MEDICAL CONTESTED CASE HEARING NO. 18030

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and the Rules of the Texas Department of Insurance, Division of Workers' Compensation. For the reasons discussed herein, the Administrative Law Judge (ALJ) determines that:

> Claimant is not entitled to lumbar spine epidural steroid injection at L3-4 under fluoroscopy with IV sedation due to anxiety for the compensable injury of (Date of Injury).

STATEMENT OF THE CASE

Warren E. Hancock, Jr., a Division administrative law judge, held a contested case hearing on October 30, 2018 to decide the following disputed issues:

1. Is the preponderance of the evidence contrary to the decision of the IRO that the Claimant is not entitled to lumbar spine epidural steroid injection L3-4 under fluoroscopy with IV sedation due to anxiety, for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Claimant appeared and was assisted by EM, ombudsman. Carrier appeared and was represented by RJ, attorney. After the hearing, the record was held open for a stipulation as to the accepted injury. That stipulation was received and the parties allowed to submit additional comments which were added to the record as Administrative Law Judge's Exhibit 3, and the record closed on November 14, 2018.

EVIDENCE PRESENTED

The following witnesses testified:

> For Claimant: Claimant.
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> For Carrier: None.

The following exhibits were admitted into evidence:

> ALJ's Exhibits ALJ-1 through ALJ-3.
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> Claimant's Exhibits C-1 through C-9.
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> Carrier's Exhibits CR-A through CR-I.

DISCUSSION

Claimant is a (Age)-year-old seat-belted delivery driver who was driving an 18-wheel tractor trailer rig on (Date of Injury) when the engine brake caused the truck to slow suddenly by 10 to 15 miles per hour. Claimant reported being thrown suddenly forward while he was turned to the left looking into his mirror. His right shoulder twisted toward the steering wheel with onset of pain in the low back. Claimant had an MRI which was interpreted as being consistent with disc disruption and lumbar radiculopathy. Claimant had ESI injections in his low back and two weeks of therapy. He was referred to NA, D.O. for pain management. Claimant had a lumbar epidural steroid injection (ESI) on June 5, 2018 which resulted in 70% pain relief and improved function according to Dr. A, who has recommended another injection at L3-4. On June 28, 2018, the request for treatment at issue was reviewed by Carrier's utilization reviewer, LL, M.D., a Board-certified pain management specialist, who pointed out that there was no documentation of 50 to 70% pain relief lasting 6 – 8 weeks in the medical records for the previous injection. He also indicated that IV sedation was not shown to be reasonable and necessary by the records. On request for reconsideration, the record was reviewed on July 16, 2018 by LG, D.O., a Board-certified anesthesiologist. She concluded that there was no examination of Claimant after the initial injection, and no documentation of the degree of pain relief required under Official Disability Guidelines (ODG). She agreed with Dr. L that sedation is not standard or indicated in the absence of overt anxiety. Carrier denied the requested treatment.

The denial of the requested injection was appealed to an Independent Review Organization (IRO) where it was reviewed by a specialist in pain medicine. The IRO reviewer noted that ESIs are recommended by the ODG for short-term treatment of radicular back pain defined as pain in dermatomal distribution with corroborative findings of radiculopathy in conjunction with active rehab efforts. The reviewer stated that in this case, the documentation did not describe radicular pain as defined. Although a positive straight leg raise was described, there was no documentation of weakness or sensory loss in a specific dermatomal distribution, and it was stated in the documents that Claimant had axial back pain. ESIs are not recommended for spinal stenosis or nonspecific low back pain and so the previous denial was upheld.

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. 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 Official Disability Guidelines (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 (s), "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 ODG in effect at the time of the IRO decision in this case provides as follows in the Low Back Chapter concerning ESI injections:

> **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. Not recommended for spinal stenosis or for nonspecific low back pain. See specific criteria for use below.
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> See the *Neck Chapter*, where ESIs are not recommended based on recent evidence, given the serious risks of this procedure in the cervical region and the lack of quality evidence for sustained benefit.
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> **Criteria for the use of Epidural steroid injections:**
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> *Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, the reduction of medication use and the avoidance of surgery, but this treatment alone offers no significant long-term functional benefit.*

(1) Radiculopathy (due to herniated nucleus pulposus, but not spinal stenosis) must be documented. Objective findings on examination need to be present. Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing.

(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs, muscle relaxants, and neuropathic drugs).

(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 supported. This is generally referred to as the "therapeutic phase." Indications for repeat blocks include acute exacerbation of pain, or new onset of radicular 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.)

(12) Excessive sedation should be avoided.

(13) Radiculopathy symptoms are generally due to herniated nucleus pulposus or spinal stenosis, but ESIs have not been found to be as beneficial a treatment for the latter condition. According to SPORT, ESIs are associated with less improvement in spinal stenosis. (*Radcliff, 2013*)

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.

