



CLAIMS EVAL

*Utilization Review and
Peer Review Services*

Notice of Independent Review Decision-WCN

DATE OF REVIEW: 1-13-2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Spinal cord stimulator trial lumbar 63650 L8680 outpatient

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

American Boards of Physical Medicine and Rehabilitation and 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)

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- 8-3-10 MRI of the lumbar spine.
- MD., office visits on 9-15-10, 10-11-10, and 11-9-10.
- 9-23-10 Dr. performed a left L5-S1 transforaminal epidural steroid injection.
- Physical therapy evaluation on 10-18-10.
- 11-24-10 Psychological Assessment performed by PhD.
- 12-3-10 MD., performed a Utilization Review.
- 12-28-10 DO., performed a Utilization Review.

PATIENT CLINICAL HISTORY [SUMMARY]:

MRI of the lumbar spine showed a 6.1 cm cyst in the upper pole of the right kidney. There are findings suggestive of a small spinal canal throughout, secondary to congenital spinal stenosis. The AP diameter measures approximately 9 mm throughout. Desiccation of the disc with 4 mm posterocentral disc protrusion at L5-S1. Bilateral foraminal stenosis left more than right. Status post left laminectomy.

On 9-15-10 MD., evaluated the claimant. The claimant has a history of post laminectomy syndrome. The pain radiates to the left hip, lateral thighs, lateral lower leg to the left and foot at the dorsal surface. The episode of pain started on xx/xx/xx. The claimant was lifting heavy equipment. He reported paravertebral muscle spasms, radicular leg pain and numbness in the foot. On exam, the claimant has pain to the left and right lumbar paraspinal muscles. No palpable muscle spasms. Range of motion is limited. He has a normal sensory exam. DTR are 1/4 left patella, 2/4 right patella, 2/4 left and right Achilles. Strength is 4/5 left quadriceps, 4/5 left tibialis anterior. All others were 5/5. The claimant has positive bilateral Kemp, positive left slump for back pain and radiculopathy. The evaluator reported that the claimant has tried Medrol Dosepak with only minimal relief. He is currently participating in physical therapy and has not experienced relief. The evaluator reported the claimant would benefit from a left L5-S1 transforaminal epidural steroid injection.

On 9-23-10, Dr. performed a left L5-S1 transforaminal epidural steroid injection.

Follow up with Dr. on 10-11-10 notes the claimant had no relief with the injection. He continues with pain in both ankles and also numbness in the small toes. The evaluator felt that the next step is a neurosurgical consult for further treatment.

Medical records reflect the claimant had a physical therapy evaluation on 10-18-10.

Follow up with Dr. on 11-9-10 notes the claimant was seen by Dr. who felt the claimant was not a surgical candidate. The evaluator reported that he could start therapy with a neurostimulator. He recommended a spinal cord stimulator trial with dual leads. The claimant will have an evaluation with a psychologist first and then continue with the stimulator trial.

On 11-24-10, a Psychological Assessment performed by PhD., notes there are no counter indications for his involving in implantable spinal cord stimulator.

12-3-10 MD., performed a Utilization Review. Based on the medical reports provided, there is no clear and objective documentation regarding the conservative measures available for the patient that would help in alleviating the symptoms. As per the guidelines, the Spinal Cord Stimulation is 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. There is no clear and objective documentation if indeed the patient already exhausted every possible conservative measure that is available in decreasing the amount of pain he is experiencing. Hence, the request for a Spinal Cord Stimulator Trial is deemed as not medically necessary. Determination: This request is not certified.

12-28-10 DO., performed a Utilization Review. This is an appeal request for outpatient left spinal cord stimulator trial lumbar. As per medical report dated 11-9-10, the location of pain is primarily in the lower lumbar spine. The pain radiates to the left hip, lateral thigh, lateral lower left leg and feet. On physical examination, there are stiffness, paravertebral muscle spasm, radicular left leg pain and numbness in the foot. Upon review of the report, the operative summary of the previous back surgery was not provided for review and appraisal. There is also no procedural report of the previous ESI done to assess the patient's clinical and functional response. Furthermore, there is no clear documentation of conservative treatment. Pharmacotherapy including dosage, frequency and response are not mentioned in the report. With these, the need for the request is not substantiated at this time.

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

MEDICAL RECORDS REFLECT A CLAIMANT WITH A DIAGNOSIS OF POST LAMINECTOMY SYNDROME. THE CLAIMANT HAS FAILED CONSERVATIVE TREATMENT AND IS NOT A SURGICAL CANDIDATE. THE CLAIMANT HAS LOW BACK PAIN WITH PAIN THAT RADIATES TO THE LEFT HIP, LATERAL THIGHS, LATERAL LOWER LEG TO THE LEFT AND FOOT AT THE DORSAL SURFACE. THE

CLAIMANT HAS HAD A PSYCHOLOGICAL EVALUATION CLEARING HIM FOR THE INTERVENTIONAL PROCEDURE. THE CLAIMANT HAS FAILED PRIOR CONSERVATIVE CARE AND MEETS ODG CRITERIA FOR SPINAL CORD STIMULATOR. THEREFORE, THE REQUEST FOR A SPINAL CORD STIMULATOR IS REASONABLE AND MEDICALLY INDICATED.

ODG-TWC, last update 12-15-10 Occupational Disorders - Pain – spinal cord stimulator: 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) (Frey, 2009)

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 (Deer, 2001)
- Post herpetic neuralgia, 90% success rate (Deer, 2001)
- 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)