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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Jul/12/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Outpatient back spinal cord stimulator trial

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

M.D., Board Certified Orthopedic Surgeon

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

PATIENT CLINICAL HISTORY SUMMARY

The claimant is a male who sustained a work related injury to his low back injury on xx/xx/xx when a water line exploded hitting him in the back and throwing him against a wall. The claimant eventually underwent a lumbar anterior and posterior 360 fusion from L3 to L5 in 2003. As a result of his bone graft harvest the claimant developed cluneal nerve neuralgia and received intermittent cluneal nerve blocks about every 4-5 months. The claimant also underwent a peroneal nerve block on 03/11/10. Post-operative treatments have included off duty, rest, work restrictions, physical therapy, epidural steroid injections and anti-inflammatories with mild temporary relief from his symptoms. The claimant underwent a psychological assessment on 04/20/10 regarding a spinal cord stimulator trial and no counter-indications for implantable surgery were found. When the claimant saw Dr. on 05/20/10, he complained that the pain in his back and anterolateral and posterior aspect of his left leg had progressed in intensity over the period of the last 4-5 months. The pain was aggravated with prolonged standing, repetitive bending or lifting and excessive walking. He described the back pain as aching and the leg pain as sharp and shooting. With taking his medications, he rated his pain as 5-6/10. Dr. recommended a trial of a spinal cord stimulator. Peer reviews denied the request for the stimulator trial.

In the Prospective Review (IRO) Response on 06/23/10, Dr. concluded that the necessity of the spinal cord stimulator had not been substantiated, noting that the claimant got significant relief with cluneal nerve blocks. He also noted that there had been no recent studies to determine status of the fusion and whether there might be treatable pathology. There has been no evaluation by an orthopedic surgeon in quite some time. The provider is attempting to deal with this claimant's chronic pain complaints and wean him from the use of narcotic pain medication.

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

The requested outpatient back spinal cord stimulator trial is medically necessary based on review of this medical record. This is a gentleman who had an injury back in 2002. The medical records document a subsequent lumbar fusion operation with chronic pain. There are medical records from Dr. documenting his complaints, findings, and treatment, which indicate ongoing pain medication use, and the failure of blocks to resolve his complaints. The claimant has undergone a psychologic evaluation indicating there is no contraindication to implant surgery.

ODG guidelines document the use of a spinal cord stimulator trial in patients who have a diagnosis of a failed back syndrome who have ongoing pain and limitations in function and other treatments do not seem to improve their overall level of activity and pain. That appears present in this case.

This reviewer is aware that two previous reviewers have denied this level of care. This reviewer has gone back through all the medical records and believes that an outpatient back spinal cord stimulator trial is in line with the guidelines and therefore medically necessary. The reviewer finds that there is medical necessity for outpatient back spinal cord stimulator trial.

Official Disability Guidelines Treatment in Worker's Comp, 15th edition, 2010 Updates. Low Back: Spinal Cord Stimulator

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)

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.

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

ACOEM-AMERICA 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)