MEDICAL CONTESTED CASE HEARING NO. 14013

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 July 15, 2013, to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the decision of the IRO that the claimant is not entitled to L4-5 prodisc/L5-S1 mini 360 fusion with a 2-day inpatient stay for the compensable injury of (Date of Injury)?

PARTIES PRESENT

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

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

BACKGROUND INFORMATION

On (Date of Injury), Claimant was crushed between a forklift and a rack of shelves. He sustained a compensable injury to his knee and low back, specifically the L4/5 disc. On May 03, 2001, he had a laminectomy and discectomy at the L4/5 level. His MRI dated September 25, 2000, showed a small disc protrusion at L5/S1. At the time of the injury, Claimant was having radicular pain in the left leg. Since the surgery, the radicular problems have been in the left leg.

At this time, Claimant's surgeon wants to proceed with an L4-5 prodisc/L5-S1 mini 360 fusion with a 2-day inpatient stay. The surgery was denied twice and appealed to an IRO. The IRO agreed with the denial.

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. 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(s), "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."

On the date of this medical contested case hearing, the Official Disability Guidelines provides the following with regard to an L4-5 prodisc (lumbar disc prostheses/artificial disc):

> Not recommended. While artificial disc replacement (ADR) as a strategy for treating degenerative disc disease has gained substantial attention, it is not possible to draw any positive conclusions concerning its effect on improving patient outcomes. The studies quoted below have failed to demonstrate superiority of disc replacement over lumbar fusion, which is also not a recommended treatment in ODG for degenerative disc disease. The anatomic implications of total disc replacement are different from total hip or total knee replacements, and the perceived corollary between total disc replacement and total hip or knee replacement is not justified. Furthermore, longevity of this new procedure is unknown, especially with a relatively young average age in workers' comp patients, and the consequences of failure of an implant in close proximity to caudal equina and vital organs (e.g., aorta, vena cava and iliac arteries) are of concern. Plus, adjacent segment disease seems to be a natural aging process, and despite early intentions, ADR has not proven any benefit in altering that progression compared to fusion. See separate document with all studies focusing on Disc prosthesis. (Cinotti-*Spine*, 1996) (Klara-*Spine*, 2002) (Zeegers, 1999) (Blumenthal, 2003) (Zigler, 2003) (McAfee, 2003) (Anderson-*Spine*, 2004) (Gamradt-*Spine*, 2005) (Gibson-*Cochrane*, 2005) See also the Neck Chapter.

Total disc replacements should be considered experimental procedures and should only be used in strict clinical trials. (deKleuver, 2003) At the current time radiculopathy is an exclusion criteria for the FDA studies on lumbar disc replacement. (McAfee-*Spine*, 2004) Even though medical device manufacturers expect this to be a very large market (Viscogliosi, 2005), the role of total disc replacement in the lumbar spine remains unclear and predictions that total disc replacement (TDR) will replace fusion are premature. One recent study indicates that only a small percentage (5%) of the patients currently indicated for lumbar surgery has no contraindications to TDR. (Huang-*Spine*, 2004) Because of significantly varying outcomes, indications for disc replacement need to be defined precisely. In this study better functional outcome was obtained in younger patients under 40 years of age and patients with degenerative disc disease in association with disc herniation. Multilevel disc replacement had significantly higher complication rate and inferior outcome. (Siepe, 2006) On the other hand, this case series reporting on the long-term results of one-level lumbar arthroplasty reported that after a minimum 10-year follow-up, 90% of patients had returned to work, including 78% of patients with hard labor level employment returning to the same level of work. (David, 2007) According to this prospective, randomized, multicenter FDA IDE study, the ProDisc-L has been shown to be superior to circumferential fusion by multiple clinical criteria. (Zigler, 2007)

Recent research: A high quality meta-analysis/health technology assessment concluded that there is insufficient evidence to draw extensive efficacy/effectiveness conclusions comparing artificial disc replacement (ADR) with a broad range of recommended treatment options, including conservative nonoperative care, since, other than spinal fusion, there are currently no direct comparison studies. With respect to the comparison of lumbar artificial disc replacement (L-ADR) and fusion, overall clinical success was achieved in 56% of patients receiving L-ADR and 48% receiving lumbar fusion. Though the results suggest that 24-month outcomes for L-ADR are similar to lumbar fusion, it should be noted that for the lumbar spine, the efficacy of the comparator treatment, lumbar fusion, for degenerative disc disease remains uncertain, especially when it is compared with nonoperative care. Given what is known about lumbar fusion as a comparator and having evidence that only compares L-ADR with lumbar fusion limits the ability to fully answer the efficacy/effectiveness question. (Zigler, 2007) (Blumenthal, 2005) (Dettori, 2008) Although there is fair evidence that artificial disc replacement is similarly effective compared to fusion for single level degenerative disc disease, insufficient evidence exists to judge long-term benefits or harms. (Chou, 2009) The ECRI health technology assessment concluded that the safety data on lumbar ADR are inadequate to draw conclusions about long-term safety. (ECRIa, 2009)

