MEDICAL CONTESTED CASE HEARING NO. 11097
M6-11-30192-01

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 January 6, 2011, 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 selective epidural block at L5-S1 left with trigger point injection and IV sedation is not health care reasonably necessary for the compensable injury of _____?

PARTIES PRESENT

The petitioner/claimant appeared and was represented by JS, attorney. The carrier/respondent appeared and was represented by JC, attorney.

BACKGROUND INFORMATION

The claimant testified that he has chronic and severe low back pain as a result of a compensable motor vehicle accident in (year). Dr. C requested authorization for epidural and trigger point injections at the L5-S1 level of the claimant's lumbar spine. The IV sedation request is due to the claimant's abhorrence of needles, and his reaction to the first set of injections in April, 2010.

In reviewing Dr. C's request for the epidural steroid and trigger point injections, the first utilization review doctor, a physical and rehabilitation medicine specialist, denied the request largely on the basis of a lack of documentation—no documentation of lower levels of care, of greater than 50% pain relief, of lowered medication usage, or of increased functional improvement following the injections in April, 2010. In addition, the first utilization review doctor noted that there was no evidence of radiculopathy, a finding of which is required by the Official Disability Guidelines (ODG) for epidural steroid injections.

A second review doctor, a board certified anesthesiologist, upheld the denial, again, on a lack of documentation to support any radiculopathy, and a lack of documentation in regard to the conservative treatment regimen completed as of the date of the request or of the claimant's response thereto.

An IRO reviewer, who is board certified in physical medicine and rehabilitation, board certified in pain management, and board certified in electrodiagnostic medicine, upheld the carrier's denial of the treatment requested. As did the prior two reviewers, the IRO reviewer cited the absence of any evidence of radiculopathy. In addition, he pointed out that the paresthesia complaints by the claimant originated at levels of the claimant's spine above the level proposed

for injection by Dr. C. In regard to the trigger point injections, the IRO reviewer noted that the description of the trigger points, required by the ODG, are not in the medical documentation.

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 are considered parties[sic] 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."

On the date of this medical contested case hearing, the ODG provided the following with regard to selective epidural blocks:

> 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.)

On the date of this medical contested case hearing, the ODG provided the following with regard to trigger point injections:

Not recommended in the absence of myofascial pain syndrome. See Criteria for use below. See the Pain Chapter for more information and references. The primary goal of trigger point therapy is the short-term relief of pain and tightness of the involved muscles in order to facilitate participation in an active rehabilitation program and restoration of functional capacity. The evidence for TPIs when used as a sole treatment for patients with chronic low-back pain (regardless of injectate) is inconclusive and the treatment does not appear to be more effective than treatments such as laser or ultrasound. The effectiveness of trigger point injection is uncertain, in part due to the difficulty of demonstrating advantages of active medication over injection of saline. Needling alone may be responsible for some of the therapeutic response. These injections are not recommended for typical chronic low back or neck pain, nor are they recommended for radicular pain. (Scott, 2005) (Scott, 2008) The advantage appears to be in enabling patients to undergo remedial exercise therapy more quickly. TPIs are generally considered an adjunct rather than a primary form of treatment and should not be offered as either a primary or a sole treatment modality. Steroid injection is not generally recommended nor is Botulinum toxin. (Bigos, 1999) (Nelemans-Cochrane, 2000) (Vad, 2002) (BlueCross BlueShield, 2004) (van Tulder, 2006) (VanTulder-BMJ, 2004) (Peloso, 2007) (Ho, 2007) 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)

Criteria for the use of Trigger point injections:

Trigger point injections (TPI) with a local anesthetic with or without steroid may be recommended for the treatment of chronic low back or neck pain with myofascial pain syndrome (MPS) when all of the following criteria are met:

(1) Documentation of circumscribed trigger points with evidence upon palpation of a twitch response as well as referred pain;

(2) Symptoms have persisted for more than three months;

(3) Medical management therapies such as ongoing stretching exercises, physical therapy, NSAIDs and muscle relaxants have failed to control pain;

