

MEDICAL CONTESTED CASE HEARING NO. 11100
M6-10-29960-01

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.

ISSUES

A contested case hearing was held on January 5, 2011 to decide the following disputed issue:

Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that the claimant is not entitled to monitored anesthesia care (MAC) by an on-call certified nurse anesthetist for the compensable injury of _____?

PARTIES PRESENT

Petitioner/Claimant appeared and was represented by his wife, RC, as a lay representative. Petitioner/Claimant was also assisted by SB, ombudsman. Respondent/Carrier appeared and was represented by JF, attorney.

BACKGROUND INFORMATION

It was undisputed that the Claimant sustained a compensable lumbar spine injury on _____. On August 6, 2009, because of the Claimant's symptoms, he underwent a transforaminal epidural steroid injection (TFESI) at the left L5-S1 under fluoroscopic guidance. This procedure, along with MAC by an on-call certified nurse anesthetist, was approved by the Carrier's utilization review agent on July 23, 2009. The Claimant received 100% pain relief from this procedure for six months. The Claimant again became symptomatic, and his doctor, Dr. M, who is an anesthesiologist with a subspecialty in Pain Medicine, requested a repeat TFESI with MAC by an on-call certified nurse anesthetist on or about September 2, 2010. The TFESI was approved, but the request for MAC by an on-call certified nurse anesthetist was denied by the Carrier's utilization review agent, Dr. B, who is board certified in Anesthesiology. Dr. B stated that MAC can only be used when there is a showing of the absence of other medical problems, and since no such proof was provided, the medical necessity of MAC was not demonstrated. The denial was upheld by the IRO, who is a medical doctor who is board certified in Physical Medicine and Rehabilitation. The IRO noted that while IV sedation is required when performing a lumbar ESI for some patients, since Dr. M is an anesthesiologist it is unclear why the utilization of a nurse anesthetist will be required. The IRO stated that the requestor did not provide any clear rationale for the utilization of a nurse anesthetist, so the medical necessity of that component of the request was not shown.

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 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 (t), "A decision issued by an IRO is not considered an agency decision and neither the Department nor the Division is 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 sets forth the following information regarding ESIs:

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) (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) (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, reduction of medication use 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) Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing.

(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 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.)

This case is atypical because, as noted above, the ultimate procedure that has been requested is approved; only the specific proposed method of providing anesthesia for the performance of the procedure has been denied. The ODG does not address this issue under the section for ESIs. It is important to note that at the hearing, there was no dispute between the parties that anesthesia/sedation may be required to perform a TFESI. The medical evidence in the record appears to raise three questions regarding the provision of anesthesia for a TFESI: 1) is there medical necessity for the provision of MAC in this case, as opposed to other forms of delivery of sedation, 2) is there medical necessity for the utilization of an on-call certified nurse anesthetist in connection with the provision of MAC, and 3) since Dr. M is an anesthesiologist, is there medical necessity for another independent provider to administer the anesthesia while Dr. M performs the TFESI procedure. There is no evidence in the record explaining the issues in this case from Dr. M, which appears in large part to be the basis of the Carrier’s and the IRO’s denials. The Claimant presented the medical opinion of a board certified anesthesiologist, Dr. U, which posits that the provision of anesthesia by a skilled anesthesia provider, like an anesthesiologist or a certified nurse anesthetist, is medically necessary and within the standard of care for the performance of a TFESI. He opines that the anesthesia provider must be someone other than the surgeon (Dr. M) because the surgeon must be focused on performing the injection and it would be a violation of the standard of care, as well as physically impossible, for the surgeon to perform both of these tasks for this procedure. The Claimant also presented evidence-based medical evidence, in the form of literature published by the American Society of Anesthesiologists, which discusses various methods of achieving sedation for surgical procedures, including MAC, moderate sedation and deep sedation, as well as the recommendation that it is prudent with both moderate and deep sedation to have another individual monitoring the anesthesia separate and apart from the individual performing the procedure. The Claimant’s position in this case is persuasive, but what is lacking is evidence-based medical evidence that explains the medical necessity of the specific service in dispute, namely, *MAC by an on-call certified nurse anesthetist* in connection with performing a TFESI. For this reason, it is determined that the Claimant did not meet his burden to overcome the IRO decision.

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. On _____, Employer had workers' compensation insurance coverage with Zurich American Insurance Co., Carrier.
 - D. On _____, the Claimant sustained a compensable lumbar spine injury.
 - E. The IRO report in this case dated October 5, 2010 upheld the Carrier's denial of MAC by an on-call certified nurse anesthetist for the compensable injury of _____.
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. MAC by an on-call certified nurse anesthetist is 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. The preponderance of the evidence is not contrary to the decision of the IRO that MAC by an on-call nurse anesthetist is not health care reasonably required for the compensable injury of _____.

DECISION

Claimant is not entitled to MAC by an on-call nurse anesthetist 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 **ZURICH AMERICAN INSURANCE COMPANY**, and the name and address of its registered agent for service of process is:

**CORPORATION SERVICE COMPANY
701 BRAZOS STREET, SUITE 620
AUSTIN, TEXAS 78701-3218**

Signed this 11th day of January, 2011.

Patrice Fleming-Squirewell
Hearing Officer