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## Notice of Independent Review Decision

**DATE OF REVIEW:** 11/23/2009

**IRO CASE #:**

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

The item in dispute is the prospective medical necessity of an osteogenesis stimulator, low intensity, non-invasive.

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

The reviewer is a Medical Doctor who is board certified in Orthopedic Surgery. The reviewer has been practicing for greater than 15 years and performs this type of service in daily practice.

### **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)

The reviewer agrees with the previous adverse determination regarding the prospective medical necessity of an osteogenesis stimulator, low intensity, non-invasive.

### **INFORMATION PROVIDED TO THE IRO FOR REVIEW**

Records were received and reviewed from the following parties:

These records consist of the following (duplicate records are only listed from one source): Records reviewed : Denial letters – 10/3/09 & 10/15/09; review – 10/1/09; Solutions review – 10/13/09; Medical Necessity fax – 9/30/09, Reconsideration request – 10/9/09; Faxed notes – 10/27/09; , MD page 2 of 2 Chart Documents – undated.

Records reviewed letter – 10/28/09, Exogen Prescription Form & Certificate of Medical Necessity – 9/18/09; MD letter – 10/8/09; MD MRI Report – 9/18/09; ODG Guidelines for Bone Growth Stimulators; Orthopedics Patient Information and Contact Information – undated; denial letter – 10/2/09.

A copy of the ODG was provided by the Carrier and Requestor for this review.

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is a male. He tripped over a rug and sustained a right navicular foot fracture on xx/xx/xx. The patient smokes ½ pack of cigarettes daily. The MRI of xx/xx/xx notes no vascular or soft tissue damage. The patient is neurovascularly intact in his right foot.

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

The ODG limits use of bone stimulators to use in tibias for fresh fractures. No apparent effort at smoking cessation has been recorded. Website states stimulator is indicated for closed radius fractures and closed or open grade 1 tibia fractures.

According to the ODG: The ODG notes that most fresh fractures heal without complications with the use of standard fracture care, but that ultrasound may be considered for treatment of tibia fractures in patients with risk factors.

Criteria for the use of Ultrasound fracture healing:

Fresh Fractures: Most fresh fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization. However, low intensity ultrasound treatment may be considered medically necessary for the treatment of fresh, closed or Grade I open fractures of the tibia in skeletally mature adults when at least one of the following significant risk factors for delayed fracture healing or nonunion are present: (1) Diabetes; (2) Osteoporosis; (3) Steroid therapy; (4) Currently smoking; (5) Fractures associated with extensive soft tissue or vascular damage. Other factors that may indicate use of ultrasound bone healing depending on their severity may include: Obesity, nutritional or hormonal deficiency, age, low activity level, anemia, infection, or comminuted or other especially complicated fractures.

Smith Nephew web site cite - The EXOGEN<sup>◊</sup> 4000+, or any other EXOGEN<sup>◊</sup> Bone Healing System, is indicated for the non-invasive treatment of established nonunions<sup>†</sup> excluding skull and vertebra. In addition, they are indicated for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopaedically managed by closed reduction and cast immobilization.

The reviewer disagrees with the medical necessity of this product as it does not meet the ODG requirements for such a device. This is based upon the records provided by all parties.

**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)