MEDICAL CONTESTED CASE HEARING NO. 13031

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 December 5, 2012 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 a C4-5-6 revision, hardware removal, C6-7 ACDF with instrumentation and one day LOS for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by IG, ombudsman.

Respondent/Carrier appeared and was represented by BJ, attorney.

BACKGROUND INFORMATION

Claimant sustained a compensable injury to her cervical spine on (Date of Injury). Claimant underwent an anterior cervical discectomy and fusion from C3 to C6 on August 6, 2008. On August 3, 2010, a dorsal column stimulator was implanted and reported to have improved Claimant's condition but was removed in 2011. Claimant testified that the surgery improved her cervical spine symptoms temporarily but the headaches and radiculopathy returned. Claimant has undergone subsequent diagnostic studies, including an MRI of the cervical spine (May 11, 2011), an EMG/NCV (December 1, 2011) and flexion/extension x-rays (June 12, 2012). Claimant's treating surgeon, Dr. E, has recommended a C4-5-6 revision, hardware removal, C6-7 ACDF with instrumentation and one day LOS. The request for a cervical surgery was denied by the Carrier and submitted to an IRO who upheld the Carrier's denial.

The IRO reviewer, identified as a board certified orthopedic surgeon, determined the recommended surgical procedure was not medically necessary based on the clinical documentation provided for review as well as the ODG (Official Disability Guidelines). The IRO reviewer noted that there was no clinical documentation of any pseudoarthrosis or failure of the fusion graft from C4 to C6 and that the most recent radiograph studies did not identify any hardware failure and no updated imaging studies, including an MRI, were provided for review identifying evidence of pseudoarthrosis of the fusion graft. The IRO reviewer also pointed out that the flexion/extension x-rays performed in June 2012 fail to identify any significant

horizontal translation that meets the clinical guidelines regarding motion segment integrity at the C6-7 level and that the EMG studies failed to identify any significant nerve root irritation at C6-7 which would support surgical intervention.

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 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."

Pursuant to the ODG recommendations for the proposed procedures:

Recommended as an option in combination with anterior cervical discectomy for approved indications, although current evidence is conflicting about the benefit of fusion in general. (See Discectomy/laminectomy/laminoplasty.) Evidence is also conflicting as to whether autograft or allograft is preferable and/or what specific benefits are provided with fixation devices. Many patients have been found to have excellent outcomes while undergoing simple discectomy alone

(for one- to two-level procedures), and have also been found to go on to develop spontaneous fusion after an anterior discectomy. (Bertalanffy, 1988) (Savolainen, 1998) (Donaldson, 2002) (Rosenorn, 1983) Cervical fusion for degenerative disease resulting in axial neck pain and no radiculopathy remains controversial and conservative therapy remains the choice if there is no evidence of instability. (Bambakidis, 2005) Conservative anterior cervical fusion techniques appear to be equally effective compared to techniques using allografts, plates or cages. (Savolainen, 1998) (Dowd, 1999) (Colorado, 2001) (Fouyas-Cochrane, 2002) (Goffin, 2003) Cervical fusion may demonstrate good results in appropriately chosen patients with cervical spondylosis and axial neck pain. (Wieser, 2007) This evidence was substantiated in a recent Cochrane review that stated that hard evidence for the need for a fusion procedure after discectomy was lacking, as outlined below:

(1) Anterior cervical discectomy compared to anterior cervical discectomy with interbody fusion with a bone graft or substitute: Three of the six randomized controlled studies discussed in the 2004 Cochrane review found no difference between the two techniques and/or that fusion was not necessary. The Cochrane review felt there was conflicting evidence of the relative effectiveness of either procedure. Overall it was noted that patients with discectomy only had shorter hospital stays, and shorter length of operation. There was moderate evidence that pain relief after five to six weeks was higher for the patients who had discectomy with fusion. Return to work was higher early on (five weeks) in the patients with discectomy with fusion, but there was no significant difference at ten weeks. (Jacobs-Cochrane, 2004) (Abd-Alrahman, 1999) (Dowd, 1999) (Martins, 1976) (van den Bent, 1996) (Savolainen, 1998) One disadvantage of fusion appears to be abnormal kinematic strain on adjacent spinal levels. (Ragab, 2006) (Eck, 2002) (Matsunaga, 1999) (Katsuura, 2001) The advantage of fusion appears to be a decreased rate of kyphosis in the operated segments. (Yamamoto, 1991) (Abd-Alrahman, 1999)