This RCT compared disc prosthesis with multidisciplinary rehabilitation for 12-15 days, and found differences in favor of surgery, but the difference between groups was smaller than the difference that the study was designed to detect. In concluding, given the association of surgery with potentially serious complications, and the considerable improvement in the rehabilitation group, they recommended considering a multidisciplinary rehabilitation first. (Hellum, 2011) A just-released Cochrane systematic review concludes that the lumbar artificial disc is still not ready for routine clinical use because the long-term risks and benefits of this treatment have not been documented adequately. (Jacobs, 2012) A *Back Letter* article entitled, "Future Still Uncertain for the Lumbar Artificial Disc," reports that patients, physicians, and healthcare systems were wise to resist the massive wave of publicity in favor of the artificial disc for the treatment of chronic back pain. (Wiesel, 2012)

Safety & Complications: There is moderate evidence that L-ADR is as safe as lumbar anterior or circumferential fusion. The studies primarily reflect outcomes measured up to 24 months and therefore questions remain regarding the long-term safety and efficacy of L-ADR compared with fusion. This is an important matter, particularly in workers' comp patients who may be younger. Since these are mechanical devices, future failure is a possibility and may influence complication rates and costs in the longer-term. (Dettori, 2008) Revision procedures have included posterior stabilization or anterior revision or conversion to arthrodesis. Risk of great vessel and retroperitoneal injury is greater than with primary procedures. (Patel, 2008) We do not know the long-term failure rate or impact of particular wear on these devices, and the theoretical position that symptomatic adjacent segment disease leads to more surgery after fusion compared to less aggressive treatment is poorly founded, plus theses devices appear at best to yield results equal to or only incrementally better than fusion for the same indications. (Resnick, 2007)

Indications: Indications for L-ADR include, among other factors, primary back pain and/or leg pain in the absence of nerve root compression with single level disease. This group of patients is different than those undergoing cervical ADR and results from one group should not be inferred to the other. Cervical ADR is performed in patients with radiculopathy (cervical nerve root compression) causing arm pain and possibly motor weakness, or even myelopathy (compression of the spinal cord that could affect upper extremities, lower extremities, bowel, and bladder function). The problem of identifying those likely to respond to treatment is of concern for L-ADR in that the surgical procedure is designed to treat degenerative disc disease that is thought to be the origin of the patient's pain, but certainty around the diagnosis as the cause of low back symptoms varies.

Though L-ADR for degenerative disc disease has been compared with lumbar fusion, not all patients who get a fusion are candidates for L-ADR, including patients with nerve root compression, spondylolisthesis, stenosis, facet mediated pain and osteoporosis. In fact, the proportion of patients who have an indication for L-ADR make up only about 5% of those who might undergo lumbar fusion. (Dettori, 2008)

Current US treatment coverage recommendations: Variations exist in coverage policies for ADR for CMS and selected bell-weather payers. *Medicare:* The Centers for Medicare and Medicaid Services (CMS) will not cover lumbar ADR for patients older than 60 years of age and decisions regarding coverage of patients younger than 60 years of age are at the discretion of local CMS contractors. (Medicare, 2007) *Aetna* considers prosthetic intervertebral discs medically necessary for degenerative disc disease at one level. (Aetna, 2007) *Blue Cross/Blue Shield:* Coverage is not recommended. (Blue Cross/Blue Shield, 2007) *Cigna* covers the lumbar intervertebral disc prosthesis. (Cigna, 2007) *Harvard Pilgrim* does not cover artificial disc replacement for DDD as an alternative to spinal fusion. (Harvard Pilgrim, 2006) *Washington State Department of Labor and Industries:* Initially concluded that data insufficient to draw conclusions, L-ADR should be considered experimental only. (Washington LNI, 2004) Then in March of 2009, based on the 2008 Washington Technology Assessment (Dettori, 2008), Washington LNI released an official Coverage Determination stating that Lumbar ADR would be covered under these conditions: (1) Post-completion of a multi-disciplinary pain program; (2) Age 60 or less; (3) Consistent with FDA approved indications (i.e., failure of 6-months non-operative treatment, skeletally mature patient, single disc only, no infection, no sensitivity to implant materials, no osteoporosis or spondylosis). (Washington, 2009) *Health Net* considers both artificial lumbar and cervical disc replacements investigational and therefore not medically necessary. (Health Net, 2012)

On the date of this medical contested case hearing, the Official Disability Guidelines provides the following with regard to a L5-S1 mini 360 fusion:

Patient Selection Criteria for Lumbar Spinal Fusion:

For chronic low back problems, fusion should not be considered within the first 6 months of symptoms, except for fracture, dislocation or progressive neurologic loss. Indications for spinal fusion may include:

(1) Neural Arch Defect - Spondylolytic spondylolisthesis, congenital neural arch hypoplasia.

