MEDICAL CONTESTED CASE HEARING NO 12090
M6-12-38043-01

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 March 15, 2012, to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (hereinafter "IRO") that Claimant is not entitled to external battery recharging system for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Claimant appeared and was assisted by ombudsman NT. Carrier appeared and was represented by attorney MM.

BACKGROUND INFORMATION

Claimant was the sole witness at the March 15, 2012, CCH. At the time of the (Date of Injury), compensable injury Claimant was employed as a triage nurse. Carrier had accepted a contusion to the coccyx as a compensable injury, and after a contested case hearing, it was determined that the compensable injury extended to and included the L-5 nerve root/sciatic irritation. Claimant testified that as a result of her compensable injury she was provided "drug therapy" and injections, but that eventually her doctor recommended a spinal cord stimulator in order to control her pain. According to Claimant, in December of 2006, a spinal cord stimulator was implanted in the upper left quadrant of her left hip, and in August of 2011, the battery went out.

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. 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. (Division Rule 133.308 (t).)

The requested pre-authorization request was coded L8689 – external recharging system for spinal cord stimulator. (See Carrier Exhibit B, page 8). The IRO doctor, board-certified in anesthesiology/pain management upheld the denial of the external battery recharging system, and used the following excerpts from the Official Disability Guidelines in reference to spinal cord stimulators (SCS) and battery life:

> Spinal cord stimulators (SCS)
> 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). (Cruccu, 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.
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> *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 rechargable 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).

In evidence as Carrier Exhibit B, page 14, is an excerpt from the utilization review that noted that the company representative for the external battery recharging system would be contacted to check the generator as well as the charging unit and to determine if there were a malfunction. It was also noted that, "Oftentimes, a simple office visit with recalibration can be performed to increase the overall pain coverage and prolong the life of the stimulator." From the evidence presented, a Boston Scientific technician checked out the unit on or about October 18, 2011, and determined that the generator was working effectively but that the charging unit and remote were having difficulty and this is what the request for replacement was for. (See Carrier Exhibit C, page 5).

The IRO doctor, board-certified in anesthesiology/pain management upheld the denial of the external battery recharging system. The IRO reviewer noted that Claimant underwent spinal cord stimulator trial on September 20, 2006, with subsequent implantation on November 13, 2006. It was noted in a follow-up note dated December 6, 2006, that Claimant reported 50% decreased pain. Follow-up notes dated September 29, 2011, indicated that Claimant reported approximately two weeks prior that she was having difficulty charging her unit and she thought

she had a problem with the generator or the charger. It was also noted that Claimant had not been able to use her stimulator recently due to the difficulty with charging and that she had to use more Hydrocodone for breakthrough pain. The IRO reviewer noted, "Initial request for external battery recharging system was non-certified on October 18, 2011, noting that there is no clear documentation of a condition/diagnosis for which spinal cord stimulator is indicated." The IRO reviewer then held, "Therefore, the medical necessity of the request has not been substantiated."

The IRO denial was based upon medical necessity for a spinal cord stimulator, not for the requested pre-authorized procedure, which was 2012 HCPCS Code L8689 which is defined as an external recharging system for battery (internal) for use with implantable neurostimulator, replacement only. HCPCS is an acronym for Healthcare Common Procedure Coding System and this coding system was developed in 1983 by the Centers for Medicare and Medicaid Services (CMS), (formerly Health Care Financing Administration) for the purposes of standardizing the medical billing and coding systems used to process Medicare claims. The HCPCS coding system is primarily used to bill Medicare for supplies, materials and injections and for certain services and procedures that are not defined in the Current Procedure Terminology (known as CPT). HCPCS codes must be used when billing Medicare carriers. In the instant case, the external battery recharging system does not have a CPT code and the applicable HCPCS descriptor is L8689. In evidence as Claimant's Exhibit 4, page 1 is a "To Whom It May Concern" letter from Claimant's treating doctor, Dr. C, M.D. He writes, "Recently she has been having problems with charging the spinal cord stimulator generator. Because of this she is not able to use the stimulator which has caused her to have increased pain and decreased physical function and activity level. She has now returned to needing to use a cane for ambulation." He also writes, "The stimulator is over 5 years old now and a malfunction of an external component would not be that surprising with general wear and tear. She is requesting a replacement of only the external components as the internal leads and generator are functioning well at this time. This was approved by Worker's (sic) Comp as a legitimate treatment in 2006 for a sciatic injury and has significantly improved the quality of life of Mrs. B. The internal components (surgically placed in her body) cannot function without the external charger and remote. Thus, these components need to be replaced as part of her approved treatment."

The question in this case, is not whether a spinal cord stimulator should be implanted. That question has already been resolved in Claimant's favor. The only issue is whether or not Claimant is entitled to an external recharging system for battery (internal) for use with implantable neurostimulator replaced. That is the issue and that is how it was coded and requested for pre-authorization. This was the issue as litigated at the CCH. The IRO determination has been overcome by the preponderance of the other evidence-based medical evidence.

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 Texas Health Resources, Employer.

   C. On (Date of Injury), Employer provided workers' compensation insurance through Carrier American Casualty Company of Reading, Pa.

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

   E. The IRO determined that Claimant is not entitled to an external battery recharging system 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. An external battery recharging system replacement is 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 contrary to the decision of the IRO that an external battery recharging system replacement is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is entitled to an external battery recharging system replacement for the compensable injury of (Date of Injury).

ORDER

Carrier is 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 **AMERICAN CASUALTY COMPANY OF READING, PA.,** and the name and address of its registered agent for service of process is:

CT CORPORATION SYSTEMS
350 N. ST. PAUL STREET
DALLAS, TX 75201

Signed this 16th day of March, 2012.

Cheryl Dean
Hearing Officer