(2) Fusion with autograft versus allograft: The Cochrane review found limited evidence that the use of autograft provided better pain reduction than animal allograft. It also found that there was no difference between biocompatible osteoconductive polymer or autograft (limited evidence). (Jacobs-Cochrane, 2004) (McConnell, 2003) A problem with autograft is morbidity as related to the donor site including infection, prolonged drainage, hematomas, persistent pain and sensory loss. (Younger, 1989) (Sawin, 1998) (Sasso, 2005) Autograft is thought to increase fusion rates with less graft collapse. (Deutsch, 2007). See Decompression, myelopathy.

(3) Fusion with autograft with plate fixation versus allograft with plate fixation, Single level: A recent retrospective review of patients who

received allograft with plate fixation versus autograft with plate fixation at a single level found fusion rates in 100% versus 90.3% respectively. This was not statistically significant. Satisfactory outcomes were noted in all non-union patients. (Samartzis, 2005)

(4) Fusion with different types of autograft: The Cochrane review did not find evidence that a vertebral body graft was superior to an iliac crest graft. (McGuire, 1994)

(5) Fusion with autograft versus fusion with autograft and additional instrumentation:

Plate Fixation: In single-level surgery there is limited evidence that there is any difference between the use of plates and fusion with autograft in terms of union rates. For two-level surgery, there was moderate evidence that there was more improvement in arm pain for patients treated with a plate than for those without a plate. Fusion rate is improved with plating in multi-level surgery. (Wright, 2007) See Plate fixation, cervical spine surgery.

Cage: Donor site pain may be decreased with the use of a cage rather than a plate, but donor site pain was not presented in a standardized manner. At two years pseudoarthrosis rate has been found to be lower in the fusion group (15%) versus the cage group (44%). A six-year follow-up of the same study group revealed no significant difference in outcome variables between the two treatment groups (both groups had pain relief). In the subgroup of patients with the cage who attained fusion, the overall outcome was better than with fusion alone. Patients treated with cage instrumentation have less segmental kyphosis and better-preserved disc height. This only appears to affect outcome in a positive way in cage patients that achieve fusion (versus cage patients with pseudoarthrosis). (Poelsson, 2007) (Varuch, 2002) (Hacker 2000) See also Adjacent segment disease/degeneration (fusion).

(6) Fusion with allograft alone versus with allograft and additional instrumentation:

Plate Fixation: Retrospective studies indicate high levels of pseudoarthrosis rates (as high as 20% for one-level and 50% for two-level procedures) using allograft alone. In a recent comparative retrospective study examining fusion rate with plating, successful fusion was achieved in 96% of single-level cases and 91% of two-level procedures. This could be compared to a previous retrospective study by the same authors of non-plated cases that achieved successful fusion in 90% of single-level

procedures and 72% of two-level procedures. (Kaiser, 2002) (Martin, 1999) See Plate fixation, cervical spine surgery.

Complications: Collapse of the grafted bone and loss of cervical lordosis: collapse of grafted bone has been found to be less likely in plated groups for patients with multiple-level fusion. Plating has been found to maintain cervical lordosis in both multi-level and one-level procedures. (Troyanovich, 2002) (Herrmann, 2004) (Katsuura, 1996) The significance on outcome of kyphosis or loss of cervical lordosis in terms of prediction of clinical outcome remains under investigation. (Peolsson, 2004) (Haden, 2005) (Poelsson, 2007) (Hwang, 2007)

Pseudoarthrosis: This is recognized as an etiology of continued cervical pain and unsatisfactory outcome. Treatment options include a revision anterior approach vs. a posterior approach. Regardless of approach, there is a high rate of continued moderate to severe pain even after solid fusion is achieved. (Kuhns, 2005) (Mummaneni, 2004) (Coric, 1997)

Anterior versus posterior fusion: In a study based on 932,009 hospital discharges associated with cervical spine surgery, anterior fusions were shown to have a much lower rate of complications compared to posterior fusions, with the overall percent of cases with complications being 2.40% for anterior decompression, 3.44% for anterior fusion, and 10.49% for posterior fusion. (Wang, 2007)

