MEDICAL CONTESTED CASE HEARING NO. 13019

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 medical contested case hearing was held on October 11, 2012 to decide the following disputed issue:

> Is the preponderance of the evidence-based medical evidence contrary to the decision of the Independent Review Organization (IRO) that the Claimant is not entitled to cervical fusion at C4-7, 1 day LOS for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant (hereinafter "Claimant") appeared and was assisted by LL, ombudsman. Respondent/Carrier (hereinafter "Carrier") appeared and was represented by BJ, attorney.

BACKGROUND INFORMATION

It was undisputed that the Claimant sustained a compensable cervical spine injury while working for (Employer) on (Date of Injury). The Claimant eventually came under the care of Dr. K L, a board certified orthopedic surgeon, on January 12, 2010, after having received treatment from doctors at Concentra Medical Center and Dr. ER. Because the Claimant had failed conservative care, Dr. L requested to perform a cervical fusion at levels C4-7 on February 28, 2012. The request was denied by the Carrier's utilization review agents and the Claimant appealed the denial to an IRO. The IRO, who is also a board certified orthopedic surgeon, upheld the Carrier's denial on the basis that there is a lack of objective evidence of pathology that would meet the criteria for the requested anterior cervical discectomy and fusion under the *Official Disability Guidelines* (ODG). The Claimant appealed the IRO decision to a medical contested case hearing.

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 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 anterior cervical fusion:

> 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)

For hospital LOS after admission criteria are met, see Hospital length of stay (LOS).

Regarding cervical discectomy, the ODG sets forth the following:

Recommended as an option if there is a radiographically demonstrated abnormality to support clinical findings consistent with one of the following:

(1) Progression of myelopathy or focal motor deficit;

(2) Intractable radicular pain in the presence of documented clinical and radiographic findings; or

(3) Presence of spinal instability when performed in conjunction with stabilization.

(See Fusion, anterior cervical.) Surgery is not recommended for disc herniation in a patient with non-specific symptoms and no physical signs. In addition, although surgery for spondylosis and radiculopathy may offer some short term benefit, non-operative treatment with PT can provide similar improvement in pain and function at 12-16 months for patients without progressive neurologic deficits or instability. (Persson, 1997) The American Academy of Orthopaedic Surgeons has recommended that an anterior approach is appropriate when there is evidence of radiculopathy, and/or when there is evidence of central location and there is any degree of segmental kyphosis. A posterior approach has been suggested by the same group when there is evidence of lateral soft disc herniations with predominate arm pain and for caudal lesions in large, short-necked individuals. (Albert, 1999) The overall goals of cervical surgery should be decompression, restoration of alignment, and stability. (Jacobs-*Cochrane*, 2004) (Dowd, 1999) (Colorado, 2001) In terms of posterior procedures, there does not appear to be sufficient evidence to support the use of laminoplasty versus laminectomy based on outcomes or post-operative morbidity. Research has indicated that as many as 60% of patients who received laminoplasty had posterior neck and shoulder girdle pain post-operatively (versus 25% in the laminectomy group). (Hosono, 1996) (Heller, 2001) Some authors continue to prefer laminoplasty to anterior spinal decompression and fusion (for myelopathy due to disc herniation) as they feel the risk of chronic neck pain is less troublesome than the risk of bone graft complications and/or adjacent spondylosis that can be found with the fusion procedure. (Sakaura, 2005) It is not clear from the evidence that long-term outcomes are improved with the surgical treatment of cervical radiculopathy compared with nonoperative measures. However, relatively rapid and substantial relief of pain and impairment in the

short term (6-12 weeks after surgery) after surgical treatment appears to have been reliably achieved. (Haldeman, 2008)

Late deterioration: Has been found with both anterior and posterior approaches. (Rao, 2006) With the anterior approach, recurrent symptoms have been found secondary to deterioration of the adjacent segment, inadequate decompression at the time of the initial surgery, pseudoarthrosis, graft or implant failure, and/or continued growth of osteophytes. With the posterior approach, recurrent symptoms have been found secondary to development of kyphosis, instability, spread of ossification of the posterior longitudinal ligament, and development of stenosis at new levels. 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)

Pre-operative evaluation:

MRI: This is a very sensitive test for radicular disorders but has a lower negative predictive value. Disc bulges have been found in one study in 52% of subjects and protrusions in 27% without back pain. At age 60 years, 93% of subjects in one study had disc degeneration/bulges on MRI. (Boden, 1990)

EMG: Optional for cervical surgery. See Electromyography.