(2) Segmental Instability (objectively demonstrable) - Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy, with relative angular motion greater than 20 degrees. (Andersson, 2000) (Luers, 2007)]
(3) Primary Mechanical Back Pain (i.e., pain aggravated by physical activity)/Functional Spinal Unit Failure/Instability, including one or two level segmental failure with progressive degenerative changes, loss of height, disc loading capability. In cases of workers' compensation, patient outcomes related to fusion may have other confounding variables that may affect overall success of the procedure, which should be considered. There is a lack of support for fusion for mechanical low back pain for subjects with failure to participate effectively in active rehab pre-op, total disability over 6 months, active psych diagnosis, and narcotic dependence. Spinal instability criteria includes lumbar inter-segmental movement of more than 4.5 mm. (Andersson, 2000)
(4) Revision Surgery for failed previous operation(s) if significant functional gains are anticipated. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature.
(5) Infection, Tumor, or Deformity of the lumbosacral spine that cause intractable pain, neurological deficit and/or functional disability.
(6) After failure of two discectomies on the same disc, fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria.

(See ODG Indications for Surgery -- Discectomy.)

Pre-Operative Surgical Indications Recommended: Pre-operative clinical surgical indications for spinal fusion should include all of the following:

(1) All pain generators are identified and treated; &
(2) All physical medicine and manual therapy interventions are completed; &
(3) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or discography (see discography criteria) & MRI demonstrating disc pathology correlated with symptoms and exam findings; &
(4) Spine pathology limited to two levels; &
(5) Psychosocial screen with confounding issues addressed.
(6) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing.

(Colorado, 2001) (BlueCross BlueShield, 2002)

Currently the Official Disability Guidelines does not recommend a lumbar disc prostheses. Claimant's surgeon does not explain, based upon evidence based medicine, how Claimant's condition falls outside the Official Disability Guidelines.

As for the fusion, Claimant's surgeon does not explain how Claimant has meet all of the pre-operative surgical indications that have been recommended by the Official Disability Guidelines. The Official Disability Guidelines states a fusion is not recommended for degenerative disc disease. Also, the requesting surgeon does not explain, based upon evidence based medicine, how Claimant's condition falls outside the Official Disability Guidelines.

Claimant's surgeon explains he and his facility are on the cutting edge of the technology and that he believes Claimant would be a good candidate for the two procedures simultaneously, but he does not explain how this hybrid procedure meets the Official Disability Guidelines or how, as an outlier, the procedures are reasonable, necessary and based upon evidence based medicine.

Finally, taking the procedures together, Claimant has two problems. One is that the requested procedure cannot be determined in his favor because the procedures cannot be approved piecemeal. The procedures have to be found in Claimant's favor together. Because the artificial disc is not recommended by the Official Disability Guidelines, the procedure as a whole cannot be determined in Claimant's favor. The other problem is that the L5/S1 disc has been found not to be part of the compensable injury, so the procedure cannot be authorized.

Claimant did not meet his burden of proof.

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 sustained a compensable injury while employed by (Employer), Employer

    C. On (Date of Injury), Employer provided workers' compensation insurance with The Travelers Indemnity Company of Connecticut, Carrier.

    D. Claimant's doctor requested pre-authorization for an artificial disc replacement at L4/5 and a 360 fusion at L5/S1 with a 2-day inpatient stay.

    E. Carrier refused to pre-authorize the requested surgery and the denial was appealed to an IRO.

F. The Texas Department of Insurance appointed The Dyll Review as the IRO.

G. The IRO upheld Carrier's denial of pre-authorization for the proposed procedure.

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. An L4-5 prodisc/L5-S1 mini 360 fusion with a 2-day inpatient stay 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 is not contrary to the decision of the IRO that L4-5 prodisc/L5-S1 mini 360 fusion with a 2-day inpatient stay is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to L4-5 prodisc/L5-S1 mini 360 fusion with a 2-day inpatient stay for the compensable injury of (Date of Injury).

ORDER

Carrier is/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 **TRAVELERS INDEMNITY COMPANY OF CONNECTICUT** and the name and address of its registered agent for service of process is

CORPORATION SERVICE COMPANY
D/B/A CSC-LAWYERS INCORPORATING SERVICE COMPANY
211 EAST 7TH STREET, SUITE 620
AUSTIN, TX 78701.

Signed this 09th day of October, 2013.

KEN WROBEL
Hearing Officer