for service of process is

CORPORATION SERVICES COMPANY
701 BRAZOS STREET, SUITE 1050
AUSTIN, TEXAS 78701

Signed this 13th day of April, 2009.

David Paul Weston
Hearing Officer