



CLAIMS EVAL

*Utilization Review and
Peer Review Services*

Notice of Independent Review Decision-WCN

DATE OF REVIEW: 10-26-09

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Exogen Ultrasound bone growth stimulator E0760

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

American Board of Orthopaedic Surgery-Board Certified

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)

Provide a 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

- MD., office visits from 5-14-09 through 8-20-09.
- 8-3-09 MD., performed a Utilization Review.
- 9-1-09 MD., performed a Utilization Review.

PATIENT CLINICAL HISTORY [SUMMARY]:

Office visit with MD., dated 5-14-09 notes the claimant is a male who states was in the ER and was told he had a tibia fracture. The injury was work related. The injury occurred on xx/xx/xx when he slipped and fell on a large wheel run over his left leg. The claimant has swelling and stiffness. He claimant was immobilized with a splint and was using crutches. The claimant was neurovascularly intact. The cast was in good condition. The left leg is in a sugar tong splint. The claimant has adequate pedal pulses with cap refills. No ankle tenderness, medial or lateral. No knee pain. X-rays show a mildly displaced distal tibia fracture. Assessment: Closed fracture of shaft on tibia. The claimant was provided with a prescription for Vicodin 5/500 mg. The evaluator reapplied posterior splint. The claimant was advised to keep left leg/foot above heart level. The claimant will be monitored for compartment syndrome.

Followup with Dr. dated 5-8-09 notes the claimant is less tender in mid tibia. X-rays show no changes in alignment. The claimant was placed on Darvocet N-100. The claimant was provided on a toe touch weight bearing cam walker.

Followup with Dr. on 6-18-09 notes the claimant reports he feels better except when he walks a lot. His pain gets worse at night. X-rays show healing fracture mild hypertrophy. The claimant was reassured.

Follow up with Dr. dated 7-2-09 notes x-rays show healing fracture. The evaluator recommended physical therapy 2-3 x 3 weeks. The claimant was advised to take multivitamin with 1500 mg of calcium.

Followup with Dr. dated 7-23-09 notes the claimant reported he is doing well. He has had 6 physical therapy sessions. Most of his pain is when he walks and develops intermittent swelling. X-rays show pending hypertrophic delayed union. The evaluator reported that since the claimant has potential hypertrophic nonunion, a bone stimulator will be provided. The claimant is to continue with physical therapy.

On 8-3-09, MD., performed a Utilization Review. It was his opinion that in the medical notes dated 7-23-09, the patient is complaining of leg pain. On physical examination of the left knee, there is normal alignment and no effusion. There is still some tenderness over the fracture site. Both quadriceps and hamstring strength and tone were normal. There is no clinical documentation that the patient has significant risk factors for nonunion to include diabetes, osteoporosis, smoking habit, or nutritional deficiency. Additionally, no official reports of imaging studies were submitted for review documenting the severity of the reported fracture of the tibia. Without documentation of significant risk factors for nonunion and lack of imaging studies, medical necessity for the request cannot be established at this time.

Follow up visit with Dr. dated 8-20-09 notes the claimant has intermittent pain, which is sharp and moderate. X-rays show nonunion of tibia, early hypertrophic formation. The evaluator reported that he will try a bone stimulator. If this fails, he may need stabilization with IM rod.

On 8-20-09, a Letter provided notes the claimant is now over xxxx months from his date of injury. X-rays taken on 8-20-09 reveal the fracture line is still present and now has a "nonunion". This patient is also obese with a Body Mass Index of >30 = obese. Studies have shown that obesity can slow the production of osteoblasts, resulting in a nonunion. Exogen Ultrasound bone healing system is proven to help mitigate the negative effect of comorbidities, such as obesity. The claimant has a nonunion fracture and is over 90 days from his date of injury with no significant signs of healing.

On 9-1-09, MD., performed a Utilization Review. It was his opinion that the request for Exogen ultrasound bone growth stimulator E0760 is not recommended as medically necessary. The patient sustained a closed left tibia fracture and radiographs reportedly reveal nonunion; however, no radiographic reports were submitted for review to document nonunion or that the fracture gap is one centimeter or less as required by current evidence based guidelines. There is no indication that the patient meets any of the inclusion criteria as set forth by the Official Disability Guidelines for utilization of a bone growth stimulator. Given the current clinical data, the requested bone growth stimulator is not indicated as medically necessary at this time.

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

This case lacks sufficient information to warrant use of an ultrasound bone growth stimulator. The records do not document the location of the tibial fracture, stability of fracture, additional testing such as CAT scan of fracture or other comorbid factors such as smoking or diabetes. Therefore, at this juncture, non-certification is provided for the requested Exogen Ultrasound bone growth stimulator E0760.

ODG-TWC, last update 10-12-09 Occupational Disorders of the Knee and Leg – Ultrasound 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 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.

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)

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)