

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 August 23, 2010, to decide the following disputed issue:

Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that Claimant is not entitled to an outpatient lumbar epidural steroid injection and lumbosacral orthosis back brace for the compensable injury of _____?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by SD, ombudsman. Respondent/Carrier appeared and was represented by BJ, attorney.

BACKGROUND INFORMATION

Claimant, a truck driver, sustained a compensable injury on _____. Claimant claimed that his compensable injury was to his low back. Claimant has not undergone lumbar surgery. Dr. H, D.O., diagnosed Claimant with a lumbar strain with radiculopathy, recommended Claimant undergo lumbar X-rays and an MRI, and prescribed a regimen of medication and physical therapy. The lumbar X-rays and MRI revealed that Claimant had degenerative disc disease of the lumbar spine that was predominant at L4/5 and L5/S1. Dr. H recommended that Claimant undergo a neurosurgical consultation, and referred Claimant to Dr. Z, M.D. Dr. Z, a board certified neurosurgeon, examined Claimant on March 29, 2010, diagnosed Claimant with displacement of the lumbar intervertebral disc, and determined that Claimant was not a surgical candidate. Dr. Z recommended that Claimant undergo conservative medical treatment, and requested preauthorization to administer an outpatient lumbar epidural steroid injection (ESI) and a lumbosacral orthosis (LSO) back brace for the compensable injury.

Carrier's utilization review (UR) determined that the outpatient lumbar ESI and LSO back brace were not medically necessary for Claimant's compensable injury, and denied Dr. Z's request. Carrier's UR opined that Claimant did not meet the Official Disability Guidelines (ODG) criteria for an outpatient lumbar ESI and that the LSO back brace was not recommended for the compensable injury.

Dr. Z requested an IRO review. On May 12, 2010, the IRO reviewer, a board certified orthopedic surgeon, reviewed Claimant's medical records, and determined that the outpatient lumbar ESI and LSO back brace for the compensable injury was not medically necessary. The IRO reviewer cited the current edition of the ODG concerning an outpatient lumbar ESI and LSO back brace. The IRO opined that Claimant did not meet the ODG criteria for lumbar ESI, and that the LSO back brace was not recommended for lower back pain. In regard to the outpatient lumbar ESI, the IRO reviewer determined that Claimant did not have any objective findings of acute radiculopathy, and there was no clear indication that Claimant was

unresponsive to conservative treatment, including physical therapy. Concerning the LSO back brace, the IRO reviewer determined that lumbar supports are not recommended, do not demonstrate a significant efficacy to prevent low back pain, and that the lumbar supports are at best under study regarding the effective treatment of low back pain.

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. 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 further 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 in making decisions about the care of individual patients. 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. Also, 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."

With regard to lumbar ESIs, the current edition of the ODG provides:

“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 no long-term benefit.)”

With regard to the LSO back brace, the current edition of the ODG provides:

“Not recommended for prevention. Under study for treatment of nonspecific LBP. Recommended as an option for compression fractures and specific treatment of spondylolisthesis, documented instability, or post-operative treatment. There is strong and consistent evidence that lumbar supports were not effective in preventing neck and back pain. (Jellema-Cochrane, 2001) (van Poppel, 1997) (Linton, 2001) (Assendelft-Cochrane, 2004) (van Poppel, 2004) (Resnick, 2005) Lumbar supports do not prevent LBP. (Kinkade, 2007) Among home care workers with previous low back pain, adding patient-directed use of lumbar supports to a short course on healthy working methods may reduce the number of days when low back pain occurs, but not overall work absenteeism. (Roelofs, 2007) Acute osteoporotic vertebral compression fracture management includes bracing, analgesics, and functional restoration, and patients with chronic pain beyond 2 months may be candidates for vertebral body augmentation, i.e., vertebroplasty. (Kim, 2006) An RCT to evaluate the effects of an elastic lumbar belt on functional capacity and pain intensity in low back pain treatment found an improvement in physical restoration compared to control and decreased pharmacologic consumption. (Calmels, 2009) A systematic review on preventing episodes of back problems found strong, consistent evidence that exercise interventions are effective and other interventions not effective, including stress management, shoe inserts, back supports, ergonomic/back education, and reduced lifting programs. (Bigos, 2009) See also Back brace, post operative (fusion).”

In accordance with Division Rule 133.308(t), Claimant, the appealing party of the IRO decision, had the burden of overcoming the IRO decision by a preponderance of evidence-based medical evidence. In support of his position, Claimant testified on his behalf, and offered the medical records from Drs. H and Z. Dr. T, M.D., testified on behalf of Carrier. Dr. T, a board certified orthopedic surgeon, stated that he agreed with the determination of the IRO reviewer, and opined that Claimant did not meet the ODG criteria for an outpatient lumbar ESI and that a LSO back brace is not recommended treatment for the compensable injury. Dr. T stated that he reviewed Claimant's medical records, and determined that Claimant did not meet four of the eleven ODG criteria for an outpatient lumbar ESI. In particular, Dr. T opined that Claimant did not meet the ODG criteria numbered one, two, five, and six. Dr. T stated that Claimant did not have objective findings based on an examination of documented radiculopathy, there was no indication that Claimant was initially unresponsive to conservative treatment, no indication as to the number of nerve root levels that would be injected using transforaminal blocks, and no indication as to the number of interlaminar levels that would be injected at one session. Dr. T further stated that the ODG criteria numbered three, four, seven, eight, nine, ten, and eleven were not applicable. In regard to the LSO back brace, Dr. T opined that the current edition of the ODG does not

recommend a LSO back brace and that the LSO back brace could worsen and cause more harm to Claimant's low back condition.

After a careful review and consideration given to the evidence, Claimant did not meet his burden of proof of overcoming the IRO decision by a preponderance of evidence-based medical evidence. The preponderance of the evidence-based medical evidence is not contrary to the decision of the IRO that Claimant is not entitled to an outpatient lumbar ESI and LSO back brace for the compensable injury of _____.

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 was the employee of (Employer).
 - C. Claimant sustained a compensable injury on _____.
 - D. The IRO determined that Claimant is not entitled to an outpatient lumbar epidural steroid injection and lumbosacral orthosis back brace for the compensable injury of _____.
2. Carrier delivered to Petitioner/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 did not provide evidence-based medical evidence to overcome the determination of the IRO.
4. The requested outpatient lumbar epidural steroid injection and lumbosacral orthosis back brace is not health care reasonably required for Claimant's 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 the Independent Review Organization (IRO) that Claimant is not entitled to an outpatient lumbar epidural steroid injection and lumbosacral orthosis back brace for the compensable injury of _____.

DECISION

Claimant is not entitled to an outpatient lumbar epidural steroid injection and lumbosacral orthosis back brace 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 of _____, in accordance with Texas Labor Code Ann. §408.021.

The true corporate name of the insurance carrier is **TEXAS MUTUAL INSURANCE COMPANY**, and the name and address of its registered agent for service of process is

**RUSSELL RAY OLIVER, PRESIDENT
6210 EAST HIGHWAY 290
AUSTIN, TEXAS 78723**

Signed this 23rd day of September, 2010.

Wes Peyton
Hearing Officer