

MEDICAL CONTESTED CASE HEARING NO. 13120

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 25, 2013 to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the IRO that the claimant is not entitled to Outpatient Lumbar Revision of Dorsal Column Stimulator, Lead and Generator, Electrode, and Analysis for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by TL, ombudsman.
Respondent/Carrier appeared and was represented by JL, attorney.
Petitioner/Provider appeared and was represented by KB, M.D., attorney.

BACKGROUND INFORMATION

Claimant injured in the course and scope of his employment underwent a bilateral partial laminectomy and foraminotomy on April 20, 2007, and subsequently re-injured his back in a work related motor vehicle accident. He underwent a redo bilateral L5-S1 discectomy on November 9, 2007. On October 16, 2009, he underwent implantation of permanent spinal cord stimulator, placement of connector, and placement of Itrel-3 pulse generator. On December 31, 2009, Claimant underwent thoracic laminectomy, epidural neurolysis and replacement of spinal cord stimulator with resumed TL lead. Claimant later underwent several additional surgeries which included but were not limited to decompression and revisions of lumbar decompression and facetectomy in the lumbar and placement of pedicle screws and internal fixation. Since receiving the Dorsal Column Stimulator, Claimant testified that he has experienced severe pain in his lower back where the wires are connected. These severe pains have knocked Claimant to his knees on several occasions. Claimant testified that sometimes the stimulator turns itself on. In addition, Claimant stated that he often times receives shocks from the stimulator.

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 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."

Evidence Based Medicine (EBM)

Dr. B opines that Outpatient Lumbar Revision of Dorsal Column Stimulator, Lead and Generator, Electrode, and Analysis is health care reasonably required for the compensable injury of (Date of Injury), due to the malfunctions of which Claimant has been experiencing recently. Dr. B noted that the requested procedure was needed in an effort to shorten the wires or at least to determine the origin of the damage to the equipment, if any.

Dr. WN testified on behalf of the Carrier reporting that X-rays taken did not reveal any objective evidence of any defects with the stimulator. Dr. N also indicated that there were electronic tools available of which to test whether there were any technical issues related to the equipment and that without sufficient evidence documented of a defect in the device then the ODG does not support a revision.

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)

- (1) *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, i.e. 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)

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

The ODG Inapplicable

Dr. B opined that the ODG has no section on point to speak to the matter of defective devices and that subjective evidence presented by the Claimant was sufficient to warrant a replacement and or revisions of the stimulator.

The IRO reviewer, who is Board certified by the American Board of Orthopaedic Surgery with over 40 years of experience, upheld the adverse determination based upon finding no objective evidence that the spinal column stimulator was out of place or not working properly to warrant adjustment, revision, etc.

Dr. N along with KF, M.D., who performed the initial review and JO, M.D., who performed the reconsideration/appeal review were more persuasive in their argument that solid objective documentation of failure of the spinal cord stimulator or lead placement was needed from the technician other than subjective reports of shock like symptoms documented on physical examination in order to determine that the requested treatment was health care reasonably required for the compensable injury of (Date of Injury).

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), Claimant sustained a compensable injury.
 - D. The Independent Review Organization (IRO) determined that the health care at issue in this case was not reasonably required for the compensable injury of (Date of Injury).
2. Carrier delivered to Claimant and Provider 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 of Dorsal Column Stimulator, Lead and Generator, Electrode, and Analysis are 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 Outpatient Lumbar Revision of Dorsal Column Stimulator, Lead and Generator, Electrode, and Analysis is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to Outpatient Lumbar Revision of Dorsal Column Stimulator, Lead and Generator, Electrode, 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 13th day of August, 2013.

Jacqueline Harrison
Hearing Officer