MEDICAL CONTESTED CASE HEARING NO. 12116
M6-12-37690-01

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 April 5, 2012 to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the IRO that the Claimant is not entitled to radiofrequency ablation right at L4-L5 and S1 under fluoroscopy for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Claimant appeared and was assisted by JO, ombudsman. Petitioner/Provider Dr. KB appeared telephonically as a witness in this matter. Respondent/Carrier appeared and was represented by JB, adjuster.

BACKGROUND INFORMATION

Claimant sustained a lumbar spine injury. Dr. B requested pre-authorization for radiofrequency ablation right at L4-L5 and S1 under fluoroscopy. Two utilization reviews were conducted. Both URAs denied the request. Dr. B appealed the Carrier's decision to an IRO. The IRO upheld the Carrier's denial and noted that:

> As noted in the Division mandated Official Disability guidelines, facet joint radiofrequency neurotomy is "under study" thus, the efficacy of this procedure has not been thoroughly objectified. The facet joint medial branch block is not recommended except as a diagnostic tool. In this case there was some relief albeit for a very temporary period. Therefore, there is no clear clinical indication of any efficacy associated with this type of procedure.
>
> The second issue is that as per the criteria for facet joint radiofrequency neurotomy (4). No more than two joint levels are to be performed at one time. There is some confusion as to the request as one place indicated that the L4, L5, and S1 nerve roots were to be treated and another note indicated the L4/5 and L5/S1 levels. This confusion does not support the request.

> Therefore, overall, there is insufficient clinical data presented to support this request. There is significant doubt as to the efficacy of such an injection and overall this type of intervention has not been established as the prevailing standard of care. Consequently, the non-certification is 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 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. A decision issued by an IRO is not considered an agency decision and neither the Department nor the Division is considered a party 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. (Division Rule 133.308 (t).)

With regard to Facet joint radiofrequency neurotomy, the ODG provides as follows:

> Under study. Conflicting evidence is available as to the efficacy of this procedure and approval of treatment should be made on a case-by-case basis (only 3 RCTs with one suggesting pain benefit without functional gains, potential benefit if used to reduce narcotics). Studies have not demonstrated improved function. Also called Facet rhizotomy, Radiofrequency medial branch neurotomy, or

Radiofrequency ablation (RFA), this is a type of injection procedure in which a heat lesion is created on specific nerves to interrupt pain signals to the brain, with a medial branch neurotomy affecting the nerves carrying pain from the facet joints.

Current research: Multiple placebo-controlled trials have been completed on this topic, but these studies all had potential clinical methodologic flaws including the use of non-controlled diagnostic blocks and potential discrepancies in technique of lesioning from that which is currently recommended. (Hooten, 2005) (van Kleef, 1999) (Boswell, 2005) (Leclaire, 2001) (Van Kleef, 1999) (Gallagher, 1994) (van Wijk, 2005) A recent small RCT found that the percutaneous radiofrequency neurotomy treatment group showed statistically significant improvement not only in back and leg pain but also back and hip movement as well as the sacro-iliac joint test. There was significant improvement in quality of life variables, global perception of improvement, and generalized pain. But RF neurotomy was not a total treatment, and it provided relief for only one component of the patients' pain. (Nath, 2008)

Observational Trials: One observational trial found 60% of patients received 90% relief at 12 months and 87% had 60% pain relief. The authors used confirmatory blocks with 80% pain relief. (Dreyfuss, 2000) Clinical audits have reported pain relief in almost 70% of patients at 6 months. (Gofeld, 2007)

Systematic reviews: When compiled into systematic reviews, the evidence has been found to be conflicting for a short-term effect (Niemisto-*Cochrane,* 2003) (Niemesto-Cochrane, 2006) and moderate to strong for a long-term effect when compared to a placebo. (Geurts, 2001) (Boswell, 2005) The latter systematic review failed to distinguish results between lumbar and cervical patients. A critical nonsystematic review by Slipman et al. reported “sparse evidence” to support use in the lumbar region (Slipman, 2003) and the ICSI did not feel the current scientific evidence allowed for a conclusion on the subject. (ICSI, 2005) Boswell et al have recently published a systematic review that included several new observational studies that came to the conclusion that the evidence for neurotomy was moderate (Level III) for long-term relief of cervical and lumbar facet joint pain. This conclusion was based on the standard techniques used in the United States. (Boswell2, 2007) Interventional strategies, such as prolotherapy, botulinum toxin injections, radiofrequency denervation, and intradiskal electrothermal therapy, are not supported by convincing, consistent evidence of benefit from randomized trials. (Chou, 2008)

