

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.

ISSUES

A contested case hearing was held on March 16, 2010, to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that a lumbar caudal epidural steroid injection is not reasonably required health care for the compensable injury of _____?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by RH, ombudsman. Respondent/Carrier appeared and was represented by JT, attorney.

BACKGROUND INFORMATION

Claimant sustained a compensable injury in ____ while attempting to step up onto a dock at the (Self-Insured). Claimant testified that her compensable injuries included her neck, shoulder, and low back. She began treating with Dr. F, M.D. sometime in 2001. Medical records indicate that Dr. F has been administering lumbar caudal epidural steroid injections (ESI) to Claimant on an irregular basis since August 2, 2004. The most recently documented ESI was administered on February 9, 2009. On October 6, 2009, Dr. F requested preauthorization for another ESI.

On October 8, 2009, Dr. F, Carrier's utilization review agent, sent Dr. F notice that preauthorization for the ESI was denied because documentation of the outcome of Claimant's last ESI had not been provided. Dr. F made notations on Dr. F's October 8, 2009, Notice of Utilization Review Findings (URA notice), asserting that Claimant met all of the Official Disability Guidelines (ODG) criteria listed in notice, and faxed it back to Dr. F. Dr. F acknowledged receipt of the request for reconsideration on October 8, 2009.

On October 15, 2009, Dr. F sent a second URA notice to Dr. F, advising him that the prior denial of preauthorization had been upheld because the degree and duration of the pain relief from the February 9, 2009, ESI had not been documented and there was no documented left lower extremity reflex abnormality or motor impairment in the L5 myotome. The second URA notice stated that the request for preauthorization was denied because Claimant "does not demonstrate clear objective findings of lumbosacral radiculopathy according to the AMA guides, 5th edition." The second URA notice also noted that Dr. F had not specified the level for the intended lumbar ESI. Carrier's denial was appealed under Texas Labor Code Section 413.031(d) and Division Rule 133.308(a).

The Department appointed (Independent Review Organization) as the Independent Review Organization (IRO) in this matter. (Independent Review Organization) issued a Notice of Independent Review Decision on December 9, 2009, stating that the case had been reviewed by a (Independent Review Organization) Physician Reviewer certified by the American Board of Physical Medicine & Rehabilitation with a subspecialty certification in Pain Management. The IRO physician reviewer upheld Carrier's denial of the requested ESI. The IRO physician reviewer stated that the medical records provided for review failed to document that the February 9, 2009, injection had met the ODG criteria for repeat ESI injections, that there was no assessment of the degree or duration of the relief following the February 9, 2009, ESI, and that medical necessity for the repeat injection had not been established. Claimant appealed the IRO decision pursuant to Division Rule 133.308(t).

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. Health care reasonably required is further defined in Texas Labor Code Section 401.011 (22a) 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 evidence based medicine or, if evidence based medicine is not available, then generally accepted standards of medical practice recognized in the medical community. Health care under the Texas Workers' Compensation system must be consistent with evidence based medicine if that evidence is available. Evidence based medicine is defined in Texas Labor Code Section 401.011 (18a) to be 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. The Commissioner of the Division of Workers' compensation is required to adopt treatment guidelines that are evidence-based, scientifically valid, outcome-focused and designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care. Texas Labor Code Section 413.011(e). Medical services consistent with the medical policies and fee guidelines adopted by the commissioner are presumed reasonable in accordance with Texas Labor Code Section 413.017(1).

In accordance with the above statutory guidance, the Division of Workers' Compensation has adopted treatment guidelines by Division Rule 137.100. This rule directs health care providers to provide treatment in accordance with the current edition of the ODG, and such treatment is presumed to be health care reasonably required as defined in the Texas Labor Code. Thus, the focus of any health care dispute starts with the health care set out in the ODG.

It is undisputed that repeat therapeutic ESIs are addressed by the current edition of the ODG (updated March 4, 2010) for treatment of low back pain. The Low Back section of the current ODG Treatment Guidelines provides the following guidance:

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.)

In accordance with Division Rule 133.308 (t), "A decision issued by an IRO is not considered an agency decision and neither the Department nor the Division are considered parties to an appeal. In a Contested Case Hearing (CCH), the party appealing the IRO decision has the burden of overcoming the decision issued by an IRO by a preponderance of evidence-based medical evidence." The URA doctors, the IRO physician reviewer, and Dr. F all rely upon the ODG and assert that the information in the ODG either supports or contravenes the request for a repeat therapeutic ESI.

As previously noted, when Dr. F requested reconsideration of the first denial of preauthorization, he asserted that Claimant met all of the criteria under the ODG for a repeat ESI. In doing so, he wrote "Yes" next to the criteria numbers 1, 2, 4, 5, 7, 8, 10 and 11 and "OK" next to criterion number 9. The criteria addressed by Dr. F in response to Carrier's initial denial are the same as set forth in the current edition of the ODG.

