MEDICAL CONTESTED CASE HEARING NO. 14062

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and the Rules of the Division of Workers' Compensation. For the reasons discussed herein, the Hearing Officer determines that Claimant is not entitled to an outpatient lumbar revision dorsal column stimulator, lead and generator, electrodes and analysis for the compensable injury of (Date of Injury).

STATEMENT OF THE CASE

A contested case hearing was held on April 24, 2014 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 an outpatient lumbar revision dorsal column stimulator, lead and generator, electrodes and analysis for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Provider appeared by telephone and represented himself. Claimant appeared and was assisted by TL, ombudsman. Respondent/Carrier appeared and was represented by JL, attorney.

BACKGROUND INFORMATION

The evidence presented in the hearing revealed that during 2005, the Claimant sustained a prior lumbar spine injury and that on (Date of Injury), Claimant sustained a compensable injury to his lumbar spine resulting in decompressive laminectomies, discectomies at level L4-L5 and L5-S1 and a revision surgery with fusion. On October 16, 2009, DT, M.D., performed the implantation of the spinal cord stimulator procedure and placement of connector and pulse generator. On December 31, 2009, Dr. T performed a thoracic laminectomy, epidural neurolysis and replacement spinal cord stimulator with resumed TL lead, however, Claimant continued to suffer from chronic low back pain and leg pain. Claimant's testimony in the hearing indicated that he receives random "zaps" when he moves around and/or turns the wrong way and that he can only use the spinal cord stimulator when he is lying in bed. Claimant's testimony indicated that the random zaps cause a sharp pain to his lower back which have caused him to drop to his knees. The evidence indicated that sometimes the battery on the spinal cord stimulator will not shut off and that when the Claimant goes into a department store that has security sensors, it triggers the stimulator to turn on and shock him and he is not able to turn it off until he finds his remote control at home.

The evidence further reflected that Claimant began receiving treatment for the compensable injury from KB, M.D., an orthopedic surgeon, during June 2010. Because of continued complaints of lumbar pain and intermittent shocks produced by the spinal cord stimulator, Dr. B resubmitted his request that Claimant undergo an outpatient lumbar revision of dorsal column stimulator, lead and generator, electrodes and analysis procedure ("proposed revision surgery"). On July 25, 2013, a prior medical contested case hearing (MCCH) was held to address this same issue. On August 13, 2013, the Hearing Officer determined that the preponderance of the evidence is not contrary to the decision of the IRO that the outpatient lumbar revision of dorsal column stimulator, lead and generator, electrode and analysis procedure is not health care reasonably required for the compensable injury of (Date of Injury).

Dr. B's request for the proposed revision surgery was denied by two Utilization Review Agents (URAs) – one on an initial review, the other following a request for reconsideration. After the adverse determination by the URA, Dr. B appealed to an Independent Review Organization (IRO). The IRO reviewer, who is board-certified orthopedic surgeon, upheld the URA denial of the procedure. The IRO reviewer determined that the requested outpatient lumbar revision dorsal column stimulator, lead and generator, electrodes and analysis was not health care reasonably required for Claimant's compensable injury of (Date of Injury). As part of the IRO report, on November 12, 2013, the IRO reviewer noted the Claimant has a very complex past history of two separate lumbar spine injuries in 2005 and 2007, and that Claimant has failed multiple modalities and surgeries for the treatment of chronic low back pain and failed back syndrome. Dr. B appealed the IRO decision and requested this MCCH to determine the medical necessity of the proposed revision surgery.

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."

Petitioner/Provider and Claimant, as the parties challenging the IRO decision, have the burden of proof to overcome that decision by a preponderance of evidence-based medical evidence. Evidence-based medical evidence entails the opinion of a qualified expert that has some basis in evidence-based medicine. Expert evidence is required in all medical necessity disputes and Claimant's lay testimony is not probative on questions requiring expert evidence, such as the inquiry into the medical necessity of the procedure at issue.

