MEDICAL CONTESTED CASE HEARING NO. 18017

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and the Rules of the Texas Department of Insurance, Division of Workers' Compensation. For the reasons discussed herein, the Administrative Law Judge determines that Claimant is not entitled to the fusion transforaminal interbody MIS, staelth navigation-spinal and neuromonitoring (CPT: 22634, 22633, 63047, 63048, 22842, 22853, 61783, 20930, 20931) for the compensable injury of (Date of Injury).

STATEMENT OF THE CASE

On May 1, 2018, Jeff Carothers, a Division administrative law judge, held a contested case hearing to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that Claimant is not entitled to the fusion transforaminal interbody MIS, staelth navigation-spinal and neuromonitoring (CPT: 22634, 22633, 63047, 63048, 22842, 22853, 61783, 20930, 20931) for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Claimant appeared and was assisted by CN, ombudsman. Carrier appeared and was represented by BQ, attorney.

DISCUSSION

Claimant sustained a compensable injury to his low back on (Date of Injury). The medical records presented show that Claimant's post-injury medical treatment included a lumbar fusion at L5/S1. The medical records from Claimant's medical treatment in 2017 as summarized by the IRO show that Claimant has complained of persistent low back pain with pain radiating into both of his legs. On July 27, 2017, CG, M.D., recommended Claimant undergo a transforaminal lumbar interbody fusion at L2-L3, L3-L4, and L4-L5.

Carrier denied the surgery requested by Dr. G which was described in the request as a fusion transforaminal interbody MIS, staelth navigation-spinal and neuromonitoring (CPT: 22634, 22633, 63047, 63048, 22842, 22853, 61783, 20930, 20931). Claimant then sought review by an IRO. The IRO reviewer, identified as an orthopedic surgeon, upheld Carrier's denial. In upholding Carrier's denial of the requested service, the IRO reviewer referred to the recommendations in the Official Disability Guidelines (ODG) and stated that the request did not

meet standard guidelines due to the lack of specific levels identified in the requested service and the lack of documentation of appropriate physical therapy trial for nonoperative management. The IRO reviewer further stated that a computer-assisted navigation surgery is not recommended per the guidelines as well.

Texas Labor Code §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 §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 §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 §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 §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(s), "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."

For the requested spinal fusion, the ODG provides:

> Patient Selection Criteria for Lumbar Spinal Fusion:
>
> (A) Recommended as an option for the following conditions with ongoing symptoms, corroborating physical findings and imaging, and after failure of non-operative treatment (unless contraindicated, e.g., acute traumatic unstable fracture, dislocation, spinal cord injury) subject to criteria below:

(1) Spondylolisthesis (isthmic or degenerative) with at least one of these:
   (a) instability, and/or
   (b) symptomatic radiculopathy, and/or
   (c) symptomatic spinal stenosis;
(2) Disc herniation with symptomatic radiculopathy undergoing a third decompression at the same level;
(3) Revision of pseudoarthrosis (single revision attempt);
(4) Unstable fracture;
(5) Dislocation;
(6) Acute spinal cord injury (SCI) with post-traumatic instability;
(7) Spinal infections with resultant instability;
(8) Scoliosis with progressive pain, cardiopulmonary or neurologic symptoms, and structural deformity;
(9) Scheuermann's kyphosis;
(10) Tumors.

(B) Not recommended in workers' compensation patients for the following conditions:
(1) Degenerative disc disease (DDD);
(2) Disc herniation;
(3) Spinal stenosis without degenerative spondylolisthesis or instability;
(4) Nonspecific low back pain.

(C) Instability criteria: Segmental Instability (objectively demonstrable) - Excessive motion, as in isthmic or 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 15 degrees L1-2 through L3-4, 20 degrees L4-5, 25 degrees L5-S1. Spinal instability criteria include lumbar inter-segmental translational movement of more than 4.5 mm. (*Andersson, 2000*) (*Luers, 2007*) (*Rondinelli, 2008*)

(D) After failure of two discectomies on the same disc [(A)(2) above], 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*.)

(E) Revision Surgery for failed previous fusion at the same disc level [(A)(3) above] if there are ongoing symptoms and functional limitations that have not responded to non-operative care; there is imaging confirmation of pseudoarthrosis and/or hardware breakage/malposition; and significant functional gains are reasonably expected. 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. Workers compensation and opioid

use may be associated with failure to achieve minimum clinically important difference after revision for pseudoarthrosis (*Djurasovic, 2011*) There is low probability of significant clinical improvement from a second revision at the same fusion level(s), and therefore multiple revision surgeries at the same level(s) are not supported.

