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Notice of Independent Review Decision

DATE OF REVIEW: 5/25/2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

E 0760 Exogen Bone Growth Stimulator

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

M.D. Board Certified Orthopedic Surgeon/ Fellowship Trained Spine 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

Document Type	Date(s) - Month/Day/Year
Texas Department of Insurance Notice of Case Assignment	5/06/2011
Health Care Fax	5/06/2011
Workers' Comp Services Notification of Determination	3/08/2011 4/06/2011
, Inc.	
Prior authorization Request	3/30/2011-4/28/2011
Request for IRO	5/04/2011
Standard Appeal to Denial	
Medical necessity Form	3/11/2011
Bone Healing system	
Order Form	3/17/2011
Workers' Compensation Verification	1/04/2010
Orthopedic Clinic	
Progress Note	1/04/2011-4/20/2011
X-ray Report	1/04/2011-4/20/2011
Orthopedic& sport Medicine Clinic	1/04/2011
Patient Demographics Form	

PATIENT CLINICAL HISTORY [SUMMARY]:

female sustained a sub-trochanteric left femur fracture on xx/xx/xx after a fall. The patient has a history of a left femoral neck fracture sustained 4-5 years ago that was treated with cannulated screws across the femoral neck. Regarding her new injury, the patient subsequently underwent ORIF of the fracture, removal of the previous cannulated screws, and intramedullary nailing of the sub-troch fracture. The patient's history is also significant for morbid obesity, thyroid disorder, uterine cancer, asthma, hepatitis, bladder infections, and further complicated by a post operative cellulitis. Due to a fracture gap of 1 to 1.5 cm, the patient underwent revision fixation of the fracture on 2/14/11 with dynamization of the nail and allograft and PRPP gel at the fracture site. The treating surgeon is now requesting an external bone growth stimulator to promote union of the fracture site.

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

Based on ODG guidelines, electrical bone growth stimulators are recommended as indicated below:

An electrical bone growth stimulator (EBS) uses electric current to promote bone healing. The current may generate a direct, direct pulsating or pulsating electromagnetic field (PEMF). Bone growth stimulators may be invasive, semi-invasive, or noninvasive. Direct current electrical bone-growth stimulators may be appropriate for non-unions, failed fusions, and congenital pseudarthrosis where there is no evidence of progression of healing for three or more months despite appropriate fracture care.

Criteria for the use of non-invasive electrical bone growth stimulators:

Non-union of long bone fracture (5-10% exhibit signs of delayed or impaired healing) must meet ALL of the following:

- The two portions of the bone involved in the non-union are separated by less than one centimeter; AND- Location in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities); AND- The bone is stable at both ends by means of a cast or fixation; AND
- A minimum of 90 days has elapsed from the time of the original fracture and serial radiographs over three months show no progressive signs of healing (except in cases where the bone is infected, and the 90-day waiting period would not be required)

Ultrasound Based Bone Growth Stimulators:

Recommended as indicated below. Recent studies have shown an accelerating effect of low-intensity pulsed ultrasound (LIPUS) on fracture repair. LIPUS treatment should be started within 6 months of the most recent operation. Because LIPUS has been shown to be effective without causing either serious invasiveness or any undue risk to the patient, it may be considered the treatment of first choice for cases of postoperative delayed union or nonunion. ([Jingushi, 2007](#)) ([Busse, 2002](#)) ([Warden, 2006](#)) Low-intensity pulsed ultrasound has been principally investigated as a technique to accelerate healing of fresh fractures, but more recently as a treatment of fracture nonunions. Ultrasound can be delivered noninvasively with the use of a transducer applied to the skin surface overlying the fracture site. Ultrasound treatment can be self-administered with one daily 20-minute treatment, continuing until the fracture has healed. The mechanism of action at the cellular level is not precisely known, but is thought to be related to a mechanical effect on cell deformation or indirectly, by an electrical effect caused

by cell deformation. With respect to healing of fresh fractures, evidence limits use of low-intensity ultrasound to closed fractures. (BlueCross BlueShield, 2005) (Nolte, 2001) (Ricardo, 2006) The Sonic Accelerated Fracture Healing System (SAFHS) may accelerate healing of fresh fractures, fusions, or delayed unions of the shaft of the tibia that are open or segmental. (When applied over a fracture site, the SAFHS device produces an ultrasonic wave, which delivers mechanical pressure to the bone tissue at the fracture site. Although the mechanism by which the low intensity pulsed ultrasound device accelerates bone healing is uncertain, it is thought to promote bone formation in a manner comparable to bone responses to mechanical stress.) (Aetna, 2004) Evidence for the effect of low intensity pulsed ultrasonography on healing of fractures is moderate to very low in quality and provides conflicting results, when focusing on patient important outcomes, in particular functional recovery, as opposed to radiographic healing as the end point. (Busse, 2009)

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 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 communitied or other especially complicated fractures.

Nonunions: Low intensity ultrasound treatment may be considered medically necessary in patients with nonunion of bones, excluding the skull and vertebrae, when all of the following criteria are met: (1) At least three months have elapsed since the date of fracture and the initiation of conventional fracture treatments; (2) Serial x-rays have confirmed that no progressive signs of healing have occurred; (3) The fracture gap is one centimeter or less; & (4) fracture is adequately immobilized. (Leung, 2004) (BlueCross Blue Shield, 2007)

In reviewing the patient's history, the request is non-certified based on lack of fulfillment of ODG guideline criteria 2 (of note, all the other criteria are met save criteria 2), namely that serial x-rays must confirm that no progressive signs of healing have occurred. In reviewing the radiographic reports, the note dated 04/20/2011 reveals that the fracture site gap had decreased from 2cm to less than 1 cm. The reduction in the fracture gap site suggests progressive signs of healing have occurred, and therefore the request for the bone growth stimulator does not meet ODG guideline criteria.

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 KNOWLEDGBASE
- 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)