In determining the weight to be given to the opinion of an expert, a trier of fact must first determine if the expert is qualified to offer it. Dr. F and the IRO physician reviewer were both identified as pain management specialists and are deemed by the hearing officer to be qualified to offer their respective opinions on the appropriateness of the repeat lumbar ESI at issue herein.

The trier of fact must then, however, determine whether the opinion is relevant to the issues at bar and whether it is based upon a solid foundation. An expert's bald assurance of validity is not enough. *See Black vs. Food Lion, Inc.*, 171 F.3rd 308 (5th Cir. 1999); *E.I. Du Pont De Nemours and Company, Inc. v. Robinson*, 923 S.W.2d 549 (Tex. 1995). Evidence is considered in terms of (1) general acceptance of the theory and technique by the relevant scientific community; (2) the expert's qualifications; (3) the existence of literature supporting or rejecting the theory; (4) the technique's potential rate of error; (5) the availability of other experts to test and evaluate the technique; and (7) the experience and skill of the person who applied the technique on the occasion in question. *Kelly v. State*, 792 S.W.2d 579 (Tex.App.-Fort Worth 1990). A medical doctor is not automatically qualified as an expert on every medical question and an unsupported opinion has little, if any, weight. *Black v. Food Lion, Inc.*, 171 F.3rd 308 (5th Cir. 1999).

In a report dated January 18, 2010, Dr. F stated:

... I have been treating [Claimant] for [her] on-the-job injury over the past several years and with ESIs sporadically administered she has had some pain relief.

...

The carrier has denied [Claimant's] ESI that I requested more recently and sighted (sic) ODG and criteria that I used.

... this patient has a severe spinal stenosis and ESIs are known to play a role in treating that. She is a surgical candidate, but has many other medical issues, which preclude that approach at this state. Furthermore, my office notes of September 10, 2008, clearly documented that she did get excellent relief from the lumbar ESI that were (sic) administered sometime before that but all the pain had come back.

Dr. F' records indicate that the ESI prior to the office visit of September 9, 2008, had been administered on August 22, 2008. Relief from that injection lasted less than 18 days. Dr. F administered another ESI on February 9, 2009. Several weeks later, Claimant was examined by Dr. R, DO, a spinal surgeon. Dr. R's office note of February 27, 2009, states that Claimant reported she was "still having severe low back pain with [bilateral] radiculopathy ... left more so than right." Claimant told him she was receiving injections from Dr. F, but they only helped temporarily.

Dr. F did not provide a response to the IRO report, nor did Claimant offer into evidence any medical records not previously provided to the IRO physician reviewer. The ODG directly contradicts Dr. F' assertion that ESIs are known to play a role in the treatment of severe stenosis and the medical records in evidence indicate that Claimant received only a short period of pain relief from the most recent ESIs administered in late 2008 and early 2009. Dr. F gave no rationale other than extended pain relief that allowed for a reduction in medication use for utilizing ESIs for the treatment of Claimant's chronic pain. In light of the limited duration of the effects of the most recent ESIs, Claimant has failed to establish that the preponderance of the evidence-based medical evidence is contrary to the decision of the IRO.

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:
2.
 - A. Venue is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.
 - B. On _____, Claimant was the employee of (Self-Insured), Employer.
 - C. Claimant sustained a compensable injury on _____.

- D. The Texas Department of Insurance appointed (Independent Review Organization) as the Independent Review Organization to review Carrier's denial of the requested lumbar epidural steroid injection.
 - E. The Independent Review Organization upheld Carrier's denial of the requested lumbar epidural steroid injection.
2. Carrier delivered to Claimant a single document stating the true corporate name of Carrier, and the name and street address of Carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.
 3. Claimant received some short term pain relief from ESIs administered on August 22, 2008, and February 9, 2009, but pain relief from those injections was not objectively quantified and lasted for less than three weeks.
 4. A repeat lumbar caudal epidural steroid injection is not reasonably required medical treatment 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. The preponderance of the evidence is not contrary to the decision of IRO that a lumbar caudal epidural steroid injection is not reasonably required medical care for the compensable injury of _____.

DECISION

Claimant is not entitled to a lumbar caudal epidural steroid injection for the compensable injury of _____.

ORDER

Carrier is not liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **(SELF-INSURED)** and the name and address of its registered agent for service of process is

(SELF-INSURED)
JB, EXECUTIVE DIRECTOR

Mailing Address
(P.O. BOX)
(CITY), TX (ZIP CODE)

Physical Address
(STREET ADDRESS)
(BUILDING)
(FLOOR)
(CITY), TX (ZIP CODE)

Signed this 18th day of March, 2010.

KENNETH A. HUCHTON
Hearing Officer