

MEDICAL CONTESTED CASE HEARING NO. 15015

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. For the reasons discussed herein, the Hearing Officer determines that the preponderance of the evidence-based medical evidence is not contrary to the Independent Review Organization (IRO) decision that the Claimant/Petitioner is not entitled to explants spinal cord stimulator (SCS)/replace with MRI-compatible SCS lumbar spine for the compensable injury of (Date of Injury).

STATEMENT OF THE CASE

A contested case hearing was held on November 17, 2014 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 explant SCS/replace with MRI-compatible SCS lumbar spine for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by SB, ombudsman. Respondent/Carrier appeared and was represented by RJ, attorney.

DISCUSSION

It was undisputed that the Claimant sustained a compensable cervical and lumbar injury on (Date of Injury) while working for (Employer). Eventually, the Claimant had an SCS implanted for the control of his lumbar/leg symptoms, and it is undisputed that the SCS continues to work well to relieve the Claimant's lumbar/leg symptoms. The evidence shows that the Claimant has had significant cervical discomfort, including radiculopathy, since at least 2011. In and after 2011, the Claimant's doctors made several requests for pre-authorization of a CT myelogram to investigate the Claimant's cervical condition, but these requests were denied, and apparently there was no pursuit of an independent review in connection with any of these denials.

Thereafter, because the Claimant's implanted SCS is not compatible with the performance of an MRI study, the Claimant's doctor, Dr. CF, requested the procedure in dispute. The request is to remove the Claimant's current SCS and replace it with one that is compatible with the Claimant undergoing a cervical MRI. This request was denied by two Carrier utilization review agents (URAs), both of whom are doctors. The Carrier denials were upheld by an IRO. The IRO physician reviewer, who is board certified in anesthesiology and pain management, reasoned that the requested procedure is not medically necessary since the Claimant gets good relief from his current SCS. The IRO also stated that it is not wise to remove a functioning SCS to replace it

with an MRI-compatible one because such could subject the Claimant to possible surgical and anesthetic complications. The IRO noted that the decision was based upon the Official Disability Guidelines (ODG).

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(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.”

The ODG does not directly address the explanation of a lumbar SCS, but it does address the medical necessity of the implantation of a lumbar SCS as follows:

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 above-cited section of the ODG refers the reader to its Pain Chapter, which further addresses the medical necessity of the implantation of a spinal cord stimulator as follows:

Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, for specific conditions indicated below, and following a successful temporary trial. Although there is limited evidence in favor of Spinal Cord Stimulators (SCS) for Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS) Type I, more trials are needed to confirm whether SCS is an effective treatment for certain types of chronic pain. (Mailis-Gagnon-Cochrane, 2004) (BlueCross BlueShield, 2004) See indications list below. See Complete list of SCS References. This supporting evidence is significantly supplemented and enhanced when combined with the individually based observational evidence gained through an individual trial prior to implant. This individually based observational evidence should be used to demonstrate effectiveness and to determine appropriate subsequent treatment. (Sundaraj, 2005) 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. (Furlan-Cochrane, 2004) 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 and CRPS. (Taylor, 2005) (Taylor, 2006) SCS for treatment of chronic nonmalignant pain, including FBSS, has demonstrated a 74% long-term success rate (Kumar, 2006). SCS for treatment of failed back surgery syndrome (FBSS) reported better effectiveness compared to reoperation (North, 2005). A cost utility analysis of SCS versus reoperation for FBSS based on this RCT concluded that SCS was less expensive and more effective than reoperation, and should be the initial therapy of choice. Should SCS fail, reoperation is unlikely to succeed. (North, 2007) CRPS patients implanted with SCS reported pain relief of at least 50% over a median follow-up period of 33 months. (Taylor, 2006) SCS appears to be an effective therapy in the management of patients with CRPS. (Kemler, 2004) (Kemler, 2000) Recently published 5-year data from this study showed that change in pain intensity was not significantly different between the SCS plus PT group and the PT alone group, but in the subgroup analysis of implanted SCS patients, the change in pain intensity between the two groups approached statistical significance in favor of SCS, and 95% of patients with an implant would repeat the treatment for the same result. A thorough understanding of these results including the merits of intention-to-treat and as-treated forms of analysis as they relate to this therapy (where trial stimulation may result in a large drop-out rate) should be undertaken prior to definitive conclusions being made. (Kemler, 2008) Permanent pain relief in CRPS-I can be attained under long-term SCS therapy combined with physical therapy. (Harke, 2005) Neuromodulation may be successfully applied in the treatment of visceral pain, a common form of pain when internal organs are damaged or injured, if more traditional analgesic treatments have been unsuccessful. (Kapural, 2006) (Prager, 2007) A recent RCT of 100 failed back surgery syndrome (FBSS) patients randomized to receive spinal cord stimulation plus conventional medical management (SCS group) or conventional medical management alone (CMM group), found that 48% of SCS patients versus 9% of CMM patients achieved the primary outcome of 50% or more pain relief at 6 months. This study, funded by Medtronic, suggested that FBSS patients

randomized to spinal cord stimulation had 9 times the odds of achieving the primary end point. (Kumar, 2007) According to the European Federation of Neurological Societies (EFNS), spinal cord stimulation (SCS) is efficacious in failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS) type I (level B recommendation). (Crucchi, 2007) 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 chronic neuropathic pain lasting at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation. Recommended conditions include failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS). (NICE, 2008) See also Psychological evaluations (SCS) in the Stress & Other Mental Conditions Chapter.

