

Applied Assessments LLC

An Independent Review Organization

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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Sep/09/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Spinal Cord Stimulator Trial

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

Board Certified in Physical Medicine and Rehabilitation

Subspecialty Board Certified in Pain Management

Subspecialty Board Certified in Electrodiagnostic Medicine

Residency Training PMR and ORTHOPAEDIC SURGERY

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

OD Guidelines

Denial Letters 7/31/09 and 8/10/09

Pre-Surgical Screening No Date

6/16/09 thru 8/3/09

Radiology Reports 11/3/08

Dr. 4/30/09

Records from 1993-2009

PATIENT CLINICAL HISTORY SUMMARY

This is a xx-year-old man injured in xxxx. He had reportedly 4 spinal surgeries in the past, with the most recent being a fusion performed in 1996. He had ongoing back pain with reduced sensation in the right L5/S1 dermatomes. There is no motor weakness. A CT myelogram showed disc bulging and post fusion stenosis at L4/5 with lesser at L2/3 and L3/4. He had an EMG, but the results were not provided. Dr. felt a spinal stimulator would be justified. Dr. agreed. Dr. noted a history of bipolar disorder and depression, plus an old and

apparently inactive history (20 years) of pain medication and Soma abuse. He had epidural injections per Dr. that did not help. Dr. performed the psychological screen and felt that “there is no evidence of factors that would indicate a negative outcome to invasive medical techniques.” He had no or minimal depression on his BDI and no or mild anxiety on the BAI. There were no suicidal issues. Dr. , however, mentioned nothing about the prior drug abuse or bipolar history and specifically said he “has not seen a mental health professional.”

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

The ODG recognizes the role of a spinal cord stimulator. The history of substance abuse is old rather than an active or current problem. This man apparently is not a candidate for decompression of the fusion for the spinal stenosis. The Reviewer presumes that he had chronic pain from a failed back syndrome per Dr. , but Dr. did not explicitly discuss that. Dr. assessment, although somewhat incomplete, did state there were no contraindications to the procedure. These addressed issues 2 and 3 of the indicators. The criterion 1 is another issue. The Reviewer knows he had the spinal injections by Dr. . He is on Opana and Norco for pain. There is nothing written about the use of neuroleptics in the records. Lastly, the first criteria states the pain needs to be primarily in the lower extremities more than the back (note the spelling error in the ODG). Dr. wrote that “His painful symptoms are present in both legs...He also has lower back pain...” This would appear to meet these criteria as well. Therefore, the trial of the stimulator is warranted.

Spinal cord stimulators (SCS)

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](#)

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](#))

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;

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 ERVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)