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An Independent Review Organization
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Notice of Independent Review Decision

DATE OF REVIEW: October 1, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Permanent Spinal Cord Stimulator

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

Board Certified in Physical Medicine and Rehabilitation

Subspecialty Board Certified in Pain Management

REVIEW OUTCOME

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

OD Guidelines

Denial Letters 7/24/08 and 8/20/08

Records from 8/06 thru 8/08

Records from South 8/06 thru 6/08

Letter from Patient 9/10/08

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a xx year old man who injured his neck in xxxx. He subsequently underwent a fusion from C5-7. The date is not provided. He has ongoing shoulder pain, posterior occipital headaches and interscapular pain, myofascial pain and neck pain. Dr. wrote that he has complex regional pain disorder. He apparently had a dorsal column spinal stimulator. It was removed March 12, 2008 when the battery pack failed and the wires may have shifted. Attempts to reinsert the wires failed. He reported that he had 40%

reduction in his pain, especially the sharp pain, while having the stimulator. He is on Lortab, trazadone, Lunestra, Lexapro, Flexeril, Arthrotec, Prevacid and Soma. He underwent two cervical epidural steroid injections at C7/T1 in August and September 2007. The 3/21/08 note, 9 days post removal described less pain and better sleep. A new spinal stimulator was requested. He also had trigger point injections.

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

The ODG generally addresses spinal stimulator for failed lumbar problems and CRPS. There is very little cited that shows its value post cervical surgery. Dr. noted that this man had a good response with the Dorsal Column stimulator, but the Reviewer does not know for how long it was used. Secondly, Dr. cited it was used for CRPS, an accepted condition per the ODG.

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](#).

Indications for stimulator implantation:

- Failed back syndrome (persistent pain in patients who have undergone at least one previous back operation), more helpful for lower extremity than low back pain, although both stand to benefit, 40-60% success rate 5 years after surgery. It works best for neuropathic pain. 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.
- **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](#))

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

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)