(F) Pre-operative clinical surgical indications for spinal fusion should include all of the following:

(1) All physical medicine and manual therapy interventions are completed with documentation of reasonable patient participation with rehabilitation efforts including skilled therapy visits, and performance of home exercise program during and after formal therapy. Physical medicine and manual therapy interventions should include cognitive behavioral advice (e.g., ordinary activities are not harmful to the back, patients should remain active, etc.);

(2) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or MRI demonstrating nerve root impingement correlated with symptoms and exam findings;

(3) Spine fusion to be performed at one or two levels;

(4) Psychosocial screen with confounding issues addressed; the evaluating mental health professional should document the presence and/or absence of identified psychological barriers that are known to preclude post-operative recovery;

(5) 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*)

(6) There should be documentation that the surgeon has discussed potential alternatives, benefits and risks of fusion with the patient;

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

For the requested computer-assisted navigation surgery, the ODG provides:

> Not recommended for spinal surgery because this method remains an unproven and controversial technology. However, because some surgeons routinely utilize various forms of navigation assistance without causing worsened outcomes, its selective use “incidental to the primary surgical procedure” and not separately billable may be considered medically reasonable. Obstacles to computer-assisted techniques include increased operating time, additional exposure to ionizing radiation, and steep learning curves requiring extensive training of the surgical team. There is still insufficient evidence to draw strong scientific conclusions

regarding any superiority or added value of computer-assisted technologies for spine surgery compared to conventional methods. Long-term effectiveness has simply not been reasonably demonstrated, despite several decades of development. Further studies are needed to determine whether such computer/robotic navigation systems for orthopedic procedures can actually improve functional outcomes, including decreased pain and disability as well as improved range of motion, joint function, and flexibility.

Most published studies examining computer-assisted or robotic applications for spine surgery have focused specifically on attempts to improve the accuracy and reliability of pedicle screw placement for intervertebral fusion. The development of these tools over the past several decades has changed considerably; however, mid- to long-term clinical outcome improvements have not been convincingly demonstrated with any technique. The earliest systems used pre-operative CT scans for "stereotactic navigation," but several problems hindered technical success: failure to adjust imaging parameters to exclude non-osseous structures, registration errors due to intra-procedural movement and patient positioning (different than CT supine), and increased operative time, cost, and radiation exposure. Over the past decade, the majority of surgeons have used some form of basic fluoroscopic guidance to assist pedicle screw placement. This approach eventually led to obtaining multiple fluoroscopic projections intra-operatively, then constructing a computer-generated model in real-time, thus eliminating the lengthy registration issues with pre-operative CT-based systems. This method has been synonymously referred to as 2D fluoroscopy-based navigation or "virtual fluoroscopy." Finally, 3D fluoroscopy-based navigation, also confusingly described as "intraoperative CT," utilizes a 2-minute motorized rotating 180- or 360-degree specialized C-arm to produce CT-like navigation images. These machines are quite expensive, so these units have been mostly isolated to tertiary facilities, but lower pedicle breach rates and radiation exposure have been reported for 3D navigation. (*Bourgeois, 2015a*)

While reports of improvements in actual clinical outcomes are disappointingly lacking for navigation, several studies have examined the accuracy of screw placement and pedicle breaches. A systematic review (SR) of 68 articles, including 3442 patients with 43,305 pedicle screws, indicated that the most widely used method of reporting was based on 2-mm breach increments measured on post-operative CT. Safe zone placement of 91% free-hand and 97% navigation were estimated. (*Aoude, 2015*) An earlier SR noted wide variations of reported accuracy improvements with navigation, but the review interestingly observed that when perforations of the laminar cortex did occur, they tended to be medial with free-hand and lateral with navigation approaches. (*Gelalis, 2012*) Another

more recent SR of 1105 screws (5 studies) using “robot-assisted” vs. free-hand methods reported no differences in the accuracy of screw placement; these authors also specifically indicated a need for further high-quality studies. (Liu, 2016) A prospective randomized controlled trial (RCT) comparing free-hand with robot-assisted techniques found no differences in intrapedicular accuracy, but facet joint violations were more common with free-hand methods. (*Kim, 2016*) A similar SR of 1308 screws (5 studies) comparing robot-assisted and simple fluoroscopic guidance actually noted slightly more favorable accuracy with fluoroscopy alone, citing a need for more high-quality research. (*Marcus, 2014*) A matched cohort study of robot-assisted and fluoroscopy-guided screw placement found no differences between the groups. It was also mentioned that technical difficulties remain using robotics and that standard fluoroscopy backup is advocated. (*Schatlo, 2014*) An SR of 30 studies, including 12 fluoroscopy data sets, 8 2D, and 20 3D with a total of 9310 screws, reported accuracies of 68%, 84%, and 96%, respectively. These results from 3D systems appeared to be encouraging. (*Mason, 2014*) Cohorts of 1434 screws placed with and without 3D navigation (the latter group using fluoroscopy only) reported similar 18-20% cortical breaches, although the 3D group was deemed to have been “more complex.” (*Luther, 2015*) Another cohort of 599 “minimally invasive” 3D navigation patients (2132 screws) had 1.15% per person and 0.33% per screw breach incidences, compared to a meta-analysis-derived comparison of 13.1% with 2D navigation systems. (*Bourgeois, 2015b*) An RCT involving 143 patients compared 3D navigation with conventional methods, using both open and minimally invasive approaches for screw placement. The findings indicated that 3D was less accurate for percutaneous use but more accurate in open procedures. (*Ruatti, 2016*) This study has been criticized for having a questionable methodology, too many treatment arms and variables, and an unacceptable 24% screw misplacement rate in the minimally invasive 3D group. (*Sembrano, 2016*)

