MEDICAL CONTESTED CASE HEARING NO. 10170
M6-10-25004-01

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 contested case hearing was held on April 26, 2010 to decide the following disputed issue:

> Is the preponderance of the evidence-based medicine contrary to the decision of the Independent Review Organization (IRO) that Claimant is not entitled to outpatient caudal epidural steroid injections with lysis of adhesions for the compensable injury of _____?

PARTIES PRESENT

Claimant appeared, and was assisted by Ombudsman SA; Carrier appeared, and was represented by Attorney JL.

EVIDENCE PRESENTED

The following witnesses testified:

For Petitioner/Claimant:
WE, Jr.

For Respondent/Self-insured:
None

The following exhibits were admitted into evidence:

Hearing Officer's Exhibits 1 through 3
Petitioner/Claimant's Exhibits 1 through 6
Respondent/Self-insured's Exhibits A through F

BACKGROUND INFORMATION

Claimant sustained a compensable lumbar injury on the date indicated, and underwent spinal fusion surgery in August of 2002. In addition to surgical intervention, Claimant has also undergone epidural steroid injections, with mixed results. He stated that his earlier injections afforded him pain relief for up to nine months, but that his most recent injection was unsuccessful in easing his pain because, according to his understanding, it was not administered sufficiently deeply.

In support of his position that the proposed procedures were appropriate treatment for his compensable injury, Claimant provided the records of his recent medical care, but offered no published scientific research regarding the advisability of either of these procedures.

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(22-a) 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, and 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. 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 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."

Insofar as epidural steroid injections are concerned, the ODG criteria are set forth below:

> Recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy). See specific criteria for use below. [NOTE: This treatment for Low back & Neck pain is primarily covered in those respective chapters.] Most current guidelines recommend no more than 2 ESI injections. This is in contradiction to previous generally cited recommendations for a “series of three” ESIs. These early recommendations were primarily based on anecdotal evidence. Research has now shown that, on average, less than two injections are required for a successful ESI outcome. Current recommendations suggest a second epidural injection if partial success is produced with the first injection, and a third ESI is rarely recommended. 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. See the Low Back Chapter for more information and references. The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral 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, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. (Armon, 2007) See also Epidural steroid injections, "series of three". Also see the Neck and Upper Back Chapter.

Sedation: There is no evidence-based literature to make a firm recommendation as to sedation during an ESI. The use of sedation introduces some potential diagnostic and safety issues, making unnecessary use less than ideal. A major concern is that sedation may result in the inability of the patient to experience the expected pain and paresthesias associated with spinal cord irritation. This is of particular concern in the cervical region. (Hodges 1999) Routine use is not recommended except for patients with anxiety. The least amount of sedation for the shortest duration of effect is recommended. The general agent recommended is a benzodiazepine. (Trentman 2008) (Kim 2007) (Cuccuzzella 2006) While sedation is not recommended for facet injections (especially with opioids) because it may alter the anesthetic diagnostic response, sedation is not generally necessary for an ESI but is not contraindicated. As far as monitored anesthesia care (MAC) administered by someone besides the surgeon, there should be evidence of a pre-anesthetic exam and evaluation, prescription of anesthesia care, completion of the record, administration of medication and provision of post-op care. Supervision services provided by the operating physician are considered part of the surgical service provided.

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 by physical examination and 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) for guidance.

4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at 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) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general

recommendation of no more than 4 blocks per region per year. (Manchikanti, 2003) (CMS, 2004) (Boswell, 2007)

8) Current research does not support a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections.

9) Epidural steroid injection is not to be performed on the same day as trigger point injection, sacroiliac joint injection, facet joint injection or medial branch block.