For spinal stenosis: The use of epidural steroid injection (ESI) in patients with lumbar spinal stenosis is common, but there is little evidence in the literature to demonstrate its long-term benefit. Despite equivalent baseline status, ESIs are associated with significantly less improvement at 4 years among all patients with spinal stenosis. Furthermore, ESIs were associated with longer duration of surgery and longer hospital stay. There was no improvement in outcome with ESI whether patients were treated surgically or nonsurgically. There was no distinct surgical avoidance noted with ESI. (*Radcliff, 2013*) This systematic review found the data was limited to suggest that ESI is effective in lumbar spinal stenosis. (*Bresnahan, 2013*) An RCT addressed the use of ESIs for treatment of spinal stenosis, and there was no statistical difference except in pain intensity and Roland Morris

Disability Index and this was at two weeks only. (*Koc, 2009*) According to the APS/ ACP guidelines, ESIs are not for nonspecific low back pain or spinal stenosis. (*Chou, 2008*) According to a high-quality RCT, in the treatment of symptoms of lumbar spinal stenosis, epidural injections of glucocorticoids plus lidocaine offered minimal or no benefit over epidural injections of lidocaine alone at 6 weeks. At 3 weeks, the glucocorticoid-lidocaine group had greater improvement than the lidocaine-alone group, but the differences were clinically insignificant. Despite a rapid increase in the use of epidural glucocorticoid injections for lumbar spinal stenosis, there is little evidence of effectiveness from clinical trials. (*Friedly, 2014*)

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*) Two recent RCTs of caudal injections had different conclusions. This study concluded that caudal injections demonstrated 50% pain relief in 70% of the patients, but required an average of 3-4 procedures per year. (*Manchikanti, 2011*) This higher quality study concluded that caudal injections are not recommended for chronic lumbar radiculopathy. (*Iversen, 2011*) Transforaminal epidural steroid injections, despite being generally regarded as superior to interlaminar injections, are not significantly better in providing pain relief or functional improvement, according to a new systematic review. (*Chien, 2014*)

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, 2005*) (*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 and 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 (PT)*, 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*) Not recommended post-op. The evidence for ESI for post lumbar surgery syndrome is poor. (*Manchikanti, 2012*)

Patient selection: Radiculopathy must be documented, as indicated in the ODG criteria. In addition, ESIs are more often successful in patients without significant compression of the nerve root and, therefore, in whom an inflammatory basis for radicular pain is most likely. In such patients, a success rate of 75% renders ESI an attractive temporary alternative to surgery, but in patients with significant compression of the nerve root, the likelihood of benefiting from ESI is low (26%). This success rate may be no more than that of a placebo effect, and surgery may be a more appropriate consideration. (*Ghahreman, 2011*) Injections for spinal pain have high failure rates, emphasizing the importance of patient selection. Individuals with centralized pain, such as those with fibromyalgia and chronic widespread pain, and poorly controlled depression, may be poor candidates. (*Brummett, 2013*)

MRIs: According to this RCT, the use of MRI before ESIs does not improve patient outcomes and has a minimal effect on decision making, but the use of MRI might have reduced the total number of injections required and may have improved outcomes in a subset of patients. Given these potential benefits as well as concerns related to missing important rare contraindications to epidural steroid injection, plus the small benefits of ESIs themselves, ODG continues to

recommend that radiculopathy be corroborated by imaging studies and/or electrodiagnostic testing. (*Cohen, 2012*)

Fracture risk: Lumbar ESIs are associated with an increased risk for spinal fracture. Each single additional ESI increased the risk for fracture by 21%, with an increasing number of ESIs associated with an increasing likelihood of fracture. Use of ESIs seems to promote deterioration of skeletal quality. This definable fracture risk should be balanced with the best available evidence regarding the long-term efficacy of ESIs, which is limited. Clinicians should consider these findings before prescribing ESIs for elderly patients. (*Mandel, 2013*)

Sedation: The use of sedation during ESI remains controversial. Sedation is less often indicated during lumbar ESI compared with cervical ESI because fewer patients experience a vasovagal reaction, which is likely an indicator of anxiety. (*Trentman, 2009*) According to a multidisciplinary collaboration led by the FDA, heavy sedation should be avoided in favor of sedation light enough to allow the patient to communicate during the procedure. (*Rathmell, 2015*) For a more extensive discussion, see the *Pain Chapter*. See also the *Neck Chapter*.

