

Notice of Independent Review Decision

DATE OF REVIEW:

12/01/2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Spinal Cord Stimulator (SCS) Trial 63650 x 2, 95972 x 2.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

Doctor of Osteopathy, Board Certified Anesthesiologist, Specializing in Pain Management.

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be: **Upheld**

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

The requested Spinal Cord Stimulator (SCS) Trial (63650 x 2, 95972 x 2) is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- TDI/DIVISION OF WORKERS' COMPENSATION referral form
- 11/18/08 MCMC Referral
- 11/18/08 memo from M.D., Client Relations Specialist
- 11/17/08 report
- 11/17/08 Notice To Utilization Review Agent Of Assignment
- 11/17/08 Notice to MCMC, LLC Of Case Assignment
- 11/14/08 Confirmation Of Receipt Of A Request For A Review, DWC
- 11/13/08 letter
- 11/06/08 Request For A Review By An Independent Review Organization
- 11/06/08 Additional Remarks note
- 11/03/08 letter
- 10/31/08 memo with peer review from M.D.
- 10/29/08 memo from Medical Claims Specialist
- 11/13/08, 11/06/08, 10/28/08 office notes
- 10/14/08 Psychology Progress Note, PhD
- 09/15/08 memo from M.D. with memo
- 09/10/08 memo from RN

- 08/27/08 Psychology Initial Evaluation, PhD
- 08/20/08 letter from M.D.
- 10/14/08, 07/11/08 Progress Note, M.D.
- 04/15/08 MRI lumbar spine, M.D.
- 02/16/07 to 11/13/08 chart notes
- Undated Worker's Compensation Patient Information
- Undated ODG Treatment Guidelines

PATIENT CLINICAL HISTORY [SUMMARY]:

The injured individual is a female with date of injury xxxx. The injured individual caught her right fingers in a door and in pulling her arm out, states she twisted her neck. She has a history of thoracic outlet surgery xxxx earlier. She had a carpal tunnel surgery, trigger finger and ulnar nerve surgery since the injury with no benefit. She had some cervical epidural steroid injections (ESIs) with no benefit. She has not had stellate ganglion blocks (SGBs) as Dr. feels they will be of no long term benefit. She has decreased range of motion (ROM) in her hand, decreased sensation, tenderness, and allodynia. The attending provider requested a SCS trial in 07/2008. Her psychiatric evaluation of 08/2008 stated she needs further education on this and had high levels of somatization and was focused on her physical condition excessively. She had six psychotherapy sessions since with no change in her condition per the note of 10/2008.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

The SCS is denied for three reasons. First, the injured individual had a psychiatric evaluation in 08/2008 that noted she was focused on her physical symptoms and needed more education on the SCS. Despite having had six psychotherapy sessions since then, the psychiatric note of 10/14/2008 states she has not changed in her outlook or profile. Second, Dr. writes in 10/2008 that the injured individual wants to discuss the SCS but there is no indication this was done. Finally, Dr. states she has a diagnosis of Complex Regional Pain Syndrome (CRPS) but has never had a diagnostic SGB which may or may not be beneficial to her but should be considered before committing to a SCS which is a much more aggressive form of treatment.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

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.

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)

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
- Post herpetic neuralgia, 90% success rate
- 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)