The DYLL REVIEW
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25 Highland Park Village #100-177 Dallas TX 75205
Phone: 888-950-4333 Fax: 888-9504-4443

Notice of Independent Review Decision

DATE OF REVIEW: 11/07/2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

DME Purchase Exogen Ultrasound Bone Healing System E0760

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

The physician performing this review is Board Certified, American Board of Physical Medicine & Rehabilitation. He is certified in pain management. He is a member of the Texas Medical Board. He has a private practice of Physical Medicine & Rehabilitation, Electrodiagnostic Medicine & Pain Management in Texas. He has published in medical journals. He is a member of his state and national medical societies.

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.

Upon independent review, this reviewer finds that the previous adverse determination should be overturned (disagree).

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records Received: 16 page fax 10/27/11 Texas Department of Insurance IRO request, 21 page fax 11/01/11 URA response to disputed services including

administrative and medical, 6 page fax 11/01/11 Provider response to disputed services including administrative and medical. Dates of documents range from 06/14/11 (DOI) to 10/27/11

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the information in the above documents, this individual injured the right foot when she stepped on a toy at work. She injured the right foot. She denied any past history of pain in the foot before the injury. She was seen at, where an old-appearing fracture at the metadiaphyseal junction of the fourth metatarsal base was noted. She was allowed to return to work, as she was having only mild symptoms at the time. Symptoms ultimately resolved, but a few days prior to 08/03/11, at which time she saw Dr. she had increased pain in the area and came to Dr. for evaluation. The pain was described as sharp, throbbing, and constant, awakening her at night. It was worse with weight bearing. It was better with rest, elevation, ice, and heat. The patient is described in Dr. records as being morbidly obese and with diabetes, two significant risk factors for failure for fracture to heal. The patient has had a short period of immobilization but apparently no casting. The patient was provided a beginning trial of the EXOGEN ultrasound bone-stimulating device about 08/31/11. The patient is currently recommended for obtaining preauthorization for this device, but this has not been approved.

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

Based on the *ODG* criteria as found in both the foot and ankle sections as well as the knee section, where the ultrasound bone stimulator comments are located, there does appear to be some conflict in the recommendations. However, given the fact that she appears to have had continuing evidence of non-healing of this bone fracture for a period of greater than four months, as well as having significant risk factors of obesity and diabetes, along with persisting and recurring pain in the foot, the recommendation would be reasonable for consideration of approval of the ultrasound external bone stimulator.

ODG Criteria Ultrasonic External Bone Stimulator
IRO #37772
Tammy Page

Bone growth stimulators, ultrasound	Recommended as an option for non-union of long bone fractures or fresh fractures with significant risk factors. Also, limited studies show that patients who received post-operative low intensity ultrasound following ankle fusion showed a statistically significant faster healing rate on plain radiographs at 9 weeks and CT scan at 12 weeks. A 100% fusion rate was noted. (Coughlin, 2008) (Ishikawa, 2002) (Jones, 2006) (Khan, 2008) (Siska, 2008) Limited evidence has been shown

	for the use of ultrasound fracture healing in Charcot neuroarthropathy. (Strauss, 1998) See the Knee Chapter for specific indications.

Bone growth stimulators, ultrasound	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 communited 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)

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Jones Fracture Information

http://www.athleticadvisor.com/injuries/LE/Foot&Ankle/5th_metatarsal.htm

5th Metatarsal Fractures & Treatment

Fractures of the fifth metatarsal (shaft of the small toe) are common in athletics. The method of injury is similar to that of an ankle sprain. The athlete will invert and dorsiflex the foot, this can result in a twisting force about the base of the 5th metatarsal. Do not discount pain at the base of the foot when evaluating an ankle sprain to avoid missing a fracture of the 5th.

There are four basic types of fractures that can occur to the 5th metatarsal.

- Avulsion fracture of the tuberosity of the 5th.
- Jones Fracture.
- Shaft fracture of 5th metatarsal.
- Stress Fracture

All of these fractures need to be treated appropriately to avoid long term problems.

The diagnosis of a Jones Fracture has been used to describe several injuries. The true Jones Fracture is a transverse fracture at the junction of the diaphysis and metaphysis of the fifth metatarsal. This is the blue highlighted area in the diagram.

This is potentially the worst fracture of the 5th metatarsal. The area in question has a very limited blood supply. Due to this healing is very slow and many times healing may not occur. The x-ray below the diagram shows a Jones Fracture (red arrow).

In an athlete, surgical fixation may be the first treatment option. Non-surgical treatment can consist of six to 16 weeks in a cast. Since this area does not heal well, many athletes treated without surgery, experience recurrent fractures of this bone.

During surgery, the physician will drill a hole in the bone from the tuberosity (bump on the outside of the base of the 5th metatarsal) into the shaft of the bone. The surgeon then inserts a screw into the hole to hold the two fragments of the bone together. The fluoroscopic picture shows the bone after the screw has been inserted.

The athlete is then placed in a cast, non-weight bearing for four to 6 weeks. During this time, the athlete is performing light range of motion and strength training exercises. After weight bearing is allowed, the athlete can begin more difficult strength training, proprioception (balance and coordination) exercises, and finally sport specific drills.
Avulsion fractures happen in the red area shown in this picture. This injury happens, most often, in a skeletally immature athlete. The peroneus brevis tendon attaches near the growth plate at the base of the 5th metatarsal. The mechanism of injury is similar to an ankle sprain. The ankle "rolls over," the peroneal muscles contract to prevent the sprain, and the growth plate is fractured. The picture above shows an avulsion fracture of the 5th metatarsal.
Treatment for this injury is usually conservative. The young athlete will be casted for four to six weeks. The athlete then begins rehabilitation exercises for range of motion, strength, and proprioception. These injuries heal with little or no long term disabilities, return to full athletic competition is normal.
Fractures to the shaft of the 5th metatarsal are the next group of injuries. Fractures can happen along the entire shaft of the bone. Treatment depends upon the location of the fracture.
Treatment can range from conservative casting and non-weight bearing to internal fixation with a screw. This x-ray shows a shaft fracture with internal fixation.
Chronic pain on the outside of the foot following an acute injury can be indicative of a fracture that was missed on the initial evaluation. If the athlete continues to have low grade pain on the outside of the foot 3 to 6 weeks after the initial injury, repeat x-rays should be taken to rule out a stress fracture.
This x-ray shows a healing stress fracture (arrow). The white area surrounding the line at the arrow is indicative of an area of healing. This fracture may have been missed on the initial x-ray due to its small size. The athlete may have attempted return to normal activities but was limited by chronic low grade pain in the outside of the foot.
Again, a fracture in this area, may or may not heal. As the x-ray shows, the bone near the fracture site is changing this is indicative of the fracture failing to heal. A recurrent stress fracture may respond to internal fixation with better healing results than conservative treatment (casting) only.
Pain in the outside of the foot, especially after an ankle sprain needs to be investigated. The differential evaluation should include the fifth metatarsal. Skeletally immature athletes should be evaluated by an orthopaedic surgeon to rule out fractures, especially avulsion fractures of the ankle and to the base of the fifth metatarsal Chronic pain should also be investigated to rule out a chronic stress fracture.

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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)