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## Notice of Independent Review Decision

**DATE OF REVIEW:** 4/25/11

**IRO CASE #:**

### **DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

The item in dispute is the prospective medical necessity of a spinal cord stimulator trial (63650), analyze neurostim complex (95972), anesthesia spine cord surgery (00630), analyze neurostim simple (95971) and needle localization by x-ray (77002).

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

The reviewer is a Medical Doctor who is board certified in Orthopedic Surgery. The reviewer has been practicing for greater than 10 years.

### **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)

The reviewer agrees with the previous adverse determination regarding the prospective medical necessity of a spinal cord stimulator trial (63650), analyze neurostim complex (95972), anesthesia spine cord surgery (00630), analyze neurostim simple (95971) and needle localization by x-ray (77002).

### **INFORMATION PROVIDED TO THE IRO FOR REVIEW**

Records were received and reviewed from the following parties:

These records consist of the following (duplicate records are only listed from one source): Records reviewed from: preauth trial of dated 3/21/11, 3/24/11 denial letter, comprehensive pain management (CPM) progress notes 3/18/11, 2/24/11

follow up note by MD, 12/1/10 lumbar MRI report, undated pain scale, undated patient intake form CPM, undated lumbar Transforaminal ESI procedure note, 10/26/09 diagnostic testing request form, undated DWC 32, 10/26/09 agreement to perform diagnostic test form, 11/24/08 initial eval by, DC, 5/8/09 re-exam note by Dr., 5/8/09 electrodiagnostic report and 11/2/10 initial eval report by MD.

ARCFMI: 4/13/11 letter by, 4/12/11 IRO summary letter, 6/2/08 DWC 1, 6/2/08 request for medical care letter, 6/2/08 associate statement, 6/2/08 and 11/23/09 bona fide job offers, various DWC 73 forms, 6/2/08 to 10/26/09 radiology reports, 6/2/08 to 7/1/08 physical status reports, 6/2/08 script, 6/7/08 to 7/1/08 Hx forms, 6/30/08 RTW form, 7/31/08 DWC 69 by Dr. (no report attached), Coastal daily progress notes 12/24/08 to 7/27/09, 4/2/09 DD report by MD, 10/30/09 to 2/14/11 office notes by Dr. 10/23/09 diagnostic test request form, 11/2/09 FCE report, 10/20/09 DD report by Dr. 5/20/10 preauth request, anesthesia records, 9/13/10 confirmatory report, 3/28/11 and 4/7/11 letters by and 4/4/11 denial letter.

A copy of the ODG was not provided by the Carrier or URA for this review.

#### **PATIENT CLINICAL HISTORY [SUMMARY]:**

On 3/18/11, the claimant was noted to have low back and right leg pain. This was associated with an injury sustained in xx/xx in which she had fallen off a chair. The motor exam was intact and the right knee reflex was reduced to 1+. Right L4 and S1 dysthesias were noted. A 12/1/10 dated MRI of the lumbar spine revealed multi-level disc bulges. A 9/30/08 dated lumbar MRI report was also noted. Electrical studies from 6/1/08 discussed a left L4 nerve root denervation/innervation, along with denervation of S1 bilaterally. Reportedly, the claimant had failed non-op. treatment and was not felt to be a surgical candidate, as per the AP. On 2/24/11, back pain with bilateral radicular complaints was noted, along with "noncompressive" findings on MRI. The claimant was having mechanical and neuropathic complaints and was felt to have an indication for pain stimulator trial.

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

The ODG indicates the SCS is 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.

Typically, such a stimulator procedure trial and analysis is reserved for a failed back syndrome and/or when less invasive procedures have failed or are not indicated. In this case, subjective and objective findings do not correlate with

either the electrical or MRI findings. In addition, there is no evidence of the claimant having had any prior surgery or scarring attributable to same. There is no evidence that such an invasive procedure is at all reasonable or necessary, based on the lack of correlation of all the clinical and ancillary tests. Because the requested treatment does not meet the above guidelines, the requested procedure is not medically necessary at this time.

**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)