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Notice of Independent Review Decision

DATE OF REVIEW: MAY 3, 2010 **AMENDED DATE: MAY 4, 2010**

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Purchase of Exogen Bone Healing System between 4/5/10 and 6/4/10.

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

This physician has over 40 years of experience as a Board Certified Orthopaedic Surgeon with a secondary specialty in hand surgery.

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

On xxxxxx, M.D. performed an EMG on the claimant. Impression:
1. Bilateral median nerve lesions at the wrists compatible with moderate left carpal tunnel syndrome and mild right carpal tunnel syndrome. 2. There is no electrophysiologic evidence of peripheral neuropathy or cervical radiculopathy.

On December 31, 2009, M.D., an orthopedic hand surgeon, evaluated the claimant. Examination revealed the claimant had full range of motion of his fingers of the right hand. noted right wrist radial-deformity, positive ballottement test, positive ulnar carpal grind test, and positive pisiform boost test. Radiographs: Three views of the wrist show the volar plate is in position. He has an intraarticular deformity possible intraarticular hardware. The scapholunate diastasis is a little bit enlarged. He has an unreduced basi-styloid fracture of the distal ulna consistent with a TFC tear and distal radioulnar joint instability. Assessment: 1. I need to get a copy of his nerve study to rule out posttraumatic carpal tunnel syndrome. 2. I need to get a CAT scan. He obviously has an intraarticular deformity. The reduction is non-optimal. He may have arthritis.

On January 22, 2010, CT of the right wrist without contrast was performed, read by M.D. Impression: Status post ORIF of an incompletely healed intra-articular fracture involving the distal radius. Status post avulsion fracture at the base of the ulnar styloid process, without evidence of healing.

On January 28, 2010, M.D. re-examined the claimant. Impression: Distal radius nonunion. Ulnar styloid nonunion, with DRUJ instability. Carpal tunnel syndrome.

On March 8, 2010, per the operative report M.D. performed the following procedures: 1. ORIF of right distal radius nonunion through a previously surgically altered field. 2. Hardware removal. 3. Olecranon bone graft. 4. Ulnar styloid excision. 5. Triangular fibrocartliage repair through a separate incision. 6. Endoscopic carpal tunnel release through a separate incision. 7. Antebrachial fasciotomy. Postoperative diagnoses: Distal radius nonunion. Distal radial ulnar joint instability. Carpal tunnel syndrome.

On March 23, 2010, M.D. re-examined the claimant. Radiographs: Two x-rays of the wrist show that the hardware is in good position. Examination: His paraesthesias have resolved.

On April 2, 2010, M.D., a PM&R physician, performed a peer review on the claimant. Conclusion: Based on the submitted clinical notes there was no mention of the claimant's risk factors or co-morbidities that may affect fracture/bone graft healing. There was no official report of the x-ray of the wrist that pertain a possibility of non-union complication. The request for purchase of Exogen Bone Healing System is not medically necessary.

On April 5, 2010, responded to peer review. Per response, " was seen on 3/23/10 one year from initial injury. The x-ray was taken showed fixation of the non-united piece that is clearly a repaired non-union at this point although at this point showing no signs of healing. The claimant is a smoker, which impedes fracture healing which is why further treatment is required to heal this claimant.

EXOGEN has been shown to have the strongest effectiveness throughout the healing process. It has the highest clinical efficacy rate of 38% for fresh fracture and 86% for non-unions.

On April 9, 2010, M.D., an orthopedic hand surgeon, performed a peer review on the claimant. Decision: ODG recommends at least 3 months have elasped since the date of fracture and the initiation of conventional fracture treatments. While 3 months have passed since the date of the fracture there is insufficient evidence submitted for review, including physical therapy and medication management. Guidelines also recommend serial x-rays that have confirmed that no progressive signs of healing have occurred. There are no x-rays or series of x-rays submitted for review, status post ORIF, that suggests that there is a lack of progressive healing. The fracture gap should be one cm or less. There are no imaging studies, status post ORIF, submitted for review, that deomstrate that there is a 1cm gap present.

PATIENT CLINICAL HISTORY:

On xx/xx/xx, the claimant injured his right hand when he fell from a height of 6 feet onto his right hand.

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

Upon independent review the reviewer finds that the previous determination/adverse determinations should be overturned.

The efficacy of Ultrasound in the management of established non-union of fractures is well established in the medical literature (Heckman et al 94, Jungushi et al 07, Busse et al 07, Warden et al, and 06 Zura et al 07.) The ODG recommendation, the 3-month interval since conventional fracture treatment and the serial X-rays showing no progressive signs of healing, required to determine the presence of a nonunion, have certainly been met in this case. It had been a full year since the original fracture treatment prior to surgery and the presence of the nonunion was irrefutably established by the preoperative CT Scan. The definition of any nonunion requires that there is a gap between the non-united bone fragments and this gap would necessarily be 1cm or less. The addition of the Exogen System as an adjuvant to bone grafting procedure would a good idea in the presence of the established nonunion. The fact that there was an intra-articular nonunion (more difficult to treat), the earlier return to work and the less requirement for prolonged rehabilitation, all certainly seem to justify the Exogen System in this case.

PER THE ODG:

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)

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)