(4) Radiculopathy is not an indication (however, if a patient has MPS plus radiculopathy a TPI may be given to treat the MPS);

(5) Not more than 3-4 injections per session;

(6) No repeat injections unless a greater than 50% pain relief with reduced medication use is obtained for six weeks after an injection and there is documented evidence of functional improvement;

(7) Frequency should not be at an interval less than two months;

(8) Trigger point injections with any substance (e.g., saline or glucose) other than local anesthetic with or without steroid are not recommended;

(9) There should be evidence of continued ongoing conservative treatment including home exercise and stretching. Use as a sole treatment is not recommended;

(10) If pain persists after 2 to 3 injections the treatment plan should be re-examined as this may indicate an incorrect diagnosis, a lack of success with this procedure, or a lack of incorporation of other more conservative treatment modalities for myofascial pain. It should be remembered that trigger point injections are considered an adjunct, not a primary treatment.

The only evidence-based medicine presented at the hearing was the ODG. The Claimant did not present any other evidence-based medicine in support of the requested procedures. The ODG requires documentation of radiculopathy as an essential ingredient for recommendation of epidural steroid injections. There have been no EMGs performed, much less any clinical observations by Dr. C of atrophy or loss of relevant reflexes in the claimant's lower extremities. The one such measurement that was made, by RME Dr. H, M. D. in August, 2009, indicated that there has been no atrophy. In regard to trigger point injections, the ODG states that “all” of the criteria must be met for such injections to be recommended. Those criteria include “Documentation of circumscribed trigger points with evidence upon palpation of a twitch response as well as referred pain.” As with the evidence required for steroid injections, it is not known whether Dr. C did not observe the missing criteria, or whether he simply has not documented his findings.

Based on a careful review of the evidence presented in the hearing, the claimant failed to meet his burden of overcoming the IRO decision by a preponderance of the evidence-based medical

evidence. The IRO decision in this case is based on the ODG and the evidence revealed that the claimant failed to meet all of the necessary criteria for a selective epidural block at L5-S1 left with trigger point injection and IV sedation prescribed in the ODG. The preponderance of the evidence-based medical evidence is not contrary to the decision of the IRO and, consequently, the claimant is not entitled to the proposed selective epidural block at L5-S1 left with trigger point injection and IV sedation.

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 Workers' Compensation Division of the Texas Department of Insurance.

   B. On _____, the claimant was the employee of (Employer).

   C. On _____, the claimant sustained a compensable injury.

   D. The Texas Department of Insurance appointed (Independent Review Organization) as the IRO to review carrier's denial of the pre-authorization request for a selective epidural block at L5-S1 left with trigger point injection and IV sedation.

   E. The IRO determined that the claimant is not entitled to a selective epidural block at L5-S1 left with trigger point injection and IV sedation.

2. The carrier delivered to the claimant a single document stating the true corporate name of the carrier, and the name and street address of the carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.

3. There is no documented evidence that the claimant has radiculopathy in his lower extremities, as required by the ODG for epidural steroid injections.

4. The claimant did not establish by a preponderance of the evidence-based medical evidence that a selective epidural block at L5-S1 left with trigger point injection and IV sedation is health care reasonably required for the compensable injury of _____.

CONCLUSIONS OF LAW

1. The Workers' Compensation Division of the Texas Department of Insurance 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 a selective epidural block at L5-S1 left with trigger point injection and IV sedation is not health care reasonably required for the compensable injury of _____.

DECISION

The claimant is not entitled to a selective epidural block at L5-S1 left with trigger point injection and IV sedation for the compensable injury of _____.

ORDER

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

The true corporate name of the insurance carrier is **AMERICAN CASUALTY COMPANY OF READING, PENNSYLVANIA,** and the name and address of its registered agent for service of process is:

CT CORPORATION SYSTEM
350 NORTH ST PAUL STREET
DALLAS, TEXAS 75201

Signed this 11th day of January, 2011.

William M. Routon, II
Hearing Officer