The ODG Low Back Chapter provides as follows in the entry related to Spinal Cord Stimulation (SCS)–

> Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated. See the Pain Chapter for *Indications for stimulator implantation*. There is some evidence supporting the use of Spinal Cord Stimulation (SCS) for Failed Back Surgery Syndrome (FBSS) and other selected chronic pain conditions. Spinal Cord Stimulation is a treatment that has been used for more than 30 years, but only in the past five years has it met with widespread acceptance and recognition by the medical community. In the first decade after its introduction, SCS was extensively practiced and applied to a wide spectrum of pain diagnoses, probably indiscriminately. The results at follow-up were poor and the method soon fell in disrepute. In the last decade there has been growing awareness that SCS is a reasonably effective therapy for many patients suffering from neuropathic pain for which there is no alternative therapy. There are several reasons for this development, the principal one being that the indications have been more clearly identified. The enhanced design of electrodes, leads, and receivers/stimulators has substantially decreased the incidence of re-operations for device failure. Further, the introduction of the percutaneous electrode implantation has enabled trial stimulation, which is now commonly

recognized as an indispensable step in assessing whether the treatment is appropriate for individual patients. These implantable devices have a very high initial cost relative to conventional medical management (CMM); however, over the lifetime of the carefully selected patient, SCS may lead to cost-saving and more health gain relative to CMM for FBSS. See the Pain Chapter for complete list of references. Fair evidence supports the use of spinal cord stimulation in failed back surgery syndrome, those with persistent radiculopathy after surgery, according to the recently released joint American College of Physicians/ American Pain Society guideline recommendations on surgery and interventional treatments. (Chou, 2008). The National Institute for Health and Clinical Excellence (NICE) of the UK just completed their Final Appraisal Determination (FAD) of the medical evidence on spinal cord stimulation (SCS), concluding that SCS is recommended as a treatment option for adults with failed back surgery syndrome lasting at least 6 months despite appropriate conventional medical management. (NICE, 2008)

Recent research: New 24-month data is available from a study randomizing 100 failed back surgery syndrome patients to receive spinal cord stimulation (SCS) plus conventional medical management (CMM) or CMM alone. At 24 months, the primary outcome was achieved by 37% randomized to SCS versus 2% to conventional medical management (CMM), and by 47% of patients who received SCS as final treatment versus 7% for CMM. All 100 patients in the study had undergone at least one previous anatomically successful spine surgery for a herniated disk but continued to experience moderate to severe pain in one or both legs, and to a lesser degree in the back, at least six months later. Conventional medical therapies included oral medications, nerve blocks, steroid injections, physical and psychological therapy and/or chiropractic care. (Kumar, 2008) There is fair evidence that spinal cord stimulation is moderately effective for failed back surgery syndrome with persistent radiculopathy, though device-related complications are common. (Chou3, 2009) A nonrandomized, prospective cohort study in workers comp patients with chronic back and leg pain after spine surgery, ie failed back surgery syndrome (FBSS), found no significant difference in pain, disability, or opioid use between patients that received (at least a trial of) SCS, care at a pain clinic, or neither (usual care) at 12 and 24 months. Only 25% of SCS patients in this study received psychological screening prior to the trial, whereas ODG recommends psychological screening prior to all SCS implantations. Because few patients in any group in this study achieved success at any follow-up, the authors suggested that no treatment has a substantial impact on average in this patient group. (Turner, 2010) In this sample of workers' compensation recipients, the high procedure cost of SCS was not counterbalanced by lower costs of subsequent care, and SCS was not cost-effective. The benefits

> and potential cost savings reported in RCTs may not be replicated in workers' comp patients. (Hollingworth, 2011)
>
> For average hospital LOS if criteria are met, see Hospital length of stay (LOS).

