

Independent Resolutions Inc.

An Independent Review Organization

835 E. Lamar Blvd. #394

Arlington, TX 76011

Fax: 817-549-0310

Notice of Independent Review Decision

DATE OF REVIEW: July 27, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Testing of Spinal Cord Stimulation Leads & Possible Replacement, Possible Replacement of Lead Extension & IPG w/ New Lead Extension & Rechargeable IPG, Under Fluoroscopy, Analysis, and Reprogramming (Possible Observation Status).

A 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

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 6/26/08 and 6/30/08

Medical Records from Dr. 5/17/07 thru 6/26/08

Radiology Reports 7/3/08

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a xx year old lady who had a spinal stimulator implanted in 2003. She did well until earlier this year. It was felt that the battery was dead. A replacement was done, but

she did not get a satisfactory result. There apparently were problems with the impedance of the leads found at the time of the battery replacement and when checked afterwards. The manufacturer representative advises surgical reassessment of the system.

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

She had successful relief of pain for several years. The relief ended when the battery died. She did not improve with a change in the battery. The manufacturer advised open assessment and possible replacement of the equipment. The failure appears to be from high impedance of the electrodes. This would suggest fibrosis at the electrodes rather than electrode migration. The Reviewer could not find any specific articles regarding replacement or revision of these stimulator devices. There are individual reports, but none that would be compatible with an evidence based medical approach. There appears to be no way of reassessment without the procedure advised by the manufacturer. There does not appear to be any alternative treatment program to offer her so a replacement would be appropriate. Therefore, the request is medically necessary.

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)**