Predictors of outcome of ACDF: Predictors of good outcome include non-smoking, a pre-operative lower pain level, soft disc disease, disease in one level, greater segmental kyphosis pre-operatively, radicular pain without additional neck or lumbar pain, short duration of symptoms, younger age, no use of analgesics, gainful employment, higher preoperative NDI and normal ratings on biopsychosoical tests such as the Distress and Risk Assessment Method (DRAM). Predictors of poor outcomes include non-specific neck pain, psychological distress, psychosomatic problems and poor general health, litigation and workers' compensation. (Anderson, 2009) (Peolsson, 2006) (Peolsson, 2003) Patients who smoke have compromised fusion outcomes. (Peolsson, 2008)

See Plate fixation, cervical spine surgery. See also Adjacent segment disease/degeneration (fusion) & Iliac crest donor-site pain treatment.

Use of Bone-morphogenetic protein (BMP): FDA informed healthcare professionals of reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine for spinal fusion. The safety and effectiveness of rhBMP

> in the cervical spine have not been demonstrated, and these products are not approved for this use. These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. (FDA MedWatch, 2008) Bone-morphogenetic protein was used in approximately 25% of all spinal fusions nationally in 2006, with use associated with more frequent complications for anterior cervical fusions. No differences were seen for lumbar, thoracic, or posterior cervical procedures, but the use of BMP in anterior cervical fusion procedures was associated with a higher rate of complication occurrence (7.09% with BMP vs 4.68% without BMP) with the primary increases seen in wound-related complications (1.22% with vs 0.65% without) and dysphagia or hoarseness (4.35% with vs 2.45% without). (Cahill-JAMA, 2009)
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> For hospital LOS after admission criteria are met, see Hospital length of stay (LOS).

Dr. E testified that he disagreed with the IRO who based the denial on the ODG recommendations because the ODG is not the standard of care. Dr. E testified that Claimant suffers from cervical myelopathy and that she has "mechanical" instability which requires the proposed surgical intervention. Dr. T testified that, according to Claimant's medical records, she does not meet the ODG criteria for the proposed surgery and he explained how he reached that conclusion. Dr. T testified that, not only did Claimant not meet the ODG criteria for the proposed surgery but that the recommended surgery would not be in Claimant's best interest medically. Dr. E did not provide a response to the concerns raised by the IRO reviewer other than stating that the ODG is not the acceptable minimal standard for practicing medicine. Although Dr. E testified that the surgery is medically necessary based on the "standard of care," he failed to offer an opinion supported by evidence-based medicine to justify his recommendation for the cervical spine surgery. Based on the evidence presented, Claimant failed to provide an evidence-based medical opinion sufficient to contradict the determination of the IRO and the preponderance of the evidence is not contrary to the decision 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, when she sustained a compensable cervical spine injury.

C. The IRO determined that the requested cervical surgical intervention was not reasonable and necessary health care 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 Hearing Officer's Exhibit Number 2.

3. The treating doctor requested Claimant undergo a C4-5-6 revision, hardware removal, C6-7 ACDF with instrumentation and one day LOS for the compensable injury of (Date of Injury).

4. Claimant does not meet the requirements of the ODG for a C4-5-6 revision, hardware removal, C6-7 ACDF with instrumentation and one day LOS and she failed to present other evidence based medicine sufficient to overcome the determination of the IRO.

5. A C4-5-6 revision, hardware removal, C6-7 ACDF with instrumentation and one day LOS is not 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-based medical evidence is not contrary to the decision of the IRO that a C4-5-6 revision, hardware removal, C6-7 ACDF with instrumentation and one day LOS is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to a C4-5-6 revision, hardware removal, C6-7 ACDF with instrumentation and one day LOS for the compensable injury of (Date of Injury).

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 **TEXAS MUTUAL INSURANCE COMPANY** and the name and address of its registered agent for service of process is:

RON O. WRIGHT
6210 EAST HIGHWAY 290
AUSTIN, TX 78723

Signed this 5th day of December, 2012.

Carol A. Fougerat
Hearing Officer