The ODG Low Back Chapter provides as follows concerning psychological screenings –

> Recommended as an option prior to surgery, or in cases with expectations of delayed recovery. Before referral for surgery, clinicians should consider referral for psychological screening to improve surgical outcomes, possibly including standard tests such as MMPI (Minnesota Multiphasic Personality Inventory) and Waddell signs. However, the screening should be performed by a neutral independent psychologist or psychiatrist unaffiliated with treating physician/ spine surgeon to avoid bias. (Scalzitti, 1997) (Fritz, 2000) (Gaines, 1999) (Gatchel, 1995) (McIntosh, 2000) (Polatin, 1997) (Riley, 1995) (Block, 2001) (Airaksinen, 2006) A recent study concluded that psychological distress is a more reliable predictor of back pain than most diagnostic tests. (Carragee, 2004) The new ACP/APS guideline as compared to the old AHCPR guideline is a bit stronger on emphasizing the need for psychosocial assessment to help predict potentially delayed recovery. (Shekelle, 2008) Two factors from the adapted stress process model, *cognitive appraisal and emotional distress*, were identified as significant predictive factors of number of days of absence at 12 months and functional disability at 6 and 12 months. The adapted stress process model suggested that psychological variables act differently according to the variable predicted and to the period of time considered. (Truchon, 2010) The most helpful components for predicting persistent disabling low back pain were maladaptive pain coping behaviors, nonorganic signs, functional impairment, general health status, and presence of psychiatric comorbidities. (Chou, 2010) In workers' comp it is recommended to screen for presurgical biopsychosocial variables because they are important predictors of discectomy outcomes. (DeBerard, 2011) For more information, see the Pain Chapter, including Psychological Tests Commonly Used in the Assessment of Chronic Pain Patients, and the Stress/Mental Chapter.

Dr. B provided expert testimony in the hearing in support of the medical necessity of the proposed revision surgery. He opined that the lumbar revision surgery is health care reasonably required for the compensable injury of (Date of Injury), due to a malfunction of the device which causes the Claimant to receive intermittent shocks. A Medtronic report with numerical data was admitted into evidence. The Medtronic report contained handwritten notations recommending a revision surgery; however, there was insufficient evidence to identify the Medtronic representative who made the notations or whether the representative was a physician. Further, it was unclear what the numerical data meant. Albeit Claimant reported subjective complaints to

support his position that the device was defective, the Medtronic report was not compelling or persuasive objective evidence to support the assertion that there was a mechanical problem with the device or that the device was defective or malfunctioned.

WN, M.D., testified on behalf of the Carrier stating that he agreed with the IRO decision. Dr. N testified that the Claimant continues to suffer from chronic pain after multiple failed treatments and so, Dr. B should not reapply care that has failed. Further, Dr. N's testimony in the hearing indicated that Claimant underwent psychological testing in 2009; however, no current psychological assessment has been performed. Dr. N opined that new testing ought to be performed pursuant to the ODG and the Claimant's interceding surgical procedures.

Based on the evidence presented, Petitioner/Provider and Claimant did not meet their burden of proof to overcome the decision of the IRO by a preponderance of evidence-based medical evidence. As a preponderance of the evidence is found not to be contrary to the decision of the IRO that the requested outpatient lumbar revision dorsal column stimulator lead and generator, electrodes and analysis is not health care reasonably required for the compensable injury of (Date of Injury), Claimant is held not to be entitled to that procedure.

The Hearing Officer 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 and sustained a compensable injury.

    C. On (Date of Injury), Employer provided workers' compensation insurance coverage through Texas Association of School Boards (TASB) as a self-insured, Carrier.

    D. The Independent Review Organization (IRO) determined that the health care at issue is not reasonably required 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. Outpatient lumbar revision dorsal column stimulator, lead and generator, electrodes and analysis 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 Independent Review Organization (IRO) that an outpatient lumbar revision dorsal column stimulator, lead and generator, electrodes and analysis is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to an outpatient lumbar revision dorsal column stimulator, lead and generator, electrodes and analysis 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 ASSOCIATION OF SCHOOL BOARDS RISK MANAGEMENT FUND** and the name and address of its registered agent for service of process is

JAMES B. CROW
7703 N. LAMAR
AUSTIN, TEXAS 78752

Signed this 1st day of May, 2014.

Marilyn J. Allen
Hearing Officer