

# US Resolutions Inc.

An Independent Review Organization  
71 Court Street  
Belfast, ME 04915  
Phone: (512) 782-4560  
Fax: (207) 470-1035  
Email: manager@us-resolutions.com

## NOTICE OF INDEPENDENT REVIEW DECISION

**DATE OF REVIEW:**

Aug/06/2009

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Osteogenesis Stimulator, Electrical, non-invasive, Spinal applications

**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**

ODG Guidelines and Treatment Guidelines

Adverse Determination Letters, 6/8/09, 06/24/09

X-rays L-S spine, Dr. 7/5/05

EMG/NCS, 7/29/05, 01/10/06, 04/04/07, 6/03/08

Office note, Dr. 9/1/05, 02/09/06, 10/06/06, 01/09/08, 04/28/08, 09/18/08, 11/13/08, 05/14/09

X-rays lumbar Spine, Dr. 9/1/05

Lumbar myelogram, 10/20/05

CT scan, 10/20/05

X-rays, Dr. 12/6/05

Lumbar MRI, 1/3/06

Procedure report, Dr. 9/8/06

Procedure report, Dr. 4/2/07

CT scan lumbar spine, 7/2/07

Procedure report, 2/18/08, 4/23/08

Lumbar CT scan, 9/29/08

Letter of appeal, Dr. 6/16/09

Letter, company, 7/17/09

Spinal stim order form

## **PATIENT CLINICAL HISTORY SUMMARY**

The claimant is a male with a history of L5 discectomy in 1986 and 1987. In January 2003 he underwent L4-5 fusion. X-rays on 07/05/05 per Dr. indicated that the transpedicular fixation device at L4-5 was in good position. An interbody cage was noted on the right which did not appear to be consolidated. There were radiolucent lines about the cage and there was no evidence of bony formation on the left. There appeared to be a radiolucent line about the screws in the L4 pedicle as well. The claimant was also diagnosed with an L3-4 disc herniation and instability as well as segmental spondylosis at L5-S1 and radiculopathy by EMG/NCS. On 10/06/06 Dr. recommended decompression and stabilization of L3-4 and L5-S1 and exploration of the L4-5 fusion. Surgery was denied on peer review.

The claimant continued to treat conservatively. On 01/09/08 Dr. noted that the claimant was not a surgical candidate due to his obesity. He was 5'9" and 286 pounds. He was diabetic and taking Avandia. Other medications included hydrocodone, Cymbalta, Neurontin and Coumadin. The claimant did not smoke. In 2008 the claimant underwent two epidural steroid injections. On 04/28/08 Dr. again discussed surgery as the claimant had lost some weight. Updated imaging studies were done at that time, however, the claimant continued to treat conservatively.

On 11/13/08 the claimant continued to complain of low back pain radiating to the lower extremities. He had numbness and tingling in his feet and legs at times. A CT/myelogram was recommended. On 05/14/09 the claimant had worsening low back pain and bilateral leg pain, left greater than right. Dr. noted that lumbar x-ray showed a transpedicular device at L4-5 in good position. There appeared to be a halo around all the transpedicular screws. There was no evidence of trabeculation in the anterior column arthrodesis. The AP films did not show any lateral bone as well. Per an addendum note there was radiographic evidence of remaining graft at the L4-5 fusion site. The diagnosis was non union at L4-5 and a bone growth stimulator was ordered. It was denied on peer review. Dr. indicated in a letter of appeal that the bone growth stimulator was ordered as a non operative salvage of his current fusion. The Company authored a letter of appeal dated 07/17/09 indicating that risk factors included failed fusion and obesity. The claimant's weight was 275 pounds and x-ray of 05/14/09 indicated there was evidence of graft remaining at the L4-5 fusion.

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

Request is for osteogenesis stimulator noninvasive spinal application. The claimant underwent a previous fusion in 2003. He is now nearly six years out from the procedure. At this juncture, there is no conclusive evidence that invasive or noninvasive electrical bone growth stimulator would help his condition at this period of time. The claimant is a diabetic but at three years out from the procedure, use of the bone growth stimulator would not be justified. The request does not conform to the ODG criteria for use. The reviewer finds that medical necessity does not exist for Osteogenesis Stimulator, Electrical, non-invasive, Spinal applications.

Official Disability Guidelines Treatment in Worker's Comp, 14th edition, 2009 Updates. Low back

### **Bone growth stimulator**

Under study. There is conflicting evidence, so case by case recommendations are necessary (some RCTs with efficacy for high risk cases). Some limited evidence exists for improving the fusion rate of spinal fusion surgery in high risk cases (e.g., revision pseudoarthrosis, instability, smoker). (Mooney, 1990) (Marks, 2000) (Akai, 2002) (Simmons, 2004) There is no consistent medical evidence to support or refute use of these devices for improving patient outcomes; there may be a beneficial effect on fusion rates in patients at "high risk", but this has not been convincingly demonstrated. (Resnick, 2005) Also see Fusion for limited number of indications for spinal fusion surgery. See Knee & Leg Chapter for more information on use of Bone-growth stimulators for long bone fractures, where they are recommended for certain conditions

Criteria for use for invasive or non-invasive electrical bone growth stimulators

Either invasive or noninvasive methods of electrical bone growth stimulation may be considered medically necessary as an adjunct to spinal fusion surgery for patients with any of the following risk factors for failed fusion: (1) One or more previous failed spinal fusion(s); (2) Grade III or worse spondylolisthesis; (3) Fusion to be performed at more than one level; (4) Current smoking habit (Note: Other tobacco use such as chewing tobacco is not considered a risk factor); (5) Diabetes, Renal disease, Alcoholism; or (6) Significant osteoporosis which has been demonstrated on radiographs. (Kucharzyk, 1999) (Rogozinski, 1996) (Hodges, 200

**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)