Technique: There are several techniques. (Gofeld2, 2007) The North American technique uses tangential insertion of a curve-tipped cannula parallel to the nerves. There is a long learning curve and results vary among operators. The European technique relies on radiologic appearance. Potential technical flaws

include inadequate exposure of the tip to the target nerve and generation of a lesion that is too small to ablate the nerve. There is also an Australian technique.
Factors associated with failed treatment: These include increased pain with hyperextension and axial rotation (facet loading), longer duration of pain and disability, significant opioid dependence, and history of back surgery.
Factors associated with success: Pain above the knee (upper leg or groin); paraspinal tenderness. (Cohen2, 2007)
Duration of pain relief: One retrospective analysis has determined that the mean duration of relief is approximately 10-12 months (range 4-19 months). Subsequent procedures may not be as successful (possibly secondary to technical failure or progression of spinal degeneration). (Schofferman, 2004) In a more recent study 68.4% of patients reported good to excellent pain relief at 6 months and showed consistent results with the above findings. (Gofeld, 2007)
Complications: Potential side effects include painful cutaneous dysesthesias, increased pain due to neuritis or neurogenic inflammation, and cutaneous hyperesthesia. Neuritis is the most frequent complication (5% incidence). (Boswell, 2005) (Boswell2, 2007) (Cohen, 2007) The clinician must be aware of the risk of developing a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures. This procedure is commonly used to provide a window of pain relief allowing for participation in active therapy. (Washington, 2005) (Manchikanti, 2003) See also Facet joint diagnostic blocks (injections); Facet joint pain, signs & symptoms; Facet joint medial branch blocks (therapeutic injections); Facet joint intra-articular injections (therapeutic blocks). Also see Neck Chapter and Pain Chapter.

Criteria for use of facet joint radiofrequency neurotomy:

(1) Treatment requires a diagnosis of facet joint pain using a medial branch block as described above. See Facet joint diagnostic blocks (injections).
(2) While repeat neurotomies may be required, they should not occur at an interval of less than 6 months from the first procedure. A neurotomy should not be repeated unless duration of relief from the first procedure is documented for at least 12 weeks at ≥ 50% relief. The current literature does not support that the procedure is successful without sustained pain relief (generally of at least 6 months duration). No more than 3 procedures should be performed in a year's period.
(3) Approval of repeat neurotomies depends on variables such as evidence of adequate diagnostic blocks, documented improvement in VAS score, decreased medications and documented improvement in function.
(4) No more than two joint levels are to be performed at one time.

(5) If different regions require neural blockade, these should be performed at intervals of no sooner than one week, and preferably 2 weeks for most blocks.
(6) There should be evidence of a formal plan of additional evidence-based conservative care in addition to facet joint therapy

Claimant's requesting doctor, KB, M.D., a board certified orthopedic surgeon, testified that the relevant evidence based medicine cited in several studies in the ODG indicate that the requested procedure provides good to excellent relief in a majority of the cases. He also noted that in the Claimant's case, there will be secondary benefit also cited in the ODG, that "the procedure is commonly used to provide a window of pain relief allowing for participation in active therapy."

Dr. B further testified that the Claimant meets the criteria outlined in the ODG regarding facet joint radiofrequency neurotomy. A medial branch block was pre-authorized and performed on September 12, 2011 confirming facet joint pain. It is the first neurotomy. No more than two joint levels will be performed and it is the same region. And Dr. B testified that he has a formal plan of additional evidence-based conservative care in addition to facet joint therapy.

Dr. B's testimony supports the medical necessity of the facet joint radiofrequency neurotomy and constitutes evidence based medicine which outweighs the findings of the IRO.

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

   C. Claimant sustained a compensable injury on (Date of Injury).

   D. The Independent Review Organization (IRO) determined that the Claimant should not have radiofrequency ablation right at L4-L5 and S1 under fluoroscopy.

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. Radiofrequency ablation right at L4-L5 and S1 under fluoroscopy is health care reasonably required 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 contrary to the decision of the IRO that to radiofrequency ablation right at L4-L5 and S1 under fluoroscopy is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is entitled to radiofrequency ablation right at L4-L5 and S1 under fluoroscopy.

ORDER

Carrier is 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 **COMMERCE & INDUSTRY INSURANCE COMPANY** and the name and address of its registered agent for service of process is:

CORPORATION SERVICE COMPANY
211 EAST 7th STREET, SUITE 620
AUSTIN, TEXAS 78701-3218

Signed this 11th day of June, 2012.

Katherine D'Aunno-Buchanan
Hearing Officer