Battery Life for SCS: As batteries for both rechargeable and nonrechargeable systems are nearing end of life, there are both early replacement indicators and end of service notifications. Typical life may be 8-9 years for rechargeable batteries, but this depends on the unit. In addition, the physician programmer can be used to interrogate the implanted device and determine the estimated remaining battery life. (Restore, 2011)

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) (Frey, 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)

Indications for stimulator implantation:

Failed back syndrome (persistent pain in patients who have undergone at least one previous back operation and are not candidates for repeat surgery), when all of the following are present:

- (1) symptoms are primarily lower extremity radicular pain; there has been limited response to non-interventional care (e.g. neuroleptic agents, analgesics, injections, physical therapy, etc.);
- (2) psychological clearance indicates realistic expectations and clearance for the procedure;
- (3) there is no current evidence of substance abuse issues;
- (4) there are no contraindications to a trial;
- (5) Permanent placement requires evidence of 50% pain relief and medication reduction or functional improvement after temporary trial.

Estimates are in the range of 40-60% success rate 5 years after surgery.

Neurostimulation is generally considered to be ineffective in treating nociceptive pain. The procedure should be employed with more caution in the cervical region than in the thoracic or lumbar due to potential complications and limited literature evidence.

Complex Regional Pain Syndrome (CRPS)/Reflex sympathetic dystrophy (RSD), 70-90% success rate, at 14 to 41 months after surgery. (Note: This is a controversial diagnosis.)

Post amputation pain (phantom limb pain), 68% success rate (Deer, 2001)

Post herpetic neuralgia, 90% success rate (Deer, 2001)

Spinal cord injury dysesthesias (pain in lower extremities associated with spinal cord injury)

Pain associated with multiple sclerosis

Peripheral vascular disease (insufficient blood flow to the lower extremity, causing pain and placing it at risk for amputation), 80% success at avoiding the need for amputation when the initial implant trial was successful. The data is also very strong for angina. (Flotte, 2004)

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

The testimony of Dr. MVH, who is a board-certified orthopedic surgeon, was helpful and persuasive in analyzing the issue in this case. He testified that he agrees with the IRO decision in this case, and that he strongly disagrees that the requested procedure is medically necessary. Since the Claimant's spinal cord stimulator is sought to be removed solely to accommodate the performance of an MRI, Dr. VH first noted that there are procedures other than an MRI that can be used to assess the Claimant's cervical condition, including a CT myelogram. He also noted that given the Claimant's age (70 years old), there are increased risks in removing the SCS, and significant complications can arise. In that connection, he noted that the evidence shows that the Claimant's current SCS is effective at relieving the Claimant's lumbar symptoms, so it should not be replaced. It should be noted here that the Claimant's testimony and other evidence in the record credibly establish that he has significant cervical symptoms. The medical evidence, however, does not establish that removing his current SCS is medically necessary. After a careful review of the entire record, it is determined that there is no evidence-based medical evidence presented to oppose the IRO's decision in this case. For this reason, it is determined that the record does not establish that the preponderance of the evidence-based medicine is contrary to the IRO decision. Accordingly, it is determined that the record does not establish that the requested procedure to explant the Claimant's SCS to replace it with an MRI-compatible one is health care reasonably required for the Claimant's compensable (Date of Injury) injury.

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.
 - C. On (Date of Injury), Employer had workers' compensation insurance coverage with Liberty Mutual Fire Insurance Co., Carrier.
 - D. On (Date of Injury), the Claimant sustained a compensable cervical and lumbar injury while in the course and scope of his employment with (Employer).
 - E. The decision of the IRO herein dated June 10, 2014 upheld the Carrier's denial of the procedure in dispute.

2. The explanation of the Claimant's SCS to replace it with an MRI-compatible one is not shown to be health care reasonably required for the Claimant's compensable (Date of Injury) injury.
3. The Carrier delivered to Claimant a single document stating the true corporate name of the Carrier, and the name and street address of the Carrier's registered agent, which was admitted into evidence as Hearing Officer's Exhibit Number 1.

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 Claimant is not entitled to the explanation of his SCS to replace it with an MRI compatible one for the compensable injury of (Date of Injury).

DECISION

The Claimant is not entitled to the explanation of his SCS to replace it with an MRI-compatible one for the compensable injury of (Date of Injury).

ORDER

The Carrier is not liable for the benefits at issue in this hearing. The Claimant remains entitled to medical benefits for the compensable injury in accordance with Section 408.021 of the Act.

The true corporate name of the insurance carrier is LIBERTY MUTUAL FIRE INSURANCE COMPANY, and the name and address of its registered agent for service of process is

**CORPORATION SERVICE COMPANY
211 E. 7TH STREET, STE. 620
AUSTIN, TX 78701**

Signed this 8th day of December, 2014.

Patrice Fleming-Squirewell
Hearing Officer