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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Aug/20/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Trial of a Neurostimulator (63650 x 2; L8680 x 16; 95972; Q9965; 77003)

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

MD, Board Certified in Physical Medicine and Rehabilitation
Board Certified in Pain Management
Board Certified in Electrodiagnostic Medicine

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

ODG Guidelines and Treatment Guidelines
Adverse Determination Letters, 6/17/10, 6/28/10
M.D. 6/2/10 to 7/29/10
M.D. 7/9/10, 7/12/10, 3/29/10, 3/10/10, 3/3/10
M.D. 5/2/10
D.O. 7/23/09, 2/25/10, 2/18/10, 1/19/10, 1/12/10, 1/4/10
Hospital 10/22/09, 3/11/10, 3/8/10
M.D. 9/29/09
FCE 6/19/09
4/24/09 to 6/9/09
Health Methodist Hospital 4/14/09
9/29/09
Pain Recovery Center 12/10/09
Physical Medicine Associates 5/28/09

PATIENT CLINICAL HISTORY SUMMARY

This is a man who had prior lumbar fusions in 2005, 2006 and 2008. He subsequently fell from a truck on x/xx/xx and developed new back pain down the legs. Work up was limited to CT myelogram due to the prior operations. He could not tolerate any electrodiagnostic studies. He was found to have a herniated disc at L3/4 and underwent a wide decompression and pedicle fusion from L3 to L4 on 3/11/10 by Dr. Dr. felt he would need a spinal cord stimulator prior to this procedure. In effect he had a fusion from L3 to the sacrum from the multiple operations. He reportedly had no lower extremity pain for a few weeks, and then developed severe pain. Dr. wrote that Dr. felt it was an exacerbation of a preexisting condition. He has been managed by multiple opiates and opioids (Oxycontin, Methadone, Avinza, Embedda, Dilaudid) with the development of allergic responses (including urticaria) to most. The others were ineffective. He continues to have pain. He was described as having some relief with ibuprofen and Darvocet, but had some GI bleeding with the ibuprofen.

He had a psychological assessment that described anxiety and depression. There was no contraindication to the procedure, however.

A prior request for a spinal cord stimulator was denied based upon ACOEM criteria that reportedly showed it to have no documented benefits for failed back syndrome or radiculopathy. This man walks with a walker. He is diagnosed by Dr. and Dr. with failed back syndrome and radiculitis/radiculopathy. Dr. noted his chief complaint on 6/2/10 "I have constant, aching, dull pain across the lower back and it runs down both legs causing weakness, numbness and tingling." Dr wrote (6/10/10) that he has "chronic intractable post surgical pain syndrome, and lumbar radiculitis." Dr., noted on 7/9/10 that there were no further surgical options for treatment of his pain. Further, he wrote "In fact today, he is not having any pain in his lower extremities. His main complaint is lower back pain." Dr. saw him for a DD exam on 9/29/09. He wrote "The old level cannot be discounted since again he had a new significant, high trauma /velocity injury. Despite lower extremity radicular symptoms, there are no clear-cut signs of nerve root irritation or focal neurological deficits following a particular nerve root pattern. "

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

While the ACOEM criteria reportedly excluded the stimulator for radiculopathy in failed back syndromes, the ODG supports its use in some patients with failed back syndrome. There is some evidence for its use. Dr. has stated in his notes that the patient's pain was largely in the back, but Dr. has noted both back and lower extremity pain. Dr. felt the pain prior to surgery was more radicular pain, and even Dr. noted the improvement with surgery. However, this patient cannot find relief or cannot tolerate most pain medications. Weighing all factors along with the ODG, the reviewer finds that there is adequate justification for the medical necessity for this procedure. The reviewer finds that medical necessity exists for Trial of a Neurostimulator (63650 x 2; L8680 x 16; 95972; Q9965; 77003).

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 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)