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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Mar/24/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Bone growth stimulator / Orthofix Spinal Stim E0748

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

MD, Board Certified Neurosurgeon

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

Adverse Determination Letters, 2/4/10, 2/24/10

M.D. 05/12/2009 Operative report 10/16/2009

2/1/10, 2/17/10

PA 1/12/10

2010 Official Disability Guidelines

PATIENT CLINICAL HISTORY SUMMARY

The claimant is a female with a date of injury xx/xx/xx, when she fell. She is status post lumbar decompression and interbody fusion at L5-S1 on 10/16/2009. In 01/2010 she fell and an X-ray in the ER showed no evidence of fracture or disruption of hardware. She has undergone 6 weeks of physical therapy. She is a smoker (half a pack of cigarettes per day). Plain films were recently performed. A bone growth stimulator is requested.

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

According to the ODG, "Low Back" chapter, bone growth stimulators are "Under study. There is conflicting evidence, so case by case recommendations are necessary (some RCTs with efficacy for high risk cases)." In this particular case, the claimant had surgery five months ago. A bone growth stimulator would be medically necessary if there was evidence of delayed bony fusion. However, if there appears to be a solid fusion, this device is not medically necessary. It is unclear, from the submitted documentation, that there is any delay

in bony fusion. The reviewer finds that medical necessity does not exist for Bone growth stimulator / Orthofix Spinal Stim E0748.

2010 Official Disability Guidelines

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, 2003)

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)