With regard to adhesiolysis (lysis of adhesions), however, the ODG states as follows:

Not recommended due to the lack of sufficient literature evidence (risk vs. benefit, conflicting literarure). Also referred to as epidural neurolysis, epidural neuroplasty, or lysis of epidural adhesions, percutaneous adhesiolysis is a treatment for chronic back pain that involves disruption, reduction, and/or elimination of fibrous tissue from the epidural space. Lysis of adhesions is carried out by catheter manipulation and/or injection of saline (hypertonic saline may provide the best results). Epidural injection of local anesthetic and steroid is also performed. It has been suggested that the purpose of the intervention is to eliminate the effect of scar formation, allowing for direct application of drugs to the involved nerves and tissue, but the exact mechanism of success has not been determined. There is a large amount of variability in the technique used, and the technical ability of the physician appears to play a large role in the success of the procedure. In addition, research into the identification of the patient who is best served by this intervention remains largely uninvestigated. Adverse reactions include dural puncture, spinal cord compression, catheter shearing, infection, excessive spinal cord compression, hematoma, bleeding, and dural puncture. Duration of pain relief appears to range from 3-4 months. Given the limited evidence available for percutaneous epidural adhesiolysis it is recommended that this procedure be regarded as investigational at this time. (Gerdesmeyer, 2003) (Heavner, 1999) (Belozer, 2004) (BlueCross BlueShield, 2004) (Belozer, 2004) (Boswell, 2005) (Boswell, 2007) (The Regence Group, 2005) (Chopra, 2005) (Manchikanti1, 2004) (Epter, 2009) This recent RCT found that after 3 months, the visual analog scale (VAS) score for back and leg pain was significantly reduced in the epidural neuroplasty group, compared to to conservative treatment with physical therapy, and the VAS for back and leg pain as well as the Oswestry disability score were significantly reduced 12 months after the procedure in contrast to the group that received conservative treatment. (Veihelmann, 2006)

Preliminary suggested criteria for percutaneous adhesiolysis while under study:

- The 1-day protocol is preferred over the 3-day protocol.

- All conservative treatment modalities have failed, including epidural steroid injections.

- The physician intends to conduct the adhesiolysis in order to administer drugs closer to a nerve.

- The physician documents strong suspicion of adhesions blocking access to the nerve.

- Adhesions blocking access to the nerve have been identified by Gallium MRI or Fluoroscopy during epidural steroid injections.

Even if Claimant is able to demonstrate that he meets the above ODG criteria for the recommended caudal epidural steroid injections, he can not overcome the ODG recommendation and IRO decision against performing lysis of adhesions, since he has presented no evidence-based medical evidence, as that term is statutorily defined, to demonstrate that lysis of adhesions is, indeed, appropriate treatment in his case. Since the procedures in question were recommended to be performed together, Claimant's inability to meet his burden of proof as to either of these procedures equates to a failure to meet the requisite burden of proof as to his case, as a whole. As it must therefore be determined that Claimant has failed to meet his burden of proof, a decision in Self-insured's favor will be entered as to the sole issue presented for resolution herein.

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. On _____, Claimant was employed by the (Self-Insured), Employer.

2. On _____, Employer was self-insured for workers' compensation purposes.

3. On _____, Claimant's residence was located within seventy-five miles of the (City) office of the Texas Department of Insurance, Division of Workers' Compensation.

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

5. On _____, Claimant sustained damage or harm to the physical structure of his body while he was within the course and scope of his employment with Employer.

6. The injury referenced in the previous Finding of Fact arose out of Claimant's employment with Employer.

7. Caudal epidural steroid injections with lysis of adhesions 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-based medicine is not contrary to the decision of the Independent Review Organization that caudal epidural steroid injections with lysis of

adhesions is not health care reasonably required for the compensable injury of _____.

DECISION

Claimant is not entitled to caudal epidural steroid injections with lysis of adhesions for the compensable injury of _____.

ORDER

Self-insured 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 self-insured is **(SELF-INSURED),** and the name and address of its registered agent for service of process is

H M
(STREET ADDRESS)
(CITY), TEXAS (ZIP CODE)

Signed this 3rd day of May, 2010.

Ellen Vannah
Hearing Officer