ODG Indications for Surgery™ -- Discectomy/laminectomy (excluding fractures):

Washington State has published guidelines for cervical surgery for the entrapment of a single nerve root and/or multiple nerve roots. (Washington, 2004) Their recommendations require the presence of all of the following criteria prior to surgery for each nerve root that has been planned for intervention (but ODG does not agree with the EMG requirement):

A. There must be evidence of radicular pain and sensory symptoms in a cervical distribution that correlate with the involved cervical level or presence of a positive Spurling test.
B. There should be evidence of motor deficit or reflex changes or positive EMG findings that correlate with the cervical level. *Note:* Despite what the Washington State guidelines say, ODG recommends that EMG is optional if there is other evidence of motor deficit or reflex changes. EMG is useful in cases where clinical findings are unclear, there is a discrepancy in imaging, or to identify other etiologies of symptoms such as metabolic (diabetes/thyroid) or peripheral pathology (such as carpal tunnel). For more information, see EMG.

C. An abnormal imaging (CT/myelogram and/or MRI) study must show positive findings that correlate with nerve root involvement that is found with the previous objective physical and/or diagnostic findings. If there is no evidence of sensory, motor, reflex or EMG changes, confirmatory selective nerve root blocks may be substituted if these blocks correlate with the imaging study. The block should produce pain in the abnormal nerve root and provide at least 75% pain relief for the duration of the local anesthetic.

D. Etiologies of pain such as metabolic sources (diabetes/thyroid disease) non-structural radiculopathies (inflammatory, malignant or motor neuron disease), and/or peripheral sources (carpal tunnel syndrome) should be addressed prior to cervical surgical procedures.

E. There must be evidence that the patient has received and failed at least a 6-8 week trial of conservative care.

For hospital LOS after admission criteria are met, see Hospital length of stay (LOS).

To overcome the IRO decision, the Claimant presented his testimony, Dr. L's records, and other records, including two cervical MRIs dated May 28, 2009 and January 3, 2011, an EMG dated June 15, 2009, and physical therapy notes from Concentra. The first MRI, the EMG and the physical therapy notes were not provided to the IRO according to its report. The Carrier presented the testimony of Dr. NT, who is the Carrier's Medical Director and is also a board certified orthopedic surgeon. Dr. T's opinion, based on his review of the medical records in this case, is that the recommended surgery is not medically necessary. Dr. T testified that the January 3, 2011 MRI does not reflect any nerve compression, and it is his opinion that the June 15, 2009 EMG is unreliable because there was no accompanying physical examination, the test was conducted by an untrained technician, and it was read by Dr. MP by telephone. Dr. T also testified that there is no evidence of any instability in the Claimant's cervical spine.

After a careful review of the entire record, it is determined that the evidence does not reflect that Dr. L explains how the ODG or any other evidence-based medicine was utilized to make a decision concerning the medical necessity of the surgery in question. The Claimant did not present any evidence-based medicine to overcome the IRO decision. Therefore, the IRO decision is upheld.

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. On (Date of Injury), Employer had workers' compensation insurance coverage with Texas Mutual Insurance Co., Carrier.

   D. On (Date of Injury), the Claimant sustained a compensable cervical spine injury while in the course and scope of his employment with (Employer).

   E. The IRO upheld the Carrier's denial of the surgery in question.

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. A cervical fusion at C4-7, 1 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 cervical fusion at C4-7, 1 day LOS is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to a cervical fusion at C4-7, 1 day LOS for his compensable (Date of Injury) 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, PRESIDENT

TEXAS MUTUAL INSURANCE COMPANY

6210 EAST HIGHWAY 290

AUSTIN, TX 78723

Signed this 5th day of November, 2012.

Patrice Fleming-Squirewell
Hearing Officer