Recent research: 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, 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*) In this RCT there were no statistically significant differences between any of the three groups at any time points. This study had some limitations: only one type of steroid in one dose was tested; the approach used was caudal and transforaminal injections might provide superior results. (*Weiner, 2012*) Effects are short-term and minimal. At follow-up of up to 3 months, epidural steroids were associated with statistically significant reductions in mean leg pain and mean disability score, but neither of these short-term improvements reached the threshold for clinical significance. There were no significant differences in either leg pain or disability at the 12-month follow-up. (*Pinto, 2012*) According to this systematic review, ESIs without the drug (epidural nonsteroid injections), often used as a placebo treatment, were as effective as ESIs and better than no epidural injections. (*Bicket, 2013*) This meta-analysis suggested that ESI did not improve back-specific

> disability more than a placebo or other procedure long-term (6 months), and did not significantly decrease the number of patients who underwent subsequent surgery. (*Choi, 2013*) The FDA is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. (*FDA, 2014*) This study shows that ESIs had a significant beneficial effect as an additional treatment for lumbosacral radicular syndrome in general practice, but the effect was too small to be considered clinically relevant to patients, so the authors do not recommend ESIs as a regular intervention in general practice. (*Spijker-Huiges, 2014*) A high-quality RCT concluded that gabapentin and ESIs for radicular pain both resulted in modest improvements in pain and function, which persisted through three months. Some differences favored ESIs, but these tended to be small and transient. They recommended a trial with neuropathic drugs as a reasonable first line treatment option. (*Cohen, 2015*) The AHRQ comparative effectiveness study on injection therapies for LBP concluded that ESIs for radiculopathy were associated with immediate improvements in pain and might be associated with immediate improvements in function, but benefits were small and not sustained, and there was no effect on long-term risk of surgery. Evidence did not suggest that effectiveness varies based on injection technique, corticosteroid, dose, or comparator. Limited evidence suggested that epidural corticosteroid injections are not effective for spinal stenosis or nonradicular back pain. (*Chou, 2015*) In another systematic review, evidence was only robust for positive effects in patients with chronic radiculopathy, with statistically significant effects on immediate (5 days to ≤2 weeks) improvement in pain, and short-term (>2 weeks to ≤3 months) surgery risk. (*Chou, 2015b*)

Claimant relied on a letter from Dr. A in this case dated October 16, 2018 which contended that the requested treatment is justified under the ODG because the June 5, 2018 injection resulted in 70% pain relief with improved function and reduction in required medications. Dr. A did not address the issue raised by the IRO reviewer as to whether radicular pain as defined in the ODG is involved. Claimant submitted a report from GW, M.D., a board certified orthopedic surgeon, who examined Claimant and reviewed his records on September 6, 2018 and reviewed the MRI of April 13, 2018. Dr. W pointed out that the MRI does not show disc protrusions that cause any kind of significant distortion or compromise of the neural foramina. His physical exam noted intact reflexes in both legs at the knees and ankles, and he could not detect any motor deficit on either the right or left side. There were complaints about low back pain with the straight leg raise test, but Claimant did not have a pattern of findings that is dermatomal extending down his legs. There was no lesion shown which Dr. W found to require surgical intervention. This analysis is consistent with the conclusions of the IRO reviewer that the records of Claimant's examination and treatment do not show that Claimant has the type of radicular symptoms that

justify treatment by ESI. The preponderance of the evidence is not contrary to the determination of the IRO that Claimant is not entitled to the requested treatment.

The Administrative Law Judge considered all of the evidence admitted. The Findings of Fact and Conclusions of Law are based on an assessment of all of the evidence whether or not the evidence is specifically discussed in this Decision and Order.

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 (Date of Injury), Claimant was the employee of (Employer), Employer.

   C. On (Date of Injury), Employer provided workers' compensation coverage through L M Insurance Company, Carrier.

   D. Claimant sustained a compensable injury on in the form of at least the Carrier-accepted conditions of sprain of ligaments of the lumbar spine; low back pain, intervertebral disc disorders with radiculopathy, lumbar region; strain of muscle, fascia and tendons of the low back; and radiculopathy, lumbar region.

   E. The compensable injury is covered under Liberty Healthcare Network, a workers' compensation healthcare network.

   F. The IRO determined that lumbar spine epidural steroid injection at L3-4 under fluoroscopy with IV sedation due to anxiety is not reasonable and necessary healthcare for the compensable injury of (Date of Injury).

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 Administrative Law Judge's Exhibit Number 2.

3. Lumbar spine epidural steroid injection at L3-4 under fluoroscopy with IV sedation due to anxiety is not reasonable and necessary healthcare for the compensable injury of (Date of Injury).

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 IRO that Lumbar spine epidural steroid injection at L3-4 under fluoroscopy with IV sedation due to anxiety is not reasonable and necessary healthcare for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to lumbar spine epidural steroid injection at L3-4 under fluoroscopy with IV sedation due to anxiety for the compensable injury of (Date of Injury).

ORDER

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

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

CORPORATION SERVICE COMPANY
211 E 7TH STREET, SUITE 620
AUSTIN, TX 78701

Signed this 14th day of November, 2018.

Warren E. Hancock, Jr.
Administrative Law Judge