Computer-assisted navigation for spine applications still appears to be only at the beginning of its evolution. It has become evident that systems based on pre-operative CT do not improve accuracy of pedicle screw placement compared to fluoroscopic approaches. Future lower cost and “hybrid” systems remain under development. (*Zheng, 2015*) Although 3D systems do appear to show some promise regarding accuracy of pedicle screw placement, empirically confirmed improvements in clinical outcomes are ultimately needed to recommend it, especially considering the high cost of current technologies. The majority of insurers consider computerized assistance to be incidental to the primary surgical procedure and therefore not separately billable. The type of instruments, technique, and/or approach of these procedures should certainly be left to the

discretion of the surgeon, but additional payments should be based on proven outcomes of the assistive techniques (*see ODG Background and Description*).

Because Claimant is the party appealing the IRO decision, he has the burden of overcoming the decision issued by the IRO by a preponderance of evidence-based medical evidence. Claimant's evidence included two narratives written by Dr. G. In one narrative, Dr. G described his impression of Claimant's clinical condition, stated that he offered Claimant a three-level lumbar fusion, and stated that Claimant was cleared by neuropsychology and stopped smoking. Dr. G does not address whether Claimant completed an appropriate physical therapy trial for nonoperative management, one of the bases cited by the IRO reviewer in upholding Carrier's denial of the requested surgery. In another more detailed narrative, Dr. G states that Claimant had adjacent segment disease at L4/L5 along with disc degeneration at L2/L3 and L3/L4 contributing to Claimant's low back pain. Citing a study by *Ryu et al*, a copy of which was introduced into evidence, Dr. G states that the most appropriate medical treatment for Claimant is to fuse L2/L3, L3/L4, and L4/L5. The *Ryu et al* study cited by Dr. G concerns the appropriate surgical procedure for adjacent segment disease and concluded that fusion extension should be considered instead of segmental limited surgery when certain risk factors are present because of the high failure rate of segmental limited surgery. However, again, Dr. G does not address the bases cited by the IRO in upholding the denial of the requested surgery, including the exhaustion of conservative measures, nor does he assert that the *Ryu et al* study should be considered over the ODG and makes the proposed treatment medically necessary.

Claimant also presented a narrative written by KG, M.D. Dr. KG opines that Claimant did meet the requirements for the requested surgery, including the requirement of conservative treatment. While it is true that Claimant did participate in a course of physical therapy, that participation occurred after the IRO decision. Medical records created after an IRO review cannot be considered by the Administrative Law Judge in determining the medical necessity of proposed treatment, though such reports may be the basis for a resubmission request to Carrier.

Considering all the evidence in the record, the Administrative Law Judge determines that Claimant has not met his burden to overcome the decision of the IRO by a preponderance of evidence-based medical evidence. Therefore, it is determined that Claimant is not entitled to the fusion transforaminal interbody MIS, staelth navigation-spinal and neuromonitoring (CPT: 22634, 22633, 63047, 63048, 22842, 22853, 61783, 20930, 20931) for the compensable injury of (Date of Injury).

The Administrative Law Judge considered all of the evidence admitted. The Findings of Fact and Conclusions of Law are based on an assessment of all of the evidence whether or not the evidence is specifically discussed in this Decision and Order.

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 provided workers' compensation insurance coverage with Travelers Indemnity Company of Connecticut, Carrier.

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

   E. The IRO determined that the fusion transforaminal interbody MIS, staelth navigation-spinal and neuromonitoring (CPT: 22634, 22633, 63047, 63048, 22842, 22853, 61783, 20930, 20931) is not medically necessary 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 Administrative Law Judge's Exhibit Number 2.

3. Claimant does not meet the requirements of the ODG for the fusion transforaminal interbody MIS, staelth navigation-spinal and neuromonitoring (CPT: 22634, 22633, 63047, 63048, 22842, 22853, 61783, 20930, 20931).

4. The fusion transforaminal interbody MIS, staelth navigation-spinal and neuromonitoring (CPT: 22634, 22633, 63047, 63048, 22842, 22853, 61783, 20930, 20931) 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 the fusion transforaminal interbody MIS, staelth navigation-spinal and neuromonitoring (CPT: 22634, 22633, 63047, 63048, 22842, 22853, 61783, 20930, 20931) is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to the fusion transforaminal interbody MIS, staelth navigation-spinal and neuromonitoring (CPT: 22634, 22633, 63047, 63048, 22842, 22853, 61783, 20930, 20931) 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 Texas Labor Code §408.021.

The true corporate name of the insurance carrier is **TRAVELERS INDEMNITY COMPANIES**, and the name and address of its registered agent for service of process is:

CORPORATION SERVICE CO.
D/B/A CSC-LAWYERS INCORPORATING SERVICE
211 EAST 7TH STREET
SUITE 620
AUSTIN, TX 78701-3218

Signed this 8th day of May, 2018.

Jeff Carothers
Administrative Law Judge