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**Notice of Independent Review Decision**

**DATE OF REVIEW:** 8/23/11

**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.

**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 disagrees with the previous adverse determination regarding the prospective medical necessity of a spinal cord stimulator trial.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

Records were received and reviewed from the following parties:  
Pain Management.

These records consist of the following (duplicate records are only listed from one source): Records reviewed from Pain Management: letters by DO dated 6/21/11 and 7/7/11, 6/8/11 denial letter, telephone notes by Dr. 3/25/11 to 6/28/11, letters by MD 10/21/10 to 6/16/11, follow up notes by Dr. 8/16/10 to 9/20/10, psychological evaluation of 3/3/11 by Ph D, office notes by Dr. 3/7/11 to 7/28/11 and 1/10/11 to 2/7/11 office note by DO.

HDI: 10/8/10 lumbar CT scan report. (all other records were duplicative)

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

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The claimant is post a lumbar spinal injury in and, is also post L4-5 and L5-S1 fusion in 3/2000. A 10/8/10 CT scan revealed multi-level disc protrusions with foraminal stenosis, a HNP at L5-S1 and post-surgical changes. Despite treatments, the claimant continues with back and leg pain. Denial letters were reviewed with rationale including the unanswered questions as to if the claimant has ongoing neuropathic pain and/or is a potential candidate for another surgical procedure. As of 6/16/11, the claimant's reduced lumbar motion and positive straight leg raise was noted. There were no other neuro. abnormalities. The claimant had a prior psychosocial clearance on 3/3/11.

The AP (Dr.) appeal letter dated 7/7/11 was reviewed, as were prior AP records. The 6/21/11 dated AP record documented the primarily leg pain, along with post-laminectomy syndrome and lumbar neuritis. The claimant was noted to have been referred for pain management by a surgeon who (in a 6/16/11 note) deemed the claimant to not be a surgical candidate and a stimulator candidate). The lack of adequate relief with various medications and ESIs (for neuropathic pain) was noted. Right L4 myotomal weakness, dermatomal pain complaints with sciatica were reiterated, as was the lack of substance abuse with overall positive compliance with treatment. Prior records from Dr. were also reviewed. These evidenced some EHL weakness and absent Achilles reflex, as noted on 8/16/10.

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

Even without consistent abnormal reflex, motor or sensory exam findings; the claimant clearly has subjective and overall objective findings (including + straight leg raise) of post laminectomy neuropathic pain. The claimant has a failed back syndrome that has been quite reasonably documented. This is on the basis of post-fusion scarring, which has not responded to other forms of treatment. The claimant is clearly noted to not be a surgical candidate, has complied with treatment, has no evidence of substance abuse and has passed a psychosocial screen. There are no contraindications for such a trial as proposed. Applicable ODG criteria have now been met for the proposed treatment. As noted in the Pain Chapter, indications for the proposed include: "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.."

## 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)

#### Pain Chapter

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.

According to the records reviewed, the patient meets the above criteria for SCS trial. Therefore, the procedure is 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)