

Envoy Medical Systems, L.P.  
1726 Cricket Hollow Dr.  
Austin, TX 78758

PH: (512) 248-9020  
FAX: (512) 491-5145

**Notice of Independent Review Decision**

**DATE OF REVIEW:** 8/4/10

**IRO CASE #:**

Description of the Service or Services In Dispute  
spinal cord stimulator with equipment

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

Physician Board Certified in neurological Surgery

**REVIEW OUTCOME**

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

X Upheld	(Agree)
Overtured	(Disagree)
Partially Overtured	(Agree in part/Disagree in part)

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**

Adverse determination letters, 7/9/10, 6/14/10  
Request 6/1/10  
Psychological evaluation 5/8/10, Diagnostic interview report 3/8/10 Dr.  
DDE report 8/31/09, 3/10/09  
Follow up notes 2007, 2008, Dr.  
Radiology reports 3/7/08, 2/7/08, 11/29/07, 9/6/07, 9/17/07, 6/27/06, 9/17/07  
Peer review 11/11/08, Dr.  
EMG/NCS report 9/24/07  
Operative reports ESI 1/7/08, 10/8/07,  
History report 7/6/10, 6/1/10, 2/23/10, 12/10/08, Dr.  
Report 4/14/10, Dr.  
Office evaluation 3/12/09, Dr.  
Consultants reports 2007, 2008  
ODG guidelines

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is a female who in xx/xxxx, was struck in the right side of her head, causing an electric shock sensation on the right side of her arm and body. Neck and arm pain continued, and MRI evaluation suggested a problem at the C4-5 and C5-6 disk spaces. In March 2007 an ACDF was carried out at C4-5 and C5-6 but the patient's pain has continued. A cervical CT myelogram on 11/29/07 was negative, showing the fusions in good position and indicating no reason continued pain. The patient also developed lumbar spine pain, with some lower extremity pain in association with her injury, that became more severe in 2007, but a lumbar MRI at that time revealed only minor

changes at L5-S1 that were not thought surgically significant. She has continued pain in her lumbar spine and lower extremities and neck and shoulders, with these being about equal in severity. A primal cord stimulator had been recommended, but apparently only for the lumbar region. There are no definite notes by the surgeon, but these facts were indicated in other reports.

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

I agree with the denial of the trial spinal cord stimulator, and possible permanent implantation. The proposal for the spinal cord stimulation is for the lumbar region only, and according to the ODG, at least one previous back operation and the patient not being a candidate for any repeat surgery is indicated before spinal cord stimulation is thought to be indicated. In addition notes in the patient's chart that there is neck and arm pain about equal in severity to the back pain, and these two areas of pain cannot be covered by the recommended spinal cord stimulation. It is doubtful that spinal cord stimulation for relief of the lower extremity and low back pain alone would be of significant benefit regarding the patient's requirement for medication for continued pain in the neck and shoulder. A more thorough work up for possibly surgically correctable pathology in the lumbar spine, might be beneficial, after which a pain specialist might be able to more directly approach the neck and upper extremity pain.

**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)